Public Health Law and Ethics

Public Health Law and Ethics

A Reader
Third Edition

EDITED BY
Lawrence O. Gostin
and Lindsay F. Wiley

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Preface to the Third Edition

The field of public health is typically regarded as a positivistic pursuit. Our understanding of and response to disease and injury at the population level are undoubtedly guided by the scientific method. Public health policies, however, are shaped not only by science but also by ethical values, legal norms, and political oversight. *Public Health Law and Ethics: A Reader* probes this complex interplay through a careful selection of excerpts from judicial opinions, statutes, regulations, government reports, and scholarly articles.

Now in its third edition, this reader provides a resource for scholars, students, practitioners, teachers, and interested members of the public. Each chapter illuminates key issues in public health law and ethics and frames relevant questions. We introduce the selected excerpts, provide commentary on their significance, and suggest additional resources for readers interested in further exploration.

The reader can also be used as a companion to the third edition of *Public Health Law: Power, Duty, Restraint,* published in 2016. The treatise provides a careful analysis of the major tensions in public health law theory and practice, while this reader offers cases and materials selected to inspire informed discussion and debate.

This reader, like the companion text, is organized into four major parts:

Part One. Conceptual Foundations of Public Health Law and Ethics

Part Two. Legal Foundations of Public Health

Part Three. Modes of Legal Intervention

Part Four. Public Health Law in Context

Part One covers the conceptual foundations of public health law and ethics in two chapters—one developing a theory and definition of the field and the other offering a systematic scientific and ethical evaluation of public health regulation.

Part Two comprises three chapters that cover the legal foundations of public health powers and practices at the federal, state, and local level: constitutional law, administrative law, and local government law. These chapters contain considerable discussion of legal doctrine that may, at once, be insufficiently detailed for public health practitioners and students new to the study of law and overly pedantic for lawyers and law students who are familiar with much of what is presented. Despite the unavoidable difficulties of addressing multiple audiences, we felt it important to develop a common understanding of the legal basis for the exercise of public health powers and the limits on those powers.

Part Three, consisting of three chapters, explores the modes of legal intervention identified in the book's opening chapter: direct regulation and deregulation; indirect regulation through tort liability; and indirect regulation via taxation and spending. These chapters examine the regulatory toolkit in detail, including through case studies. We address the advantages and detriments of various approaches, including in terms of economic efficiency, political accountability, and vulnerability to legal challenge.

Part Four, made up of six chapters, examines legal issues and ethical dilemmas within the context of several major silos of public health practice. We explore key concepts and trends in public health surveillance and research, infectious diseases, emergency preparedness and response, and prevention of injuries and violence. We run the risk of providing too cursory a review for lawyers new to the study of public health while reviewing concepts too elementary for experienced public health practitioners and students. Nonetheless, this approach illuminates the paradoxes of public health law (e.g., the fact that public health regulation is often challenged or neglected because the benefits cannot be traced to any particular individual while personal and economic burdens are more evident). We conclude with reflections on the future of public health law, with particular attention to the devastating impact of health disparities on our society and the challenges of balancing trans-

parency and democratic accountability with the need for expeditious and far-reaching action to ensure a greater measure of justice for disadvantaged groups.

We have used a modified version of *The Chicago Manual of Style* (sixteenth edition) for the bibliography and endnotes and *The Bluebook: A Uniform System of Citation* (twentieth edition) for judicial cases, statutes, and regulations.

We have heavily edited many of the excerpts collected in the reader to highlight the most essential issues in public health law and ethics. In a few cases, we have condensed edited paragraphs to maintain the flow of analysis. In the case of judicial opinions, we have often omitted internal quotation marks and citations to prior case law.

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We thank, most of all, the people who mean the most to us and to whom this book is dedicated: our families, Jean, Bryn, Jen, Kieran, and Isley Gostin; and Henry, Grady, Gwendolyn, and Eva Wiley.

Lawrence O. Gostin
Lindsay F. Wiley
Washington, DC, April 2018

PART ONE

Conceptual Foundations of Public Health Law and Ethics

PHOTO 1.1. A doctor gives a typhoid inoculation at a rural school in Texas, 1943. Typhoid fever, a bacterial infection with a high fatality rate, was once common in the United States. Incidence decreased rapidly in the 1940s due to improvements in sanitation (especially chlorination of drinking water), development of effective antibiotic treatments, and vaccination. Today, there are only about 400 cases of typhoid in the United States each year, the vast majority among travelers returning from regions where infection remains endemic. Routine vaccination of schoolchildren is no longer recommended, but voluntary vaccination of travelers is crucial to protect the public's health, particularly in light of the growing prevalence of multidrug-resistant strains of typhoid. Photograph by John Vachon for the Farm Security Administration.

CHAPTER ONE

Law and the Public's Health

Mapping the Terrain

The theory and practice of public health raise questions that are not resolved solely through scientific inquiry; rather, law and ethics guide the public health enterprise alongside epidemiology and biostatistics. Despite the close interplay among public health science, law, and ethics, each has its own methods and terminology. Until recently, cross-fertilization was rare. Most scholars and practitioners in the fields of law and ethics who have engaged in sustained examination of issues in health have focused principally on the financing and delivery of medical care and the conduct of medical research. The distinct perspectives and practices of public health have received far less attention. Fortunately, a growing number of practitioners, scholars, and organizations are developing public health law and public health ethics into fully fledged fields that stand alongside the related fields of health care law and bioethics.

Before applying ethics or law to problems in public health, it is important first to understand what we mean by public health. In this chapter, we highlight the prevention orientation, population perspective, and commitment to social justice that distinguish public health from medicine. We describe evolving models of public health science and practice, culminating in the social-ecological model. We conclude by surveying an ongoing debate over the legitimate scope of public health law, triggered by increased attention to noncommunicable diseases (e.g., cancer, heart disease, diabetes), injuries (e.g., motor vehicle,

firearm, and overdose fatalities), and the social, economic, and environmental determinants of health in recent decades.

THE PREVENTION ORIENTATION AND THE POPULATION PERSPECTIVE

Public health inquiries and interventions are aimed at the prevention of injury, disease, and premature death at the population level. The Institute of Medicine (IOM) (1988, 19) in its landmark report *The Future of Public Health* proposed one of the most influential contemporary definitions of public health: "Public health is what we, as a society, do collectively to assure the conditions for people to be healthy." The IOM's emphasis on cooperative and mutually shared obligation ("we, as a society") reinforces that collective entities (e.g., governments and communities) take responsibility for healthy populations. The definition also adopts a broad focus on social, environmental, cultural, and economic factors ("the conditions for people to be healthy") that shape health-related behaviors and outcomes.

In the excerpt that follows, Rose offers a comparison between how medicine and public health approach questions of causation and methods for prevention. "Why did this patient get this disease at this time?" is a common question in medicine, underscoring a physician's principle concern for individuals. By contrast, those interested in public health seek knowledge about why ill health occurs in the population and how it can be prevented through structural, rather than individual, interventions.

SICK INDIVIDUALS AND SICK POPULATIONS*

Geoffrey Rose

THE DETERMINANTS OF INDIVIDUAL CASES

In teaching epidemiology to medical students, I have often encouraged them to consider a question which I first heard enunciated by Roy Acheson: "Why did *this* patient get *this* disease at *this* time?" It is an excellent starting point, because students and doctors feel a natural concern for the problems of the individual. Indeed, the central ethos of medicine is seen as an acceptance of responsibility for sick individuals.

It is an integral part of good doctoring to ask not only, "What is the diagnosis, and what is the treatment?" but also, "Why did this happen, and could it have been pre-

* Reprinted from 1985. *International Journal of Epidemiology* 14 (1): 32–38 by permission of Oxford University Press.

vented?" Such thinking shapes the approach to nearly all clinical and laboratory research into the causes and mechanisms of illness. Hypertension research, for example, is almost wholly preoccupied with the characteristics which distinguish individuals at the hypertensive and normotensive ends of the blood pressure distribution. Research into diabetes looks for genetic, nutritional and metabolic reasons to explain why some people get diabetes and others do not. The constant aim in such work is to answer Acheson's question, "Why did this patient get this disease at this time?"

The same concern has continued to shape the thinking of all of us who came to epidemiology from a background in clinical practice. The whole basis of the case-control method [(a retrospective study design in which researchers compare the history of individuals who have a condition ["cases"] to the history of individuals who do not ["controls"])] is to discover how sick and healthy individuals differ. Equally the basis of many cohort studies [(prospective studies in which researchers follow a group of similarly situated individuals over time to see which of them develops the condition of interest)] is the search for "risk factors," which identify certain individuals as being more susceptible to disease; and from this we proceed to test whether these risk factors are also causes, capable of explaining why some individuals get sick while others remain healthy, and applicable as a guide to prevention. . . .

Unfortunately this approach to the search for causes, and the measuring of their potency, has to assume a heterogeneity of exposure within the study population. If everyone smoked 20 cigarettes a day, then clinical, case-control and cohort studies alike would lead us to conclude that lung cancer was a genetic disease; and in one sense that would be true, since if everyone is exposed to the necessary agent, then the distribution of cases is wholly determined by individual susceptibility. Within Scotland and other mountainous parts there is no discernible relation between local cardiovascular death rates and the softness of the public water supply. The reason is apparent if one extends the enquiry to the whole of the UK. In Scotland, everyone's water is soft [meaning that it contains low levels of calcium and magnesium]; and the possibly adverse effect becomes recognizable only when study is extended to other regions which have a much wider range of exposure. . . . Even more clearly, a case-control study of this question within Scotland would have been futile. Everyone is exposed, and other factors operate to determine the varying risk. Epidemiology is often defined in terms of study of the determinants of the distribution of the disease; but we should not forget that the more widespread is a particular cause, the less it explains the distribution of cases. The hardest cause to identify is the one that is universally present, for then it has no influence on the distribution of disease.

THE DETERMINANTS OF POPULATION INCIDENCE RATE

I find it increasingly helpful to distinguish two kinds of etiological question. The first seeks the causes of cases, and the second seeks the causes of incidence. "Why do some individuals have hypertension?" is a quite different question from "Why do some populations have much hypertension, whilst in others it is rare?" The questions require different kinds of study, and they have different answers. . . .

To find the determinants of prevalence and incidence rates, we need to study characteristics of populations, not characteristics of individuals. . . . Within populations it has proved almost impossible to demonstrate any relation between an individual's diet

and his serum cholesterol level; and the same applies to the relation of individual diet to blood pressure and to overweight. But at the level of populations it is a different story: it has proved easy to show strong associations between population mean values for saturated fat intake *versus* serum cholesterol level and coronary heart disease incidence, sodium intake *versus* blood pressure, or energy intake *versus* overweight. The determinants of incidence are not necessarily the same as the causes of cases. . . .

PREVENTION

These two approaches to etiology—the individual and the population-based—have their counterparts in prevention. In the first, preventive strategy seeks to identify high-risk susceptible individuals and to offer them some individual protection. In contrast, the "population strategy" seeks to control the determinants of incidence in the population as a whole.

The "High-Risk" Strategy

This is the traditional and natural medical approach to prevention. If a doctor accepts that he is responsible for an individual who is sick today, then it is a short step to accept responsibility also for the individual who may well be sick tomorrow. Thus screening is used to detect certain individuals who hitherto thought they were well but who must now understand that they are in effect patients. . . .

What the "high-risk" strategy seeks to achieve is something like a truncation of the risk distribution. This general concept applies to all special preventive action in high-risk individuals—in at-risk pregnancies, in small babies, or in any other particularly susceptible group. It is a strategy with some clear and important advantages. . . .

The "high-risk" approach offers a more cost-effective use of limited resources. . . . [I]t is more effective to concentrate limited medical services and time where the need—and therefore also the benefit—is likely to be greatest. . . . If intervention must carry some adverse effects or costs, and if the risk and cost are much the same for everybody, then the ratio of the costs to the benefits will be more favorable where the benefits are larger.

Unfortunately the "high-risk" strategy of prevention also has some serious disadvantages and limitations. . . . [I]t is palliative and temporary, not radical. It does not seek to alter the underlying causes of the disease but to identify individuals who are particularly susceptible to those causes. Presumably in every generation there will be such susceptibles; and if prevention and control efforts were confined to these high-risk individuals, then that approach would need to be sustained year after year and generation after generation. It does not deal with the root of the problem, but seeks to protect those who are vulnerable to it; and they will always be around.

The potential for this approach is limited—sometimes more than we could have expected—both for the individual and for the population. There are two reasons for this. The first is that our power to predict future disease is usually very weak. Most individuals with risk factors will remain well, at least for some years; contrariwise, unexpected illness may happen to someone who has just received an "all clear" report from a screening examination. One of the limitations of the relative risk statistic is that it gives no idea of the absolute level of danger. . . .

This point came home to me only recently. I have long congratulated myself on my low levels of coronary risk factors, and I joked to my friends that if I were to die suddenly, I should be very surprised. I even speculated on what other disease—perhaps colon cancer—would be the commonest cause of death for a man in the lowest group of cardiovascular risk. The painful truth is that for such an individual in a Western population the commonest cause of death—by far—is coronary heart disease! Everyone, in fact, is a high-risk individual for this uniquely mass disease.

There is another, related reason why the predictive basis of the "high-risk" strategy of prevention is weak. It is well illustrated by . . . the [correlation of] occurrence of Down's syndrome births to maternal age. Mothers under 30 years are individually at minimal risk; but because they are so numerous, they generate half the cases. High-risk individuals aged 40 and above generate only 13% of the cases. The lesson from this example is that *a large number of people at a small risk may give rise to more cases of disease than the small number who are at a high risk.* This situation seems to be common, and it limits the utility of the "high-risk" approach to prevention.

A further disadvantage of the "high-risk" strategy is that it is behaviorally inappropriate. Eating, smoking, exercise and all our other life-style characteristics are constrained by social norms. If we try to eat differently from our friends it will not only be inconvenient, but we risk being regarded as cranks or hypochondriacs. If a man's work environment encourages heavy drinking, then advice that he is damaging his liver is unlikely to have any effect. No one who has attempted any sort of health education effort in individuals needs to be told that it is difficult for such people to step out of line with their peers. This is what the "high-risk" preventive strategy requires them to do.

The Population Strategy

This is the attempt to control the determinants of incidence, to lower the mean level of risk factors, to shift the whole distribution of exposure in a favorable direction. In its traditional "public health" form it has involved mass environmental control methods; in its modern form it is attempting (less successfully) to alter some of society's norms of behavior.

The advantages are powerful. The first is that it is radical. It attempts to remove the underlying causes that make the disease common. It has a large potential—often larger than one would have expected—for the population as a whole. . . .

The approach is behaviorally appropriate. If non-smoking eventually becomes "normal," then it will be much less necessary to keep on persuading individuals. Once a social norm of behavior has become accepted and (as in the case of diet) once the supply industries have adapted themselves to the new pattern, then the maintenance of that situation no longer requires effort from individuals. The health education phase aimed at changing individuals is, we hope, a temporary necessity, pending changes in the norms of what is socially acceptable.

Unfortunately the population strategy of prevention has also some weighty drawbacks. It offers only a small benefit to each individual, since most of them were going to be all right anyway, at least for many years. This leads to the Prevention Paradox (Rose 1981): "A preventive measure which brings much benefit to the population offers little to each participating individual." This has been the history of public health—of immunization, the wearing of seat belts and now the attempt to change various

life-style characteristics. Of enormous potential importance to the population as a whole, these measures offer very little—particularly in the short term—to each individual; and thus there is poor motivation of the subject. We should not be surprised that health education tends to be relatively ineffective for individuals and in the short term. Mostly people act for substantial and immediate rewards, and the medical motivation for health education is inherently weak. Their health next year is not likely to be much better if they accept our advice or if they reject it. Much more powerful as motivators for health education are the social rewards of enhanced self-esteem and social approval. . . .

CONCLUSIONS

The "high-risk" strategy of prevention is an interim expedient, needed in order to protect susceptible individuals, but only for so long as the underlying causes of incidence remain unknown or uncontrollable; if causes can be removed, susceptibility ceases to matter.

Realistically, many diseases will long continue to call for both approaches, and fortunately competition between them is usually unnecessary. Nevertheless, the priority of concern should always be the discovery and control of the causes of incidence.

. . .

Michael J. McGinnis and William H. Foege noted in 1993 that the biomedical model of record keeping and the societal need to explain a cause of death in terms of a discrete medical condition can distract the public from the root causes of disease. Medical explanations of death, often in the form of code numbers from the International Classification of Disease (ICD) on death certificates, point to discrete pathophysiological conditions or events, such as heart attack, stroke, cancer, diabetes, pneumonia, or suicide. In contrast, from the population perspective, McGinnis and Foege focused on what they labeled the "actual causes of death": tobacco, diet and activity patterns, alcohol, firearms, sexual behavior, motor vehicles, and illicit drug use. Ten years later, Ali H. Mokdad and his coauthors (2004) updated the statistics marshaled by McGinnis and Foege, noting trends in the leading modifiable causes of death over time. Sandro Galea and his coauthors (2011) built on this framework by assessing the impact of individual-level factors (e.g., educational attainment, household income, health insurance status, employment status, job stress, household conditions, level of social support, experience of racism or discrimination, housing conditions, and early childhood stressors) as well as community-level factors (e.g., area-level poverty, income inequality, deteriorating built environment, racial segregation, crime and violence, social capital, and availability of open or green spaces). They attributed approximately 245,000 premature

deaths in the United States each year to low education, 176,000 to racial segregation, 162,000 to low social support, 133,000 to individual-level poverty, 119,000 to income inequality, and 39,000 to area-level poverty (Galea et al. 2011, 1462). Similarly, Anne Case and Angus Deaton (2017) have found that increases in "deaths of despair" (e.g., drug overdoses, suicides, and deaths due to alcohol-related liver disease) are attributable to a "long-standing process of cumulative disadvantage for those with less than a college degree," contributing to an overall increase in premature mortality among middle-aged non-Hispanic white people in recent years. Attributing deaths to economic despair, experiences of racism, early childhood stressors, and other social determinants of health may seem foreign to those accustomed to measuring mortality in terms of discrete medical causes such as cardiovascular disease or cancer. It is a powerful expression of the population perspective adopted by public health experts.

There are, of course, many things that individuals can do to protect their own health, particularly if they have the economic means to do so. They can purchase housing, clothing, food, and medical care. Each person can also behave in ways that promote health and safety by eating a balanced diet, being physically active, using safety equipment (e.g., seatbelts, motorcycle helmets, smoke detectors, and protective equipment at work), refraining from tobacco use and drug and alcohol abuse, using sunscreen, and getting recommended vaccinations and screening tests. But, as the work of Case, Deaton, Galea, Mokdad, McGinnis, Foege, and others shows, these individual behaviors are shaped by social determinants. Law itself acts as a social determinant of health, allocating resources, creating incentives and disincentives, and shaping the social environment, the information environment, and the built environment in which people make choices that affect their health.

Furthermore, there are some kinds of health protection that no individual, acting alone, can achieve fully. The classic example is community immunity. A vaccination may by highly effective—providing protection from a communicable disease to, for example, 95% of those who are immunized. Some individuals may be unable to get vaccinated because of medical conditions, such as leukemia, that make it medically inadvisable. Others may opt out of immunizations due to religious or philosophical objections. Others may get a vaccination, but have the misfortune of being among the 5% of those who are vaccinated but nonetheless are vulnerable to infection. Only community immunity (also known as herd immunity) can ensure eradication of an infectious disease by

protecting everyone—the vaccinated as well as the unvaccinated—from infection (see chapter 10). Acting alone, individuals cannot achieve control of infectious disease, clean air and surface water, uncontaminated food and drinking water, safe roads and products, and community norms and social structures that support safer, healthier lifestyles.

Protecting public health also requires actions that no individual is fully incentivized to take, even if it were within one's power to do so, because it is impossible to know which individuals will benefit. For example, policymakers know that reducing tobacco use saves lives. Statisticians can document how many fewer people are smoking today than were smoking in the 1960s before tobacco control measures were in place. Epidemiologists can measure the impact of cigarette taxes on smoking prevention. But it is impossible to point to any specific individual and say, "this person's life was saved because the cigarette tax was high enough to keep her from taking up smoking when she was fourteen." Similarly, it is well known that exposure to lead-contaminated water and soil and deteriorating lead paint causes intellectual impairment and behavioral disorders. Health agencies can document how many children have blood lead levels that are unsafe. At the population level, epidemiologists may even be able to estimate the amount of intellectual impairment and behavioral disorder attributable to lead paint exposure. But it is exceedingly difficult to prove that any given individual would not be experiencing an intellectual impairment or behavioral disorder but for his exposure to lead paint.

Indeed, the collective action problem in public health is the often at the root of its politicization. This is the prevention paradox that Rose describes above. Measures that have the greatest potential for improving health at the population level (e.g., reduction of sodium content in restaurant food) offer little traceable benefit to any identifiable individual. Measures that heroically save identifiable lives (e.g., heart transplants) make no significant contribution to the population's health. This tension between individual interests and collective needs can be seen in how success is quantified for health interventions. The answer to the question "Was this patient's health improved?" indicates success for the physician. For the public health professional, the key question is whether the disease and injury burden were reduced at the population level, with virtually no ability to tie names or faces to such an achievement. Although Rose acknowledges that medical interventions appear more heroic and are more likely to be welcomed by patients, he favors the broad and powerful impact of successful population-based campaigns.

Ongoing partisan disagreements over health care reform have focused the nation's attention on access to heroic medical interventions. In town halls across the country, individuals describe their dire need for subsidized health insurance coverage as they battle cancer, congestive heart failure, and other serious conditions. At the same time, sweeping changes in how health care is financed have led policymakers to view prevention as a key cost-control strategy. The Affordable Care Act included several measures to increase access to preventive health care and promote community-level prevention. In the following excerpt, Harry J. Heiman and Samantha Artiga place these trends in context and highlight the crucial importance of the social determinants of health.

BEYOND HEALTH CARE: THE ROLE OF SOCIAL DETERMINANTS IN PROMOTING HEALTH AND HEALTH EQUITY*

Harry J. Heiman and Samantha Artiga

Efforts to improve health in the United States have traditionally looked to the health care system as the key driver of health and health outcomes. The Affordable Care Act (ACA) increased opportunities to improve health by expanding access to health coverage and supporting reforms to the health care delivery system. While increasing access to health care and transforming the health care delivery system are important, research demonstrates that improving population health and achieving health equity also will require broader approaches that address social, economic, and environmental factors that influence health. . . .

DETERMINANTS OF HEALTH

Many factors combine to affect the health of individuals and communities. Despite annual health care expenditures projected to exceed $3 trillion, health outcomes in the United States continue to fall behind other developed countries. Recent analysis shows that, although overall spending on social services and health care in the United States is comparable to other Western countries, the United States disproportionately spends less on social services and more on health care. Though health care is essential to health, research demonstrates that it is a relatively weak health determinant. Health behaviors, such as smoking and diet and exercise, are the most important determinants of premature death (figure [1.1]). Moreover, there is growing recognition that a broad range of social, economic, and environmental factors shape individuals' opportunities and barriers to engage in healthy behaviors.

Social determinants have a significant impact on health outcomes. Social determinants of health are "the structural determinants and conditions in which people are born, grow, live, work and age" (Marmot et al. 2008). They include factors like socioeconomic

* Reprinted from *Kaiser Family Foundation Issue Brief* (November 2015).

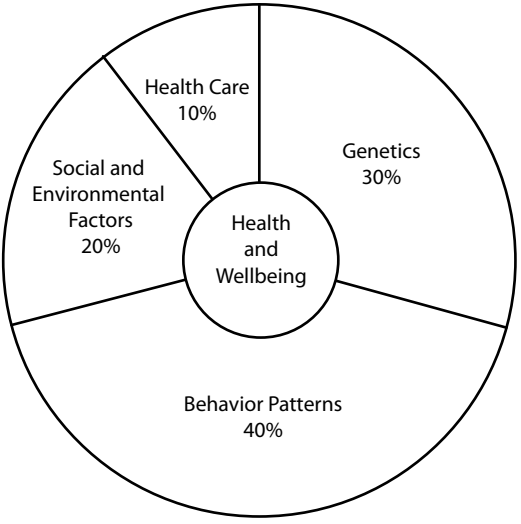

FIGURE 1.1. The determinants of premature death.

Adapted from Heiman, Harry J., and Samantha Artiga. 2015. "Beyond Health Care: The Role of Social Determinants in Promoting Health and Health Equity." *Kaiser Family Foundation*.

Source: McGinnis, J. Michael, Pamela Williams-Russo, and James R. Knickman. 2002. "The Case for More Active Policy Attention to Health Promotion." *Health Affairs* 21 (2): 78–93.

status, education, the physical environment, employment, and social support networks, as well as access to health care ([see table 1.1]). Based on a meta-analysis of nearly 50 studies, researchers found that social factors, including education, racial segregation, social supports, and poverty accounted for over a third of total deaths in the United States in a year. In the United States, the likelihood of premature death increases as income goes down. Similarly, lower education levels are directly correlated with lower income, higher likelihood of smoking, and shorter life expectancy. Children born to parents who have not completed high school are more likely to live in an environment that poses barriers to health. Their neighborhoods are more likely to be unsafe, have exposed garbage or litter, and have poor or dilapidated housing and vandalism. They also are less likely to have sidewalks, parks or playgrounds, recreation centers, or a library. In addition, poor members of racial and ethnic minority communities are more likely to live in neighborhoods with concentrated poverty than their poor White counterparts. There is also growing evidence demonstrating that stress negatively impacts health for children and adults across the lifespan. Recent research showing that where a child grows up impacts his or her future economic opportunities as an adult also suggests that the environment in which an individual lives may have multi-generational impacts.

TABLE 1.1 SOCIAL DETERMINANTS OF HEALTH

Economic Stability	Neighborhood and Physical Environment	Education	Food	Community and Social Context	Health Care System
Employment	Housing	Literacy	Hunger	Social integration	Health coverage
Income	Transportation	Language	Access to healthy options	Support systems	Provider availability
Expenses	Safety	Early childhood education		Community engagement	Provider linguistic and cultural competency
Debt	Parks	Vocational training		Discrimination	
Medical bills	Playgrounds	Higher education			Quality of care
Support	Walkability				
Health Outcomes					
Mortality, Morbidity, Life Expectancy, Health Care Expenditures, Health Status, Functional Limitations					

SOURCE: Reprinted from Heiman, Harry J., and Samantha Artiga. 2015. "Beyond Health Care: The Role of Social Determinants in Promoting Health and Health Equity." *Kaiser Family Foundation Issue Brief.*

Addressing social determinants of health is important for achieving greater health equity. The presence of health disparities is well established in the United States. Longstanding research has consistently identified disparities experienced by racial and ethnic minority, low-income, and other vulnerable communities. [In its ten-year plan for improving the nation's health, Healthy People 2020, t]he Department of Health and Human Services defines health disparities as "differences in health outcomes that are closely linked with social, economic, and environmental disadvantage." Healthy People 2020 goes on to state that "health disparities adversely affect groups of people who have systematically experienced greater obstacles to health based on their racial or ethnic group; religion; socioeconomic status; gender; age; mental health; cognitive, sensory, or physical disability; sexual orientation or gender identity; geographic location; or other characteristics historically linked to discrimination or exclusion." These definitions recognize that health disparities are rooted in the social, economic, and environmental context in which people live. Achieving health equity—defined by Healthy People 2020 as the highest level of health for all people—will require addressing these social and environmental determinants through both broad population-based approaches and targeted approaches focused on those communities experiencing the greatest disparities.

ADDRESSING SOCIAL DETERMINANTS OF HEALTH

Recently there has been increasing recognition of the importance of social determinants of health. A growing number of initiatives are emerging to address these broader determinants of health and develop integrated solutions within the context of the health care delivery system. . . .

Mapping and Place-Based Approaches

A number of initiatives are using geospatial analysis and community needs assessments to guide place-based approaches to address social and environmental factors impacting individual and community health. The importance of mapping and geospatial analysis for assessing and addressing health needs dates back to John Snow's work in 1854 to identify the source of the London cholera epidemic. Today, the importance of the relationship between neighborhoods and health continues to be recognized, with zip code understood to be a stronger predictor of a person's health than their genetic code. As described in the examples below, [a] number of initiatives in place today focus on neighborhoods with social, economic, and environmental barriers that lead to poor health outcomes and health disparities.

One example of these place-based approaches is an initiative in Camden, New Jersey, that focuses on high utilizers of hospital care. The population of Camden has a high poverty rate and historically poor access to care, with a high share of emergency department and hospital visits for preventable conditions that are treatable by a primary care provider. Individuals were having difficulty accessing primary care along with a number of behavioral, social, and medical issues. In response to these challenges, the Camden Coalition of Health Care Providers created a citywide care management system to help connect high utilizers of hospital emergency departments with primary care providers. The care management team includes providers and a social worker who connects with patients in the community to help identify and address both their medical and social needs. Results show that patients managed through the initiative have decreased emergency department and hospital utilization and improved management of health conditions. The initiative has also been successful in connecting patients to primary care following a hospital discharge.

The Harlem Children's Zone (HCZ) Project is a multi-dimensional, place-based approach to developing a healthy neighborhood and supporting the healthy development of children from birth to adulthood. The program focuses on children within a 100-block area in Central Harlem that had chronic disease and infant mortality rates that exceeded rates for many other sections of the city as well as high rates of poverty and unemployment. HCZ seeks to improve the educational, economic, and health outcomes of the community through a broad range of family, social service, and health programs. Programs include training and education of expectant parents, full-day pre-K, community centers that offer after-school and weekend programming, nutrition education, recreation options, and food services that provide healthy meals to students. HCZ tracks metrics across its initiatives and reports a 92% college acceptance rate across its programs.

In Colorado, the Colorado Health Foundation is leading an initiative called Healthy Places: Designing an Active Colorado. This initiative aims to reduce obesity by fostering a built environment that supports physical activity and connectivity within three com-

munities. Examples of projects implemented under this initiative include building new parks, playgrounds and walking trails; creating new family-based recreational opportunities; and increasing bicycle and pedestrian infrastructure.

The Healthy Food Financing Initiative is a public-private partnership that has leveraged over $1 billion to support over 200 projects in over 30 states since 2011 to improve access to healthy foods in low-income communities. Pilot studies for the Philadelphia Healthy Corner Store Initiative, now bringing healthier products to over 600 corner stores, showed a 60% increase in the sales of fresh produce. In addition, they demonstrated increased local economic activity and jobs and generation of local tax revenue.

Health in All Policies

Since the early 2000s, there has been a growing movement in the public health community to adopt a "Health in All Policies" approach. This approach recognizes the need to address social determinants of health to improve population health and seeks to ensure that decision-makers across different sectors are informed about the health, equity, and sustainability consequences of policy decisions in non-health sectors. In much the same way that environmental impact assessments allow for evaluation of the environmental impact of policies, health impact assessments evaluate the health impact of policies and practices across sectors that have not traditionally considered their impact on health.

Policies and practices in areas as diverse as education and early child development, economic and community development, transportation, and agricultural and food policy all have impacts on health and health equity. For example, providing early childhood education programs to children in low-income and racial and ethnic minority communities helps to reduce achievement gaps, improve the health of low-income students, and promote health equity. The availability and accessibility of public transportation affects access to employment, affordable healthy foods, health care, and other important drivers of health and wellness. Policies and practices in food policy can also promote health by supporting healthier corner stores in low-income communities, farm to school programs and community and school gardens, as well as through broader efforts to support the production and consumption of healthy foods.

Health in All Policies approaches are being promoted and implemented at the federal level, by local and state governments, community organizations, and funders. The National Prevention Council, created by the ACA, for the first time brings together senior leadership from 20 federal departments, agencies, and offices around a shared health agenda. Under the leadership of the Surgeon General, the council developed the National Prevention Strategy, identifying collaborative opportunities through a public health lens to advance health and wellness across all federal agencies. Similar approaches are being adopted at the state level. The California Health in All Policies Task Force was established by executive order in 2010 with the goal of bringing together 22 state agencies, departments, and offices to support a healthier and more sustainable California. The task force has developed interagency initiatives focused on crime prevention, access to healthy food, and active transportation. In 2010, King County, Washington, adopted an ordinance that codified bringing a health and health equity lens—a "fair and just" principle—to the county's new strategic plan. Through this prioritization of health equity across all policies, the county has focused on issues ranging from educational attainment and workforce development to affordable transit.

National and local funders are also shifting focus to support broader policies and practices that promote opportunities for health. For example, the Robert Wood Johnson Foundation underwent a major strategic reorientation aligned with its vision of building a national "Culture of Health." This vision seeks to look beyond health care to improve population health and change the way the nation thinks about health by focusing on collective impact and cross sector collaboration in areas ranging from early childhood education to food access and community development.

THE SOCIAL JUSTICE COMMITMENT

Like medicine, public health is not a purely positivistic pursuit. It is fundamentally driven by its progressive aim: to prevent disease, injury, and premature death. Its aggregative approach to measuring success may at first glance appear to be utilitarian. But, as the preceding excerpt demonstrates, public health is deeply interested in the distribution of good and ill health within populations. Improving aggregate health status by further improving the health of the privileged few is not the aim of public health. Rather, the aim is to shift the whole distribution of disease and injury downward, as Rose describes.

Deep and enduring socioeconomic disparities in health form the backdrop to any public health policy, and these disparities help explain why social justice is a core value of public health. As Angus Deaton (2002, 13) explains, "Poorer people die younger and are sicker than richer people; indeed, mortality and morbidity rates are inversely related to many correlates of socioeconomic status [SES] such as income, wealth, education, or social class." Scholars often use the term *health-wealth gradient* to refer the correlation between SES and health to reflect the frequently demonstrated trend whereby health improves more or less continuously as SES increases. British epidemiologist Sir Michael Marmot (2006) offers a powerful illustration of the SES gradient. For every mile traveled on the Metro's Red Line in the District of Columbia from the impoverished northeast to the affluent northwest, average life expectancy increases by one and a half years. Marmot's pioneering work on the social determinants of health has had enormous influence on the science, practice, ethics, and law of public health.

Social disparities in health outcomes are of interest for a number of reasons. An association between heart disease rates and household income indicates that modifiable factors are at work, highlighting the potential for disruption of causal pathways and prevention of unnecessary illness and premature death. A difference in cancer mortality between Black women and non-Hispanic white women could indicate a

genetic difference, but given the nature of race as a construct having more to do with social position than biological difference, it is at least as likely to indicate that social determinants are influencing outcomes. Even more importantly, these disparities are unconscionable because poor health limits the capabilities of individuals and communities to achieve their self-defined aims in life. Social, economic, and cultural disadvantages may compound health disparities and vice versa.

The excerpts that follow explore the commitment of public health practice, policy, and ethics to social justice, which has both a distributive (fairness in the distribution of benefits and burdens) and a participatory (fairness in the representation and recognition of diverse voices and interests in the identification and evaluation of priorities and interventions) dimension. The commitment to social justice is intertwined with public health's focus on communities both as the objects of its inquiries and interventions and as participatory subjects in democratic processes of identifying priorities, developing interventions, and evaluating both. Public health's commitment to social justice, augmented by the relatively new scientific methods of social epidemiology, has led to growing understanding of the social determinants of health over the last few decades. In turn, this understanding is shaping the boundaries of public health science, practice, and law.

We begin with Paula Braveman and her coauthors, who discuss the crucial and challenging task of defining health disparities and health equity as a foundation for social justice in public health. Building on this foundation, we then present an article by Dan Beauchamp, a pioneer in public health ethics. He analyzes the central tension between the need for collective action to achieve population-level improvements in health and the ethos of American individualism, which at times seems to require only that one refrain from harming others.

HEALTH DISPARITIES AND HEALTH EQUITY: THE ISSUE IS JUSTICE*

Paula A. Braveman, Shiriki Kumanyika, Jonathan Fielding, Thomas LaVeist, Luisa N. Borrell, Ron Manderscheid, and Adewale Troutman

Eliminating health disparities is a *Healthy People* goal. Given the diverse and sometimes broad definitions of health disparities commonly used, a subcommittee convened

* Reprinted from 2011. *American Journal of Public Health* 101 Suppl 1 (S1): S149–S155.

TABLE 1.2 HEALTH DISPARITIES AND HEALTH EQUITY

Health disparities are health differences that adversely affect socially disadvantaged groups.
Health disparities are systematic, plausibly avoidable health differences according to race/ethnicity, skin color, religion, or nationality; socioeconomic resources or position (reflected by, e.g., income, wealth, education, or occupation); gender, sexual orientation, gender identity; age, geography, disability, illness, political or other affiliation; or other characteristics associated with discrimination or marginalization. These categories reflect social advantage or disadvantage when they determine an individual's or group's position in a social hierarchy (see [Table 1.3]).
Health disparities do not refer generically to all health differences, or even to all health differences warranting focused attention. They are a specific subset of health differences of particular relevance to social justice because they may arise from intentional or unintentional discrimination or marginalization and, in any case, are likely to reinforce social disadvantage and vulnerability.
Disparities in health and its determinants are the metric for assessing health equity, the principle underlying a commitment to reducing disparities in health and its determinants; health equity is social justice in health.

SOURCE: Reprinted from Braveman, Paula A., Shiriki Kumanyika, Jonathan Fielding, Thomas LaVeist, Luisa N. Borrell, Ron Manderscheid, and Adewale Troutman. 2011. "Health Disparities and Health Equity: The Issue Is Justice." *American Journal of Public Health* 101 (1): S149–S155.

by the [Health and Human Services] Secretary's Advisory Committee for *Healthy People 2020* proposed an operational definition for use in developing objectives and targets, determining resource allocation priorities, and assessing progress.

Based on that subcommittee's work, we propose that health disparities are systematic, plausibly avoidable health differences adversely affecting socially disadvantaged groups; they may reflect social disadvantage, but causality need not be established. This definition, grounded in ethical and human rights principles, focuses on the subset of health differences reflecting social injustice, distinguishing health disparities from other health differences also warranting concerted attention, and from health differences in general.

We explain the definition, its underlying concepts, the challenges it addresses, and the rationale for applying it to United States public health policy.

[Federal agencies have identified achievement of health equity and elimination of health disparities (including differences in health outcomes and determinants based on gender, race, ethnicity, education, income, disability, residence in rural areas, and sexual orientation) as overarching goals.] However, the rationale for identifying disparities in relation to these particular population groups [has not always been clearly] articulated. . . . [T]he relatively nonspecific definitions of disparities used by federal agencies leave considerable room for ambiguity as to what other groups might also be relevant. . . .

[This] paper . . . elaborate[s] on the definitions [developed by a committee of experts for use in *Healthy People 2020* (see [table 1.2]) and explain[s] their ration-

ale. . . . Clarifying these concepts will enable medical and public health practitioners and leaders to be more effective in reducing disparities in medical care and in advocating for social policies (e.g., in child care, education, housing, labor, and urban planning) that can have major impacts on population health. . . .

UNDERLYING VALUES AND PRINCIPLES

Drawing on ethical and human rights concepts, key principles underlying the concepts of health disparities and health equity include the following:

All people should be valued equally. . . . Equal worth of all human beings is at the core of the human rights principle that all human beings equally possess certain rights.

Health has a particular value for individuals because it is essential to an individual's well-being and ability to participate fully in the workforce and a democratic society. Ill health means potential suffering, disability, and/or loss of life, threatens one's ability to earn a living, and is an obstacle to fully expressing one's views and engaging in the political process. The Nobel Laureate economist Amartya Sen (1999) viewed health as a fundamental capability required to function in society; similarly, ill health can be a barrier to fully realizing one's human rights. . . .

Nondiscrimination and equality. Every person should be able to achieve his/her optimal health status, without distinction based on race or ethnic group, skin color, religion, language, or nationality; socioeconomic resources or position; gender, sexual orientation, or gender identity; age; physical, mental, or emotional disability or illness; geography; political or other affiliation; or other characteristics that have been linked historically to discrimination or marginalization (exclusion from social, economic, or political opportunities). The groups represented by these characteristics substantively agree with those specified by the United Nations Committee on Economic, Social and Cultural Rights as vulnerable groups whose rights are at particular risk of being unrealized, due to historic discrimination. This directly reflects the human rights principles of nondiscrimination and equality; nondiscrimination includes not only intentional but also unintentional or de facto discrimination, meaning discriminatory treatment embedded in structures and institutions, regardless of whether there is conscious intent to discriminate. . . .

Health is also of special importance for society because a nation's prosperity depends on the entire population's health. Healthy workers are more productive and generate lower annual medical care costs. A healthier population has more workers available for the workforce. Health can facilitate political participation, which is essential for democracy.

Rights to health and to a standard of living adequate for health. International human rights agreements, to which virtually all countries are signatories, obligate governments to respect, protect, fulfill, and promote all human rights of all persons, including the "right to the highest attainable standard of health" and the right to a standard of living adequate for health and well-being. Governments must demonstrate good faith in progressively removing obstacles to realizing these rights. The United States signed but did not ratify the International Covenant on Economic, Social, and Cultural Rights, which articulated the right to health. Signing a treaty, however, is considered an endorsement of its principles and reflects acceptance of a good faith commitment to honor its contents. The "right to health" (i.e., "the right of everyone to the enjoyment of the highest attainable standard of physical and mental health") is "not to be

understood as a right to be *healthy,*" because too many factors beyond states' control influence health. Rather, it is "the right to a system of health protection which provides equality of opportunity to enjoy the highest attainable level of health." It includes the right to equal access to cost-effective medical care as well as to child care, education, housing, environmental protection, and other factors that are also crucial to health and well-being.

Health differences adversely affecting socially disadvantaged groups are particularly unacceptable because ill health can be an obstacle to overcoming social disadvantage. This consideration resonates with common sense notions of fairness, as well as with ethical concepts of justice, notably, the concept that need should be a key determinant of resource allocation for health, and [the late philosopher John Rawls's (1971)] notion of the obligation to maximize the well-being of those worst off. Sen (2002) noted as a "particularly serious . . . injustice . . . the lack of opportunity that some may have to achieve good health because of inadequate social arrangements. . . . " Sen argued that health is a prerequisite for the capability to function normally in society. It is therefore particularly unjust that those who are socially disadvantaged should also experience additional obstacles to opportunity based on having worse health. . . .

The resources needed to be healthy (i.e., the determinants of health, including living and working conditions necessary for health, as well as medical care) should be distributed fairly. To do so requires considering need (along with capacity to benefit and efficiency) rather than ability to pay or influence in society. This principle, along with principles cited previously, reflects the ethical notion of distributive justice (a just distribution of resources needed for health) and the human rights principles of nondiscrimination and equality, as well as the right to a standard of living adequate for health. Investments in medical care intended to reduce disparities must be weighed against other potentially more effective investments that address disparities in other health determinants.

Health equity is the value underlying a commitment to reduce and ultimately eliminate health disparities. . . . Health equity means social justice with respect to health and reflects the ethical and human rights concerns articulated previously. . . . In accord with the other ethical principles of beneficence (doing good) and nonmalfeasance (doing no harm), equity requires concerted effort to achieve more rapid improvements among those who were worse off to start, within an overall strategy to improve everyone's health. Closing health gaps by worsening advantaged groups' health is not a way to achieve equity. Reductions in health disparities (by improving the health of the socially disadvantaged) are the metric by which progress toward health equity is measured. . . .

HEALTH DISPARITIES: DEFINITION AND RATIONALE

Health disparities are systematic, plausibly avoidable health differences adversely affecting socially disadvantaged groups. They may reflect social disadvantage, although a causal link need not be demonstrated. Differences among groups in their levels of social advantage or disadvantage, which can be thought of as where groups rank in social hierarchies, are indicated by measures reflecting the extent of wealth, political or economic influence, prestige, respect, or social acceptance of different population groups [(see table 1.3)].

TABLE 1.3 SOCIAL DISADVANTAGE

Health disparities and health equity cannot be defined without defining social disadvantage.

Social disadvantage refers to the unfavorable social, economic, or political conditions that some groups of people systematically experience based on their relative position in social hierarchies. It means restricted ability to participate fully in society and enjoy the benefits of progress. Social disadvantage is reflected, for example, by low levels of wealth, income, education, or occupational rank, or by less representation at high levels of political office. Criteria for social disadvantage can be absolute (e.g., the federal poverty threshold in the United States is based on an estimate of the income needed to obtain a defined set of basic necessities for a family of a given size) or relative (e.g., poverty levels in a number of European countries are defined in relation to the median income, e.g., less than 50% of the median income).

Not all members of a disadvantaged group will necessarily be (uniformly) disadvantaged, and not all socially disadvantaged groups will necessarily manifest measurable adverse health consequences. The extent (whether in a single or multiple domains), depth (severity), and duration (e.g., across multiple generations) of disadvantage matter. Social disadvantage is different from unavoidable physical disadvantage due to, for example, an unavoidable physical disability. However, when disabled persons are put at an unnecessary disadvantage in society due to lack of feasible supports (e.g., accessible public buildings and transportation) or to discrimination against them in hiring for work that they could perform, this would constitute social disadvantage, reflecting discriminatory treatment, whether intentional or unintentional.

SOURCE: Reprinted from Braveman, Paula A., Shirki Kumanyika, Jonathan Fielding, Thomas Laveist, Luisa N. Borrell, Ron Mandershcheid, and Adewale Troutman. 2011. "Health Disparities and Health Equity: The Issue Is Justice." *American Journal of Public Health* 101 Suppl 1 (S1): S149–S155.

Systematic but Not Necessarily Causal Links with Social Disadvantage

As noted by Starfield (2001), health disparities are systematic, that is, not isolated or exceptional findings. . . . Whether or not a causal link exists, health disparities adversely affect groups who are already disadvantaged socially, putting them at further disadvantage with respect to their health, thereby making it potentially more difficult to overcome social disadvantage. This reinforcement or compounding of social disadvantage is what makes health disparities relevant to social justice even when knowledge of their causation is lacking. . . . For example, the large Black–White disparity in low birth weight and premature birth strongly predicts disparities in infant mortality and child development, and likely in adult chronic disease. Although the causes of racial disparity in birth outcomes are not established, credible scientific sources have identified biological mechanisms that plausibly contribute to the disparities, which reflect phenomena shaped by social contexts and thus are, at least theoretically, avoidable.

Plausibly Avoidable Differences in Health Given Sufficient Political Will

It must be plausible, but not necessarily proven, that policies could reduce the disparities, including not only policies affecting medical care but also social policies addressing important nonmedical determinants of health and health disparities, such as a decent standard of living; a level of schooling permitting full social participation, including participation in the workforce and political activities; health-promoting living and working conditions, including both social and physical environments; and respect and social acceptance. . . .

Avoidability can be highly subjective. For example, one person may believe that ill health caused by poverty is avoidable; another, however, may believe that both poverty and ill health among the poor are inevitable; hence, these disparities are unavoidable. According to the proposed definition, the criterion is whether the given condition is theoretically avoidable, based on current knowledge of plausible causal pathways and biological mechanisms, and assuming the existence of sufficient political will. . . .

Disadvantaged Groups Are Not Necessarily Uniformly Disadvantaged

Although health disparities are systematic, a socially disadvantaged group will not necessarily fare worse on all health indicators, and might fare better on some. For example, non-Hispanic European American or White women over age 40 have higher incidence of breast cancer than non-Hispanic African American or Black women, and babies born to Hispanic immigrant women often have more favorable birth weights than those born to non-Hispanic Whites. Neither of these differences—although both deserve public health attention—would be a health disparity by the proposed definition. Regardless of this type of exception in relation to a health outcome, Whites as a group are more socially advantaged than Blacks and Hispanics, as data on income, wealth, education, occupations, and political office have documented. Furthermore, on most health indicators, including breast cancer mortality, White women are healthier than Black women. . . .

The fact that not all members of a disadvantaged group (e.g., Blacks) appear to be severely disadvantaged (e.g., we have a Black United States President, and some Blacks are highly educated, in high professional positions, and/or wealthy) does not contradict considering that group as generally disadvantaged. The issue is whether the group has been on the whole more disadvantaged than Whites. Ample evidence has documented a longstanding pattern of less wealth, lower incomes, lower educational attainment, and under-representation in positions of high occupational rank and financial and political power among Blacks as a group compared with Whites. Despite an end to legal racial segregation decades ago, racial residential segregation persists and with it, de facto educational segregation, condemning many Black children to poor quality schools. This reduces their chances of obtaining good jobs with adequate income as adults, perpetuating social disadvantage across generations.

Similarly, although many United States women are affluent and some now hold high professional and political offices, as a group, they are more likely than men to be poor, to earn less at a given educational level, and to be underrepresented in high political office. Human rights documents on nondiscrimination explicitly name women as a vul-

nerable group warranting special protection from discrimination. Patterns suggesting clinically unjustified underreceipt of certain cardiac treatments by women compared with men would reflect a gender disparity in a determinant of health (medical care, in this instance). Shorter life expectancy among men in general, if likely avoidable, would clearly be an issue of public health importance based on the magnitude of potential population impact. However, men as a group have more wealth, influence, and prestige, so this difference would not be a social injustice and, therefore, not a health disparity or equity issue. . . . [Other e]xamples of health differences that would not be considered health disparities according to our definitions . . . include: elderly adults generally having worse health than nonelderly adults; skiers being at higher risk of long-bone fractures than nonskiers; and men not having obstetric problems, whereas women do. . . .

The Issue Is Justice

Previous official approaches to defining health disparities in the United States have avoided being explicit about values and principles, perhaps for fear of stirring political opposition, because of genuine differences in values or because of the prevailing ethos that enjoins researchers to avoid the realm of values that might compromise the integrity of their science. Scientists, like all others, should be guided by ethical and human rights values. The first decade of the 21st century has ended with little if any evidence of progress toward eliminating health disparities by race or socioeconomic status. It is time to be explicit that the heart of a commitment to addressing health disparities is a commitment to achieving a more just society.

COMMUNITY: THE NEGLECTED TRADITION OF PUBLIC HEALTH*

Dan E. Beauchamp

What are the limits of government in protecting the health and safety of the public? As more and more states regulate personal behavior to protect the public health and safety, this question again becomes central. Can there be good reasons for public health paternalism in a democracy? Are health and safety individual interests, or also common and shared ends? . . . [Proposals to influence lifestyle choices have] reopened an old theme in democratic theory—paternalism and the meaning of the common good.

THE MEANING OF THE COMMON GOOD

In one version of democratic theory, the state has no legitimate role in restricting personal conduct that is substantially voluntary and that has little or no direct consequence for anyone other than the individual. This strong antipaternalist position is associated with John Stuart Mill. In his essay, "On Liberty," which has deeply influenced American and British thought, Mill wrote: "[t]he only purpose for which power can be rightfully exercised over any member of a civilized community, against his will,

* Reprinted from 1985. *Hastings Center Report* 15 (6): 28–36.

is to prevent harms to others." Mill restricts paternalism to children and minors. In his view the common good consists in maximizing the freedom of each individual to pursue his or her own interests, subject to a like freedom for every other individual. In the words of Blackstone, "The public good is in nothing more essentially interested than the protection of every individual's private rights."

In a second version, health and safety remain private interests but some paternalism is accepted, albeit reluctantly. . . . [C]ommonsense makes us reject a thoroughgoing antipaternalism. Many restrictions on liberty are relatively minor and the savings in life and limb extremely great. Further, often voluntary choices are not completely so; many choices are impaired in some sense. But . . . even where choices are not impaired, as in the choice not to wear seatbelts or to take up smoking, paternalism might still be accepted, because the alternative would be a great loss of life and a society in which each citizen was, for many important decisions, left alone with the consequences of his or her choice. . . . Another alternative is to redefine voluntary risks to an individual as risks to others. Indeed, many argue that all such risks have serious consequences for others, and that the state may therefore limit such activities on the basis of the harm principle. Others challenge the category of voluntariness head on, arguing that most such risks, like cigarettes and alcohol use, have powerful social determinants.

The constitutional basis for the protection of the public health and safety has largely been ignored in this debate. This tradition, and particularly the regulatory power (often called the police power), flows from a view of democracy that sees the essential task of government as protecting and promoting *both* private and group interests. Government is supposed to defend both sets of interests through an evolving set of practices and institutions, and it is left to the legislatures to determine which set of interests predominate when conflicts arise.

In the constitutional tradition, the common good refers to the welfare of individuals considered as a group, the public or the people generally, the "body politic" or the "commonwealth" as it was termed in the early days of the American Republic. The public or the people were presumed to have an interest, held in common, in self-protection or preservation from threats of all kinds to their welfare. . . .

The central principles underlying the police or regulatory power were the treatment of health and safety as a shared purpose and need of the community and (aside from basic constitutional rights such as due process) the subordination of the market, property, and individual liberty to protect compelling community interests.

This republican image of democracy was a blending of social contract and republican thought, as well as Judeo-Christian notions of covenant. In the republican vision of society, the individual has a dual status. On the one hand, individuals have private interests and private rights; political association serves to protect these rights. On the other hand, individuals are members of a political community—a body politic.

This common citizenship, despite diversity and divergence of interests, presumes an underlying shared set of loyalties and obligations to support the ends of the political community, among which public health and safety are central. In this scheme, public health and safety are not simply the aggregate of each private individual's interest in health and safety, interests which can be pursued more effectively through collective action. Public health and safety are community or group interests (often referred to as "state interests" in the law), interests that can transcend and take priority over private interests if the legislature so chooses.

The idea of democracy as promoting the common or group interest is captured in Joseph Tussman's classic work (1960, 27–28) on political obligation: "[T]he government's concern for the individual is not to be understood as special concern for this or that individual but rather as concern for all individuals. Government, that is to say, serves the welfare of the community." This emphasis on the *public*'s health has never meant that the state's power to protect health and safety is unlimited. It has meant that individual liberty and the institutions of the market and private property, operating in the public world, are subject to a developing set of practices designed to defend the common life and the community. . . .

THE LANGUAGE OF PUBLIC HEALTH

The constitutional tradition for public health constitutes one of those "second languages" of republicanism that Robert Bellah and his coauthors speak of in . . . *Habits of the Heart*. In their book, the first language (or tradition of moral discourse) of American politics is political individualism. But there are "second languages" of community rooted in the republican and biblical tradition that limit and qualify the scope and consequences of political individualism.

Public health as a second language reminds us that we are not only individuals, we are also a community and a body politic, and that we have shared commitments to one another and promises to keep. . . .

The danger is that we can come to discuss public health exclusively within the dominant discourse of political individualism, relying either on the harm principle or a narrow paternalism justified on grounds of self-protection alone. By ignoring the communitarian language of public health, we risk shrinking its claims. We also risk undermining the sense in which health and safety are a signal commitment of the common life—a central practice by which the body-politic defines itself and affirms its values. . . .

Public health belongs to the realm of the political and the ethical. Public health belongs to the ethical because it is concerned not only with explaining the occurrence of illness and disease in society, but also with ameliorating them. Beyond instrumental goals, public health is concerned with integrative goals—expressing the commitment of the whole people to face the threat of death and disease in solidarity. . . .

To Mill [(1882, 135–36)], all paternalism was wrong because the individual is best placed to know his own good: "He is the person most interested in his own well-being: the interest which any other person, except in cases of strong personal attachment, can have in it, is trifling. . . ." But precisely because public health paternalism is aimed at the group and its practices, and not the specific individual, Mill's point is wrong. The good of the particular person is not the aim of health policy in a democracy which defends both the community and the individual. In fact, Mill is wrong twice, because particular individuals are often very poorly placed to judge the effects that market arrangements and practices have on the population as a whole. This is the task for legislatures, for organized groups of citizens, and for other agents of the public, including the citizen as voter.

Mill's dichotomy of either the harm principle or self-protection is too limited; the world of harms is not exhausted by self-imposed and other-imposed injuries. There is a third and very large set of problems that afflicts the community as a whole and that results primarily from inadequate safeguards over the practices of the common life. . . .

Creating, extending, or strengthening the practices of public health—and the collective goods principle that underlies it—ought to be the primary justification for our

PHOTO 1.2. Residents share their concerns about local environmental issues at a town hall meeting. Town hall meetings convened by the Agency for Toxic Substances and Disease Registry, part of the U.S. Centers for Disease Control, allow residents to express concerns and ask questions. Photograph by Cade Martin for the Centers for Disease Control and Prevention, 2009.

health and safety policy. Instead we usually base these regulations on the harm principle. We usually justify regulating the steel or coal industry on the grounds that workers and the general public have the risks of pollution or black lung visited on them, but consumers are not obliged to drink alcohol or smoke cigarettes. While this may be true, in the communitarian language and categories of public health, fixing blame is not the main point. We regulate the steel or coal industry because market competition undervalues collective goods like a clean environment or workers' safety. Using social organization to secure collective goods like public health, not preventing harms to others, is the proper rationale for health and safety regulations imposed on the steel or coal industry, or the alcohol or cigarette industry.

In an interesting passage in "On Liberty[,"] Mill touched on the issue in the case of the alcohol industry. Mill conceded that the alcohol industry had an interest in intemperance: "The interest, however, of these dealers in promoting intemperance is a real evil, and justifies the State in imposing restrictions and requiring guarantees which but for that justification would be infringements of real liberty." Actually, industry has far more than an "interest in intemperance." The alcohol industry and business generally have a strong interest in unsafety and lower levels of public health, resisting vigorously public health measures to regulate either pollution or smoking and drinking.

The main lesson to learn from public health paternalism as it has developed in the constitutional tradition may well be that the second language of community and the

virtues of cooperation and beneficence still exist, albeit precariously, alongside a tradition of political individualism. Strengthening the public health includes not only the practical task of improving aggregate welfare, it also involves the task of reacquainting the American public with its republican and communitarian heritage, and encouraging citizens to share in reasonable and practical group schemes to promote a wider welfare, of which their own welfare is only a part.

EVOLVING MODELS OF PUBLIC HEALTH

The population perspective, prevention orientation, and social justice commitment of public health have been relatively constant influences on public health science and practice (though the public health community has not always faithfully adhered to the principle of social justice, as we discuss in chapter 2). Over the last 200-plus years, however, the models that have guided public health problem solving have evolved considerably in response to changing disease trends and scientific discoveries. An understanding of this history informs our exploration of current approaches to public health intervention throughout this reader and is particularly relevant to the debate over the legitimate scope of public health law, to which we turn in the next section of this chapter.

We begin with a survey of the three basic models or paradigms that guided public health problem solving prior to the emergence of the now-dominant social-ecological model. The first model, developed in the nineteenth century by sanitarian campaigners, is widely referred to as the *miasma* model. The second, which emerged during the late nineteenth century in response to germ theory, is referred to interchangeably as the *agent, microbial,* or *germ* model. The third, which is now widely referred to as the *behavioral* model, emerged during the mid- to late twentieth century, when Mervyn and Ezra Susser termed it the *black box* paradigm. By the late 1990s, the Sussers lent their voices to a growing call for a new approach, which would eventually emerge as the *social-ecological* model.

CHOOSING A FUTURE FOR EPIDEMIOLOGY: I. ERAS AND PARADIGMS*

Mervyn Susser and Ezra Susser

[O]ne can discern at least three eras in epidemiology, each with its own dominant paradigm: (1) the era of sanitary statistics with its paradigm, miasma; (2) the era of

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infectious disease epidemiology with its paradigm, the germ theory; and (3) the era of chronic disease epidemiology with its paradigm, the black box.

SANITARY STATISTICS AND MIASMA

Miasma was the prevailing theory of the Sanitarians for the greater part of the 19th century. Sanitary statistics made plain the toll of sickness and death in the city slums of England, France, Germany, Scandinavia, and the United States. . . . For the conditions in these slums, the Sanitarian hypothesis of miasma impugned poisoning by foul emanations from the soil, water, and environing air. . . . Closed drainage and sewage systems, supplemented by garbage collection, public baths, and housing, were the remedies that would disperse miasma, reduce mortality and morbidity (as indeed they did), and dispel the poverty of the new urban poor (as indeed they did not). A foremost proponent—and in some cases, the originator—of these innovations was Edwin Chadwick. Chadwick was a reformist who argued that disease engendered by the physical environment caused poverty. Friedrich Engels, his contemporary, was a revolutionary who, in documenting the ills of Manchester factory workers, understood poverty to be the cause rather than the consequence of their ills. But both agreed that the issues were societal and that the appropriate measures thus had to be applied across society. . . .

Unmodified, the miasma paradigm could not survive advances in microbiology, and its demise brought an end to the Sanitary Era. . . . An irony of the history of public health is that, while the sanitarians were mistaken in their causal theory of foul emanations, they nonetheless demonstrated how and where to conduct the search for causes in terms of the clustering of morbidity and mortality. The reforms they helped to achieve in drainage, sewage, water supplies, and sanitation generally brought major improvements in health. Their mistake lay in the specifics of biology rather than in the broad attribution of cause to environment. . . .

INFECTIOUS DISEASE EPIDEMIOLOGY AND THE GERM THEORY

[Germ theory] led in the end to the narrow laboratory perspective of a specific cause model—namely, single agents relating one to one to specific diseases. The germ theory and its attendant view of specific cause dominated medical and public health sciences from the last quarter of the 19th century through at least the mid-20th century. Single agents of disease were sought by the isolation and culture of microorganisms from disease sites, the experimental transmission of these microorganisms, and the reproduction of lesions. The appropriate responses were to limit transmission by vaccines, to isolate those affected, and, ultimately, to cure with chemotherapy and antibiotics. . . . The search for other than microbiological causes of disease in the environment stumbled if it did not altogether cease. . . .

The irony of the Sanitary Era was here reversed. While, within their limited frame of reference, the germ theorists were accurate in their causal attributions for many diseases, their narrow focus retarded the creative use of bacterial discoveries to advance the science of epidemiology. . . .

Whatever the causes, the great scourges of communicable disease did come under control in the developed countries. Once the major infectious agents seemed all to have been identified and communicable disease no longer overwhelmed all other mortal disorders, the force of the germ theory paradigm faded. . . . [F]ew anticipated

PHOTO 1.3. A Red Cross worker lights a cigarette for a wounded soldier, 1918. During World War I, cigarette companies promoted smoking as a way for soldiers to relax and charitable organizations distributed free cigarettes to troops. By the mid-twentieth century, lung cancer rates were soaring among middle-aged American men. Observational studies linked lung cancer to smoking, prompting the rise of the behavioral, or "black box," model of public health. Photograph by unidentified photographer for the U.S. Army Signal Corps.

the recrudescence of communicable disease or new global epidemics. With the emerging predominance of chronic disease of unknown cause, under any credible causal paradigm the social and physical environment had now to be reckoned with once more.

CHRONIC DISEASE EPIDEMIOLOGY AND THE BLACK BOX

World War II serves as a convenient watershed for the beginning of the Chronic Disease Era and the black box paradigm. Shortly after the war ended in 1945, it was clear that, in the developed world, rising chronic disease mortality had overtaken mortality from infectious disease. The rise was not owed to the aging of populations alone. In middle-aged men specifically, the rises in peptic ulcer disease, coronary heart disease, and lung cancer were in each case fast and frightening enough to earn place and title as epidemics. . . .

The case-control and cohort studies on smoking and lung cancer, and the early cohort studies on coronary heart disease that established serum cholesterol and smoking as risk factors, demonstrated the power of the observational method and established its credentials. These studies carried the invisible imprimatur of the black box paradigm ("black box" being the general metaphor for a self-contained unit whose inner processes are hidden from the viewer). This paradigm related exposure to outcome without any necessary obligation to interpolate either intervening factors or

even pathogenesis. . . . Epidemiologists were faced once more, as in the Sanitary Era, with major mortal diseases of completely unknown origin. . . . [They] were obliged to depart from the specific-cause model of the germ theory. The metaphor of a "web of causation" characterized the multicausal nature of public health problems, particularly those of chronic disease. . . .

MOMENTUM FOR A NEW ERA

The climax and, in all likelihood, the culmination of the black box as dominant paradigm is already upon us. [Among the forces] blunting the black box paradigm [is] a transformation in global health patterns [exemplified by] the human immunodeficiency virus (HIV) epidemic [which] has demonstrated that both developing and developed countries remain vulnerable to devastation by infectious disease. . . . No vaccine now in prospect seems likely to achieve the efficacy level that could also achieve epidemic control. Absent such efficacy, the failure to control the disease resides in our lack of understanding of transmission and illness in the social context. We know which social behaviors need to change, but we know little about how to change them, even when entire societies are at stake.

In retrospect, our confidence during the Chronic Disease Era about the control of infectious diseases seems naive and also blind to the less developed world. For the majority of the world's population, chronic infections—tuberculosis, syphilis, malaria, and many others—were never under control. As with HIV infection, the immediate causes and the risk factors were known, but this knowledge could not be translated into protection of the public health.

Similarly, our confidence in our ability to control chronic noncommunicable diseases themselves by modifying behavior that carries risk has been shaken. Again, knowledge of risk factors and interventions directed solely at changing the behavior of individuals . . . have proven insufficient.

Health problems driven by societal problems point to the location of the underlying difficulties. The black box paradigm alone does not elucidate societal forces or their relation to health. The focus on populations is generally directed at the individuals within them. . . .

In the evolution of modem epidemiology, dominant paradigms have been displaced by new ones as health patterns and technologies have shifted. As happened with previous paradigms, the black box, strained beyond its limits, is soon likely to be subsumed if not superseded entirely by another paradigm. This paradigm reflects a particular era in our development as a discipline. In our view, we stand at the verge of a new era.

. . .

Susser and Susser were not alone in their call for a new model for public health. The black box paradigm—which public health experts now refer to as the *behavioral* model of public health—was criticized by many as descriptively inadequate and normatively problematic. Robert Crawford argued that the behavioral model supported an individualistic, victim-blaming "masquerade":

> The complexities of social causation are only beginning to be explored. The ideology of individual responsibility, however, inhibits that understanding and substitutes instead an unrealistic behavioral model. It both ignores what is known about human behavior and minimizes the importance of evidence about the environmental assault on health. It instructs people to be individually responsible at a time when they are becoming less capable as individuals of controlling their total health environment. Although environmental factors are often recognized as "also relevant," the implication is that little can be done about an ineluctable, technological, and industrial society. . . . What must be questioned is both the effectiveness and the political uses of a focus on life-styles and on changing individual behavior without changing social structure and processes. (Crawford 1979, 256)

Sylvia Tesh criticized the behavioral model on similar grounds: "[It] approaches disease as though ill health is the result of personal failure. It dismisses with a wave of a hand most environmental toxins and it ignores the crucial connection between individual behavior and social norms and rewards. It is, in fact, a victim-blaming approach to disease" (Tesh 1981, 379).

Amid these criticisms, a new model began to emerge, which Kenneth R. McLeroy and his colleagues described as an *ecological* model for health promotion. They began by noting that "the language we use, and the models we adopt for health promotion programming, may inadvertently serve to direct our attention toward certain types of interventions and away from others. Specifically, the use of terms such as 'life-style,' and 'health behavior' may focus attention on changing individuals, rather than changing the social and physical environment which serves to maintain and reinforce unhealthy behaviors" (McLeroy et al. 1988, 353). They emphasized that behavior patterns are determined by

1. intrapersonal factors—characteristics of the individual such as knowledge, attitudes, behavior, self-concept, skills, etc. This includes the developmental history of the individual.
2. interpersonal processes and primary groups—formal and informal social network and social support systems, including the family, work group, and friendship networks.
3. institutional factors—social institutions with organizational characteristics, and formal (and informal) rules and regulations for operation.
4. community factors—relationships among organizations, institutions, and informal networks within defined boundaries.
5. public policy—local, state, and national laws and policies. (355)

From its beginning, the social-ecological model represented a return to the social justice roots of the sanitarian movement, with a focus on reaching "groups in society who are at greatest risk for behaviorally related health care problems, such as the poor, intravenous drug users, delinquent adolescents, and the socially isolated" (354). McLeroy and his colleagues cautioned, however, that the shift from the behavioral model to the social-ecological model would involve new ethical trade-offs:

> While strategies based on an ecological model tend to minimize the likelihood of victim blaming, they can result in charges of coercion. Policy approaches, such as raising the taxes on cigarettes, or banning smoking in public spaces, may be viewed as restricting individual rights and freedoms . . . Social support interventions may . . . be coercive when interpersonal social influences are used to achieve behavioral changes. Even mass media approaches may be coercive when they are based on appeals to emotions, or manipulate information. Such approaches can also be viewed as a form of paternalism and are considered by some to be an invasion of privacy. (368–69)

McLeroy and his colleagues proposed that engagement with affected populations would minimize problems of coercion and paternalism. Noting that "[t]he process of using ecological strategies . . . is one of consensus building," they argued for "active involvement of the target population in problem definition, the selection of targets of change and appropriate interventions, implementation, and evaluation" (369).

WHAT IS THE LEGITIMATE SCOPE OF PUBLIC HEALTH LAW?

As we have just seen, answering the question "What is public health?" is more difficult than it first appears. With this preliminary overview of the population perspective, prevention orientation, social justice commitment, and problem-solving models of public health science and practice as our foundation, we now turn our attention to defining public health law. In chapter 2 we will turn our attention to a similar examination of public health ethics.

We define public health law as follows (Gostin and Wiley 2016, 4):

> Public health law is the study of the legal powers and duties of the state to assure the conditions for people to be healthy (to identify, prevent, and ameliorate risks to health in the population) and the limitations on the power of the state to constrain the autonomy, privacy, liberty, proprietary, or other legally protected interests of individuals for the common good. The prime objective of

> public health law is to pursue the highest possible level of physical and mental health in the population, consistent with the values of social justice.

This definition, which first appeared in the 2000 edition of *Public Health Law: Power, Duty, Restraint,* is not without controversy. As public health law comes into its own as a field, the project of defining its identity and scope has benefited from diverse viewpoints, which we present in the excerpts and discussion that follow.

In our view, the fields of public health science and practice, public health law, and public health ethics are inextricably intertwined. It is undeniable that law and ethics should govern the conduct of scientific inquiry and the practice of public health. More controversially, developments in public health science and practice are expanding the scope of public health law and ethics beyond a narrow focus on communicable disease control. Our expansive definition of public health law is influenced by the social-ecological model of public health science and practice. Indeed, our conception of law as offering a toolkit for public health intervention (including direct regulation, indirect regulation through tort liability, taxation, and spending, and deregulation to remove legal barriers to good public health practice, each of which are explored in Part Three of this reader) implicitly adopts an understanding of law itself as a crucial social determinant of population health.

Law and policy strategies influenced by the social-ecological model of public health generate controversy on multiple levels. Media pundits serve up scathing condemnations of what they view as overreaching public health interventions. In Congress, state legislatures, and city council meetings, representatives debate the extent to which health is a matter of personal or collective responsibility. In the courts, litigants argue about which health and safety concerns are legitimately viewed as public in nature, such that doctrines privileging the role of the state should be brought into play. And in the academic literature, a handful of scholars have put forward a critique of the expanding scope of public health law. In the excerpts and discussion that follow, Mark Hall and Richard Epstein argue that the scope of public health law should be limited, even as the scope of public health science and practice expands in response to changing disease trends (the growing importance of noncommunicable diseases and injuries in the United States and globally) and to evidence that social, environmental, and economic determinants play a powerful role in shaping population health.

THE SCOPE AND LIMITS OF PUBLIC HEALTH LAW*

Mark A. Hall

This essay explores the proper scope of public health legal authority in response to compelling scientific evidence about the social determinants of health. It does so using four stories from my own experience.

FOUR STORIES ABOUT PUBLIC HEALTH LAW

My Daughter's New Puppy

Last year, we got a new puppy. One day, when it was two months old, it playfully bit my daughter, barely breaking her skin, but my daughter has germ-phobic tendencies that are aggravated by the constant warnings she receives in her school's mandatory health education courses, including warnings about rabies. To ease her anxiety, my wife called the vet to reassure her that a brand-new puppy could not have rabies, but the vet, following standard health department orders, notified the authorities. They called our home (having somehow traced our phone number) to ask whether the puppy had gotten a rabies shot. We pointed out that the health department's own rules don't allow rabies shots until a puppy is three months old, but the health department nevertheless demanded we turn over our public menace for quarantine. When we initially demurred, they threatened to send out the authorities to seize the puppy and arrest us for resisting, so the puppy had to spend three weeks in lock-up. This forever damaged its psyche and that of my daughter, who feels responsible for the hysterical overreaction.

The Strategy of Anti-Tobacco Activists

A few months ago at a wedding reception, I was chatting with a person who happened to be a public health official in charge of tobacco control in another state. I remarked on the tremendous success the public health community has had in creating a strong social stigma against cigarette smoking, even in Winston-Salem where I live, by forcing smokers to huddle in designated spots outside of public spaces and most larger workplaces. She gleefully explained that this was exactly the activist public health strategy all along: to publicize the dangers of secondhand smoke in order to enlist the public's support against smokers' rights and to shift social norms so that smoking is seen as deviant and smokers are visibly ostracized.

Childhood Obesity and Parental Abuse

The following story is compiled from newspaper articles, as recounted recently in the *Boston University Law Review* (Arani 2002):

> On August 25, 2000, New Mexico state officials removed three-year-old Anamarie from the custody of her parents, Miguel and Adela. "We heard her screaming all the way down the hall," recalled Adela. "We sat there in shock that they actually took her away from us." . . . New Mexico officials charged Anamarie's parents with failing to

* Reprinted from 2003. *Perspectives in Biology and Medicine* 46 (3): S199–S209.

> follow a doctor's instructions to treat their daughter's obesity. . . . At the age of three, Anamarie stood almost four feet tall and weighed 131 pounds. She was admitted to the University of New Mexico Hospital for three weeks and placed on a liquid diet limited to 550 calories per day. After losing ten pounds, Anamarie was sent home with instructions from the treating physicians to maintain the liquid diet. Nevertheless, . . . by August 16, 2000, Anamarie's weight had risen, and she was once again hospitalized for a fever and irregular breathing. She remained hospitalized until her weight dropped to 117 pounds. Alarmed by the child's continuing condition, the family's physician brought his concern to the attention of the [child protective authorities, who] agreed that . . . her parents' . . . failure to keep Anamarie on a liquid diet was endangering her life. . . . After spending more than two months in state custody, the court allowed Anamarie to return home.

Correcting the Socioeconomic Gradient of Health

Finally, this is a quote from an article about the role that public health authorities should play in changing the social conditions that contribute to poor health. The article is by three authors now on the Harvard faculty, two of whom are leading voices in the public health community:

> Research on the social determinants of health warns us that antipoverty policies do not go far enough in reducing unjust health disparities. . . . Addressing the social gradient in health requires action above and beyond the elimination of poverty. To address comprehensively the problem of health inequalities, governments must begin to address the issue of economic inequalities per se. . . . Most importantly, economic disparities seem to influence the degree of equality in political participation, in the form of voting, donating to campaigns, contacting elected officials, and other forms of activity. . . . Who participates matters for political out-comes, and the resulting policies have an important impact on the opportunities for the poor to lead a healthy life. For both of the foregoing reasons—that it yields a higher level of health achievement as well as greater political participation—the reduction of income disparity ought to be a priority of government concerned about addressing social inequalities in health. (Daniels, Kennedy, and Kawachi 1999)

WHEN EPIDEMIOLOGISTS BECOME LAWMAKERS

These four insights into the mindset of the public health community give us a lot to think about. I want to stress one core thought: that public health law needs to more clearly differentiate between public health analysis and public health authority, or, if you will, between public health diagnosis and public health treatment. Public health officials are charged with two broad responsibilities: (1) advancing understanding and knowledge of the causes and patterns of health conditions in society; and (2) eliminating threats to public health. The first is the domain of public health as a scientific

discipline. The second is the domain of public health law. The central point of this essay is that public health law is much more limited than public health science.

These definitional boundaries matter a great deal because the law operates through categories, and classification has huge effects on how legal issues are analyzed. The same events will have profoundly different legal consequences depending on whether they are classified under the distinct legal domains of contract, tort, property, or criminal law. Likewise, health care law and public health law operate from fundamentally different sets of assumptions and heuristics. Take childhood immunizations for polio as an example. Viewed under health care law, the starting premise is the individual's (or parent's) right to be informed of options and their consequences, and to decide whether or not to be vaccinated. Polio vaccinations should be offered, but refusals should be readily honored, and patients should be told which forms of the vaccine are safest for them. Health care law is about maximizing patients' options, protecting their individual best interests, and enforcing obligations that arise from the fiduciary characteristics of the treatment relationship. Courts protect patients' rights and options, sometimes with constitutional fervor (as, for example, with respect to abortion and the refusal of life support), and limitations on these rights occur only as exceptions, such as in emergencies, situations of limited competence, or acute threats of injury to third parties.

Public health law is about enforcing government efforts to promote health. It starts with the assumption that public authority is plenary and sets restraints on this authority only it if invades fundamental interests or is demonstrably unbalanced or excessive. Under public health law, the presumptions are all in favor of intervention, whereas under health care law, the presumptions are all in favor of privacy. Public health law is not troubled by making vaccinations mandatory, despite possible harm from side effects that may greatly outweigh the benefits of vaccination to any one individual (due to an individual's ability to free ride on the "herd immunity" of the community), nor is public health law troubled by requiring that more potent and riskier forms of a vaccine be used, even though the enhanced benefits accrue to people other than those who take on the risk.

These two perspectives are not ends of a spectrum; instead, they function as polar and mutually exclusive categories. This, then, is what makes the definitional game worth all the marbles. The public health perspective has transformative power to radically reframe society's attitudes about social issues. This explains why some public health advocates, like the one in my conversation about tobacco control policy, seek to colonize other social arenas, such as seat belts, firearms, and alcohol consumption. Viewed from one perspective, these are issues of individual choice. Viewed from another perspective, however, each of these is a public health problem, one that justifies coercive government intervention to prevent individuals' choices from harming themselves or others. At this juncture, my point is not that one perspective or the other is right or wrong. Rather, it is simply that government agencies would not have pushed nearly as far as they have in these arenas, and society would not have been nearly as receptive as it has been, if these had not been classified as public health issues.

This analysis helps to explain the strong inclination to apply the public health paradigm to new problems, such as obesity. Viewing excess weight as a public health concern rather than simply as a matter of individual health behavior leads to a whole new way of thinking about such issues as parental abuse and neglect, consumer product safety, regulation of the fast food industry, health insurance rating and underwriting practices, and countless others.

Classifying problems as public health problems tends to invoke public health legal principles, because public health officials are bathed in public health law. They are taught its principles in school and in professional meetings; they live it and breathe it. Accordingly, the public health law outlook has a pervasive effect on public health officials' sense of what they are entitled to do and of the tools that are available to address a public health problem. The uncompromising authoritarian and utilitarian public health perspective demonstrated by my puppy story is intensely ends-oriented, which tends to ingrain the following habit of thought: once having identified a causal connection to a widespread health problem, action is necessary to eradicate the cause and eliminate the problem at its source, and it falls within the authority of public health or other government officials to take the necessary actions. The necessary actions are those that produce the desired results. Public health officials may start with less intrusive, more innocuous measures, such as information, education, or taxation, but if these fail, then the case is even stronger for pursuing a panoply of more aggressive and coercive strategies, including mandates and bans, closures and seizures, quarantine, and criminal sanctions. The metaphors of public health strategy are war-like. Its rhetoric is to attack, conquer, and eradicate, rather than to exercise prudence, balance, and restraint.

Public health officials are aware that individual rights need to be weighed against public health objectives, and modern statutes such as the Model State Emergency Health Powers Act seek to carefully delineate when more coercive powers can legitimately be used. However, my point is not that any particular enactment goes overboard, or that any particular set of regulators have excessive powers. Instead, I wish to focus on the general attitude that advocates take when a problem area is identified as being an issue of public health. They use existing authority to eliminate the problem as thoroughly as they can, and if they lack sufficient authority, they seek additional powers to deal with the threat. These powers can be conferred on traditional health department regulators or they can be given to other agencies of government that pursue public health policies. This leads to dangerous conditions in which public health officials can overstep the proper bounds of public health law, even though they arguably are continuing to exercise proper analytical tools for understanding public health problems.

LET THE SHOEMAKER STICK TO HIS LAST: A DEFENSE OF THE "OLD" PUBLIC HEALTH*

Richard Allen Epstein

This paper investigates the proper understanding of the discipline of public health. How far does it run and what does it encompass? Dealing with this question requires moving back and forth between the conception of public health that is internal to the public health discipline, and the conception of public health as it has been understood outside the public health field by historians and lawyers who are interested in defining the appropriate use and limitations of the state power of coercion. The old public health established the principle that epidemics offer strong reason for decisive public intervention, whether by quarantine, vaccination, or the creation of public sewers and waste disposal systems. Today, the new public health uses the term "epidemic" to

* Reprinted from 2003. *Perspectives in Biology and Medicine* 46 (3): S199–S209.

justify state regulation to limit tobacco consumption or control obesity, even though these activities do not pose risks of communicable disease or any other form of recognizable externalities (*pace* secondhand smoke) to other individuals.

For its part, the old public health tracks the idea of public goods in economics, namely, those non-excludable goods that cannot be supplied to one unless they are also given to another. . . . It thus invokes an analogous concept for "public bads": those harms inflicted on others without their consent, as, for example, both communicable diseases and pollution. In contrast, the new public health covers matters of general public importance, including obesity, smoking, and genetic diseases.

My broad thesis is that the "old" public health is superior to the new, whose broad (and meddlesome) definitions of public health help spur state actions—including the regulation of product and labor markets—that in all likelihood jeopardize the health of the very individuals the new public health seeks to protect. The new public health extends regulation into inappropriate areas, and thus saps the social resources and focus to deal with public health matters more narrowly construed. . . .

TWO RIVAL CONCEPTIONS OF PUBLIC HEALTH

One narrow account of the police power was offered by Justice Harlan in *Jacobson v. Massachusetts* (1905), the bellwether public health case that upheld a compulsory vaccination law:

> Although this court has refrained from any attempt to define the limits of that power, yet it has distinctly recognized the authority of a State to enact quarantine laws and "health laws of every description"; indeed, all laws that relate to matters completely within its territory and which do not by their necessary operation affect the people of other States. According to settled principles the police power of a State must be held to embrace, at least, such reasonable regulations, established directly by legislative enactment as will protect the public health and the public safety.

Even this definition of public health gives rise to the well-known tension between individual liberty and the common good, which Justice Harlan articulated as follows:

> But the liberty secured by the Constitution of the United States to every person within its jurisdiction does not import an absolute right in each person to be, at all times and in all circumstances, wholly freed from restraint. There are manifold restraints to which every person is necessarily subject for the common good. On any other basis, organized society could not exist with safety to its members. Society based on the rule that each one is a law unto himself would soon be confronted with disorder and anarchy. Real liberty for all could not exist under the operation of a principle which recognizes the right of each individual to use his own, whether in respect to his person or his property, regardless of the injury that may be done to others.

In contrast, the more modern account of public health is best described in the language of its defenders:

> The broad pole of public health defines a very wide scope of organized activities, concerned not only with the provision of all types of health services, preventive and therapeutic, but also with the many other components relevant to the operation of a national health system. These involve questions of health behavior and the environment as well as the production of resources (personnel and facilities), the organization of programs, the development of economic support, and the many strategies required to ensure equity and quality in the distribution of health services. (Tulchinsky and Varavikova 2000, xix)

In similar fashion, Lawrence Gostin (2000) quite consciously entwines old functions (which are, rightly, not abandoned), with new ones in his account of the scope of public health:

> The mission of public health is broad, encompassing systematic efforts to promote physical and mental health and to prevent disease, injury and disability. The core functions of public health agencies are to prevent epidemics, protect against environmental hazards, promote healthy behaviors, respond to disasters and assist communities in recovery, and assure the quality and accessibility of health care services.

On both these issues, we can see a powerful transformation from the old to the newer view. On the question of public health or common good, the original definition was confined (not perfectly, but by and large) to those goods, or bads, that raised serious issues of market failure. It included dealing directly with risks of communicable disease and, of course, pollution, but only to the extent that these were directly linked to particular pathogens or substances. As such, it applied only to situations where competitive markets based on strong individual rights of private property could not be relied on to achieve anything close to the social optimum. The modern view simply invokes the idea of the common good (or the public interest) to allow state regulation on any matter of business or social life that affects a substantial fraction of the community, where the allocative outcomes of the competitive marketplace no longer supply a normative baseline against which to measure the efficacy and validity of state regulation. The broader view allows for extensive regulation of competitive markets that the narrower view limits. . . . [T]hese may be goals that are worth achieving, but they should not be transformed into public health goals as such. . . .

CONCLUSION

In one sense, the debate over the proper response to public health offers but one arena in which to test the relative power of the classical liberal as opposed to the modern social welfare model of the state. Here, too, I think that the classical model outperforms its rival. By stressing the importance of private wealth creation through private property and voluntary exchange, the classical model gives individuals the resources that allow them to take effective individual measures to ensure and promote their own health. By offering focused intervention in matters of communicable disease, it seeks

to control externalities that private forces cannot resist. The two efforts are not unrelated. The increase in private wealth will result in greater public revenues, at lower tax rates, to create the social infrastructure and environmental control systems needed to contain these public health risks in the first place. . . . The modern public health makes every social change relevant to health issues. But once it opens up the field to examine the gains from more infrastructure and greater income equality, it must take into account the public health losses, now broadly defined, from the failure to create new wealth and maintain higher standards of living. At this point, the new public health is scarcely distinguishable from a general social welfarist position whose benefits it shares, and whose fatal deficiencies it cannot escape.

. . .

In addition to the civil libertarian and economic critiques put forth by Hall and Epstein above, Mark Rothstein (2002) has advanced a distinctly progressive critique of our expansive definition of public health law. He begins by noting that "[t]here is a growing trend to include within the sphere of public health all the societal factors that affect health. . . . including war, violence, poverty, economic development, income distribution, natural resources, diet and lifestyle, health-care infrastructure, overpopulation, and civil rights." He acknowledges that

> There is much to recommend viewing the sources of health broadly. . . . Yet the conceptual value of considering the health of a population in light of a wide array of factors does not necessarily translate into a practical framework for implementing policy. . . . It is understandable why knowledgeable and caring health professionals would want to improve the health of individuals and communities by focusing on the root causes of illness and disease. Analyzing political, economic, and social issues in a scientific manner is appealing by providing essential data and more rigorous methodology. It also seems to help make the concerns more objective and their remediation more achievable. Unfortunately, labeling so many activities as public health does little if anything to eliminate the problem of poor health.

Rothstein warns against the "public healthification" of social problems, arguing that "public health provides too narrow a perspective to be effective [because] public health research questions as currently conceptualized are less complex than the social and political issues (conflicting interest groups, conflicting value systems, power relationships) that need to be resolved for interventions to be successfully applied." He poses intuitively appealing rhetorical questions:

> What curriculum could possibly train public health professionals on all the various root causes of poor health? What political system or public health budget will support far-ranging interventions by those charged with protecting public health? What effect will such seemingly quixotic activities have on the

> ability of public health professionals to combat traditional public health problems, such as infectious diseases and poor sanitation, as well as new threats, such as bioterrorism? Individuals trained in public health should not give up the noble struggle to ensure that every person has a minimum standard of living to support a healthy life. But this battle must be fought together with people from all disciplines and all walks of life and without using the self-defeating strategy of annexing human rights into the public health domain.

Rothstein ends with caution that harkens back to Hall's and Epstein's libertarian concerns:

> It is incongruous to embrace the broadest meaning of public health at the same time that our legal system and public health infrastructure are based on a narrow definition of public health jurisdiction, authority, and remedies. Moreover, the boundless conception of public health now gaining in popularity not only may fail to achieve its goal of alleviating the economic and social roots of ill health, but it may actually impede the ability of public health officials to provide traditional public health services. The moral and political power of governments to act in the realm of public health devolves from the existence of a serious threat to the public. Coercive public health measures are justified by the natural law principle of self-preservation applied on a societal basis. Indeed, modern public health traces its philosophical roots to nineteenth century utilitarianism. The broad power of government to protect public health includes the authority to supersede individual liberty and property interests in the name of preserving the greater public good. It is an awesome responsibility, and therefore it cannot and must not be used indiscriminately.

Criticism of the new public health law was to some extent inevitable. As Roger Magnusson (2007, 572) has explained, "[t]he use of law as a policy tool to respond comprehensively to environmental exposures, unhealthy lifestyles, and accidental injuries threatens to impinge on the interests of a wide variety of industries, and to significantly expand sites for state intervention." By exploring (and ultimately seeking to disrupt) causal connections between ill-health and such powerful institutions as tobacco companies, industrial polluters, firearm manufacturers, and fast-food chains, modern public health provokes backlash.

Certainly, the critical response to new public health is motivated in part by material interests. But it also arises out of deep-seated philosophical and cultural views about whether the degree of government intrusion long-supported by the Supreme Court in canonical decisions like *Jacobson v. Massachusetts* (1905), which upheld compulsory vaccination (discussed in chapter 4), is justified when applied to noncommunicable diseases, injuries, and the social determinants of health.

On a philosophical level, the debate over new public health law arises out of a tension between public health's communitarian foundations and the liberal foundations of American law and policy. Thaddeus Pope (2011), another critic of the expansive vision of public health law, has articulated the tension in terms of core values: "[l]iberalism demands that liberty limitation be carefully, narrowly, and thoroughly justified. Communitarianism, in contrast, holds that individual rights and social responsibilities are equivalent, and that liberty and the common good have equal standing."

On a cultural level, the expansion of public health law highlights a central tension between the behavioral model and the social-ecological model. Characterizing the chief task of public health as the control of risky behavior (e.g., unsafe sexual practices, unhealthy eating, or tobacco use) "can quickly become, for cultural and political reasons, a warrant for treating health entirely as a matter of personal responsibility" (Gostin, Burris, and Lazzarini 1999, 72). The behavioral model's notion of health as a matter of personal responsibility has been so influential that critics of the new public health law have adopted it implicitly in their critique of the social-ecological model's emphasis on collective responsibility for public health. Critics of the "revolution" in public health have wrongly posited a shift from the "old" agent model to the "new" social-ecological model. Ironically, this oversimplified story both omits and tacitly adopts the behavioral model's view that law has little relevance to modern public health problems. It also ignores the extent to which the social-ecological model represents a return to the nineteenth-century sanitarians' focus on societal causes and structural solutions.

Hall and Epstein begin from the proposition that regardless of the validity of social epidemiology as a scientific matter, it does not necessarily follow that state authority to intervene "under the banner of public health" should be expanded. In a subtle but fundamental way, the division between science and law they champion would disconnect public health from the explicitly progressive mission that has been integral to its disciplinary identity for centuries. It is not possible for the science of public health (the activity of "[a]dvancing understanding and knowledge of the causes and patterns of health conditions in society" in Hall's words) to exist in a vacuum. The questions it seeks to answer (and the answers it eventually provides) are informed by practice, policy, and law. The scientific identification of causal pathways is intimately tied to the policy work of developing and evaluating potential interventions to disrupt them. The practice of public health (by which we mean the

activity of implementing interventions to protect and promote health, only some of which make use of legal tools) is useless unless it is informed by science and guided by policy. And public health policy (by which we mean the body of defined objectives of public health science and practice) easily blends into the law, in which it is expressed.

Defenders of an expansive scope for public health law argue that the liberal framework tends to discount social, economic, and environmental influences on individual choice. This position is no longer fully tenable in the public health context, in light of the findings of social epidemiologists. Do Epstein's, Hall's, and Rothstein's arguments for a division between the science and the law of public health present a viable solution to this conundrum? We believe not. Rather, our response is to root new public health law more deeply in the science of social epidemiology. The defenders of new public health law must continually strive to convey the power of scientific insights about the social, economic, and environmental determinants of health in ways that judges, policymakers, and the public find compelling. These insights ultimately provide the strongest source of support for understanding an expanding range of health threats as legitimately public in nature and amenable to structural solutions. Individual choice is of course a cherished value. But individuals do not exist in a vacuum; they are embedded in families, neighborhoods, and social networks (e.g., friends, schools, and faith communities). They are also heavily influenced by the economic and physical conditions in which they live, the information to which they are exposed (e.g., media and marketing), and so forth. What the evidence tells us is that the conditions in which people live, learn, and work affect their individual choices in powerful ways. As Daniel Goldberg argued in his defense of a broad model of public health,

> either the social epidemiologists' contention that socioeconomic disparities are a primary factor in causing good public health is accurate, or it is not. . . . [I]f socioeconomic disparities are truly productive of public health, policies consistent with the narrow model [of old public health], which by definition do nothing to ameliorate social conditions, will do little to actually improve health in the aggregate. . . . If public health practice is not intended to facilitate the public's health, it is unclear what use such a practice has and why public monies should be forthcoming to support it. (Goldberg 2009, 73–75)

After having heard the arguments on all sides, what is the appropriate balance between unfettered personal choice and altering the conditions under which those choices are made? What is the appropriate role for

the government in protecting and promoting the public's health? What is the appropriate scope of inquiry and action for public health science and public health law?

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PHOTO 2.1. President Carter's motorcade departs the Three Mile Island Nuclear Generating Station, 1979. The president visited Three Mile Island a few days after one of the plant's reactors partially melted down in an effort to calm the public's fears. The accident was the most serious commercial nuclear accident in U.S. history. Regulatory agencies maintain that the incident did not result in any detectable health effects for plant workers or residents, a claim that antinuclear advocacy groups dispute. Media coverage of the incident played a significant role in solidifying public opposition to nuclear power, which many environmental health experts argue is out of proportion to the risks involved. Unknown photographer, President's Commission on the Accident at Three Mile Island.

CHAPTER TWO

Public Health Ethics

Science, Values, and the Regulation of Risk

Public health ethics seeks to understand and clarify principles and values that guide public health actions, offering a framework for making decisions and a means of evaluating and justifying them. Because public health interventions are directed toward populations, rather than individual patients or research subjects, the principles and values of the field differ from those that guide actions in health care and medical research.

The last two decades have seen an explosion of interest in public health ethics as an area of inquiry distinct from traditional bioethics. Developments in this emerging field have proceeded in two core areas: the ethics of public health professionals (professional ethics) and the ethics that guide public health theory and practice (applied ethics, advocacy ethics, and critical ethics). Both of these areas are addressed by the Principles of the Ethical Practice of Public Health, developed by the Public Health Leadership Society (PHLS) and adopted by the American Public Health Association (see table 2.1). The values and beliefs underlying this code (see table 2.2) reflect the population perspective, prevention orientation, and social justice commitment that distinguish public health from medicine.

Professional ethics are role oriented, guiding practitioners to act in virtuous ways as they undertake their functions. The ethical dimensions of public health professionalism and the duties that accompany the trust society bestows on public health professionals to act for the common welfare are the subject of professional codes (for public health

TABLE 2.1 PRINCIPLES OF THE ETHICAL PRACTICE OF PUBLIC HEALTH

1. Public health should address principally the fundamental causes of disease and requirements for health, aiming to prevent adverse health outcomes.
2. Public health should achieve community health in a way that respects the rights of individuals in the community.
3. Public health policies, programs, and priorities should be developed and evaluated through processes that ensure an opportunity for input from community members.
4. Public health should advocate and work for the empowerment of disenfranchised community members, aiming to ensure that the basic resources and conditions necessary for health are accessible to all.
5. Public health should seek the information needed to implement effective policies and programs that protect and promote health.
6. Public health institutions should provide communities with the information they have that is needed for decisions on policies or programs and should obtain the community's consent for their implementation.
7. Public health institutions should act in a timely manner on the information they have within the resources and the mandate given to them by the public.
8. Public health programs and policies should incorporate a variety of approaches that anticipate and respect diverse values, beliefs, and cultures in the community.
9. Public health programs and policies should be implemented in a manner that most enhances the physical and social environment.
10. Public health institutions should protect the confidentiality of information that can bring harm to an individual or community if made public. Exceptions must be justified on the basis of the high likelihood of significant harm to the individual or others.
11. Public health institutions should ensure the professional competence of their employees.
12. Public health institutions and their employees should engage in collaborations and affiliations in ways that build the public's trust and the institution's effectiveness.

SOURCE: Public Health Leadership Society. 2002. *Principles of the Ethical Practice of Public Health.*

professionals as such, as well as for the various professions within public health, such as epidemiologists and health educators) and model curricula, and a growing number of courses in schools of public health, medicine, and social work. The movement toward national accreditation of local health departments (discussed further in chapter 5) has also supported the development of professional ethics for public health practitioners. This form of ethical discourse stresses professionalism among public health students and practitioners. It instills in professionals a sense of public duty and trust.

A salient issue within the professional ethics of public health is the question of fiduciary duty. To whom do public health professionals owe a duty of loyalty? Physicians, attorneys, and accountants have a

TABLE 2.2 VALUES AND BELIEFS UNDERLYING THE PRINCIPLES OF ETHICAL PRACTICE OF PUBLIC HEALTH

Health
1. *Humans have a right to the resources necessary for health.* The Public Health Code of Ethics affirms Article 25 of the Universal Declaration of Human Rights, which states, in part, "Everyone has the right to a standard of living adequate for the health and well-being of himself and his family . . ."
Community
2. *Humans are inherently social and interdependent.* Humans look to one another for companionship in friendships, families, and community, and rely upon one another for safety and survival. Positive relationships among individuals and positive collaborations among institutions are signs of a healthy community. The rightful concern for the physical individuality of humans and one's right to make decisions for oneself must be balanced against the fact that each person's actions affect other people.
3. *The effectiveness of institutions depends heavily on the public's trust.* Factors that contribute to trust in an institution include the following actions on the part of the institution: communication; truth telling; transparency (i.e., not concealing information); accountability; reliability; and reciprocity. One critical form of reciprocity and communication is listening to as well as speaking with the community.
4. *Collaboration is a key element to public health.* The public health infrastructure of a society is composed of a wide variety of agencies and professional disciplines. To be effective, they must work together well. Moreover, new collaborations will be needed to rise to new public health challenges.
5. *People and their physical environment are interdependent.* People depend upon the resources of their natural and constructed environments for life itself. A damaged or unbalanced natural environment, and a constructed environment of poor design or in poor condition, will have an adverse effect on the health of people. Conversely, people can have a profound effect on their natural environment through consumption of resources and generation of waste.
6. *Each person in a community should have an opportunity to contribute to public discourse.* Contributions to discourse may occur through a direct or a representative system of government. In the process of developing and evaluating policy, it is important to discern whether all who would like to contribute to the discussion have an opportunity to do so, even though expressing a concern does not mean that it will necessarily be addressed in the final policy.
7. *Identifying and promoting the fundamental requirements for health in a community are of primary concern to public health.* The way in which a society is structured is reflected in the health of a community. The primary concern of public health is with these underlying structural aspects. While some important public health programs are curative in nature, the field as a whole must never lose sight of underlying causes and prevention. Because fundamental social structures affect many aspects of health, addressing the fundamental causes rather than more proximal causes is more truly preventive.

(continued)

TABLE 2.2 *(continued)*

Bases for Action
8. *Knowledge is important and powerful.* We are to seek to improve our understanding of health and the means of protecting it through research and the accumulation of knowledge. Once obtained, there is a moral obligation in some instances to share what is known. For example, active and informed participation in policymaking processes requires access to relevant information. In other instances, such as information provided in confidence, there is an obligation to protect information.
9. *Science is the basis for much of our public health knowledge.* The scientific method provides a relatively objective means of identifying the factors necessary for health in a population, and for evaluating policies and programs to protect and promote health. The full range of scientific tools, including both quantitative and qualitative methods, and collaboration among the sciences is needed.
10. *People are responsible to act on the basis of what they know.* Knowledge is not morally neutral and often demands action. Moreover, information is not to be gathered for idle interest. Public health should seek to translate available information into timely action. Often, the action required is research to fill in the gaps of what we don't know.
11. *Action is not based on information alone.* In many instances, action is required in the absence of all the information one would like. In other instances, policies are demanded by the fundamental value and dignity of each human being, even if implementing them is not calculated to be optimally efficient or cost-beneficial. In both of these situations, values inform the application of information or the action in the absence of information.

SOURCE: Public Health Leadership Society. 2002. *Principles of the Ethical Practice of Public Health.*

fiduciary duty to the clients they serve. These client-centered professions are typically guided by the principle that the professional serves goals defined by the client, advises the client fully and honestly, and avoids acting against the client's interests. In the context of public health, the community as a whole might be regarded as the "client," but the notion of a community is often vaguely defined. In any given situation, multiple stakeholders may make conflicting claims to represent community interests. If the community's wants and needs are not easily ascertained, should public health professionals make their own judgments about communal interests? Alternatively, should politically accountable government actors guide public health professionals? Should a fiduciary duty to serve goals developed and expressed through the political process hold sway even when those goals are counter to scientific knowledge?

These questions prompted by efforts to develop the professional ethics of public health readily lead us to broader questions of applied, advocacy, and critical ethics. Because this reader focuses on the relationship between public health ethics and public health law, our emphasis is on the ethical principles, values, and methodologies that guide public health interventions. As the following chapters demonstrate, law and policy tools often facilitate these interventions. Additionally, the ethical principles that guide the public health enterprise are intimately related to the constitutional principles that define public health duty, authority, and constraints on that authority as a matter of law.

Virtually every aspect of public health theory and practice demands ethical inquiry and evaluation. We will address many of these issues alongside legal issues in the remainder of this volume. Here, our focus is on the cross-cutting issue of risk regulation, including the role of science and values (ethical values as well as values expressed through the political process) in risk assessment and public health intervention.

THE EMERGENCE OF PUBLIC HEALTH ETHICS

The fields of bioethics and medical ethics have richly informed the development and use of biotechnologies, the allocation of scarce health care resources, and the practice of medicine. Ethicists have not devoted the same sustained attention to problems in public health, but that is beginning to change with the appearance of interesting and important scholarship in public health ethics. As public health ethics has emerged as a distinct field, scholars have focused on the features that distinguish it from traditional bioethics. They raise a critical question: Do public health science, theory, and practice require ethical principles and values and methods of ethical analysis that are materially different because they address populations, rather than individuals? Or, as John Coggan has cautioned, are we risking "simplistic repackaging of old arguments, or artificial fencing off of relevant arguments," by developing public health ethics as a distinct field (Coggan 2012, 86)?

In the excerpts that follow, Ronald Bayer and Amy Fairchild describe the emergence of public health ethics as a distinct field in response to several controversies in the late twentieth and early twenty-first century. Incompatibility between epidemiological research and stringent protections for human research subjects, the challenges presented by the acquired immune deficiency syndrome (AIDS) epidemic and severe

acute respiratory syndrome (SARS) outbreak, and efforts to reduce tobacco consumption demonstrated the limits of traditional bioethics, which privileges individual autonomy over other values.

These public health crises required a more nuanced balancing of individual interests against collective needs, prompting calls for greater emphasis on collective concerns within the bioethics tradition and development of a new ethical tradition custom-built for public health. Daniel Callahan and Bruce Jennings map several broadly defined areas of concern that are the focus of the emerging ethics of public health: health promotion and disease prevention, risk reduction, epidemiological and other forms of public health research, and structural and socioeconomic disparities in health status. They also explore the various types of ethical analysis relevant to the public health enterprise, including professional ethics, applied ethics, advocacy ethics, and critical ethics.

THE GENESIS OF PUBLIC HEALTH ETHICS*

Ronald Bayer and Amy L. Fairchild

In the beginning there was bioethics. [In the] 1960s and 1970s . . . the paternalistic authority of physicians was brought into question by a new medical ethics that gave pride of place to the concept of autonomy. Paralleling the challenges to medical practice were those that involved the research enterprise. Against a backdrop of scandal and abuse, . . . a new ethics of research took hold. . . . The ethics of clinical research and the ethics of medical practice were conjoined by a commitment to autonomy and individual rights.

Remarkably, as bioethics emerged and began to have enormous impacts on the practice of medicine and research . . . little attention was given to the question of the ethics of public health. This was all the more striking since the core values and practices of public health, often entailing the subordination of the individual for the common good, seemed to stand as a rebuke to the ideological impulses of bioethics. . . .

Of what relevance is autonomy-focused bioethics for public health, with its mix of justifications including those that are either implicitly or explicitly paternalistic or that seek to impose strictures on individuals and communities in the name of collective welfare? To examine the deep divide between the central commitments of bioethics and the values that animate the practice of public health, we focus on a series of controversies implicating the concepts of privacy, liberty, and paternalism.

FIRST ENCOUNTERS: EPIDEMIOLOGICAL RESEARCH AND THE LIMITS OF CONSENT

Epidemiology is the foundational science of public health. . . . Beginning in the 1970s, a discussion began about whether the emerging rules and regulations for human sub-

* Reprinted from 2004. *Bioethics* 18 (6): 473–92.

jects' research would apply to epidemiological studies. Was informed consent necessary when research involved the use of extant records? Would imposing consent requirements for the examination of data sets involving large numbers of people—many of whom would be difficult or impossible to locate—render epidemiological research virtually impossible? . . . In 1981, the United States Department of Health and Human Services (DHHS) issued regulations for the protection of human subjects explicitly exempting epidemiological research involving already existing data from informed consent requirements provided the risk to subjects was minimal, the research did not record data in a way that was individually identifiable, and the research could not otherwise be conducted. The concession represented a relaxation of the fundamental principle that individuals could not be conscripted into research without their consent, for it was clear that the benefits of records-based research were significant enough to trump the claims of the individual. . . .

AIDS, PUBLIC HEALTH, AND ETHICS

[W]hen those schooled in bioethics first sought to address the ethical challenges posed by AIDS, . . . [their] efforts were informed by the intense concern of gay men about threats to privacy and civil liberties advocates fearful that AIDS would provide the occasion for the erosion of a set of substantive and procedural constitutional rights forged by the US Supreme Court. . . .

Emerging from the complex mix of ideological, moral, and political forces was a commitment to treating AIDS differently from what the history of epidemic control might have suggested. In lieu of the compulsory tradition, that often involved mandatory case reporting by name, contact investigation, and where necessary the use of isolation, an "exceptionalist" perspective took hold. Focused on the centrality of education for mass behavioral change, the protection of the rights and privacy of people infected with HIV, and a rejection of coercive measures, the approach to AIDS was voluntarist at its core. A simple dictum emerged: no public health policy that violated the rights of individuals could be effective in controlling the spread of HIV. There was, therefore, no tension between public health and civil liberties. Indeed, the protection of civil liberties was critical to the public health. . . .

SURVEILLANCE AND THE LIMITS OF PRIVACY

Central to the effort to monitor and intervene in the face of threats to the public health, surveillance has imposed on healthcare institutions and especially physicians the duty to report cases to confidential registries. Almost always such reports have included the names of the afflicted. Hence surveillance has represented a striking example of the ways in which the claims of public health could intrude upon the privacy of the clinical relationship. For most of the twentieth century such practices, *once established,* went unchallenged. AIDS provided the context for an assault on the privacy-limiting features of surveillance activities.

[Soon after the first cases of AIDS were identified, state health departments began to require that physicians report by name each newly diagnosed case. Once a test for the HIV antibody became available, it was only a matter of time until reporting requirements were extended to HIV.] The rationale for such reporting drew upon the history of public health: reporting would alert public health officials to the presence of individuals

infected with a lethal infection; would allow them to counsel infected individuals about what they needed to do to prevent further transmission; would permit the authorities to monitor the incidence and prevalence of infection. Alert to concerns about privacy and confidentiality, health officials underscored the existence of administrative, regulatory, and statutory protections for reported names. . . .

To these propositions, gay community–based antagonists to name-based reporting and civil liberties advocates retorted that AIDS was different: social hostility and AIDS-related hysteria could lead to changes in policy, legislatively imposed, that would permit breaches that would never occur with other conditions. And then those in registries would lose their jobs, their housing, and perhaps their liberty. . . . Reporting, they came to believe, would be counterproductive; it would drive people away from testing and counseling. . . . It did not matter that public health departments had an exemplary record in protecting name-based reports. If those most at risk for HIV had fears about what would happen to them, then that was all that mattered. . . .

The debates that occurred over name-based reporting in the context of the AIDS epidemic would inevitably raise questions about the practice of surveillance itself as advocates of privacy, to the astonishment of public health practitioners, suggested that the warrant for the violation of privacy in the early twentieth century no longer deserved unquestioned obeisance.

CONFINEMENT AND THE LIMITS OF LIBERTY

Isolation and quarantine represent the most plenary exercise of the state's authority in the name of public health. Historically, the imposition of isolation and quarantines to control infectious threats was bounded by few procedural protections. The rights of the individual were viewed as subservient to the judgements of those with public health authority. As the pattern of morbidity and mortality underwent an epidemiological transformation in the twentieth century, as chronic conditions replaced infectious diseases as the pre-eminent threat, the role of quarantine and isolation became marginal to the practice of public health in the United States. . . .

[During the 2002 outbreak of severe acute respiratory syndrome (SARS), however, countries relied on these ancient public health tools to contain the epidemic.] Confinement of individuals with disease and those exposed raised questions about the level of risk that justified loss of liberty. Frank cases needed to be isolated, but when a case was unconfirmed or when the individual had simply been exposed or was suspected of being exposed the justification for restricting liberty was problematical. . . .

PATERNALISM AND THE LIMITS OF AUTONOMY

[R]estrictions on those who represent a risk to others . . . raise issues that are fundamentally different from those posed by behaviors that represent primarily a threat to individuals themselves. It is here that the specter of paternalism emerges, and that the tension between public health perspectives and autonomy-focused bioethics is positioned in its boldest relief.

Tobacco consumption . . . serves as an object lesson in the ways in which the antagonism towards paternalism has both shaped and limited public health policy. [Advocates of tobacco control] sought to demonstrate that it was third parties, innocent

victims, or children that were the object of protective measures. . . . Efforts to limit tobacco advertising . . . almost always focused on the claims of children. It was they who were vulnerable to the manipulations and seductions of advertising. If in order to protect them, it was necessary to limit advertising that could be viewed by adults . . . that was a price that had to be paid. . . . [T]he public justification of [cigarette taxes] was almost always that either increasing the price of cigarettes would render them too costly for adolescents or that those who smoked cigarettes imposed healthcare costs on the non-smoking population. . . . [T]he effort to restrict smoking in public settings . . . *preceded* the first evidence that side-stream smoke posed a hazard . . . by more than a decade. . . . Debate over how far to press such restrictions ultimately had to confront the question of whether bans on outdoor smoking could be justified in terms of annoyance abatement rather than disease promotion. . . .

[B]y the end of the twentieth century, the willingness to embrace explicitly paternalistic justifications for antismoking policy was becoming more evident, no doubt facilitated by the emergence of a sharp social gradient in cigarette consumption—those who are educated smoke less and less, those at the bottom of the social ladder continue to smoke.

The most dramatic reflection of the willingness to embrace paternalism was to be found in measures seeking to "denormalize" smoking. We typically do not think of health promotion campaigns as paternalistic. But when they go beyond the provision of information and systematically seek to transform the very desires and preferences of those to whom they are directed, they assume a fundamentally different character. . . .

TOWARD AN ETHICS OF PUBLIC HEALTH

In the end, a focus on population-based health requires a population-based analysis and a willingness to recognize that the ethics of collective health may require far more extensive limitations on privacy, as in the case of public health surveillance, and on liberty, as in the case of isolation and quarantine, than would be justified from the perspective of the autonomy-focused orientation of the dominant current in bioethics. Compulsion and, indeed, coercion—so anathema to this tradition of bioethics—are central to public health. Nevertheless, it is important to recognize that while mandatory measures and recourse to coercion may be necessary, efforts designed to elicit the voluntary co-operation of those at risk for acquiring or transmitting infectious diseases are preferable [from an ethical perspective] and, [as a practical matter], may be more effective. . . . Thus, while a public health perspective will not privilege liberty and privacy, it does not follow that it should be insensitive to the importance of protecting individual rights. . . .

The effort to shape public health policy in liberal societies will require a forthright acknowledgement of the tensions and trade-offs that will inevitably arise when the claims of public welfare and well-being intrude on privacy, individual choice, and liberty. Recognizing the role of moral values in decision-making was one of the signal contributions of bioethics in its formative period. . . . [But bioethics] cannot serve as a basis for thinking about the balances required in the defense of the public's health. As we commence the process of shaping an ethics of public health, it is clear that bioethics is the wrong place to start.

ETHICS AND PUBLIC HEALTH: FORGING A STRONG RELATIONSHIP*

Daniel Callahan and Bruce Jennings

As the concern of health policymakers turns toward health outcomes, cost-effectiveness, and preventive measures throughout the life cycle . . . the field of public health is gaining increased public and legislative attention. As the field of public health becomes more prominent, so will the ethical issues associated with it. . . . [It] is important to begin a focused conversation within the field and between the field and others. . . .

For its part, bioethics has become restless for change, and it is particularly looking for a value orientation that may bring it into closer proximity with public health. There has always been an undercurrent of resistance to the individualistic, autonomy-driven mainstream orientation within bioethics, [yet] that orientation has held sway. And why not? . . . [I]t has often brought together the political left and the market-oriented right in a celebration of choice and freedom. But the obvious need for universal health care, the persistence of racial and ethnic disparities in health status, and the importance of background social and economic factors have caught the eye of many. . . .

THE SCOPE OF PUBLIC HEALTH ETHICS

If ethics is understood to be a search for those values, virtues, and principles necessary for people to live together in peace, mutual respect, and justice, then there are few issues in public health that do not admit of an ethical perspective. To begin to map the scope of this broad terrain, general categories of such issues should be noted: health promotion and disease prevention, risk reduction, epidemiological and other forms of public health research, and structural and socioeconomic disparities in health status.

Health Promotion and Disease Prevention

Programs designed to promote health and prevent disease and injury raise questions about the responsibility of individuals to live healthy lives; about the government's role in creating an environment in which individuals are able to exercise their health-related responsibility; about the role of government in coercing or influencing health-related behavior or in developing educational programs; about the use of incentives, economic or otherwise, to promote good health; and about the relative importance for society of pursuing good health, particularly in a culture that prizes autonomy and does not always look fondly on government intervention.

Risk Reduction

Risks to the health of the public are many, and many methods are used to reduce or eliminate them. Almost all can pose one or more ethical problems. The concept of risk itself is seemingly impossible to define in value-neutral terms and is inherently controversial. Even more ethically charged is the question of what level or degree of risk is

* Reprinted from 2002. *American Journal of Public Health* 92 (2): 169–76.

socially acceptable to individuals and communities. Who should decide about that, and how should exposure to risk be distributed across the affected population? . . .

Epidemiological and Other Public Health Research

Is the biomedical model—focused on individual informed consent and tightly regulated research with those at risk of exploitation—an appropriate model for public health, one that may either pose no medical or other risks to individuals or make consent impractical to gain in research encompassing large communities? . . .

Structural and Socioeconomic Disparities

It has been known for many years that socioeconomic disparities have a major impact on health status. . . . What is the appropriate role for the public health community in seeking greater justice in health care, and how should it balance its fact-finding and education role with its historically strong advocacy mission? Finally, to what extent, if any, should the field adopt a politically partisan posture, taking a public stand on important policy issues and legislative initiatives?

TYPES OF ETHICAL ANALYSIS

While the preceding classification of broad issues by no means exhausts the possible categories of topics, it is sufficient to make evident that no single method of ethical analysis can be used for all of them. . . . Ethical analysis can be usefully divided into a number of different types, depending on the point of view and needs from which it originates. . . .

Professional Ethics

The study of professional ethics tends to seek out the values and standards that have been developed by the practitioners and leaders of a given profession over a long period of time and to identify those values that seem most salient and inherent in the profession itself. Applied to public health, this perspective entails identifying the central mission of the profession (e.g., protection and promotion of the health of all members of society) and building up a body of ethical principles and standards that would protect the trust and legitimacy the profession should maintain. . . .

Applied Ethics

The applied ethics perspective differs from the professional ethics perspective principally in that it adopts a point of view from outside the history and values of the profession. From this more general moral and social point of view, applied ethics seeks to devise general principles that can then be applied to real-world examples of professional conduct or decision making. These principles and their application are designed to give professionals guidance and to provide those individuals affected by professional behavior, as well as the general public, with standards to use in assessing the professions. Thus, in applied ethics, there is a tendency to reason abstractly and to draw from general ethical theories rather than from the folkways and knowledge base of the professions. . . .

Advocacy Ethics

While on occasion it can pose difficulties for civil servants, the ethical persuasion most lively in the field is a stance of advocacy for those social goals and reforms that public health professionals believe will enhance general health and well-being, especially among those least well off in society. Such advocacy is in keeping with the natural priorities of those who devote their careers to public health. It has a strong orientation toward equality and social justice. Much of the research and expertise in public health throughout its history has shown how social deprivation, inequality, poverty, and powerlessness are directly linked to poor health and the burden of disease. . . .

Critical Ethics

Like professional ethics, [critical ethics] is historically informed and practically oriented toward the specific real-world and real-time problems of public health, but, like applied ethics, it brings larger social values and historical trends to bear in its understanding of the current situation of public health and the moral problems faced. These problems are not only the result of the behavior of certain disease organisms or particular individuals. They are also the result of institutional arrangements and prevailing structures of cultural attitudes and social power. . . .

One possible advantage of critical ethics is its call for discussions of ethics and public health policy to be genuinely public or civic endeavors: not the advocacy of a well-intentioned elite on behalf of needy clients, but a search for forums and programs of meaningful participation, open deliberation, and civic problem solving and capacity building. . . .

LAW AND ETHICS

Public health is one of the few professions that has, in many matters, legal power—in particular, the police power of the state—behind it. It can, through use of the law, coerce citizens into behaving in some approved, healthy way. . . . Public health also has the distinction, along with a few others—such as city management, public administration, and law enforcement—of being a profession in which many practitioners are government employees and officials. It thus has an obligation both toward government, which controls it, and toward the public that it serves.

Because of its public and governmental roles, public health has ethical problems unlike those of most other professions. The relationship between ethics and law is a long and tangled one, but it is safe to say that most public health laws and regulations have behind them an explicitly moral purpose: that of promoting and protecting the lives of citizens. Because the police power of the state is involved, however, a number of moral conflicts are generated. The tension between individual health and rights, on the one hand, and government obligations and population health, on the other, is an obvious instance of this kind of conflict. The economic and social impact on communities of public health measures, requiring some form of cost-benefit analysis, is another.

Health is an important human need, and good health is highly valued. But health is not the only need or good health the only value. Laws must always find ways of balancing various goods and the centrality of laws for the work of public health brings uncommon visibility to its actions and an uncommon need for public accountability.

POLITICS AND PUBLIC HEALTH

As public arguments over [water] fluoridation or HIV disease amply demonstrate, public health measures can quickly become politicized. Political controversy is often treated as some kind of disaster for calm reflection and measured rationality . . . [but] politics is unavoidable and necessary. It is unavoidable because there is no way to stop the public from turning to legislatures or the courts to express their values and needs; nor should there be. Politics is a necessary component of public health, moreover, precisely in order to achieve public health policies and practices consistent with American traditions and values. Politics is the messy arena in which ultimate questions of the public good are worked out.

. . .

Bayer, Fairchild, Callahan, Jennings, and other pioneers of public health ethics began by mapping a wide range of ethical issues raised by public health theory, science, and practice. These issues and more will be addressed in Part Four of this reader, which examines public health law and ethics in the context of the various silos of public health practice, including surveillance, infectious diseases, emergency preparedness, noncommunicable diseases, and injuries. In the remainder of this chapter, we focus more narrowly on the applied ethics of risk regulation, an issue that cuts across the various silos of public health science and practice.

THE SCIENCE AND ETHICS OF RISK REGULATION

The application of ethical principles and values to public health decisions can be complex and controversial. Problems in public health often involve numerous causal factors, the evidence for which is sometimes indeterminate or difficult to ascertain due to financial and ethical constraints. Public health solutions may affect multiple stakeholders with conflicting material interests and diverse perspectives on matters of individual liberty, equity, and the common good.

Scholars continue to hone ethical frameworks for evaluating proposed public health interventions, many of which are facilitated using the law and policy tools discussed in Part Three of this reader. These ethical frameworks are distinct from, but intimately related to, constitutional doctrines constraining public health authority in the United States, which are discussed in Part Two. Before turning to our examination of public health law in the following chapters, we continue our focus on public health ethics with a particular emphasis on balancing science and values in the context of risk regulation.

We begin with a recent summary by Marckmann et al. of a systematic framework for evaluating public health interventions. As the authors note, other scholars have articulated a range of ethical frameworks for public health—we present our own "stepwise evaluation" in *Public Health Law: Power Duty Restraint* (2016, 43)—but most are similar in their requirement that the benefits and costs of a proposed intervention be assessed using the best available scientific evidence, that burdens on individuals be minimized, and that burdens and benefits be distributed fairly.

Marckmann and his coauthors delve somewhat more deeply into the philosophical foundations touched upon in the excerpts above. They note the extent to which many public health ethical frameworks rely upon consequentialism, which judges the rightness of an action by the consequences, effects, or outcomes it produces. The public health enterprise is often associated with utilitarianism, which is perhaps the most influential form of consequentialism.

This facile connection between utilitarianism and public health deserves more probing inquiry, however. Some have chastised the "public health model" of ethical reasoning for uncritically assuming the appropriate methodology is a simplistic form of cost-benefit calculation weighing benefits and burdens in the aggregate, sacrificing the most fundamental interests of individuals in pursuit of utility maximization. This characterization is based on an erroneous understanding of the public health approach. Consequentialist utilitarian thinking does not easily accommodate the commitment to social justice that has characterized the public health enterprise at least since the days of the sanitarians. Public health scholars and practitioners care deeply about the *processes* by which public health goals are pursued and the *distribution* of the burdens and benefits (not merely the aggregate impact on welfare) produced by their efforts.

In their quest for an alternative to consequentialism, Marckmann et al. turn to coherentism, exemplified by the "reflective equilibrium" championed by John Rawls. The Public Health Leadership Society's (PHLS) collaborative deliberation on the judgments and values that guide public health (table 2.2) and creation of coherent principles that reflect those judgments (table 2.1) offer an example of coherentism in action. The PHLS principles and the systematic framework described in the excerpt that follows reflect close attention to procedural fairness, distributional fairness, and burdens on individual interests, none of which is served by consequentialism.

PUTTING PUBLIC HEALTH ETHICS INTO PRACTICE: A SYSTEMATIC FRAMEWORK*

Georg Marckmann, Harald Schmidt, Neema Sofaer, and Daniel Stretch

In this article, we . . . present a systematic framework for addressing ethical issues in the field of [public health (PH)] that tries to satisfy both foundational and methodological requirements. The framework comprises (1) an explicit *normative foundation* with five [substantive] ethical criteria and seven procedural conditions guiding a fair decision process, and (2) a six-step *methodological approach* for applying the ethical criteria and conditions. . . .

THE NORMATIVE FOUNDATIONS

Substantive Normative Criteria

Table [2.3] presents the substantive normative criteria that should guide ethical analysis in PH. . . . They are linked to the specific characteristics of the field of PH, thereby taking into account that PH focuses on populations rather than individuals, works preventively rather than curatively, and usually requires action at the population rather than the individual level. . . .

1. What are the expected health benefits of the intervention for the target population?

An ethical evaluation of a PH intervention must start with assessing its expected benefit. This requires defining the goals of the intervention with the range of expected effects. These can be surrogate endpoints, e.g., the identification of cancer in its early stages, or more patient-oriented endpoints, e.g., lowering the cancer-specific mortality rate. . . . In addition, the validity of the available evidence is relevant. . . . Only if a *relevant* health-related effect can be demonstrated or justified on the basis of sufficiently *valid* study results, does it make sense to speak of "benefits" of a certain PH intervention. The intervention-specific, health-related benefit should be higher than the potential benefits of alternative interventions, thereby providing an *additional* benefit for the target population.

An expected benefit can seem plausible even if the underlying evidence is not of the highest desirable . . . validity. In this case, it is necessary to explicitly state the reasons for the lack of suitable data and the arguments why it nevertheless seems appropriate to implement the intervention. This transparency is a necessary prerequisite for dealing appropriately with the frequently uncertain demonstration of benefits in the field of PH. . . .

2. What are the potential burdens and harms of the intervention?

Oftentimes, beneficial PH interventions are associated with social and health risks and burdens (e.g., false positive findings [that trigger] unnecessary interventions in the case of cancer screening). For this reason, it is important to assess not only potential benefits but also potential harms. . . . It is one of the central goals of the ethical

* Reprinted from 2015. *Frontiers in Public Health* 3:23.

TABLE 2.3 SUBSTANTIVE NORMATIVE CRITERIA FOR ETHICAL ANALYSIS IN PUBLIC HEALTH

1. Expected health benefits for the target population
Range of expected effects (endpoints)
Magnitude and likelihood of such effects
Strength of evidence of each effect
Public health (practical) relevance of effects
Incremental benefits compared to alternative interventions
2. Potential harm and burdens
Range of potential negative effects (endpoints)
Magnitude and likelihood of each negative effect
Strength of evidence for each negative effect
Public health (practical) relevance of the negative effects
Burdens and harms compared to alternative interventions
3. Impact on autonomy
Health-related empowerment (e.g., improved health literacy)
Respect for individual autonomous choice (e.g., possibility of informed consent, least restrictive means)
Protection of privacy and confidentiality (e.g., data protection)
4. Impact on equity
Access to the public health intervention
Distribution of the intervention's benefits, burdens and risk
Impact on health disparities
Need for compensation?
5. Expected efficiency
Incremental cost-benefit/cost-effectiveness ratio
Strength of evidence for expected efficiency

SOURCE: Reprinted from Marckmann, Georg, Harald Schmidt, Neema Sofaer, and Daniel Strech. 2015. "Putting Public Health Ethics into Practice: A Systematic Framework." *Frontiers in Public Health* 3 (23).

assessment to recommend suitable measures for reducing the—often unavoidable—risk of harm for the individual as much as possible. . . .

3. How does the intervention affect the autonomy of the individuals in the target population?. . .

[I]n light of the usually unavoidable burdens and risks, individuals should generally be able to decide themselves about their participation in a certain PH program after being sufficiently informed (informed consent). If individual informed consent to participation is not possible (e.g., tap water fluoridation), there should be a democratically legitimate public decision process about the implementation of the PH intervention.

If certain PH goals can only be achieved effectively by influencing or even restricting individual freedom of choice (e.g., incentive systems, legal obligations, or quarantine interventions), this requires a special justification. In particular, it has to be demonstrated that the PH goal cannot be achieved with a less restrictive or less manipulative intervention. . . .

4. Impact on equity: how are benefits and burden distributed?

Public health interventions often have an impact on the distribution of health outcomes and therefore the opportunities that citizens are offered in a society. For reasons of *equity,* therefore, all people who might benefit should have equal access to a given PH intervention. Both financial and non-financial barriers to access have to be taken into account. In addition, the distribution of potential benefits and harm has to be examined. . . .

When PH interventions accept a potential harm for certain subgroups to achieve a significant expected benefit for another subgroup, strategies to compensate for these risks have to be considered for the sake of compensatory justice. For example, people placed under quarantine need to be given appropriate psychological support . . .

5. Expected efficiency: what are the costs and opportunity costs of the intervention?

In the light of limited public resources, the *efficiency* of a PH intervention has to be assessed. This requires determining the incremental cost-benefit ratio, i.e., the ratio between additional costs and additional benefit compared to alternative interventions (if available). . . .

Procedural Conditions for a Fair Decision Process

Since PH interventions have an impact on the well-being and autonomy of individuals and often require collective efforts, they should be implemented by a *legitimate* decision-making authority within a fair process. Even reasonable and fair-minded people often come to different conclusions in the face of complex moral deliberations. Among other things, this is due to the fact that many evaluations—e.g., of health-related benefits—can only be made on the basis of . . . visions of a good or fulfilled life. How can we make *legitimate* decisions under these conditions of moral controversy? [One approach is] to supplement the general substantive principles of justice with a fair decision process [characterized by] transparency, . . . reasonable explanation, . . . openness for revision, . . . and the regulation of adherence to the other three conditions. We suggest adding consistency, participation, and managing conflicts of interest, so that any ethical analysis of PH interventions has to assess how far the seven conditions for a fair decision process described in table [2.4] are met. . . .

METHODOLOGICAL APPROACH TO PHE

After having laid out substantive ethical criteria and conditions for a fair decision process, we now present a step-by-step methodological approach that shall guide the ethical evaluation of a given PH intervention in the different phases of its development, implementation, and evaluation.

1. Description of the public health intervention

Any ethical analysis must start with a thorough characterization of the PH intervention, the context in which it will be applied, and possible alternative interventions

TABLE 2.4 CONDITIONS OF A FAIR DECISION PROCESS

1. Transparency	Decision process including database and underlying normative assumptions should be transparent and public.
2. Consistency	Application of the same principles, criteria and rules across different public health interventions[;] equal treatment of different populations.
3. Justification	Decisions should be based on relevant reasons, i.e., based on the normative criteria for PHE.
4. Participation	Populations affected by the PH intervention should be able to participate in the decision about the implementation.
5. Managing conflicts of interest	Decisions about PH interventions should be organized so as to minimize any existing and manage any remaining conflicts of interests of decision makers.
6. Openness for revision	Implementations of PH interventions should be open for revision (e.g., if data basis changes or certain aspects have been neglected).
7. Regulation	Voluntary or legal regulation should guarantee that these conditions for a fair decision process are met.

SOURCE: Reprinted from Marckmann, Georg, Harald Schmidt, Neema Sofaer, and Daniel Strech. 2015. "Putting Public Health Ethics into Practice: A Systematic Framework." *Frontiers in Public Health* 3 (23).

to achieve the PH goal that might minimize potential negative impact on PH, individual autonomy, equity, or efficiency.

2. Specification and modification of the normative criteria. . . .

The practical relevance of each principle should be clarified, starting with a concrete statement of the content and scope of the principle for the PH intervention at hand. Different policy makers or evaluators may arrive at different specifications with potentially different results in the analysis. While this cannot be eliminated completely, using this explicit framework at least requires the evaluators to explicitly define and justify the specifications so that the underlying sources of disagreement become transparent—and thereby open to revision. . . .

3. Evaluation of the public health intervention using the specified criteria

In the third step, each of the specified normative criteria is used to evaluate the PH intervention. The evaluators must ask, for example: what are the expected benefits of the intervention? What are the program's implications for the autonomy of members of the target population? A step-by-step assessment can reveal currently unresolved controversies and identify the need for further conceptual or empirical studies.

4. Synthesis: overall evaluation of the public health intervention

The fourth step . . . involves identifying conflicts between the criteria and balancing the conflicting ethical obligations. Balancing requires finding convincing reasons why one criterion or the other should prevail. Being explicit about the reasons that determine the relative weights of the conflicting criteria creates transparency and allows a

TABLE 2.5 METHODOLOGICAL APPROACH FOR PUTTING PUBLIC HEALTH ETHICS INTO PRACTICE

1. Description	Describe the goals, methods, target population, etc., of the PH program
2. Specification	Specify or supplement (if necessary) the five normative criteria for the PH intervention
3. Evaluation	Evaluate the PH intervention based on each of the 5 single evaluations of step 3 to arrive at an overall evaluation of the PH intervention
4. Synthesis	Balance and integrate the 5 single evaluations of step 3 to arrive at an overall evaluation of the PH intervention
5. Recommendation	Develop recommendations for the design, implementation, or modification of the PH intervention
6. Monitoring	Monitor and re-evaluate the ethical implications in regular time intervals

SOURCE: Reprinted from Marckmann, Georg, Harald Schmidt, Neema Sofaer, and Daniel Strech. 2015. "Putting Public Health Ethics into Practice: A Systematic Framework." *Frontiers in Public Health* 3 (23).

revision of the balancing by challenging the underlying reasons. . . . [For example,] in considering a quarantine of a tuberculosis patient, we have to balance respect for autonomy (criterion 3) and protecting others from the risk of a transmitted tuberculosis infection (here: criterion 1). The severity and high likelihood of the anticipated harm to others could be a good reason to assign more weight to protecting others than to the freedom of the infected patient. . . .

5. Generating recommendations

In most cases, the overall ethical evaluation will not result in a clear-cut rejection or endorsement of the PH intervention, but rather in a stronger or weaker recommendation . . . to implement or—in the cases of a negative evaluation—forgo the intervention (see table [2.5]). [I]t will identify various aspects and conflicts that have to be considered from an ethical perspective [as well as] recommendations on how to maximize the intervention's expected benefits and minimize the expected costs. . . .

6. Monitoring

After successful implementation, any PH program should be followed-up and monitored in regular intervals to assess (1) whether the ethical evaluation was adequate, (2) whether there are new ethical issues arising, and (3) whether the recommendations are followed and whether they are effective in assuring an ethically appropriate execution of the PH program. . . .

We have developed the framework primarily to provide *practical guidance*. The transparent, systematic approach will enable those who implement a PH intervention and those affected by it (i.e., the target population) to critically assess whether and how the required ethical considerations have been taken into account.

• • •

The systematic ethical framework for evaluating public health interventions presented above is perhaps somewhat idealistic in its demand for rigorous epidemiological evidence—to identify and characterize the risk, demonstrate the intervention's effectiveness, and assess the intervention's burdens and benefits and any available alternatives. Indeed, some argue ethical considerations should bar action in cases where the evidence is uncertain or unavailable, at least where the intervention imposes significant burdens. Before considering the role of values in risk assessment and the dilemmas faced by public health officials when they are called upon to act in situations where evidence is unavailable or inadequate, it is useful to review the basic scientific approach to risk assessment.

In the following excerpt, legal scholar Michael Green and epidemiologists Michal Freedman and Leon Gordis guide non-scientists through the process of evaluating epidemiological evidence of risk and causation. The guide excerpted here was written for judges adjudicating individual disputes such as torts cases (see chapter 7), but it is also useful to policymakers, practitioners, and scholars of ethics and law who may not have the benefit of rigorous training in epidemiology and biostatistics. The authors' focus is primarily on risks associated with exposure to toxic agents (e.g., lead, benzene, asbestos, or pharmaceuticals), but the concepts they review are applicable to risks—and benefits—associated with exposure to other conditions (e.g., experiencing racial discrimination or living in proximity to high-quality recreational facilities) and health-related behaviors (e.g., eating a diet high in sugar or being physically active).

Epidemiology seeks to elucidate the tangled web of causation by which good—and ill—health are produced in social context. When an exposure, condition, or behavior is associated with poorer health outcomes, it is described as a *risk factor.* When it is associated with better health outcomes, it is termed a *protective factor.* Both risk factors and protective factors are considered *determinants* of health. Epidemiologists seek to identify these determinants and study the *causal pathways* by which they contribute to health outcomes. Lawyers, ethicists, policymakers, epidemiologists, and social scientists may then collaborate across disciplines (and with the public and other stakeholders) to identify sites for intervention where a determinant or causal pathway might be disrupted. Risk assessment is thus intimately intertwined with the process of policy development. Epidemiological studies of the sort Green, Freedman, and Gordis describe below may also be used to evaluate legal interventions after implementation to assess the effectiveness, for example, of bans on smoking in subsidized housing, seat-

belt mandates, or deregulated access to clean syringes for intravenous drug users.

REFERENCE GUIDE ON EPIDEMIOLOGY*

Michael D. Green, D. Michal Freedman, and Leon Gordis

Epidemiology is the field of public health and medicine that studies the incidence, distribution, and etiology of disease in human populations. The purpose of epidemiology is to better understand disease causation and to prevent disease in groups of individuals. Epidemiology assumes that disease is not distributed randomly in a group of individuals and that identifiable subgroups, including those exposed to certain agents [or conditions or who engage in certain behaviors], are at increased risk of contracting particular diseases.

Epidemiologic evidence identifies agents that are associated with an increased risk of disease in groups of individuals, quantifies the amount of excess disease that is associated with an agent, and provides a profile of the type of individual who is likely to contract a disease after being exposed to an agent. Epidemiology focuses on the question of general causation (i.e., is the agent capable of causing disease?) rather than that of specific causation (i.e., did it cause disease in a particular individual?). For example, in the 1950s, . . . studies showed that smokers who smoked 10 to 20 cigarettes a day had a lung cancer mortality rate that was about 10 times higher than that for nonsmokers. These studies identified an association between smoking cigarettes and death from lung cancer that contributed to the determination that smoking causes lung cancer.

However, it should be emphasized that an association is not equivalent to causation. An association identified in an epidemiologic study may or may not be causal. Assessing whether an association is causal requires an understanding of the strengths and weaknesses of the study's design and implementation, as well as a judgment about how the study findings fit with other scientific knowledge. It is important to emphasize that all studies have "flaws" in the sense of limitations that add uncertainty about the proper interpretation of the results. Some flaws are inevitable given the limits of technology, resources, the ability and willingness of persons to participate in a study, and ethical constraints. In evaluating epidemiologic evidence, the key questions, then, are the extent to which a study's limitations compromise its findings and permit inferences about causation. . . .

[This guide] explains the different kinds of epidemiologic studies[,] addresses the meaning of their outcomes[,] examines concerns about the methodological validity of a study, including the problem of sampling error[,] discusses general causation, considering whether an agent is capable of causing disease[, and] deals with methods for combining the results of multiple epidemiologic studies and the difficulties entailed in extracting a single global measure of risk from multiple studies.

* Reprinted from 2011. In *Reference Manual on Scientific Evidence,* 549–632. Washington, DC: National Academy Press.

WHAT DIFFERENT KINDS OF EPIDEMIOLOGIC STUDIES EXIST?

Experimental and Observational Studies

To determine whether an agent is related to the risk of developing a certain disease or an adverse health outcome, we might ideally want to conduct an experimental study in which the subjects would be randomly assigned to one of two groups: one group exposed to the agent of interest and the other not exposed. After a period of time, the study participants in both groups would be evaluated for the development of the disease. This type of study, called a randomized trial, clinical trial, or true experiment, is considered the gold standard for determining the relationship of an agent to a health outcome or adverse side effect. Such a study design is often used to evaluate new drugs or medical treatments and is the best way to ensure that any observed difference in outcome between the two groups is likely to be the result of exposure to the drug or medical treatment.

Randomization minimizes the likelihood that there are differences in relevant characteristics between those exposed to the agent and those not exposed. Researchers conducting clinical trials attempt to use study designs that are placebo controlled, which means that the group not receiving the active agent or treatment is given an inactive ingredient that appears similar to the active agent under study. They also use double blinding where possible, which means that neither the participants nor those conducting the study know which group is receiving the agent or treatment and which group is given the placebo. However, ethical and practical constraints limit the use of such experimental methodologies to assess the value of agents that are thought to be beneficial to human beings.

When an agent's effects are suspected to be harmful, researchers cannot knowingly expose people to the agent. Instead epidemiologic studies typically "observe" a group of individuals who have been exposed to an agent of interest, such as cigarette smoke or an industrial chemical and compare them with another group of individuals who have not been exposed. Thus, the investigator identifies a group of subjects who have been exposed and compares their rate of disease or death with that of an unexposed group. In contrast to clinical studies in which potential risk factors can be controlled, epidemiologic investigations generally focus on individuals living in the community, for whom characteristics other than the one of interest, such as diet, exercise, exposure to other environmental agents, and genetic background, may distort a study's results. Because these characteristics cannot be controlled directly by the investigator, the investigator addresses their possible role in the relationship being studied by considering them in the design of the study and in the analysis and interpretation of the study results. We emphasize that the Achilles' heel of observational studies is the possibility of differences in the two populations being studied with regard to risk factors other than exposure to the agent. By contrast, experimental studies, in which subjects are randomized, generally avoid this problem. . . .

The two main types of observational studies are cohort studies and case-control studies. A third type of observational study is a cross-sectional study. . . . A final type of observational study, one in which data about individuals are not gathered, but rather population data about exposure and disease are used, is an ecological study.

The difference between cohort studies and case-control studies is that cohort studies measure and compare the incidence of disease in the exposed and unexposed ("control") groups, while case-control studies measure and compare the frequency of

exposure in the group with the disease (the "cases") and the group without the disease (the "controls"). In a case-control study, the rates of exposure in the cases and the rates in the controls are compared, and the odds of having the disease when exposed to a suspected agent can be compared with the odds when not exposed. The critical difference between cohort studies and case-control studies is that cohort studies begin with exposed people and unexposed people, while case-control studies begin with individuals who are selected based on whether they have the disease or do not have the disease and their exposure to the agent in question is measured. The goal of both types of studies is to determine if there is an association between exposure to an agent and a disease and the strength (magnitude) of that association. . . .

As an example, in 1950 a cohort study was begun to determine whether uranium miners exposed to radon were at increased risk for lung cancer as compared with nonminers. The study group (also referred to as the exposed cohort) consisted of 3400 white, underground miners. The control group (which need not be the same size as the exposed cohort) comprised white nonminers from the same geographic area. Members of the exposed cohort were examined every 3 years, and the degree of this cohort's exposure to radon was measured from samples taken in the mines. Ongoing testing for radioactivity and periodic medical monitoring of lungs permitted the researchers to examine whether disease was linked to prior work exposure to radiation and allowed them to discern the relationship between exposure to radiation and disease. . . .

In case-control studies, the researcher begins with a group of individuals who have a disease (cases). . . . [F]or example, in the late 1960s, doctors in Boston were confronted with an unusual number of young female patients with vaginal adenocarcinoma. Those patients became the "cases" in a case-control study (because they had the disease in question) and were matched with "controls," who did not have the disease. Controls were selected based on their being born in the same hospitals and at the same time as the cases. The cases and controls were compared for exposure to agents that might be responsible, and researchers found maternal ingestion of DES (diethylstilbestrol) in all but one of the cases but none of the controls.

An advantage of the case-control study is that it usually can be completed in less time and with less expense than a cohort study. Case-control studies are also particularly useful in the study of rare diseases, because if a cohort study were conducted, an extremely large group would have to be studied in order to observe the development of a sufficient number of cases for analysis. . . .

In [a cross-sectional] study, individuals are interviewed or examined, and the presence of both the exposure of interest and the disease of interest is determined in each individual at a single point in time. Cross-sectional studies determine the presence (prevalence) of both exposure and disease in the subjects and do not determine the development of disease or risk of disease (incidence). Moreover, because both exposure and disease are determined in an individual at the same point in time, it is not possible to establish the temporal relation between exposure and disease—that is, that the exposure preceded the disease, which would be necessary for drawing any causal inference. Thus, a researcher may use a cross-sectional study to determine the connection between a personal characteristic that does not change over time, such as blood type, and existence of a disease, such as aplastic anemia. . . .

Up to now, we have discussed studies in which data on both exposure and health outcome are obtained for each individual included in the study. In contrast, studies

that collect data only about the group as a whole are called ecological studies. In ecological studies, information about individuals is generally not gathered; instead, overall rates of disease or death for different groups are obtained and compared. The objective is to identify some difference between the two groups, such as diet, genetic makeup, or alcohol consumption, that might explain differences in the risk of disease observed in the two groups. Such studies may be useful for identifying associations, but they rarely provide definitive causal answers. . . .

If a researcher were interested in determining whether a high dietary fat intake is associated with breast cancer, [for example,] he or she could compare different countries in terms of their average fat intakes and their average rates of breast cancer. If a country with a high average fat intake also tends to have a high rate of breast cancer, the finding would suggest an association between dietary fat and breast cancer. However, such a finding would be far from conclusive, because it lacks particularized information about an individual's exposure and disease status. . . . Nevertheless, the study is useful in that it identifies an area for further research. . . .

Another epidemiologic approach is to compare disease rates over time and focus on disease rates before and after a point in time when some event of interest took place. For example, thalidomide's teratogenicity (capacity to cause birth defects) was discovered after Dr. Widukind Lenz found a dramatic increase in the incidence of limb reduction birth defects in Germany beginning in 1960. Yet, other than with such powerful agents as thalidomide, which increased the incidence of limb reduction defects by several orders of magnitude, these secular-trend studies (also known as time-line studies) are less reliable and less able to detect modest causal effects than the observational studies described above. . . .

HOW SHOULD RESULTS OF AN EPIDEMIOLOGIC STUDY BE INTERPRETED?

[T]he first question an epidemiologist addresses is whether an association exists between exposure to the agent and disease. An association between exposure to an agent and disease exists when they occur together more frequently than one would expect by chance. Although a causal relationship is one possible explanation for an observed association between an exposure and a disease, an association does not necessarily mean that there is a cause-effect relationship. . . .

The strength of an association between exposure and disease can be stated in various ways, including as a relative risk, an odds ratio, or an attributable risk. Each of these measurements of association examines the degree to which the risk of disease increases when individuals are exposed to an agent.

Relative Risk

A commonly used approach for expressing the association between an agent and disease is relative risk (RR). It is defined as the ratio of the incidence rate . . . of disease in exposed individuals to the incidence rate in unexposed individuals:

RR = (Incidence rate in the exposed) / (Incidence rate in the unexposed)

The incidence rate of disease is defined as the number of cases of disease that develop during a specified period of time divided by the number of persons in the cohort under

study. Thus, the incidence rate expresses the risk that a member of the population will develop the disease within a specified period of time.

For example, a researcher studies 100 individuals who are exposed to an agent and 200 who are not exposed. After 1 year, 40 of the exposed individuals are diagnosed as having a disease, and 20 of the unexposed individuals also are diagnosed as having the disease. The relative risk of contracting the disease is calculated as follows:

- The incidence rate of disease in the exposed individuals is 40 cases per year per 100 persons (40/100), or 0.4.
- The incidence rate of disease in the unexposed individuals is 20 cases per year per 200 persons (20/200), or 0.1.
- The relative risk is calculated as the incidence rate in the exposed group (0.4) divided by the incidence rate in the unexposed group (0.1), or 4.0. A relative risk of 4.0 indicates that the risk of disease in the exposed group is four times as high as the risk of disease in the unexposed group.

In general, the relative risk can be interpreted as follows:

- If the relative risk equals 1.0, the risk in exposed individuals is the same as the risk in unexposed individuals. There is no association between exposure to the agent and disease.
- If the relative risk is greater than 1.0, the risk in exposed individuals is greater than the risk in unexposed individuals. There is a positive association between exposure to the agent and the disease, which could be causal.
- If the relative risk is less than 1.0, the risk in exposed individuals is less than the risk in unexposed individuals. There is a negative association, which could reflect a protective or curative effect of the agent on risk of disease. . . .

Odds Ratio

The odds ratio (OR) is similar to a relative risk in that it expresses in quantitative terms the association between exposure to an agent and a disease. It is a convenient way to estimate the relative risk in a case-control study when the disease under investigation is rare. . . .

In a case-control study, the odds ratio is the ratio of the odds that a case (one with the disease) was exposed to the odds that a control (one without the disease) was exposed. In a cohort study, the odds ratio is the ratio of the odds of developing a disease when exposed to a suspected agent to the odds of developing the disease when not exposed. . . .

If the disease is relatively rare in the general population (about 5% or less), the odds ratio is a good approximation of the relative risk.

Attributable Risk

A frequently used measurement of risk is the attributable risk (AR). The attributable risk represents the amount of disease among exposed individuals that can be attributed to the exposure. . . . [I]f the association is causal, the attributable risk is the proportion of disease in an exposed population that might be caused by the agent and that might be prevented by eliminating exposure to that agent. . . .

Adjustment for Study Groups That Are Not Comparable

Populations often differ in characteristics that relate to disease risk, such as age, sex, and race. Those who live in Florida have a much higher death rate than those who live in Alaska. Is sunshine dangerous? Perhaps, but the Florida population is much older than the Alaska population, and some adjustment must be made for the differences in age distribution in the two states in order to compare disease or death rates between populations. . . . In direct adjustment (e.g., when based on age), overall disease/death rates are calculated for each population as though each had the age distribution of another standard, or reference, population, using the age-specific disease/death rates for each study population. We can then compare these overall rates, called age-adjusted rates, knowing that any difference between these rates cannot be attributed to differences in age, since both age-adjusted rates were generated using the same standard population. . . . [I]t is also possible to adjust for any number of other variables, such as gender, race, occupation, and socioeconomic status. . . .

WHAT SOURCES OF ERROR MIGHT HAVE PRODUCED A FALSE RESULT?

Three general categories of phenomena can result in an association found in a study to be erroneous: chance, bias, and confounding. Before any inferences about causation are drawn from a study, the possibility of these phenomena must be examined.

The findings of a study may be the result of chance (or random error). In designing a study, the size of the sample can be increased to reduce (but not eliminate) the likelihood of random error. Once a study has been completed, statistical methods . . . permit an assessment of the extent to which the results of a study may be due to random error.

The two main techniques for assessing random error are statistical significance and confidence intervals. A study that is statistically significant has results that are unlikely to be the result of random error, although any criterion for "significance" is somewhat arbitrary. A confidence interval provides both the relative risk (or other risk measure) found in the study and a range (interval) within which the risk likely would fall if the study were repeated numerous times. . . . We should emphasize a matter that those unfamiliar with statistical methodology frequently find confusing: That a study's results are statistically significant says nothing about the importance of the magnitude of any association (i.e., the relative risk or odds ratio) found in a study or about the biological or clinical importance of the finding. "Significant," as used with the adjective "statistically," does not mean important. . . .

Bias (or systematic error) also can produce error in the outcome of a study. Epidemiologists attempt to minimize bias through their study design. . . . [For example, selection bias can be minimized through randomization.] However, even the best designed and conducted studies have biases, which may be subtle. Consequently, after data collection is completed, analytical tools are often used to evaluate potential sources of bias. . . .

Finally, a study may reach incorrect conclusions about causation because, although the agent and disease are associated, the agent is not a true causal factor. Rather, the agent may be associated with another agent that is the true causal factor, and this latter factor confounds the relationship being examined in the study. Statistical methods allow for adjustment of results in light of identified confounding factors. . . .

GENERAL CAUSATION: IS AN EXPOSURE A CAUSE OF THE DISEASE?

[E]pidemiology cannot prove causation; rather, causation is a judgment for epidemiologists and others interpreting the epidemiologic data. Moreover, scientific determinations of causation are inherently tentative. The scientific enterprise must always remain open to reassessing the validity of past judgments as new evidence develops. . . . Generally, researchers are conservative when it comes to assessing causal relationships, often calling for stronger evidence and more research before a conclusion of causation is drawn.

The factors that guide epidemiologists in making judgments about causation . . . are (1) Temporal relationship, (2) Strength of the association, (3) Dose–response relationship, (4) Replication of the findings, (5) Biological plausibility (coherence with existing knowledge), (5) Consideration of alternative explanations, (6) Cessation of exposure, (7) Specificity of the association, and (8) Consistency with other knowledge. . . . Drawing causal inferences after finding an association and considering these factors requires judgment and searching analysis. . . . Although the drawing of causal inferences is informed by scientific expertise, it is not a determination that is made by using an objective or algorithmic methodology. . . .

WHAT METHODS EXIST FOR COMBINING THE RESULTS OF MULTIPLE STUDIES?

Not infrequently, the scientific record may include a number of epidemiologic studies whose findings differ. . . . Meta-analysis is a method of pooling study results to arrive at a single figure to represent the totality of the studies reviewed. . . . [S]tudies are given different weights in proportion to the sizes of their study populations and other characteristics. . . . The appeal of a meta-analysis is that it generates a single estimate of risk (along with an associated confidence interval), but this . . . may lead to a false sense of security regarding the certainty of the estimate. . . . People often tend to have an inordinate belief in the validity of the findings when a single number is attached to them, and many of the difficulties that may arise in conducting a meta-analysis, especially of observational studies such as epidemiologic ones, may consequently be overlooked.

PUBLIC PERCEPTION AND THE ROLE OF VALUES IN RISK REGULATION

With the scientific risk assessment methods relied upon by epidemiologists described above as our foundation, we now turn to the public's perception of risk and the role of values in risk regulation. As the PHLS statement of values presented in table 2.1 notes: "action is not based on information alone." Values—ethical values and the values expressed by the public through the political process—guide our use of information and our actions in the face of incomplete information.

The public does not evaluate risk the same way epidemiologists do. How should health officials respond to the public's lack of scientific

understanding of risk? Should public perceptions be understood to reflect values worthy of balancing alongside the scientific risk assessments of experts? Or should they be treated as irrationalities to be corrected (through education programs) or circumvented (through reliance on expertise-driven administrative agencies insulated from democratic accountability)? As you read the writings of Paul Slovic (a sociologist whose groundbreaking work on risk perception has informed this debate) and Stephen Breyer (a sitting Justice of the United States Supreme Court with particular expertise in administrative law), consider how the authors' answers to these questions are implicit in their analysis.

PERCEPTION OF RISK*

Paul Slovic

The ability to sense and avoid harmful environmental conditions is necessary for the survival of all living organisms. Survival is also aided by an ability to codify and learn from past experience. Humans have an additional capability that allows them to alter their environment as well as respond to it. This capacity both creates and reduces risk. . . .

[T]he development of chemical and nuclear technologies has been accompanied by the potential to cause catastrophic and long-lasting damage to the earth and the life forms that inhabit it. The mechanisms underlying these complex technologies are unfamiliar and incomprehensible to most citizens. Their most harmful consequences are rare and often delayed, hence difficult to assess by statistical analysis and not well suited to management by trial-and-error learning. The elusive and hard to manage qualities of today's hazards have forced the creation of a new intellectual discipline called risk assessment, designed to aid in identifying, characterizing, and quantifying risk.

Whereas technologically sophisticated analysts employ risk assessment to evaluate hazards, the majority of citizens rely on intuitive risk judgments, typically called "risk perceptions." For these people, experience with hazards tends to come from the news media, which rather thoroughly document mishaps and threats occurring throughout the world. The dominant perception for most Americans (and one that contrasts sharply with the views of professional risk assessors) is that they face more risk today than in the past and that future risks will be even greater than today's. Similar views appear to be held by citizens of many other industrialized nations. These perceptions and the opposition to technology that accompanies them have puzzled and frustrated industrialists and regulators and have led numerous observers to argue that the American public's apparent pursuit of a "zero-risk society" threatens the nation's political and economic stability. . . .

* Reprinted from 1987. *Science* 236 (4799): 280–85.

[Research] examining the opinions that people express when they are asked, in a variety of ways, to evaluate hazardous activities, substances, and technologies [has sought] to discover what people mean when they say that something is (or is not) "risky," and to determine what factors underlie those perceptions. The basic assumption underlying these efforts is that those who promote and regulate health and safety need to understand the ways in which people think about and respond to risk.

If successful, this research should aid policy-makers by improving communication between them and the public, by directing educational efforts, and by predicting public responses to new technologies (for example, genetic engineering), events (for example, a good safety record or an accident), and new risk management strategies (for example, warning labels, regulations, substitute products). . . .

A major development in this area has been the discovery of a set of mental strategies, or heuristics, that people employ in order to make sense out of an uncertain world. Although these rules are valid in some circumstances, in others they lead to large and persistent biases, with serious implications for risk assessment. In particular, laboratory research on basic perceptions and cognitions has shown that difficulties in understanding probabilistic processes, biased media coverage, misleading personal experiences, and the anxieties generated by life's gambles cause uncertainty to be denied, risks to be misjudged (sometimes overestimated and sometimes underestimated), and judgments of fact to be held with unwarranted confidence. Experts' judgments appear to be prone to many of the same biases as those of the general public, particularly when experts are forced to go beyond the limits of available data and rely on intuition.

Research further indicates that disagreements about risk should not be expected to evaporate in the presence of evidence. Strong initial views are resistant to change because they influence the way that subsequent information is interpreted. New evidence appears reliable and informative if it is consistent with one's initial beliefs; contrary evidence tends to be dismissed as unreliable, erroneous, or unrepresentative. When people lack strong prior opinions, the opposite situation exists—they are at the mercy of the problem formulation. Presenting the same information about risk in different ways (for example, mortality rates as opposed to survival rates) alters people's perspectives and actions. . . .

[P]eople are willing to tolerate higher risks from activities seen as highly beneficial. . . . [O]ther (perceived) characteristics such as familiarity, control, catastrophic potential, equity, and level of knowledge also seem to influence the relation between perceived risk, perceived benefit, and risk acceptance. . . . [T]he broader domain of characteristics can be condensed into [two main factors (see figure 2.1)]. . . . Factor 1, labeled "dread risk," is defined at its high . . . end by perceived lack of control, dread, catastrophic potential, fatal consequences, and the inequitable distribution of risks and benefits. Nuclear weapons and nuclear power score highest on the characteristics that make up this factor. Factor 2, labeled "unknown risk," is defined at its high end by hazards judged to be unobservable, unknown, new, and delayed in their manifestation of harm. Chemical technologies score particularly high on this factor. A third factor, reflecting the number of people exposed to the risk, has been [noted] in several studies. . . .

Research has shown that lay people's risk perceptions and attitudes are closely related to [these factors]. Most important is the [degree of perceived] "dread risk." The

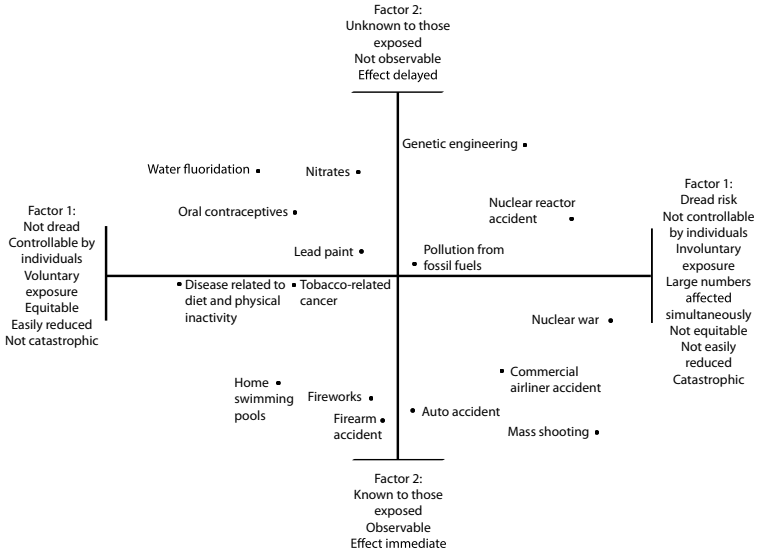

FIGURE 2.1. Factors influencing perceived risk. (Adapted from Slovic, Paul. 1987. *Science* 236 [4799]: 280–85.) Two groups of factors influence perceived risk. Factor 1, which Slovic and others have labeled *dread risk,* captures perceived lack of control over the risk (e.g., individuals have no control over the risk that the plane they are riding in will crash, but perceive themselves to be in control of the risk that the car they are driving will crash), catastrophic potential, and numbers of people affected simultaneously (e.g., people may overestimate their risk of dying in a mass shooting while underestimating the risk that they will be unintentionally injured by a firearm); inequitable distribution of costs and benefits associated with the risk (e.g., the risks of nuclear power generation are concentrated in the areas immediately surrounding power plants, whereas the benefits are more widespread). Factor 2, labeled *unknown risk,* captures the observability of exposure to risk (e.g., pedestrians and vehicle occupants are aware of their exposure to a crash, whereas individuals are less likely to be aware of their consumption of genetically modified crops); the immediacy of the effect (e.g., a fireworks explosion causes immediate harm, whereas the effects of water fluoridation, if any, are likely to be latent for a long time). Lay people are likely to underestimate risks located toward the bottom left corner of the graph and overestimate risks located toward the top right corner. For example, the public tends to overestimate the risks associated with nuclear reactor accidents while underestimating the risks associated with motor vehicle travel. Following the reactor meltdowns at the Fuushima power plant in Japan in 2011, the Swiss embassy announced that it would evacuate all staff to Osaka. Environmentalist Mark Lynas wrote: "I do hope their staff have a safe journey: they will be exposed to vastly greater dangers from an accident on the road journey down to Osaka than if they had stayed put in Tokyo with its infinitesimally raised levels of radiation." Mark Lynas, "Nuclear: Difference between Two and Three Degrees?" March 21, 2011, www.marklynas.org/2011/03/176/.

higher a hazard's score on this factor . . . the higher its perceived risk, the more people want to see its current risks reduced, and the more they want to see strict regulation employed to achieve the desired reduction in risk. In contrast, experts' perceptions of risk are not closely related to any of the various risk characteristics or factors. . . . Instead, . . . experts appear to see riskiness as synonymous with expected annual mortality. As a result, conflicts over "risk" may result from experts and lay people having different definitions of the concept. . . . In short, "riskiness" means more to people than "expected number of fatalities." Attempts to characterize, compare, and regulate risks must be sensitive to this broader conception of risk. . . .

Perhaps the most important message from this research is that there is wisdom as well as error in public attitudes and perceptions. Lay people sometimes lack certain information about hazards. However, their basic conceptualization of risk is much richer than that of the experts and reflects legitimate concerns that are typically omitted from expert risk assessments. As a result, risk communication and risk management efforts are destined to fail unless they are structured as a two-way process. Each side, expert and public, has something valid to contribute. Each side must respect the insights and intelligence of the other.

BREAKING THE VICIOUS CIRCLE: TOWARD EFFECTIVE RISK REGULATION*

Stephen Breyer

. . . [P]ublic perceptions, Congressional actions and reactions, and technical regulatory methods reinforce each other. They tend to create a vicious circle, diminishing public trust in regulatory institutions and thereby inhibiting more rational regulation. Congress reacts to the public and influences the regulators, who, in their choice of methods and problems, in turn influence both public perception and Congressional reaction. . . .

PUBLIC PERCEPTIONS

Study after study shows that the public's evaluation of risk problems differs radically from any consensus of experts in the field. Risks associated with toxic waste dumps and nuclear power appear near the bottom of most expert lists; they appear near the top of the public's list of concerns, which more directly influences regulatory agendas. . . . There is a far simpler explanation for the public's aversion to toxic waste dumps than an enormous desire for supersafety, or a strong aversion to the tiniest risk of harm—namely, the public does not *believe* that the risks are tiny. The public's "nonexpert" reactions reflect not different values but different understandings about the underlying risk-related facts. . . . Psychologists have found several examples of thinking that impede rational understanding. . . . The following, rather well-documented aspects of risk perception are probably familiar.

Rules of Thumb. In daily life most of us do not weigh all the pros and cons of feasible alternatives. We use rules of thumb, more formally called "heuristic devices." We simplify radically; we reason with the help of a few readily understandable examples; we categorize (events and other people) in simple ways that tend to create binary choices—yes/no, friend/foe, eat/abstain, safe/dangerous, act/don't act. . . . The resulting categorizations do not always accurately describe another person or circumstance, but they help us make quick decisions, most of which prove helpful. This kind of quick decision-making may help cut a swath through the modern information jungle, but it oversimplifies dramatically and thereby inhibits an understanding of risks, particularly small risks.

Prominence. People react more strongly, and give greater importance, to events that stand out from the background. Unusual events are striking. We more likely notice the (low-risk) nuclear waste disposal truck driving past the school than the (much higher-risk) gasoline delivery trucks on their way to local service stations. Journalists, whose job is to write interesting stories, know this psychological fact well. The American Medical Association examined how the press treated two similar stories, one finding increased leukemia rates among nuclear workers, the other finding no increased cancer rates among those living near nuclear plants. More than half of the newspapers in the study mentioned the first story but not the second; and more than half of those that mentioned both emphasized the first.

Ethics. The strength of our feelings of ethical obligation seems to diminish with distance. That is to say, feelings of obligation are stronger (or we have different, more time-consuming obligations) toward family, neighbors, friends, community, and those with whom we have direct contact, those whom we see, than toward those who live in distant places, whom we do not see but only read or hear about.

Trust in Experts. People cannot easily judge between experts when those experts disagree with each other. The public, since the mid-1960s, has shown increasing distrust of experts and the institutions, private, academic, or governmental, that employ them.

Fixed Decisions. A person who has made up his or her mind about something is very reluctant to change it.

Mathematics. Most people have considerable difficulty understanding the mathematical probabilities involved in assessing risk. People consistently overestimate small probabilities [and] underestimate large ones. . . . People cannot detect inconsistencies in their own risk-related choices. . . .

We have "seen" Chernobyl and Three Mile Island, and we may therefore doubt nuclear power's safety, whether or not experts tell us that the reactor at Chernobyl was not properly designed, that the accident at Three Mile Island hurt no one, that military weapons, not electric power generators, are responsible for 99 percent of all nuclear waste, that nuclear power's risks are miniscule compared to the risks of coal-generated power. Add a few disagreements among experts and the fact that most members of the public made up their minds long ago, and one can understand nuclear power's position on the public perception risk charts.

These few propositions suggest that better "risk communications," such as efforts to explain risks to the public at open meetings, may not suffice to alleviate risk regulation problems. . . . There is little reason to hope for better risk communication over time. . . . It is hard to make the normal human mind grapple with this inhuman type of

problem. To change public reaction, one would either have to institute widespread public education in risk analysis or generate greater public trust in some particular group of experts or the institutions that employ them. The first alternative seems unlikely. The second, over the past thirty years, has not occurred. . . .

EVIDENCE-BASED POLICY AND THE PRECAUTIONARY PRINCIPLE

The difficult balance between science and values in risk regulation is thrown into sharp relief when full information is unavailable, yet public concern is high. The rigorous scientific assessments demanded by Marckmann's framework for ethical interventions may not be feasible due to incomplete information. The most reliable scientific studies are typically the most expensive to conduct. Unlike pharmaceuticals or medical devices, public health interventions are not backed by financially powerful industries willing to produce rigorous scientific studies at private expense. In other cases (as demonstrated by the Baltimore lead study challenged in *Grimes v. Kennedy Krieger,* which is excerpted in the section below), ethical constraints limit our ability to assess the causal relationship between an agent, condition, or behavior on the one hand and public health outcomes on the other.

How should policymakers respond when evidence is uncertain, incomplete, or unavailable? As you read the excerpts below, consider whether the precautionary principle—which advises action to protect human health and the environment in the face of unknown risks—is an ethical principle that ought to apply in evaluating most or all public health interventions.

A COMPASS FOR HEALTH: RETHINKING PRECAUTION AND ITS ROLE IN SCIENCE AND PUBLIC HEALTH*

Joel A. Tickner, David Kriebel, and Sara Wright

. . . The precautionary principle encourages policies that protect human health and the environment in the face of uncertain risks. In this broad sense, it is not a new concept. Precaution is at the heart of medical and public health practice, as embodied in the "first do no harm" tenet of medicine. The term "precautionary principle" can be traced to the German word *Vorsorgeprinzip.* An alternative translation of this word might be

* Reprinted from 2003. *International Journal of Epidemiology* 32 (4): 489–92.

the foresight or "forecaring" principle—emphasizing anticipatory, forward-looking action rather than reactive impeding of progress.

A widely cited definition of the precautionary principle is the Wingspread Statement, which states: "when an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically." . . .

PRECAUTION AND INNOVATION

The precautionary principle encourages making decisions using the broadest possible range of information and participants. It does not create rigid prohibitions to new technologies when there is risk of harm. Absolute proof of safety is impossible; the challenge for policy makers is to find the balance between potential risk and social benefit in the absence of proof of safety. . . .

Proponents of genetically modified food, for example, claim that the precautionary principle would block development and use of the technology on the basis of a hypothetical risk, with negative consequences for feeding the hungry in less-developed countries. A precautionary approach to regulation of this potentially powerful technology would begin by clarifying its intended purposes. Is the purpose of genetic modification of food to increase food production, to support a more ecologically sustainable form of agriculture, or to create business opportunities? Once the purpose is identified, alternative methods of achieving this purpose should be identified, and weighed against the genetic technology, both in terms of efficacy and potential risks. This alternatives analysis should be very broad—examining a wide range of food production strategies, and including the full range of interested parties. . . .

Does precaution stifle innovation? Some technologies and substances probably should be slowed or blocked, after a careful review of their benefits, risks, alternatives, and overall uncertainties. Precaution encourages this review, but does not indiscriminately stifle innovation. To the contrary, a thorough search for alternative ways to achieve the same social goals will often identify technologies that should be encouraged. . . .

PRECAUTION AND TRADE-OFFS

Well-intended precautionary public health interventions can and often do result in serious adverse consequences. Often, however, these adverse consequences are the result of incomplete analysis, lack of foresight, and inadequate consideration of uncertainties, rather than a failure of precaution.

Critics have suggested, for example, that the precautionary principle might dictate a ban on DDT because of its long-term environmental effects, with serious negative consequences for the control of mosquitoes that spread malaria. DDT is cheap, evidently effective, and readily available, but also persistent in the environment, with significant ecological impacts. How can we use the compass of the precautionary principle in this dilemma? . . .

The . . . error is to begin from too small a set of options—either spray a pesticide with uncertain human impacts or let people die from malaria. This dichotomy ignores several important points: for example, there may be many other effective options for controlling malaria and protecting people, and DDT may not be as effective as it once was, due to mosquito resistance. Including members of communities where malaria is endemic in the assessment and choice of alternatives will also help insure that decisions reflect a full

range of information, uncertainties, values, and needs of those affected. The DDT debate also highlights a common bias towards addressing short-term, knowable risks (such as malaria), at the expense of more subtle, long-term risks with less-direct causal links (such as cancer) and disruption of natural ecosystems where DDT is sprayed. . . .

PRECAUTION AND "FALSE POSITIVES"

One concern often raised against precaution is that it may lead to acting against false-positive risks—over-regulation that diverts important resources from "real" risks. . . . A decision to act on limited knowledge about a hazard may ultimately turn out to have been due to a "false positive," but if it spurs innovations, stimulates new economic forces, and raises awareness of ecologic cycles and other lessons of sustainability, then it may still be judged to have been a worthwhile decision. . . .

For example, arguments that organic food is safer than conventional food because of its lack of pesticide residues may in the end be a considered a false positive because research has not demonstrated clear health benefits associated with this food. . . . One might decide, on a precautionary basis, that . . . reduction in exposure [to pesticides] is sufficient justification to buy organic foods, but this is very different from the risk-based approach in which one would wait for strong evidence that these levels of pesticides were harmful before trying to avoid them. Because of the limits of observational epidemiology, this strong evidence of risk may never be found. Thus, from the narrow perspective of traditional risk assessment, "buying organic" for health reasons may represent a "false positive."

However, there are myriad other benefits from promoting organic agriculture, including increased biodiversity, reduced use of synthetic fertilizer and pesticides (which can contaminate soil, air, surface and groundwater, and lead to human exposure), reduced energy use, and improved worker safety. These benefits are not directly associated with the health of people who eat organic food, but they are significant and indirect benefits nonetheless. . . .

The concern for false positives should also be weighed against the very substantial evidence of numerous false negatives that have resulted from past practices. . . . [L]ack of scientific proof of harm was misinterpreted as evidence of safety in science and policy in [many] cases including asbestos, lead, and polychlorinated biphenyls (PCB).

CONCLUSIONS: PRECAUTION AND FORESIGHT

Many recent environmental crises have arisen from the failure to act quickly to avoid unintended consequences of seemingly beneficial technologies, and precaution is seen as a way to avoid these mistakes in future decisions. There is, of course, no such thing as absolute safety, nor absolute certainty, and so mistaken regulations, and failures to regulate, will occur. But we believe that society has not yet realized the full potential of science-based policy to prevent damage to ecosystems and health while ensuring progress towards a healthier and economically sustainable future. Far from being anti-science, precautionary policies can stimulate innovations in science, medicine, and technology to promote the health and safety of the planet.

• • •

Controversies over risk-risk trade-offs (such as the trade-off between malaria control and the ecological impacts of DDT described in the

PHOTO 2.2. Aerial insecticide spraying for malaria control in Savannah. The controversial insecticide DDT was widely used in the southeastern United States to suppress malaria transmission near military training facilities during World War II. In 1972, the EPA restricted the use of DDT to protect fish and wildlife. Environmental advocacy groups continue to express concerns about other insecticides used to prevent the spread of mosquito-borne diseases, including West Nile virus and Zika. Unknown Photographer, U.S. Centers for Disease Control and Prevention.

excerpt above) plague public health and may diminish the public's trust in public health recommendations. Tickner and his colleagues caution against under-regulation of more remote environmental risks (like the risk posed by DDT to bird populations) in favor of more proximate health risks (like the risk of malaria transmission in the absence of DDT). Yet Slovic's work would suggest the opposite: over-regulation of environmental risks perceived to be "unknown"—unobservable, delayed, and associated with new technologies (like DDT)—and under-regulation of more mundane, familiar risks (like malaria transmission). Similar dilemmas are posed by efforts to balance the risk of vaccine-induced injuries against the risk of vaccine-preventable disease, or to balance the

risk of undetected early-stage breast or prostate cancer against the risk of harm from invasive follow-up testing (e.g., surgical biopsy or tumor excision) in response to false-positive screening test results.

Mounting tension between mainstream public health experts and consumer advocates who seek to promote a "natural," "chemical-free," and "GMO-free" lifestyle similarly illustrates the complexity of risk regulation. As Slovic notes, providing more information to someone with strong views is not necessarily an effective strategy. It is human nature to reject new evidence that does not conform to previously formed beliefs as biased or otherwise unreliable. For example, studies suggest exposing parents who refuse or delay vaccines to scientifically sound information about the minimal risks and considerable benefits of vaccines *increases* their resistance to vaccinating their children on schedule (Pluviano et al. 2017).

The role of values in risk perception, assessment, and communication is unavoidable. Public health officials must earn the public's trust by ensuring that interventions are carried out fairly and transparently. They also must recognize the limits of evidence-based policy. Even for relatively uncontroversial policy goals, like reducing children's exposure to secondhand smoke, scientific inquiry can only take us so far, as the following excerpt by Ray Pawson, Geoff Wong, and Lesley Owen on the limits of evidence-based policy demonstrates. The questions scientists can answer with accuracy and validity are typically painstakingly narrow (e.g., What quantity of particulate matter is inhaled by a child in the rear seat of a car when a person in the front seat of the car is smoking a cigarette under precisely defined conditions with regard to rate of smoking, size of passenger compartment, speed of travel, and extent to which windows are open?) compared to the broad assessments policymakers and the public demand (e.g., Should we ban smoking in cars carrying children?).

KNOWN KNOWNS, KNOWN UNKNOWNS, UNKNOWN UNKNOWNS: THE PREDICAMENT OF EVIDENCE-BASED POLICY*

Ray Pawson, Geoff Wong, and Lesley Owen

. . . [This] paper seeks to explore the limits of evidence-based policy when, as always happens, the knowledge base falls short of absolute, indubitable truth. . . . We [use the case study of] the potential effectiveness of a law banning smoking in cars carrying

* Reprinted from 2011. *American Journal of Evaluation* 32 (4): 518–46.

TABLE 2.6 TESTING QUESTIONS OF THE EFFICACY OF A BAN ON SMOKING IN CARS CARRYING CHILDREN

1. Is the severity of the problem sufficient to justify a law?
Does exposure to secondhand smoke (SHS) in cars leads to ill-health?
What toxicity levels are encountered in a car when cigarettes are smoked?
Does ventilation make a difference?
Are the toxicity levels comparable to other risky environments?
How does the potential harm compare to formally approved air quality standards?
2. Is there likely to be public support for such a law?
What is the overall magnitude of support for such a law?
What are the levels of support among smokers?
What is the motivation behind public support?
Does endorsement depend on the extent and success of previous smoking bans?
3. Is there likely to be effective pressure group opposition to the ban?
Has the tobacco lobby opposed this particular ban and will they do so in future?
What is the broader strategy behind tobacco company opposition to smoking control?
How does the "smoke-free" lobby interpret and respond to tobacco industry tactics?
4. Is the law enforceable?
What are the main barriers and facilitators in discharging the law?
What is the optimal enforcement strategy?

SOURCE: Adapated from from Pawson, Ray, Geoff Wong, and Lesley Owen. 2011. "Known Knowns, Known Unknowns, Unknown Unknowns: The Predicament of Evidence-Based Policy." *American Journal of Evaluation* 32 (4): 518–46.

children. . . . A massive range of assumptions . . . lies behind [legislative interventions]. An abbreviated list of some of key pitfalls worthy of interrogation . . . is presented in [table 2.6]. The catalogue is organized under four main questions, each one carrying a sample of critical subissues that need to be "evidenced" in order to warrant the claim that there is a sound empirical foundation for the intervention. . . .

IS THE SEVERITY OF THE PROBLEM SUFFICIENT TO JUSTIFY THE LAW?

There is now a substantial, accumulating body of evidence on the dangers of subjection to [secondhand smoke (SHS)], much of it summarized in the U.S. Surgeon General's Report: *The Health Consequences of Involuntary Exposure to Tobacco Smoke* (U.S. Department of Health and Human Services 2006). Vast as his report is[,] the Surgeon General has nothing to say about the health impact of the microenvironment inhabited by the child cocooned with a smoker in the cabin space of the car. The review thus begins by hunting evidence on this very specific known unknown. [Figure 2.2]

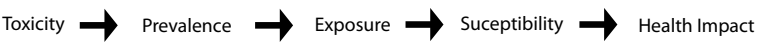

FIGURE 2.2. The secondhand-smoke causal chain: from dose to response. Adapted from Pawson, Ray, Geoff Wong, and Lesley Owen. 2011. "Known Knowns, Known Unknowns, Unknown Unknowns: The Predicament of Evidence-Based Policy." *American Journal of Evaluation* 32 (4) 518–46.

represents the causal chain and predicament of primary researchers (and their secondary reviewers) in trying to determine the risks involved.

First is the matter of the pollutants under study. SHS is a complex mixture of thousands of chemicals emitted from burning tobacco, all with potential health effects, 50 of them considered potentially carcinogenic. Tracing their lingering concentrations in vehicles is difficult, especially under different volume, speed, and ventilation conditions. At Step 2, there is prevalence, the extent of within-vehicle smoking and smokers. This is also difficult to monitor closely in the private space of a moving vehicle and reliance is generally placed on potentially erratic self-report in surveys. Then we move to the rear seat of the car the equally taxing matter of estimating the extent of subjection to SHS of children in these locations. . . . Step 4 is susceptibility, which governs the reactions to a potential toxin. Children's metabolic systems are suspected of showing greater sensitivity to most toxins, another factor that needs to be inserted into the risk equation. Finally, we come to health impact, once again furiously difficult to chart because of the potential pathways of so many toxins to so many organs and thus to myriad disease pathologies—short-term, long-term, and terminal. . . .

Does Exposure to SHS in Cars Lead to Ill-Health?

A typical [study charts] the association between home and vehicle environmental tobacco smoke (ETS) and chronic bronchitis. [Health survey r]espondents are asked to self-report on: (a) whether there were regular smokers in their household[,] (b) whether there was regular exposure to smoke in cars[,] (c) whether they had been diagnosed with chronic bronchitis[, and] (d) a range of potential background intervening variables.

Results are reported as follows: "The proportion of respondents who reported ETS exposure in the home and vehicle was 9.0% and 8.4%, respectively. The prevalence of self-reported doctor diagnosed bronchitis was 1.5%. When considered separately, home and vehicle ETS were both statistically associated with chronic bronchitis in children and adolescents aged 12–19 years. Neither home nor vehicle ETS exposure was significantly associated with chronic bronchitis in age groups greater than 19 years. When home and vehicle exposure were considered together, and sex, age, allergies, marital status, and race were controlled for, home ETS exposure was not a significant predictor of chronic bronchitis while vehicle ETS was." . . .

The evidence here is, of course, associational and derives from survey data and so comes with the standard caveat that correlation does not imply causation. These data, perforce, do not follow and monitor unfolding disease pathologies. They are a snapshot relying on self-report of different events at different times. . . . The findings here are highly susceptible to the vagaries of the respondents' memories and are subject to bias though arbitrary operationalization and question wording. . . . [For example,] participants with active respiratory symptoms and a formal diagnosis have much more

cause to recall exposure to ETS. These issues are raised not to dismiss this particular study but to establish a more generic type of technical uncertainty that besets this form of public health evidence. What such surveys produce are indicative tendencies rather than known knowns. . . .

What Toxicity Levels Are Encountered in a Car when Cigarettes Are Smoked?

Several studies have attempted to gauge toxicity, under different driving conditions, when smoking occurs in the vehicle. In most cases, a volunteer smoker is asked to light up and an air quality monitor, strategically located, is set to record the fluctuations in toxicity levels. As with all "in vivo" experiments, these studies have to contend with significant natural variation in the behavior under study. The investigation requires a smoker and a child (substituted by an air quality monitor) but, thereafter, the encounter will vary according to: traffic conditions, climatic conditions, speed of vehicle, type of vehicle, duration of journey, number of passengers, number of smokers, number and frequency of cigarettes smoked, proximity of smoker and passenger, history of smoking in the car, and the ventilation conditions. . . .

Such data might understandably be termed "hard evidence" and indeed they come closest to the elusive "known knowns" in this review. A more accurate description of their status might read "conditional knowns." In specific and specified circumstances—low speeds, windows closed, passengers in close proximity, several cigarettes smoked, and so on—vast levels of toxins are observed.

Does Ventilation Make a Difference?

One of these conditions, especially, has aroused much research interest. What happens if the driver opens windows or operates the air conditioning? This "ventilation solution" has for some time been part of the argument of the "informed-choice" lobby and evidence is needed to settle the debate. . . . Many smokers who drive cars carrying children do so under informal rules about reducing their consumption during journeys and having windows open in order to achieve "safe levels." Are they correct? The answer is "not yet known." We now have splendid evidence on how toxicity gradients vary under different in-car conditions but this study cannot decipher the cutting point of acceptable air quality standards. Nor can it tell us, though we might well guess, whether a law could survive the ambiguity of trying to prespecify how ventilation should operate.

Are Toxicity Levels Comparable to Other Risky Environments?

One way of determining pertinent benchmarks is to examine precedents and relativities—comparisons of vehicle toxicity data with measurements of air quality made in other domains already subject to smoking restrictions. The rationale for doing so is obvious—"if intervention was needful there, then surely the same applies here." This sentiment is uttered in virtually all lobbying for banning smoking in cars carrying children. The "smoky bar," the bête noir of public health advocates, is the favored precedent. . . .

Drawing parallels on air quality levels across the two situations is not straightforward, however. [P]eak levels [of respirable particulate matter, known as PM2.5,] in cars under closed conditions are over 3,000 mg/m^3, seemingly even more dangerous [than

the mean level of 400 mg/m^3 found in studies of bars prior to the introduction of smoking bans]. Then again, if a comparison is drawn with mean levels in a well-ventilated car, [the car study's] measure at 97 mg/m^3 is lower [than the mean levels found in smoky bars]. The upshot . . . is that . . . toxic environments . . . vary widely according to context and usage. . . . In a world of conditional knowns, there is no such thing as a clear precedent.

How Does the Potential Harm Compare with Formally Approved Air Quality Standards?

Another compelling option for gauging the risk associated with in-vehicle smoking is to compare it with publicly sanctioned benchmarks—formal air quality standards recognized by official agencies such as the U.S. Environmental Protection Agency (EPA). These have considerable attraction for evidence-based policy, being what [one] might term "official knowns." We begin by extracting the EPA's figure of the "primary standards" for PM2.5 concentrations. Aptly, primary standards are intended to set limits to protect the health of "sensitive" populations such as asthmatics, children, and the elderly. Two exposure figures are presented limiting the acceptable standards [for] ambient air to 15 mg/m^3 annually and 35 mg/m^3 in a 24-hour period. These baseline levels represent very low magnitudes indeed when compared to the car exposure levels reported earlier. . . .

Consider next the primary standard of the Office of U.S. Surgeon General: "The scientific evidence indicates that there is no risk-free level of exposure to second hand smoke" . . . "The US Surgeon General has concluded that breathing even a little second hand smoke is bad for your health." *Ipso facto,* it follows that any amount of smoking in cars carrying children should be considered a significant risk. Under these benchmarks, we move from strong to unequivocal support for the in-car ban.

[This conclusion is] underpinned by a fundamental change in the interpretation of "risk." In classic academic toxicology an ancient maxim, the Paracelsus principle, is considered the cornerstone of public health standards: "All substances are poisons; there is none which is not a poison. The right dose differentiates a poison from a remedy." The rule is that a substance only becomes poisonous when ingested at above some tolerable level. Caffeine is an exemplar—commonplace in range of foodstuffs without leading to illness but capable of causing death at 50-times standard exposure levels.

More recently, an alternative credo has come to the fore known as "the precautionary principle." It states that, "in cases of serious or irreversible threats to the health of humans or ecosystems, acknowledged scientific uncertainty should not be used as a reason to postpone preventive measures." The principle originated as a tool to bridge uncertain scientific information and the political responsibility to act to prevent damage to human health. . . . By definition the zero emission, zero tolerance standards are not empirically derived—they concede that the evidence is not yet in. Their role is thus to acknowledge uncertainty but to remove doubt . . . [moving] from evidence to advocacy. Invoking the maxim stifles the search for further evidence. . . .

SUMMARY

The above represents a brief sample of some key studies relating to the toxicology of SHS in cars carrying children. Some powerful evidence comes to light, which can be

summarized thus: (a) because of the confined cabin space, and (b) under [poor] ventilation conditions, and (c) in terms of peak contamination, the research permits us to say that smoking in cars generates bursts of fine particulate concentrations that are, (d) very rarely experienced in the realm of air-quality studies, and that will constitute a health risk. . . .

Our task . . . is thus to evaluate the authority of evidence when the issue under investigation depends on many, many contingent conditions, which change over time and with location. [The] absence of known knowns has led others to leap into the arms of the precautionary principle. Wisely, this tenet tells us not to wait for certitude. Unwisely, as above, it then slopes back to certitude via the production of arbitrary, absolute standards that sit most uncomfortably with the mass of conditional truths produced by the science. . . .

What actually sits between known knowns and unknown unknowns are partial knowns and partial knowledge remains a useful tool for policy makers. The fact that more research is always needed does not involve an indefinite wait. What the evidence above supplies is a framework for decision making and some incredibly useful nudges on the dynamics of risk. It enables the decision maker to identify key issues and consider how each in turn applies to the policy and the place under consideration. A thorough immersion in [contingencies] is the basis for making a balanced judgment. . . . [E]vidence-based policy is a journey rather than a destination.

ETHICAL CONSTRAINTS ON PUBLIC HEALTH RESEARCH

In some cases, evidence is unavailable because it would be prohibitively expensive to produce. In other cases, ethical constraints limit the design of research studies. As you read the case below—in which the supreme court of the state of Maryland considers the claims of participants in a public health research study that they should be compensated for harms caused by the institution that conducted the research—consider why the researchers might have designed this controversial and unethical study the way that they did. What questions were they trying to answer? What benefits might flow from having the answers? What alternatives were available?

*GRIMES V. KENNEDY KRIEGER INSTITUTE, INC.**

Maryland Court of Appeals
Decided August 16, 2001

[This appeal consolidates two separate negligence actions involving children who allegedly developed unsafe blood lead levels while participating in a research study

* 782 A.2d 807.

conducted by Kennedy Krieger Institute, Inc. The children are seeking compensation from the Institute. They allege that as a medical researcher, the Institute owed a duty of care to them, as subjects in the research study. They contend specifically that the Institute was negligent because it breached its duty to: (1) design a study that did not involve placing children at unnecessary risk; (2) inform participants in the study of results in a timely manner; and (3) completely and accurately inform participants in the research study of all the hazards and risks involved in the study.]

In these present cases, a prestigious research institute, associated with Johns Hopkins University, *based on this record,* created a nontherapeutic research program whereby it required certain classes of homes to have only partial lead paint abatement modifications performed, and in at least some instances, including at least one of the cases at bar, arranged for the landlords to receive public funding by way of grants or loans to aid in the modifications. The research institute then encouraged, and in at least one of the cases at bar, required, the landlords to rent the premises to families with young children. In the event young children already resided in one of the study houses, it was contemplated that a child would remain in the premises, and the child was encouraged to remain, in order for his or her blood to be periodically analyzed. In other words, the continuing presence of the children that were the subjects of the study was required in order for the study to be complete. Apparently, the children and their parents involved in [these cases] were from a lower economic strata and were, at least in one case, minorities.

The purpose of the research was to determine how effective varying degrees of lead paint abatement procedures were. Success was to be determined [in part] by measuring the extent to which the theretofore healthy children's blood became contaminated with lead, and comparing that contamination with levels of lead dust in the houses over the same periods of time. In respect to one of the protocols presented to the Environmental Protection Agency [which funded the study] and/or . . . the Johns Hopkins Institutional Review Board (IRB), the researchers stated: "To help insure that study dwellings are occupied by families with young children, City Homes will give priority to families with young children when renting the vacant units following [Repair and Maintenance] interventions." . . .

In an article reporting [a previous] study, the very same researchers said: "Exposure to lead-bearing dust is particularly hazardous for children because hand-to-mouth activity is recognized as a major route of entry of lead into the body and because absorption of lead is inversely related to particle size." . . .

There was no complete and clear explanation in the consent agreements signed by the parents of the children that the research to be conducted was designed, at least in significant part, to measure the success of the abatement procedures by measuring the extent to which the children's blood was being contaminated. . . .

Institutional Review Boards (IRB) are oversight entities within the institutional family to which an entity conducting research belongs. In research experiments, an IRB can be required in some instances by either federal or state regulation, or sometimes by the conditions attached to governmental grants that are used to fund research projects. . . . One of the most important objectives of such review is the review of the potential safety and the health hazard impact of a research project on the human subjects of the experiment, especially on vulnerable subjects such as children. . . . [T]he IRB involved here, the Johns Hopkins University Joint Committee on

PHOTO 2.3. Lead paint warning sign. Ingestion of lead—from paint chips, toys, and contaminated drinking water and soil—poses serious risks to young children. Courtesy of Ben+Sam via Flickr.

Clinical Investigation, in part, abdicated that responsibility, instead suggesting to the researchers a way to miscast the characteristics of the study in order to avoid the responsibility inherent in nontherapeutic research involving children. . . .

Otherwise healthy children, in our view, should not be enticed into living in, or remaining in, potentially lead-tainted housing and intentionally subjected to a research program, which contemplates the probability, or even the possibility, of lead poisoning or even the accumulation of lower levels of lead in blood, in order for the extent of the contamination of the children's blood to be used by scientific researchers to assess the success of lead paint or lead dust abatement measures. Moreover, in our view, parents, whether improperly enticed by trinkets, food stamps, money or other items, have no more right to intentionally and unnecessarily place children in potentially hazardous nontherapeutic research surroundings, than do researchers. In such cases, parental consent, no matter how informed, is insufficient. . . .

[T]he research was clearly nontherapeutic in nature. The experiment was simply a "for the greater good" project. The specific children's health was put at risk, in order to develop low-cost abatement measures that would help all children, the landlords, and the general public as well. . . . In *Olmstead v. United States,* 277 U.S. 438 (1928), Justice Brandis, dissenting, noted: "Experience should teach us to be most on our guard to protect liberty when the Government's purposes are beneficent. Men born to freedom are naturally alert to repel invasion of their liberty by evil-minded rulers. The greatest dangers to liberty lurk in insidious encroachment by men of zeal, well-meaning but without understanding."

> The research project at issue here, and its apparent protocols, differs in large degree from, but presents similar problems as those in the Tuskegee Syphilis Study conducted from 1932 until 1972, the intentional exposure of soldiers to radiation in the 1940s and 50s, the tests involving the exposure of Navajo miners to radiation, the secret administration of LSD to soldiers by the CIA and the Army in the 1950s and 60s, . . . the Jewish Hospital study[,] . . . the notorious use of "plague bombs" by the Japanese military in World War II where entire villages were infected in order for the results to be "studied[,"] and perhaps most notorious, the deliberate use of infection in a nontherapeutic project in order to study the degree of infection and the rapidity of the course of the disease in the Rose and Mrugowsky typhus experiments at Buchenwald concentration camp during World War II. These programs were somewhat alike in the vulnerability of the subjects; uneducated African-American men, debilitated patients in a charity hospital, prisoners of war, inmates of concentration camps and others falling within the custody and control of the agencies conducting or approving the experiments. In the present case, children, especially young children, living in lower economic circumstances, albeit not as vulnerable as the other examples, are nonetheless, vulnerable as well. . . .
>
> We hold that in Maryland a parent, appropriate relative, or other applicable surrogate, cannot consent to the participation of a child or other person under legal disability in nontherapeutic research or studies in which there is any risk of injury or damage to the health of the subject. We hold that informed consent agreements in nontherapeutic research projects, under certain circumstances can constitute contracts; and that, under certain circumstances, such research agreements can, as a matter of law, constitute "special relationships" giving rise to duties, out of the breach of which negligence actions may arise. We also hold that, normally, such special relationships are created between researchers and the human subjects used by the researchers. . . . The determination as to whether a "special relationship" actually exists is to be done on a case by case basis. . . . Accordingly, we vacate the rulings [by the trial court in favor of the Institute] and remand these cases to that court for further proceedings consistent with this opinion.

. . .

Ethical norms and state and federal laws governing research involving human subjects, including public health research, require that specific actions be taken to ensure the well-being of participants, such as the granting of informed consent by study participants and review of the study design by an institutional review board. Additional protections relevant to the privacy, security, and confidentiality of personally identifiable health information will be discussed in chapter 9.

As the court notes in *Grimes*, the history of public health is marred by notoriously unethical research. Should the Baltimore lead study now stand alongside the more infamous Tuskegee syphilis study (a forty-year study that left the syphilis infections of Black men in Alabama untreated to observe the "natural" progression of the disease, even though a cure for the debilitating and highly infectious disease was available) as a

cautionary tale for public health researchers, policymakers, and society at large? Or was the research in *Grimes* ethically and scientifically justified?

Several commentators criticized the social value of the Baltimore lead study, arguing that "what is needed in these situations is not more knowledge aimed at testing a 'feasible' but less costly intervention but the political will to transfer resources to supply a known effective treatment" (Buchanan and Miller 2006, 783). Do the ethical and legal constraints articulated by the court have implications for the ability of public health researchers to determine whether less-burdensome interventions (such as partial abatement of lead paint) might have benefits comparable to higher-cost interventions (such as full abatement)? If so, should ethicists and judges continue to demand an air-tight evidentiary justification for risk regulation that balances burdens on individual rights and financial costs against benefits to the community at large? We will return to these questions in the following chapters when we take up the issue of judicial review of government actions and the level of justification required by courts.

Tensions between science and values appear to be mounting. Popular books declare the "War on Science" (Otto 2016) and the "Death of Expertise" (Nichols 2017). President Trump has appointed government officials with close ties to industries that sow doubt regarding the scientific evidence that their products and practices are harmful. Evangelical Protestants, a group whose interests the Trump administration has appeared to prioritize in a somewhat uneasy political alliance, are widely perceived as being anti-science. At the annual March for Science, hundreds of thousands of people protest budget cuts to scientific agencies and censorship of scientific research while calling for evidence-based policy.

But the view that policymakers must choose between science and values is overly simplistic. Science has never been and will never be devoid of values. Value judgments inevitably shape scientific inquiry and policy responses to scientific findings. What are needed are fair and transparent processes for making policy determinations informed by science and based on values. Additionally, government action must be constrained by the fundamental rights of individuals, which are protected from majoritarian interference. In our legal system, these rights are enshrined in the Constitution, to which we turn in the next chapter.

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PART TWO

Legal Foundations of Public Health

PHOTO 3.1. A driver delivers supplies from a federal nutrition assistance program to a resident of Flint, Michigan, 2016. Flint residents were exposed to high lead levels for several months after a state-appointed manager switched the city's water supply to river water that corroded pipes, causing toxic lead to leach into the water. The Disaster Household Distribution Program of the Food and Nutrition Service of the United States Department of (USDA) distributed nutrient-targeted food packages, containing foods rich in calcium, iron, and Vitamin C to Flint residents. These nutrients may help reduce lead absorption. Photograph by Lance Cheung for USDA.

CHAPTER THREE

Public Health Duties and Powers

In Part Two of this reader, we ask three important questions about government intervention to promote the common good: (1) Does government have a duty to protect the public's health and safety? (2) What power does government have to protect the public's health and safety? (3) What are the limits on the exercise of public health powers? Limits on public health powers are derived from individual rights (a topic discussed in more detail in chapter 4) or from structural constraints that apply to particular government actors based on their jurisdictional level (state, federal, or local) or branch of government within that jurisdictional level (legislative, executive, judicial).

We begin this chapter with a case study on the Flint water crisis that will inform our discussion of public health powers and duties. Drawing on this case study, we discuss the primacy of negative rights in the U.S. Constitution. We then turn to structural constraints on government action based on the constitutional principle of federalism, which defines the boundaries between state and federal authority. In chapter 4, we turn to the topic of individual constitutional rights as limits on public health power. In chapter 5, we wrap up Part Two of the reader with a discussion of the particular structural constraints that apply to local governments and administrative agencies, which both exercise powers delegated by other government entities.

THE FLINT WATER CRISIS: A CASE STUDY ON PUBLIC HEALTH DUTIES AND POWERS

In 2014, Flint, Michigan, switched the city's water supply from Lake Huron to the Flint River. The river water was more corrosive than the lake water but the river water was not treated with anti-corrosive agents as required by federal law. Flint residents immediately reported concerns about the water coming from their taps. Within months, there was an outbreak of Legionella (a water-borne bacterial infection). The following year, a local pediatrician raised concerns about a spike in blood lead levels among Flint's children. Corrosive water from the river had caused lead and iron to leach from aging supply lines into the water, causing irreversible neurological damage to the city's children. Lead toxicity is associated with intellectual impairment and behavioral disorders, among other negative health effects. The impact of this public health failure will reverberate for decades to come.

As you read the excerpt that follows, consider the responsibility of governmental actors at the local, state, and federal level for the health of Flint residents. This case study also illustrates deeply entrenched problems of coordination among administrative agencies within the same level of government (e.g., state health and environmental agencies), the relationship between state and local governments, the difficulty of holding government officials accountable for common law torts, the public's trust, and environmental justice.

FLINT WATER ADVISORY TASK FORCE FINAL REPORT

Commissioned by the Office of Governor Rick Snyder, State of Michigan, March 2016

In April 2014, the City of Flint began treating Flint River water at the Flint [Water Treatment Plant (WTP)] on a full-time basis and distributing the treated water to its customers. A critical element of that treatment—corrosion control, as required under EPA's Lead and Copper Rule (LCR)—was (incorrectly) determined by [Michigan Department of Environmental Quality (MDEQ)] not to be required immediately; instead, Flint could complete two 6-month monitoring periods and MDEQ would then determine whether corrosion control was necessary. Soon after the City began distributing treated water from the Flint WTP, Flint residents began to complain about its odor, taste and appearance. . . . Ultimately, the corrosiveness of the drinking water leached lead from pipes and plumbing fixtures, and it may have increased the likelihood of water contamination with *Legionella*. . . .

ROLES OF GOVERNMENT ENTITIES IN THE FLINT WATER CRISIS

Many individuals, agencies and groups participated in the events leading to the Flint water crisis and the subsequent response. . . .

Michigan Department of Environmental Quality

MDEQ is responsible for enforcement of the [Safe Drinking Water Act (SDWA)] (including the Lead and Copper Rule [LCR]), the Clean Water Act (CWA) and other environmental regulations in the State of Michigan. . . . MDEQ advised Flint WTP staff, in contradiction to longstanding federal policy under the LCR, that corrosion control treatment was not required. MDEQ did not require appropriate sampling of tap water quality as mandated by the LCR. MDEQ obstinately used water quality test results based on flawed sampling and insisted on the accuracy of the erroneous data. MDEQ dismissed expressed concerns of Flint residents, elected officials, and external subject matter experts (as well as EPA). MDEQ inaccurately reported information about Flint's corrosion control to EPA, stating that Flint had an optimized corrosion control program when, in fact, it was not employing corrosion control treatment. . . . MDEQ insisted, even after compelling evidence of lead poisoning of children was presented, that Flint water quality met applicable SDWA standards. MDEQ failed (for more than a year) to work with [Michigan Department of Health and Human Services] leadership and staff to ensure an appropriate and comprehensive public health response to repeated requests to address health concerns related to drinking water. MDEQ continued to insist the water was safe and met all federal requirements, and discouraged any statements that would imply that the water was not safe. . . .

MDEQ caused this crisis to happen. Moreover, when confronted with evidence of its failures, MDEQ responded publicly through formal communications with a degree of intransigence and belligerence that has no place in government. These failures are not diminished, nor should focus on them be deflected, by the fact that other parties contributed to the disastrous decisions or the prolonging of their consequences. . . .

Michigan Department of Health and Human Services

The Michigan Department of Health and Human Services (MDHHS) is responsible for addressing all matters of public health for the population of the state. . . . MDHHS includes the Childhood Lead Poisoning Prevention Program (CLPPP), which is responsible for tracking the results of all children's blood lead tests. . . . The CLPPP operated under the assumption that children with elevated blood lead levels were being managed by their respective healthcare professionals. Therefore, no urgency was given to performing the comparisons that they published in annual reports, which were posted online without any public announcements. . . .

[After academic researchers documented that children's blood levels were clearly abnormal at a higher rate that in prior years,] MDHHS changed its approach and began to analyze blood lead level data in the CLPPP database on a basis closer to "real time." In a series of reports released approximately every 2 weeks since November 2015, MDHHS has communicated with the public regarding the proportion of children in Flint with blood lead tests ≠5 micrograms/deciliter. This is a promising step in transparency and timeliness. . . .

Despite the unmistakable connection between the quality of drinking water and public health, there is no liaison between MDEQ and MDHHS to ensure that complaints or concerns about water are brought to the attention of MDHHS staff in a timely fashion to prompt investigative action. . . .

Michigan Governor's Office

The Governor and the Governor's office must rely heavily on information from state departments to make decisions, set directions, and take action. In this case, the individuals and departments on which the Governor relied for guidance provided wrong information, particularly on the issues related to lead in the drinking water and elevated blood lead levels in children. . . .

As the Flint water crisis unfolded, certain state agencies' perceived need to defend the original decision to switch to the Flint River and resist a return to [obtaining water from Lake Huron] resulted in public relations and communications efforts that have, at times, been inappropriate. . . . Citizen concerns were at times derided and dismissed, in spite of the fact that various members of the Governor's staff had expressed—and were expressing—concerns about the water situation in Flint at the same time. . . .

State-appointed Emergency Managers

Owing to significant declines in economic vitality and substantial outmigration since (at least) the 1990s, Flint was first placed in financial receivership under an emergency "financial" manager between 2002 and 2004. Since 2011, the City has been under some form of state-ordered and controlled emergency financial management. . . . Numerous decisions were made between December 2011 and April 2015 that had some impact on the decision to use the Flint River as the primary source of drinking water for the City of Flint. Various state-appointed [Emergency Managers (EMs)] served during this timeframe and it was these EMs who made these decisions, *not locally elected officials.* Although it is true that some locally elected officials supported, acknowledged, embraced, and even celebrated some of the decisions, the decisions were not theirs to make. . . . In March 2015, [for example,] nearly one year after the source water conversion, [EM] Jerry Ambrose stated that a reconnection to [Lake Huron] would cost the City $10.1 million per year and that water purchases could be as high as $1 million per month—essentially asserting that it was unaffordable. . . .

City of Flint

City of Flint Public Works executive leadership and staff were immediately responsible for treating Flint River water and for monitoring water quality in the distribution system. SDWA compliance is the obligation of the public water supplier, and it is [in] their hands that public trust is placed. . . . The City relied on Flint Utilities Department staff's limited experience, consultant advice, and most substantially MDEQ for technical support. In this respect, Flint was similar to many communities in Michigan that rely on MDEQ for technical assistance and advice on regulatory compliance requirements. However, in Flint, that reliance was tragically misplaced. . . . Flint WTP supervisory personnel expressed concerns regarding readiness . . . —including appropriate LCR-mandated sampling—and these concerns went unheeded. . . . [I]t seems clear that these concerns were voiced in an environment that was unreceptive to reconsideration of the City's chosen course, mandated by its EMs. . . .

Genesee County Health Department

As a local health department, the Genesee County Health Department (GCHD) is responsible for all government public health functions for residents in their jurisdic-

tion, including the City of Flint. Like the vast majority of cities in Michigan, Flint does not have its own public health officials and instead relies on its county health department (GCHD) to perform public health functions.

GCHD must coordinate and communicate effectively with city officials and the public. Specific to the Flint water crisis, GCHD responsibilities include investigating outbreaks of reportable diseases such as Legionellosis and conducting timely in-home assessments of potential sources of lead exposure for children found to have elevated blood lead levels.

Importantly, the functions of local health departments also include cooperative coordination with state public health authorities ([the Michigan Department of Health and Human Services] [MDHHS]), and in turn with federal public health authorities (for example, Centers for Disease Control and Prevention [CDC]) as needed. The expectation is that local health departments manage issues that arise in their jurisdictions. State public health authorities become involved at the request of local authorities and/or when events such as an outbreak involve more than one jurisdiction (that is, more than one local health department). In turn, MDHHS requests help from the CDC as needed. This local-to-state-to-federal sequence is designed to facilitate communication, coordination, and follow-up among officials at multiple levels of authority, and it requires mutual trust, collaboration and effective communications across agencies. . . .

Since the switch to the Flint River, a higher proportion of children in Flint have had elevated lead levels that would prompt in-home assessments [by GCHD]. . . . As of late January 2016, only about one-fifth of children known to have had elevated blood lead levels in Flint since April 2014 had received in-home environmental assessments (including water testing).

After the switch to the Flint River in 2014, the Flint Utilities Department began flushing water mains citywide to address brown-colored water resulting from corrosion of pipes in the distribution system. Many fire hydrants ran for days, which may have disrupted the "biofilm," a slime coating (which is distinct from the scaling provided by corrosion control treatment) on the inside surface of the water mains and water service lines. When the biofilm was disrupted, *Legionella* and other bacteria may have been released. In addition, EPA experts . . . believe that corroding pipes likely absorbed chlorine in the water, leading to extremely low chlorine levels that were insufficient to kill *Legionella* in the water. . . . In Flint, neither the Flint EM nor his appointed City Administrator, GCHD, or MDHHS fully disclosed the Legionellosis outbreak to local medical professionals or the general public. Moreover, this outbreak, *which is always associated with water supplies,* was not communicated by MDEQ with sufficient urgency to the Governor's office. . . .

U.S. Environmental Protection Agency Oversight and the Lead and Copper Rule

EPA['s regional office] was first notified of a potential problem in Flint by resident LeeAnne Walters, who called to inform them of the high lead level . . . found in her drinking water. In early 2015, EPA's Miguel Del Toral worked with Walters to diagnose water quality problems at her residence. During this time, EPA inquired (repeatedly) about [corrosion control treatment (CCT)] at the Flint WTP, advised MDEQ that the LCR unambiguously requires CCT, and were told incorrectly that Flint had an optimized corrosion control program. . . . Ultimately, it required LeeAnne Walters's inquiry of Flint Utilities Department personnel for EPA to learn that Flint did not have CCT in place. It

took 2 months from EPA's first inquiry for MDEQ to acknowledge that Flint was not implementing CCT. . . .

EPA did not cause the problem in Flint, and it was EPA employees (in particular Del Toral) who asserted the need for Flint to have CCT in place. Unfortunately, EPA was not insistent or forceful enough to prompt MDEQ to require Flint to add CCT for almost 3 months after EPA was aware of its absence. This needlessly extended the time during which Flint residents were exposed to corrosive drinking water with potentially high levels of lead. . . .

ISSUES PRESENTED BY THE FLINT WATER CRISIS

While our review has enabled us to draw a number of findings and conclusions about respective roles, it also occasions us to speak to issues and consequences that transcend the accountabilities assigned to individual agencies or entities. These issues . . . speak to the opportunities for the crisis to improve the conduct and performance of government.

The Reality of Environmental Injustice

Environmental justice embraces two fundamental principles: (1) the fair, non-discriminatory treatment of all people; and (2) the provision for meaningful public involvement of all people—regardless of race, color, national origin or income—in government decision-making regarding environmental laws, regulations and polices. Environmental justice or injustice, therefore, is not about intent. Rather, it is about process and results—fair treatment, equal protection, and meaningful participation in neutral forums that honor human dignity. . . . Environmental injustices [can] occur when parties charged with the responsibility to protect public health fail to do so. . . .

The facts of the Flint water crisis lead us to the inescapable conclusion that this is a case of environmental injustice. Flint residents, who are majority Black or African American and among the most impoverished of any metropolitan area in the United States, did not enjoy the same degree of protection from environmental and health hazards as that provided to other communities. Moreover, by virtue of their being subject to emergency management, Flint residents were not provided equal access to, and meaningful involvement in, the government decision-making process. . . .

PERSPECTIVES FROM FLINT

The Flint water crisis is a chronic toxic exposure of an entire population in a sharply demarcated geographic area. Several key aspects point to the long-term health and social consequences. . . . Documented risks of learning, behavioral, and cognitive problems are present for all potentially exposed children in Flint. Aggressive and impulsive behaviors that can emerge in adolescence related to lead exposure put children in the crosshairs of the criminal justice system, unemployment and underachievement. The risk of kidney problems, hypertension, gout and stillbirths may affect exposed adults in Flint over the coming years and decades.

For those serving in Flint's already distressed schools and mental health agencies, new and unprecedented challenges derive from balancing the need to track children and adults in a toxic exposure registry for preventative and supportive services, while being mindful of the stigma of low expectations for those listed in the registry.

For well-intentioned parents, there is a need for significant sensitivity and expertise as they struggle to address and understand the guilt and depression that derive from unknowingly exposing their children, based on the hollow reassurances of those appointed and elected at city and state levels that the water was safe.

For non-English-speaking Flint residents, equally subject to the toxic effects of lead and related psychological trauma, communications and instructions regarding water use were not available, especially for those not literate in their native language. The sight of uniformed state troopers and National Guardsmen entering neighborhoods in convoys with flashing lights frightened many who did not open their doors to accept filter or water distributions. Initial requirements for identification scared many families away from distribution sites. There has been no provision for necessary medical and behavioral services for undocumented residents, regardless of age. There is fear that those presenting for extensive medical services will be deported, potentially dividing families. While there are several organizations that provide services regardless of status, it is essential that trusted members of the community can vouch for those organizations and help with appropriate documents which are unfamiliar to local service providers.

Among African American seniors, the protracted Flint water crisis echoes the tragic Tuskegee syphilis study and the decision not to treat smallpox among freedmen in the aftermath of the American Civil War. From this perspective, it is noted that measuring blood lead levels without removing the sources of lead from the environment—in this case, lead-tainted water—appears the equivalent of using Flint's children (and adults) as human bioassays.

From the perspective of Flint community leaders, these consequences are traumatic and contribute to a dynamic that requires care and interventions as for any survivors of a traumatic event. These interventions must occur for individuals, neighborhoods and the community.

Leaders must work to counter the doubtful views of many residents that public health and political systems do not have the will to sustain primary prevention but, rather, are willing to consign some people by virtue of their home address to the long-lasting neurodevelopmental and health impacts of lead exposure. Flint will have to engage in self-care and healing as it dissects the implications of what has occurred and is reminded of how much further we must go to become a just society.

• • •

Most commentators agree that it will be difficult to hold government officials legally accountable for the harm that's been done to Flint's children. Federal prosecutors brought criminal charges against state officials. The Michigan attorney general brought criminal charges accusing Flint's Emergency Managers with misconduct in office, willful neglect of duties, and other charges. The state also brought criminal charges against several current and former state and local officials, including the Michigan Health and Human Services Director and the Michigan Chief Medical Executive, who were charged with involuntary manslaughter and misconduct in office. These charges focus on the outbreak of Legionnaire's

disease in Genesee County, which killed twelve people in 2014 and 2015. Prosecutors face many challenges, including the difficulty of proving that government officials engaged in willful and knowing misconduct.

Families who drank contaminated water filed suit to hold the state and local governments (as well as government officials in their personal capacity) responsible for monetary damages. These suits relied on violations of individual constitutional rights and common law tort claims (discussed in chapter 7). In 2018, the U.S. Supreme Court declined to review a federal circuit court's decision to allow two class action suits by Flint residents to proceed in spite of the defendants' argument that the suits were preempted by a federal statute governing safe drinking water, *Boler v. Earley*, 865 F.3d 391 (6th Cir. 2017). Although these suits have survived an initial hurdle, they continue to face an uphill battle. The U.S. legal system is, in a variety of ways, hostile to private actors seeking to hold the government accountable for the public's health. Lawsuits by private parties to vindicate Flint residents' constitutional rights under the Fourteenth Amendment are likely to fail if courts characterize the alleged government failures as nonfeasance, rather than misfeasance. Judges may find common law tort claims to be preempted by federal regulations. Private claims based on violations of federal statutes may be barred by the doctrine of sovereign immunity, derived from the Eleventh Amendment's protection of state sovereignty. Although government actors at the state, local, and federal levels all had authority—and nominal responsibility—for protecting the health of Flint residents, translating that power and duty into legal accountability is difficult.

Notably, the Legionnaire's deaths and the increase in blood lead levels in Flint from 2014 to 2016 are attributable to the discrete acts (and failures to act) of identifiable parties, many of which were contrary to established law (e.g., failure to adopt corrosion control and implement testing protocols required by the Lead and Copper Rule). In contrast, the underlying public health problems facing the people of Flint—high rates of infant mortality, diabetes, depression, and other chronic conditions—are more difficult to trace to specific policy choices. It will be challenging to hold officials legally accountable for the identifiable instances of negligence, recklessness, and fraud that led to the Flint water crisis. It is virtually impossible to hold them legally accountable for the devastating public health consequences of their chronic disregard for the lives of people living in poverty in Flint and elsewhere across the country.

THE NEGATIVE CONSTITUTION

Political theorists often distinguish positive rights (such as the right to clean water or the right to be protected by environmental regulations) from negative rights (such as the right to speak freely or hold private property without government interference). Whereas positive rights obligate government to take affirmative steps to protect the populace from the actions of others (e.g., by regulating private conduct that poses a health or safety risk) and fulfill the rights of the populace (e.g., by ensuring universal access to health care and essential public health services), negative rights require only that the government respect the rights of the people by refraining from interfering with them. Of course, in many respects, the distinction between positive and negative rights is unclear. There are many negative rights that require affirmative government action. Consider the right to due process—a negative right firmly entrenched in the Constitution. To ensure due process the government must provide a system of fair trials including courts, judges, and legal representation for the poor.

The U.S. Constitution is widely regarded as a negative constitution. It secures individual liberties against interference by government and mandates equal treatment of individuals by government. In either case—civil liberties or civil rights—the element of *state action* must be present for a court to find a constitutional violation. A government ("state" in this parlance does not refer to a specific jurisdictional level) actor must have done something to interfere with the rights of the individuals.

In the cases that follow, private parties sought to hold government officials accountable for failing to protect them from violence. In both cases, the claimants used a federal statute known as Section 1983 as a vehicle for bringing suit in federal court for alleged violations of their constitutional rights. Both point to the Due Process Clause of the Constitution, which holds that no state "shall deprive any person of life, liberty, or property without due process of law" (Amdt. 14, §1). In *Deshaney v. Winnebago Co. Dept. of Social Svs.*, the plaintiff argued that county officials' failure to protect him from his abusive father violated his right to liberty (a substantive due process claim). In *Castle Rock v. Gonzales,* the plaintiff argued that the failure of the town of Castle Rock, Colorado, to enforce a restraining order against her violent husband amounted to deprivation of her property interest in the order without sufficient procedural protections (a procedural due process claim).

The doctrines of substantive and procedural due process will be addressed in chapter 4. For now, our focus is on the narrow circumstances in which the Supreme Court recognizes governmental obligations to act. Aside from legalistic interpretations of the text of the Constitution, are there practical reasons why the Court might decline to recognize and adjudicate broader governmental obligations to protect the health and safety of the populace? Might one articulate a principled distinction between obligations owed to the populace as a whole and those owed to (and enforceable by) harmed individuals?

*DESHANEY V. WINNEBAGO COUNTY DEPARTMENT OF SOCIAL SERVICES**

Supreme Court of the United States
Decided February 22, 1989

Chief Justice Rehnquist delivered the opinion of the Court.

. . . The facts of this case are undeniably tragic. Petitioner Joshua DeShaney was born in 1979. In 1980, a Wyoming court granted his parents a divorce and awarded custody of Joshua to his father, Randy DeShaney. . . . The Winnebago County authorities first learned that Joshua DeShaney might be a victim of child abuse in January 1982, when his father's second wife complained to the police, at the time of their divorce, that he had previously "hit the boy causing marks and [was] a prime case for child abuse." The Winnebago County Department of Social Services (DSS) interviewed the father, but he denied the accusations, and DSS did not pursue them further. In January 1983, Joshua was admitted to a local hospital with multiple bruises and abrasions. The examining physician suspected child abuse and notified DSS, which immediately obtained an order from a Wisconsin juvenile court placing Joshua in the temporary custody of the hospital. [Upon further consideration, a county-convened Child Protection Team] decided that there was insufficient evidence of child abuse to retain Joshua in the custody of the court. The Team did, however, decide to recommend several measures to protect Joshua, including enrolling him in a preschool program, providing his father with certain counselling services, and encouraging his father's girlfriend to move out of the home. Randy DeShaney entered into a voluntary agreement with DSS in which he promised to cooperate with them in accomplishing these goals. . . .

A month later, emergency room personnel called the DSS caseworker handling Joshua's case to report that he had once again been treated for suspicious injuries. The caseworker concluded that there was no basis for action. For the next six months, the caseworker made monthly visits to the DeShaney home, during which she observed a number of suspicious injuries on Joshua's head; she also noticed that he had not been enrolled in school, and that the girlfriend had not moved out. The caseworker

* 489 U.S. 189.

dutifully recorded these incidents in her files, along with her continuing suspicions that someone in the DeShaney household was physically abusing Joshua, but she did nothing more. In November 1983, the emergency room notified DSS that Joshua had been treated once again for injuries that they believed to be caused by child abuse. On the caseworker's next two visits to the DeShaney home, she was told that Joshua was too ill to see her. Still DSS took no action.

In March 1984, Randy DeShaney beat 4-year-old Joshua so severely that he fell into a life-threatening coma. Emergency brain surgery revealed a series of hemorrhages caused by traumatic injuries to the head inflicted over a long period of time. Joshua did not die, but he suffered brain damage so severe that he is expected to spend the rest of his life confined to an institution for the profoundly retarded. Randy DeShaney was subsequently tried and convicted of child abuse.

Joshua and his mother brought this action under 42 U.S.C. § 1983 . . . against respondents Winnebago County, DSS, and various individual employees of DSS. The complaint alleged that respondents had deprived Joshua of his liberty without due process of law, in violation of his rights under the Fourteenth Amendment, by failing to intervene to protect him against a risk of violence at his father's hands of which they knew or should have known. The Due Process Clause of the Fourteenth Amendment provides that "[n]o State shall . . . deprive any person of life, liberty, or property, without due process of law." Petitioners contend that the State deprived Joshua of his liberty interest in "free[dom] from . . . unjustified intrusions on personal security," by failing to provide him with adequate protection against his father's violence. The claim is one invoking the substantive rather than the procedural component of the Due Process Clause; petitioners do not claim that the State denied Joshua protection without according him appropriate procedural safeguards, but that it was categorically obligated to protect him in these circumstances.

But nothing in the language of the Due Process Clause itself requires the State to protect the life, liberty, and property of its citizens against invasion by private actors. The Clause is phrased as a limitation on the State's power to act, not as a guarantee of certain minimal levels of safety and security. It forbids the State itself to deprive individuals of life, liberty, or property without "due process of law," but its language cannot fairly be extended to impose an affirmative obligation on the State to ensure that those interests do not come to harm through other means. Nor does history support such an expansive reading of the constitutional text. Like its counterpart in the Fifth Amendment, the Due Process Clause of the Fourteenth Amendment was intended to prevent government "from abusing [its] power, or employing it as an instrument of oppression." Its purpose was to protect the people from the State, not to ensure that the State protected them from each other. The Framers were content to leave the extent of governmental obligation in the latter area to the democratic political processes.

Consistent with these principles, our cases have recognized that the Due Process Clauses generally confer no affirmative right to governmental aid, even where such aid may be necessary to secure life, liberty, or property interests of which the government itself may not deprive the individual. . . . As we said in *Harris* v. *McRae:* "Although the liberty protected by the Due Process Clause affords protection against unwarranted *government* interference. . ., it does not confer an entitlement to such [governmental aid] as may be necessary to realize all the advantages of that freedom." 448 U.S. 297,

317–318 (1980). If the Due Process Clause does not require the State to provide its citizens with particular protective services, it follows that the State cannot be held liable under the Clause for injuries that could have been averted had it chosen to provide them. As a general matter, then, we conclude that a State's failure to protect an individual against private violence simply does not constitute a violation of the Due Process Clause. . . .

Judges and lawyers, like other humans, are moved by natural sympathy in a case like this to find a way for Joshua and his mother to receive adequate compensation for the grievous harm inflicted upon them. But before yielding to that impulse, it is well to remember once again that the harm was inflicted not by the State of Wisconsin, but by Joshua's father. The most that can be said of the state functionaries in this case is that they stood by and did nothing when suspicious circumstances dictated a more active role for them. In defense of them it must also be said that had they moved too soon to take custody of the son away from the father, they would likely have been met with charges of improperly intruding into the parent-child relationship, charges based on the same Due Process Clause that forms the basis for the present charge of failure to provide adequate protection.

The people of Wisconsin may well prefer a system of liability which would place upon the State and its officials the responsibility for failure to act in situations such as the present one. They may create such a system, if they do not have it already, by changing the tort law of the State in accordance with the regular lawmaking process. But they should not have it thrust upon them by this Court's expansion of the Due Process Clause of the Fourteenth Amendment.

Justice Brennan, with whom Justice Marshall and Justice Blackmun join, dissenting.

. . . The Court's baseline is the absence of positive rights in the Constitution and a concomitant suspicion of any claim that seems to depend on such rights. . . . I would begin from the opposite direction. I would focus first on the action that Wisconsin *has* taken with respect to Joshua and children like him, rather than on the actions that the State failed to take. . . .

Wisconsin has established a child-welfare system specifically designed to help children like Joshua. Wisconsin law places upon the local departments of social services . . . a duty to investigate reported instances of child abuse. While other governmental bodies and private persons are largely responsible for the reporting of possible cases of child abuse, Wisconsin law channels all such reports to the local departments of social services for evaluation and, if necessary, further action. . . .

Through its child-welfare program, . . . the State of Wisconsin has relieved ordinary citizens and governmental bodies other than the Department of any sense of obligation to do anything more than report their suspicions of child abuse to DSS. If DSS ignores or dismisses these suspicions, no one will step in to fill the gap. Wisconsin's child-protection program thus effectively confined Joshua DeShaney within the walls of Randy DeShaney's violent home until such time as DSS took action to remove him. Conceivably, then, children like Joshua are made worse off by the existence of this program when the persons and entities charged with carrying it out fail to do their jobs. . . .

As the Court today reminds us, "the Due Process Clause of the Fourteenth Amendment was intended to prevent government from abusing [its] power, or employing it as

an instrument of oppression." My disagreement with the Court arises from its failure to see that inaction can be every bit as abusive of power as action, that oppression can result when a State undertakes a vital duty and then ignores it. . . .

CASTLE ROCK V. GONZALES*

Supreme Court of the United States
Decided June 27, 2005

Justice Scalia delivered the opinion of the Court.

. . . Jessica Gonzales . . . alleges that petitioner, the town of Castle Rock, Colorado, violated the Due Process Clause of the Fourteenth Amendment to the United States Constitution when its police officers, acting pursuant to official policy or custom, failed to respond properly to her repeated reports that her estranged husband was violating the terms of a restraining order.

The restraining order had been issued by a state trial court several weeks earlier in conjunction with respondent's divorce proceedings. . . . [It] commanded him not to "molest or disturb the peace of [respondent] or of any child," and to remain at least 100 yards from the family home at all times. . . . According to the complaint, at about 5 or 5:30 p.m. on Tuesday, June 22, 1999, respondent's husband took the three daughters while they were playing outside the family home. . . . At about 7:30 p.m., [respondent] called the Castle Rock Police Department, which dispatched two officers. [She showed them a copy of the TRO, but they said there was nothing they could do and suggested that she call again if the children did not return by 10 p.m.] At approximately 8:30 p.m., respondent talked to her husband on his cellular telephone. [He told her where he and the children were located, she called the police and asked them to have someone check for them there, but the officer refused to do so, telling her to wait until 10 p.m.] At approximately 10:10 p.m., respondent called the police and said her children were still missing, but she was now told to wait until midnight. She called at midnight and told the dispatcher her children were still missing. She went to her husband's apartment and, finding nobody there, called the police at 12:10 a.m.; she was told to wait for an officer to arrive. When none came, she went to the police station at 12:50 a.m. and submitted an incident report. The officer who took the report "made no reasonable effort to enforce the TRO or locate the three children. Instead, he went to dinner." . . . At approximately 3:20 a.m., respondent's husband arrived at the police station and opened fire with a semiautomatic handgun he had purchased earlier that evening. Police shot back, killing him. Inside the cab of his pickup truck, they found the bodies of all three daughters, whom he had already murdered. . . .

Respondent claims the benefit of [the procedural component of the Due Process Clause] on the ground that she had a property interest in police enforcement of the restraining order against her husband; and that the town deprived her of this property without due process by having a policy that tolerated nonenforcement of restraining orders. . . . [I]n *DeShaney* v. *Winnebago County Dep't of Social Servs.*, . . . [w]e held that the so-called "substantive" component of the Due Process Clause does not "requir[e]

* 545 U.S. 748.

the State to protect the life, liberty, and property of its citizens against invasion by private actors." We noted, however, that the petitioner had not properly preserved the argument that—and we thus "decline[d] to consider" whether—state "child protection statutes gave [him] an 'entitlement' to receive protective services in accordance with the terms of the statute, an entitlement which would enjoy due process protection." . . .

"To have a property interest in a benefit, a person clearly must have more than an abstract need or desire" and "more than a unilateral expectation of it. He must, instead, have a legitimate claim of entitlement to it." Such entitlements are, of course, not created by the Constitution. Rather, they are created and their dimensions are defined by existing rules or understandings that stem from an independent source such as state law. Our cases recognize that a benefit is not a protected entitlement if government officials may grant or deny it in their discretion. . . .

The ultimate issue [is] whether what Colorado law has given respondent constitutes a property interest for purposes of the Fourteenth Amendment. . . . We do not believe that [the relevant] provisions of Colorado law truly made enforcement of restraining orders *mandatory.* A well established tradition of police discretion has long coexisted with apparently mandatory arrest statutes. . . . Against that backdrop, a true mandate of police action would require some stronger indication from the Colorado Legislature than [the statement in the relevant statute that police officers] "shall use every reasonable means to enforce a restraining order" (or even "shall arrest . . . or . . . seek a warrant"). . . .

We conclude that [the Colorado TRO law does not create an] entitlement. . . . Even if we were to think otherwise. . ., it is by no means clear that an individual entitlement to enforcement of a restraining order could constitute a "property" interest for purposes of the Due Process Clause. Such a right would not, of course, resemble any traditional conception of property. . . . We conclude, therefore, that respondent did not, for purposes of the Due Process Clause, have a property interest in police enforcement of the restraining order against her husband. . . .

In light of today's decision and that in *DeShaney,* the benefit that a third party may receive from having someone else arrested for a crime generally does not trigger protections under the Due Process Clause, neither in its procedural nor in its "substantive" manifestations. . . .

Justice Stevens, with whom Justice Ginsberg joins, dissenting.

In this case, Colorado law *guaranteed* the provision of a certain service, in certain defined circumstances, to a certain class of beneficiaries, and respondent reasonably relied on that guarantee. . . . Because respondent had a property interest in the enforcement of the restraining order, state officials could not deprive her of that interest without observing fair procedures. . . .

• • •

The dissenting Justices in *Deshaney* and *Castle Rock* highlight the arbitrariness of drawing a line between affirmative acts for which the government is responsible (misfeasance) and failures for which it is not (nonfeasance). Was Joshua Deshaney's devastating injury a result of the County's failure to intervene or its affirmative acts in establishing a

social services program that discouraged others from intervening? Were the deaths of Jessica Gonzales's daughters—aged seven, eight, and 10—a result of police officers' failure to act or the affirmative establishment of a process for obtaining and enforcing a restraining order? An investigation revealed that Simon Gonzales was able to purchase a semiautomatic handgun shortly after abducting the children. He passed a federal background check because the restraining order was not properly registered in the system. Was that error an act or an omission?

Many commentators have noted the extent to which accountability for government misfeasance and nonfeasance is inextricably intertwined in notions of good governance. Some argue that the Supreme Court's cramped characterization of the Constitution was far from inevitable, noting that the historical context of the Constitution could be read to support rights to basic human needs such as housing, education, and health care (Sunstein 2005, Amar 1990). In spite of these arguments, the negative Constitution is now firmly rooted in U.S. jurisprudence. Because of precedents like *Deshaney* and *Castle Rock*, the Flint plaintiffs' due process claims are unlikely to be successful.

The dominant understanding of the U.S. Constitution as guaranteeing only negative rights (rights to be left alone by government) stands in contrast to the vision of positive rights to health and the basic necessities of life (rights to protection from the acts of third parties and fulfillment of needs by government) articulated in several international instruments and national constitutions. The United States is not a party to international treaties recognizing health as a human right. Nonetheless, General Comment 14, in which the United Nations Committee on Economic, Social, and Cultural Rights describes the multifaceted nature of governmental obligations inherent in the right to health, provides a useful framework for assessing government action and inaction as a social determinant of health. In the words of the Committee,

> The right to health, like all human rights, imposes three types or levels of obligations on States parties: the obligations to *respect, protect* and *fulfill*. . . . The obligation to *respect* requires States to refrain from interfering directly or indirectly with the enjoyment of the right to health. The obligation to *protect* requires States to take measures that prevent third parties from interfering with [the right to health]. Finally, the obligation to *fulfill* requires States to adopt appropriate legislative, administrative, budgetary, judicial, promotional and other measures towards the full realization of the right to health. . . .

The Committee offers several examples of how each type of obligation might be violated by a government:

> Examples [of violations of the obligation to respect] include the denial of access to health facilities, goods and services to particular individuals or groups as a result of de jure or de facto discrimination; the deliberate withholding or misrepresentation of information vital to health protection or treatment; [and] the adoption of laws or policies that interfere with the enjoyment of any of the components of the right to health. . . .
>
> Violations of the obligation to protect [include] the failure to protect consumers and workers from practices detrimental to health, e.g. by employers and manufacturers of medicines or food; the failure to discourage production, marketing and consumption of tobacco, narcotics and other harmful substances; the failure to protect women against violence or to prosecute perpetrators; . . . and the failure to enact or enforce laws to prevent the pollution of water, air and soil by extractive and manufacturing industries. . . .
>
> Examples [of violations of the obligation to fulfill] include . . . insufficient expenditure or misallocation of public resources which results in the nonenjoyment of the right to health by individuals or groups, particularly the vulnerable or marginalized; . . . the failure to take measures to reduce the inequitable distribution of health facilities, goods and services; . . . and the failure to reduce infant and maternal mortality rates.

In this terminology, Joshua Deshaney's catastrophic injuries, the murder of Jessica Gonzales's three young daughters, the Flint water crisis, and the underlying public health problems faced by residents of Flint and other people living in poverty across the country can be described as a result of multiple failures to respect, protect, and fulfill the right to health. Would a constitutional right to health of the sort recognized by most countries in the world make it easier to hold government officials accountable for health of the population? International and domestic tribunals have sometimes found the justiciability of the right to health—that is, its enforceability through claims brought by individuals against the government in court—to be limited. Nonetheless, do other benefits flow from explicit recognition of the right to health in the foundational texts of government?

We will return to due process—both procedural and substantive—in chapter 4's discussion of individual rights as constraints on public health powers. Now, we move on to a discussion of the Constitution's allocation of powers between federal and state governments and associated structural constraints on public health interventions.

THE POLICE POWER EXERCISED BY STATE GOVERNMENTS

In addition to recognizing various individual rights as constraints on government action, the Constitution provides the framework for

distribution of governmental power across jurisdictional levels (federal, state, local) and branches of government (legislative, executive, judicial).

One of the primary challenges faced by the drafters of the Constitution was to divide powers between the state and federal governments. The state governments—founded as colonies of the British crown—predated the formation of the union. Many feared a centralized national government would pose a threat to individual liberty. On the other hand, the country's experience with a weak national government under the Articles of Confederation demonstrated the necessity of a federal executive (the president), courts, the power to collect taxes, and other powers to address matters of national concern.

The resulting compromise recognizes states' plenary power to safeguard and promote the welfare of the general public (subject to the limits imposed by individual rights, as discussed in chapter 4) and the federal government's limited power to act pursuant to specific powers enumerated in the Constitution. When a state legislature acts, it need not point to any particular source of authority to do so. The Constitution recognizes this authority in the Tenth Amendment, which reserves those powers not granted to the federal government to the states or to the people. In contrast, the federal legislature (Congress) must confine its actions within the powers granted to it in the Constitution. Before turning to the enumerated powers of the federal government, we discuss the police power enjoyed by states (and often delegated by the states to local governments, as discussed in chapter 5).

In the treatise accompanying this reader, we define the police power as "the inherent authority of the state (and through delegation, local government) to enact laws and promulgate regulations to protect, preserve, and promote the health, safety, morals, and general welfare of the people. To achieve these communal benefits, the state retains the power to restrict, within federal and state constitutional limits, private interests—personal interests in autonomy, privacy, association, and liberty as well as economic interests in freedom to contract and uses of property" (Gostin and Wiley 2016, 87–88).

The police power is the foundation of virtually all public health intervention. Consequently, states and local governments have primary responsibility for the public's health. As William Novak demonstrates, state and local governments have a long history of using the police power to adopt a plethora of regulations of private conduct to ensure communities and individuals flourish. Novak's description of a well-regulated society, dating back to the early years of the Republic, stands

in contrast to the myths of limited government and individualism central to American culture and national identity.

GOVERNANCE, POLICE, AND AMERICAN LIBERAL MYTHOLOGY*

William J. Novak

A distinctive and powerful governmental tradition devoted in theory and practice to the vision of a well-regulated society dominated United States social and economic policymaking from 1787 to 1877. . . . At the heart of the well-regulated society was a plethora of bylaws, ordinances, statutes, and common law restrictions regulating nearly every aspect of early American economy and society, from Sunday observance to the carting of offal. These laws . . . explode tenacious myths about nineteenth-century government (or its absence) and demonstrate the pervasiveness of regulation in early American versions of the good society: regulations for *public safety* and security (protecting the very existence of the population from catastrophic enemies like fire and invasion); the construction of a *public economy* (determining the rules by which the people would acquire and exchange food and public squares); all-important restraints on *public morals* (establishing the social and cultural conditions of public order); and the open-ended regulatory powers granted to public officials to guarantee *public health* (securing the population's well-being, longevity, and productivity). Public regulation—the power of the state to restrict individual liberty and property for the common welfare—colored all facets of early American development. It was the central component of a reigning theory and practice of governance committed to the pursuit of the people's welfare and happiness in well-ordered society and polity. . . .

[There are] four interrelated and surprisingly resilient myths about nineteenth-century America challenged by this [essay]: the myth of statelessness, the myth of liberal individualism, the myth of the great transformation, and the myth of American exceptionalism. . . . Cousin to the most notorious fallacy in American historiography, the laissez-faire thesis, the myth of statelessness holds that the essence of nineteenth-century government was its absence. America was essentially born free, without elaborate bureaucratic, governmental, or political philosophical traditions. . . . The cultural and ideological complement to the myth of statelessness is the myth of liberal individualism. . . . American liberalism has been defined narrowly with primary emphasis on its possessive, transactional, self-interested, and individualistic attributes. . . . Along with national myths about culture and institutions come fictions about time and sequence. One of the most powerful in Western history is the [myth of the great transformation:] the notion of a deep rupture separating modernity from its past. . . . [H]istorians contend that 1776 marked the beginning of a new positivistic and instrumental legal order, where ancient notions like natural law, oracular styles of judging, and community justice were jettisoned to force a fungible and useful legality suited to a modernizing, capitalist society. . . . Finally, all these myths about the opening of Amer-

ican society, the victory of individual rights, and the arrival of economic and market freedom are part of a general [myth of American exceptionalism] that pervades histories of the early nineteenth century. . . .

Together these four organizing myths constitute a master narrative of American political development in which liberty *against* government serves as the fulcrum of a constant and distinctively American liberal-constitutional tradition. The reigning paradigms of American politics (self-interested liberalism), law (constitutionalism), and economics (neoclassical market theory) conspire with this mythic historiography to produce a gross overemphasis on individual rights, constitutional limitations, and the invisible hand; and a terminal neglect of the positive activities and public responsibilities of American government over time. . . .

The well-regulated society confronts the myths of statelessness, individualism, transformation, and exceptionalism with four distinguishing principles of positive governance: public spirit, local self-government, civil liberty, and law. While very much at odds with modern conceptions of the sovereign state and the rights-bearing individual, these principles were the heart of the nineteenth-century vision of a well-regulated society. . . .

PUBLIC SPIRIT

[T]he influential common law maxim *salus populi suprema lex est* (the welfare of the people is the supreme law) [was] one of the fundamental ordering principles of the early American polity. Nineteenth-century America was a *public* society in ways hard to imagine after the invention of twentieth-century privacy. Its governance was predicated on the elemental assumption that public interest was superior to private interest. Government and society were not created to protect preexisting private rights, but to further the welfare of the whole people and community. . . .

LOCAL SELF-GOVERNMENT

[N]ineteenth-century American governance remained decidedly local. . . . Though its antidespotic thrust is often mistaken for liberal individualism, local self-government conceived of liberty and autonomy as collective attributes—badges of participation, things achieved in common through social and political interaction with others. The independent lawmaking authority of local communities . . . was to be defended from usurpation by despots, courtly mandarins, or other central powers. But within communities, individuals were expected to conform their behavior to local rules and expectation. No community was deemed free without the power and right of members to govern themselves, *that is,* to determine the rules under which the locality as a whole would be organized and regulated. Such open-ended local regulatory power was simply a necessary attribute of any truly popular sovereignty. . . .

CIVIL LIBERTY

Integral to local self-government was a unique conception of civil or regulated liberty. . . . Such liberty was never absolute, it always had to conform to the superior power of self-governing communities to legislate and regulate in the public interest. From time immemorial, as the common law saying went, this liberty was subject to local bylaws for the promotion and maintenance of community order, comfort, safety,

health, and well-being. Freedom and regulation in this tradition were not viewed as antithetical but as complementary and mutually reinforcing. . . .

LAW

By definition, any history of early American government must also be a legal history. . . . As Thomas Paine noted, "in America the law is king." . . . The nineteenth century was not simply an age of private contract and public constitutional limitations. It was an epoch in which strong common law notions of public prerogatives and the duties and obligations of government persisted amid a torrent of private adjudication and constitution writing. The rule of law, a distinctly public and social ideal, . . . dominated most thinking about governance in the nineteenth century. . . .

Public spirit, local self-government, civil liberty, and common law were part of a worldview decidedly different from our own and from the one we have imposed on an unsuspecting past. Their reference point was the relationship of a citizen to a republic rather than an individual subject to a sovereign nation-state. . . . In particular, the four principles outlined here found clearest expression in countless nineteenth-century exertions of what is known in legal parlance as a *state police power*. . . .

[Definitions proposed by early-twentieth-century scholars] cover three essential components of police power: law, regulations, and people's welfare. Police power was the ability of a state or locality to enact and enforce public laws regulating or even destroying private right, interest, liberty, or property for the common good (i.e., for the public safety, comfort, welfare, morals, or health). Such broad compass has led some to conclude that state police power was the essence of governance, the hallmark of sovereignty and statecraft. . . .

[H]istorians have successfully deconstructed the American myth of equality. Countless histories . . . have demonstrated how the idealistic pretension of the Declaration of Independence's claim that "all men are created equal" masked a deeper reality and ongoing paradox in American history wherein unprecedented freedom for some was continually purchased with the enslavement of others. The vast, largely unwritten history of American governance and police regulation suggests that it is time to refocus attention on another founding paradox—the myth of American liberty. For . . . the storied history of liberty in the United States, with its vaunted rhetoric of unprecedented rights of property, contract, mobility, privacy, and bodily integrity, was built directly upon a strong and consistent willingness to employ the full, coercive, and regulatory powers of law and government. . . .

FEDERAL PREEMPTION OF STATE AND LOCAL POWER

States, unlike the federal government, enjoy plenary police power and need not point to any specific source—constitutional or statutory—of authority to protect the public's health. When the federal government acts pursuant to its enumerated powers, however, it has authority to preempt (or supersede) state and local government law to ensure regulatory uniformity across jurisdictional lines. The Supremacy Clause of the

Constitution declares that the "Constitution . . . and the Laws of the United States . . . and all Treaties made . . . shall be the supreme law of the Land" (Article IV). Consequently Congress can enact legislation with the express or implied intent to supersede state law.

The doctrine of federal preemption holds that if Congress has enacted legislation on a particular subject that law is controlling over state and local laws. In addition to blocking direct regulation by state and local governments, federal preemption also can thwart indirect regulation via common law tort actions (see chapter 7). State law can also preempt local law, as discussed in chapter 5.

Preemption has antiregulatory effects in areas ranging from environmental protection, tobacco control, gun control, food labeling, occupational hazards, and motor vehicle safety to safety of foods, pharmaceuticals, and medical devices. Because the impact of preemption can be so far-reaching, it is crucial to carefully delineate the areas in which state and local authority is constrained by preemption. Congress may be quite explicit in preempting some state and local laws while saving others from preemption. Nonetheless, when a preemption dispute arises (typically in a case where a private actor is seeking to halt implementation or enforcement of a state or local regulation or avoid liability under state common law) the courts must ultimately determine whether federal law preempts state or local law. The touchstone of this analysis is to discern congressional intent to preempt because Congress has undoubted power to supersede any state or local law, provided it is acting within a valid sphere of enumerated powers. The problem, of course, is ascertaining what Congress actually intended—which is often hard to do. The judicial opinion excerpted below demonstrates the complexity of determining which state and local actions are preempted when Congress acts.

*23-34 94TH ST. GROCERY CORP. V. NEW YORK CITY BOARD OF HEALTH**

United States Court of Appeals for the Second Circuit
Decided July 10, 2012

In 1965, Congress enacted the Federal Cigarette Labeling and Advertising Act[, which requires that] cigarette packages and advertisements must contain the phrase "Surgeon General's Warning" followed by one of the following four cautions: (1) Smoking Causes Lung Cancer, Heart Disease, Emphysema, and May Complicate Pregnancy. (2)

* 685 F.3d 174.

Quitting Smoking Now Greatly Reduces Serious Risks to Your Health. (3) Smoking By Pregnant Women May Result in Fetal Injury, Premature Birth, and Low Birth Weight. (4) Cigarette Smoke Contains Carbon Monoxide. . . .

Congress also included a preemption provision in the Labeling Act, limiting the extent to which states may regulate the labeling, advertising, and promotion of cigarettes. First, the preemption provision prohibits states from requiring any additional "statement relating to smoking and health, other than the statement required by [the federal Labeling Act] on any cigarette package." Second, [it] provides that "[n]o requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes" labeled in conformity with the Act. Finally, [the savings clause] states: "a State or locality may enact statutes and promulgate regulations, based on smoking and health, . . . imposing specific bans or restrictions on the time, place, and manner, but not content, of the advertising or promotion of any cigarettes."

On September 22, 2009, the Board of Health adopted a resolution amending Article 181.19 of the New York City Health Code [to require tobacco retailers to "prominently display tobacco health warning and smoking cessation signage produced by the Department [of Health]. . . . The Department produced three signs, any one of which retailers could display to comply with the Resolution. One shows an x-ray image of a cancerous lung over the warning "Smoking Causes Lung Cancer." Another depicts a photograph of a decaying, extracted tooth over the warning "Smoking Causes Tooth Decay." The third is an MRI of a brain with damaged tissue resulting from a stroke, and states, "Smoking Causes Stroke." Each sign also reads, "Quit Smoking Today. Call 311 or 1-866-NYQUITS FREE." . . .

The City passed the Resolution to "promote further reductions in smoking prevalence in New York City." . . . Specifically, the City observed that cigarette advertising was particularly "prominent" in retail locations, but the "retail environment lack[ed] information about tobacco health risks." It also noted research indicating that "pictorial warnings" were "more effective and engaging than text-only warnings," especially among youths. The City concluded that requiring graphic images at retail locations would "[c]ounteract tobacco advertising" and "further de-normalize smoking." . . .

[P]laintiffs-appellees—two cigarette retailers, two trade associations, and three of the nation's largest cigarette manufacturers—initiated the action below against the Board, the Department of Health, the Department of Consumer Affairs, and their respective commissioners, seeking a declaration that the Resolution was preempted by federal labeling laws and violated their First Amendment rights. . . .

To determine whether a state or local law is preempted by federal law, we look to Congress's intent. . . . The existence of an express preemption clause, however, does not immediately end the inquiry because the question of the substance and scope of Congress's displacement of state law still remains. Accordingly, courts may look to the statute as a whole to determine the extent to which Congress intended federal law to occupy the legislative field. We assume that a federal statute has not supplanted state law unless Congress has made such an intention clear and manifest. . . .

We recognize our duty to assume that a local regulation is not preempted unless Congress has made such an intention clear and manifest. We find, however, that Congress has clearly manifested its intent to preempt the Resolution through (1) the language of the preemption provision and (2) the overall statutory scheme.

The Labeling Act prohibits states from imposing any "requirement or prohibition based on smoking and health . . . with respect to the advertising or promotion of . . . cigarettes." The parties agree that the Resolution is a "requirement or prohibition based on smoking and health." They dispute, however, whether the Resolution is "with respect to the advertising or promotion of" cigarettes. Plaintiffs argue that it is a requirement with respect to promotion; defendants argue that it is only a requirement with respect to sale. We agree with plaintiffs that the Resolution is a requirement with respect to the promotion of cigarettes. . . .

The word "promotion" is not defined in the Labeling Act. Hence, we look to the word's plain meaning. Specifically, we consider the ordinary, common-sense meaning of the word. *Merriam–Webster* defines "promotion" as "the act of furthering the growth or development of something; especially: the furtherance of the acceptance and sale of merchandise through advertising, publicity, or discounting." . . .

The Resolution requires that every tobacco retailer place signage either (1) next to the register or (2) next to each tobacco product display. Option (2) directly affects the promotion of cigarettes. . . . [A] display is a form of publicity that can further the sale of merchandise. It is an opportunity for the manufacturer to present the consumer with its trade dress, product pricing, and any deals—or sales—that the manufacturer may be offering. Placing a graphic warning adjacent to a product display necessarily affects—or "treads on"—the content of the image projected and the message conveyed to the consumer by that display.

Whether option (1) affects promotion is a closer call, as it does not explicitly reference the display of tobacco products. Indirectly, however, it is likely to affect product display, and therefore, product promotion. New York law requires retailers to place cigarettes either "behind a counter . . . accessible only to [store] personnel" or "in a locked container." As a result, the vast majority of retailers choose to place cigarettes behind the counter, where the registers are located, prominently displayed in plain view but accessible only to store personnel. In such circumstances, placing signage at the register is practically the same as placing it at the point of display. Furthermore, the Resolution may very well prompt retailers to choose *not* to place cigarettes near the register—a decision that would affect promotion.

The City's primary argument is that the Resolution is a not a requirement with respect to the *promotion* of cigarettes, but rather, a requirement with respect to the *sale* of cigarettes. Specifically, it argues that it is not regulating or restricting a manufacturer's ability to advertise or promote; it is simply requiring any establishment that sells cigarettes to post warning signs, regardless of whether any advertising or promotion occurs at the particular retail establishment. While it is true that the Resolution only explicitly requires action on the part of the seller, not the manufacturer, the City ignores the practical effect the Resolution has on the manufacturer's promotional activity at the retail location. . . .

To be clear, we do not hold that every state or local regulation affecting promotion violates the Labeling Act's preemption clause. [The Labeling Act] provides a safe harbor for laws regulating the time, place, or manner of promotional activity. For example, the City's requirement that retailers display cigarettes only behind the counter or in a locked container . . . clearly affects promotional display, but would fall within this exception, as it only affects the place and manner of the display. Only requirements or prohibitions directly affecting the *content* of the manufacturers' promotional message to consumers are preempted. . . .

> The Labeling Act seeks to strike a balance between two competing interests: (1) ensuring that Americans are adequately warned about the health consequences of smoking; and (2) protecting free commerce. The Resolution affects this balance by seeking to advance the first interest at the expense of the second. The requirement that retailers post graphic images might serve to further educate consumers, but it does so by imposing a direct burden on cigarette retailers.
>
> The Resolution was born of the assumption that the federally mandated warnings did not adequately or effectively inform consumers of the health risks of smoking. Specifically, the City apparently believed that "there remain[ed] significant gaps in smokers' understanding of these risks." It also observed that the "retail environment lacks information about tobacco health risks," and highlighted research indicating textual warnings (such as the ones currently mandated by Congress) were not as effective as pictorial warnings. In other words, the City was not satisfied with the balance struck by Congress, and it sought to shift the balance further in favor of discouraging smoking, at the expense of free commerce. . . . Allowing state or local authorities to mandate supplementary warnings on or near cigarette displays risks the creation of diverse, nonuniform, and confusing regulations. . . .
>
> For the foregoing reasons, we hold that the Resolution, Article 181.19 of the New York City Health Code, is preempted by the Labeling Act. . . . In light of this determination, we do not decide whether the Resolution violates the First Amendment.

. . .

The plaintiffs in *23–34 94th St. Grocery* (tobacco retailers and manufacturers seeking to avoid local government regulation) relied on *express preemption*. In the Labeling Act, Congress explicitly stated its intent to supersede state and local law. The dispute centered on the local health department's argument that the local regulation fell within a savings clause explicitly exempting certain types of state and local laws from preemption.

In addition to express preemption, courts also recognize *implied preemption* in cases where when the language of the statute and its legislative history imply Congress's intent to supersede state and local law, without expressly declaring it. There are two forms of implied preemption: field preemption and conflict preemption. *Field preemption* occurs when a court deems a scheme of federal regulation to be so comprehensive as to occupy the entire field, and thus infers that Congress did not intend for states to supplement it. *Conflict preemption* is inferred by courts in two types of cases: (1) when compliance with both federal and state regulations would be impossible; and (2) when the purpose of federal law would be thwarted by state law. The latter, more expansive form of conflict preemption is sometimes called *obstacle preemption* or "purposes and objectives preemption." The broad power it gives une-

lected judges to invalidate state and local law makes obstacle preemption controversial among progressives and conservatives alike.

Congress's purpose in preempting federal law may be to set a minimal standard of protection, allowing state and local governments to adopt overlapping regulatory regimes that serve the aims of federal regulation. Many federal laws (e.g., the Americans with Disabilities Act, the Clean Air Act, and the HIPAA Privacy Rule) provide a floor of protection. Under this *floor preemption,* federal law supersedes weaker state laws, while allowing states to create additional layers of protection. Public health advocates are more concerned about *ceiling preemption,* which prevents states from adopting laws stronger than or different from federal law, effectively invalidating state and local requirements not identical to federal law, as was the case in *23–34 94th St. Grocery.*

FEDERAL POWER TO SAFEGUARD THE PUBLIC'S HEALTH

When the federal government acts, it has sweeping authority to preempt state and local law. On the other hand, federal government action is confined to those powers expressly enumerated in the Constitution. For public health purposes, the foremost of these are the power to regulate interstate commerce and the power to tax and spend for the general welfare. Congress has authority to raise revenue for public health services and to regulate, both directly and indirectly via taxation and conditional spending.

The Constitution also affords Congress other powers with public health significance. Congress has the power to enforce the civil rights amendments (the Thirteenth, Fourteenth, and Fifteenth Amendments); and it has the power to "promote the Progress of Science" by securing for inventors the exclusive right to their discoveries through the granting of patents (Article 1, section 8, clause 8). The Constitution also grants the president authority to make treaties with the Senate's advice and consent. Finally, the Necessary and Proper Clause in Article 1, section 8, of the Constitution permits Congress to employ all means reasonably appropriate to achieve the objectives of enumerated national powers.

The courts have interpreted these powers in ways that give the federal government considerable authority to ensure the conditions required for people to be healthy. Federal regulation now covers broad aspects of public health, such as air and water quality, food and drug safety, emergency preparedness and response, consumer product safety,

PHOTO 3.2. Demonstrators protest the Affordable Care Act during a Tea Party rally on tax day, 2010. Photograph courtesy of Fibionacci Blue via Flickr.

occupational health and safety, and access to health care. Nonetheless, the enumerated powers doctrine does constrain Congress's ability to address pressing matters of national concern, as demonstrated by the Supreme Court's opinion narrowly upholding the Affordable Care Act's individual mandate and striking down its expansion of Medicaid eligibility. In the excerpt from *NFIB v. Sebelius* that follows, the justices articulate the bounds of federal authority to regulate interstate commerce, and to tax and spend for the general welfare.

*NATIONAL FEDERATION OF INDEPENDENT BUSINESS v. SEBELIUS**

Supreme Court of the United States
Decided June 28, 2012

Chief Justice Roberts.

Today we resolve constitutional challenges to two provisions of the Patient Protection and Affordable Care Act of 2010: the individual mandate, which requires individu-

* 567 U.S. 519.

als to purchase a health insurance policy providing a minimum level of coverage; and the Medicaid expansion, which gives funds to the States on the condition that they provide specified health care to all citizens whose income falls below a certain threshold. We do not consider whether the Act embodies sound policies. That judgment is entrusted to the Nation's elected leaders. We ask only whether Congress has the power under the Constitution to enact the challenged provisions. . . .

The Federal Government "is acknowledged by all to be one of enumerated powers." That is, rather than granting general authority to perform all the conceivable functions of government, the Constitution lists, or enumerates, the Federal Government's powers. . . . The enumeration of powers is also a limitation of powers. . . . The Constitution's express conferral of some powers makes clear that it does not grant others. . . .

Today, the restrictions on government power foremost in many Americans' minds are likely to be affirmative prohibitions, such as contained in the Bill of Rights. These affirmative prohibitions come into play, however, only where the Government possesses authority to act in the first place. If no enumerated power authorizes Congress to pass a certain law, that law may not be enacted, even if it would not violate any of the express prohibitions in the Bill of Rights or elsewhere in the Constitution. . . .

The same does not apply to the States, because the Constitution is not the source of their power. The Constitution may restrict state governments—as it does, for example, by forbidding them to deny any person the equal protection of the laws. But where such prohibitions do not apply, state governments do not need constitutional authorization to act. The States thus can and do perform many of the vital functions of modern government—punishing street crime, running public schools, and zoning property for development, to name but a few—even though the Constitution's text does not authorize any government to do so. Our cases refer to this general power of governing, possessed by the States but not by the Federal Government, as the "police power."

State sovereignty is not just an end in itself: Rather, federalism secures to citizens the liberties that derive from the diffusion of sovereign power. Because the police power is controlled by 50 different States instead of one national sovereign, the facets of governing that touch on citizens' daily lives are normally administered by smaller governments closer to the governed. The Framers thus ensured that powers which "in the ordinary course of affairs, concern the lives, liberties, and properties of the people" were held by governments more local and more accountable than a distant federal bureaucracy. The independent power of the States also serves as a check on the power of the Federal Government: By denying any one government complete jurisdiction over all the concerns of public life, federalism protects the liberty of the individual from arbitrary power.

This case concerns two powers that the Constitution does grant the Federal Government, but which must be read carefully to avoid creating a general federal authority akin to the police power. The Constitution authorizes Congress to "regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes." Art. I, §8, cl. 3. Our precedents read that to mean that Congress may regulate "the channels of interstate commerce," "persons or things in interstate commerce," and "those activities that substantially affect interstate commerce." The power over activities that substantially affect interstate commerce can be expansive. That power has been held to authorize federal regulation of such seemingly local matters as a farmer's decision to grow wheat for himself and his livestock, and a loan shark's extortionate collections from a neighborhood butcher shop.

Congress may also "lay and collect Taxes, Duties, Imposts and Excises, to pay the Debts and provide for the common Defence and general Welfare of the United States." U.S. Const., Art. I, §8, cl. 1. Put simply, Congress may tax and spend. This grant gives the Federal Government considerable influence even in areas where it cannot directly regulate. The Federal Government may enact a tax on an activity that it cannot authorize, forbid, or otherwise control. And in exercising its spending power, Congress may offer funds to the States, and may condition those offers on compliance with specified conditions. These offers may well induce the States to adopt policies that the Federal Government itself could not impose. *See, e.g., South Dakota v. Dole,* 483 U.S. 203, 205–206 (1987) (conditioning federal highway funds on States raising their drinking age to 21). . . .

Our permissive reading of these powers is explained in part by a general reticence to invalidate the acts of the Nation's elected leaders. . . . Members of this Court are vested with the authority to interpret the law; we possess neither the expertise nor the prerogative to make policy judgments. Those decisions are entrusted to our Nation's elected leaders, who can be thrown out of office if the people disagree with them. It is not our job to protect the people from the consequences of their political choices. . . .

The Government advances two theories for the proposition that Congress had constitutional authority to enact the individual mandate. First, the Government argues that Congress had the power to enact the mandate under the Commerce Clause. Under that theory, Congress may order individuals to buy health insurance because the failure to do so affects interstate commerce, and could undercut the Affordable Care Act's other reforms. Second, the Government argues that if the commerce power does not support the mandate, we should nonetheless uphold it as an exercise of Congress's power to tax. According to the Government, even if Congress lacks the power to direct individuals to buy insurance, the only effect of the individual mandate is to raise taxes on those who do not do so, and thus the law may be upheld as a tax.

The Government's first argument is that the individual mandate is a valid exercise of Congress's power under the Commerce Clause and the Necessary and Proper Clause. According to the Government, the health care market is characterized by a significant cost-shifting problem. Everyone will eventually need health care at a time and to an extent they cannot predict, but if they do not have insurance, they often will not be able to pay for it. Because state and federal laws nonetheless require hospitals to provide a certain degree of care to individuals without regard to their ability to pay hospitals end up receiving compensation for only a portion of the services they provide. To recoup the losses, hospitals pass on the cost to insurers through higher rates, and insurers, in turn, pass on the cost to policy holders in the form of higher premiums. In the Affordable Care Act, Congress addressed the problem of those who cannot obtain insurance coverage because of preexisting conditions or other health issues. It did so through the Act's "guaranteed-issue" and "community-rating" provisions. These provisions together prohibit insurance companies from denying coverage to those with such conditions or charging unhealthy individuals higher premiums than healthy individuals.

The guaranteed-issue and community-rating reforms do not, however, address the issue of healthy individuals who choose not to purchase insurance to cover potential health care needs. In fact, the reforms sharply exacerbate that problem, by providing an incentive for individuals to delay purchasing health insurance until they become sick, relying on the promise of guaranteed and affordable coverage.

The reforms also threaten to impose massive new costs on insurers, who are required to accept unhealthy individuals but prohibited from charging them rates necessary to pay for their coverage. This will lead insurers to significantly increase premiums on everyone.

The individual mandate was Congress's solution to these problems. By requiring that individuals purchase health insurance, the mandate prevents cost-shifting by those who would otherwise go without it. . . .

The Government contends that the individual mandate is within Congress's power because the failure to purchase insurance "has a substantial and deleterious effect on interstate commerce" by creating the cost-shifting problem. . . . We have recognized . . . that the power of Congress over interstate commerce . . . extends to activities that have a substantial effect on interstate commerce. Congress's power, moreover, is not limited to regulation of an activity that by itself substantially affects interstate commerce, but also extends to activities that do so only when aggregated with similar activities of others.

Given its expansive scope, it is no surprise that Congress has employed the commerce power in a wide variety of ways to address the pressing needs of the time. But Congress has never attempted to rely on that power to compel individuals not engaged in commerce to purchase an unwanted product. . . . As expansive as our cases construing the scope of the commerce power have been, they all have one thing in common: They uniformly describe the power as reaching "activity." . . . The individual mandate, however, does not regulate existing commercial activity. It instead compels individuals to become active in commerce by purchasing a product, on the ground that their failure to do so affects interstate commerce. Construing the Commerce Clause to permit Congress to regulate individuals precisely because they are doing nothing would open a new and potentially vast domain to congressional authority. . . .

Indeed, the Government's logic would justify a mandatory purchase to solve almost any problem. To consider a different example in the health care market, many Americans do not eat a balanced diet. That group makes up a larger percentage of the total population than those without health insurance. The failure of that group to have a healthy diet increases health care costs, to a greater extent than the failure of the uninsured to purchase insurance. Those increased costs are borne in part by other Americans who must pay more, just as the uninsured shift costs to the insured.

Congress addressed the insurance problem by ordering everyone to buy insurance. Under the Government's theory, Congress could address the diet problem by ordering everyone to buy vegetables. . . . Congress already enjoys vast power to regulate much of what we do. Accepting the Government's theory would give Congress the same license to regulate what we do not do, fundamentally changing the relation between the citizen and the Federal Government. . . .

The Government's tax power argument asks us to view the statute differently than we did in considering its commerce power theory. In making its Commerce Clause argument, the Government defended the mandate as a regulation requiring individuals to purchase health insurance. The Government does not claim that the taxing power allows Congress to issue such a command. Instead, the Government asks us to read the mandate not as ordering individuals to buy insurance, but rather as imposing a tax on those who do not buy that product. . . . The question is not whether that is the most natural interpretation of the mandate, but only whether it is a "fairly possible" one. As

we have explained, every reasonable construction must be resorted to, in order to save a statute from unconstitutionality. . . .

The exaction the Affordable Care Act imposes on those without health insurance looks like a tax in many respects. The "[s]hared responsibility payment," as the statute entitles it, is paid into the Treasury by "taxpayer[s]" when they file their tax returns. It does not apply to individuals who do not pay federal income taxes because their household income is less than the filing threshold in the Internal Revenue Code. For taxpayers who do owe the payment, its amount is determined by such familiar factors as taxable income, number of dependents, and joint filing status. The requirement to pay is found in the Internal Revenue Code and enforced by the IRS, which . . . must assess and collect it "in the same manner as taxes." This process yields the essential feature of any tax: it produces at least some revenue for the Government. . . . It is of course true that the Act describes the payment as a "penalty," not a "tax." That choice does not, however, control whether an exaction is within Congress's constitutional power to tax. . . .

None of this is to say that the payment is not intended to affect individual conduct. . . . But taxes that seek to influence conduct are nothing new. Some of our earliest federal taxes sought to deter the purchase of imported manufactured goods in order to foster the growth of domestic industry. Today, federal and state taxes can compose more than half the retail price of cigarettes, not just to raise more money, but to encourage people to quit smoking. And we have upheld such obviously regulatory measures as taxes on selling marijuana and sawed-off shotguns. Indeed, every tax is in some measure regulatory. To some extent it interposes an economic impediment to the activity taxed as compared with others not taxed. That [the ACA] seeks to shape decisions about whether to buy health insurance does not mean that it cannot be a valid exercise of the taxing power. . . .

There may, however, be [an] objection to a tax on those who lack health insurance. Even if only a tax, the payment under [the ACA] remains a burden that the Federal Government imposes for an omission, not an act. If it is troubling to interpret the Commerce Clause as authorizing Congress to regulate those who abstain from commerce, perhaps it should be similarly troubling to permit Congress to impose a tax for not doing something.

Three considerations allay this concern. First, and most importantly, it is abundantly clear the Constitution does not guarantee that individuals may avoid taxation through inactivity. . . . The Court today holds that our Constitution protects us from federal regulation under the Commerce Clause so long as we abstain from the regulated activity. But from its creation, the Constitution has made no such promise with respect to taxes. . . .

Second, Congress's ability to use its taxing power to influence conduct is not without limits. A few of our cases policed these limits aggressively, invalidating punitive exactions obviously designed to regulate behavior otherwise regarded at the time as beyond federal authority. More often and more recently we have declined to closely examine the regulatory motive or effect of revenue-raising measures. We have nonetheless maintained that there comes a time in the extension of the penalizing features of the so-called tax when it loses its character as such and becomes a mere penalty with the characteristics of regulation and punishment. . . . Because the tax at hand is within even those strict limits, we need not here decide the precise point at

which an exaction becomes so punitive that the taxing power does not authorize it. It remains true, however, that the power to tax is not the power to destroy while this Court sits.

Third, although the breadth of Congress's power to tax is greater than its power to regulate commerce, the taxing power does not give Congress the same degree of control over individual behavior[;] Congress's authority under the taxing power is limited to requiring an individual to pay money into the Federal Treasury, no more. . . .

The Affordable Care Act's requirement that certain individuals pay a financial penalty for not obtaining health insurance may reasonably be characterized as a tax. Because the Constitution permits such a tax, it is not our role to forbid it, or to pass upon its wisdom or fairness.

The States also contend that the Medicaid expansion exceeds Congress's authority under the Spending Clause. They claim that Congress is coercing the States to adopt the changes it wants by threatening to withhold all of a State's Medicaid grants, unless the State accepts the new expanded funding and complies with the conditions that come with it. This, they argue, violates the basic principle that the Federal Government may not compel the States to enact or administer a federal regulatory program.

There is no doubt that the Act dramatically increases state obligations under Medicaid. The current Medicaid program requires States to cover only certain discrete categories of needy individuals—pregnant women, children, needy families, the blind, the elderly, and the disabled. There is no mandatory coverage for most childless adults, and the States typically do not offer any such coverage. The States also enjoy considerable flexibility with respect to the coverage levels for parents of needy families. On average States cover only those unemployed parents who make less than 37 percent of the federal poverty level, and only those employed parents who make less than 63 percent of the poverty line.

The Medicaid provisions of the Affordable Care Act, in contrast, require States to expand their Medicaid programs by 2014 to cover all individuals under the age of 65 with incomes below 133 percent of the federal poverty line. . . . The Affordable Care Act provides that the Federal Government will pay 100 percent of the costs of covering these newly eligible individuals through 2016. In the following years, the federal payment level gradually decreases, to a minimum of 90 percent. . . .

The Spending Clause grants Congress the power "to pay the Debts and provide for the . . . general Welfare of the United States." U.S. Const., Art. I, §8, cl. 1. We have long recognized that Congress may use this power to grant federal funds to the States, and may condition such a grant upon the States' taking certain actions that Congress could not require them to take. . . .

At the same time, our cases have recognized limits on Congress's power under the Spending Clause to secure state compliance with federal objectives. We have repeatedly characterized Spending Clause legislation as "much in the nature of a contract." The legitimacy of Congress's exercise of the spending power thus rests on whether the State voluntarily and knowingly accepts the terms of the "contract." Respecting this limitation is critical to ensuring that Spending Clause legislation does not undermine the status of the States as independent sovereigns in our federal system. . . .

That insight has . . . led us to scrutinize Spending Clause legislation to ensure that Congress is not using financial inducements to exert a "power akin to undue influence." Congress may use its spending power to create incentives for States to act in

accordance with federal policies. But when "pressure turns into compulsion," the legislation runs contrary to our system of federalism. . . .

Permitting the Federal Government to force the States to implement a federal program would threaten the political accountability key to our federal system. Where the Federal Government directs the States to regulate, it may be state officials who will bear the brunt of public disapproval, while the federal officials who devised the regulatory program may remain insulated from the electoral ramifications of their decision. Spending Clause programs do not pose this danger when a State has a legitimate choice whether to accept the federal conditions in exchange for federal funds. In such a situation, state officials can fairly be held politically accountable for choosing to accept or refuse the federal offer. . . .

In this case, the financial "inducement" Congress has chosen is much more than "relatively mild encouragement"—it is a gun to the head. . . . A State that opts out of the Affordable Care Act's expansion in health care coverage thus stands to lose not merely a relatively small percentage of its existing Medicaid funding, but all of it. Medicaid spending accounts for over 20 percent of the average State's total budget, with federal funds covering 50 to 83 percent of those costs. . . .

[T]he Government claims that the Medicaid expansion is properly viewed merely as a modification of the existing program because the States agreed that Congress could change the terms of Medicaid when they signed on in the first place. The Government observes that the Social Security Act, which includes the original Medicaid provisions, contains a clause expressly reserving "[t]he right to alter, amend, or repeal any provision" of that statute. . . . The Medicaid expansion, however, accomplishes a shift in kind, not merely degree. . . . It is no longer a program to care for the neediest among us, but rather an element of a comprehensive national plan to provide universal health insurance coverage. . . .

The Framers created a Federal Government of limited powers, and assigned to this Court the duty of enforcing those limits. The Court does so today. But the Court does not express any opinion on the wisdom of the Affordable Care Act. Under the Constitution, that judgment is reserved to the people. . . .

Justice Ginsberg, writing in dissent.

The provision of health care is today a concern of national dimension, just as the provision of old-age and survivors' benefits was in the 1930's. In the Social Security Act, Congress installed a federal system to provide monthly benefits to retired wage earners and, eventually, to their survivors. Beyond question, Congress could have adopted a similar scheme for health care. Congress chose, instead, to preserve a central role for private insurers and state governments. According to the Chief Justice, the Commerce Clause does not permit that preservation. . . . The Chief Justice's crabbed reading of the Commerce Clause harks back to the era in which the Court routinely thwarted Congress' efforts to regulate the national economy in the interest of those who labor to sustain it. It is a reading that should not have staying power. . . .

The spending power conferred by the Constitution, the Court has never doubted, permits Congress to define the contours of programs financed with federal funds. . . . Medicaid is a prototypical example of federal-state cooperation in serving the Nation's general welfare. Rather than authorizing a federal agency to administer a uniform national health-care system for the poor, Congress offered States the opportunity to

tailor Medicaid grants to their particular needs, so long as they remain within bounds set by federal law. . . .

The Chief Justice acknowledges that Congress may "condition the receipt of [federal] funds on the States' complying with restrictions on the use of those funds," but nevertheless concludes that the 2010 expansion is unduly coercive. . . . The Chief Justice therefore—for the first time ever—finds an exercise of Congress' spending power unconstitutionally coercive. . . .

For the reasons stated, I agree with the Chief Justice . . . as to the validity of the minimum coverage provision. . . . In my view, the provision encounters no constitutional obstruction. Further, I would [hold] that the Medicaid expansion is within Congress' spending power.

. . .

The opinions in *NFIB v. Sebelius* are badly fractured. Five justices (Roberts, Ginsberg, Kagan, Breyer, and Sotomayor) agreed the individual mandate was a valid exercise of Congress's power to tax. Four of them (Ginsberg, Kagan, Breyer, and Sotomayor) would have also upheld it under the commerce power and Necessary and Proper Clause. None of the justices joined Chief Justice Roberts's opinion that the individual mandate exceeded Congress's commerce power, although four justices writing in dissent (Scalia, Thomas, Alito, and Kennedy) would have struck down the mandate on similar grounds. With regard to the Medicaid expansion, seven justices agreed Congress lacked authority to make the expansion mandatory. Roberts was joined in this part of his opinion by only two other justices, Kagan and Breyer. Justices Scalia, Thomas, Alito, and Kennedy would have struck down the Medicaid expansion in its entirety (along with the entire ACA). Two justices (Ginsberg and Sotomayor) would have upheld the Medicaid expansion as Congress drafted it.

We will discuss the implications of *NFIB v. Sebelius* for health care access in more detail in chapter 8. For now, the key lesson to be drawn from *NFIB v. Sebelius* is that the Supreme Court polices the boundaries of federal power and, in recent years, it has done so with increased scrutiny. The Court discussed three distinct issues: (1) the scope of Congress's authority under the Commerce Clause; (2) the scope of Congress's authority to regulate indirectly via taxation; and (3) the scope of Congress's authority to regulate indirectly by imposing conditions on states' acceptance of federal funds.

The Commerce Power

For most of the twentieth century, the Court did not strike down a single federal law for exceeding Congress's power to regulate interstate

commerce. Beginning during Franklin Delano Roosevelt's New Deal era, the Supreme Court interpreted the Commerce Clause broadly, giving Congress the ability to regulate almost any area of activity, as long as it had national effects. In 1995, the Court broke with long-standing deference to Congress to strike down a law making possession of a firearm in school zones a federal crime. Chief Justice Rehnquist's opinion in *United States v. Lopez,* 514 U.S. 549, did not question the importance of firearm control as a legitimate public health function. Rather, he argued that controlling the mere possession of guns in and near schools was outside the sphere of the federal commerce power. Five years later, in *United States v. Morrison,* 529 U.S. 598 (2000), the Court again struck down a popular federal law for exceeding Congress's commerce power. At issue was the private civil rights remedy created by the Violence Against Women Act of 1994, which allowed survivors to bring federal lawsuits against perpetrators of gender-motivated crimes of violence. Congress proclaimed violence against women impairs women's ability to work, harms businesses, and increases national health care costs. But the Court found no national effects of violence against women and struck down the law.

These two cases suggested the Court was prepared to narrow the scope of federal commerce power. In *Gonzales v. Raich,* 545 U.S. 1 (2005), however, the Court said *Lopez* and *Morrison* should not be read too broadly and held federal law enforcement authorities could criminally prosecute patients for possessing marijuana prescribed by a physician in accordance with state law. Justice Stevens's opinion for the Court held Congress's authority to regulate interstate commerce includes the power to prohibit purely local cultivation and use of marijuana. He found "striking similarities" between the marijuana case and *Wickard v. Filburn,* 317 U.S. 111 (1942), in which the Court upheld a federal prohibition on a farmer growing wheat for his own consumption: "Like the farmer in *Wickard,* respondents are cultivating, for home consumption, a fungible commodity for which there is an established, albeit illegal, interstate market."

The 5–4 decision in *Raich* revealed a fissure within the coalition on the Court, setting the stage for *NFIB*'s fractured decision in which five justices agreed the individual mandate exceeded Congress's commerce power, but on somewhat distinct grounds. The Chief Justice joined the Court's conservative wing, finding the Commerce Clause did not empower Congress to compel individuals to buy insurance. His opinion endorsed the activity/inactivity distinction that had permeated the health care debate.

The Power to Tax

The Court's decision surprised many commentators who had assumed the constitutionality of the minimum coverage requirement would rise or fall on the determination of whether Congress had exceeded its commerce powers. Chief Justice Roberts broke with the dissenting conservative justices, however, in viewing the individual mandate as a valid exercise of Congress's broad taxing power. In his view, individuals had a choice between purchasing insurance or paying a tax. The taxing power provides an independent source of federal legislative authority. Congress may regulate through the tax system for purposes unauthorized under its other enumerated powers.

The Court's decision to uphold the mandate under the taxing power reinforces taxation as a powerful tool for public health regulation. The power to tax and spend enables the federal government to raise revenue to provide for the public good, making possible such services as health care for the poor, elderly, and people with disabilities, income support for low-income families, nutritional assistance, and education. Equally important, the taxing and spending powers make it possible to regulate risky behavior and influence health-promoting activities. Through its taxing power, government can create incentives to engage in beneficial activities (e.g., favorable tax treatment for contributions to employer-sponsored health plans) or disincentives to engage in risky behaviors (e.g., cigarette taxes).

Conditional Spending and the Anti-Coercion Doctrine

The power of the purse allows for considerable indirect regulation. Many federal public health, safety, environmental protection, and education programs are built on a system of cooperative federalism whereby the federal government offers funding to induce states to adopt federal regulatory standards.

States have periodically challenged programs premised on conditional spending, arguing that when used inappropriately, conditions impermissibly coerce states, thus infringing on their sovereignty. This anti-coercion principle was articulated by the Court in *South Dakota v. Dole,* 483 U.S. 203 (1987), which reviewed the federal government's ability to encourage states to raise the minimum drinking age to twenty-one by setting conditions on the acceptance of federal highway funds. The Court's opinion in *Dole* upholding the conditions based

on the reasonable relationship between funding for highways and motor vehicle crashes associated with teenage drinking illustrates the Court's permissive view of the federal spending power prior to *NFIB*. In *NFIB,* the Court departed from this precedent, expanding the concept of coercion considerably and rendering a host of cooperative federalism programs vulnerable to constitutional challenge.

Reserved Powers and the Anti-Commandeering Doctrine

Chief Justice Roberts's opinion in *NFIB* bolstered the anti-coercion doctrine with the related doctrine of reserved powers. He relied upon *New York v. United States,* 505 U.S. 144 (1992), in which the Court, for only the second time in more than half a century, invalidated a federal statute on the ground that the Tenth Amendment reserves those powers not granted to the federal government to the states or to the people. Congress had adopted various incentives to induce states to provide for disposal of radioactive waste generated within their borders. To ensure effective action, if a state was unable to dispose of its own waste, it was required under the statute to "take title" and possession of the waste. The Court invalidated the "take title" provision because the Constitution does not confer upon Congress the ability to "commandeer the legislative processes of the States by directly compelling them to enact and enforce a federal regulatory program."

According to this anti-commandeering principle, although Congress may exercise its legislative authority directly over private persons or businesses, it lacks the power to compel states to regulate according to federal standards. In *Printz v. United States,* 521 U.S. 898 (1997), the Court relied on similar reasoning to overturn provisions in the Brady Handgun Violence Prevention Act, which directed state and local law enforcement officers to conduct background checks on prospective handgun purchasers. In *New York,* the Court held that state legislatures are not subject to federal direction. In *Printz,* the Court held that federal authorities may not supplant the state executive branch. In this instance, Congress did not require the state to make policy, but only to assist in implementing the federal law. The Court rejected the distinction between "making" law or policy on the one hand and merely enforcing or implementing it on the other hand. As a result of *New York* and *Printz* (and, to a lesser extent, *NFIB*) the Tenth Amendment has become a vehicle for challenging federal statutes that compel state legislative or administrative action.

Some commentators have suggested the 2012 decision to rewrite the Medicaid expansion signals that the Roberts Court's brand of state sovereignty will focus on the anti-coercion and anti-commandeering doctrines at least as much if not more than limits on the commerce power (Huberfeld et al. 2013). The new limits on the spending power suggested by the plurality opinion in *NFIB v. Sebelius* have been criticized for their lack of coherence (Ryan 2014). The Court's evolving anti-coercion and anti-commandeering jurisprudence could have implications for other aspects of health care access, education (much of education funding comes from the federal government, allowing Congress to make various demands on state-run public school systems), environmental protection (much of which is jointly administered by the states and the federal government, as discussed in the Flint water crisis Task Force Report), and many other areas.

In the next section, we explore cooperative federalism, which is playing an important role as the federal government takes on a more prominent role in public health, traditionally an area of state and local concern. By limiting Congress's ability to encourage state compliance with federal priorities, the more vigorous anti-coercion doctrine articulated in *NFIB* may steer Congress toward greater reliance on cooperative federalism while simultaneously rendering cooperative federalism less effective.

COOPERATIVE FEDERALISM AND THE LABORATORIES OF DEMOCRACY

Notwithstanding a handful of cases indicating a trend toward a less permissive Supreme Court, the federal government's enumerated powers continue to be interpreted quite broadly. Meanwhile, the states enjoy plenary police power to regulate in the interest of the public's health, safety, and welfare. Thus, as a constitutional matter, authority with regard to most issues of public health importance is shared between the federal government and the states. There are three distinct paths open to Congress when it regulates in an area of shared state and federal concern: (1) it may preempt state law, and thus achieve exclusive jurisdiction via statute; (2) it may eschew preemption, embracing a dual federalism whereby separate federal and state regulatory regimes each operate in their separate spheres, often in an uncoordinated manner; or (3) it may seek to regulate cooperatively with the states.

How cooperative federalism works depends on the enumerated power relied upon by Congress. Where Congress acts pursuant to its

spending power, the federal government establishes national goals and funding but leaves administration to the states within a framework of broadly defined federal rules. Unlike Medicare and Social Security (which are funded and administered solely by the federal government) Medicaid and other federal spending programs must balance between the need for uniform national standards and the need to give states sufficient flexibility to entice them to participate.

Where Congress acts under the commerce power, it may offer states the choice of either regulating according to federal standards or having federal regulation preempt state law. This model is found in regulatory regimes concerning occupational health and safety, environmental protection and conservation, and regulation of private health insurance (Krotoszynski 2012). It is the predominant approach to federal-state relations in environmental law. Under this model, federal agencies (e.g., the EPA) establish minimum national standards, and states retain the choice to administer the federal standards themselves or have federal authorities implement national standards.

Cooperative federalism has many advantages. True to the vision voiced by Justice Louis Brandeis in an opinion from 1932 in which he described states as the "laboratories of democracy," cooperative federalism allows states to experiment with a diversity of regulatory responses while preserving some degree of federal oversight. In the following excerpt, Erwin Chermerinsky and his co-authors analyze how the interrelated principles of federal preemption and reserved powers are shaping an emerging issue with public health importance: state regulation of legalized marijuana. They recommend cooperative federalism as an approach that allows the federal government to ensure that its priorities—including minimization of potential harms to the public's health and safety—guide state regulation while still allowing states to legalize marijuana at the behest of their citizens.

COOPERATIVE FEDERALISM AND MARIJUANA REGULATION*

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The struggle over marijuana regulation is one of the most important federalism conflicts in a generation. Unprecedented public support for legalizing marijuana has

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emboldened Brandeisian experimentation across the country. Since 1996 twenty-three states have legalized marijuana for medical purposes and in November 2013 Colorado and Washington State went even further, legalizing marijuana for adult recreational use. [Yet] marijuana remains a prohibited substance under federal law. . . .

[T]he federal government should adopt a cooperative federalism approach that allows states meeting criteria specified by Congress or the [Department of Justice (DOJ)] to opt out of the federal Controlled Substances Act (CSA) provisions relating to marijuana. State law satisfying these federal guidelines would exclusively govern marijuana activities within those states opting out of the CSA. But nothing would change in those states content with the CSA's terms. . . .

THE CSA AND FEDERAL PREEMPTION OF STATE MARIJUANA LAWS

The preemption doctrine is based on the Constitution's Supremacy Clause, which makes federal law "the supreme law of the land" trumping conflicting state laws. The constitutional question that will determine the outcome of any preemption lawsuit seeking to invalidate state marijuana laws is whether state laws allowing the sale, cultivation, and use of limited amounts of marijuana create an impermissible "conflict"—as that term has been defined by the Supreme Court—with the CSA provisions prohibiting marijuana altogether.

But there is a significant constitutional counterweight to the Supremacy Clause: the Tenth Amendment's anticommandeering doctrine. The federal government may not commandeer states by forcing them to enact laws or by requiring state officers to assist the federal government in enforcing its own laws within the state. Under this doctrine, the federal government cannot require states to enact or maintain on the books any laws prohibiting marijuana.

Taken together, the commandeering prohibition and the Supremacy Clause help define the contours of our federalist system of coexisting state and federal governments. . . . While states cannot stop the federal government from enforcing federal law within their territory, the federal government cannot command the state to create a law criminalizing the conduct. . . .

CHANGING FEDERAL LAW TO ACCOMMODATE STATE MARIJUANA LAWS

[E]ven if no criminal marijuana prosecutions are brought under the CSA, the tension between federal law and state laws with regard to marijuana enforcement generates an untenable status quo. Expectations are unsettled and state policy goals are frustrated by the legal-but-not-entirely-legal status of marijuana in twenty-three states. . . . Under either a permissive or cooperative federalism approach, the federal government could allow states to govern marijuana laws and regulations within their borders so long as the state regulatory schemes comply with specified federal requirements. . . .

Permissive Federalism

Under a permissive federalism approach, Congress could allow an administrative agency to grant state-level temporary, revocable waivers of the CSA marijuana provisions based on specified criteria. During the period of the waiver, participating states

could experiment with their own laws and regulations while the federal government agrees not to enforce federal law. . . .

Revocable waivers could be a good first step toward permitting states to experiment with novel approaches to legalizing and regulating marijuana. . . . But as long as the federal government merely agrees not to enforce federal law in opt-out states, and thus conduct is illegal but not prosecuted, most, if not all, the ancillary problems flowing from the continued illegality under federal law are likely to remain.

Cooperative Federalism

In light of this concern with a permissive revocable waiver, we suggest that a cooperative federalism approach is a better solution. Congress could amend the CSA to allow states to opt out of most of the CSA's marijuana provisions within its borders, thereby making conduct allowed by state law actually legal under federal law within that state.

Cooperative federalism . . . allows federal and state laws to solve problems jointly rather than conflict with each other. In the interest of cooperation, certain federal statutes permit cooperative agreements between the federal government and the states to solve issues of mutual concern. In the context of marijuana policy, such agreements would provide that only state law governs marijuana enforcement within opt-out states so long as the states comply with federal guidelines. In all other states, the CSA would continue to control.

Examples of cooperative frameworks can be found in several federal statutes. . . . Under the CAA, [for example,] each state has primary responsibility for the air quality within its geographic area. States may promulgate their own air pollution prevention plans, but if those plans do not meet the requirements of the CAA then a federal plan will be promulgated instead. . . . It is easy to see how [such] statutes avoid running afoul of the anticommandeering doctrine. States are not obligated to do a thing. They may legislate if they wish—subject to federal guidelines—or they may do nothing and be subject to federal regulation instead. . . .

Applying the Cooperative Federalism Approach to Marijuana Laws

Importantly, modifying the CSA to allow cooperative agreements between the states and the federal government would allow the federal government to guide state policy without commandeering the state legislatures while giving states the freedom to develop the best approach for regulating marijuana. Furthermore, variations among the state laws and regulations would allow for experimentation just short of full legalization. While some states would maintain their current marijuana prohibitions, others would likely test out different regulatory schemes permitting more or less marijuana activity. The relative successes and failures of the various marijuana legalization models would help inform other states—and possibly the federal government—about the best practices for legalizing marijuana for adults while maintaining public safety. Moreover, this model mitigates the impact of marijuana legalization on states choosing to maintain the status quo.

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Decriminalization of marijuana could have public health benefits—by reducing mass incarceration, for example. Legalization of marijuana

also presents significant public health challenges, however. As we discuss in the next chapter, the Supreme Court's increasing protection of corporate free speech rights is trending toward an "all or nothing" approach whereby any product or service not banned outright may be difficult for government to regulate effectively.

Chemerinsky and his coauthors extol the virtues of cooperative federalism as a sensible approach to balancing state and federal interests. There are, however, significant problems raised by this approach in some contexts. Lack of uniformity from state to state can lead to spectacularly unjust results, as described in *NFIB v. Sebelius* with regard to the wide variation in states' coverage of low-income parents under Medicaid. As the health reform experience illustrates, even if states opt into a federal program, they may not be fully committed to federal goals. As a result, their enforcement may be lax and sluggish or even outright obstructionist. Were Congress to amend the Controlled Substances Act to permit state legalization of marijuana within the confines of federal regulations to protect the public's health and safety, as Chermerinsky et al. recommend, those regulations would likely suffer from the same enforcement challenges that plague other federal health and environmental laws.

Enforcement of spending programs that aim for cooperative federalism is particularly challenging. Federal agencies are generally authorized to revoke federal funds (in the case of a spending program such as Medicaid) or take over a state's programs (in the case of a commerce regulation such as the Clean Water Act), but those crude tools are virtually never used. Indeed, one of the problems highlighted by the Flint water crisis Task Force Report is the EPA's failure to step in even when it should have been clear that the state environmental agency's enforcement was inadequate.

Further complicating enforcement within cooperative federalism programs, the Supreme Court has sharply curtailed the ability of private parties to enforce federal requirements against states through civil litigation. It has done so through statutory interpretations that cut off private rights of action and the constitutional doctrine of sovereign immunity. As we will discuss further in chapter 8, the Court has interpreted the federal Medicaid statute and similar laws in new ways that significantly narrow the grounds on which private parties may bring suit to force states to comply with federal requirements. Additionally, the doctrine of state sovereign immunity protects states and government officials from private suits to enforce state and federal law. For example, while the Flint residents' constitutional claims could founder on the grounds that

defendant officials' failures amount to nonfeasance rather than misfeasance (as discussed above), their claims under federal environmental laws and state tort laws could be barred by sovereign immunity.

With regard to private suits to enforce federal law, the Supreme Court has held that Congress cannot subject states to lawsuits by private parties unless it acts pursuant to its authority to enforce the Civil War Amendments (e.g., to vindicate rights to equal protection and due process) or its spending power (i.e., a state may waive its sovereign immunity by accepting federal funds so long as that condition is clearly expressed). Environmental regulations are typically understood as relying on the commerce power, however, under which Congress lacks the authority to circumvent state sovereign immunity. The legislative and executive branches at the local, state, and federal level have failed the people of Flint. They are likely to be failed by the state and federal courts as well.

Even as Congress has relied more heavily on a "cooperative" approach, federal-state relations on social and economic policy continue to be highly contentious. In response to Obama administration policies on health reform and gun control, several states passed "nullification statutes" purporting to block implementation or even criminalize enforcement of federal law (Card 2010). In response to the Trump administration's mass deportations of undocumented immigrants, several state and local governments have taken a similarly defiant stance as self-declared "sanctuaries." State nullification has been consistently rejected by the Supreme Court as incompatible with the Supremacy Clause, but the statement these laws make demonstrates the marked polarization of state and federal politics. And even when state and federal priorities are seemingly in alignment and enjoy broad bipartisan support (e.g., preventing lead exposure among young children), cooperative federalism and overlapping responsibility may result in neglect of pressing needs and insufficient accountability.

The readings in this chapter illustrate the complexity of the constitutional doctrines delineating government powers and duties to protect the public's health. Generally speaking, the Supreme Court recognizes few governmental obligations, but does permit wide-ranging powers to act for the common good. The federal government possesses enumerated powers enabling it to regulate in most areas relevant to public health. The states retain police powers—inherent authority to safeguard the health, safety, and welfare of the community.

Federalism is among the most divisive issues in constitutional law. In recent years, the Court has shifted the balance of power, denying the

national government authority to invade poorly defined spheres of state sovereignty. Whether this trend will continue during the Trump administration, as many state and local governments seek to protect residents from federal immigration enforcement, remains to be seen.

The Roberts Court, in particular, has defended state sovereignty as an indirect means for safeguarding individual liberty. In the next chapter, we turn to another area of constitutional law that has divided the country every bit as much as federalism and has equally crucial importance to the public's health: the constitutional rights of individuals to be free from government interference.

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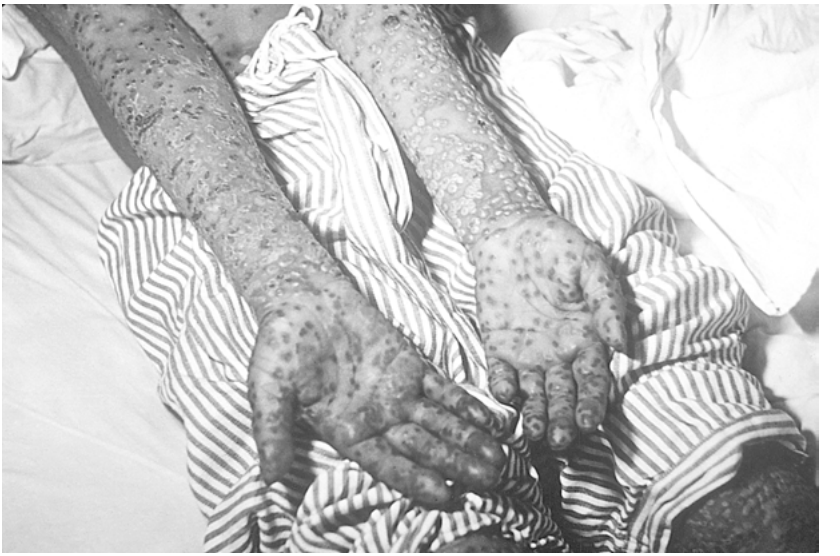

PHOTO 4.1. A girl in Yugoslavia displays smallpox lesions on her arms for a doctor to examine, 1972. The disease, which was fatal in about 30% of cases, was declared eradicated in 1979. Unidentified photographer for the U.S. Centers for Disease Control.

CHAPTER FOUR

Public Health and the Protection of Individual Rights

Due Process, Equal Protection, and the First Amendment

The legitimating purpose of government is to secure the community's welfare. Regulations may target individuals (e.g., imposing restrictions on those with communicable diseases), professionals (e.g., requiring licenses), and businesses (e.g., zoning restrictions and safety standards). The previous chapter emphasized the broad *powers and duties* of government to safeguard the public's health. This chapter considers *constraints* on government power derived from individual rights to autonomy, privacy, liberty, property, and freedom of religion and speech. Individuals also have the rights to due process and equal protection of the law.

Like public health ethics, public health law is concerned with the trade-offs that the exercise of government power entails. Under what circumstances is government permitted to act to achieve a public good when the consequence of that act is to invade a sphere of personal or economic liberty? When is unequal treatment of groups prohibited and when does justice permit—or even demand—that groups be treated differently? Constitutional doctrines protecting individual rights set forth the legal standards by which courts review government action.

The cases and commentary in this chapter trace the evolution of judicial thought on the balance between public health power and protection of individual rights. Public health jurisprudence is neither static nor immune from political and social influences. Rather, judicial review of public health interventions has changed over time and with the varying composition of the Supreme Court. These changes, moreover, often

reflect prevailing social and political thought. In the early twentieth century, the Court articulated a strong notion of economic liberty, striking down vast swaths of social legislation. During the New Deal era, the Court became far more deferential to the social and economic judgments of the elected branches. The Warren Court's defense of personal freedom and nondiscrimination can be linked to the civil rights movements for African Americans and women during the 1960s. The Rehnquist Court's decisions on federalism were influenced by a predisposition toward states' rights. The Roberts Court has continued to emphasize structural constraints as a means for protecting individual liberty from a strong centralized government. It has also expanded the individual rights protections enjoyed by corporations. At the same time, a majority of the Court has been influenced by the civil rights movement to recognize a right to same-sex marriage.

We begin with *Jacobson v. Massachusetts,* a foundational case establishing that government may infringe upon individual rights in the interest of securing the public's health. After a discussion of historical limits on the police power, we turn to the modern framework for protecting individual rights from government intrusion. We review five areas of constitutional protection: procedural due process, substantive due process, equal protection, freedom of speech, and freedom of religion. Our focus is on the federal Constitution, but, as some cases excerpted in this chapter reveal, similar protections may be found in the constitutions adopted by the various states. Statutes enacted by legislatures may also grant individual rights, including rights to be free from discrimination by non-state actors, such as private employers, educational institutions, and businesses. Unlike constitutional rights, however, statutory rights generally do not act as counter-majoritarian constraints on future action by the same legislature.

HISTORICAL LIMITS ON GOVERNMENT POWER

As discussed in the previous chapter, the main text of the U.S. Constitution focuses primarily on defining the roles of the states versus the federal government and of the three branches of the federal government. The Bill of Rights, comprising the first ten amendments to the Constitution and ratified in 1791, secured several fundamental individual rights against federal government intrusion and reinforced the notion that powers not expressly granted to the federal government were reserved to the states. In the aftermath of the Civil War, the Reconstruction

Amendments abolished slavery (Thirteenth Amendment) and secured the right to vote regardless of race, color, or previous status as a slave (Fifteenth Amendment). More broadly, the Fourteenth Amendment provided that "No State shall make or enforce any law which shall abridge the privileges or immunities of citizens of the United States; nor shall any State deprive any person of life, liberty, or property, without due process of law; nor deny to any person within its jurisdiction the equal protection of the laws."

In the nineteenth century, businesses and tradespeople relied upon the Fourteenth Amendment to challenge officials' efforts to create more sanitary living and working conditions. For example, in the *Slaughterhouse Cases,* 83 U.S. 36 (1872), the Supreme Court upheld the state of Louisiana's authority to consolidate slaughterhouse operations into a single corporation so as to move them en masse from a location just upstream from New Orleans, where offal contaminated the city's drinking water, to a location downstream from the city. Hundreds of individual butchers and businesses sued on the grounds that the Fourteenth Amendment (ratified by the states just five years earlier) protected their right to exercise their trade without restrictions. The plaintiffs relied on the broad language of the Fourteenth Amendment, which, unlike the other Reconstruction Amendments, does not refer specifically to slavery, race, or color. The Court rejected the plaintiffs' argument, preferring a narrow reading of the Fourteenth Amendment, on the grounds that the alternative would transform the Court into a "perpetual censor upon all legislation of the States." The Court noted that "the security of social order, the life and health of the citizen, the comfort of an existence in a thickly populated community, the enjoyment of private social life, and the beneficial use of property" depend upon the states' exercise of broad police power. Modern constitutional scholars are rightly critical of the Court's excessively narrow reading of the Fourteenth Amendment in the *Slaughterhouse Cases,* which they argue opened the door for the Court's infamous decision in *Plessy v. Ferguson,* 163 U.S. 537 (1896), upholding the disgrace of "separate but equal" racial segregation.

In the early twentieth century, the Court's interpretation of the Fourteenth Amendment continued to evolve. In two landmark cases in 1905, the Court again grappled with the tension between the police power and individual rights. *Jacobson v. Massachusetts* is, to this day, considered a foundational case in public health law, articulating the limits of individual liberty at least in cases where there is a risk of harm to others. In contrast, *Lochner v. New York,* 198 U.S. 45 (1905), has been

thoroughly disclaimed by the Court. In this section, we also present *Jew Ho v. Williamson*, an opinion by a lower federal court articulating the Fourteenth Amendment's guarantee of equal protection under the law as a limit on government quarantine powers. The principles, tensions, and contradictions evident in these early twentieth-century cases provide rich fodder for discussion of the proper balance between individual rights and the power and duty of government to protect the public's health, safety, and welfare.

*JACOBSON V. MASSACHUSETTS**

Supreme Court of the United States
Decided February 20, 1905

Justice Harlan delivered the opinion of the Court.

This case involves the validity, under the Constitution of the United States, of certain provisions in the statutes of Massachusetts relating to vaccination[, which] provide that "the board of health of a city or town, if, in its opinion, it is necessary for the public health or safety, shall require and enforce the vaccination and revaccination of all the inhabitants thereof, and shall provide them with the means of free vaccination. Whoever, being over twenty-one years of age and not under guardianship, refuses or neglects to comply with such requirement shall forfeit $5." An exception is made in favor of "children who present a certificate, signed by a registered physician, that they are unfit subjects for vaccination."

Proceeding under the above statutes, the board of health of the city of Cambridge, Massachusetts, [adopted regulations noting that] "smallpox has been prevalent to some extent in the city of Cambridge, and still continues to increase . . . " [and ordering] "that all the inhabitants of the city who have not been successfully vaccinated since March 1st, 1897, be vaccinated or revaccinated." . . .

The above regulations being in force, [Jacobson] was proceeded against by a criminal complaint[, which] charged that . . . the defendant, being over twenty-one years of age and not under guardianship, refused and neglected to comply with such requirement. [Jacobson] pleaded not guilty. The government . . . made proof tending to show that its chairman informed [Jacobson] that, by refusing to be vaccinated, he would incur the penalty provided by the statute, and would be prosecuted therefor; that he offered to vaccinate the defendant without expense to him; and that the offer was declined, and defendant refused to be vaccinated. . . .

[T]he defendant made numerous offers of proof [relating to alleged injurious or dangerous effects of vaccination]. But the trial court ruled that each and all of the facts offered to be proved by the defendant were immaterial, and excluded all proof of them. . . . The defendant [requested that the jury be instructed that the state vaccination statute] . . . was in derogation of the rights secured to the defendant by the 14th Amendment of the Constitution of the United States. . . . [The court rejected these

* 197 U.S. 11.

PHOTO 4.2. Death the Vaccinator. This flier published by the London Society for the Abolition of Compulsory Vaccination from the late 1800s illustrates the long history of public concerns that vaccinations are unsafe.

requests and the jury returned a guilty verdict, which was upheld on appeal. He] was sentenced by the court to pay a fine of $5. And the court ordered that he stand committed until the fine was paid. . . .

The authority of the State to enact this statute is . . . what is commonly called the police power—a power which the State did not surrender when becoming a member of the Union under the Constitution. Although this court has refrained from any attempt to define the limits of that power, yet it has distinctly recognized the authority of a State to enact quarantine laws and "health laws of every description;" indeed, all laws that relate to matters completely within its territory and which do not by their necessary operation affect the people of other States. According to settled principles, the police power of a State must be held to embrace, at least, such reasonable regulations established directly by legislative enactment as will protect the public health and the public safety. *Gibbons v. Ogden,* 22 U.S. 9 Wheat. 1 [(1824)]. . . . The mode or manner in which those results are to be accomplished is within the discretion of the State, subject, of course, so far as Federal power is concerned, only to the condition that no rule prescribed by a State, nor any regulation adopted by a local governmental agency acting under the sanction of state legislation, shall contravene the Constitution of the United States or infringe any right granted or secured by that instrument. . . .

The defendant insists that his liberty is invaded when the State subjects him to fine or imprisonment for neglecting or refusing to submit to vaccination; that a compulsory vaccination law is unreasonable, arbitrary, and oppressive, and, therefore, hostile to the inherent right of every freeman to care for his own body and health in such way as to him seems best; and that the execution of such a law against one who objects to vaccination, no matter for what reason, is nothing short of an assault upon his person. But the liberty secured by the Constitution of the United States to every person within its jurisdiction does not import an absolute right in each person to be, at all times and in all circumstances, wholly freed from restraint. There are manifold restraints to which every person is necessarily subject for the common good. . . . Real liberty for all could not exist under the operation of a principle which recognizes the right of each individual person to use his own, whether in respect of his person or his property, regardless of the injury that may be done to others. This court has more than once recognized it as a fundamental principle that persons and property are subjected to all kinds of restraints and burdens, in order to secure the general comfort, health, and prosperity of the State. . . .

In the constitution of Massachusetts adopted in 1780 it was laid down as a fundamental principle of the social compact that the whole people covenants with each citizen, and each citizen with the whole people, that all shall be governed by certain laws for "the common good," and that government is instituted "for the common good, for the protection, safety, prosperity and happiness of the people, and not for the profit, honor or private interests of any one man, family or class of men." The good and welfare of the Commonwealth, of which the legislature is primarily the judge, is the basis on which the police power rests in Massachusetts.

Applying these principles to the present case, it is to be observed that the legislature of Massachusetts required the inhabitants of a city or town to be vaccinated only when, in the opinion of the Board of Health, that was necessary for the public health or the public safety. The authority to determine for all what ought to be done in such an

emergency must have been lodged somewhere or in some body; and surely it was appropriate for the legislature to refer that question, in the first instance, to a Board of Health, composed of persons residing in the locality affected and appointed, presumably, because of their fitness to determine such questions. To invest such a body with authority over such matters was not an unusual nor an unreasonable or arbitrary requirement. Upon the principle of self-defense, of paramount necessity, a community has the right to protect itself against an epidemic of disease which threatens the safety of its members. . . . [T]he court would usurp the functions of another branch of government if it adjudged, as matter of law, that the mode adopted under the sanction of the State, to protect the people at large, was arbitrary and not justified by the necessities of the case. We say necessities of the case, because it might be that an acknowledged power of a local community to protect itself against an epidemic threatening the safety of all, might be exercised in particular circumstances and in reference to particular persons in such an arbitrary, unreasonable manner, or might go so far beyond what was reasonably required for the safety of the public, as to authorize or compel the courts to interfere for the protection of such persons. . . . If the mode adopted by the Commonwealth of Massachusetts for the protection of its local communities against smallpox proved to be distressing, inconvenient or objectionable to some—if nothing more could be reasonably affirmed of the statute in question—the answer is that it was the duty of the constituted authorities primarily to keep in view the welfare, comfort and safety of the many, and not permit the interests of the many to be subordinated to the wishes or convenience of the few. . . . An American citizen, arriving at an American port on a vessel in which, during the voyage, there had been cases of yellow fever or Asiatic cholera, although apparently free from disease himself, may yet, in some circumstances, be held in quarantine against his will. . . . The liberty secured by the 14th Amendment, this court has said, consists, in part, in the right of a person "to live and work where he will," and yet he may be compelled, by force if need be, against his will and without regard to his personal wishes or his pecuniary interests, or even his religious or political convictions, to take his place in the ranks of the army of his country and risk the chance of being shot down in its defense. It is not, therefore, true that the power of the public to guard itself against imminent danger depends in every case involving the control of one's body upon his willingness to submit to reasonable regulations established by the constituted authorities, under the sanction of the State, for the purpose of protecting the public collectively against such danger.

It is said, however, that the statute, as interpreted by the state court, although making an exception in favor of children certified by a registered physician to be unfit subjects for vaccination, makes no exception in the case of adults in like condition. But this cannot be deemed a denial of the equal protection of the laws to adults; for the statute is applicable equally to all in like condition and there are obviously reasons why regulations may be appropriate for adults which could not be safely applied to persons of tender years.

Looking at the propositions embodied in the defendant's rejected offers of proof it is clear that they are more formidable by their number than by their inherent value. Those offers in the main seem to have had no purpose except to state the general theory of those of the medical profession who attach little or no value to vaccination as a

means of preventing the spread of smallpox or who think that vaccination causes other diseases of the body. What everybody knows the court must know, and therefore the state court judicially knew, as this court knows, that an opposite theory accords with the common belief and is maintained by high medical authority. We must assume that when the statute in question was passed, the legislature of Massachusetts was not unaware of these opposing theories, and was compelled, of necessity, to choose between them. . . . It is no part of the function of a court or a jury to determine which one of two modes was likely to be the most effective for the protection of the public against disease. . . . If there is any such power in the judiciary to review legislative action in respect of a matter affecting the general welfare, it can only be when that which the legislature has done comes within the rule that if a statute purporting to have been enacted to protect the public health, the public morals or the public safety, has no real or substantial relation to those objects, or is, beyond all question, a plain, palpable invasion of rights secured by the fundamental law, it is the duty of the courts to so adjudge, and thereby give effect to the Constitution.

Whatever may be thought of the expediency of this statute, it cannot be affirmed to be, beyond question, in palpable conflict with the Constitution. Nor, in view of the methods employed to stamp out the disease of smallpox, can anyone confidently assert that the means prescribed by the State to that end has no real or substantial relation to the protection of the public health and the public safety. Such an assertion would not be consistent with the experience of this and other countries whose authorities have dealt with the disease of smallpox. And the principle of vaccination as a means to prevent the spread of smallpox has been enforced in many States by statutes making the vaccination of children a condition of their right to enter or remain in public schools.

The latest case upon the subject of which we are aware is *Viemeister* v. *White*[, 72 N.E. 97 (N.Y. 1904)], decided very recently by the Court of Appeals of New York. . . . That case involved the validity of a statute excluding from the public schools all children who had not been vaccinated. One contention was that the statute and the regulation adopted in exercise of its provisions [were] inconsistent with the rights, privileges and liberties of the citizen. The contention was overruled, the court saying, among other things:

> Smallpox is known of all to be a dangerous and contagious disease. If vaccination strongly tends to prevent the transmission or spread of this disease, it logically follows that children may be refused admission to the public schools until they have been vaccinated. . . . It must be conceded that some laymen, both learned and unlearned, and some physicians of great skill and repute, do not believe that vaccination is a preventive of smallpox. The common belief, however, is that it has a decided tendency to prevent the spread of this fearful disease and to render it less dangerous to those who contract it. . . . In a free country, where the government is by the people, through their chosen representatives, practical legislation admits of no other standard of action; for what the people believe is for the common welfare must be accepted as tending to promote the common welfare, whether it does in fact or not. Any other basis would conflict

> with the spirit of the Constitution, and would sanction measures opposed to a republican form of government. While we do not decide and cannot decide that vaccination is a preventive of smallpox, we take judicial notice of the fact that this is the common belief of the people of the State, and with this fact as a foundation we hold that the statute in question is a health law, enacted in a reasonable and proper exercise of the police power.

[*Id.* at 98–99]. . . .

The defendant offered to prove that . . . [he] refused to submit to vaccination for the reason that he had, "when a child," been caused great and extreme suffering for a long period by a disease produced by vaccination; and that he had witnessed a similar result of vaccination not only in the case of his son, but in the case of others. . . . But the defendant did not offer to prove that, by reason of his then condition, he was in fact not a fit subject of vaccination at the time he was informed of the requirement of the regulation adopted by the Board of Health. . . . Was defendant exempted from the operation of the statute simply because of this dread of the same evil results experienced by him when a child and had observed in the cases of his son and other children? Could he reasonably claim such an exemption because "quite often" or "occasionally" injury had resulted from vaccination, or because it was impossible, in the opinion of some, by any practical test, to determine with absolute certainty whether a particular person could be safely vaccinated? It seems to the court that an affirmative answer to these questions would practically strip the legislative department of its function to care for the public health and the public safety when endangered by epidemics of disease. . . . We are unwilling to hold it to be an element in the liberty secured by the Constitution of the United States that one person, or a minority of persons, residing in any community and enjoying the benefits of its local government, should have the power . . . to dominate the majority when supported in their action by the authority of the State. . . .

[T]he police power of a State . . . may be exerted in such circumstances or by regulations so arbitrary and oppressive in particular cases as to justify the interference of the courts to prevent wrong and oppression. . . . It is easy, for instance, to suppose the case of an adult who is embraced by the mere words of the act, but yet to subject whom to vaccination in a particular condition of his health or body, would be cruel and inhuman in the last degree. We are not to be understood as holding that the statute was intended to be applied to such a case, or, if it was so intended, that the judiciary would not be competent to interfere and protect the health and life of the individual concerned. . . .

We now decide only that the statute covers the present case, and that nothing clearly appears that would justify this court in holding it to be unconstitutional and inoperative in its application to the plaintiff in error.

. . .

Jacobson continues to be cited by the Supreme Court and lower courts as settled doctrine. Legal battles over the validity of vaccination mandates continue, however. The Supreme Court has declined to grant certiorari in several cases in which the lower courts have upheld

vaccination mandates, including those that do not recognize exceptions for philosophical or religious objectors. When the Supreme Court denies certiorari, it sometimes means that the Court is comfortable allowing the lower court decision to stand (in this case, keeping the vaccination mandate in place) or because the Court prefers to allow lower court jurisprudence to evolve further before stepping in. Were the Supreme Court to consider a case like *Jacobson* today, most commentators agree that it would probably reach the same result. But because of several developments in constitutional jurisprudence during the last century, the Court's reasoning would be quite different.

As described in the sections on due process below, the modern Court has adopted a different framework for assessing the types of arguments Jacobson raised. Although the *Jacobson* Court uses words like "necessary" to describe the purpose of the mandate and its tailoring, the Court does not appear to have applied what modern jurists refer to as *strict scrutiny,* requiring that the intervention be narrowly tailored to further a compelling government purpose. Modern courts reviewing the validity of vaccination mandates have, in some cases, found that they must be strictly scrutinized because they infringe upon the individual right to bodily integrity. Nonetheless, as we describe in chapter 10, courts have consistently found that vaccination mandates satisfy the strict scrutiny test.

It is also important to note that the Court in *Jacobson* did not address the question of religious freedom. In 1905, when *Jacobson* was decided, the Court had not yet applied the First Amendment to state and local governments via incorporation into the Fourteenth Amendment's Due Process Clause.

One of the enduring principles illustrated by *Jacobson* is judicial deference to the elected branches of government when it comes to matters of health and welfare. As noted in the previous chapter on public health ethics, values and scientific expertise play important roles in assessing and regulating risk. The Court's deference to politically accountable branches and expertise-driven agencies (boards of health and other administrative agencies) reflects its understanding that nine unelected judges are in no position to impose counter-majoritarian constraints upon the government's capacity to protect the health and welfare of the populace absent an extraordinary reason to do so.

The deferential stance of the Court in *Jacobson* is in stark contrast to the activist approach the Court took in another case decided the same term, *Lochner v. New York*.

*LOCHNER V. NEW YORK**

Supreme Court of the United States
Decided April 17, 1905

Justice Peckham delivered the opinion of the Court.

[A New York law prohibited the employment of bakery employees for more than 10 hours a day or 60 hours a week. Lochner, who owned a bakery in Utica, New York, was convicted and fined for violating the law.]

When the State, . . . in the assumed exercise of its police powers, has passed an act which seriously limits the right to labor or the right of contract . . . it becomes of great importance to determine which shall prevail—the right of the individual to labor for such time as he may choose, or the right of the State to prevent the individual from laboring . . . beyond a certain time prescribed by the State. . . .

It must, of course, be conceded that there is a limit to the valid exercise of the police power by the State. . . . Otherwise the Fourteenth Amendment would have no efficacy and the legislatures of the States would have unbounded power, and it would be enough to say that any piece of legislation was enacted to conserve the morals, the health or the safety of the people; such legislation would be valid, no matter how absolutely without foundation the claim might be. . . . In every case that comes before this court, therefore, where legislation of this character is concerned and where the protection of the Federal Constitution is sought, the question necessarily arises: Is this a fair, reasonable and appropriate exercise of the police power of the State, or is it an unreasonable, unnecessary and arbitrary interference with the right of the individual to his personal liberty or to enter into those contracts in relation to labor which may seem to him appropriate or necessary for the support of himself and his family? . . .

The law must be upheld, if at all, as a law pertaining to the health of the individual engaged in the occupation of a baker. It does not affect any other portion of the public than those who are engaged in that occupation. Clean and wholesome bread does not depend upon whether the baker works but ten hours per day or only sixty hours a week. . . .

We think that there can be no fair doubt that the trade of a baker, in and of itself, is not an unhealthy one to that degree which would authorize the legislature to interfere with the right to labor, and with the right of free contract on the part of the individual, either as employer or employee. . . . It might be safely affirmed that almost all occupations more or less affect the health. There must be more than the mere fact of the possible existence of some small amount of unhealthiness to warrant legislative interference with liberty. . . . No trade, no occupation, no mode of earning one's living . . . could escape this all-pervading power, and the acts of the legislature in limiting the hours of labor in all employments would be valid, although such limitation might seriously cripple the ability of the laborer to support himself and his family. . . .

We think that such a law as this, although passed in the assumed exercise of the police power, and as relating to the public health, or the health of the employees named, is not within that power, and is invalid. The act is not, within any fair meaning of the term, a health law, but is an illegal interference with the rights of individuals,

* 198 U.S. 45.

both employers and employees, to make contracts regarding labor upon such terms as they may think best. . . .

Justice Harlan, dissenting:

It is plain that this statute was enacted in order to protect the physical well-being of those who work in bakery and confectionery establishments. . . .

[A writer describes the health impact of such labor:]

> The constant inhaling of flour dust causes inflammation of the lungs and of the bronchial tubes. The eyes also suffer through this dust. . . . The average age of a baker is below that of other workmen; they seldom live over their fiftieth year. . . . During periods of epidemic diseases the bakers are generally the first to succumb to the disease, and the number swept away during such periods far exceeds the number of other crafts in comparison to the men employed in the respective industries. . . .

There are many reasons of a weighty, substantial character, based upon the experience of mankind, in support of the theory that, all things considered, more than ten hours' steady work each day, from week to week, in a bakery or confectionery establishment, may endanger the health, and shorten the lives of the workmen, thereby diminishing their physical and mental capacity to serve the State, and to provide for those dependent upon them. . . .

Let the State alone in the management of its purely domestic affairs, so long as it does not appear beyond all question that it has violated the Federal Constitution. This view necessarily results from the principle that the health and safety of the people of a State are primarily for the State to guard and protect.

• • •

During the so-called *Lochner* era from 1905 to 1937, the Court struck down a wide range of regulations, including those protecting consumers from unsafe products and imposing licensing requirements and other regulations of businesses in the interest of the public's health and safety—all on the ground that they violated economic liberty. As Justice Harlan's dissent warned, *Lochner* "cripple[d] the inherent power of the states to care for the lives, health, and well-being of their citizens." During the early twentieth century, *Jacobson*'s deference to the policy judgments of politically accountable legislatures was the exception, rather than the norm. The Court was quick to conduct searching review of legislative purposes and means, substituting its own judgment for that of elected officials in the name of individual rights to economic liberty and freedom of contract.

Early-twentieth-century courts also sometimes declined to defer to the politically accountable branches when the government's actions evinced a discriminatory intent. The Court has not always lived up to

the principle that invidious discrimination against a discrete and insular minority cannot be justified by majority rule. In some cases, however, the courts have intervened to invalidate government action that unjustifiably discriminates against a protected class. In *Yick Wo v. Hopkins*, 118 U.S. 356 (1886), for example, the Supreme Court found unlawful discrimination when a San Francisco ordinance prohibiting the washing of clothes in public laundries after 10 PM was enforced only against Chinese owners. The loose framework used by early-twentieth-century courts to impose equity-based limits on public health intervention is illustrated in *Jew Ho v. Williamson*, a case decided by a federal appellate court in California.

*JEW HO V. WILLIAMSON**

Circuit Court, Northern District of California, decided June 15, 1900

[The board of health of San Francisco adopted a resolution authorizing a quarantine after nine people died of bubonic plague. The complainant, who resided in the quarantined district, alleged that the resolution was enforced only against persons of Chinese descent. Additionally, the complainant alleged that there were no cases of bubonic plague within the limits of the quarantined district in the thirty days preceding the filling of the complaint.]

[T]his court will, of course, uphold any reasonable regulation that may be imposed for the purpose of protecting the people of the city from the invasion of epidemic disease. In the presence of a great calamity, the court will go to the greatest extent, and give the widest discretion, in construing the regulations that may be adopted by the board of health or the board of supervisors. But is the regulation in this case a reasonable one? Is it a proper regulation, directed to accomplish the purpose that appears to have been in view? That is a question for this court to determine. . . .

The quarantined district comprises 12 blocks. . . . There are, I believe, 7 or 8 blocks in which it is claimed that deaths have occurred on account of what is said to be this disease. In 2 or 3 blocks it has not appeared at all. Yet this quarantine has been thrown around the entire district. The people therein obtain their food and other supplies, and communicate freely with each other in all their affairs. . . . The court cannot but see the practical question that is presented to it as to the ineffectiveness of this method of quarantine against such a disease as this. So, upon that ground, the court must hold that this quarantine is not a reasonable regulation to accomplish the purposes sought. It is not in harmony with the declared purpose of the board of health or of the board of supervisors. . . .

[Additionally,] it seems that the board of health, in executing the ordinance, left out certain persons, members of races other than Chinese. This is precisely the point

* 103 F. 10.

noticed by the supreme court of the United States, namely, the administration of a law "with an evil eye and an unequal hand." *Yick Wo v. Hopkins,* 118 U.S. 356, 373–74 (1886). . . .

This quarantine cannot be continued, by reason of the fact that it is unreasonable, unjust, and oppressive, and therefore contrary to the laws limiting the police powers of the state and municipality in such matters; and, second, that it is discriminating in its character, and is contrary to the provisions of the fourteenth amendment of the constitution of the United States. The counsel for complainant will prepare an injunction, which shall, however, permit the board to maintain a quarantine around such places as it may have reason to believe are infected by contagious or infectious diseases, but that the general quarantine of the whole district must not be continued, and that the people residing in that district, so far as they have been restricted or limited in their persons and their business, have that limitation and restraint removed.

INDIVIDUAL RIGHTS IN THE MODERN CONSTITUTIONAL ERA

In the remainder of this chapter, we turn to the frameworks used by modern courts to impose counter-majoritarian constraints on public health action. These constraints safeguard values we hold dear: individual liberty and autonomy, equality in the eyes of the law, and freedom of expression and religion. Yet, personal rights must continually be weighed against collective needs for health, safety, and security.

As the opinions excerpted above suggest, individual rights limit the otherwise plenary police power exercised by state and local governments. They also act as additional limits on the exercise of enumerated powers by the federal government. Although all government actors are bound to some extent by individual rights, the particularities of which rights apply and how are shaped by the text of the Constitution and the doctrine of incorporation (see table 4.1). As noted above, states (and their local government subsidiaries) are constrained by the Due Process Clause of the Fourteenth Amendment. The federal government is constrained by identical language in the Fifth Amendment. The Fourteenth Amendment's Equal Protection Clause was drafted to apply only to the states (and their local government subsidiaries), but has been held by the Supreme Court to be "incorporated" into the Fifth Amendment's Due Process Clause, making it applicable to the federal government as well. Similarly, the First Amendment (which protects freedom of speech and exercise of religion, among other rights) was drafted to apply only to the federal government, but in the mid-twentieth century, the Supreme Court held that it applied to the states via incorporation. Indeed, the Court has applied most of the individual rights secured in

TABLE 4.1 INDIVIDUAL RIGHTS SECURED IN THE U.S. CONSTITUTION

	Applicable to the federal government	Applicable to state and local governments	Relevance
Due Process	Fifth Amendment: "[N]or shall any person . . . be deprived of life, liberty, or property, without due process of law. . . ."	Fourteenth Amendment: "[N]or shall any State deprive any person of life, liberty, or property, without due process of law. . . ."	Guarantees procedural protections in cases of quarantine, travel restrictions, and other infringements of liberty or property rights. Secures other fundamental rights, e.g., to privacy, from government intrusion, requiring a compelling government purpose and narrow means-ends fit. Prohibits arbitrary and capricious action by government.
Equal Protection	Incorporated in the Fifth Amendment's guarantee of due process.	Fourteenth Amendment: "[N]or shall any State . . . deny to any person within its jurisdiction the equal protection of the laws."	Limits government action that relies upon classification. Level of judicial scrutiny depends on type of classification drawn.
Right to Just Compensation for Private Property Taken for Public Use	Fifth Amendment: "private property [shall not] be taken for public use, without just compensation."	Incorporated in the Fourteenth Amendment's guarantee of due process.	Limit public disclosure of trade secrets (e.g., cigarette ingredient labeling) and land use restrictions.
Freedom of Religion and Speech	First Amendment: "Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof; or abridging the freedom of speech. . . ."	Incorporated in the Fourteenth Amendment's guarantee of due process.	Restricts laws that purposefully target particular religious groups, though facially neutral laws (e.g., vaccination mandates) are generally permitted. Limits government restrictions on advertising and mandatory disclosures (e.g., warning labels)

(continued)

TABLE 4.1 *(continued)*

	Applicable to the federal government	Applicable to state and local governments	Relevance
The Right to Keep and Bear Arms	Second Amendment: "A well regulated militia, being necessary to the security of a free State, the right of the People to keep and bear arms, shall not be infringed."	Incorporated in the Fourteenth Amendment's guarantee of due process.	Limits government regulation of firearms.
Freedom from Unreasonable Search and Seizure	Incorporated in the Fifth Amendment's guarantee of due process.	Fourth Amendment: "The right of the people to be secure in their persons, houses, papers, and effects, against unreasonable searches and seizures, shall not be violated, and no Warrants shall issue, but upon probable cause, supported by Oath or affirmation, and particularly describing the place to be searched, and the persons or things . . ."	May require a warrant for law enforcement access to medical records, drug testing, etc. Inspection and drug testing conducted by administrative agencies pursuant to statutory schemes are often allowed without a warrant.

the first eight amendments to all jurisdictions via incorporation. The Second Amendment, which protects the right to bear arms, was incorporated to apply to state and local jurisdictions just within the last decade (see chapter 13).

In this chapter, we introduce the doctrines of due process, equal protection, freedom of speech, and freedom of religion. These rights are explored in greater detail throughout the remainder of this reader in chapters focused on particular modes of public health law intervention and various silos of public health practice. Additional individual rights (e.g., the right to just compensation when private property is taken for public purposes, the right to bear arms, and freedom from unreasonable search and seizure) are also discussed in the chapters that follow.

PROCEDURAL DUE PROCESS

Broadly speaking, individual rights impose two types of limits on government power. The first type of constraint is substantive in nature, requiring an adequate justification for government intrusion on individual interests. As the intrusion upon protected individual interests intensifies, the government must offer an increasingly strong justification and must establish that the means it adopts are well suited to the government's objective. The second type of constraint on government power is procedural, requiring government to provide a fair process (often a hearing) before depriving a person of important liberty or property interests. Government actions that affect important interests—for example, a liberty interest denied by quarantine or a property interest denied by confiscation of contaminated goods—require procedural safeguards to ensure fairness. In doctrinal terms, this second type of constraint is termed *procedural due process*. This seemingly redundant label is used to distinguish it from the doctrine of *substantive due process,* whereby substantive constraints are implied in the Due Process Clause.

In some cases, such as *Castle Rock v. Gonzales,* excerpted in the previous chapter, courts reject a party's procedural due process claim on the grounds that there is no protected liberty or property interest at stake. Once a court determines that a protected property or liberty interest is at stake, the question becomes "What process is due?"—that is, how elaborate must the procedures be to satisfy the due process requirement? In *Mathews v. Eldridge,* 424 U.S. 471, 481 (1976) (a case in which the Court determined that individuals have a protected property interest in Social Security benefits, which therefore cannot be

terminated without due process of law), the Court set the modern standard for fair procedures under the Due Process Clause:

> Due process is flexible and calls for such procedural protections as the particular situation demands. Accordingly, resolution of the issue whether the administrative procedures provided . . . are constitutionally sufficient requires analysis of the governmental and private interests that are affected. More precisely, . . . identification of the specific dictates of due process generally requires consideration of three distinct factors: First, the private interest that will be affected by the official action; second, the risk of an erroneous deprivation of such interest through the procedures used, and the probable value, if any, of additional or substitute procedural safeguards; and the fiscal and administrative burdens that the additional or substitute procedural requirement would entail.

Balancing these factors, the Court ultimately determined that a predeprivation hearing was not required for termination of Social Security benefits. In *Greene v. Edwards,* the West Virginia Supreme Court applied this standard to isolation of a tuberculosis (TB) patient.

*GREENE V. EDWARDS**

Supreme Court of Appeals of West Virginia,
Decided March 11, 1980

William Arthur Greene, the realtor in this . . . habeas corpus proceeding, is involuntarily confined in Pinecrest Hospital under an order of the Circuit Court of McDowell County entered pursuant to the terms of the West Virginia Tuberculosis Control Act. He alleges, among other points, that the Tuberculosis Control Act does not afford procedural due process because: (1) it fails to guarantee the alleged tubercular person the right to counsel; (2) it fails to insure that he may cross-examine, confront and present witnesses; and (3) it fails to require that he be committed only upon clear, cogent and convincing proof. We agree. . . .

[The West Virginia Tuberculosis Control Act] provides in part:

> If [a] practicing physician, public health officer, or chief medical officer having under observation or care any person who is suffering from TB in a communicable stage is of the opinion that the environmental conditions of such person are not suitable for proper isolation or control by any type of local quarantine as prescribed by the state health department, and that such person is unable or unwilling to conduct himself and to live in such a manner as not to expose members of his family or household or other persons with whom he may be associated to danger of infection, he shall report the facts to the department of health which shall forthwith investigate . . . the circumstances alleged. If it shall find that any such

* 263 S.E.2d 661.

> person's physical condition is a health menace to others, the department of health shall petition the circuit court of the county in which such person resides . . . requesting an order of the court committing such person to one of the state TB institutions. Upon receiving the petition, the court shall fix a date for hearing thereof and notice of such petition and the time and place for hearing thereof shall be served personally, at least seven days before the hearing, upon the person who is afflicted with TB and alleged to be dangerous to the health of others. If, upon such hearing, it shall appear that the complaint of the department of health is well founded, that such person is afflicted with communicable tuberculosis, and that such person is a source of danger to others, the court shall commit the individual to an institution maintained for the care and treatment of persons afflicted with TB. . . .

It is evident from an examination of this statute that its purpose is to prevent a person suffering from active communicable tuberculosis from becoming a danger to others. A like rationale underlies our statute governing the involuntary commitment of a mentally ill person. . . .

In *State ex rel. Hawks* v. *Lazaro,* [(202 S.E.2d 109 (W. Va. 1974)], we examined the procedural safeguards which must be extended to persons charged under our statute governing the involuntary hospitalization of the mentally ill. We noted that . . . the West Virginia Constitution and the Fifth Amendment to the United States Constitution provide that no person shall be deprived of life, liberty, or property without due process of law. . . .

We concluded that due process required that persons charged under [the West Virginia statute governing involuntary commitment for the mentally ill] must be afforded: (1) an adequate written notice detailing the grounds and underlying facts on which commitment is sought; (2) the right to counsel; (3) the right to be present, cross-examine, confront and present witnesses; (4) the standard of proof to warrant commitment to be by clear, cogent and convincing evidence; and (5) the right to a verbatim transcript of the proceeding for purposes of appeal. . . .

Because the Tuberculosis Control Act and the Act for the Involuntary Hospitalization of the Mentally Ill have like rationales, and because involuntary commitment for having communicable TB impinges upon the right to "liberty, full and complete liberty" no less than involuntary commitment for being mentally ill, we conclude that the procedural safeguards set forth in *State ex rel. Hawks* v. *Lazaro,* must, and do, extend to persons charged under [the Tuberculosis Control Act]. . . .

We noted in *State ex rel. Hawks* v. *Lazaro* that where counsel is to be appointed in proceedings for the involuntary hospitalization of the mentally ill, the law contemplates representation of the individual by the appointed guardian in the most zealous, adversary fashion consistent with the Code of Professional Responsibility. . . .

In the case before us, counsel was not appointed for Mr. Greene until after the commencement of the commitment hearing. Under the circumstances, counsel could not have been properly prepared to defend Mr. Greene. For this reason, the realtor's writ must be awarded and he must be accorded a new hearing. . . .

We note that our interpretation of the West Virginia Tuberculosis Control Act has radically changed the administration of that law. . . . The writ of habeas corpus is

awarded, and the realtor is ordered discharged, but the discharge is hereby delayed for a period of thirty days during which time the State may entertain further proceedings to be conducted in accordance with the principles expressed herein.

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The US Supreme Court has not directly addressed the issue of what due process requires for confinement of individuals who are actually or potentially infected with a contagious disease. The lower courts, like the West Virginia Supreme Court in *Greene,* have relied heavily on US Supreme Court cases reviewing civil commitment of individuals with mental illness. With the emergence of multi-drug resistant tuberculosis and other infectious disease risks, courts continue to grapple with what the Constitution requires in terms of procedural protections for those whose liberty is constrained for public health purposes. We will discuss this issue further in chapters 10 and 11.

SUBSTANTIVE DUE PROCESS

The Due Process Clause has long been understood to impose substantive, as well as procedural, requirements to justify government actions that infringe on liberty and property interests. For example, patients with tuberculosis have relied on the Fourteenth Amendment to argue that civil confinement is unwarranted—regardless of how many procedural safeguards are in place—if it cannot be justified as the least restrictive alternative for serving the state's compelling interest in controlling the spread of disease. This determination requires an individualized assessment of the patient and his or her circumstances, including past or present adherence to treatment and degree of infectiousness.

As *Jacobson* and *Lochner* demonstrate, substantive due process also protects individual rights that extend beyond freedom from physical confinement and confiscation of personal property. Recall that in *Lochner,* businesses challenged the work hours limitation on the grounds that it infringed on the individual right to contract without restrictions. Jacobson alleged that by subjecting him to a fine or imprisonment for failing to submit to vaccination the state invaded his liberty. He also argued that the mandate was "hostile to the inherent right of every freeman to care for his own body and health in such a way as to him seems best" and that enforcement of the law would amount to "nothing short of an assault upon his person." Thus, he relied on a conception of lib-

erty that includes autonomy with regard to important personal decisions (sometimes referred to as *decisional privacy*) and freedom from invasion of his bodily integrity (sometimes described as a form of *physical privacy*). These forms of privacy are distinct from *informational privacy,* a topic we will discuss in chapter 9.

The extent to which the substantive due process doctrine protects privacy rights continues to be among the most hotly debated issues in constitutional law. The text of the Constitution does not include any explicit reference to privacy. Nonetheless, the Supreme Court has recognized that some rights are so fundamental as to be "implicit in the concept of ordered liberty." These fundamental rights are protected by the Constitution in spite of not being specifically enumerated in its text. Relying on the "penumbras" of the First, Fourth (prohibiting unreasonable searches and seizures), Fifth (prohibiting compelled self-incrimination), and Fourteenth Amendments, the Supreme Court has inferred that the Constitution protects at least some privacy rights.

The Supreme Court has held that government actions that infringe on fundamental rights must be narrowly tailored to serve a compelling government interest. The review that courts conduct to determine whether that threshold is met is referred to as *strict scrutiny*. In the absence of a fundamental right, the courts adopt a far more deferential stance toward the judgments of the politically accountable branches with regard to the purpose and means of government intervention. Under these circumstances, judges ask whether the government's action is rationally related to a legitimate purpose—a so-called *mere rationality* or *rational basis review.* In rare cases, courts have staked out a middle position, engaging in what is typically referred to as *heightened* or *intermediate scrutiny*. These levels of review—strict, intermediate, and rational basis—also form the basic framework by which courts have evaluated equal protection and First Amendment claims, as we will discuss below.

The Court sometimes takes a more flexible approach, however, particularly in when it addresses highly controversial matters such as end of life decisions, abortion, and same-sex marriage. In *Cruzan v. Director, Missouri Dept. of Health,* 497 U.S. 261 (1990), for example, the Court adopted a deferential stance toward the state legislature, holding that nothing in the Constitution prohibits the state from imposing a high bar on the family of an incapacitated patient seeking termination of life-sustaining medical treatment. In effect, this decision allowed the state to insist on continuing care over the objection of the patient's family because

they could not produce compelling evidence that the patient would have declined life-saving treatment. Writing for the majority, Chief Justice Rehnquist was willing to "assume without deciding" that the Constitution protects a competent individual's right to refuse life-sustaining treatment, leaving this important question open. We will discuss constitutional rights to refuse medical treatment further in chapter 10.

Perhaps the best-known Supreme Court decision regarding privacy rights is *Roe v. Wade,* 410 U.S. 113 (1973), holding that a woman's right to choose an abortion prior to viability of the fetus is entitled to the highest constitutional protection, adopting a strict scrutiny test. The Court relied on a string of decisions regarding the privacy of intimate marital relations and decisions about contraception. Later, in *Planned Parenthood of Southeastern Pa. v Casey,* 505 US 833 (1992), the Court articulated a more flexible balancing test, barring government action that "unduly burdens" access to abortion prior to viability of the fetus. Encouraged by the Court's apparently softening stance on the right to choose abortion, states enacted hundreds of restrictions on abortion access and abortion providers. In the following case, the Court evaluated two "targeted regulation of abortion provider" (TRAP) provisions under *Casey*'s undue burden test.

WHOLE WOMAN'S HEALTH V. HELLERSTEDT*

Supreme Court of the United States
Decided June 27, 2016

Justice Breyer delivered the opinion of the Court.

In *Planned Parenthood of Southeastern Pa. v. Casey,* 505 U.S. 833, 878 (1992), a plurality of the Court concluded that there "exists" an "undue burden" on a woman's right to decide to have an abortion, and consequently a provision of law is constitutionally invalid, if the *"purpose or effect"* of the provision *"is to place a substantial obstacle* in the path of a woman seeking an abortion before the fetus attains viability." The plurality added that "[u]nnecessary health regulations that have the purpose or effect of presenting a substantial obstacle to a woman seeking an abortion impose an undue burden on the right."

We must here decide whether two provisions of Texas' House Bill 2 violate the Federal Constitution as interpreted in *Casey*. . . . We conclude that neither of these provisions confers medical benefits sufficient to justify the burdens upon access that each imposes. Each places a substantial obstacle in the path of women seeking an abortion, each constitutes an undue burden on abortion access, and each violates the Federal Constitution. Amdt. 14, §1. . . .

* 136 S. Ct. 2292.

UNDUE BURDEN—ADMITTING-PRIVILEGES REQUIREMENT

Before the enactment of H.B. 2, doctors who provided abortions were required to "have admitting privileges *or* have a working arrangement with a physician(s) who has admitting privileges at a local hospital in order to ensure the necessary back up for medical complications." The new law changed this requirement by requiring that a "physician performing or inducing an abortion . . . must, on the date the abortion is performed or induced, have active admitting privileges at a hospital that . . . is located not further than 30 miles from the location at which the abortion is performed or induced." . . .

The purpose of the admitting-privileges requirement is to help ensure that women have easy access to a hospital should complications arise during an abortion procedure. But the District Court found that it brought about no such health-related benefit. The court found that "[t]he great weight of evidence demonstrates that, before the act's passage, abortion in Texas was extremely safe with particularly low rates of serious complications and virtually no deaths occurring on account of the procedure." Thus, there was no significant health-related problem that the new law helped to cure.

The evidence upon which the court based this conclusion included, among other things: . . . [P]eer-reviewed studies on abortion complications . . . showing that the highest rate of major complications [for first-trimester abortions] was less than one-quarter of 1% [and that] the highest complication rate found for the much rarer second trimester abortion was less than one-half of 1%. Expert testimony to the effect that complications rarely require hospital admission, much less immediate transfer to a hospital from an outpatient clinic. Expert testimony stating that "it is extremely unlikely that a patient will experience a serious complication at the clinic that requires emergent hospitalization" and "in the rare case in which [one does], the quality of care that the patient receives is not affected by whether the abortion provider has admitting privileges at the hospital." Expert testimony stating that in respect to surgical abortion patients who do suffer complications requiring hospitalization, most of these complications occur in the days after the abortion, not on the spot. Expert testimony stating that a delay before the onset of complications is also expected for medical abortions, as "abortifacient drugs take time to exert their effects, and thus the abortion itself almost always occurs after the patient has left the abortion facility." Some experts added that, if a patient needs a hospital in the day or week following her abortion, she will likely seek medical attention at the hospital nearest her home.

We have found nothing in Texas' record evidence that shows that, compared to prior law, . . . the new law advanced Texas' legitimate interest in protecting women's health. We add that, when directly asked at oral argument whether Texas knew of a single instance in which the new requirement would have helped even one woman obtain better treatment, Texas admitted that there was no evidence in the record of such a case. . . .

At the same time, the record evidence indicates that the admitting-privileges requirement places a "substantial obstacle in the path of a woman's choice." . . . [A] brief filed in this Court by the Society of Hospital Medicine . . . describes the undisputed general fact that "hospitals often condition admitting privileges on reaching a certain number of admissions per year." . . . [I]n direct testimony, the president of Nova Health Systems . . . pointed out that it would be difficult for doctors regularly perform-

ing abortions at the El Paso clinic to obtain admitting privileges at nearby hospitals because "[d]uring the past 10 years, over 17,000 abortion procedures were performed at the El Paso clinic [and n]ot a single one of those patients had to be transferred to a hospital for emergency treatment, much less admitted to the hospital." In a word, doctors would be unable to maintain admitting privileges or obtain those privileges for the future, because the fact that abortions are so safe meant that providers were unlikely to have any patients to admit. . . .

In our view, the record contains sufficient evidence that the admitting-privileges requirement led to the closure of half of Texas' clinics, or thereabouts. Those closures meant fewer doctors, longer waiting times, and increased crowding. Record evidence also supports the finding that after the admitting-privileges provision went into effect, the "number of women of reproductive age living in a county . . . more than 150 miles from a provider increased from approximately 86,000 to 400,000 . . . and the number of women living in a county more than 200 miles from a provider from approximately 10,000 to 290,000." . . .

UNDUE BURDEN—SURGICAL-CENTER REQUIREMENT

Prior to enactment of the [surgical center] requirement, Texas law required abortion facilities to meet a host of health and safety requirements. . . . H.B. 2 added the requirement that an "abortion facility" meet the "minimum standards . . . for ambulatory surgical centers" under Texas law. . . .

The record makes clear that the surgical-center requirement provides no benefit when complications arise in the context of an abortion produced through medication. That is because, in such a case, complications would almost always arise only after the patient has left the facility. The record also contains evidence indicating that abortions taking place in an abortion facility are safe—indeed, safer than numerous procedures that take place outside hospitals and to which Texas does not apply its surgical-center requirements. The total number of deaths in Texas from abortions was five in the period from 2001 to 2012, or about one every two years (that is to say, one out of about 120,000 to 144,000 abortions). Nationwide, childbirth is 14 times more likely than abortion to result in death, but Texas law allows a midwife to oversee childbirth in the patient's own home. Colonoscopy, a procedure that typically takes place outside a hospital (or surgical center) setting, has a mortality rate 10 times higher than an abortion. Medical treatment after an incomplete miscarriage often involves a procedure identical to that involved in a nonmedical abortion, but it often takes place outside a hospital or surgical center. And Texas partly or wholly grandfathers (or waives in whole or in part the surgical-center requirement for) about two-thirds of the facilities to which the surgical-center standards apply. But it neither grandfathers nor provides waivers for any of the facilities that perform abortions. These facts indicate that the surgical-center provision imposes "a requirement that simply is not based on differences" between abortion and other surgical procedures "that are reasonably related to" preserving women's health, the asserted "purpos[e] of the Act in which it is found." *Roe,* 410 U.S., at 194.

Moreover, many surgical-center requirements are inappropriate as applied to surgical abortions. Requiring scrub facilities; maintaining a one-way traffic pattern through the facility; having ceiling, wall, and floor finishes; separating soiled utility and sterilization rooms; and regulating air pressure, filtration, and humidity control can help

PHOTO 4.3. Demonstrators on the steps of the Supreme Court protest a Texas law regulating abortion, 2016. Courtesy of Lorie Shaull via Flickr.

reduce infection where doctors conduct procedures that penetrate the skin. But abortions typically involve either the administration of medicines or procedures performed through the natural opening of the birth canal, which is itself not sterile. Nor do provisions designed to safeguard heavily sedated patients (unable to help themselves) during fire emergencies . . . provide any help to abortion patients, as abortion facilities do not use general anesthesia or deep sedation. Further, since the few instances in which serious complications do arise following an abortion almost always require hospitalization, not treatment at a surgical center, surgical-center standards will not help in those instances either. . . .

At the same time, the record provides adequate evidentiary support for the District Court's conclusion that the surgical-center requirement places a substantial obstacle in the path of women seeking an abortion. The parties stipulated that the requirement would further reduce the number of abortion facilities available to seven or eight facilities, located in Houston, Austin, San Antonio, and Dallas/Fort Worth. In the District Court's view, the proposition that these "seven or eight providers could meet the demand of the entire State stretches credulity." . . .

We agree with the District Court that the surgical-center requirement, like the admitting-privileges requirement, provides few, if any, health benefits for women, poses a substantial obstacle to women seeking abortions, and constitutes an "undue burden" on their constitutional right to do so. . . .

Justice Thomas, dissenting.

. . . [T]oday's opinion tells the courts that, when the law's justifications are medically uncertain, they need not defer to the legislature, and must instead assess medical

justifications for abortion restrictions by scrutinizing the record themselves. . . . These precepts are nowhere to be found in *Casey* or its successors, and transform the undue-burden test to something much more akin to strict scrutiny. . . .

If our recent cases illustrate anything, it is how easily the Court tinkers with levels of scrutiny to achieve its desired result. . . . The Court should abandon the pretense that anything other than policy preferences underlies its balancing of constitutional rights and interests in any given case.

. . .

As Justice Thomas's dissent highlights, the majority opinion in *Whole Woman's Health* refused to defer to the Texas legislature's judgment, instead demanding sound evidence that TRAP laws would provide medical benefit. The Court's less deferential approach is consistent with recognition that the right to choose abortion remains a fundamental right (a position with which Justice Thomas disagrees). Indeed, the very premise of strict scrutiny is that individual rights impose counter-majoritarian constraints on government action, demanding a more active role for the judiciary and less deference to the elected branches. Whether the Court continues to recognize a woman's fundamental right to choose abortion as the composition of the Court changes in coming years remains to be seen.

The level of judicial scrutiny triggered by privacy rights has far-reaching significance for public health. In *Lawrence v. Texas,* 539 U.S. 558 (2003), for example, the Court invalidated a state anti-sodomy statute on the grounds that the privacy of intimate sexual conduct among consenting adults is protected by substantive due process. The decision has been lauded by public health advocates who argue that privacy protections encourage at-risk individuals to seek out testing and counseling about safer sexual practices. In his opinion for the majority, Justice Kennedy described the privacy rights protected in the Constitution as encompassing "personal decisions relating to marriage, procreation, contraception, family relationships, [and] child rearing."

The privacy of intimate relationships has important implications for efforts to prevent sexually transmitted infections. In the excerpt that follows (which also touches on the right to freedom of association protected by the First Amendment), a New York state trial court grapples with the right to privacy in the context of the state's efforts to combat the HIV/AIDS epidemic using traditional police power authority to shut down facilities deemed a nuisance to the public's health, safety, and welfare. As you read the opinion, consider the cultural context of an outbreak of a dreaded disease that, at the time, was primarily associated with unsafe sexual practices among gay and bisexual men, who faced

significant discrimination and even violence because of their sexual orientation. What degree of judicial deference to the determinations of public health officials is appropriate under such circumstances? Is deference likely to exacerbate or ameliorate the influence of social stigma and bias?

*NEW YORK V. NEW ST. MARK'S BATHS**

Supreme Court of New York
Decided January 6, 1986

This action by the health authorities of the City of New York is taken against defendant The New St. Marks Baths as a step to limit the spread of the disease known as AIDS (Acquired Immune Deficiency Syndrome). The parties are in agreement with respect to the deadly character of this disease and the dire threat that its spread, now in epidemic proportions, poses to the health and well-being of the community. . . .

On October 25, 1985, the State Public Health Council, with the approval of the intervening New York State Commissioner of Health, adopted an emergency resolution adding a new regulation to the State Sanitary Code. This added regulation . . . provided: "Prohibited Facilities: No establishment shall make facilities available for the purpose of sexual activities in which facilities high risk sexual activity takes place. Such facilities shall constitute a public nuisance dangerous to the public health." . . . [T]he regulation furnished definitions:

a. "Establishment" shall mean any place in which entry, membership, goods or services are purchased.
b. "High Risk Sexual Activity" shall mean anal intercourse and fellatio.

The Public Health Council based this regulation on the Commissioner's "findings" that:

> Establishments including certain bars, clubs and bathhouses which are used as places for engaging in high risk sexual activities contribute to the propagation and spread of such AIDS-associated retro-viruses; Appropriate public health intervention to discontinue such exposure at such establishments is essential to interrupting the epidemic among the people of the State of New York.

Thereafter, on or about December 9, 1985, the City commenced this action . . . for an injunction closing the New St. Mark's Baths (St. Mark's) as a public nuisance citing the health risks at St. Mark's as defined in the state regulation. . . . Defendants challenged the state regulation on the grounds that it was an invasion of defendants' patrons' rights to privacy and freedom of association under the United States Constitution. . . .

The City has submitted ample supporting proof that high risk sexual activity has been taking place at St. Mark's on a continuous and regular basis. Following numerous on-site visits by City inspectors, over 14 separate days, these investigators have

* 497 N.Y.S. 2d 979.

submitted affidavits describing 49 acts of high risk sexual activity. . . . This evidence of high risk sexual activity, all occurring either in public areas of St. Mark's or in enclosed cubicles left visible to the observer without intrusion therein, demonstrates the inadequacy of self-regulatory procedures by the St. Mark's attendant staff, and the futility of any less intrusive solution to the problem other than closure.

With a demonstrated death rate from AIDS . . . plaintiffs and the intervening State officers have demonstrated a compelling State interest in acting to preserve the health of the population. Where such a compelling State interest is demonstrated even the constitutional rights of privacy and free association must give way provided, as here, it is also shown that the remedy adopted is the least intrusive reasonably available. Furthermore, it is by no means clear that defendants' rights will, in actuality, be adversely affected in a constitutionally recognized sense by closure of St. Mark's. The privacy protection of sexual activity conducted in a private home (e.g., *Griswold v. Connecticut,* 381 U.S. 479 (1965); *Stanley v. Georgia,* 394 U.S. 557 (1969); accord, *People v. Onofre,* 51 N.Y.2d 476 (N.Y. 1980) does not extend to commercial establishments simply because they provide an opportunity for intimate behavior or sexual release. . . . As stated in *Stratton v. Drumm,* 445 F. Supp. 1305, 1309 (D. Conn. 1978): "privacy and freedom of association . . . rights do not extend to commercial ventures."

[Four self-identified patrons of St. Marks who intervened in the action to assert their individual rights], of course, are not commercial venturers. However, the closure of this bath house does not extinguish their opportunities for unrestricted association in establishments which avoid creating a serious risk to the public health.

Also, State police power has been upheld over claims of 1st Amendment rights of association where the nature of the assemblage is not for the advancement of beliefs and ideas but predominantly either for entertainment or gratification. A tangential impact upon association or expression is insufficient to obstruct the exercise of the State's police power to protect public health and safety.

To be sure, defendants and the intervening patrons challenge the soundness of the scientific judgments upon which the Health Council regulation is based, citing, inter alia, the observation of the City's former Commissioner of Health in a memorandum dated October 22, 1985 that "closure of bathhouses will contribute little if anything to the control of AIDS." Defendants particularly assail the regulation's inclusion of fellatio as a high risk sexual activity and argue that enforced use of prophylactic sheaths would be a more appropriate regulatory response. They go further and argue that facilities such as St. Mark's, which attempts to educate its patrons with written materials, signed pledges, and posted notices as to the advisability of safe sexual practices, provide a positive force in combatting AIDS, and a valuable communication link between public health authorities and the homosexual community. While these arguments and proposals may have varying degrees of merit, they overlook a fundamental principle of applicable law: "It is not for the courts to determine which scientific view is correct in ruling upon whether the police power has been properly exercised. The judicial function is exhausted with the discovery that the relation between means and end is not wholly vain and fanciful, an illusory pretense." . . . Justification for plaintiffs' application here more than meets that test. . . .

• • •

The St. Mark's bathhouse and its patrons relied on cases recognizing privacy interests as fundamental rights in the context of access to contraception, laws criminalizing private possession of pornographic materials depicting consenting adults, and laws criminalizing sexual conduct between consenting adults in private settings. The court was reluctant to extend these protections to what it characterized as a commercial context. Does the opinion reflect strict scrutiny, rational basis review, or something in between? It does not specify. The court noted that the state had established a compelling purpose (as would be required to satisfy strict scrutiny) and had demonstrated that the state's action was the least restrictive alternative (but was it really?). On the other hand, the court exercised restraint, deferring to the scientific judgments of regulators, as would be appropriate under a mere rationality standard. The court maintained this deferential stance even when presented with evidence of disagreement among scientific experts as to the likely effectiveness of bathhouse closures as a measure to control the spread of AIDS. In the end, the court's insistence that "[t]he judicial function is exhausted with the discovery that the relation between means and end is not wholly vain and fanciful" is a classic description of rational basis review.

Notably, *St. Mark's* and *Whole Woman's Health* are the first cases we have excerpted in which businesses, rather than natural persons, challenged government action on the grounds that it violated the individual rights of third parties. St. Mark's argued that the City's efforts to shut it down should be barred based on the infringement of its patrons' rights. Indeed, the court specifically noted that the business itself does not have protected rights to privacy or association. Similarly, in *Whole Woman's Health,* the dissenting justices took issue with the majority's willingness to allow abortion providers to challenge the Texas TRAP law based on their patients' rights. In other cases, businesses assert constitutional rights on their own behalf, rather than serving as a mere conduit for asserting the rights of their owners, employees, or patrons. In the *Slaughterhouse Cases* and *Lochner,* for example, the parties asserting constitutional rights included business associations as well as individual tradespeople.

The question of whether and when business associations enjoy constitutionally protected individual rights (referred to as *corporate personhood*) has generated significant controversy in recent years. The Supreme Court's decision in *Citizens United v. Federal Election*

Commission, 558 U.S. 310 (2010), that certain campaign finance laws impermissibly infringe on the free speech rights of corporations prompted public outcry about the outsize influence of corporate interests in politics. What many protesters fail to appreciate, however, is that the Court has a long history of holding that corporations are persons within the meaning of at least *some* portions of the Bill of Rights. In the cases that follow, we will continue to address the difficult issue of which constitutional rights should be understood to protect business associations as entities distinct from their individual owners.

EQUAL PROTECTION

In addition to safeguarding due process, the Fourteenth Amendment also prohibits a state from "deny[ing] to any person within its jurisdiction equal protection of the laws." The right to equal protection under the law has been applied to the federal government via incorporation into the Fifth Amendment. The most famous equal protection cases are those in which the Court has applied strict scrutiny to invalidate laws based on *suspect* classifications, such as race, color, or national origin. A suspect classification is found when a group has historically been subject to invidious discrimination. This rationale was set forth in a famous footnote in *U.S. v. Carolene Products Co.*, 304 U.S. 144 (1938) in which the Court suggested that "prejudice against discrete and insular minorities may be a special condition, which tends seriously to curtail the operation of those political processes ordinarily to be relied upon to protect minorities, and which may call for a correspondingly more searching judicial inquiry." In *Brown v. Board of Education,* (1954), for example, the Court held that racial segregation in public schools denied Black children equal protection under the law. *Yick Wo v. Hopkins* and *Jew Ho v. Williamson,* discussed above, predated the Court's adoption of the "levels of review" framework established in *Carolene Products,* but the opinions in those cases reflect similar analysis. Notably, discrimination on the basis of sex and disability (which are treated as quasi-suspect classifications) has been deemed by the Court to trigger intermediate scrutiny, rather than the strict scrutiny applied to classifications based on race, color, or national origin.

In addition to indicating that laws based on suspect classifications would be subject to strict scrutiny, Justice Harlan's opinion in *Carolene Products* also exemplifies the Court's post–New Deal jurisprudence, in

which it repudiated many of its *Lochner*-era decisions and adopted a highly deferential stance toward legislative judgments on matters of economic regulation. In *Carolene,* the Court rejected a food and beverage corporation's claim that federal regulations prohibiting the interstate transport of filled milk (skim milk compounded with oil) violated its constitutionally protected rights. The Court noted that the regulation was properly within legislative discretion, and hence was not for the courts to overrule because it was supported by substantial public health evidence, and was not arbitrary or irrational. *Carolene Products* marked the Court's first articulation of the rational basis test. The Court also endorsed an incremental approach to regulation, noting that the Equal Protection Clause does not require government "to prohibit all like evils, or none. A Legislature may hit at an abuse which it has found, even though it has failed to strike at another."

In Justice Harlan's view, the role of the courts is to correct failures of the democratic process, imposing counter-majoritarian constraints on government action to protect fundamental rights and minority groups historically subjected to discrimination, but otherwise leaving matters of social and economic policy to the democratically accountable branches of government. As one constitutional scholar has noted, this approach "defined the federal courts' agenda for a generation—one of the most momentous generations in the history of the Supreme Court and the federal judiciary. And today, when the influence of the footnote has diminished, to say the least, it presents probably the most impressive challenge to the course that the Court is taking" (Strauss 2010, 1253).

And just what is the current course that the Court is taking? In recent years, the Supreme Court and many lower courts have become far less deferential in their exercise of rational basis review. In some cases, such as those invalidating laws that discriminate on the basis of sexual orientation, this approach has been greeted with praise from progressives. But in other cases, such as those in which for-profit corporations assert individual rights as a shield from economic regulation, the impact on the public's health and safety is lamentable. In the excerpt that follows, we present an example of this trend in the context of an equal protection claim brought by a major drugstore chain to invalidate local regulations aimed at reducing tobacco use. The trend is also evident in recent cases increasing the First Amendment protection afforded to commercial advertising, which we discuss in the section that follows.

*WALGREEN CO. V. CITY AND CO. OF SAN FRANCISCO**

Court of Appeals of California, First District
Decided June 8, 2010

. . . The legislation challenged in this appeal amended the San Francisco Health Code to provide that "No person shall sell tobacco products in a pharmacy." . . . The prohibition on sales of tobacco products is not limited to the licensed pharmacy portion of a store but instead applies to the establishment as a whole.

In addition to traditional independent pharmacies, which sell little more than prescription drugs, over-the-counter medications, and personal care items, the term "pharmacy" encompasses chain stores, supermarkets, and big box stores that sell a variety of products such as food, beverages, paper goods, and miscellaneous items in addition to prescription drugs. However, although a "general grocery store" or a "big box store" that contains a licensed pharmacy qualifies as a "pharmacy" under the ordinance, the ordinance specifically excludes these establishments from the prohibition on sales of tobacco products. As a result, the ordinance prohibits a Walgreens that contains a licensed pharmacy from selling tobacco products but imposes no such limitation on a Safeway supermarket or a Costco big box store that contains a licensed pharmacy.

The legislative findings associated with the ordinance cite the adverse health effects associated with tobacco use. The principal finding upon which the ordinance is premised states: "Through the sale of tobacco products, pharmacies convey tacit approval of the purchase and use of tobacco products. This approval sends a mixed message to consumers who generally patronize pharmacies for health care services. . . . " As further support for the ordinance, the City's Board of Supervisors also found that "[p]harmacies and drugstores are among the most accessible and trusted sources of health information among the public. . .," and that "[c]linicians can have a significant effect on smokers' probability of quitting smoking. . . . "

As reflected in the legislative findings, various medical and pharmaceutical organizations advocate prohibiting sales of tobacco products in pharmacies. . . . As far back as 1970 the American Pharmaceutical Association declared that "mass display of cigarettes in pharmacies is in direct contradiction to the role of a pharmacy as a public health facility." . . .

During public hearings on the ordinance, one of its main proponents, Dr. Mitchell Katz, the City's director of public health, addressed why the legislation was directed at only certain stores containing licensed pharmacies. Dr. Katz explained: " . . . I ask you, in your own experience, if we stop people going into a Walgreens, going into a Rite-Aid, going into one of these independent pharmacies and said, What kind of store are you going into? [T]hey would say, Pharmacy. If you stop someone going into a supermarket, and [say], What kind of store are you going into? [E]ven a supermarket that has a drugstore, they'd say, I'm going into a supermarket. And that's the social perceptibility difference. . . . You can see as a total of sales that Walgreens, Rite-Aid, and the two chain stores, [pharmacy sales are] their major line of work, and to me that makes a big

* 110 Cal. Rptr. 3d 498.

difference in terms of how those establishments are viewed by vulnerable adolescents." . . .

The Fourteenth Amendment to the United States Constitution provides that "No State shall . . . deny to any person within its jurisdiction the equal protection of the laws." The California Constitution likewise prohibits the denial of equal protection. The concept of the equal protection of the laws compels recognition of the proposition that persons similarly situated with respect to the legitimate purpose of the law receive like treatment. A corporation is considered a "person" entitled to the constitutional guarantee of equal protection. . . .

The City concedes that, for purposes of the challenged ordinance, all retail establishments containing licensed pharmacies are similarly situated. [Thus,] Walgreens has met its threshold burden to show that the different types of stores containing licensed pharmacies are sufficiently similar to merit application of some level of scrutiny to determine whether distinctions between the two groups justify the unequal treatment. The next step in the analysis is to determine the appropriate level of scrutiny to apply.

In resolving equal protection issues, the United States Supreme Court has used three levels of analysis. Distinctions in statutes that involve suspect classifications or touch upon fundamental interests are subject to strict scrutiny, and can be sustained only if they are necessary to achieve a compelling state interest. Classifications based on gender are subject to an intermediate level of review. But most legislation is tested only to determine if the challenged classification bears a rational relationship to a legitimate state purpose. Because the challenged ordinance does not involve a suspect classification or interfere with the exercise of a fundamental right, the parties agree that the deferential "rational relationship" or "rational basis" test governs our consideration of Walgreens's equal protection claim.

Rational basis review . . . manifests restraint by the judiciary in relation to the discretionary act of a co-equal branch of government; in so doing it invests legislation involving . . . differentiated treatment with a presumption of constitutionality and requires merely that distinctions drawn by a challenged statute bear some rational relationship to a conceivable legitimate state purpose. "[A] legislative choice is not subject to courtroom factfinding and may be based on rational speculation unsupported by evidence or empirical data." *FCC v. Beach Communications, Inc.*, 508 U.S. 307 (1993).

"[T]hose attacking the rationality of the legislative classification have the burden to negative every conceivable basis which might support it." *Id.* . . . But this is not an impossible task. The rationale must be plausible and the factual basis for that rationale must be *reasonably* conceivable. And even in the ordinary equal protection case calling for the most deferential of standards, courts must ascertain the relation between the classification adopted and the object to be attained. The search for the link between classification and objective gives substance to the Equal Protection Clause. . . .

[A]llegations in the complaint concerning the similarities between Walgreens and general grocery stores support the contention there is no difference in any implied message that might be conveyed by selling tobacco products in the two types of stores. These allegations appear to be beyond dispute, with the City conceding that similarities exist. Thus, for example, at both Walgreens and the exempt general grocery stores, the licensed pharmacy is located in the back of the store. . . . Stores

subject to the ordinance and grocery stores exempt from it typically advertise themselves as health promoting and have signage on the outside of the store advertising the licensed pharmacy within. Indeed, Safeway advertised itself as promoting "Healthy Living." . . .

[T]he fact that the public considers it more likely to find a licensed pharmacy in a Walgreens than in a supermarket, or is more likely to purchase prescription drugs at a Walgreens than in a supermarket, does not rationally explain why in those stores that contain a licensed pharmacy, the implied approval of smoking is greater in one than the other.

It is true, as the City argues, that courts do not force policymakers to tackle an entire problem at one time. Past decisions establish that, under the rational relationship test, the state may recognize that different categories or classes of persons within a larger classification may pose varying degrees of risk of harm, and properly may limit a regulation to those classes of persons as to whom the need for regulation is thought to be more crucial or imperative. It is also the case, however, that the legislative body, when it chooses to address a particular area of concern in less than comprehensive fashion by merely "striking the evil where it is felt most" may not do so wholly at its whim. Further, even when a classification is considered an incremental or partial step in addressing a problem, the differentiation must still be based on some plausible reason, based on reasonably conceivable facts. . . .

[T]he City urges it is rational to favor supermarkets over stores such as Walgreens in order to discourage them from leaving the City. . . . [This] rationale for favoring supermarkets is questionable, at best. There is nothing in the record to suggest the City has a policy of favoring supermarkets over stores such as Walgreens, and none of the ordinance's findings mention an economic basis for the exemptions afforded to general grocery stores. Moreover, given that big box stores as well as general grocery stores enjoy the exemption from the ban on sales of tobacco products, it seems unlikely the exemption could have been motivated by a desire to encourage supermarkets to remain in the City. In short, the economic rationale for the exemption falls into that category of "fictitious purposes that could not have been within the contemplation of the Legislature. . . ."

For the reasons set forth above, Walgreens's complaint adequately states causes of action for a violation of the equal protection provisions of the United States and California Constitutions. . . .

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Walgreen remains an outlier among equal protection cases. For the most part, if the classification a law draws between the entities to which it does and does not apply is not *suspect*, the courts apply rational basis review in a highly deferential manner and the law is very likely to pass muster. Many other jurisdictions have upheld laws similar to the tobacco control measure at issue in *Walgreen*. Furthermore, the direct impact of the decision in California was minimal. San Francisco immediately redrafted its ordinance to apply to all pharmacies and the new version

survived a legal challenge based on equal protection, substantive due process, and preemption (see chapter 12). Nonetheless, *Walgreen* is indicative of a movement gaining traction among some judges, one that is concerning to public health advocates because of the *Lochner*-style limits on the police power its adherents seek to impose.

When courts take a deferential stance toward the elected branches of government, bad laws are sometimes upheld. Some of the laws upheld following rational basis review are clearly the product of interest group lobbying rather than concern for the public's health, safety, and welfare. The filled milk regulation at issue in *Carolene Products,* for example, though purportedly aimed at protecting the public's health and preventing fraud, was certainly a boon to the condensed milk industry with which Carolene was competing. It may be that the San Francisco Board of Supervisors excluded big box stores and grocery stores because their owners made significant campaign contributions. But does the potential for police power regulations to reflect special interests justify sweeping authority for unelected judges to substitute their own judgment as to what ends government should pursue and how? In the section that follows, we take up this issue in the context of First Amendment protections for commercial speech.

FREEDOM OF SPEECH

The First Amendment provides that "Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof; or abridging the freedom of speech, or of the press; or the right of the people peaceably to assemble, and to petition the Government for a redress of grievances." These guarantees set the United States apart from many other democracies, which do not place quite so high a value on the free exchange of ideas. The First Amendment and freedom of speech "came of age" in the twentieth century "occupy[ing] the status of constitutional and cultural lodestars." Indeed, some have argued that the tiered approach to judicial review typically attributed to *Carolene Products* actually began several years earlier "with the perception that speech was a special sort of liberty and deserved particular judicial solicitude in a modern democratic society" (White 1996, 300–301).

The free exchange of ideas is indeed essential to effective and legitimate democratic governance. It also has many benefits for the public's health, as the following opinion indicates.

*AGENCY FOR INTERNATIONAL DEVELOPMENT V. ALLIANCE FOR OPEN SOCIETY INTERNATIONAL, INC.**

Supreme Court of the United States
Decided June 20, 2013

Chief Justice Roberts delivered the opinion of the Court.

The United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003 outlined a comprehensive strategy to combat the spread of HIV/AIDS around the world. As part of that strategy, Congress authorized the appropriation of billions of dollars to fund efforts by nongovernmental organizations to assist in the fight. The Act imposes two related conditions on that funding: First, no funds made available by the Act "may be used to promote or advocate the legalization or practice of prostitution or sex trafficking." And second, no funds may be used by an organization "that does not have a policy explicitly opposing prostitution and sex trafficking." This case concerns the second of these conditions, referred to as the Policy Requirement. The question is whether that funding condition violates a recipient's First Amendment rights. . . .

The Act's approach to reducing behavioral risks is multifaceted. The President's strategy for addressing such risks must, for example, promote abstinence, encourage monogamy, increase the availability of condoms, promote voluntary counseling and treatment for drug users, and, as relevant here, "educat[e] men and boys about the risks of procuring sex commercially" as well as "promote alternative livelihoods, safety, and social reintegration strategies for commercial sex workers." Congress found that the "sex industry, the trafficking of individuals into such industry, and sexual violence" were factors in the spread of the HIV/AIDS epidemic, and determined that "it should be the policy of the United States to eradicate" prostitution and "other sexual victimization." . . .

To enforce the Policy Requirement, the [Department of Health and Human Services (HHS) and the United States Agency for International Development (USAID)] have directed that the recipient of any funding under the Act agree in the award document that it is opposed to "prostitution and sex trafficking because of the psychological and physical risks they pose for women, men, and children."

Respondents are a group of domestic organizations engaged in combating HIV/AIDS overseas. . . . Respondents fear that adopting a policy explicitly opposing prostitution may alienate certain host governments, and may diminish the effectiveness of some of their programs by making it more difficult to work with prostitutes in the fight against HIV/AIDS. They are also concerned that the Policy Requirement may require them to censor their privately funded discussions in publications, at conferences, and in other forums about how best to prevent the spread of HIV/AIDS among prostitutes. In 2005, respondents . . . commenced this litigation, seeking a declaratory judgment that the Government's implementation of the Policy Requirement violated their First Amendment rights. Respondents sought a preliminary injunction barring the Government from cutting off their funding under the Act for the duration of the litigation, from unilaterally terminating their cooperative agreements with the United States, or from otherwise taking action solely on the basis of respondents' own privately funded

* 133 S. Ct. 2321.

speech. The District Court granted such a preliminary injunction, and the Government appealed. . . .

At the heart of the First Amendment lies the principle that each person should decide for himself or herself the ideas and beliefs deserving of expression, consideration, and adherence. Were it enacted as a direct regulation of speech, the Policy Requirement would plainly violate the First Amendment. The question is whether the Government may nonetheless impose that requirement as a condition on the receipt of federal funds. . . .

As a general matter, if a party objects to a condition on the receipt of federal funding, its recourse is to decline the funds. . . . At the same time, however, we have held that the Government may not deny a benefit to a person on a basis that infringes his constitutionally protected . . . freedom of speech even if he has no entitlement to that benefit. In some cases, a funding condition can result in an unconstitutional burden on First Amendment rights. . . .

In the present context, the relevant distinction that has emerged from our cases is between conditions that define the limits of the government spending program—those that specify the activities Congress wants to subsidize—and conditions that seek to leverage funding to regulate speech outside the contours of the program itself. The line is hardly clear, in part because the definition of a particular program can always be manipulated to subsume the challenged condition. . . .

[T]he Government contends that "if organizations awarded federal funds to implement Leadership Act programs could at the same time promote or affirmatively condone prostitution or sex trafficking, whether using public *or private* funds, it would undermine the government's program and confuse its message opposing prostitution and sex trafficking." But the Policy Requirement goes beyond preventing recipients from using private funds in a way that would undermine the federal program. It requires them to pledge allegiance to the Government's policy of eradicating prostitution. As to that, we cannot improve upon what Justice Jackson wrote for the Court 70 years ago: "If there is any fixed star in our constitutional constellation, it is that no official, high or petty, can prescribe what shall be orthodox in politics, nationalism, religion, or other matters of opinion or force citizens to confess by word or act their faith therein." . . .

The Policy Requirement compels as a condition of federal funding the affirmation of a belief that by its nature cannot be confined within the scope of the Government program. In so doing, it violates the First Amendment and cannot be sustained.

. . .

Private non-profit organizations like Open Society provide many essential public health services, supplementing underfunded governmental efforts in the United States and globally. Restrictions on their provision of accurate information are detrimental to the public's health. At the same time, civil society organizations often campaign for health protection, and defending their right to do so is vital.

Nonetheless, some private speech encourages unhealthy behavior and threatens the public's health. Prior to the mid-1970s, commercial speech aimed at marketing goods and services was not granted any First

Amendment protection whatsoever. Commercial advertising by manufacturers and retailers of products and services that are potentially harmful to the public's health, such as tobacco products, unhealthy food and beverage products, pharmaceuticals, and alcoholic beverages poses a risk to the public's health. The courts, until relatively recently, almost uniformly upheld advertising restrictions and disclosure mandates. In recent years, however, the Court has steadily increased First Amendment protection for commercial speech. We will discuss the use of the First Amendment to strike down advertising restrictions and disclosure mandates in chapter 12. Here, we focus on the overarching issue of the First Amendment's deregulatory impact when applied to commercial speech.

As you read the Supreme Court opinion that follows, consider the interests of the various stakeholders involved: pharmaceutical companies, physicians, and consumers. The government also has a major stake because it pays for health care through publically funded insurance programs. Why does the Court hold that pharmaceutical companies' interest in marketing brand-name drugs to physicians (whose prescribing records indicate that they have favored less expensive generics or other competitors' products) trumps other interests?

*SORRELL V. IMS HEALTH INC.**

Supreme Court of the United States
Decided June 23, 2011

Justice Kennedy delivered the opinion of the Court.

. . . Pharmaceutical manufacturers promote their drugs to doctors through a process called "detailing." This often involves a scheduled visit to a doctor's office to persuade the doctor to prescribe a particular pharmaceutical. Detailers bring drug samples as well as medical studies that explain the "details" and potential advantages of various prescription drugs. . . . Knowledge of a physician's prescription practices—called "prescriber-identifying information"—enables a detailer better to ascertain which doctors are likely to be interested in a particular drug and how best to present a particular sales message. Detailing is an expensive undertaking, so pharmaceutical companies most often use it to promote high-profit brand-name drugs protected by patent. Once a brand-name drug's patent expires, less expensive bioequivalent generic alternatives are manufactured and sold.

Pharmacies, as a matter of business routine and federal law, receive prescriber-identifying information when processing prescriptions. Many pharmacies sell this information to "data miners," firms that analyze prescriber-identifying information

* 564 U.S. 552.

and produce reports on prescriber behavior. Data miners lease these reports to pharmaceutical manufacturers subject to nondisclosure agreements. Detailers, who represent the manufacturers, then use the reports to refine their marketing tactics and increase sales.

In 2007, Vermont enacted the Prescription Confidentiality Law. . . . The provision begins by prohibiting pharmacies, health insurers, and similar entities from selling prescriber-identifying information, absent the prescriber's consent. . . . The provision then goes on to prohibit pharmacies, health insurers, and similar entities from allowing prescriber-identifying information to be used for marketing, unless the prescriber consents. This prohibition in effect bars pharmacies from disclosing the information for marketing purposes. Finally, the provision . . . bars pharmaceutical manufacturers and pharmaceutical marketers from using prescriber-identifying information for marketing, again absent the prescriber's consent. The Vermont attorney general may pursue civil remedies against violators. . . .

The present case involves two consolidated suits. One was brought by three Vermont data miners, the other by an association of pharmaceutical manufacturers that produce brand-name drugs. . . . Contending that § 4631(d) violates their First Amendment rights as incorporated by the Fourteenth Amendment, the respondents sought declaratory and injunctive relief against the petitioners, the Attorney General and other officials of the State of Vermont. [The Second Circuit Court of Appeals held the Vermont law unconstitutional. This holding conflicted with the First Circuit Court of Appeals decisions upholding similar laws passed in Maine and New Hampshire.] Recognizing a division of authority regarding the constitutionality of state statutes, this Court granted certiorari. . . .

The questions . . . are whether § 4631(d) must be tested by heightened judicial scrutiny and, if so, whether the State can justify the law.

On its face, Vermont's law enacts content- and speaker-based restrictions on the sale, disclosure, and use of prescriber-identifying information. The provision first forbids sale subject to exceptions based in large part on the content of a purchaser's speech. . . . The statute . . . disfavors marketing, that is, speech with a particular content. More than that, the statute disfavors specific speakers, namely pharmaceutical manufacturers. . . . For example, it appears that Vermont could supply academic organizations with prescriber-identifying information to use in countering the messages of brand-name pharmaceutical manufacturers and in promoting the prescription of generic drugs. . . .

The First Amendment requires heightened scrutiny whenever the government creates a regulation of speech because of disagreement with the message it conveys. . . . Commercial speech is no exception. A consumer's concern for the free flow of commercial speech often may be far keener than his concern for urgent political dialogue. That reality has great relevance in the fields of medicine and public health, where information can save lives.

The State argues that heightened judicial scrutiny is unwarranted because its law is a mere commercial regulation. It is true that restrictions on protected expression are distinct from restrictions on economic activity or, more generally, on nonexpressive conduct. It is also true that the First Amendment does not prevent restrictions directed at commerce or conduct from imposing incidental burdens on speech. That is why a ban on race-based hiring may require employers to remove "White Applicants

Only" signs; why an ordinance against outdoor fires might forbid burning a flag; and why antitrust laws can prohibit agreements in restraint of trade. But § 4631(d) imposes more than an incidental burden on protected expression. Both on its face and in its practical operation, Vermont's law imposes a burden based on the content of speech and the identity of the speaker. . . .

When it enacted § 4631(d), the Vermont Legislature found that the "marketplace for ideas on medicine safety and effectiveness is frequently one-sided in that brand-name companies invest in expensive pharmaceutical marketing campaigns to doctors." "The goals of marketing programs," the legislature said, "are often in conflict with the goals of the state." . . . The State has burdened a form of protected expression that it found too persuasive. At the same time, the State has left unburdened those speakers whose messages are in accord with its own views. This the State cannot do.

Justice Breyer, with whom Justice Ginsburg and Justice Kagan join, dissenting.

. . . [U]ntil today, this Court has *never* found that the First Amendment prohibits the government from restricting the use of information gathered pursuant to a regulatory mandate—whether the information rests in government files or has remained in the hands of the private firms that gathered it. Nor has this Court *ever* previously applied any form of "heightened" scrutiny in any even roughly similar case. . . .

[T]he Court's vision of its reviewing task threatens to return us to a happily bygone era when judges scrutinized legislation for its interference with economic liberty. History shows that the power was much abused and resulted in the constitutionalization of economic theories preferred by individual jurists. . . . At best the Court opens a Pandora's Box of First Amendment challenges to many ordinary regulatory practices that may only incidentally affect a commercial message. At worst, it reawakens *Lochner*'s pre–New Deal threat of substituting judicial for democratic decisionmaking where ordinary economic regulation is at issue.

FREEDOM OF RELIGION

The First Amendment also protects the freedom of religion. The Establishment Clause has been used to invalidate some types of religious exemptions to vaccination mandates, an issue that we will take up in chapter 10. Here, our focus is on the Free Exercise Clause.

Courts have long struggled with how to secure freedom of religion when religious practices or beliefs conflict with generally applicable regulations that do not expressly target a particular religious group. In *Employment Division, Dep't of Human Resources of Oregon v. Smith*, 494 U.S. 872 (1990), the Supreme Court ruled in favor of generally applicable regulations, upholding an Oregon law regulating controlled substances against a challenge by members of the Native American Church who were denied unemployment benefits after being fired from their jobs for ingesting peyote for sacramental purposes. The Court's decision, authored by Justice Scalia, held that generally applicable

regulations were not subject to heightened scrutiny merely because they imposed an incidental burden on religious practices. As a matter of constitutional law, although government has the *power* to accommodate religious practices by creating exemptions from otherwise applicable regulations, it is not *required* to do so.

Smith generated significant backlash from religious freedom advocates. In its aftermath, constitutional claims to religious exemptions from generally applicable regulations—including vaccination mandates—face an uphill battle. Relying on dicta in *Smith,* some lower courts have held that religious objectors may be entitled to more searching judicial review of burdensome government interventions when they assert *hybrid rights* claims combining their religious freedom argument with other protected interest such as the right to bodily integrity or freedom of expression. For example, in a 2018 Supreme Court case, *Masterpiece Cakeshop, Ltd., v. Colorado Civil Rights Commission,* 584 U.S. ___, a baker who refused to sell a wedding cake to a same-sex couple asserted that his freedom of religion and freedom of expression are infringed by state laws prohibiting discrimination on the basis of sexual orientation. The Court decided the case on narrow grounds without discussing the plaintiff's hybrid rights claim. Similarly, some parents argue that vaccination programs that do not readily grant religious exemptions simultaneously burden their exercise of religion and right to privacy. We will discuss this issue in more detail in chapter 10.

In the absence of strong constitutional protections for individuals who claim their religious freedom is burdened by generally applicable government actions, lawmakers have created statutory protections. Under federal law, for example, health care providers have the right to accommodations in cases where they object to providing services—such as contraceptives, abortions, or termination of life-sustaining treatment—on the basis of their religious beliefs. In 2018, President Trump announced the creation of a new Conscience and Religious Freedom Division within the Department of Health and Human Services to enforce these protections. How these laws apply in cases where patients claim constitutional rights to nondiscrimination and medical autonomy is a matter of debate.

Congress responded to the Supreme Court's decision in *Smith* by passing the Religious Freedom Restoration Act (RFRA), which sought to reinstate heightened review for generally applicable regulations that burden religious exercise. Congress drafted RFRA to apply to all government action, but the Supreme Court later held that Congress lacked authority to impose such restrictions on state and local governments. As

a result, federal statutes are subject to heightened scrutiny under RFRA unless Congress specifies in the challenged statute that RFRA does not apply. State and local action is not subject to review under the federal RFRA (an important limit given that vaccination mandates operate almost exclusively at the state level), but many state legislatures have adopted their own religious freedom statutes.

RFRA does not amend the Constitution to create stronger protections for religious liberty; it is not possible for Congress to overturn a Supreme Court decision without a constitutional amendment ratified by three-quarters of the states. As the opinion excerpted below demonstrates, however, statutory rights such as those created by RFRA can constrain government action in important ways, in spite of their sub-constitutional status.

*BURWELL V. HOBBY LOBBY STORES, INC.**

Supreme Court of the United States
Decided June 30, 2014

Justice Alito delivered the opinion of the Court.

. . . At issue in these cases are [Department of Health and Human Services (HHS)] regulations promulgated under the Patient Protection and Affordable Care Act of 2010 (ACA). . . . Unless an exception applies, ACA requires an employer's group health plan or group-health-insurance coverage to furnish "preventive care and screenings" for women without "any cost sharing requirements." Congress itself, however, did not specify what types of preventive care must be covered. Instead, Congress authorized the Health Resources and Services Administration (HRSA), a component of HHS, to make that important and sensitive decision. The HRSA in turn consulted the Institute of Medicine, a nonprofit group of volunteer advisers, in determining which preventive services to require.

In August 2011, based on the Institute's recommendations, the HRSA promulgated the Women's Preventive Services Guidelines. The Guidelines provide that nonexempt employers are generally required to provide "coverage, without cost sharing" for "[a]ll Food and Drug Administration [(FDA)] approved contraceptive methods, sterilization procedures, and patient education and counseling." Although many of the required, FDA-approved methods of contraception work by preventing the fertilization of an egg, four of those methods (those specifically at issue in these cases) may have the effect of preventing an already fertilized egg from developing any further by inhibiting its attachment to the uterus.

HHS also authorized the HRSA to establish exemptions from the contraceptive mandate for "religious employers." That category encompasses "churches, their integrated auxiliaries, and conventions or associations of churches," as well as "the exclusively religious activities of any religious order." In its Guidelines, HRSA exempted these organizations from the requirement to cover contraceptive services.

* 134 S. Ct. 2751.

In addition, HHS has effectively exempted [any religious nonprofit organization] that "holds itself out as a religious organization" and "opposes providing coverage for some or all of any contraceptive services required to be covered . . . on account of religious objections." . . . When a group-health-insurance issuer receives notice that one of its clients has invoked this provision, the issuer must then exclude contraceptive coverage from the employer's plan and provide separate payments for contraceptive services for plan participants without imposing any cost-sharing requirements on the eligible organization, its insurance plan, or its employee beneficiaries. Although this procedure requires the issuer to bear the cost of these services, HHS has determined that this obligation will not impose any net expense on issuers because its cost will be less than or equal to the cost savings resulting from the services. . . .

[The Religious Freedom Restoration Act (RFRA)] prohibits the "Government [from] substantially burden[ing] *a person's* exercise of religion even if the burden results from a rule of general applicability" unless the Government "demonstrates that application of the burden to *the person*—(1) is in furtherance of a compelling governmental interest; and (2) is the least restrictive means of furthering that compelling governmental interest" (emphasis added). The first question that we must address is whether this provision applies to regulations that govern the activities of for-profit corporations like Hobby Lobby, Conestoga, and Mardel.

HHS contends that neither these companies nor their owners can even be heard under RFRA. According to HHS, the companies cannot sue because they seek to make a profit for their owners, and the owners cannot be heard because the regulations, at least as a formal matter, apply only to the companies and not to the owners as individuals. . . .

Congress provided protection for people like the Hahns and Greens by employing a familiar legal fiction: It included corporations within RFRA's definition of "persons." But it is important to keep in mind that the purpose of this fiction is to provide protection for human beings. . . . [P]rotecting the free-exercise rights of corporations like Hobby Lobby, Conestoga, and Mardel protects the religious liberty of the humans who own and control those companies. . . .

The principal argument advanced by HHS and the principal dissent regarding RFRA protection for Hobby Lobby, Conestoga, and Mardel [focus] not on the statutory term "person," but on the phrase "exercise of religion." According to HHS and the dissent, these corporations are not protected by RFRA because they cannot exercise religion. . . .

Some lower court judges have suggested that RFRA does not protect for-profit corporations because the purpose of such corporations is simply to make money. . . . While it is certainly true that a central objective of forprofit corporations is to make money, modern corporate law does not require for-profit corporations to pursue profit at the expense of everything else, and many do not do so. For-profit corporations, with ownership approval, support a wide variety of charitable causes, and it is not at all uncommon for such corporations to further humanitarian and other altruistic objectives.

The Hahns and Greens believe that providing the coverage demanded by the HHS regulations is connected to the destruction of an embryo in a way that is sufficient to make it immoral for them to provide the coverage. This belief implicates a difficult and important question of religion and moral philosophy, namely, the circumstances under which it is wrong for a person to perform an act that is innocent in itself but that has

the effect of enabling or facilitating the commission of an immoral act by another. Arrogating the authority to provide a binding national answer to this religious and philosophical question, HHS and the principal dissent in effect tell the plaintiffs that their beliefs are flawed. For good reason, we have repeatedly refused to take such a step. . . .

Since the HHS contraceptive mandate imposes a substantial burden on the exercise of religion, we must move on and decide whether HHS has shown that the mandate both "(1) is in furtherance of a compelling governmental interest; and (2) is the least restrictive means of furthering that compelling governmental interest."

HHS asserts that the contraceptive mandate serves a variety of important interests, but many of these are couched in very broad terms, such as promoting "public health" and "gender equality." . . . We will assume that the interest in guaranteeing cost-free access to the four challenged contraceptive methods is compelling within the meaning of RFRA, and we will proceed to consider . . . whether HHS has shown that the contraceptive mandate is the least restrictive means of furthering that compelling governmental interest.

The least-restrictive-means standard is exceptionally demanding, and it is not satisfied here. . . . HHS itself has demonstrated that it has at its disposal an approach that is less restrictive than requiring employers to fund contraceptive methods that violate their religious beliefs. As we explained above, HHS has already established an accommodation for nonprofit organizations with religious objections. . . .

[O]ur decision in these cases is concerned solely with the contraceptive mandate. Our decision should not be understood to hold that an insurance coverage mandate must necessarily fall if it conflicts with an employer's religious beliefs. Other coverage requirements, such as immunizations, may be supported by different interests (for example, the need to combat the spread of infectious diseases) and may involve different arguments about the least restrictive means of providing them. . . .

Justice Ginsburg, with whom Justice Sotomayor, Justice Breyer, and Justice Kagan join, dissenting.

In a decision of startling breadth, the Court holds that commercial enterprises, including corporations, along with partnerships and sole proprietorships, can opt out of any law (saving only tax laws) they judge incompatible with their sincerely held religious beliefs. . . .

[U]ntil today, religious exemptions had never been extended to any entity operating in the commercial, profit-making world. . . . The reason why is hardly obscure. Religious organizations exist to foster the interests of persons subscribing to the same religious faith. Not so of for-profit corporations. Workers who sustain the operations of those corporations commonly are not drawn from one religious community. Indeed, by law, no religion-based criterion can restrict the work force of for-profit corporations. . . . By incorporating a business, . . . an individual separates herself from the entity and escapes personal responsibility for the entity's obligations. One might ask why the separation should hold only when it serves the interest of those who control the corporation. . . .

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As described above, the Court has determined whether individual rights apply to corporations on a case-by-case basis. Historically, its decisions tended to recognize rights related to corporations' property interests. The Court has held, for example, that corporations are protected by the Fourth Amendment from unreasonable searches and seizures, but are not protected from compelled self-incrimination under the Fifth Amendment. In the mid-1970s, the Court began to recognize corporations' right to freedom of speech. As the dissent notes, *Hobby Lobby* marked the first time the Court afforded for-profit corporations rights to free exercise of religion. Many have questioned the extent to which the *Hobby Lobby* decision can be cabined as the majority indicates.

BEYOND RIGID DOCTRINAL CATEGORIES

Although it is helpful for pedagogical purposes to segment constitutional protections into tidy categories (e.g., due process, equal protection, freedom of speech, freedom of religion) and levels of review (strict scrutiny, intermediate scrutiny, and rational basis), the Supreme Court's jurisprudence often does not adhere to rigid classifications. Rights to substantive and procedural due process and equal protection are intimately intertwined. Jurisprudence in one area inevitably influences court decisions in another. For example, seven years after the Court held that the substantive due process right to privacy of intimate marital relations encompassed married couples' right of access to contraception, it turned to the Equal Protection Clause to hold that if married couples had a right of access to contraception, it was impermissible to discriminate against unmarried couples in barring their access to the same.

The Court's recent decisions on marriage equality exhibit a similar intertwining of individual rights doctrines. Justice Kennedy's opinion in *Obergefell v. Hodges* did not explicitly recognize sexual orientation as a suspect classification demanding strict scrutiny (as one lower court considering the case had done). Instead, the Court emphasized the intersectionality of rights to due process and equal protection. *Obergefell* and other recent decisions suggest that the Court is moving away from the tiered standards of review that dominated its decisions for decades and toward a sliding-scale approach whereby the level of scrutiny increases along with the degree of government intrusion. As you read the excerpt that follows, consider the benefits and drawbacks of a

sliding-scale approach—in the context of decisions about same-sex marriage and beyond.

*OBERGEFELL v. HODGES**

Supreme Court of the United States
Decided June 26, 2015

Justice Kennedy delivered the opinion of the Court.

. . . These cases come from Michigan, Kentucky, Ohio, and Tennessee, States that define marriage as a union between one man and one woman. The petitioners are 14 same-sex couples and two men whose same-sex partners are deceased. The respondents are state officials responsible for enforcing the laws in question. The petitioners claim the respondents violate the Fourteenth Amendment by denying them the right to marry or to have their marriages, lawfully performed in another State, given full recognition. . . .

The fundamental liberties protected by [the Due Process] Clause . . . extend to certain personal choices central to individual dignity and autonomy, including intimate choices that define personal identity and beliefs. . . . The Court has long held the right to marry is protected by the Constitution. In *Loving v. Virginia,* 388 U.S. 1, 12 (1967), which invalidated bans on interracial unions, a unanimous Court held marriage is "one of the vital personal rights essential to the orderly pursuit of happiness by free men." . . . Over time and in other contexts, the Court has reiterated that the right to marry is fundamental under the Due Process Clause. It cannot be denied that this Court's cases describing the right to marry presumed a relationship involving opposite-sex partners. The Court, like many institutions, has made assumptions defined by the world and time of which it is a part. . . .

The limitation of marriage to opposite-sex couples may long have seemed natural and just, but its inconsistency with the central meaning of the fundamental right to marry is now manifest. With that knowledge must come the recognition that laws excluding same-sex couples from the marriage right impose stigma and injury of the kind prohibited by our basic charter. . . .

If rights were defined by who exercised them in the past, then received practices could serve as their own continued justification and new groups could not invoke rights once denied. This Court has rejected that approach, both with respect to the right to marry and the rights of gays and lesbians. . . .

It is now clear that the challenged laws burden the liberty of same-sex couples, and it must be further acknowledged that they abridge central precepts of equality. Here the marriage laws enforced by the respondents are in essence unequal: same-sex couples are denied all the benefits afforded to opposite-sex couples and are barred from exercising a fundamental right. Especially against a long history of disapproval of their relationships, this denial to same-sex couples of the right to marry works a grave and continuing harm. The imposition of this disability on gays and lesbians

* 135 S. Ct. 2584.

serves to disrespect and subordinate them. And the Equal Protection Clause, like the Due Process Clause, prohibits this unjustified infringement of the fundamental right to marry.

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Obergefell recognizes a principle advanced by several academic commentators: that liberty and equality are often intertwined. Constitutional law scholar Kenji Yoshino refers to intersectional liberty/equality arguments as *dignity* claims. The notion of intersectionality has intuitive appeal. Social, economic, political, and cultural factors intersect with race, sex, gender identity, sexual orientation, socio-economic class, national origin, and disability; these factors shape one another through dynamic constitutive processes. As an emerging principle of constitutional analysis, however, intersectionality—along with the related doctrine of hybrid rights developed by religious freedom advocates in the wake of *Smith*—introduce a new level of unpredictability into judicial decisions. Writing in dissent, Chief Justice Roberts placed *Obergefell* within an "unprincipled tradition of judicial policymaking that characterized discredited decisions such as *Lochner* v. *New York*." The Court's jurisprudence is undoubtedly evolving toward an implicit sliding-scale approach, whereby the more intrusive government action is, the more compelling the justification must be. In remains to be seen, however, whether the Court will be able to agree on a consistent and principled basis for distinguishing between the claims of same-sex couples and those of chain drug stores—one that can replace the rigidly tiered levels of review without leaving matters entirely to the unpredictable discretion of judges.

The individual rights recognized in the Constitution are powerful tools. They impose counter-majoritarian constraints on government power to secure the public's health, safety, welfare, and morals. As such, they give considerable power to judges to invalidate the work of the elected branches of government. This authority can be used to shore up the democratic process by ensuring freedom of expression, the right to vote, and equal protection under the law for historically disadvantaged groups. It can also be used to shield business interests from regulation, with potentially dire consequences for the public's health. In the next chapter, we continue to examine the power of the judiciary to constrain government action in the context of limits on the authority of administrative agencies and local governments.

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PHOTO 5.1. Officials from federal and local agencies observe hazardous waste cleanup efforts in American Samoa following a tsunami in 2009. Management of hazardous waste requires coordination among multiple jurisdictions and sectors. Photograph by Casey Deshong for the Federal Emergency Management Authority.

CHAPTER FIVE

Public Health Governance

Administrative Agencies and Local Governments

The previous two chapters examined limits on government action derived from federalism and individual rights recognized in the U.S. Constitution. This chapter addresses the structural constraints that apply to administrative agencies and local governments. Local governments and administrative agencies undertake most public health activities. As discussed in chapter 3, local governments have long exercised primary authority over matters of public health; their powers and duties are thus of particular importance. Governance of complex public health risks demands the expertise of administrative agencies whose staff provides a degree of continuity across the relatively short tenures of most elected officials. Thus, the powers and duties of administrative agencies at the federal, state, and local level are also central to public health law.

The U.S. Constitution does not speak to the powers and duties of local governments. Local governments exercise police powers delegated to them by the citizenry (via the state constitution) or the state legislature (via statute). Similarly, although the U.S. Constitution sets forth the fundamental principle of separation of powers among the three branches of government—executive, legislative, and judicial—it provides minimal guidance regarding the vast array of administrative agencies that perform a mix of executive, quasi-legislative, and quasi-judicial functions within the federal government pursuant to statutory delegations.

Two specialized areas of law police the delegation of public health authority from one component of government to another: local

government law and administrative law. There is considerable doctrinal variation from state to state in these areas. It is possible, however, to characterize broadly the various ways in which the law balances democratic accountability with efficient and effective public health governance. We begin with local government law and an issue of great importance to public health: state preemption of local government authority. We also focus on the features of local governments that have led them to become important innovators in public health regulation, particularly in the areas of healthy eating and tobacco and alcohol regulation. We then transition to administrative law at the state and federal level with an emphasis on the role of the executive, legislature, and judiciary in determining when agencies *may* act and when they *must* act.

LOCAL GOVERNMENT AUTHORITY TO PROTECT THE PUBLIC'S HEALTH

Any given individual or business may be subject to regulation, taxation, and service provision by multiple layers of government: federal, state, county, municipal, and various special purpose districts (e.g. school, utility, fire, police, water resource management, sanitation, mosquito abatement, and hospital districts). There are more than 3,000 county governments, nearly 20,000 municipalities, and 16,000 townships in the United States—resulting in considerable variation throughout the country. Although federal and state law touch on matters of importance to every silo of public health practice, local governments continue to bear primary responsibility for most matters affecting the public's health, including licensing (e.g., of daycares, restaurants, groceries, tattoo and body piercing studios, tobacco and alcohol retailers, and firearms dealers), zoning (dividing a jurisdiction into zones where various uses and building designs are permitted), sanitation and water service, hospital services (about 20% of hospitals in the United States are county-owned and operated) and mosquito, pest, and animal control.

The structure of local governments varies. The legislative branch of a local government may take the form of a city, county, or township council. Council members are typically elected and thus are accountable to residents directly, rather than answering to the mayor or other executive. In some cases, the local government executive is a city or county manager who reports to the council rather than being independently accountable to voters.

Unlike state governments, which enjoy plenary police power, local government action must be authorized by the state government or the citizenry. Grants of authority may be found in the state constitution, state statutes, or a combination of the two. A fundamental issue in local government law is the extent to which local governments exercise home rule. Home rule is defined as autonomous authority over local affairs enjoyed by a local government. The extent of home rule varies from state to state and may also vary from locality to locality within a state. In Colorado, for example, some counties and municipalities are designated home rule governments while others are not. In the majority of states, at least some local governments exercise home rule, allowing them broad authority to regulate for the protection of the public's health, safety, and welfare, to license, to tax, and to incur debt, subject only to the limits imposed by the state and federal constitutions. Home rule can insulate local governments from state interference with local public health matters. Although federal preemption trumps local home rule, state-level efforts to preempt local government authority may be invalidated on the basis of a state constitutional home-rule provision. The case that follows provides an illustration of the framework used by one state's judiciary to resolve conflicts between state and local governments over preemption.

*CLEVELAND V. STATE**

Eighth Appellate District, County of Cuyahoga
Decided March 28, 2013

. . . In April of 2011, the city [of Cleveland] adopted [an ordinance] entitled "Foods Containing Industrially-Produced Trans Fat Restricted." The ordinance provides as follows:

> No foods containing industrially-produced trans fat, as defined in this section, shall be stored, distributed, held for service, used in preparation of any menu item or served in any food shop, as defined [elsewhere in the code], except food that is being served directly to patrons in a manufacturer's original sealed package. . . .

In 2011, the Ohio General Assembly enacted [House Bill (H.B.)] 153 . . . entitled "Regulation of food nutrition information at food service operations" [which] states:

* 989 N.E.2d 1072.

(A) As used in this section:

(1) "Food nutrition information" includes, but is not limited to, the caloric, fat, carbohydrate, cholesterol, fiber, sugar, potassium, protein, vitamin, mineral, allergen, and sodium content of food. "Food nutrition information" also includes the designation of food as healthy or unhealthy. . . .

(3) "Consumer incentive item" means any licensed media character, toy, game, trading card, contest, point accumulation, club membership, admission ticket, token, code or password for digital access, coupon, voucher, incentive, crayons, coloring placemat, or other premium, prize, or consumer product that is associated with a meal served by or acquired from a food service operation.

(B) The director of agriculture has sole and exclusive authority in this state to regulate the provision of food nutrition information and consumer incentive items at food service operations. The director may adopt rules for that purpose. . . .

(C) No political subdivision shall do any of the following:

(1) Enact, adopt, or continue in effect local legislation relating to the provision or nonprovision of food nutrition information or consumer incentive items at food service operations;

(2) Condition a license, a permit, or regulatory approval on the provision or nonprovision of food nutrition information or consumer incentive items at food service operations;

(3) Ban, prohibit, or otherwise restrict food at food service operations based on the food nutrition information or on the provision or nonprovision of consumer incentive items;

(4) Condition a license, a permit, or regulatory approval for a food service operation on the existence or nonexistence of food-based health disparities;

(5) Where food service operations are permitted to operate, ban, prohibit, or otherwise restrict a food service operation based on the existence or nonexistence of food-based health disparities. . . .

On January 3, 2012, the City filed a declaratory judgment against the state of Ohio, seeking determinations that [the state nutrition preemption statute] is not a "general law," that [it] represents an unconstitutional attempt to preempt the city's municipal home rule authority, . . . and that the city's enactment and enforcement of [the trans fat ordinance] is a proper exercise of local home rule authority. . . .

[T]he Home Rule Amendment [to the Ohio Constitution] gives municipalities the "authority to exercise all powers of local self-government and to adopt and enforce within their limits such local police, sanitary and other similar regulations, as are not in conflict with general laws."

As [the Ohio Supreme Court has explained]:

> [T]he constitutional provision as adopted gave municipalities the exclusive power to govern themselves, as well as additional power to enact local health and safety measures not in conflict with general laws, [but] exclusive state power was retained in those areas where a municipality would in no way be affected or where state dominance seemed to be required.

The Ohio Supreme Court has set forth a three-step process for evaluating conflicts under the home-rule amendment. A state statute takes precedence over a local ordinance when (1) the ordinance is an exercise of the police power, rather than of local self-government, (2) the statute is a general law, and (3) the ordinance is in conflict with the statute. Where the statute fails to meet all of these conditions, it is not a general law, and, as such, it must yield to the municipal ordinance in question.

In the present case, it is undisputed that the first part of the home rule test is satisfied in that [the trans fat ordinance] is an exercise of the municipality's police power. Similarly, there is little dispute among the parties as to the conflict between [the preemption statute and the trans fat ordinance]. . . . As the first and third prongs of the home rule test are satisfied we next examine whether [the nutrition preemption statute] constitutes a general law.

A general law has been described as one which promotes statewide uniformity. Once a matter has become of such general interest that it is necessary to make it subject to statewide control as to require uniform statewide regulation, the municipality can no longer legislate in the field so as to conflict with the state.

The Ohio Supreme Court has adopted a four-part test for determining whether a statute is a general law for purposes of home-rule analysis. The statute must: (1) be part of a statewide and comprehensive legislative enactment, (2) apply to all parts of the state alike and operate uniformly throughout the state, (3) set forth police, sanitary, or similar regulations, rather than purport only to grant or limit legislative power of a municipal corporation to set forth police, sanitary or similar regulations, and (4) prescribe a rule of conduct upon citizens generally. . . .

The state likens the present case to the situation addressed by the Ohio Supreme Court in *Cleveland v. Ohio,* 942 N.E.2d 370, wherein the court upheld Ohio's regulation of firearms . . . as a valid general law and struck down Cleveland ordinances seeking to impose certain stricter firearm regulations. The court upheld [the state firearm preemption statute] as a statewide and comprehensive legislative enactment, in part, based upon its placement in the context of "a host of state and federal laws regulating firearms." The state presently asserts that [the nutrition statute's] provisions preempting municipal authority in the area of food content regulation and documentation are but one part of a broader legislative scheme regulating all aspects of food service operations and retail food establishments including food content. In light of the relative void of food content regulation under Ohio law, we cannot agree. In the present case we do not have statewide comprehensive legislation regarding the content of food served in restaurants. Neither Ohio nor federal law specifically prohibit or allow for industrially-produced trans fat content in food. Instead, we are confronted with a broad, flat ban by the General Assembly prohibiting municipalities from exercising their police powers in this area. . . .

General laws must "apply to all parts of the state alike." The state correctly points out that [the nutrition preemption statute] applies to all parts of the state without exception. We are troubled, however, by the statute's inexplicable failure to address retail food establishments. . . .

The state argues that, taken as a whole with other Ohio statutes, [the nutrition preemption statute] regulates food nutrition labeling, a valid exercise of police power and is but one part of a statewide and comprehensive legislative system that uniformly

prescribes a rule of conduct upon the food industry with respect to food content, nutrition, labeling, presentation and safety. We cannot agree. [The statute's] operation extends far beyond the regulation of food labeling cited by the state. . . . By its own terms [the statute] preempts any regulatory action by a municipality in the realm of food content without providing for any regulation of its own. By failing to set forth any regulation of this topic, [the statute's] function is to preempt municipal legislative action and maintain a regulatory void in regard to food content. . . .

Finally, a general law must "prescribe a rule of conduct upon citizens generally." . . . The state argues that [the nutrition preemption statute] prescribes a rule of conduct upon the citizens of Ohio with respect to food nutrition information and food safety and pertains to all food service operations and retail food establishments. [But] beyond the food labeling regulations promulgated [by the director of agriculture under the statute], the statute fails to prescribe any rule of conduct upon the citizens of Ohio in regard to the broader topics of food nutrition information and food content that it purports to regulate. As such the statute fails the fourth prong of the general law test.

In accordance with the foregoing, [the nutrition preemption statute] does not meet the test set forth [by the state supreme court] so we conclude that it is not a general law. Further, because [it] is not a general law, it unconstitutionally attempts to limit municipal home-rule authority. . . .

We also have concerns regarding the process behind how the [preemption statute was] passed. In response to the city of Cleveland's trans-fats Ordinance, the Ohio Restaurant Association (ORA) sent an email to the Ohio Department of Agriculture with an attached legislative proposal. The email stated that the Ordinance was "exactly what we want to preempt with the attached amendment." The email also stated that the amendment was "a high priority for Wendy's, McDonalds and YUM!, [which operates or licenses KFC, Taco Bell, and Pizza Hut]." According to the email, a senator had already been given a copy of ORA's proposed legislation and would offer it in the Senate Finance Committee. Thus, the amendments were drafted on behalf of a special interest group with the specific purpose of snuffing out the Ordinance.

The [preemption provisions] were tucked away in . . . the state's appropriations act for the 2011–2013 Biennium and were not vetted by the usual committee process. The House did not vote on the [preemption provisions], because the House had already passed the appropriations bill before [they] were inserted into the bill. There were no hearings on the amendments in any of the House Committees, nor in any Senate Committee. Although [they] will impact the health of Ohioans, there was no testimony to any legislative committees from any nutritionist, dietician, or any kind of other health care professional explaining the health effects of trans fats. Similarly, there was no testimony presented by ORA or from the fast-food restaurants whose interests were being represented by ORA. The [preemption provisions] constitute a rider taking up less than two pages of an appropriations bill in excess of 3,000 pages.

The facts giving rise to the birth of the [preemption provisions], coupled with the lack of a nexus between the [preemption provisions] and the appropriations bill, create a strong suggestion that the provisions were combined for tactical reasons. The [preemption provisions] in this case present us with a classic instance of impermissible logrolling.

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The home-rule provision relied on by the court to invalidate the Ohio legislature's attempt to preempt local government authority is specific to the Ohio constitution. As noted above, the extent to which local government authority is protected by the state's constitution varies considerably from state to state and from locality to locality within many states. In some states, a preemption bill exactly like the one invalidated in *Cleveland v. State* would be entirely constitutional.

In addition to indicating the importance of state law regarding the home rule authority of local governments, *Cleveland v. State* also illustrates a recent phenomenon of particular importance to public health. After a long period during which public health law became increasingly federalized, local governments like Cleveland have reemerged as key public health law innovators. At a time when the federal legislature has been crippled by partisan divisions and industry influence, several local governments have been experimenting with innovative approaches to public health problems, especially in the areas of tobacco control and healthy eating, issues we discuss in more detail in chapter 12. In the excerpt that follows, local government law scholar Paul Diller explores the factors that have contributed to this trend.

WHY DO CITIES INNOVATE IN PUBLIC HEALTH? IMPLICATIONS OF SCALE AND STRUCTURE*

Paul A. Diller

[M]any big cities fight tobacco use and obesity by adopting regulations that are more stringent than those emanating from the state and national political systems. This Article attempts to explain why. . . .

Although the public health community has long identified local governments as a fertile venue for increased regulation, prominent scholarly narratives in law, economics, and political science, by contrast, posit that cities are unlikely to adopt regulations that go beyond the state and national regulatory floors. . . .

Public choice assumes that government officials, like all people, "rationally" seek to maximize their utility, thus rejecting the notion that legislatures or administrative agencies regulate for the "public good." . . . According to classic public choice accounts, interest groups—organized collections of individuals who share an intense interest in a particular subject—influence the political process more than they would if all voters' policy preferences were weighted equally. Given their uniquely intense interests, these groups invest substantial time, money, and effort in electing and lobbying public officials to achieve favorable governmental outputs like laws, regulations, tax rates, and subsidies. In seeking to influence government, interest groups prey on the self-interest

* 2014. Washington University Law Review 91 (5): 1219–91.

of public decisionmakers, such as lawmakers, their staffs, administrative agency personnel, and civil servants. . . .

According to conventional public choice theory, Big Tobacco, the Food Industry, and their allies on specific issues aim to block regulations that could hurt their profits. Since the benefits to the general population from government regulation are diffusely spread, support for public health regulation will often be weak. . . . Public choice does not forestall the possibility that government will ever impose costly regulations on powerful industries at discrete political moments. Rather, it predicts that it will be difficult politically to do so, and that if science or economics could prescribe an optimal amount of public health regulation, there are good reasons to expect the political system to underregulate. *Ceteris paribus,* one would expect such regulation to be equally difficult at the local level. That cities regulate Big Tobacco and the Food Industry beyond the state and federal floor in many instances suggests that everything is not equal, and thus presses the question of why cities are more inviting "hosts" for the interest groups promoting public health regulation. The need for a compelling explanation of local regulatory activism is all the more pressing because cities, as compared to states and the federal government, likely have less to gain financially from lowering the rates of tobacco use and obesity. Federally funded Medicare, as well as Medicaid (funded mostly by the federal government), bear billions in long-term medical costs associated with tobacco and obesity. Cities, by contrast, do not contribute any money to Medicare, and in most states, they contribute no or proportionally scant money to Medicaid. . . .

Given that there are thousands of cities, as compared to a mere fifty states and one federal government, one might suspect, per Brandeis's famous dicta about laboratories of democracy, that a greater number of cities will inevitably lead to more innovation at the local level. On the other hand, . . . there is relatively little to gain from a "successful" policy innovation, whereas a failure can hurt a candidate's chances significantly. Thus, a self-interested, lower-level, elected official has little incentive to innovate. Moreover, because information about innovation diffuses to other jurisdictions, other policymakers may "free ride" on the first-mover's innovation. Because innovation is costly and its political return speculative, the free-rider effect leads to a collective action problem in which the many jurisdictions wait for others to innovate first, thus producing sub-optimal policy innovation. One would expect the collective action problem to be greater when there are more jurisdictions; thus, cities should be less likely to innovate than states. . . .

"[P]olicy evangelists" may be particularly well-suited to overcoming the free-rider problem because they generally want other jurisdictions to copy their innovations. Perhaps, then, policy evangelism helps explain the local innovation in public health, but why evangelists achieve more success at the local level than at higher levels remains unanswered. Surely, the most evangelistic would prefer to impact the greatest number of people through their innovations, and thus should prefer to act at higher levels of government, everything being equal. Scholars also note that more populous and wealthier jurisdictions—whether states or cities—are more likely to innovate given that they have more resources, including a larger bureaucracy, to devote to innovation. . . . [M]ore population density and greater wealth can also insulate cities from capital flight that regulation might otherwise precipitate. . . . These factors may help explain which local governments are more receptive to public health regulation. But as an explanation for why cities are generally more receptive to height-

PHOTO 5.2. Overflowing ashtray. City governments have pioneered many tobacco control policies, including bans on smoking in workplaces, bars, restaurants, and other public places.

ened regulation, they fall short. States are always larger and more populous than the cities within them. Moreover, given their control over taxation and finances, states can lay claim to a wealthy city's revenue even if other parts of the state are poorer. . . .

[C]ities compete with each other for consumer-voters on the basis of the tax-service mix offered by the jurisdiction. [Cities might even] seek residents who prefer restrictive public health regulations because such residents will cost the city less in medical (and other social service) expenditures in the long run, or because individual preference for public health regulation is a proxy for other characteristics that cities aim to maximize, like high levels of income and education. In other words, squeeze out McDonald's, and a city keeps out the poor people who work (and eat) there. . . .

Upon further examination, however, [this] case for local public health innovation weakens. First, among the public goods that residents consider when choosing a community, public health policies likely rank quite low to the extent that they are known and considered at all. At the margins, there may be particularly ideological or sensitive persons who rank these policies quite high, but their numbers are probably relatively insignificant. Second, while [some argue] that competition among jurisdictions—at least for residents—would lead to greater efficiency, [others] argue that interlocal competition for businesses results in a "race to the bottom" in which cities offer more and more giveaways to mobile firms to the detriment of their tax bases and public services. . . . Per this narrative, cities should be loath to enact public health regulations that might chase away certain industries, especially because businesses are likely more sensitive to local regulation than residents are in choosing location. . . .

[Additionally,] cities might be more resistant to mobile capital than previously thought. For instance, McDonald's did not abandon New York City after it banned trans fats and required menu labeling, despite opposing both policies. Nor has McDonald's threatened to depart the city *en masse* since the soda-size restrictions were announced. Unlike manufacturers of moveable, durable goods, McDonald's must be physically proximate to potential customers. By leaving the New York City market, McDonald's would lose access to millions of potential consumers. Thus, so long as its franchises can remain reasonably profitable, McDonald's is likely to comply with regulations it finds burdensome or annoying rather than flee the city entirely. In this sense, the more populous cities (as well as those that are larger and more isolated geographically) are better positioned to resist capital flight. Their markets are simply too potentially profitable for certain businesses to ignore, even if they come with extra regulatory baggage. . . .

A number of scholars have theorized that cities are uniquely capable of providing a more responsive and representative form of government, which could theoretically lead to more stringent public health regulation than found at higher levels of government. . . . [One] strain of thought stresses the "communitarian" advantages of local government. Unlike . . . public choice, communitarianism is decidedly noneconomic in its approach. Instead of assuming rational, self-interested actors in public and private spheres, communitarianism draws on civic republican theory to posit that local democracy is peculiarly capable of transforming both the individuals who participate in it and what local government does. In other words, communitarians argue that public choice is less descriptively accurate at the local level than at higher levels of government. Communitarians theorize that the smaller scale of local government can smooth some of the coarser elements of national and state politics that thrive on public choice dynamics, like the naked pursuit of self-interest (by individuals and groups), the negative campaign attacks, and partisan warfare. Indeed, public health advocates, in particular, have invoked communitarian themes in explaining why cities may be better venues for regulatory policy innovation. . . .

Communitarians argue that local government is more democratically responsive, in large part due to its smaller scale. This smaller scale enables participants in local government to engage in more deliberative democracy that promotes the "public good" rather than mere interest group politics. As an explanation for local public health innovation, the utilitarian communitarian account proceeds from a premise that is difficult to defend. Many communitarians assume that citizens should and will care more about local than higher levels of government because of its closeness to them. As measured by voting rates, however, citizens care least about local government, and care much more about national government, the level from which, per communitarian theory, they should feel most removed. . . .

Even if one is skeptical of communitarianism's premises and its foundational claims of civic republicanism, the smaller scale of local government may nonetheless impact the public choice narrative. In particular, the lower constituents-to-official ratio and the physical proximity of government decisionmakers to their constituents may lower the costs of both campaigning and lobbying, key tools by which interest groups pursue their goals. The synergy between these factors may help explain why proponents of public health regulation have comparatively more influence at the local level than at the state and federal levels. . . .

[T]he absolute costs of local campaigns appear to be lower than those at higher levels of government. City council races are substantially cheaper than those for Congress and appear to be cheaper—at least usually—than those for state legislature. Hence, it takes decidedly less money for candidates to reach the electability threshold at the local level as compared to the federal level, and usually considerably less money than at the state level. . . . Assuming that campaign contributions affect politicians' stances, this dynamic may reduce the relative influence of some well-funded interest groups at the local level, thereby enabling public health organizations to achieve comparatively greater influence. . . .

Also stemming from local government's smaller scale are reduced lobbying costs for interest groups that are based within the city. . . . It may be that certain interest groups—like public health organizations—are clustered in discrete cities and, therefore, may have an advantage in these cities over other groups. . . .

One seemingly obvious explanation for heightened local public health regulation is that the residents of most large cities are notoriously politically "liberal" or "progressive." Cities, therefore, provide a concentrated political majority that is decidedly not available at the federal level, and that is rarely, if ever, available at the state level. In New York City, for instance, 69% of registered voters are Democrats, as compared to a mere 11% Republican, a 58% advantage. The closest state with such lopsided party registration is Rhode Island, in which Democrats enjoy a 37% advantage. . . .

This concentrated political liberalism gives city officials more policy space on the left of the spectrum than that enjoyed by their counterparts at the state or federal levels. . . . Compounding the partisan demographic concentration, big cities do not include within their geographic boundaries many of the agricultural interests—such as tobacco or corn farmers—that may be inclined to oppose some [public health regulations]. In addition, only some cities have the concentrated business interests—e.g., Coca-Cola in Atlanta, the tobacco service industry in Charlotte, North Carolina—that are likely to directly oppose certain public health regulations. Of course, industry groups are free to influence the democratic process in all cities by donating to political campaigns and paying for independent expenditures. As evidenced by the defeat of a handful of local soda taxes in the 2012 election, industry interests are willing to fight hard even at the local level. Moreover, even if they are not directly represented, Big Tobacco and the Food Industry likely have surrogates within populous cities to defend their interests, like convenience store owners and fast-food franchisees. Nonetheless, the Food and Tobacco Industries' reduced physical presence in many cities may diminish their influence.

There remain many reasons to be skeptical, however, of the value of political preference concentration as an explanation for local public health innovation. First, while concentrated political preferences and one-party dominance might explain residents' willingness to re-elect (or at least not reject) local officials who support heightened public health regulations, they still do not explain why such policies emerge from the local legislative process. After all, constituents might prefer a particular policy when responding to a survey, but without an organized interest group's support, that policy is unlikely to make it through the legislative process. Thus, while an ideological leaning in favor of public health policies might grease the wheels of the legislative process, the initial push behind a proposal will often emanate from an interest group, raising the question of why such interest groups seem capable of a stronger push at the local level.

Second, views on some of the specific local public health policies do not neatly track the divides at the national level between "liberal" and "conservative," or "Democrat" and "Republican." For instance, New York City's portion-cap rule for sugar-sweetened beverages has united Sarah Palin, Glenn Beck, and the NAACP in opposition. Similarly, the city's proposal, rejected by the USDA, to prohibit using SNAP benefits to pay for sugar-sweetened soft drinks had supporters and opponents on both sides of the ideological and partisan spectra. The pursuit of these programs thus cannot be explained credibly by simply pointing to New York City voters' preferences in national elections. A similar dynamic exists with respect to soda taxes, which are opposed by those who dislike higher taxes generally, as well as by advocates for the poor who consider such taxes regressive. Moreover, issue preferences at the national and local levels are hardly stable. City initiatives, whether pushed by evangelizing public officials or public health interest groups, can shape public preferences that were either nonexistent or loosely formed before cities put certain issues on the public agenda. . . .

A significant, but heretofore undervalued, reason why local governments are more amenable to local health policy innovation is their streamlined legislative structure. . . . [T]he streamlined nature of local lawmaking, combined with the lower campaign and lobbying costs discussed above, provides a more favorable venue for public health interest groups to push for heightened regulation. For any interest group to succeed in creating law, it must overcome the inertia that is endemic to the legislative process. With a more streamlined legislative process, cities are more structurally inviting for the proponents of regulatory change than the more sclerotic state and legislative processes.

Unlike the national and state governments, cities do not have bicameral legislatures. While most city charters allow for the mayor to veto bills, a supermajority of the city council can override a veto. Because city councils are unicameral, a supermajority is needed in only one legislative body—rather than two—to overcome executive resistance. For instance, when Mayor Gavin Newsom vetoed the San Francisco Board of Supervisors' bill restricting fast-food toy giveaways linked to meals of low nutritional quality, the Board overrode his veto by an 8-to-3 vote. Putting aside the potential veto threat, city councils generally do not require supermajorities to pass legislation. In Congress, by contrast, it is now almost standard that a bill must clear the sixty-vote filibuster threshold in the Senate to become law. In many states, state constitutional provisions require supermajorities to enact certain kinds of laws, particularly those related to raising taxes or revenue. City councils often also lack the extensive committee structures prevalent in state and national legislatures, which can easily bottle up a proposal's chance of becoming law. The net result is that cities have fewer and less robust "vetogates"—that is, institutional obstacles to the passage of legislation. . . .

Many municipal legislatures are nonpartisan. Congress, on the other hand, uses an extremely partisan system of selecting chamber and committee leadership, and every state legislature save Nebraska relies on partisan affiliation as well. Even where cities use partisan elections, however, the overwhelming tilt toward one political party (Democratic) in the largest cities means that city councils are unlikely to be locked in a close partisan divide. The party structure in Congress and some state legislative houses often requires that a bill have majority support of the majority caucus to move forward. Thus, a bill that enjoys the support of a majority of members of Congress may easily die if it does not meet this threshold. The reduced role of partisanship at the

local level thus lowers another barrier to legislative enactment. Of course, there remain significant barriers to passing legislation at the local level. Powerful city councilors can bottle up legislation singlehandedly. Intraparty "council wars" can be as debilitating as fierce partisan warfare. The point here is simply comparative: city councils have fewer institutional bottlenecks. . . .

[P]roponents of public health regulation are likely to be less overwhelmed by opposition spending at the local level than at higher levels of government, particularly when they are pushing for affirmative enactment of a new regulatory scheme. Moreover, since public health organizations are generally seeking more changes to the regulatory status quo, given the nature of the problems they are trying to address, they benefit disproportionately from local government's structure and lower costs. Big Tobacco and the Food Industry, by contrast, often prefer the status quo. When they seek to loosen the regulatory regime, they are unlikely to focus on the local level given cities' limited control over "private law" subjects like torts, and cities' general inability, due to preemption, to enact a regulatory floor that is lower than the state or national standard. . . .

Many commentators have lamented the "broken" state of the federal political system, with near-routine use of the filibuster in the Senate and other indicia of partisan gridlock. Local governments provide a counterexample to this tale of dysfunction, at least in the regulatory realm, as vividly demonstrated by records on public health. Whether local government's methods can be effectively replicated at higher levels of government is uncertain. In the meantime, however, big cities provide an especially inviting venue for proponents of public health regulation opposed by well-funded interest groups.

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In addition to describing the various features of local governments that have made them public health pioneers, Diller points to many aspects of federal and state legislatures that stymie efforts to adopt innovative public health laws. As Congress's productivity has ground to a near-halt due to partisan divides and procedural hurdles, local governments and administrative agencies have filled some of the gaps. In the next section, we turn to administrative law, which governs the authority of administrative agencies at the local, state, and federal level.

AUTHORITY OF ADMINISTRATIVE AGENCIES TO PROTECT THE PUBLIC'S HEALTH

Some cities, like Cleveland and Boston, have adopted innovative public health measures via legislative enactments. Others, notably New York City, have relied more heavily on rules adopted by boards of health and local health departments whose top officials are appointed by the mayor. Agency-led interventions are often perceived as less legitimate than

those adopted by the legislative branch. They are also more vulnerable to legal challenge because they must comport with administrative law doctrines designed to ensure separation of powers and democratic accountability. Local public health agencies are triply constrained: they are limited by local government law, administrative law, and the individual rights guarantees discussed in chapter 4.

Legislatures establish administrative agencies to carry out their directives. Consequently, agencies have only those powers that legislatures delegate to them. There are also constitutional limits on what powers the legislature can lawfully delegate. The nondelegation doctrine, a corollary to the constitutional principle of separation of powers, holds that some policy questions are assigned exclusively to the legislative branch and may not be handed over to executive agencies. The judiciary plays an important role in reviewing administrative agency actions to ensure that they are within the bounds of properly delegated authority. This requires both statutory interpretation (the court must determine precisely which powers the legislature has delegated to the agency by construing the delegating statute) and constitutional interpretation (the court must determine whether the statute's delegation of power to the agency comports with separation of powers).

Unlike legislatures, whose members are elected, administrative agencies are generally led by officials appointed by the jurisdiction's executive (mayor, county executive, governor, or president). These political appointees are supported by professional staff who are neither elected nor appointed by elected officials and whose service typically extends across the limited terms of elected officials. Appointed agency heads often have specialized expertise. For example, many state and local health department heads (typically referred to as secretaries or commissioners) have expertise in medicine, public health, or health policy. In many jurisdictions, such as New York City, statutes specify that a certain number of Board of Health members must have medical or public health expertise. Agency staff may include scientific experts, economists, and others with expertise relevant to the sector they regulate. As we argued in chapter 2, however, risk regulation relies as much on values as on science and expertise; legitimate public health governance thus requires officials to be democratically accountable, even if indirectly. As you read the excerpt that follows, consider the ways in which the majority and the dissent balance democratic accountability with expertise, efficacy, and efficiency.

*NEW YORK STATEWIDE COALITION OF HISPANIC CHAMBERS OF COMMERCE V. NEW YORK CITY DEPT. OF HEALTH & MENTAL HYGIENE**

New York Court of Appeals
Decided June 26, 2014

. . . The New York City Board of Health is part of the City's Department of Health and Mental Hygiene and consists of the Commissioner of that Department, the Chairperson of the Department's Mental Hygiene Advisory Board, and nine other members, appointed by the Mayor. In June 2012, as part of its effort to combat obesity among City residents, the Department proposed that the Board amend . . . the City Health Code so as to restrict the size of cups and containers used by food service establishments for the provision of sugary beverages. After a preliminary vote by the Board, a notice of public hearing was published, seeking comments from the public. The substantial number of comments both before and during the July hearing indicated a groundswell of public interest and concern. On September 13, 2012, the Board voted, with one abstention, to adopt the Department's proposed rule—referred to as the "Portion Cap Rule"—to go into effect in March 2013.

The Portion Cap Rule provides in relevant part that "[a] food service establishment may not sell, offer, or provide a sugary drink in a cup or container that is able to contain more than 16 fluid ounces" and "may not sell, offer or provide to any customer a self-service cup or container that is able to contain more than 16 fluid ounces." A "sugary drink" is defined as a nonalcoholic beverage that "is sweetened by the manufacturer or establishment with sugar or another caloric sweetener; . . . has greater than 25 calories per 8 fluid ounces of beverage; . . . [and] does not contain more than 50 percent of milk or milk substitute by volume as an ingredient." The Portion Cap Rule does not apply to establishments, such as supermarkets and convenience stores, that are subject to regulation and inspection by the New York State Department of Agriculture and Markets.

In October 2012, petitioners, six national or statewide not-for-profit and labor organizations, commenced this . . . proceeding and declaratory judgment action seeking to invalidate the Portion Cap Rule. . . .

First, we address respondents' claim that the Board, having been created by the state legislature, has legislative powers separate and apart from the City Council. The City Charter unequivocally provides for distinct legislative and executive branches of New York City government. The City Council is the sole legislative branch of City government; it is "*the* legislative body of the city. . . . vested with the legislative power of the city." NY City Charter § 21. The New York State Constitution mandates that, with an exception not applicable here, "[e]very local government . . . shall have a legislative body elective by the people thereof." NY Const, art IX, § 1 (a); *see also* Municipal Home Rule Law § 2(7), and that elective body in New York City is the City Council.

Respondents, however, contend that the Board of Health is a unique body that has inherent legislative authority. We disagree. The provision of the City Charter princi-

* 16 N.E.3d 538.

pally cited by respondents—setting out the authority of the Board to "add to and alter, amend or repeal any part of the health code, . . . [to] publish additional provisions for security of life and health in the city and [to] confer additional powers on the [Department of Health and Mental Hygiene] not inconsistent with the constitution, laws of this state or this charter," NY City Charter § 558 (b)—reflects only a regulatory mandate, not legislative authority. It is true that the Board "may embrace in the health code all matters and subjects to which the power and authority of the [Department of Health and Mental Hygiene] extends," NY City Charter § 558 (c), and that the Charter refers to the Board's supervision over "the reporting and control of communicable and chronic diseases and conditions hazardous to life and health" and "the abatement of nuisances affecting or likely to affect the public health," NY City Charter § 556 (c)(2); *see also* § 556 (c) (9) (referring to Board's authority to "supervise and regulate the food and drug supply of the city and other businesses and activities affecting public health in the city"). Nonetheless, the Charter contains no suggestion that the Board of Health has the authority to create laws. While the Charter empowers the City Council "to adopt local laws . . . for the preservation of the public health, comfort, peace and prosperity of the city and its inhabitants," NY City Charter § 28 (a), the Charter restricts the Board's rulemaking to the publication of a health code, an entirely different endeavor. . . .

Given our position that the Board's role is regulation, not legislation, the next issue raised in this appeal is whether the Board properly exercised its regulatory authority in adopting the Portion Cap Rule. The parties and the lower courts correctly analyze this question by using the conceptual framework of [*Boreali v. Axelrod,* 71 NY2d 1 (1987)]. . . .

Boreali sets out four "coalescing circumstances" present in that case that convinced the Court "that the difficult-to-define line between administrative rule-making and legislative policy-making ha[d] been transgressed." [First, whether the agency has created "a regulatory scheme laden with exceptions based solely upon economic and social concerns." Second, whether the agency has created "its own comprehensive set of rules without the benefit of legislative guidance." Third, whether the agency has "acted in an area in which the Legislature had repeatedly tried—and failed—to reach agreement in the face of substantial public debate and vigorous lobbying by a variety of interested factions." Fourth, whether the agency exercised "special expertise or technical competence" in developing the challenged regulations.] . . .

[T]he promulgation of regulations necessarily involves an analysis of societal costs and benefits. Indeed, cost-benefit analysis is the essence of reasonable regulation; if an agency adopted a particular rule without first considering whether its benefits justify its societal costs, it would be acting irrationally. Therefore, *Boreali* should not be interpreted to prohibit an agency from attempting to balance costs and benefits. Rather, the *Boreali* court found that the Public Health Council had "not been given any legislative guidelines at all for determining how the competing concerns of public health and economic cost are to be weighed."

Here, instead of an outright ban on sugary beverages, the Board decided to reduce their consumption by the expedient of limiting maximum container size, thus making it less convenient for consumers to exceed recommended limits. The more cautious approach, however, does not save the Portion Cap Rule. By restricting portions, the

Board necessarily chose between ends, including public health, the economic consequences associated with restricting profits by beverage companies and vendors, tax implications for small business owners, and personal autonomy with respect to the choices of New York City residents concerning what they consume. Most obviously, the Portion Cap Rule embodied a compromise that attempted to promote a healthy diet without significantly affecting the beverage industry. This necessarily implied a relative valuing of health considerations and economic ends, just as a complete prohibition of sugary beverages would have. Moreover, it involved more than simply balancing costs and benefits according to preexisting guidelines; the value judgments entailed difficult and complex choices between broad policy goals—choices reserved to the legislative branch.

Significantly, the Portion Cap Rule also evidenced a policy choice relating to the question of the extent to which government may legitimately influence citizens' decision-making. In deciding to use an indirect method—making it inconvenient, but not impossible, to purchase more than 16 fluid ounces of a sugary beverage while dining at a food service establishment—the Board of Health rejected alternative approaches, ranging from instruction (i.e. health warnings on large containers or near vending machines) to outright prohibition. This preference for an indirect means of achieving compliance with goals of healthier intake of sugary beverages was itself a policy choice, relating to the degree of autonomy a government permits its citizens to exercise and the ways in which it might seek to modify their behavior indirectly.

By choosing between public policy ends in these ways, the Board of Health engaged in law-making beyond its regulatory authority, under the first *Boreali* factor. Notably, such policymaking would likely not be implicated in situations where the Board regulates by means of posted warnings (e.g. calorie content on menus) or by means of an outright ban of a toxic substance (e.g. lead paint). In such cases, it could be argued that personal autonomy issues related to the regulation are nonexistent and the economic costs either minimal or clearly outweighed by the benefits to society, so that no policymaking in the *Boreali* sense is involved.

To apply the distinction between policymaking and rulemaking, a court is thus required to differentiate between levels of difficulty and complexity in the agency's task of weighing competing values. For example, when an agency regulates the purity of drinking water, or prohibits the use of interior lead paint, or requires guards in the windows of high-rise apartments housing children, it chooses among ends (e.g. a landowner's convenience and short-term profit versus the safety, health and well-being of tenants), but the choices are not very difficult or complex. This is because the connection of the regulation with the preservation of health and safety is very direct, there is minimal interference with the personal autonomy of those whose health is being protected, and value judgments concerning the underlying ends are widely shared.

By contrast, when an agency in our present time either prohibits the consumption of sugary beverages altogether or discourages it by regulating the size of the containers in which the drinks are served, its choices raise difficult, intricate and controversial issues of social policy. Few people would wish to risk the physical safety of their children who play near high-rise apartment windows for the sake of unobstructed views. However, the number of people who overindulge in sugary drinks, at a risk to their health, is clearly significant. An agency that adopts a regulation, such as the Portion

Cap Rule or an outright prohibition of sugary beverages, that interferes with commonplace daily activities preferred by large numbers of people must necessarily wrestle with complex value judgments concerning personal autonomy and economics. That is policymaking, not rulemaking.

With respect to the second *Boreali* factor, respondents are unable to point to any legislation concerning the consumption of sugary beverages by the state legislature or City Council that the Portion Cap Rule was designed to supplement. Although the Legislature is not required in its enactments to supply agencies with rigid marching orders and the legislative branch may, while declaring its policy in general terms by statute, endow administrative agencies with the power and flexibility to fill in details and interstices and to make subsidiary policy choices consistent with the enabling legislation, the policy choices made here were far from subsidiary. . . . In short, this is not a case in which the basic policy decisions underlying the challenged regulations have been made and articulated by the Legislature. . . .

With regard to the third *Boreali* factor, . . . [h]ere, inaction on the part of the state legislature and City Council, in the face of plentiful opportunity to act if so desired, simply constitutes additional evidence that the Board's adoption of the Portion Cap Rule amounted to making new policy, rather than carrying out preexisting legislative policy.

In light of *Boreali*'s central theme that an administrative agency exceeds its authority when it makes difficult choices between public policy ends, rather than finds means to an end chosen by the legislature, we need not, in this appeal, address the fourth *Boreali* factor: whether special expertise or technical competence was involved in the development of the rule. We do not mean to imply that the fourth factor will always lack significance. A court might be alerted to the broad, policy-making intent of a regulation, and the absence of any perceived need for agency expertise, by the fact that the rule was adopted with very little technical discussion. . . . Here, regardless of who or which arm of government first proposed or drafted the Portion Cap Rule, and regardless of whether the Board exercised its considerable professional expertise or merely rubber-stamped a rule drafted outside the agency, the Portion Cap Rule is invalid under *Boreali*. . . .

Judge Read (dissenting).

In *Boreali v Axelrod,* we invalidated a regulation on indoor smoking promulgated by a state health agency on the ground that it was an exercise of legislative rather than regulatory authority, and was therefore a violation of the separation-of-powers doctrine. Today the Court again declares that a controversial regulation runs afoul of separation of powers. In so doing, the majority misapprehends, mischaracterizes and thereby curtails the powers of the New York City Board of Health to address the public health threats of the early 21st century. . . .

As an initial matter, correct resolution of this appeal depends upon an accurate understanding of the source and extent of the Board's authority. . . . [W]hether those powers are *characterized* as legislative or regulatory in nature is somewhat beside the point because, in either event, its authority is broad, and its special structure allows serious issues of public health to be addressed expeditiously. . . .

[R]eview of the Board's history can lead to only one conclusion: its authority to regulate the public health in the City is delegated by the New York State Legislature,

and its regulations have the force and effect of state law. The delegation granted by the state is and always has been very broad. Of course, nothing prevents the Council from passing public health legislation if it sees fit to do so. But in light of the Board's independent authority, delegated to it by the legislature, it is of no legal consequence that the Council has not affirmatively authorized [the Portion Cap Rule] or the regulation of sugary drinks in general.

And until controversy erupted over the Rule, the Board's independent authority in the sphere of public health was well understood. For example, on December 5, 2006 the Board adopted a rule banning the use of all but tiny amounts of artificial trans fat in restaurant cooking in the City, effective January 10, 2007. The Council some months later adopted a local law, effective July 1, 2007, amending the City's Administrative Code to add provisions consistent with the Board's trans fat rule. In short, [the Board's trans fat rule] was effective in January 2007, although the Council had not authorized the regulation of trans fats at the time.

Much of the debate in this case has focused on our decision in *Boreali*. This opinion is viewed as having an outsized impact on New York law, in no small part because it suggests that we are one of the few jurisdictions with a "strong" non-delegation doctrine, at least in the eyes of some commentators. . . . The proper approach in any separation-of-powers analysis is . . . flexible and case-specific, addressing each agency or executive action in light of the relevant legislative delegation it invokes. *Boreali* represents a situation where a particular agency had taken a particular action that, in view of its particular delegation, "usurped the Legislature's prerogative."

That is not the case here. The legislature has directed the Board to oversee and protect the public health of the City of New York by enacting rules in the Health Code. Those rules extend to all responsibilities within the competence of the Department, including "the preservation of human life," "the care, promotion and protection of health," the "control of communicable and chronic diseases and conditions hazardous to life and health," and "supervis[ion] and regulat[ion of] the food and drug supply of the city and other businesses and activities affecting public health in the city [to] ensure that such businesses and activities are conducted in a manner consistent with the public interest." City Charter § 556 (a)(1); (c)(2), (9). . . .

Here, the Board identified a complicated threat to the health of city residents with many interrelated causes; i.e., obesity. As part of a wide-ranging effort to combat this threat, the Board focused on certain kinds of drinks sold in establishments over which the Department had sure jurisdiction. The Board considered several options for addressing the problem, and chose one after open public debate, calibrated to the severity of the threat and its most serious manifestations, and cognizant of the limits of its enforcement power and the feasibility of compliance. There can be little doubt that this was within the Board's statutory delegation. . . .

With all due respect to my colleagues, their proposed ends-means test is virtually inscrutable and surely unworkable. It harks back to long discredited formalistic approaches to administrative law, which were seemingly objective but instead served as camouflage for enforcement of judicial preferences. In this case, a majority of the Court just does not believe it to be a good idea for the Board to mandate the portion size of sugary drinks, apparently on the theory that the Council should be the sole arbiter of "the choices of New York City residents concerning what they consume," at least in those situations where the choices are not immediately life-threatening. I can

appreciate this vision of the world as a philosophical matter, but I see no legal basis for it here.

Because the Portion Cap Rule does not suffer from any non-delegation or separation-of-powers infirmity, the proper standard for our review is whether the regulation is "so lacking in reason for its promulgation that it is essentially arbitrary." The Rule easily passes this test.

Following the submission of public comments on [the Portion Cap Rule], the Department responded to the many concerns raised with a 13-page memorandum explaining in detail why sugary drinks were targeted, and why some drinks and establishments were excluded. The memorandum cites peer-reviewed academic research and the findings of other public health bodies. The Board debated the issues presented and responses, and placed its deliberations in the public record of its meetings. . . .

Petitioners and their supporting amici curiae, as well as Supreme Court, have countered the extensive documentation supporting the Board's reasoning with arguments that the Rule is rife with loopholes and will never achieve its goal of reducing obesity. But a rule is not irrational because there are reasons to disagree with or ways to improve it, or because it does not completely solve the targeted problem. Given the exhaustive record in this case, it is clear that the Rule is not "lacking in reason for its promulgation." If it is ineffective, that will become clear enough in time, and the Board can correct course in light of new information. But this is no basis for the courts to strike the regulation down.

What petitioners have truly asked the courts to do is to strike down an *unpopular* regulation, not an illegal one. Indeed, petitioners constantly stress just *how* unpopular the Portion Cap Rule is. But if that is so, eliminating, limiting, or preventing it via political processes should present little obstacle. Importantly, that is the appropriate way for expressing disagreement and seeking redress. *Boreali* should not be an escape hatch for those who are unhappy with a regulation, and are unable or unwilling to address it with available means. . . .

. . .

The Portion Cap Rule, like many other efforts to promote healthier eating habits, generated considerable political controversy and industry backlash. We will take up the vital public health issue of noncommunicable diseases associated with unhealthy diet, physical inactivity, and tobacco and alcohol use in chapter 12. Here, our focus is on the New York Court of Appeals' assessment of the board of health's authority vis-à-vis the city council.

In resolving the question of whether the board's authority extended to the Portion Cap Rule, both the majority and the dissent examined the board's unique history. New York City's Common Council enacted an ordinance creating the first board of health in 1805 in response to a yellow fever epidemic. The board's efforts were primarily reactive and not consistently organized or funded. In the mid-1800s, the board's incompetence and corruption crippled the city's response to a series of

cholera epidemics. As ships and sailors brought the disease from Europe, the board was reluctant to adopt measures that would unavoidably disrupt trade and commerce. As one prominent resident wrote in 1831, the board was "more afraid of merchants than of lying" (New York City Department of Health and Mental Hygiene 2005, 7). Reformers decried the influence of the city's notoriously corrupt local politicians on the board and called for it to be replaced by a new agency independent of the city council. In 1866, the state legislature responded by establishing the current board of health, delegating to it broad authority to protect and promote the public's health.

The dissent relies on this history in opining that the board's authority is broad and should not be constrained by a rigid distinction between legislative and regulatory functions that the state constitution adopted to govern state-level agencies exercising authority delegated by the state legislature. Is it relevant that the New York City Board of Health and Mental Hygiene was created by the state legislature to circumvent the corruption of local elected officials? Should this alter the balance between democratic accountability on the one hand and expertise and efficiency on the other? Is the majority's distinction between legislative and regulatory actions workable? Does it provide sufficient guidance to agency officials about what they may and may not do?

Like local government law and home rule, administrative law varies considerably from state to state and is shaped by a state's unique history. As the dissent in *Hispanic Chambers of Commerce* notes, commentators have criticized New York's separation of powers doctrine for being inflexible and more constraining of agency authority than that of other states. It may be, then, that a state or local health department in another state could undertake a measure like the portion cap rule without running afoul of administrative law constraints.

FEDERAL ADMINISTRATIVE LAW

Public health law operates primarily at the state and local level, but the federal presence in public health has grown exponentially in recent decades. In the 1930s, Franklin Delano Roosevelt's New Deal ushered in a massive expansion of federal agencies to administer the social safety net (see chapter 8). In the 1960s, President Lyndon Johnson's Great Society added major programs to combat poverty and racial discrimination, as well as to provide publicly funded health care. In the 1970s, federal agencies were established to tackle matters like consumer product safety

and environmental protection. The Department of Health and Human Services traces its origins to a much older agency, but its purview grew considerably during the twentieth century to ensure drug efficacy and safety through the Food and Drug Administration, handle expanded public health functions under the auspices of the Centers for Disease Control, and administer publicly financed health care programs like Medicare and Medicaid.

Many commentators consider administrative agencies' status as a "fourth branch" of government to be constitutionally problematic. Congress has delegated significant authority to agencies to perform functions that are quasi-legislative (rulemaking) and quasi-judicial (adjudication of disputes) alongside executive functions (enforcement of laws). Nonetheless, federal nondelegation doctrine is far weaker than the state nondelegation doctrine applied by the New York Court of Appeals in *Hispanic Chambers of Commerce,* excerpted above. Federal courts have been reluctant to invalidate broad grants of authority by Congress to agencies on the grounds that that authority is "legislative" rather than "regulatory." As a result, statutory limits and judicial doctrines regarding deference to agency interpretations of statutes do most of the work in federal administrative law.

At the federal level, the Administrative Procedure Act (APA) and other statutes demarcate agency authority. These statutory limitations reinforce the constitutional principle of separation of powers. The judiciary reviews agency action to ensure that it falls within the agency's properly delegated authority and comports with substantive and procedural requirements set forth in the APA and other statutes.

When private parties or state or local governments challenge federal agency action in court, a key question is the extent to which judges should defer to the agency's judgment on matters of law. That is, should the court give special weight to an agency's interpretation of a statute it implements? When the court grants deference, it overrules an agency's interpretation only if it is plainly erroneous. Otherwise, it approaches the issue de novo—from the beginning—deciding for itself what the law means.

If the agency asserts that it has the delegated authority to act in a certain area, or the agency interprets the authorizing statute in a certain way, the courts tend to grant deference, following a framework established in *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). *Chevron* deference is typically assessed following a three-step process. First (in what is referred to as *Chevron* step

zero), the court must determine whether *Chevron* is the appropriate framework for resolving the question of deference. In this step, a court may determine that deference is unwarranted because Congress has not granted the agency authority to make rules carrying the force of law or because the particular agency action at issue was not promulgated as an exercise of the agency's rulemaking authority. If *Chevron* is deemed applicable, the court will defer to the agency's interpretation of the statute only if the meaning of the statute is ambiguous (*Chevron* step one). The idea is that by using ambiguous language, Congress impliedly delegated the task of interpreting that language to the implementing agency. Finally, deference is not warranted if the agency's interpretation is arbitrary or capricious (*Chevron* step two). As you read the following excerpt, note the Supreme Court's resolution of questions of statutory construction and deference to the agency's interpretation of the law.

*KING V. BURWELL**

Supreme Court of the United States
Decided June 25, 2015

Chief Justice Roberts delivered the opinion of the Court.

The Patient Protection and Affordable Care Act adopts a series of interlocking reforms designed to expand coverage in the individual health insurance market. First, the Act bars insurers from taking a person's health into account when deciding whether to sell health insurance or how much to charge. Second, the Act generally requires each person to maintain insurance coverage or make a payment to the Internal Revenue Service. And third, the Act gives tax credits to certain people to make insurance more affordable.

In addition to those reforms, the Act requires the creation of an "Exchange" in each State—basically, a marketplace that allows people to compare and purchase insurance plans. The Act gives each State the opportunity to establish its own Exchange, but provides that the Federal Government will establish the Exchange if the State does not.

This case is about whether the Act's interlocking reforms apply equally in each State no matter who establishes the State's Exchange. Specifically, the question presented is whether the Act's tax credits are available in States that have a Federal Exchange. . . .

The Act initially provides that tax credits "shall be allowed" for any "applicable taxpayer." The Act then provides that the amount of the tax credit depends in part on whether the taxpayer has enrolled in an insurance plan through "an Exchange *established by the State* under section 1311 of the Patient Protection and Affordable Care Act [hereinafter 42 U.S.C. §18031]."

* 135 S. Ct. 2480.

The IRS addressed the availability of tax credits by promulgating a rule that made them available on both State and Federal Exchanges. As relevant here, the IRS Rule provides that a taxpayer is eligible for a tax credit if he enrolled in an insurance plan through "an Exchange," which is defined as "an Exchange serving the individual market . . . regardless of whether the Exchange is established and operated by a State . . . or by HHS." At this point, 16 States and the District of Columbia have established their own Exchanges; the other 34 States have elected to have HHS do so.

Petitioners are four individuals who live in Virginia, which has a Federal Exchange. They do not wish to purchase health insurance. In their view, Virginia's Exchange does not qualify as "an Exchange established by the State under [42 U.S.C. §18031]," so they should not receive any tax credits. That would make the cost of buying insurance more than eight percent of their income, which would exempt them from the Act's coverage requirement.

Under the IRS Rule, however, Virginia's Exchange *would* qualify as "an Exchange established by the State under [42 U.S.C. §18031]," so petitioners would receive tax credits. That would make the cost of buying insurance *less* than eight percent of petitioners' income, which would subject them to the Act's coverage requirement. The IRS Rule therefore requires petitioners to either buy health insurance they do not want, or make a payment to the IRS. . . .

When analyzing an agency's interpretation of a statute, we often apply the two-step framework announced in *Chevron,* 467 U.S. 837. Under that framework, we ask whether the statute is ambiguous and, if so, whether the agency's interpretation is reasonable. This approach "is premised on the theory that a statute's ambiguity constitutes an implicit delegation from Congress to the agency to fill in the statutory gaps." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 159 (2000). "In extraordinary cases, however, there may be reason to hesitate before concluding that Congress has intended such an implicit delegation." *Ibid.*

This is one of those cases. The tax credits are among the Act's key reforms, involving billions of dollars in spending each year and affecting the price of health insurance for millions of people. Whether those credits are available on Federal Exchanges is thus a question of deep "economic and political significance" that is central to this statutory scheme; had Congress wished to assign that question to an agency, it surely would have done so expressly. It is especially unlikely that Congress would have delegated this decision to the *IRS,* which has no expertise in crafting health insurance policy of this sort. This is not a case for the IRS.

It is instead our task to determine the correct reading of [the relevant statutory provision]. If the statutory language is plain, we must enforce it according to its terms. . . .

We begin with the text of Section 36B. As relevant here, Section 36B allows an individual to receive tax credits only if the individual enrolls in an insurance plan through "an Exchange established by the State under [42 U.S.C. §18031]." In other words, three things must be true: First, the individual must enroll in an insurance plan through "an Exchange." Second, that Exchange must be "established by the State." And third, that Exchange must be established "under [42 U.S.C. §18031]." . . .

[A]ll parties agree that a Federal Exchange qualifies as "an Exchange" for purposes of Section 36B. Section 18031 provides that "[e]ach State shall . . . establish an American Health Benefit Exchange . . . for the State." §18031(b)(1). Although phrased as a

requirement, the Act gives the States "flexibility" by allowing them to "elect" whether they want to establish an Exchange. §18041(b). If the State chooses not to do so, Section 18041 provides that the Secretary "shall . . . establish and operate such Exchange within the State." §18041(c)(1).

By using the phrase "such Exchange," Section 18041 instructs the Secretary to establish and operate the *same* Exchange that the State was directed to establish under Section 18031. In other words, State Exchanges and Federal Exchanges are equivalent—they must meet the same requirements, perform the same functions, and serve the same purposes. Although State and Federal Exchanges are established by different sovereigns, Sections 18031 and 18041 do not suggest that they differ in any meaningful way. A Federal Exchange therefore counts as "an Exchange" under Section 36B. . . .

After telling each State to establish an Exchange, Section 18031 provides that all Exchanges "shall make available qualified health plans to qualified individuals." Section 18032 then defines the term "qualified individual" in part as an individual who "resides in the State that established the Exchange." And that's a problem: If we give the phrase "the State that established the Exchange" its most natural meaning, there would be *no* "qualified individuals" on Federal Exchanges. But the Act clearly contemplates that there will be qualified individuals on *every* Exchange. As we just mentioned, the Act requires all Exchanges to "make available qualified health plans to qualified individuals"—something an Exchange could not do if there were no such individuals. And the Act tells the Exchange, in deciding which health plans to offer, to consider "the interests of qualified individuals . . . in the State or States in which such Exchange operates"—again, something the Exchange could not do if qualified individuals did not exist. This problem arises repeatedly throughout the Act. . . .

The Affordable Care Act contains more than a few examples of inartful drafting. Several features of the Act's passage contributed to that unfortunate reality. Congress wrote key parts of the Act behind closed doors, rather than through "the traditional legislative process." And Congress passed much of the Act using a complicated budgetary procedure known as "reconciliation," which limited opportunities for debate and amendment, and bypassed the Senate's normal 60-vote filibuster requirement. As a result, the Act does not reflect the type of care and deliberation that one might expect of such significant legislation.

Anyway, we must do our best, bearing in mind the fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme. After reading Section 36B along with other related provisions in the Act, we cannot conclude that the phrase "an Exchange established by the State under [Section 18031]" is unambiguous.

Given that the text is ambiguous, we must turn to the broader structure of the Act to determine the meaning of Section 36B. A provision that may seem ambiguous in isolation is often clarified by the remainder of the statutory scheme . . . because only one of the permissible meanings produces a substantive effect that is compatible with the rest of the law. Here, the statutory scheme compels us to reject petitioners' interpretation because it would destabilize the individual insurance market in any State with a Federal Exchange, and likely create the very "death spirals" that Congress designed the Act to avoid. . . .

In a State that establishes its own Exchange, . . . three reforms work together to expand insurance coverage. The guaranteed issue and community rating requirements

ensure that anyone can buy insurance; the coverage requirement creates an incentive for people to do so before they get sick; and the tax credits—it is hoped—make insurance more affordable. Together, those reforms "minimize . . . adverse selection and broaden the health insurance risk pool to include healthy individuals, which will lower health insurance premiums." 42 U.S.C. §18091(2)(I).

Under petitioners' reading, however, the Act would operate quite differently in a State with a Federal Exchange. As they see it, one of the Act's three major reforms—the tax credits—would not apply. And a second major reform—the coverage requirement—would not apply in a meaningful way. As explained earlier, the coverage requirement applies only when the cost of buying health insurance (minus the amount of the tax credits) is less than eight percent of an individual's income. So without the tax credits, the coverage requirement would apply to fewer individuals. And it would be a *lot* fewer. In 2014, approximately 87 percent of people who bought insurance on a Federal Exchange did so with tax credits, and virtually all of those people would become exempt. . . . The combination of no tax credits and an ineffective coverage requirement could well push a State's individual insurance market into a death spiral. . . .

It is implausible that Congress meant the Act to operate in this manner. Congress made the guaranteed issue and community rating requirements applicable in every State in the Nation. But those requirements only work when combined with the coverage requirement and the tax credits. So it stands to reason that Congress meant for those provisions to apply in every State as well . . .

Petitioners' arguments about the plain meaning of Section 36B are strong. But while the meaning of the phrase "an Exchange established by the State under [42 U.S.C. §18031]" may seem plain "when viewed in isolation," such a reading turns out to be "untenable in light of [the statute] as a whole." In this instance, the context and structure of the Act compel us to depart from what would otherwise be the most natural reading of the pertinent statutory phrase.

Reliance on context and structure in statutory interpretation is a subtle business, calling for great wariness lest what professes to be mere rendering becomes creation and attempted interpretation of legislation becomes legislation itself. For the reasons we have given, however, such reliance is appropriate in this case, and leads us to conclude that Section 36B allows tax credits for insurance purchased on any Exchange created under the Act. Those credits are necessary for the Federal Exchanges to function like their State Exchange counterparts, and to avoid the type of calamitous result that Congress plainly meant to avoid. . . .

In a democracy, the power to make the law rests with those chosen by the people. Our role is more confined—"to say what the law is." *Marbury v. Madison, 5 U.S. 137, 177 (1803).* That is easier in some cases than in others. But in every case we must respect the role of the Legislature, and take care not to undo what it has done. A fair reading of legislation demands a fair understanding of the legislative plan.

Congress passed the Affordable Care Act to improve health insurance markets, not to destroy them. If at all possible, we must interpret the Act in a way that is consistent with the former, and avoids the latter. Section 36B can fairly be read consistent with what we see as Congress's plan, and that is the reading we adopt.

• • •

In *King v. Burwell,* the Court struggled to address what common sense suggests was a simple drafting error. On one hand, perhaps courts should interpret the text of a statute literally without looking to the broader statutory scheme or congressional intent. If the result is not what Congress intended, then it can act to correct its mistake in subsequent legislation. On the other hand, perhaps the majority of the Court was correct to interpret the statute in light of congressional intent. Either approach can be justified in terms of democratic accountability. The justices who wrote in dissent argued that the Court—made up of unelected judges—was overstepping its bounds to save the Affordable Care Act. Justice Scalia sarcastically suggested that the law would be nicknamed "SCOTUS Care." Writing for the majority, Chief Justice Roberts reiterated that it is the Court's role to honor congressional intent. Efficiency and efficacy are surely on the side of the majority; had the Court disagreed with the IRS's interpretation of the statute and prohibited the provision of premium assistance tax credits to buyers in federally run health insurance exchanges, the entire architecture of the ACA would likely have crumbled after massive investment of resources in its implementation. We will return to these issues in chapter 8.

ADMINISTRATIVE AGENCIES' DUTY TO ACT

Agencies enjoy wide discretion in promulgating and enforcing regulations under their authorizing statutes. Sometimes, however, the legislature clearly instructs an agency to regulate a particular health hazard. Although the Constitution recognizes few enforceable obligations to protect the public's health (see chapter 4), these statutes may obligate agency officials to act. Courts play an important role in ensuring that agencies are accountable to Congress, which mitigates concerns about their lack of democratic accountability.

Even when Congress has made an obligation to act clear (by using language dictating that an agency head "shall" enact standards, for example), agencies, for political or other reasons, sometimes act slowly or not at all. In such cases, litigation by private parties or state or local governments may be necessary to enforce the legislature's mandate. At times, this process may take years and may involve multiple court battles.

The Clean Air Act (CAA) requires the Environmental Protection Agency (EPA) to set standards for vehicle emissions that contribute to

air pollution threatening the public's health. Nearly two decades ago, consumer organizations petitioned EPA to regulate greenhouse gas emissions from motor vehicles. In 2003, the agency denied the petition, concluding that the CAA did not grant it authority to regulate greenhouse gas emissions and that such regulation would, in any case, be unwise. Twelve states and several cities sued EPA and the case eventually reached the Supreme Court, resulting in the opinion excerpted below.

*MASSACHUSETTS V. EPA**

Supreme Court of the United States
April 2, 2007

Justice Stevens delivered the opinion of the Court. . . .

Calling global warming "the most pressing environmental challenge of our time," a group of States, local governments, and private organizations alleged in a petition for certiorari that the Environmental Protection Agency (EPA) has abdicated its responsibility under the Clean Air Act to regulate the emissions of four greenhouse gases, including carbon dioxide. Specifically, petitioners asked us to answer two questions concerning the meaning of § 202(a)(1) of the Act: whether EPA has the statutory authority to regulate greenhouse gas emissions from new motor vehicles; and if so, whether its stated reasons for refusing to do so are consistent with the statute. . . .

Section 202(a)(1) of the Clean Air Act . . . provides:

> The [EPA] Administrator shall by regulation prescribe (and from time to time revise) in accordance with the provisions of this section, standards applicable to the emission of any air pollutant from any class or classes of new motor vehicles or new motor vehicle engines, which in his judgment cause, or contribute to, air pollution which may reasonably be anticipated to endanger public health or welfare. . . .

The Act defines "air pollutant" to include "any air pollution agent or combination of such agents, including any physical, chemical, biological, radioactive . . . substance or matter which is emitted into or otherwise enters the ambient air." § 7602(g). "Welfare" is also defined broadly: among other things, it includes "effects on . . . weather . . . and climate." § 7602(h).

When Congress enacted these provisions [in 1970], the study of climate change was in its infancy. In 1959, shortly after the U.S. Weather Bureau began monitoring atmospheric carbon dioxide levels, an observatory in Mauna Loa, Hawaii, recorded a mean level of 316 parts per million. This was well above the highest carbon dioxide concentration—no more than 300 parts per million—revealed in the 420,000-year-old

* 549 U.S. 497.

PHOTO 5.3. Rush hour traffic. Emissions from cars and trucks are responsible for one-fifth of all U.S. carbon emissions, contributing significantly to global climate change. Climate change is expected to increase respiratory and cardiovascular disease, transmission of mosquito-borne diseases, and natural disasters, among other effects. Courtesy of Sanva1959 via Wikimedia Commons.

ice-core record. By the time Congress drafted § 202(a)(1) in 1970, carbon dioxide levels had reached 325 parts per million. . . .

In 1990, the Intergovernmental Panel on Climate Change (IPCC), a multinational scientific body organized under the auspices of the United Nations, published its first comprehensive report on the topic. Drawing on expert opinions from across the globe, the IPCC concluded that "emissions resulting from human activities are substantially increasing the atmospheric concentrations of . . . greenhouse gases [which] will enhance the greenhouse effect, resulting on average in an additional warming of the Earth's surface." . . .

On October 20, 1999, a group of 19 private organizations filed a rulemaking petition asking EPA to regulate "greenhouse gas emissions from new motor vehicles under § 202 of the Clean Air Act." . . . Fifteen months after the petition's submission, EPA requested public comment on "all the issues raised in [the] petition," adding a "particular" request for comments on "any scientific, technical, legal, economic or other aspect of these issues that may be relevant to EPA's consideration of this petition." EPA received more than 50,000 comments over the next five months. . . . On September 8, 2003, EPA entered an order denying the rulemaking petition. The Agency gave two reasons for its decision: (1) that contrary to the opinions of its former general counsels, the Clean Air Act does not authorize EPA to issue mandatory regulations to address global climate change; and (2) that even if the Agency had the authority to set greenhouse gas emission standards, it would be unwise to do so at this time.

EPA stated that it was "urged on in this view," by this Court's decision in *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000). In that case, relying on "tobacco['s] unique political history," we invalidated the Food and Drug Administration's reliance on its general authority to regulate drugs as a basis for asserting jurisdiction over an "industry constituting a significant portion of the American economy." EPA reasoned that climate change had its own "political history": Congress designed the original Clean Air Act to address *local* air pollutants rather than a substance that "is fairly

consistent in its concentration throughout the *world's* atmosphere"; declined in 1990 to enact proposed amendments to force EPA to set carbon dioxide emission standards for motor vehicles; and addressed global climate change in other legislation. Because of this political history, and because imposing emission limitations on greenhouse gases would have even greater economic and political repercussions than regulating tobacco, EPA was persuaded that it lacked the power to do so. In essence, EPA concluded that climate change was so important that unless Congress spoke with exacting specificity, it could not have meant the Agency to address it. . . .

On the merits, the first question is whether § 202(a)(1) of the Clean Air Act authorizes EPA to regulate greenhouse gas emissions from new motor vehicles in the event that it forms a "judgment" that such emissions contribute to climate change. We have little trouble concluding that it does. In relevant part, § 202(a)(1) provides that EPA "shall by regulation prescribe . . . standards applicable to the emission of any air pollutant from any class or classes of new motor vehicles or new motor vehicle engines, which in [the Administrator's] judgment cause, or contribute to, air pollution which may reasonably be anticipated to endanger public health or welfare." 42 U.S.C. § 7521(a)(1). Because EPA believes that Congress did not intend it to regulate substances that contribute to climate change, the agency maintains that carbon dioxide is not an "air pollutant" within the meaning of the provision.

The statutory text forecloses EPA's reading. The Clean Air Act's sweeping definition of "air pollutant" includes "*any* air pollution agent or combination of such agents, including *any* physical, chemical, . . . substance or matter which is emitted into or otherwise enters the ambient air. . . . " § 7602(g). On its face, the definition embraces all airborne compounds of whatever stripe, and underscores that intent through the repeated use of the word "any." Carbon dioxide, methane, nitrous oxide, and hydrofluorocarbons are without a doubt "physical [and] chemical . . . substance[s] which [are] emitted into . . . the ambient air." The statute is unambiguous.

Rather than relying on statutory text, EPA invokes postenactment congressional actions and deliberations it views as tantamount to a congressional command to refrain from regulating greenhouse gas emissions. Even if such postenactment legislative history could shed light on the meaning of an otherwise-unambiguous statute, EPA never identifies any action remotely suggesting that Congress meant to curtail its power to treat greenhouse gases as air pollutants. That subsequent Congresses have eschewed enacting binding emissions limitations to combat global warming tells us nothing about what Congress meant when it amended § 202(a)(1) in 1970 and 1977. And unlike EPA, we have no difficulty reconciling Congress' various efforts to promote interagency collaboration and research to better understand climate change with the Agency's pre-existing mandate to regulate "any air pollutant" that may endanger the public welfare. Collaboration and research do not conflict with any thoughtful regulatory effort; they complement it.

EPA's reliance on *Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000), is similarly misplaced. In holding that tobacco products are not "drugs" or "devices" subject to Food and Drug Administration (FDA) regulation pursuant to the Food, Drug and Cosmetic Act (FDCA), we found critical at least two considerations that have no counterpart in this case.

First, we thought it unlikely that Congress meant to ban tobacco products, which the FDCA would have required had such products been classified as "drugs" or

"devices." Here, in contrast, EPA jurisdiction would lead to no such extreme measures. EPA would only *regulate* emissions, and even then, it would have to delay any action "to permit the development and application of the requisite technology, giving appropriate consideration to the cost of compliance," § 7521(a)(2). However much a ban on tobacco products clashed with the "common sense" intuition that Congress never meant to remove those products from circulation, there is nothing counterintuitive to the notion that EPA can curtail the emission of substances that are putting the global climate out of kilter.

Second, in *Brown & Williamson* we pointed to an unbroken series of congressional enactments that made sense only if adopted "against the backdrop of the FDA's consistent and repeated statements that it lacked authority under the FDCA to regulate tobacco." We can point to no such enactments here: EPA has not identified any congressional action that conflicts in any way with the regulation of greenhouse gases from new motor vehicles. Even if it had, Congress could not have acted against a regulatory "backdrop" of disclaimers of regulatory authority. Prior to the order that provoked this litigation, EPA had never disavowed the authority to regulate greenhouse gases, and in 1998 it in fact affirmed that it *had* such authority. There is no reason, much less a compelling reason, to accept EPA's invitation to read ambiguity into a clear statute.

EPA finally argues that it cannot regulate carbon dioxide emissions from motor vehicles because doing so would require it to tighten mileage standards, a job (according to EPA) that Congress has assigned to DOT [(Department of Transportation)]. But that DOT sets mileage standards in no way licenses EPA to shirk its environmental responsibilities. EPA has been charged with protecting the public's "health" and "welfare," 42 U.S.C. § 7521(a)(1), a statutory obligation wholly independent of DOT's mandate to promote energy efficiency. The two obligations may overlap, but there is no reason to think the two agencies cannot both administer their obligations and yet avoid inconsistency.

While the Congresses that drafted § 202(a)(1) might not have appreciated the possibility that burning fossil fuels could lead to global warming, they did understand that without regulatory flexibility, changing circumstances and scientific developments would soon render the Clean Air Act obsolete. The broad language of § 202(a)(1) reflects an intentional effort to confer the flexibility necessary to forestall such obsolescence. Because greenhouse gases fit well within the Clean Air Act's capacious definition of "air pollutant," we hold that EPA has the statutory authority to regulate the emission of such gases from new motor vehicles.

The alternative basis for EPA's decision—that even if it does have statutory authority to regulate greenhouse gases, it would be unwise to do so at this time—rests on reasoning divorced from the statutory text. While the statute does condition the exercise of EPA's authority on its formation of a "judgment," 42 U.S.C.§ 7521(a)(1), that judgment must relate to whether an air pollutant "cause[s], or contribute[s] to, air pollution which may reasonably be anticipated to endanger public health or welfare." Put another way, the use of the word "judgment" is not a roving license to ignore the statutory text. It is but a direction to exercise discretion within defined statutory limits.

If EPA makes a finding of endangerment, the Clean Air Act requires the Agency to regulate emissions of the deleterious pollutant from new motor vehicles. EPA no doubt

has significant latitude as to the manner, timing, content, and coordination of its regulations with those of other agencies. But once EPA has responded to a petition for rulemaking, its reasons for action or inaction must conform to the authorizing statute. Under the clear terms of the Clean Air Act, EPA can avoid taking further action only if it determines that greenhouse gases do not contribute to climate change or if it provides some reasonable explanation as to why it cannot or will not exercise its discretion to determine whether they do. To the extent that this constrains agency discretion to pursue other priorities of the Administrator or the President, this is the congressional design.

EPA has refused to comply with this clear statutory command. Instead, it has offered a laundry list of reasons not to regulate. For example, EPA said that a number of voluntary Executive Branch programs already provide an effective response to the threat of global warming, that regulating greenhouse gases might impair the President's ability to negotiate with "key developing nations" to reduce emissions, and that curtailing motor-vehicle emissions would reflect "an inefficient, piecemeal approach to address the climate change issue."

Although we have neither the expertise nor the authority to evaluate these policy judgments, it is evident they have nothing to do with whether greenhouse gas emissions contribute to climate change. Still less do they amount to a reasoned justification for declining to form a scientific judgment. In particular, while the President has broad authority in foreign affairs, that authority does not extend to the refusal to execute domestic laws. In the Global Climate Protection Act of 1987, Congress authorized the State Department—not EPA—to formulate United States foreign policy with reference to environmental matters relating to climate. EPA has made no showing that it issued the ruling in question here after consultation with the State Department. Congress did direct EPA to consult with other agencies in the formulation of its policies and rules, but the State Department is absent from that list.

Nor can EPA avoid its statutory obligation by noting the uncertainty surrounding various features of climate change and concluding that it would therefore be better not to regulate at this time. If the scientific uncertainty is so profound that it precludes EPA from making a reasoned judgment as to whether greenhouse gases contribute to global warming, EPA must say so. That EPA would prefer not to regulate greenhouse gases because of some residual uncertainty . . . is irrelevant. The statutory question is whether sufficient information exists to make an endangerment finding.

In short, EPA has offered no reasoned explanation for its refusal to decide whether greenhouse gases cause or contribute to climate change. Its action was therefore "arbitrary, capricious, . . . or otherwise not in accordance with law." 42 U.S.C. § 7607(d)(9)(A). We need not and do not reach the question whether on remand EPA must make an endangerment finding, or whether policy concerns can inform EPA's actions in the event that it makes such a finding. We hold only that EPA must ground its reasons for action or inaction in the statute. . . .

• • •

The Court notes the EPA's shifting position regarding its authority under the CAA, but does not discuss the obvious explanation. In 1998, when EPA asserted that it did have authority to regulate greenhouse gasses, it

did so under the direction of President Bill Clinton. When it declined to regulate greenhouse gasses in 2003, EPA emphasized the Bush administration's preference for voluntary measures. After the Court rejected EPA's arguments, President George W. Bush promised to issue regulations, but he did not do so before leaving office. In 2009, the Obama administration initiated a rulemaking process culminating in a finding that six greenhouse gases "in the atmosphere may reasonably be anticipated both to endanger public health and to endanger public welfare." The following year, Alabama, Texas, Virginia, and several other parties challenged this determination in court. The U.S. Court of Appeals for the District of Columbia Circuit dismissed these challenges, upholding EPA's finding that carbon dioxide and other greenhouse gases endanger public health because of their effect on climate change.

In the final days of the Obama administration, EPA expedited ongoing review of vehicle greenhouse gas emissions standards, finalizing new rules just prior to the inauguration of President Trump. In 2018, EPA Administrator Scott Pruitt launched a process to develop more lenient emissions and fuel economy standards via notice and comment rulemaking. Agencies may be staffed by experts, but they serve at the behest of politicians.

AGENCY ACTION ACROSS SECTORS FOR PUBLIC HEALTH

As the preceding case demonstrates, agency action to protect the public's health is not confined to public health departments. EPA is subject to multiple statutory mandates that explicitly direct it to protect the public's health. Many other agencies are responsible for sectors that affect health in important ways, but their statutory mandates may not expressly recognize health as part of their missions. In a few cases, an agency's statutory mandate may actually run counter to the public's health.

An international movement to incorporate consideration of health impacts into the mandates of all agencies—referred to as "health in all policies"—is gaining ground in the United States. This approach could be incorporated into administrative law but has not yet been codified by Congress in any significant way. In the excerpt that follows, the Institute of Medicine (IOM) (now the National Academy of Medicine) describes the health in all policies movement and argues it should play a role in revitalizing public health law to meet the challenges of the early twenty-first century.

INTERSECTORAL ACTION ON HEALTH*

Institute of Medicine

THE "HEALTH IN ALL POLICIES" MOVEMENT

. . . Interest has been growing both in the United States and abroad . . . in "Health In All Policies" (HIAP), an approach to policymaking in which decision-makers outside the health sector routinely consider health outcomes: benefits, harms, and health-related costs. Kickbush and Buckett define HIAP as "public service agencies working across portfolio boundaries to achieve a shared goal and an integrated government response to particular issues. Approaches can be formal or informal, and can focus on policy development, program management and service delivery" (Kickbusch and Buckett 2010, 10). Although the HIAP concept emerged in connection with government organizations, its meaning has been extended to include private and non-profit policies as well. . . .

Rationale

Most decision-makers who set policies on housing, agricultural crop incentives, or highway construction do not usually consider the public health dimensions, in part because they have not had traditional, or statutory, responsibility for those areas. Also, health entities in the government, private, and not-for-profit sectors are similarly unlikely to connect or collaborate with those who may be considered stakeholders in the public's health. These failures to connect have consequences for all involved. Too often, proponents of a policy overlook potential health benefits in making their case or in calculating the return on investment to argue the value proposition.

Conversely, advocates of a policy do not always consider the potential harms to public health, and resulting costs, or how those harms could be mitigated. Overlooking health seems incompatible with good policymaking, not only because it creates an incomplete picture of the full outcomes of a proposed course of action, but also because it can undermine the ability to coordinate efforts across sectors to address important public health and economic priorities. . . . Working across sectors can improve effectiveness in addressing public health problems by tackling root causes that are outside the traditional health sector. It could also maximize the use of existing government, institutional, and policy resources by promoting synergy, identifying economies of scale, and reducing duplication of effort. Adopting a HIAP approach could cost little or nothing in many areas of local government. For example, in transportation, land use, or zoning decisions, some modifications that influence health may have minor or no budgetary implications for the implementing agencies.

Cross-governmental collaboration is hardly a novel notion for public health agencies. Those capacities were evident after September 11, 2001, when bioterrorism preparedness planning brought public health practitioners into closer discussions with fire, law enforcement, and emergency management communities. A need for broader collaboration to address the rising prevalence of chronic disease has strengthened the imperative for coordinated efforts across the public and private sector. . . .

* 2011. In *For the Public's Health: Revitalizing Law and Policy to Meet New Challenges,* 73–110. Washington, DC: National Academies Press.

HIAP and the Federal Government

In the past several years, reports from U.S. blue ribbon panels have offered recommendations for a coordinated, intersectoral approach to governing. For example, the Center for the Study of the Presidency and Congress issued a report by its Commission on U.S. Federal Leadership in Health and Medicine, which recommended the implementation of a HIAP approach across federal departments and agencies, including the creation of a federal coordinating council. . . .

Many of the themes of HIAP surfaced in the evolution of health care reform legislation and took statutory form in some of the provisions included in the Affordable Care Act (ACA) by Congress in 2010. Specifically, the law called for the establishment of the National Prevention, Health Promotion, and Public Health Council. The Council, created by executive order of the President and convened by the Surgeon General of the US Public Health Service, constitutes the highest-profile HIAP action in the federal government. It brings together cabinet secretaries and heads of major agencies to develop a prevention strategy for the nation and to address national health priorities from an interdepartmental and interagency perspective. Despite the distinct statutory roles, responsibilities and priorities of the separate agencies, the Council calls on its executives to think creatively about ways in which their interests may be furthered by contributing to the nation's prevention, health promotion, and public health strategy. . . .

Challenges to Implementing HIAP

The ease of implementation and the success of HIAP approaches is dependent on (1) the level of compatibility of interests among the relevant sectors; (2) the extent to which health policy or intersectoral action of some sectors can bring about the desired change on their own (compared to how much of it is dependent on changes or constraining factors in other sectors); and (3) the costs of strategies (e.g., financial, political, social) and the fact that benefits are often harder to calculate than immediate costs. Challenges to implementing health in all policies approaches also include the health sector's limited connectedness to other sectors; intersectoral differences in aims and values and organizational culture and politics; and the costs and opportunity costs of focusing on health as a primary outcome of policy. . . .

[T]he fragmented structure of government is . . . an obstacle to the HIAP approach. Federal, state, and local governments are often balkanized in silos—agencies with discrete policy interests and regulatory concerns that lack the culture, tools, and language to cross boundaries and coordinate with counterparts in other agencies. An infrastructure that supports such collaboration, such as an interagency task force, cannot be formed or operate effectively without hard work to build relationships and solve interagency barriers that impede communication, collaboration, and the sharing of resources. . . .

Structures To Support Collaboration in Promoting Health in All Policies

In its purest form, the HIAP approach entails collaboration among multiple sectors, reaching beyond the government, to foster the conditions for good health. Public health agencies or, more broadly, government, cannot alone be effective in helping a community to address tobacco use, reduce obesity, redesign the built environment,

> produce jobs, and improve children's education. Nor can the private sector do this alone. Effective strategies require collaboration as well as coordination, with the latter being important to marshal and leverage limited resources, avoid duplication, and use the talents and assets that each partner offers. Few would dispute the merits of coordination and collaboration, but the infrastructure for forming such partnerships is lacking in most communities. . . .
>
> Across the nation, new working relationships are being formed among private, nonprofit, and governmental agencies, bringing new challenges and bridging to enable shared responsibilities. Policy, in both the public and private sectors, can facilitate and guide these partnerships. . . .

. . .

The IOM report argues that the HIAP approach should extend beyond government to encompass partnerships between government and private actors. Commentators are often enthusiastic about the promise that public-private partnerships hold for tackling pressing public health challenges. Others express concern, however, about the transition from a government-led, prescriptive regulation to a more flexible approach affording regulated industries a greater role in self-governance. In the next chapter, we will take up these issues, comparing and contrasting various approaches to direct regulation as a mode of public health law intervention.

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PART THREE

Modes of Legal Intervention

PHOTO 6.1. A restaurant inspector checks the temperature of items in a food service area. Local food service ordinances designed to prevent infectious disease typically adopt the highly prescriptive "command and control" style of regulation. Local ordinances typically prescribe, for example, that specific temperature ranges must be maintained at all times. These standards are enforced through a system of inspections and fines. Photograph by Amanda Mills for CDC.

CHAPTER SIX

Direct Regulation for the Public's Health and Safety

In Part One, we explored the scope and limits of governmental public health powers. In this part, we explore how those powers are exercised. Protecting the public's health and safety requires lawmakers and regulators to grapple with hard problems. They must decide not only which risks to regulate, but also which tools to use. Should regulations prescribe specific precautions with harsh sanctions to deter and punish violations? Should private parties enforce social norms about precaution and responsibility by recourse to the courts? Should market forces be allowed to determine the appropriate level of precaution? Should government establish broadly defined targets while allowing private entities to choose the best strategies for reaching them? Should government employ financial incentives to influence the private sector?

The public health law toolkit is varied; it includes direct regulation and deregulation (the subjects of this chapter), tort liability as a form of indirect regulation (chapter 7), and taxation and spending strategies (chapter 8). Each of these modes of regulation has advantages and disadvantages in terms of effectiveness, political feasibility, fiscal and budgetary considerations, ethical acceptability, and vulnerability to legal challenge. Governments typically deploy a mix of strategies in response to complex, multifaceted social and economic problems. Moreover, the various modes of legal intervention are often interconnected, with taxation and spending incentives facilitating (or in some cases impeding) the attainment of regulatory targets and tort liability

rules filling gaps in direct regulation, often with reference to privately adopted standards of conduct.

We begin this chapter with the spectrum of regulatory strategies from the prescriptive and coercive *command and control* style of regulation to softer, market-based *new governance* strategies. Next, we turn to an issue of upmost importance in the modern regulatory state: regulatory impact analysis based on calculation of costs and benefits, which informs decisions about whether and how to regulate risk. Then, we discuss the application of market-based regulatory strategies—including public disclosure mandates, choice architecture, third-party certification, and industry self-regulation—to public health problems ranging from tobacco use to food safety. We conclude with a discussion of deregulation as a mode of legal intervention, with an emphasis on harm reduction to address problems associated with illicit drug use and commercial sex work.

FROM COMMAND AND CONTROL TO NEW GOVERNANCE

The twentieth century was a time of massive transformation for the regulatory state. In the early twentieth century, regulators sought to expand protections for workers and consumers in the rapidly industrializing and globalizing American economy. As described in previous chapters, the Supreme Court initially pushed back during the *Lochner* era, holding that the economic liberty of businesses, workers, and consumers to contract for labor and goods imposed significant constraints on government power. By the mid-twentieth century, President Franklin D. Roosevelt's New Deal led to a reversal of the Court's position and a major expansion of the social safety net (discussed in chapter 8) and health and safety regulation. This trend continued with sweeping environmental protection and consumer product safety legislation implemented in the 1970s.

Ultimately, however, the imposition of significant burdens on business interests led to a backlash against the regulatory state. The critique that regulation imposes senseless, bureaucratic requirements that strangle economic growth and innovation with little benefit to the public is too familiar to need recounting here. Economic conservatives have long argued that government should avoid meddling with economic and social affairs, leaving market forces free to achieve the most efficient outcomes. At the turn of the twenty-first century, some political scientists and legal scholars responded to the competing arguments for traditional

regulation and deregulation by staking out a middle ground: softer regulatory strategies that work with market forces to bring about change from the bottom up, rather than attempting to impose the will of social planners from the top down. In the excerpt that follows, legal scholar Orly Lobel reviews the organizing principles, strategies, and goals of the so-called new governance approach in contrast to more traditional command-and-control regulation.

THE RENEW DEAL: THE FALL OF REGULATION AND THE RISE OF GOVERNANCE IN CONTEMPORARY LEGAL THOUGHT*

Orly Lobel

. . . The establishment of the New Deal by President Franklin Roosevelt is widely understood as one of the most significant events in American politics of the twentieth century. . . . Responding to the burdens and risks of the Depression and two world wars, the New Deal instigated the creation of the modern regulatory and administrative state. . . . In a short period of time, a sweeping set of new regulations, regulatory agencies, and federal and state programs were created. As we enter the twenty-first century, commentators from across the political spectrum are signaling a second revolutionary paradigm shift—the Renew Deal. . . .

THE ORGANIZING PRINCIPLES OF THE RENEW DEAL GOVERNANCE MODEL

Participation and Partnership

During the New Deal era, a key feature of the organization of law and order was the commitment to centralized, institutional decision-making authorities relying on professional, official expertise. . . . The central proposition of the New Deal regulatory model was that a few well-educated, specially trained, and publicly appointed professionals could make the best decisions about national policies. The belief in experts and the need for regulation were mutually reinforcing. The project of centralized social engineering required focused fact-finding and professional skills. . . . External participation was thought of as a threat to the expertise and legitimacy of the administrative state, since expert agencies would be . . . prone to capture by private industry pressures.

The new governance model challenges these conventional assumptions. It broadens the decision-making playing field by involving more actors in the various stages of the legal process. It also diversifies the types of expertise and experience that these new actors bring to the table. . . . Participation has included the creation of a system of third-party government, in which the public sector uses . . . third-party agents to carry out public functions, such as the delivery of social services. Sharing tasks and responsibilities with the private sector creates more interdependence between government

* 2004. *Minnesota Law Review* 89 (2): 342–470.

and the market. . . . This cycle thus explains, for example, how today's body of federal employees is one-third smaller per-capita than it was immediately after the New Deal, even though massive new responsibilities have been undertaken by government. . . .

Of particular importance is the role of private ordering and self-regulation, particularly new instances of private standard setting, accreditation, and certification plans by independent activists, as well as monitoring by both nonprofits and for-profit consulting firms. New governance policies seek to enable individuals and organizations to act as private attorney generals and to block watch public action. . . .

Collaboration

Under the traditional regulatory model, industry and private individuals are the object of regulation. Their agency is limited to choosing whether to comply with the regulations to which they are subjected. Information flows selectively to the top while decisions flow down, following rigid parameters, and leaving decision making to a small, detached group of number-crunching experts. . . . The governance model . . . views traditional patterns of hierarchical top-down regulatory control as obsolete. . . . In a cooperative regime, the role of government changes from regulator and controller to facilitator, and law becomes a shared problem-solving process rather than an ordering activity. . . . Industry is expected to participate as part of a search for common goals, not just rigidly asserting its narrow economic or political interests. Congress has . . . endorsed the spirit of collaborative rulemaking by standardizing regulatory negotiation in the Negotiated Rulemaking Act of 1990, which was permanently reauthorized in 1996. Negotiated rulemaking is a process through which stakeholders come together to negotiate and reach consensus as to the substance of regulation. . . .

Diversity and Competition

The command-and-control regulatory model of the New Deal Era sought to control market rates, control entry into industries, and command the minimum conditions and requirements of production and service. . . . Responding to the increased complexity, diversity, and volatility of the new market, the Renew Deal aims conversely to promote diversification, pluralization of solutions, and increased competition. A central critique of the old regulatory model is its one-size-fits-all approach. The premise of the governance model is that, in order for a legal regime to be sustainable, it must encompass a multitude of values and account for conflict and compromise. It must acknowledge the diversity and changing interests of many stakeholders. It must recognize the legitimacy of private economic interests while appealing to public values. . . .

Some scholars, assuming the Renew Deal is transitional, call for more [experimentation and evaluation before settling on the best solution]. The most sophisticated articulations of the governance model, however, understand competition and diversity not as a temporary strategy before choosing the superior solution in any given scenario, but rather as a means for continuous change and improvement. . . .

Decentralization and Subsidiarity

During the New Deal era, centralization was thought to be essential to overcoming the economic crisis that the nation faced. . . . In contrast, the Renew Deal advocates a movement downward and outward—a transfer of responsibilities to the states

and localities and to the private sector, including private businesses and nonprofit organizations.

Decentralization serves at least four different purposes. First, it promotes the governance principles we have just explored—participation, diversity, competition, and experimentation. A decentralized public design realizes Justice Brandeis' metaphor of the states as laboratories of experimentation. . . . Second, decentralization affirms the pragmatic idea of subsidiarity, including the localness and partiality of human knowledge, and the difficulty of translation between localities. . . . As a guiding principle of social organization, subsidiarity maintains that all governmental tasks are best carried out at the level closest to those affected by them. Central authorities should leave the widest scope possible for local discretion to fill in the details of broadly defined policies. . . . A third function of decentralization is the creation of relational density and synergy. . . . A relatively small-scale geographic focus gives people a sense of connectedness. Indeed, there are psychological and anthropological indications that scale matters for successful engagement—the smaller the scale, the easier it is for people to communicate and to reach sustainable solutions. . . . A fourth rationale for decentralization follows naturally from the generation of multiple links among groups and individuals. The aspiration of the governance model is that increased engagement will contribute to the building of deliberative and collaborative capacities, thus sustaining an environment for democratic engagement. . . . Neighbors become able to view one another in their relationships as sellers-consumers, employers-employees, property owners-tenants, planners-citizens, and administrators-service recipients. . . . [U]nder the right architecture—increased social density that generates collaboration and interdependence—people will follow norms and conform without formal regulatory means because of the necessity of repeat dealings, adverse effects on reputation, relationship-based credibility, possibility of retribution, and the increased likelihood of reciprocation. . . .

Integration of Policy Domains

The features of participation, collaboration, decentralization, and diversity all have the potential to illuminate how widely dispersed issues are nonetheless connected at the level of those who are most influenced by them. . . . In a regulatory model, law is fragmented into distinct, specified subfields. By contrast, the governance model takes a holistic approach to problem solving. . . . Renew Deal scholarship aims to show how most social problems involve multiple issues including the interconnections between housing, employment, family, welfare, health, transportation, banking, and entrepreneurship. . . .

Flexibility and Noncoerciveness (or Softness-in-Law)

The governance model aims to create a flexible and fluid policy environment that fosters "softer" processes that either replace or complement the traditional "hard" ordering of the regulatory model. Scholars suggest a leap outside the regulatory box, developing new mechanisms to replace top-down ordering, implementation, and enforcement. . . .

The term "soft law" has been used in legal scholarship in a variety of ways. At one extreme, soft law regimes are comprised of interwoven rules of conduct, established

and enforced within the private realm in the absence of a hard-binding regulatory regime. . . . This approach urges us not to equate law with formal regulation but rather to decenter the concept of law to include multiple instances of normativity, particularly nonstate generated norms. . . . These nonregulatory instruments include social labeling, voluntary corporate codes of conduct, private accreditation and certification by nongovernmental actors.

At its best, however, the governance model assumes a harder definition of soft law; one that preserves an active role for the state and the legal regime. . . . [Formal governmental institutions may exert authority in a variety of ways.] For example, in recent years, several administrative agencies have issued "good guidance practices" instead of more conventional regulations. In the mid-1990s, the Federal Drug Administration (FDA) decreased the number of its regulations by fifty percent compared with its activities during the 1970s and 1980s. But over the same time period, the number of guidance documents it has issued increased by four hundred percent. . . .

Hard regulatory processes often include rigid requirements about the scope of participation, the forms of exchange between participants, and the ways in which decisions can be reached, such as the notice and comment requirements under the Administrative Procedure Act. Softer processes loosen these requirements to allow open communication, fluid participation, and consensus-based deliberation. [In addition, l]ess coercive sanctions can promote flexibility in implementation and compliance. . . . This aspect of soft law has been described in the context of the increasing adoption of reporting requirements rather than the imposition of penalties as "structured but unsanctioned."

[Other aspects of] softness-in-law [have] developed within the traditional regulatory model [and are continuing to interact with other forms of softening under the new model. First,] the traditional realist concept of the choice between rules and standards. . . . For example, recently adopted performance-based regulation . . . promotes flexibility in the means adopted to achieve the specified goals. Private firms are given incentives to search for the least costly approach to abide by the performance requirements. Often, along with the adoption of such mechanisms, firms are required to design plans that outline how certain goals will be achieved. The governmental agency assists the development of these plans, as well as approving or certifying them. Subsequently, firms need to show compliance with their own plans or provide reasons for divergence from them. . . .

A second and final understanding of softness that existed within the regulatory tradition is that actual enforcement of a law is weak, even as the threat of formal sanctions continues. . . . From a regulatory perspective, this kind of softness is usually seen as an unintended, undesirable result. However, from a governance perspective, it is understood as a potential tool. Hence, Renew Deal commentators have proposed formalizing this feature of incomplete enforcement and law-in-action flexibility. . . .

[D]ifferent rationales abound as to why, in certain contexts, soft mechanisms may be preferable to hard regulation. . . . A soft law approach reduces the often perverse incentives imposed by liability and sanctions. [In some circumstances,] the gap between the aspired norm and the existing reality is so large that hard regulatory provisions are meaningless. . . . Softer mechanisms allow a regime to establish minimum levels of adherence and to formalize advancement toward higher, aspirational standards. [A softer approach may also be preferable] where there is intense disagreement among decision-making authorities[,] too much political weakness to reach hard legis-

lation[,] or too much ideological resistance to ensure implementation. In such cases, . . . softer initiatives may often be enough to achieve similar results through a noncoercive, nonregulatory approach. . . .

Finally, an overarching justification for softer, flexible approaches to policy is that they increase the overall legitimacy of the system. Soft law is experienced by the different stakeholders in a polity as less oppressive than regulatory means and force. Semivoluntary compliance . . . increases people's willingness to contribute freely to the efforts of public policy; thus supporting other governance principles, including collaboration, diversity, and learning. . . .

Fallibility, Adaptability, and Dynamic Learning

The regulatory model has often proved stagnant and sluggish, curtailing revision and improvement. . . . While regulation has been an ordering act, governing is a learning process. The new model is better positioned to accept uncertainty and diversity, advancing iteratively toward workable solutions. The role of law is to promote practices that allow revision and improvement. . . . When technology is widespread and knowable and standards are easy to define, command-and-control regimes might be preferable. Yet, under the realities of fast advancements, heterogeneity, and complexity, the informational and adaptability advantages of private firms should be configured into the legal system. . . .

Law as Competence and Orchestration

The final feature of the governance model is orchestration. Orchestration renders all other aspects of the governance model meaningful, separating the model from flat processes of devolution and deregulation. . . . While power is decentralized to allow local knowledge to match solutions to their individual circumstances, decentralization must be coupled with regional and national commitments to coordinate local efforts and communicate lessons in a comprehensive manner. . . . In the Renew Deal vision, the central authority declares a need and an intention to address an issue and expresses willingness to provide resources. The role of government is to promote and standardize innovations that began locally and privately. Scaling up, facilitating innovation, standardizing good practices, and researching and replicating success stories from local or private levels are central goals of government. . . .

• • •

The new governance principles described by Lobel in glowing terms have been criticized by many public health and environmental protection advocates, as we will discuss below. Nonetheless, market-based regulatory strategies—including public disclosure mandates aimed at channeling consumers toward safer, healthier products and services, the use of choice architecture to influence the decisions made by businesses and individuals, and industry self-regulation—are here to stay. Before describing these regulatory tools in more detail, we turn next to a discussion of regulatory impact analysis based on cost-benefit calculations, one of the most influential—and controversial—aspects of new governance.

REGULATORY IMPACT ANALYSIS

Regulation has far-reaching effects, requiring evaluation to determine whether it serves health and safety goals and whether it will have unintended consequences. The dominant mode of regulatory impact analysis—assessment based on calculations of the costs and benefits—is firmly entrenched in the regulatory process. Republicans and Democrats alike have expanded its use through a process of centralized White House review. This additional layer of review has become a crucially important hurdle for health and safety regulation. In the excerpts that follow, Rena Steinzor and Matthew Wansley critique regulatory impact analysis and suggest alternatives.

THE CASE FOR ABOLISHING CENTRALIZED WHITE HOUSE REGULATORY REVIEW*

Rena Steinzor

This Article argues that centralized White House regulatory review is a primary cause of regulatory failure that the nation can well do without. Centralized review shoves policymaking behind closed doors, wastes increasingly limited government resources, confuses agency priorities, demoralizes civil servants, and, worst of all, costs the nation dearly in lost lives, avoidable illness and injury, and destruction of irreplaceable natural resources. . . .

Proponents of centralized review . . . accept as dogma that the President must exert rigorous, day-to-day control over regulatory policy making. They further argue that cost-benefit analysis must reign supreme in regulatory decision making and that [the Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs (OIRA)] must enforce that discipline. In contrast, I contend that OIRA with all the flaws inherent in its mission and institutional design, occupies such a central role in the President's universe that it blinds the White House to the existence of agency dysfunction and regulatory failure and prevents a concerted, desperately needed response to that far more significant phenomenon. . . .

THE HISTORY OF CENTRALIZED REVIEW

With the notable exception of the FDA, the most important health, safety, and environmental agencies were created in the first flush of progressive idealism and social movements catalyzed by young people's protests against the Vietnam War. The companies subject to this stunning expansion of the regulatory state appeared to have been caught by surprise, and they did not muster any effective opposition to the rapid-fire creation of these new institutions. They recovered quickly, however, and the seeds of centralized White House review controlled by political staff and economic advisers at the highest levels were planted in the early days of the Nixon administration. . . .

* 2012. *Michigan Journal of Environmental & Administrative Law* 1 (1): 209–86.

[In] 1978, President Carter issued the first executive order to mandate a comprehensive regulatory review program headquartered at OMB. Executive Order 12,044 directed that regulatory proposals should not impose "unnecessary" burdens on the economy and should be issued only after consideration of "meaningful" alternatives. It also required the preparation of a "Regulatory Analysis" to accompany all rulemaking proposals and final rules, as well as a semiannual regulatory agenda containing notice of rules under development. . . .

At the close of the Carter administration, industry champions of deregulation succeeded in getting two statutes passed to impose further controls on the agencies: the Regulatory Flexibility Act and the Paperwork Reduction Act. The second statute created OIRA. The new unit's statutory mission was limited to reviewing any proposal by a government agency or department to require the completion of additional paperwork by citizens, state or local government, or private sector entities. But OIRA's far more important role in reviewing the substance of regulations was soon fleshed out in a series of executive orders. The first, Executive Order 12,291, issued by President Reagan within one month of taking office, had three distinct mandates: 1. All covered agencies must refrain from taking action unless potential benefits outweigh potential costs. The agencies must also consider regulatory alternatives that involve the lowest net cost. 2. Agencies must prepare a "regulatory impact analysis" (RIA) containing their cost-benefit analysis for each "major" rule, defined to include any proposal that would have an annual effect on the economy of $100 million or more. 3. Agencies must send a copy of each proposed and final rule to OIRA before it is published in the Federal Register. Agencies were instructed to refrain from publishing rules until they had responded to any concerns raised by OIRA staff. Agencies were required to forward proposed and final rules, along with accompanying RIAs, to OIRA at least sixty days prior to their publication. OIRA would be "deemed to have concluded review" within thirty days of submission of a major final rule or rule proposal unless "the Director advises the agency to the contrary," in essence giving OIRA discretion to extend its review period indefinitely.

In addition to formalizing cost-benefit analysis—notably, without any statutory authority—Executive Order 12,291 is significant because of the dynamic it set up between agency heads and the OIRA Administrator. The order did not go so far as to hand OIRA the power to kill a rule outright, an outcome that arguably would be illegal under EPA's authorizing statutes, which delegate rulemaking mandates directly to the agency Administrator as opposed to the President. But given the White House's sway over agency heads, that explicit grant of final authority was unnecessary. Instead, the instruction to consult—and implicitly to satisfy—OIRA's economists set up an inside game dynamic [that is] now quite entrenched: all disputes would be negotiated behind closed doors at the staff level, no matter how difficult the dispute and how garbled the resulting compromise.

President Reagan's second and last executive order on regulatory review, Executive Order 12,498, extended OIRA's power further by requiring covered agencies to submit entire regulatory programs to OIRA on an annual basis, specifying that OIRA had the authority to "return" individual rulemaking proposals to an agency for "reconsideration" if the item had not been included or was "materially different" from what the annual agenda described. This development in effect ratified the idea that OIRA was not merely a passive recipient of whatever ideas the agencies chose to advance,

but instead had some responsibility for reviewing the wisdom of their overall regulatory priorities. . . .

[In 1993, President Bill Clinton issued Executive Order 12,866 to replace 12,291 and 12,498.] Although the Clinton approach preserved OIRA's authority to consult with respect to "significant" rules (those that would impose economic effects over $100 million annually or "adversely affect" the economy "in a material way"), it imposed some important constraints on the process. OIRA was given a series of mandatory deadlines for the conclusion of review, with the review period limited to ninety days following submission of the rule by an agency or department, although that deadline was subject to one possible extension of thirty days if the extension was approved in writing by the OIRA Administrator and the head of the agency responsible for the rule requested the extension. As significantly, Executive Order 12,866 required that after a regulatory action was published in the Federal Register, or after an agency or department had announced its decision not to pursue the regulatory action, OIRA "shall make available to the public all documents exchanged between OIRA and the agency during the review by OIRA under this section." These before-and-after documents would reveal the extent and nature of the changes OIRA demanded from the agencies. Last but not least, although the Clinton order required agencies to conduct, and OIRA to review, cost-benefit analyses, the ultimate standard for acceptance of a rule was whether benefits "justified" costs, a formula perceived as significantly more flexible than the Reagan requirement that benefits "outweigh" costs. These reforms were useful, but they did not eliminate OIRA's gatekeeper authority. . . .

THE IMPLICATIONS OF CENTRALIZED REVIEW

One-Way Ratchet

[A]ny close observer of OIRA's behavior over time would be hard pressed to assert that it ever takes a consistently neutral approach to the policy choices presented by rulemaking in the arena of health, worker safety, and environmental protection, even under chief executives with a more moderate approach to these issues, such as Presidents Clinton and Obama. Instead, the sheer weight of its history, culture, and professional composition maintain its instinctive hostility toward such protective requirements. . . .

[OIRA's] activities undermine the clear intent of ambitious, protective statutes in a process that is hidden from the public view. A far preferable way for conservatives to accomplish such changes in a democratic, federalist republic would be to garner the votes to amend these laws. If they cannot, or if Congress is too dysfunctional and polarized to make such lawmaking practical, the least OIRA can do is to be transparent and tread carefully with respect to statutory mandates. . . .

Lost Opportunity Costs

By squarely occupying the space within the Executive Branch that is concerned with regulatory policy, OIRA forestalls other players from taking the initiative and acting to remedy agency dysfunction. In effect, the White House drives blind with respect to the acute funding shortfalls that threaten the viability of [the protector agencies created to protect public health, worker safety, and the environment—including the Environ-

mental Protection Agency (EPA); the Food and Drug Administration (FDA); the Nuclear Regulatory Commission (NRC); the Mine Safety and Health Administration (MSHA); the Occupational Safety and Health Administration (OSHA); the National Highway Traffic and Safety Administration (NHTSA); and the Consumer Product Safety Commission (CPSC)]. . . . When crises . . . erupt, the White House staff and the President are forced to react. But those reactions do not appear to be informed by any comprehensive analysis of why the agencies fail to prevent such catastrophes and, as important, what reforms are needed to ensure that these disasters do not occur again.

OIRA's single-minded focus on individual regulations, and its fierce assertion of the power to oversee the entire regulatory system, also means that the White House has failed to respond to a series of cross-cutting problems that affect several agencies and can only be addressed through affirmative policy-making at the highest levels. . . . OIRA's small staff of economists, trained in the intricacies of cost-benefit analysis, steeped in the negative culture that pervades centralized review, and accustomed to mustering agencies to attack proposals rather than solve problems, is ill-equipped to undertake such a complex and challenging initiative. But because OIRA exists, and has the regulatory system as its portfolio, no other White House office has stepped into this growing breach. . . .

If Not OIRA, What?

We come . . . to the question of what should replace OIRA's brand of centralized review. . . . [T]he overarching goals of this recommendation are quite straightforward: White House staff should stop reviewing individual rules and rule proposals on a routine basis, instead delegating this responsibility to the political appointees who lead the agencies and are already accountable for making wise and balanced decisions. On the other hand, some group of the White House staff should assume responsibility for dealing with cross-cutting issues; depending on the depth and persistence of the problem, these assignments should be made on either a permanent or an *ad hoc* basis. . . .

Placing the senior agency political appointees in the driver's seat makes sense for several reasons. For all practical purposes, agency heads are the public face of an administration with respect to the highest profile regulatory issues, including environmental protection, food, drug, and product safety, and preventing life-threatening hazards in the workplace. These appointees are both confirmed by the Senate and subject to oversight by both Houses of Congress. . . . They are far sturdier surrogates than anonymous White House staff working in an office that most people have never heard of. . . .

CONCLUSION

The nation has embraced health, safety, and environmental regulation as an affirmative and important role for government. Despite this broad support for regulatory schemes, deregulatory forces have managed to hobble the regulatory state through funding shortfalls, political interference, and neglect of the crucial job of updating the agencies' statutory mandates. All of these efforts have been largely invisible to the voting public. . . . OIRA's myopia and hostility must give way to an affirmative vision of how government can protect those who truly cannot protect themselves.

COST-BENEFIT ANALYSIS AS A COMMITMENT DEVICE*

Matthew Wansley

Cost-benefit analysis purports to calibrate regulation. But the way administrative agencies practice cost-benefit analysis can, at best, calibrate a rule at the moment of its promulgation. As scientific knowledge of regulated health, safety, and environmental risks accumulates over time—and as the technology to mitigate those risks becomes more affordable—the assumptions underlying a rule's cost-benefit analysis can rapidly obsolesce. Because of the structural incentives towards agency inaction, pressure from regulated firms, or, simply, attention to other priorities, outdated rules persist. . . .

Cost-benefit analysis need not work this way. For many health, safety, and environmental regulations, cost-benefit analysis could—and should—be used as a commitment device. When an agency analyzes the costs and benefits of a proposed rule, it should explicitly anticipate the adoption of a more stringent rule than the one it promulgates. The agency should then precommit to adopting the more stringent rule when a credible demonstration has been made that it has become cost-benefit justified. Just as the *expected* costs and benefits of a rule determine its initial level of stringency, the *observed* costs and benefits of a rule should determine when and how it is updated.

Health, safety, and environment regulation should be organized as a project to gradually reduce risks when reductions become cost-benefit justified over time. Consider the history of lead regulation. At least by the early years of the twentieth century, industry and scientists were aware that lead posed serious risks to human health. . . . But at that time, epidemiologists did not understand what blood-lead *levels* were harmful—they relied on clinical symptoms to determine whether a patient was a victim of lead poisoning. . . . If the regulation of lead had seamlessly tracked the scientific understanding of the risks it posed, there would have been early, but limited, regulation, gradually tightened as epidemiologists became aware that lower blood-lead levels caused significant health harms. . . .

[O]ne can imagine a . . . future in which the administrative state regulated a lead-like risk using cost-benefit analysis as a commitment device. The agency's initial cost-benefit analysis might still suffer from the same paucity of scientific knowledge and risk-mitigating technologies. But the rulemaking would be more forward-looking. In addition to selecting a rule to be promulgated, the regulatory agency would anticipate and precommit to a second, more stringent rule, one that prohibited exposure at levels permitted under the rule to be promulgated. The agency would then specify how a private actor could trigger a reanalysis by credibly demonstrating that its innovation—like unleaded gasoline, lead-free paint, or lead-abatement technology—could bring the cost of compliance down to justify the more stringent rule. . . .

The reanalysis would be automatic. As long as the private actor seeking to trigger the reanalysis had credibly demonstrated that the anticipated rule had become justified, the agency would be compelled to conduct the reanalysis. The focus of the rean-

* 2015. *Temple Law Review* 87 (3): 447–500.

alysis would be narrow: the rulemaking would be limited to considering new information on the costs and benefits of the regulation, taking the predictions from the initial cost-benefit analysis as presumptions. . . .

The agency would not *always* adopt the anticipated rule. The reanalysis could, for example, reveal that compliance costs with the initial rule had been underestimated or that industry had substituted a regulated chemical with an even more harmful unregulated chemical and that this unforeseen cost outweighed the benefits of further regulation. In that instance, the agency might retain the existing rule or even adopt a less stringent one. Alternatively, the reanalysis could reveal that, for example, initial compliance costs were exaggerated or that switching production processes had also decreased workplace accidents. In that case, the agency might adopt a rule even more stringent than the anticipated one. . . .

It is plausible that, had lead been regulated over the past half century using cost-benefit analysis as a commitment device, the public's exposure to lead would have been reduced in a cost-justified way through more quickly tightened rules and more rapid innovation in lead replacement and abatement technologies. . . .

The insight of cost-benefit analysis is that regulatory decisions should be based on the best available evidence of the expected effects of proposed rules, even when that evidence conflicts with our unreliable intuitions. The case for the commitment device is that the best available evidence of costs and benefits should also guide when agencies update rules and how administrations set priorities. . . .

. . .

Wansley highlights a crucial challenge of public health, safety, and environmental protection. Ideally, regulation should "track seamlessly" with scientific understanding of risk. In reality, however, the democratic process, special interest groups, and bureaucratic hurdles like OIRA review influence the regulatory process. As a result, some risks are overregulated—prompting critics to paint regulation in general as unjustifiably burdensome—while others are underregulated, leaving the public insufficiently protected.

As Steinzor's and Wansley's critiques demonstrate, the politics of risk regulation are challenging. In general, softer interventions—such as the new governance strategies detailed in the remainder of this chapter—are more politically palatable than command-and-control regulation. The effectiveness of these strategies from a public health standpoint is dependent upon many factors, including the motivation for regulation and the response of industry, consumers, and other stakeholders. Furthermore, while soft governance strategies may be more politically feasible, some are more vulnerable to legal challenge than traditional command-and-control regulation, as we discuss in the following section.

INFORMATION AS REGULATION: PUBLIC DISCLOSURE MANDATES

One of the most basic forms of market-based regulation is a mandate to disclose information about a product or service to the public. The idea is that if consumers are well informed, they will naturally gravitate toward higher-quality, less risky goods and services, generating market pressure for businesses to improve quality and safety while also lowering costs.

Information-based regulation is of increasing importance to public health law. As more public health risks are associated with products (e.g., tobacco, high-sodium foods, high-calorie beverages, and pharmaceuticals) and services (e.g., artificial tanning, surgical procedures), informing consumers about risks becomes a key strategy. Regulations ensuring that consumers have access to information are generally more politically palatable than regulations that restrict consumers' access to goods and services. The effectiveness of information-based regulation with respect to various public health problems will be discussed in Part Four of the reader. Here, we focus on the mechanics of reporting and disclosure requirements and the constitutional issues they raise.

Reporting mandates require that certain data (e.g., the proportion of patients who are readmitted to a hospital with complications following an initial discharge or the proportion of health insurance premium revenues that an insurer spends on medical care versus overhead costs and profits) be reported to a government agency. In some cases, that information is then disclosed to the public, typically via a government website or report. Other disclosure mandates simply require that a manufacturer or retailer include a disclosure in its advertisements, in retail settings, or on product packaging. For example, federal law mandates that nutrition facts appear on packaged food labels.

Public disclosure mandates may be politically popular, but they are subject to particular legal constraints, making them more vulnerable to challenge by regulated industries than many forms of traditional regulation. For example, although mandated disclosure of truthful and noncontroversial information, such as ingredient lists or nutritional content, is generally permitted under the First Amendment so long as it has a rational basis, there are indications that courts are trending toward increased scrutiny (as discussed in chapters 4 and 12). Additionally, disclosure mandates may run afoul of the Fifth Amendment's prohibition on governmental takings of private property without just compensation.

PHOTO 6.2. FDA Commissioner Margaret Hamburg unveils proposed changes to the Nutrition Facts panels that appear on packaged food and beverage products, 2014. The new labels highlight calorie content and serving size in larger print and require separate labeling of added sugars. U.S. Food and Drug Administration.

The Takings Clause of the Fifth Amendment (applied to state and local governments via incorporation in the Fourteenth Amendment, as described in chapter 4) states, "Nor shall private property be taken for public use without just compensation." As the judicial opinion excerpted below explains, the simplest form of government taking is a *possessory taking*. Government may confiscate or destroy physical objects (referred to as *personal property*), for example, to redistribute scarce resources in a public health emergency or destroy infected poultry or livestock. It may also physically occupy land or buildings (referred to as *real property*), for example, to build a highway or a bike path (see chapter 12). These takings generally require compensation, though courts have historically held that destruction of diseased animals does not constitute a taking. A more expansive reading of the Takings Clause emerged in the twentieth century, holding that a taking could also be effectuated by regulation that impairs the value or utility of private property. The so-called regulatory takings doctrine arises at the intersection of the police power (see chapter 3) and the government's power of eminent domain (the right to take property for public use so long as the owner is compensated at fair market value).

The takings analysis is further complicated when the property at issue is information. Property law fosters innovation by protecting intellectual property, allowing creators to capture the benefits of their creations. For example, patents protect inventions, copyrights protect works of authorship captured in a tangible medium, and trademarks protect names, terms, and symbols that identify the source of goods or services. Trade secrets—information that a business keeps confidential to ensure a competitive advantage—are also protected intellectual property. Thus, compelled public disclosure of information that constitutes a trade secret is subject to challenge under the regulatory takings doctrine. This issue has arisen in a wide range of public health contexts, from cigarette manufacturers trying to avoid disclosing their ingredient lists to managed care organizations seeking to bar public access to their formulas for calculating incentive payments for doctors.

As you read the case that follows, consider the mechanics of the state's reporting and disclosure regime. How might public disclosure of the additives used in specific brands of tobacco products influence tobacco use? Could disclosure to the public shift public opinion about tobacco companies and their products? Pay attention as well to the court's regulatory takings analysis. What level of review is the judge applying in this case? Is there any additional evidence that the state could have presented in support of the Disclosure Act that would have satisfied the standard articulated by the court? Could the Massachusetts legislature have revised the Disclosure Act to withstand a regulatory takings challenge? How would you expect a judicial opinion like this to influence other states that might be considering adopting a new disclosure requirement for tobacco companies?

*PHILIP MORRIS V. REILLY**

United States Court of Appeals for the First Circuit
Decided December 2, 2002

[A group of] tobacco companies brought suit claiming that [a] Massachusetts statute, which allows the public disclosure of . . . ingredient lists [for all cigarettes, snuffs, and chewing tobaccos sold in the state] whenever such disclosure "could reduce risks to public health," creates an unconstitutional taking. . . .

All of the tobacco products manufactured by appellees include a variety of additives . . . used as solvents, processing aids, pH modifiers, formulation aids for reconstituted

* 312 F.3d 24.

tobacco, preservatives, humectants, tobacco protection aids, "plasticizing" agents, and, perhaps most importantly, flavorings. It is undisputed that appellees have spent millions of dollars developing formulas for their different brands, and when successful, those brands are worth billions of dollars. A major factor of each brand's success is its distinctive flavor, taste, and aroma. . . .

Each of the appellees closely guards its valuable ingredient lists. For example, within each company, only a few individuals are privy to the entire formula for any one brand. Suppliers are subject to confidentiality agreements and ship their products in packages which disguise their contents. . . .

Tobacco companies currently have to disclose their ingredient lists to both the federal government and at least two state governments. The federal government requires only that an aggregate list of all ingredients used in cigarettes and smokeless tobacco products be provided to the Department of Health and Human Services. 15 U.S.C. § 1335a. These lists, each of which contains hundreds of ingredients, neither identify the ingredients in any particular brand nor reveal which ingredients are used by which manufacturer. The Department of Health and Human Services can study and report to Congress on the health effects of tobacco additives, including information on specific ingredients which may pose a health risk to consumers. However, without further legislation and disclosure, the federal government has no ability to warn consumers of the use of harmful additives in specific brands.

Two states, besides Massachusetts, require some disclosure of additives to tobacco products. Minnesota mandates that tobacco companies report only the use of several targeted additives in their products. Texas requires that the tobacco companies report brand-specific ingredient information, in descending quantities. While this scheme superficially looks like the challenged Massachusetts legislation, Texas protects the ingredient lists by prohibiting public disclosure when those lists would be considered trade secrets under either federal or state law. The tobacco companies have complied and continue to comply with these disclosure requirements and have never challenged their validity. . . .

In Massachusetts' view, previous disclosure requirements did not allow it to investigate adequately [public health concerns about tobacco products]. For example, the publicly available ingredient lists do not identify additives according to brand or manufacturer. Therefore, Massachusetts could not study the interaction of additives and know whether those additives are actually combined. Nor could Massachusetts study the additives used in more popular brands and those brands targeted to younger consumers. No one disputes that these suggested studies are laudable and within the health and safety realm of the state's traditional police powers.

Massachusetts, however, has an additional goal to be realized through the Disclosure Act: it hopes to publicize the ingredient lists of various brands. This information, Massachusetts believes, will help consumers make more informed choices about the tobacco products they choose to consume. The envisioned effect is greater public awareness about the potential health effects of tobacco additives.

With these considerations in mind, Massachusetts enacted the Disclosure Act [in 1996]. [T]he Disclosure Act establishes two threshold requirements before an ingredient list "shall" be made public: (1) there must be a finding that publication "could reduce risks to public health"; and (2) the Massachusetts Attorney General must find that disclosure would not be an unconstitutional taking. . . .

[The] tobacco companies first argue that their ingredient lists are trade secrets and, as such, are property protected by the Takings Clause. Second, they argue that the public disclosure of these trade secrets destroys their value, thereby effecting a taking. Appellants counter . . . that the tobacco companies' interest in keeping their ingredient lists secret does not defeat the state's ability to require public disclosure where, as here, the requirement is "rationally related to a legitimate governmental interest." The asserted legitimate governmental interest is the health and safety of its citizens. . . .

The Supreme Court has distinguished between two branches of Takings Clause cases: physical takings and regulatory takings. See *Tahoe-Sierra Pres. Council, Inc. v. Tahoe Reg'l Planning Agency,* 535 U.S. 302 (2002) (distinguishing "between acquisitions of property for public uses . . . and regulations prohibiting private uses"). A physical taking occurs either when there is a condemnation or a physical appropriation of property. . . . A regulatory taking transpires when some significant restriction is placed upon an owner's use of his property for which "justice and fairness" require that compensation be given.

For the most part, courts apply a three-part "ad hoc, factual inquiry" to evaluate whether a regulatory taking has occurred: (1) what is the economic impact of the regulation; (2) whether the government action interferes with reasonable investment-backed expectations; and (3) what is the character of the government action. [*Penn Central Transportation Co. v. New York City,* 438 U.S. 104, 124 (1978)]. However, the Supreme Court has developed at least one per se rule in the regulatory takings sphere. When a regulation denies all economically beneficial or productive uses of land, it is a taking. *Lucas v. S.C. Coastal Council,* 505 U.S. 1003, 1015 (1992). . . .

I begin with a Supreme Court case from the early twentieth century[, *Corn Prods. Ref. Co. v. Eddy,* 249 U.S. 427, 431–32 (1919), in which the Court stated:]

> . . . a manufacturer or vendor has no constitutional right to sell goods without giving to the purchaser *fair information* of what it is that is being sold. The right of a manufacturer to maintain secrecy as to his compounds and processes must be held subject to the right of the state, in the exercise of its police power and in promotion of fair dealing, to require that the nature of the product be fairly set forth.

249 U.S. at 431–32 (emphasis added). While this language can be read to suggest that ingredient lists are subject to full disclosure, it refers only to "fair information." Such "fair information" could be something short of complete disclosure of all additives. For example, if Massachusetts found that the addition of one or more ingredients to tobacco products presented a health risk, disclosing when those specific ingredients are used might constitute "fair information." . . .

The appellees' have spent millions of dollars developing the formulas for different brands. The evidence shows that public disclosure of the appellees' ingredient lists, even in part, will make it much easier to reverse engineer those formulas. If competitors can obtain these formulas, they can replicate appellees' products, undermining the value of appellees' brands. Some of those brands, such as Marlboro, are worth billions of dollars. . . .

"Government regulation—by definition—involves the adjustment of rights for the public good. Often this adjustment curtails some potential for the use or economic

exploitation of private property. To require compensation in all such circumstances would effectively compel the government to regulate by *purchase*." *Andrus v. Allard,* 444 U.S. 51, 65 (1979). There is a point, however, at which compensation is due, and this is not simply a case where the tobacco companies' property has been rendered worthless. Their property right has been "extinguished." Consequently, it appears unconstitutional. . . .

I recognize that appellants have asserted a significant, perhaps compelling, state interest: a right for Massachusetts to protect and promote the health of its citizens. If I was convinced that this regulation was tailored to promote health and was the best strategy to do so, I might reconsider our analysis. Numerous cases show that a crucial part of the regulatory takings equation is the government interest. However, the cases also show that the means should bear some reasonable relationship to the ends.

I simply am not convinced that the Disclosure Act, particularly the provisions about which the tobacco companies complain, really helps to promote public health. The Disclosure Act allows for full disclosure of the ingredient lists when doing so "could" further public health. This places an extremely low burden on Massachusetts. Frankly, for a state to be able to completely destroy valuable trade secrets, it should be required to show more than a *possible* beneficial effect. The tremendous individual loss is simply not justified by such a speculative public gain. Furthermore, it is not at all clear that protecting the overall integrity of the tobacco companies' ingredient lists will interfere with Massachusetts' goal of promoting public health. . . . There is no evidence that suggests that regimes similar to those adopted by Texas and Minnesota, or some combination thereof, would not achieve the goals which appellants claim underlie the requirements of the Disclosure Act. . . .

The Disclosure Act causes the tobacco companies to lose their trade secrets, entirely, and appellants advance no convincing public policy rationale to justify the taking itself. Instead, they point to a general, laudable goal which cannot justify the specific action of which the tobacco companies complain. Therefore, I find that the Disclosure Act violates the Takings Clause by taking appellees' property without just compensation.

. . .

In many other countries, courts have held that consumers have a constitutionally protected right of access to information about the goods and services they use. In the United States, however, such rights are limited to statutory regimes, such as consumer protection laws designed to prevent fraud (discussed in chapter 7). In *Phillip Morris v. Reilly*, the court held that tobacco companies' constitutional right to maintain the confidentiality of their ingredient lists trumps consumers' statutory right to know about ingredients that could pose health risks. Technically, the court recognizes that the companies are entitled to just compensation for the regulatory taking effected by the Disclosure Act, but given that the court finds some formulas are worth billions of dollars, the compensation requirement effectively takes public disclosure off the table as a regulatory tool.

CHOICE ARCHITECTURE: HEALTH AND SAFETY NUDGES

Interventions that rely on individuals responding to straightforward information typically have little impact on population health (see chapters 12 and 13). Drawing on the social-ecological model, public health advocates have proposed interventions that alter the environment in which health-related decisions are made. Efforts to "make the healthy choice the easy choice" build on another kind of new governance strategy: choice architecture. Choice architecture refers to default rules, framing devices, and other environmental cues that influence decisions. Its key insight is that most people will take the path of least resistance unless they have a strong preference to the contrary. In the public health space, for example, default rules influence participation in sex education programs in schools. If the default rule is a presumption of parental consent and the onus is on parents who object to take affirmative steps to have their children excluded from sex education, then participation rates will be higher. If, on the other hand, the default rule is a presumption that parents object and the onus is on parents who consent to take affirmative steps to sign and return a permission slip, then participation rates will be lower. Similarly, the way in which food and beverage products are displayed in retail stores and chain restaurants influences consumption. A vehicle design in which the airbag is automatically turned on when the car starts, but can be turned off by the driver is safer than one that requires the driver to activate the air bag.

In the excerpt that follows, Cass Sunstein (a law professor who headed OIRA under President Obama) and Richard Thaler (a behavioral economist) describe choice architecture as a form of libertarian paternalism. The authors publicized their ideas in *Nudge,* a *New York Times* bestseller. As you read, consider which aspects of a "nudge" are paternalistic and which are libertarian. Can you imagine what kind of critique a traditional libertarian might offer? What about a traditional paternalist?

LIBERTARIANISM PATERNALISM IS NOT AN OXYMORON*

Cass R. Sunstein and Richard H. Thaler

. . . Libertarians embrace freedom of choice, and so they deplore paternalism. Paternalists are thought to be skeptical of unfettered freedom of choice and to deplore lib-

* 2003. *University of Chicago Law Review* 70 (2): 1159–202.

ertarianism. According to the conventional wisdom, libertarians cannot possibly embrace paternalism, and paternalists abhor libertarianism. The idea of libertarian paternalism seems to be a contradiction in terms. . . .

[W]e intend to unsettle the conventional wisdom here. We propose a form of paternalism, libertarian in spirit, that should be acceptable to those who are firmly committed to freedom of choice on grounds of either autonomy or welfare. Indeed, we urge that libertarian paternalism provides a basis for both understanding and rethinking a number of areas of contemporary law, including those aspects that deal with worker welfare, consumer protection, and the family. In the process of defending these claims, we intend to make some objections to widely held beliefs about both freedom of choice and paternalism. Our emphasis is on the fact that in many domains, people lack clear, stable, or well-ordered preferences. What they choose is strongly influenced by details of the context in which they make their choice, for example default rules, framing effects (that is, the wording of possible options), and starting points. These contextual influences render the very meaning of the term "preferences" unclear.

Consider the question whether to undergo a risky medical procedure. When people are told, "Of those who undergo this procedure, 90 percent are still alive after five years," they are far more likely to agree to the procedure than when they are told, "Of those who undergo this procedure, 10 percent are dead after five years." What, then, are the patient's "preferences" with respect to this procedure? Repeated experiences with such problems might be expected to eliminate this framing effect, but doctors too are vulnerable to it. Or return to the question of savings for retirement. It is now clear that if an employer requires employees to make an affirmative election in favor of savings, with the default rule devoting 100 percent of wages to current income, the level of savings will be far lower than if the employer adopts an automatic enrollment program from which employees are freely permitted to opt out. Can workers then be said to have well-defined preferences about how much to save? This simple example can be extended to many situations involving the behavior of workers and consumers.

As the savings problem illustrates, the design features of both legal and organizational rules have surprisingly powerful influences on people's choices. We urge that such rules should be chosen with the explicit goal of improving the welfare of the people affected by them. The libertarian aspect of our strategies lies in the straightforward insistence that, in general, people should be free to opt out of specified arrangements if they choose to do so. To borrow a phrase, libertarian paternalists urge that people should be "free to choose." Hence we do not aim to defend any approach that blocks individual choices.

The paternalistic aspect consists in the claim that it is legitimate for private and public institutions to attempt to influence people's behavior even when third-party effects are absent. In other words, we argue for self-conscious efforts, by private and public institutions, to steer people's choices in directions that will improve the choosers' own welfare. In our understanding, a policy therefore counts as "paternalistic" if it attempts to influence the choices of affected parties in a way that will make choosers better off. Drawing on some well-established findings in behavioral economics and cognitive psychology, we emphasize the possibility that in some cases individuals make inferior decisions in terms of their own welfare—decisions that they would change if they had complete information, unlimited cognitive abilities, and no lack of self-control. . . .

Libertarian paternalism is a relatively weak and nonintrusive type of paternalism, because choices are not blocked or fenced off. In its most cautious forms, libertarian paternalism imposes trivial costs on those who seek to depart from the planner's preferred option. But the approach we recommend nonetheless counts as paternalistic, because private and public planners are not trying to track people's anticipated choices, but are self-consciously attempting to move people in welfare-promoting directions. Some libertarians are likely to have little or no trouble with our endorsement of paternalism for private institutions; their chief objection is to paternalistic law and government. But as we shall show, the same points that support welfare-promoting private paternalism apply to government as well. It follows that one of our principal targets is the dogmatic anti-paternalism of numerous analysts of law, including many economists and economically oriented lawyers. We believe that this dogmatism is based on a combination of a false assumption and two misconceptions.

The false assumption is that almost all people, almost all of the time, make choices that are in their best interest or at the very least are better, by their own lights, than the choices that would be made by third parties. This claim is either tautological, and therefore uninteresting, or testable. We claim that it is testable and false, indeed obviously false. . . . [H]ow well people choose is an empirical question, one whose answer is likely to vary across domains. As a first approximation, it seems reasonable to say that people make better choices in contexts in which they have experience and good information (say, choosing ice cream flavors) than in contexts in which they are inexperienced and poorly informed (say, choosing among medical treatments or investment options). So long as people are not choosing perfectly, it is at least possible that some policy could make them better off by improving their decisions.

The first misconception is that there are viable alternatives to paternalism. In many situations, some organization or agent *must* make a choice that will affect the behavior of some other people. There is, in those situations, no alternative to a kind of paternalism—at least in the form of an intervention that affects what people choose. We are emphasizing, then, the possibility that people's preferences, in certain domains and across a certain range, are influenced by the choices made by planners. The point applies to both private and public actors, and hence to those who design legal rules as well as to those who serve consumers. As a simple example, consider the cafeteria at some organization. The cafeteria must make a multitude of decisions, including which foods to serve, which ingredients to use, and in what order to arrange the choices. Suppose that the director of the cafeteria notices that customers have a tendency to choose more of the items that are presented earlier in the line. How should the director decide in what order to present the items? To simplify, consider some alternative strategies that the director might adopt in deciding which items to place early in the line: (1) She could make choices that she thinks would make the customers best off, all things considered. (2) She could make choices at random. (3) She could choose those items that she thinks would make the customers as obese as possible. (4) She could give customers what she thinks they would choose on their own.

Option 1 appears to be paternalistic, but would anyone advocate options 2 or 3? Option 4 is what many anti-paternalists would favor, but it is much harder to implement than it might seem. Across a certain domain of possibilities, consumers will often lack well-formed preferences, in the sense of preferences that are firmly held and preexist the director's own choices about how to order the relevant items. If the arrange-

ment of the alternatives has a significant effect on the selections the customers make, then their true "preferences" do not formally exist.

Of course, market pressures will impose a discipline on the self-interested choices of those cafeteria directors who face competition. To that extent, those directors must indeed provide people with options they are willing to buy. A cafeteria that faces competition and offers healthy but terrible-tasting food is unlikely to do well. Market-oriented libertarians might urge that the cafeteria should attempt to maximize profits, selecting menus in a way that will increase net revenues. But profit maximization is not the appropriate goal for cafeterias granted a degree of monopoly power—for example, those in schools, dormitories, or some companies. Furthermore, even those cafeterias that face competition will find that some of the time, market success will come not from tracking people's ex ante preferences, but from providing goods and services that turn out, in practice, to promote their welfare, all things considered. Consumers might be surprised by what they end up liking; indeed, their preferences might change as a result of consumption. And in some cases, the discipline imposed by market pressures will nonetheless allow the director a great deal of room to maneuver, because people's preferences are not well-formed across the relevant domains.

While some libertarians will happily accept this point for private institutions, they will object to government efforts to influence choice in the name of welfare. Skepticism about government might be based on the fact that governments are disciplined less or perhaps not at all by market pressures. Or such skepticism might be based on the fear that parochial interests will drive government planners in their own preferred directions (the public choice problem). We agree that for government, the risks of mistake and overreaching are real and sometimes serious. But governments, no less than cafeterias (which governments frequently run), have to provide starting points of one or another kind; this is not avoidable. As we shall emphasize, they do so every day through the rules of contract and tort, in a way that inevitably affects some preferences and choices. In this respect, the anti-paternalist position is unhelpful—a literal nonstarter.

The second misconception is that paternalism always involves coercion. As the cafeteria example illustrates, the choice of the order in which to present food items does not coerce anyone to do anything, yet one might prefer some orders to others on grounds that are paternalistic in the sense that we use the term. Would anyone object to putting the fruit and salad before the desserts at an elementary school cafeteria if the result were to increase the consumption ratio of apples to Twinkies? Is this question fundamentally different if the customers are adults? Since no coercion is involved, we think that some types of paternalism should be acceptable to even the most ardent libertarian. In the important domain of savings behavior, we shall offer a number of illustrations. To those anti-libertarians who are suspicious of freedom of choice and would prefer to embrace welfare instead, we urge that it is often possible for paternalistic planners to make common cause with their libertarian adversaries by adopting policies that promise to promote welfare but that also make room for freedom of choice. To confident planners, we suggest that the risks of confused or ill-motivated plans are reduced if people are given the opportunity to reject the planner's preferred solutions.

The thrust of our argument is that the term "paternalistic" should not be considered pejorative, just descriptive. Once it is understood that some organizational

> decisions are inevitable, that a form of paternalism cannot be avoided, and that the alternatives to paternalism (such as choosing options to make people worse off) are unattractive, we can abandon the less interesting question of whether to be paternalistic or not, and turn to the more constructive question of how to choose among the possible choice-influencing options. . . .
>
> . . .

Sunstein and Thaler's ideas are popular with regulators and the general public alike. In theory, nudges should be politically palatable. They promote healthier, safer lifestyles without explicitly limiting personal choices. But the devil is in the details. Consider, for example, the sugary drinks portion rule discussed in chapter 5. Many commentators consider a change in portion size to be a classic nudge. Customers are not prohibited from buying and consuming as much soda as they like, but must take the affirmative step of ordering more containers if they wish to drink more than 16 ounces. Sunstein, however, is critical of the portion cap rule and disclaimed it as a use of choice architecture (Sunstein 2013). As an alternative, he argued that the MyPlate graphic representation of federal dietary guidelines (which appears on nutrition posters and some packaged food labels) was an appropriate nudge toward healthy eating. Notably, MyPlate diverged from expert advice by failing to recommend reduced intake of sugary beverages, which commentators attributed to industry influence.

Perhaps new governance is in the eye of the beholder. From the consumer's perspective, a rule that requires asking, and paying, for two cups to order 32 ounces of a sugary drink might operate like a nudge. Opting out is allowed, but requires cost and effort. From the retailer's perspective, however, the portion rule seems more like traditional command-and-control regulation. It prescribes a maximum size for beverage containers, enforced via restaurant inspections with accompanying fines. The same is true of public disclosure mandates. The federal requirement that nutrition facts be displayed on food packages is quite unobtrusive from the consumer's perspective—many appreciate having the information. But from the manufacturer's perspective it is virtually indistinguishable from command-and-control. The exact font size, color, and location of the nutrition facts panel are specified in regulations and violations are punishable by fines. Consider the controversy over Vermont's decision to require labeling of genetically modified foods. The food industry viewed it as intrusive, expensive, and scientifically unjustifiable, yet it does nothing to directly limit consumer choice.

A NEW GOVERNANCE RECIPE FOR FOOD SAFETY*

Alexia Brunet Marks

. . . The [Food Safety Modernization Act (FSMA)] aims to increase food safety by focusing on preventing foodborne illness and contaminants in both domestic and imported food. The FSMA can be considered New Governance "in action," because the proposed rules, as drafted, adopt key features of New Governance. Notably, FSMA's import-safety provisions [make] use of third-party certification and voluntary standards. . . .

[F]ifty years ago, consumers placed great trust in grocers and government agencies to certify that foods were safe to eat. Today, supply chains are long and diffuse and most of the qualities that consumers demand cannot be tested once the product has been placed on the grocery store shelf. While food can be tested for pesticides, it is nearly impossible to discern whether a product is organic, if it has been made using child labor, or if the workers involved in the production were paid fair wages. From an economic perspective, consumers demand food safety and governments try to provide it. Yet, as consumers search for a range of attributes and assurances, governments struggle to ensure the safety of foods coming from a massive and growing food industry. . . .

The use of third-party certification—independent onsite auditing of a facility or process leading to a certification—is a rapidly growing private-sector practice that provides consumers with a level of trust that existed long ago when one purchased directly from the farmer. FSMA sections 302 and 303 give the FDA authority to use certifications issued by accredited third-party auditors for two purposes. First, FSMA section 302 authorizes the FDA to create Voluntary Qualified Importer Protection, a voluntary, fee-based program that provides for expedited review and importation of foods from certified facilities. This program is designed for importers who achieve and maintain a high level of control over the safety and security of their supply chains. Second, FSMA section 303 gives the FDA authority to require that high-risk imported foods be accompanied by a credible third-party certification or other assurance of compliance as a condition of entry into the United States.

[Additional] rules are likely to [promote the use of] third-party audits for verification purposes. The Foreign Supplier Verification Program (FSVP), for instance, requires importers to perform risk-based, foreign-supplier verification activities to ensure that foreign suppliers have adequate preventive controls in place. Although the FSVP proposal does not require the use of accredited third-party auditors, the FDA anticipates that once the FDA accreditation system is in place, importers may increasingly rely on audits by accredited third parties to meet their supplier verification requirements under FSVP. . . .

Finally, FSMA highlights flexibility and voluntary initiatives, two New Governance features. The FSVP allows importers to verify that exporters comply with U.S. rules in various ways, thus providing importers with great flexibility; and further, the Voluntary Qualified Importer Protection program grants expedited entry for certified foods at a completely voluntary level. . . .

* 2016. *Loyola University Chicago Law Journal* 47 (3): 907–68.

NEW GOVERNANCE: LESSONS LEARNED

Given that New Governance has been tried and tested with varying levels of success in other fields, it becomes useful to examine these experiences to identify opportunities and pitfalls for regulators implementing New Governance features. Because third-party certification is a prototypical example of New Governance, the focus here is on implementing a third-party certification program. . . .

Opportunities

Successful third-party certification programs have been mandated by legislation, and still others have been run by the [agencies, including the] FDA. For instance, in 1992, the Mammography Quality Standards Act required the FDA [which regulates medical devices] to approve accreditation bodies to evaluate and accredit mammography facilities based upon quality standards. . . . [O]nly facilities that were accredited by an FDA-approved accreditation body received approval to legally perform mammography. In 2008, Congress enacted the Consumer Product Safety Improvement Act requiring children's products to be tested by an approved third-party laboratory to certify compliance with product safety rules. The Consumer Product Safety Commission approves accreditation bodies to accredit qualified third-party laboratories to test and certify products. Over 400 approved laboratories around the world test and certify imported and domestically manufactured products. In 2010, Congress enacted the Formaldehyde Standards for Composite-Wood Products Act to address concerns about the public's exposure to formaldehyde emissions from manufactured products and building materials. The EPA's third-party certification framework, modeled on California's program for verifying compliance with emissions limits, involves the EPA approving accreditation bodies to accredit qualified third-party certifiers.

In terms of specific benefits, the literature suggests that introducing private third parties to conduct regulatory duties such as third-party certification can provide five key benefits [under the FSMA]: (1) gatekeeping and monitoring expertise, (2) enhanced credibility and information sharing, (3) cost savings, (4) food safety gains, and (5) gaining industry cooperation and reducing the regulatory burden.

Gatekeeping and Monitoring Expertise. Third-party certification can provide a function that governments may be failing in—the ability to use third-party certifiers as "gatekeepers" rather than mere deterrence. Third-party certification also provides the ability to utilize the monitoring expertise that industries have developed through the common practice of having voluntary certification schemes in place.

Enhanced Credibility and Information Sharing. From a business-oriented perspective, third-party certifications provide credibility, information, and assurance to customers. Using the 2008 Chinese Infant Formula Scandal [in which more than 50,000 Chinese infants were hospitalized and several died after consuming infant formula adulterated with melamine] as an example, evidence suggests that consumers of foods grown and manufactured in China would have greater confidence in those products if China were to allow a wider range of certifiers and labs to operate in China, and if government-sponsored tests and certifications could be verified by private-sector third parties. Third-party certifications can also provide companies with a competitive edge on rival compa-

nies, as certification through a third-party organization creates a premium on products. Finally, giant food retailers, who have collectively chosen to obtain products from the same centralized procurement centers, use third-party certifications as a way to mitigate the risk of reputation damage from a foodborne illness outbreak that cannot definitively be traced to a single isolated store.

Third-party certification provides the ability to keep up with the growing data needs involved in market-based regulation. . . . [A]n added benefit to food safety schemes (which require third-party certification) is that, in addition to establishing higher food safety standards, schemes are reviewed and revised more regularly than the Codex General Principles of Food Hygiene Code of Practice [an international code promulgated by a joint commission of the United Nations Food and Agriculture Organization and the World Health Organization, which is incorporated into international trade law constraints on national food regulations. Thus, they are better positioned] to address issues that are currently faced by the food industry such as incident management, food defense, and allergen management.

Cost Savings. . . . Third-party certification provides the ability to shift regulatory costs to the regulated entity—suppliers incur the cost of certification—which has proven to be a great advantage for regulators. . . . [I]n times of budgetary constraints, collaborating with private assurance schemes can be a cost-effective alternative to reduce inspection costs while maintaining inspection coverage.

Food Safety Gains. . . . Third-party certification schemes have been shown to enhance food safety. Increased compliance with food safety laws was one outcome noted by the Netherlands Food and Consumer Product Safety Authority. The private auditors chosen in the enforcement program . . . tended to visit firms more often, and may have combined inspection and advice, thereby increasing compliance. . . .

Gaining Industry Cooperation and Reducing the Regulatory Burden. . . . Third-party certification can reduce an industry's regulatory burden. In 2006, the FDA and Health Canada initiated the pilot "Multipurpose Audit Program." The pilot explored the potential benefits to medical device manufacturers and agencies of using a single third party to conduct both FDA and Health Canada inspections and audits at the same time in one joint audit-inspection. . . . The results from the ten joint audit-inspections under the pilot showed that the joint approach reduced the time spent in manufacturing facilities by about one-third, on average, compared to the estimated time required for separate FDA and Health Canada audits and inspections—thereby reducing the regulatory burden for the industry. In addition, the FDA and Health Canada gained a better understanding of their respective audit and inspection approaches, providing a foundation for leveraging inspection resources in the future.

Perils

There are several downsides to experimenting with New Governance. Examples . . . drawn from country examples (the Netherlands, the United Kingdom, and Canada), as well as industry examples in the fields of finance, privacy law, and environmental law . . . highlight[] the five most prominent perils associated with third-party certification: (1) conflict of interest and lack of independence, (2) overreliance on the "checklist"

mentality, (3) auditor incompetence, (4) no requirement to disclose, and (5) mismanaging third-party certifiers.

Conflict of Interest and Lack of Independence. When private auditors are paid for by their auditees, a conflict arises between the financial interest of the auditor and protecting the public from food safety risks. . . . In economic terms, auditors have a financial interest in getting hired and rehired by suppliers, and as profit maximizers, suppliers naturally shop around for the cheapest certification they can obtain . . . thus leading to certifiers lowering their standards of inspection. The incentive is for a company to hire a certification body that provides the company with the best chance to become certified. . . .

Overreliance on the "Checklist" Mentality. A great deal of trust goes into the process of certification—trust that may perhaps be unwarranted when certifiers over-rely upon "checklists" and thereby capture a "snapshot in time." As a certification body auditor admits, "[w]e are only on a production site for 3 days out of 365. It is just a snapshot in time. The ultimate responsibility to mitigate unforeseen hazards or defects is on the producers and processors who are there 365 days, and not on us. We are just a checker." . . .

Auditor Incompetence. [In] the 2011 Colorado Listeria Outbreak, a deadly outbreak that was ultimately sourced to Colorado-based cantaloupe farmers, [t]he farmers had received a nearly perfect rating during their audit, however, the Primus Labs auditor who was responsible for auditing the Colorado outfit was young and new to the job. . . . [T]here have been many foodborne illness outbreaks linked to food processors that have passed third-party audits and inspections, raising questions about the utility of both. . . . Auditor incompetence has been cited repeatedly in the Salmonella outbreak [traced to the Peanut Corporation of America (PCA) in 2009]. In the PCA case, the auditor was an expert in fresh produce and not peanuts. With respect to auditor scope, there are instances where the audit did not include all of the ingredients. In the 2007 outbreak related to Salmonella in Pirate's Booty brand popcorn, the audit did not extend to the culprit, imported spice ingredients. Regulators should consider these examples related to auditor expertise and scope as they design improved auditor programs.

No Requirement to Disclose. The Netherlands Food and Consumer Product Safety Authority noted a problem with using private certifiers: systems, auditors, and inspectors are not required to advise and alert the agency of situations involving major noncompliance and serious risk to public health and safety. The Authority found that, without mandating the transmission of noncompliance to the agency, it is possible that firms may slip through the system. In other words, when firms are not required to report breaches in food safety, those breaches, and their corresponding threats to health and safety, will persist.

Mismanaging Third-Party Certifiers. The growth of Internet-related business and the amount of personal data that is exchanged over the Internet has heightened consumer fears over Internet security and privacy. Companies have emerged to increase consumer trust by offering third-party certification programs such as the Trusted Download Program or the web seal program from TRUSTe, a major provider of privacy certifications

for online businesses. . . . [H]owever, independent audits have reported that sites claiming to be TRUSTe-compliant often are not and that some companies offering TRUSTe-approved programs have been criticized in the past for distributing adware, spyware, and attempting to make changes to system settings on personal computers. . . .

RESISTING COMPLACENCY: A ROADMAP FOR IMPROVING THE U.S. RULES

[Under the FSMA], the United States [is], for the first time in history, . . . using private third-party certifications to monitor imports. . . . [W]e have limited options given financial constraints and international agreements [limiting the regulations that may be imposed on imports;] New Governance is the only way for the United States to raise food standards. And yet, the New Governance framework is not perfect. Regulators need to be mindful of case studies where New Governance has not been successful, in financial regulation, for instance, and in other fields. . . .

THE FOOD INDUSTRY AND SELF-REGULATION: THE STANDARDS TO PROMOTE SUCCESS AND TO AVOID PUBLIC HEALTH FAILURES*

Lisa L. Sharma, Stephen P. Teret, and Kelly D. Brownell

. . . Although many forces contribute to obesity and poor diet, food industry behaviors such as marketing unhealthy foods to children, promoting large portions and between-meal snacks, and exploiting schools for commercial gain have raised calls for government regulation and paved the path for actions such as requiring calorie labeling in restaurants. . . .

In response to public outcry and calls for government intervention, the major food industry players acted as other businesses have in the past: they pledged to adopt self-regulatory initiatives. . . . Both risks and opportunities are embedded in this environment, and much is at stake. It is instructive to examine how other industries have approached self-regulation and to define the conditions under which the public's interest is protected or harmed. . . .

We propose 8 standards for self-regulation [listed in table 6.1] derived from knowledge to date on food industry self-regulation and lessons learned from self-regulatory successes and failures in other industries. These standards are intended to maximize the likelihood that self-regulation will incorporate transparency, meaningful objectives and benchmarks, accountability and objective evaluation, and oversight.

HISTORY OF FOOD INDUSTRY SELF-REGULATION

Beverages in Schools

In 2006, the Alliance for a Healthier Generation, a partnership between the William J. Clinton Foundation and the American Heart Association, worked with the soft drink industry through its trade association, the American Beverage Association, to release

* 2010. *American Journal of Public Health* 100 (2): 240–46.

TABLE 6.1 PROPOSED STANDARDS FOR SELF-REGULATORY ACTIVITIES OF THE FOOD INDUSTRY

Aim	Standard
Transparency	Transparent self-regulatory standards created by a combination of scientists (not paid by industry) and representatives of leading nongovernmental organizations, parties involved in global governance (e.g., World Health Organization, United Nations Food and Agriculture Organization), and industry
	No one party given disproportionate power or voting authority
Meaningful objectives and benchmarks	Specific codes of acceptable behavior based on scientifically justified criteria
	Predefined benchmarks to ensure the success of self-regulation
Accountability and objective evaluation	Mandatory public reporting of adherence to codes, including progress toward achievement of full compliance with pledges and attainment of key benchmarks
	Built-in and transparent procedures for outside parties to register objections to self-regulatory standards or their enforcement.
	Objective evaluation of self-regulatory benchmarks by credible outside groups not funded by industry to assess health, economic, and social outcomes
	Periodic assessments/audits to determine compliance and outcomes.
Oversight	Possible oversight by an appropriate global regulatory or health body (e.g., World Health Organization)

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School Beverage Guidelines. . . . The guidelines include industry promises to limit portion sizes of beverages and set standards for the caloric and nutritional content of beverages to be sold in schools. . . .

The limitations of this pledge, however, create a strong need for our proposed standards. . . . Most important, the process of establishing nutrition criteria was not transparent and did not involve objective input from the scientific community. An example of flawed criteria is that high schools, where much of the sugared-beverage intake occurs, are subject to far less restriction than are elementary schools, where little intake occurs.

The pledge leaves several other concerns unaddressed: (1) predefined benchmarks (e.g., lowered sugar intake) were not established; (2) no evaluation has been undertaken by parties not funded by industry; (3) some problematic beverages are not regulated, such as calorie-dense sports drinks, diet drinks (which continue to offer branding opportunities), and new drink categories (e.g., energy drinks); (4) the long phase-in period does

not require amending existing contracts; and (5) the requirement for signatory companies to follow the guidelines is not binding. In light of these concerns, the effectiveness of beverage industry self-regulation is uncertain.

Another key consideration is whether pledges extend beyond the United States. The global health consequences of poor diet are staggering, so it is important that actions taken by industry apply across the world. This is the impetus for our suggestion that world bodies such as the World Health Organization be involved with input on self-regulatory actions and oversight of compliance and impact.

Children's Food Advertising

Another major self-regulatory move by industry is the 2007 Children's Food and Beverage Advertising Initiative, sponsored by the Council of Better Business Bureaus but with guidelines established by industry. The initiative is voluntary . . . with the goal of "shifting the mix of advertising messaging to children to encourage healthier dietary choices and healthy lifestyles." . . .

Specific pledges vary by company; however, all signatory companies agreed to devote no less than 50% of their child-directed advertising to the promotion of "healthier dietary choices and/or to messages that encourage good nutrition or healthy lifestyles." Companies also agreed to reduce or eliminate the use of third-party-licensed characters in advertising of unhealthy foods, not to seek product placement of unhealthy products, and not to use representations of unhealthy food products in interactive games targeted at children younger than 12 years. In addition, participating companies must not advertise food or beverage products in elementary schools, with the exception of "displays of food and beverage products, charitable fundraising activities, public service messaging, or items provided to school administrators."

The strength of the Council of Better Business Bureaus guidelines lies in their laudable stated goal and the fact that so many large companies are taking part, but many uncertainties remain. Will industry standards for healthy food be so lax as to require little change in marketing? Will industry comply? Will food companies do as the tobacco industry did and simply shift marketing dollars to other and perhaps more cost-effective means of marketing (e.g., from television to the Internet)? Will industry changes reduce overall exposure of children to marketing of calorie-dense foods? Will companies rely on one part of their pledge (use messages that "encourage good nutrition or healthy lifestyles") as justification for not acting on the other part (the promotion of healthier dietary choices)? Will depicting Ronald McDonald, Captain Crunch, or the Trix Rabbit being physically active make it permissible to promote unhealthy products to children? Each of these questions can and must be answered to determine whether these pledges will be effective. It will be especially important to track how variations in pledges and compliance with pledges change with time. Will the stronger actions of the more progressive companies pressure the laggards to improve, or will a lower common denominator prevail? Monitoring compliance is essential but at present has not occurred. . . . In addition to lacking transparency and objective scientific input, [the beverage pledge] provides for no benchmark to reduce children's exposure to marketing of calorie-dense foods, no mandatory public reporting, and no objective means for evaluating compliance and impact.

Character Licensing on Foods

Character licensing to promote food sales is the third arena for self-regulatory pledges. Disney and Nickelodeon promised to discontinue the use of their names and licensed characters on packaging for foods that do not meet their self-defined criteria for healthier food. For Disney, healthier food products are those that have less than 30% of calories from fat for meals and 35% for snacks; less than 10% of calories from saturated fat for meals and snacks; and less than 10% or 25% of calories from added sugar for meals and snacks, respectively. Nickelodeon, on the other hand, only states that the use of licensed characters will be "limited to products that meet 'better for you' criteria" and does not detail nutritional guidelines. . . .

Smart Choices Food Labeling

A fourth and far-reaching effort pertains to package labeling and was announced in 2008 by the Keystone Center in collaboration with several major food companies. The Smart Choices Program involves the use of a green-and-white symbol with a check and the words "Smart Choices Program: Guiding Food Choices." The symbol is to appear on designated foods, with the aim of creating a uniform system whereby food companies can indicate foods that represent more nutritious choices. . . .

One part of the Smart Choices approach, the labeling of servings and calories on the front of packages, is likely to be uncontroversial and helpful because it is factual, requires no standards or interpretation, and can be defended as a consumer's right to know. The utility of the Smart Choices symbol designating healthier foods will depend on the strength of the standards, how consumers use the symbols, and whether diets actually improve. . . .

SELF-REGULATION IN OTHER INDUSTRIES

Alcohol

Self-regulation of alcoholic beverage advertising is a classic example of an industry using voluntary codes in conjunction with government oversight to deflect government regulation. Although self-regulatory guidelines were developed originally by industry players, the FTC has been involved both formally and informally in the supervision of alcohol industry self-regulation. As part of its involvement, the FTC helps ensure that companies abide by codes, assists members on compliance issues, ensures rule enforcement, and suggests improvements. . . .

[A]lcohol advertising standards are adaptable and flexible, allowing for more restrictive guidelines as knowledge about success and acceptance evolves. In response to a 1999 FTC report criticizing the industry's self-regulatory practices as too permissive, the three largest alcohol supplier trade associations—the Distilled Spirits Council, the Wine Institute, and the Beer Institute—pledged to adopt revised self-regulatory guidelines for advertising and marketing. The new codes regulated the content and placement of advertisements and marketing efforts, requiring that each advertisement be targeted to an audience in which at least 70% of viewers were of legal drinking age. . . .

In 2008 the FTC recommended further improvements to the codes, including new regulations for Internet and other digital advertising, sponsorships, product placement

in films, expenditures to help others promote alcohol, external review of complaints, and youth access to alcohol, as well as a new system for monitoring that involves random, compulsory audits of member companies each year by the FTC. There are, however, lingering concerns over enforcement of the Distilled Spirit Council's self-regulatory practices. Public watch-dog groups have cited, among other concerns, a high degree of subjectivity in interpreting advertising content regulations and the lack of an independent third-party review board. These issues demonstrate the power of industry to exert influence, even when government oversight exists, and underscore the importance of consistent monitoring and evaluation. . . .

Tobacco

The tobacco industry's development of youth smoking prevention campaigns is arguably one of the most extreme examples of an industry abusing self-regulation to deflect legislative action. In response to public and government outcries over marketing to youths, the industry developed several youth smoking prevention programs in the early 1980s. These included youth access initiatives (e.g., the Coalition for Responsible Tobacco Retailing's We Care, the Tobacco Institute's It's the Law, and Philip Morris's Action Against Access), sponsored educational programs (e.g., the Tobacco Institute's COURSE Consortium and RJ Reynolds's Right Decisions Right Now), youth program partnerships (e.g., with the US Junior Chamber of Commerce and the National 4-H Council), and media campaigns (e.g., Philip Morris's Think. Don't Smoke.).

Analysis of publicly available tobacco industry documents indicates that industry executives used these programs to prevent and defend against government regulation that might lower company profits. Moreover, industry players were careful to design youth prevention programs that did not contradict existing tobacco advertising initiatives; not a single program included information on nicotine and addiction, the causal link between smoking and disease, or the large role of tobacco marketing in promoting smoking to youths. Some evidence suggests that these programs actually encouraged young people to smoke more. Tobacco industry programs also marginalized public health advocacy groups by creating competition with more reputable anti-smoking campaigns, such as the Truth campaign sponsored by the American Legacy Foundation. Public health advocates have found no evidence that tobacco industry programs decrease the rate of youth smoking and have concluded that they do more harm than good.

The tobacco industry's self-regulatory tactics illustrate the central danger of self-regulation: an industry can use programs and approaches that appear credible and are framed as in the public's interest but prevent legislation or regulation and damage public health. Some food industry behaviors are strikingly similar to those of the tobacco industry; it is essential that tobacco's history with self-regulation not be repeated.

Lessons Learned from Self-Regulation History

The history of food industry self-regulation is being written now. Much can be gained by reviewing the history of self-regulation in other industries to help avoid pitfalls and adopt practices that maximize chances for success. These accounts reveal critical factors that bear on such questions as whether industry can be trusted, whether

regulatory control should be ceded to industry, how criteria for evaluating self-regulation might be established, and what the overall goals might be.

An important factor is motivation for change. Industries protecting a dwindling resource [such as fisheries or forests] face the internal threat of overuse and exploitation of the environment. They have incentives to regulate effectively and can behave in ways that benefit the public (e.g., reducing deforestation protects the environment). Governance, implementation, and basic strategy all present challenges, but the potential for good is considerable. . . .

As with the tobacco and alcohol industries, food industry self-regulation appears to be motivated more by external threats: negative public attitudes, government action that restricts key business practices, and litigation. Where industry and public health objectives conflict, an industry has incentives to create a public image of concern and to promise change, but then to create weak standards with lax enforcement. The cynical practices of the tobacco industry, and to a lesser extent the alcohol industry, have shown how under the guise of self-regulation, public health problems can be increased (e.g., young people being encouraged to smoke more rather than less) and government action can be warded off. . . .

. . .

The Food Safety Modernization Act includes examples of government-mandated certification by third parties and incentives (such as expedited government approval) for voluntary certification. Meanwhile, in the largely unregulated area of high-calorie, low-nutrient foods that contribute to obesity and related illnesses, voluntary self-regulation initiatives involve virtually no government oversight and may serve primarily to mislead consumers and evade meaningful reform. Political opposition to a federal task force directed by Congress to review the Children's Food and Beverage Advertising Initiative (CFBAI) discussed by Sharma and her coauthors provides a cautionary tale. When the task force released draft guidelines recommending (but not mandating) that the CFBAI adopt more stringent standards, Congress responded to industry lobbying by mandating that the draft recommendations be subjected to cost-benefit analysis, a prohibitively expensive and unprecedented requirement for voluntary guidelines.

On the other hand, voluntary industry self-regulation programs may create standards that are eventually incorporated into a mandatory regulation and those standards could be made more rigorous over time. Voluntary standards adopted by industry may also be relied upon by judges seeking to define the standard of care for the purposes of a tort suit, as discussed in the next chapter. Before moving to indirect forms of regulation via tort litigation, taxation, and spending, we end this chapter with a discussion of deregulation as a mode of public health law intervention.

DEREGULATION AS A MODE OF PUBLIC HEALTH LAW INTERVENTION: HARM REDUCTION

Public health experts often advocate for affirmative health and safety regulation. Existing regulations, however, can act as a barrier to effective public health intervention in some instances, prompting calls for deregulation as a public health law strategy. For example, laws that criminalize sodomy contribute to less safe sexual behaviors by forcing men who have sex with men to hide their activities from health care professionals. In some jurisdictions, the simple act of carrying multiple condoms can establish probable cause for a prostitution arrest, which discourages sex workers from protecting themselves. Laws requiring a prescription to purchase injection equipment and criminalizing possession of syringes as drug paraphernalia similarly discourage the use of sterile drug injection equipment. Physician prescribing laws may also limit access to life-saving treatments such as naloxone (which halts opioid overdose if administered immediately) and make it more difficult to treat sexually transmitted infections by prescribing enough antibiotics for a patient's sexual partner as well as himself (see chapter 10). In these and other cases, public health experts advocate deregulation as a mode of public health intervention.

Deregulation is closely related to harm reduction as a strategy for minimizing the harms associated with an illicit behavior such as drug use or sex work without necessarily aiming to disrupt the activity itself. In the excerpt that follows, Katherine Beckett describes a harm reduction approach to policing of drug users and sex workers pioneered in Seattle, Washington. The program does not erase drug and prostitution laws from the books, but relies instead on the exercise of police and prosecutorial discretion to shift enforcement away from the criminal justice system and toward intensive social services. As you read, consider the influence of new governance insights on the war on drugs, broken windows policing, and the alternative approach that Beckett champions.

THE USES AND ABUSES OF POLICE DISCRETION: TOWARD HARM REDUCTION POLICING*

Katherine Beckett

. . . [R]ecent years have witnessed two major policy efforts to steer police discretion in particular ways. The first of these was the federal war on drugs, which emanated from

* 2016. *Harvard Law & Policy Review* 10 (1): 77–100.

national-level politicians but included a number of incentives aimed at encouraging state and local police departments to place greater emphasis on drug law enforcement and to employ proactive methods to identify and arrest drug law violators. Similarly, advocates of "broken windows policing" successfully urged police departments to encourage officers to react strongly to low-level (potentially) criminal behaviors such as panhandling or lying on sidewalks. Below, I briefly describe how these policy initiatives shaped the exercise of police discretion in recent years and describe the consequences of these shifts. I then advocate the adoption of an alternative policy framework that seeks to redress the human suffering that underlies most low-level criminal behavior, and to steer the homeless, drug users and sellers, sex workers, and others who spend their time on the streets toward services and away from the criminal justice system.

POLICY EFFORTS TO SHAPE POLICE DISCRETION: TWO RECENT EXAMPLES

The War on Drugs

Because anti-crime efforts are largely a state and local affair, national politicians who campaign on their anti-crime credentials often turn their attention to drugs (over which the federal government has comparatively great authority) once in office. This was certainly true for the Reagan Administration, which assumed office in 1981 and quickly advocated increased federal involvement in the war against drugs. But the fight against drugs also involves state and local authorities to a significant degree. Recognition of this led crime fighters in the 1980s and 1990s to use legislation to encourage police departments around the country to target drug law violators. The 1984 Omnibus Crime Bill, for example, authorized police departments to confiscate any assets—including cars, boats, houses, and bank accounts—they believed were acquired with drug monies, regardless of whether their (former) owners were ever convicted of, or even charged with, a drug crime. A few years later, Congress revised the program through which the federal government provides grants to state and local law enforcement agencies . . . to incentivize local law enforcement agencies to develop and expand the narcotics task forces that have served as the foot soldiers in the war on drugs. Over the years, the federal government also offered other important forms of support to local drug warriors, including resources, equipment, and training.

The federal government's effort to encourage drug law enforcement was remarkably successful, and had important and measurable consequences. Specifically, the number of drug arrests occurring in the United States nearly quadrupled, from just over a half of a million in 1981 to a peak of nearly 1.9 million in 2006. This development most significantly affected people and communities of color. Between 1980 and 2000, for example, the national black drug arrest rate increased from roughly 6.5 to 29.1 (per 1,000 persons), while the white drug arrest rate increased much more modestly, from approximately 3.5 to 4.6 (per 1,000 persons). . . .

Broken Windows Policing

The debate over broken windows policing has been simmering for decades, and was renewed again in the aftermath of the NYPD shooting of Eric Garner during his 2014 arrest for selling loose cigarettes. Broken windows policing was first articulated by

James Q. Wilson and George Kelling in a short *Atlantic Monthly* article in 1982, and became wildly popular in U.S. urban police departments in the intervening years. Proponents argue that neighborhoods that fail to fix broken windows or address other manifestations of "disorder" display a lack of informal social control, thus inviting serious criminals into the neighborhood. Advocates of broken windows policing therefore call for a fundamental reorientation of policing, one that offers city governments a broad and flexible means of regulating public spaces and removing those deemed "disorderly" from contested public spaces, often through arrest. Although the name of the theory calls attention to the built environment, it focuses in practice primarily on unwanted human behavior—particularly that which is engaged in by [what Wilson and Kelling described as] "disreputable or obstreperous or unpredictable people: panhandlers, drunks, addicts, rowdy teenagers, prostitutes, loiterers, the mentally disturbed." Problematic behaviors exhibited by these groups are seen not as a manifestation of poverty or other social ills, but rather as a sign of "disorder," a cause of diminished quality of life for other urban residents, and as a precursor of serious crime. Where departments have embraced broken windows policing, police department officials encourage officers to consider potentially misdemeanor offenses such as public drunkenness and panhandling as very serious matters. Unsurprisingly, this focus has also contributed to racial disproportionality in jail populations, as well as fueling the incarceration of the homeless and mentally ill. Despite numerous empirical studies challenging the efficacy of broken windows policing, the theory of crime that underpins broken windows policing has achieved the status of common sense in police departments across the United States and in many other countries as well. . . .

As a result of these and other policy developments, the U.S. penal system has expanded to unprecedented proportions. The U.S. incarceration rate is the highest in the world, and is five to fifteen times higher than those found in Nordic and Western European countries. . . . [T]he growth of the criminal justice system has been so consequential that the study of punishment, urban poverty and social inequality are increasingly treated as over-lapping rather than distinct areas of inquiry. Research in these areas indicates that the U.S. penal system is implicated in the accumulation of disadvantage and the reproduction of inequality for a number of reasons: the growing number of (mainly poor) people whose lives it touches; the negative impact of criminal convictions on employment and earnings; the adverse effects of confinement on inmates' mental and physical health; incarceration's destabilizing effects on families, children, and urban communities; and the widespread imposition of "collateral" or "invisible" sanctions, including the imposition of legal debt, many of which transform punishment from a temporally limited experience to a long-term status. . . .

TOWARD HARM REDUCTION POLICING

The harm reduction philosophy rests on the assumption that some people will always engage in behaviors, such as drug use, that are stigmatized and risky. Although efforts to reduce these behaviors are appropriate, it is important to recognize that no society has ever eradicated all unwanted behaviors. . . . More generally, social policy aimed at lessening the negative consequences of risky behaviors may reduce human suffering more than policies aimed at eradicating such behaviors altogether. Harm reduction practitioners therefore emphasize that the path toward abstinence may often be long,

and sometimes even non-existent. Even in the absence of abstinence, though, meaningful reductions in human suffering can be achieved.

In addition, harm reduction advocates distinguish between the primary and secondary harms associated with risky behaviors. Primary harms are those caused by the behavior itself, such as liver damage caused by excessive alcohol consumption. Secondary harms are those that flow from the policy response to the behavior in question. For example, an injection drug user who contracts HIV because clean syringes are not made available has suffered a secondary—and quite avoidable—harm. Similarly, the adverse consequences that flow from the incarceration of an addict are considered by harm reduction advocates to be both secondary and avoidable.

Indeed, from a harm reduction point of view, the active intervention of the criminal justice system is often counterproductive and a source of damage. For example, if policed aggressively, drug use and sex work may be pushed into more and more dangerous places. This may leave those who engage in those behaviors even more vulnerable to physical assault and other dangers. Drug users may inject more quickly, or in darker locales, or with dirty needles, thereby endangering themselves and others. A drug user who is convicted, incarcerated, and loses her ability to secure work and housing as a result of her conviction is more likely to relapse. Harm reduction advocates therefore argue that many forms of risky behavior should be defined not primarily as matters of criminal justice, but of public health. Absent an immediate threat to public safety, arrest and punishment are, from the harm reduction point of view, inappropriate responses to these behaviors. Instead, priority should be placed on the provision of health care and social services to help reduce overall levels of harm.

These ideas serve as the foundation of an innovative new approach to policing underway in Seattle, Washington. . . . The adoption of [Law Enforcement Assisted Diversion (LEAD)] marks a dramatic shift in Seattle's approach to drug markets and associated problems. Like many urban police agencies, the Seattle Police Department (SPD) was actively engaged in the drug war in recent decades. In fact, the city's drug arrest rate was comparatively high, and levels of racial disproportionality in drug law enforcement outcomes were quite pronounced. In 2006, for example, Seattle's black drug arrest rate was 13.6 times higher than its white drug arrest rate; for drug delivery arrests, the black arrest rate was 21 times higher.

In response to the severity and persistence of these unusually high levels of racial disparity, attorneys at the [Public Defender Association's] Racial Disparity Project [funded by grants from private foundations] mounted a selective enforcement challenge on behalf of a consolidated group of nineteen criminal defendants in 2003. . . . Eventually, litigation-fatigue and the persistence of significant public concern about Seattle's still-active drug markets inspired SPD personnel, the King County Prosecutor, and Racial Disparity Project staff to work together to identify an alternative approach that avoided reliance upon jail and prison but also took the harm associated with untreated addiction and drug market activity seriously. . . . Early in the process, stakeholders expanded the potential client population to include sex workers in order to ensure significant participation by women who suffer from addiction or extreme poverty, and spent significant time developing a protocol to guide program operations. This protocol lays out the procedures by which police officers refer people to LEAD and by which LEAD clients are engaged by social service providers. . . .

When an eligible individual is arrested on drug charges (either possession of a controlled substance or sale of small amounts of drugs for "subsistence purposes") or for prostitution, a LEAD-trained police officer may elect to refer that individual to a LEAD case manager rather than booking him or her into jail. Although several criminal background exclusions may apply, these exclusions are presumptive rather than mandatory, and participating officers retain a high degree of discretion over the referral process. That is, people with more serious criminal records *can* be referred to LEAD after booking if the arresting officer so recommends. In addition, SPD officers may elect *not* to refer those who are presumptively eligible to the program. Stakeholders granted officers this degree of discretion because they believe that officers possess deep knowledge about the people they regularly encounter and are therefore best situated to determine if a potential client is in a position to benefit from LEAD and can safely work with case managers in relatively private settings. Early on, some stakeholders expressed concern that officers might be more inclined to refer white people to LEAD. To ensure that this is not the case, data regarding the racial and ethnic composition of LEAD clients are collected and monitored. The evidence to date shows that sixty percent of all LEAD clients are black and roughly one-fourth are white.

In an arrest referral, a police officer makes an arrest, transports the arrestee to the precinct and contacts a LEAD case manager, who then goes to the police precinct to conduct an initial screening with the potential LEAD client. In most cases, the officer relinquishes custody of the referred person as soon as a caseworker arrives. Although the arrested individual has been referred to LEAD rather than booked into jail, the arresting officer nonetheless sends the arrest record to the Seattle City Attorney's office (which is responsible for prosecuting misdemeanor crimes) or to the King County Prosecutor (responsible for prosecuting felony offenses). These offices maintain the authority to charge the arrested person. However, the presumption is that charges will *not* be filed as long as the individual completes both an initial screening and a full intake assessment with LEAD case managers within thirty days of the referral. . . .

Shortly after a referred person agrees to participate in LEAD, they meet with a LEAD case manager. . . . [C]ase managers do not simply supply their clients with a "to-do" list, but actively seek out recalcitrant clients; visit newly housed clients; accompany others as they complete paperwork, keep appointments, and apply for services and housing; and engage in a myriad of other behaviors aimed at helping their clients achieve their stated goals. . . . LEAD trains case managers to meet clients "where they are at," to assist clients in identifying individual goals through techniques such as motivational interviewing, and to support their clients as they work toward those goals. . . .

[C]onsistent with the harm reduction philosophy, LEAD case managers focus [in the words of a concept paper promulgated by the Racial Disparity Project] "on individual and community wellness, rather than an exclusive focus on sobriety, by immediately addressing the participant's drug activity and any other factors driving his or her problematic behavior, even if complete abstinence from drug use is not immediately achieved." That is, case managers expect setbacks and emphasize that meaningful improvements may occur even in the absence of abstinence. Particularly at the outset, abstinence may not be among their clients' objectives, and clients are welcome to participate in LEAD regardless of whether they identify abstinence as a goal. . . .

[T]he LEAD protocol does not authorize any sanctions for "non-compliance." Although the King County Prosecuting Attorney and the Seattle City Attorney retain

their authority to file charges against LEAD participants for crimes committed in the past or while participating in LEAD, prosecutors have committed to working in cooperation with LEAD, which means exercising their discretion to *not* bring charges against LEAD participants where refraining will enhance LEAD clients' therapeutic progress. At regularly held work group meetings, law enforcement officers, case managers, and prosecutors share information about LEAD clients so that each of these actors can make informed decisions in matters pertaining to them. . . .

[T]he first years of LEAD's operations provide compelling evidence that local policy initiatives that rely upon police discretion but steer potentially arrestable people away from rather than toward the criminal justice system are, in fact, in the realm of possibility. As research on the human costs associated with concentrated poverty and mass incarceration makes abundantly clear, cities across the United States desperately need such programs. Through the development and implementation of programs that use harm reduction principles to guide the exercise of police discretion, municipalities may be able to transform the police response to low-level crime from one that exponentially increases the harm associated with those behaviors to one that notably reduces individual and community suffering.

. . .

Direct regulation has long been a staple of the public health law toolkit. Deregulation, on the other hand, is a more recent addition. In times of budgetary constraints, removing legal barriers to good public health practice may be an appealing strategy. It can be politically controversial, however. As the *Open Society* case excerpted in chapter 4 demonstrates, social conservatives worry that harm reduction implicitly condones immoral and dangerous behavior. Moreover, as Beckett's article indicates, deregulation alone is generally insufficient. Spending on social services and other resources is a crucial component of meaningful public health reform. We will turn to taxation and spending strategies and the social safety net in chapter 8. Next, we turn to another form of indirect regulation: tort liability.

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PHOTO 7.1. A U.S. Public Health Service worker collects dust samples at a Baltimore factory, 1953. Many factory and shipyard workers exposed to asbestos dust during the mid-twentieth century later developed mesothelioma and asbestosis. Industrial Hygiene Division, U.S. Public Health Service

CHAPTER SEVEN

Tort Liability as Indirect Regulation

The levers of public health regulation are often viewed as being in the hands of legislatures and executive agencies. However, private citizens and government attorneys possess a powerful means of indirect regulation through the courts. The threat of common law tort liability (e.g., for negligence, products liability, and fraud), tort-based statutory causes of action (e.g., for deceptive trade practices), and civil enforcement actions (e.g., for submission of false claims to government programs and racketeering) deters harmful behavior by private individuals and businesses. The courts are empowered to compensate injured parties and order injunctive relief to redress harms caused by hazardous products, unsafe and ineffective pharmaceuticals and medical devices, and pollution, among other health and safety threats.

Many public health law experts see litigation as an important adjunct to regulation, filling gaps that put the public's health and safety at risk. This is particularly important when the executive branch is wary of regulation—a view prominent in the Trump Administration. Some point to litigation as a tool for combatting the political power of industries harmful to the public's health. As Stephen Teret explains,

> When it was learned that rodents, mosquitoes, and other living organisms transmitted to man the etiologic agents for disease, the public health response was to control those vectors of disease. . . . But unlike rodents and mosquitoes, the modern day vehicles of injury and disease have vested interests, lobbyists and political action committees that sometimes thwart effective

> legislative and regulatory attempts to enhance the public's health. When this happens, public health advocates have turned to the third branch of government, the judiciary, to seek relief from juries. (Teret 1986)

In theory, the threat of liability provides an incentive to monitor potential hazards and innovate with regard to safety measures, rather than waiting for government regulators to impose safety requirements. On the other hand, empirical evidence regarding the deterrent impact of tort judgments is mixed at best. The public largely derides tort plaintiffs seeking monetary damages as greedy and lacking personal responsibility. Even when suits are brought by public entities, there are no guarantees that settlement funds or damage awards will be used for the public's benefit. Moreover, exposure to liability may limit access to beneficial products and services by raising prices or limiting supply. In the 1980s, for example, a wave of litigation prompted by widely publicized concerns about pertussis vaccination led to vaccine shortages. Congress responded by establishing the National Vaccine Injury Compensation Program, which provides publicly financed compensation to those harmed by vaccines on a no-fault basis and immunizes vaccine producers from many forms of liability. Litigation as a form of indirect regulation, then, holds enormous potential for improving the public's health, but also entails economic costs and political controversy.

This chapter takes a close look at litigation as a tool for protecting the public's health and safety. We begin with an examination of the many roles litigation plays in public health law. We then discuss the evaluation of scientific evidence by judges and juries. The middle sections of this chapter analyze negligence, products liability, fraud and unfair trade practices, public nuisance, and racketeering. We discuss the substantive standards that courts apply to assess liability in each of these contexts while also addressing cross-cutting issues of preemption, the role of government officials as plaintiffs, and tort reform.

LITIGATION AS A TOOL FOR PROTECTING THE PUBLIC'S HEALTH

The courts have a unique role in public health regulation. In the excerpt that follows, noted public health law scholars Wendy Parmet and Richard Daynard provide a useful typology of public health litigation, discussing the advantages and disadvantages of policymaking by the courts. As you read the excerpt, consider the mechanisms by which litigation

may lead to a reduction in injury and disease burden. Are the benefits of litigation outweighed by its costs?

THE NEW PUBLIC HEALTH LITIGATION*

Wendy E. Parmet and Richard A. Daynard

One of the most remarkable developments of the last three decades has been the increasing use of litigation as a public health tool. Although courts have long been called on to review matters concerning public health, historically the courtroom was seldom the forum of choice for public health enthusiasts. Instead, it was the place where those who wished to resist public health regulation, be they milk producers, bread makers, or parents who did not want their children to be vaccinated, went in the hope of limiting the authority of public health agencies. Although such litigants were usually not successful, public health had little to gain by the litigation. At best the regulation might be upheld; at worst, the right of the individual or business to refuse compliance might be proclaimed. The courtroom, in short, was a barrier that public health authorities sometimes needed to pass through on their way to protecting the public's health.

In recent years, however, the tables have turned. Increasingly, individuals and organizations concerned about public health have sought to use litigation to further their goals. In other words, courts are now being used affirmatively in an effort to make public health policy. Most notably, the tobacco control movement has pursued a litigation strategy, not simply to obtain compensation for tobacco's victims, but also to achieve a reduction in tobacco use. Likewise, groups concerned about gun violence have chosen to sue the gun industry. In similar fashion, the American Public Health Association has urged the use of litigation to hold paint manufacturers accountable for the injuries caused by lead paint. . . .

But is such litigation an effective public health tool? In this article we consider that question by surveying the new public health litigation and considering why these cases are being brought and what they can and cannot achieve.

REASONS FOR THE NEW PUBLIC HEALTH LITIGATION

The new public health litigation has several roots. The first is undoubtedly the prominent role played by the Supreme Court during the years when Earl Warren was Chief Justice in the quest for civil rights for African Americans, women, and disadvantaged groups. The Warren Court's landmark opinions . . . led young Americans desiring change to look to the federal courts as allies. This was a genuinely new development; nothing like it had occurred during the New Deal, the Progressive Era, or earlier reform movements. . . .

[S]ome of this new court-centered activism touched on matters of public health. For example, advocates for poor people went to court demanding government-provided

* 2000. *Annual Review of Public Health* 21 (1): 437–54.

health care. The women's rights movement sought improved access to reproductive medical care. Prisoners' rights advocates pressed for and obtained the recognition that failure to treat a prisoner's serious medical condition constituted "cruel and unusual punishment." And public interest lawyers went to court demanding that the US Food and Drug Administration regulate tobacco.

Reformers also cast their eye on manufacturers and other private entities that were thought to be responsible for unnecessary morbidity or mortality. Ralph Nader, for example, pointed to the culpability of automobile manufacturers in explaining why so many Americans died in their automobiles. The consumer movement that he helped inspire sought to hold manufacturers accountable for the injuries caused by their products. That goal became more possible because of changes that occurred in tort doctrine, especially the widespread adoption of strict liability as the standard of care in product liability cases. As a result, by the early 1980s, legal actions against manufacturers and other entities thought responsible for deleterious products had become so common that potential defendants and other critics assailed a "tort crisis" and demanded reforms making such cases more difficult to bring.

The increasing reliance on law and litigation to foster social change helped attract would-be activists to the legal profession. The result was a substantial cross-fertilization between "legal" and "activist" ways of thinking, including those involving issues of public health. [The prominence and success of tobacco litigation] in turn encouraged other public health advocates to use the courts. Thus advocates for gun control as well as those concerned about lead paint hazards have explicitly cited tobacco litigation as a model for legal campaigns designed to achieve their own public health goals.

Of course, not all litigants who bring cases pertaining to public health are would-be law reformers who are motivated by public health goals. Individuals pursue private litigation for many reasons, including prominently individual compensation. Some individuals may not even care about the public health impact of the litigation they commence. Still, their lawsuits may significantly benefit public health. In this article our concern is not whether the litigation achieves the personal goals of the plaintiffs but the degree to which it can improve the public's health by reducing rates of disease and injury. . . .

TYPOLOGY OF PUBLIC HEALTH LITIGATION

A broad array of cases characterizes the new public health litigation. Some cases are brought by individuals or by government agencies. Cases may also be brought against government officials (seeking an order that they change government policy or enforce already existing regulations) or against private parties [see table 7.1]. . . .

PUBLIC HEALTH LITIGATION AND DEMOCRATIC THEORY

A commonly made and potent criticism of litigation-centered reform movements is that they are fundamentally antidemocratic. If change is to occur in our laws, so the criticism goes, it should occur via legislation enacted by democratically accountable representatives. Situating policy development reform in the courts bypasses that political accountability in favor of less accountable judges and juries.

In public health litigation, a further related criticism may be made. In our market economy, individuals are presumed to have significant freedom as to what risks they

TABLE 7.1 TYPOLOGY OF PUBLIC HEALTH LITIGATION

1. Private plaintiff v. private defendant Example: *Cippolone v. Liggett Group*, 505 U.S. 504 (1992), a suit for fraud and other claims brought by an individual smoker against three companies that manufactured cigarettes she had smoked since age 16. After Rose Cippolone died from lung cancer, her husband and son continued the litigation on her behalf.	**2. Public plaintiff v. private defendant** Example: *City of New York v. Beretta USA Corp.*, 524 F.3d 384 (2d. Cir. 2008), a suit for public nuisance brought by the city in its *parens patriae* capacity against firearms manufacturers and wholesale distributors.
3. Private plaintiff v. public defendant Example: *Deshaney v. Winnebago Co. Dept. of Social Services*, 489 U.S. 189 (1989), a suit brought by Joshua Deshaney's mother on his behalf to hold a county agency liable for violating his constitutional rights.	**4. Public plaintiff v. public defendant** Example: *Massachusetts v. Environmental Protection Agency*, 549 U.S. 497 (2007), a suit brought by state and local governments and private environmental organizations against a federal agency asking the court to order the agency to regulate greenhouse gas emissions pursuant to the Clean Air Act.

SOURCE: Adapted from Parmet, Wendy E., and Richard A. Daynard. 2000. "The New Public Health Litigation." *Annual Review of Public Health* 21(1): 437–54.

NOTE: The vast majority of lawsuits do not result in published opinions, which are limited to cases that present novel questions of law or give the courts an opportunity to reverse previous decisions on matters of law. Most suits are settled out of court and many are decided by judicial order without a written opinion. The caption of a case—the name by which it is known—typically includes only one plaintiff and defendant, even though there may be many parties on either side of the litigation. Also, public parties may sometimes be represented by individual officials who act as plaintiff or defendant. Private parties may be individual people, corporations, or other organizations. The order in which names appear in the caption of a case does not always indicate the position of the parties. Additionally, recall that plaintiffs seeking redress must establish that they have standing to sue, a requirement derived from separation of powers principles designed to ensure that courts are confined to interpreting the law only in the context of a "real case or controversy." This can be a challenge for public plaintiffs and nongovernmental organizations seeking to represent the interests of their members.

wish to incur. To the extent that public health policies seek to reduce risks beyond the rate individuals would choose in the market, those policies may be described as inherently paternalistic and contrary to the prevailing individualistic/market ethos. When public health advocates seek to reduce those risks and achieve their aims not through legislation but via judicial decrees, they become particularly vulnerable to a charge of paternalism, for they may be seen as trying to force the public to accept what neither it nor its representatives desire. . . .

Several responses may be made to the charge that public health litigation is both antidemocratic and paternalistic. The first and narrowest is that litigation often serves to further a democratically determined policy. Even if we concede that interference with the market should be the exception rather than the norm and that such exceptions should be derived from politically accountable processes, a significant role remains for litigation. Democratically enacted laws still require interpretation and

enforcement, and that often requires litigation. For example, in 1992 Congress enacted the Residential Lead-Based Paint Hazard Reduction Act, requiring that homeowners disclose known lead paint hazards and imposing fines and damages on parties who violate the Act. This piece of public health legislation, like many others, presupposes litigation for its enforcement. Thus it can hardly be said that litigation under the statute violates democratic principles. Likewise, litigation . . . brought by advocates who seek to compel government officials to obey and enforce legislation can also be seen as supportive of democratically determined policies.

Another response to the antidemocratic critique recognizes that the judicial law making that defines "the common law" has long been an accepted part of our democratic polity. Indeed many public health policies in place today result from an interactive dialog between courts and legislatures. . . . As long as legislatures remain free to adopt, ignore, or override the common law, judicial decision making can be seen as enriching rather than undermining the democratic process.

A different response goes further to explain the use of litigation not only in enforcing legislation but also in creating new public health policies. This response questions the assumption that the legislative process itself is as democratic as the antidemocratic critique assumes. . . .

[T]he tobacco, gun, and health care industries . . . have made enormous contributions to political campaigns, while also spending millions on lobbyists. In short, the so-called normal political process is not always fully representative of the public's interests in matters of health. . . . In some situations the possibility of civil lawsuits that threaten to cost the industry more than it would lose through regulation may prompt industry to support legislation that both regulates and immunizes it. In this sense litigation may serve as a public health bargaining chip, influencing the possibility and nature of legislative action.

There is another way in which litigation may be able to force regulation onto the legislative agenda, even if the affected special interest demurs. Litigation makes compelling drama; lawsuits grab headlines, are regularly featured on talk shows, and become part of ordinary conversation. . . . Once the public and the media are actively engaged in the issue, the political calculus, in Congress and elsewhere, may change. In other words, litigation may be used not only to achieve judicially imposed changes but also to change the political climate in which issues of public health are debated.

At times, the information obtained via civil litigation's discovery process may play a critical role in disclosing information and educating the public about the nature and causes of health risks, thus making the political process itself more informed. [For example,] litigation-induced discovery of tobacco industry documents played [a vital role] in shifting the attitudes of both the public and policymakers about tobacco regulation.

To say that litigation can play a significant role in the political struggle for public health protection, however, is not to contend that litigation's impact will always be beneficial. There is no reason, a priori, to assume that judges and juries will have a better appreciation of public health threats than do legislators. . . . Many of the economic advantages that industry flaunts in the legislative process can also be used effectively in the judicial arena. In the early years of tobacco litigation, for example, the industry successfully engaged in a scorched-earth defense, epitomized by an R. J. Reynolds Tobacco Co. internal memorandum that remarked, "The way we win these

cases, to paraphrase General Patton, is not by spending all of Reynolds' money, but by making that other son-of-a-bitch spend all of his." . . .

Nevertheless, although public health litigation will not always be successful, and its place in a democratic polity should always be open to reconsideration, the experience of the new public health litigation suggests that it may at times play a constructive, if not decisive, role in the democratic struggle to protect the public's health. . . .

. . .

Judicial opinions resulting from the types of public health litigation examined by Parmet and Daynard are excerpted throughout this reader. Chapters 3 and 4, for example, explore lawsuits by private plaintiffs against public defendants to vindicate constitutional rights and to ensure compliance with federalism constraints. Chapter 5 covers suits by private parties against government agencies to ensure their compliance with statutory mandates. Suits by private plaintiffs against state governments seeking to ensure their compliance with the requirements of federal spending programs will be discussed in chapter 8. This chapter touches on issues common to all types of public health litigation (such as reliance on scientific evidence, discussed in the following section) but it focuses primarily on tort-based civil liability. Private plaintiffs bring the vast majority of tort claims against private defendants. Public plaintiffs, however, bring some suits against private defendants. Tort suits against public defendants are possible, but face hurdles derived from sovereign immunity (discussed in chapter 3) and the common law *public duty* doctrine, which holds that duties owed by government agencies (e.g., fire or police departments) are owed to the public as a whole rather than any particular individual harmed as a result of the government's failure to act.

SCIENTIFIC EVIDENCE IN THE COURTROOM

Litigators using the court system as an instrument of public health advocacy must confront the vexing questions of proof and causation. Establishing causation is particularly difficult for cases involving toxic exposures. As Tom Christoffel and Stephen Teret (1991) put it,

> During most of this century, tort law was concerned predominantly with injuries for which the cause-effect association was clear-cut: a car ran into a pedestrian, a shopper fell on a store's slippery floor, or a baby choked on a toy with small parts. . . . [Beginning in the late twentieth century,] however, tort law has been used to seek compensation for injuries in which causation is not provable by mere eyewitness testimony regarding a specific causal event.

In toxic tort cases brought against the makers of commercial products such as asbestos (associated with lung disease and cancer) and lead (associated with intellectual impairment and behavioral problems) and pharmaceuticals such as diethylstilbestrol (DES) (associated with cancer and other reproductive health harms in women whose mothers took the drug during pregnancy) and Vioxx (a pain reliever associated with increased risk of heart attack), plaintiffs must rely on epidemiological studies to establish causation.

As Parmet and Daynard note in the excerpt above, judges are no more likely to have scientific expertise than legislators. Litigants rely on qualified experts to introduce scientific evidence into the record on which judges and juries base their adjudication of plaintiffs' claims. Typically, plaintiffs and defendants each hire their own expert witnesses to review available scientific evidence and offer their opinions as to the bearing of that evidence on the case at hand. Duels between experts with conflicting opinions play out in courtrooms across the country on a daily basis. In the excerpt that follows, the Supreme Court discusses the gatekeeping role played by judges, who determine which evidence may be submitted to the jury for consideration.

*DAUBERT v. MERRELL DOW PHARMACEUTICALS, INC.**

Supreme Court of the United States
Decided June 28, 1993

Justice Blackmun delivered the opinion of the Court.

[Petitioners, two minor children and their parents, alleged in a tort suit against Merrell Dow Pharmaceuticals, Inc., (respondent) that the children's serious birth defects had been caused by their mothers' prenatal ingestion of Bendectin, a prescription drug marketed by respondent. The district court granted summary judgment in favor of Merrell Dow based on a well-credentialed expert's affidavit concluding, upon reviewing the extensive published scientific literature on the subject, that maternal use of Bendectin had not been shown to be a risk factor for human birth defects. Although petitioners supported their claims with the testimony of eight other well-credentialed experts, the petitioners' experts had based their conclusion that Bendectin can cause birth defects on animal studies, chemical structure analyses, and unpublished "reanalysis" of previously published human statistical studies. The district court determined that the petitioners' experts' testimony would not be admissible at trial because the methods relied upon had not yet gained "general acceptance" within the scientific community, as required under a 1923 federal court decision that set forth the dominant standard for the admission of expert testimony. The Ninth

* 509 U.S. 579.

Circuit Court of Appeals agreed and affirmed the grant of summary judgment for Merrell Dow.]

In this case we are called upon to determine the standard for admitting expert scientific testimony in a federal trial. . . . Rule 702, governing expert testimony, provides:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

. . . [U]nder the Rules the trial judge must ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable. . . . Rule 702 . . . clearly contemplates some degree of regulation of the subjects and theories about which an expert may testify. . . . Unlike an ordinary witness, an expert is permitted wide latitude to offer opinions, including those that are not based on firsthand knowledge. Presumably, this relaxation of the usual requirement of firsthand knowledge . . . is premised on an assumption that the expert's opinion will have a reliable basis in the knowledge and experience of his discipline.

Faced with a proffer of expert scientific testimony, then, the trial judge must determine at the outset . . . whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue. This entails a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue. We are confident that federal judges possess the capacity to undertake this review. . . . But some general observations are appropriate.

Ordinarily, a key question to be answered in determining whether a theory or technique is scientific knowledge that will assist the trier of fact will be whether it can be (and has been) tested. . . .

Another pertinent consideration is whether the theory or technique has been subjected to peer review and publication. . . . Submission to the scrutiny of the scientific community is a component of "good science," in part because it increases the likelihood that substantive flaws in methodology will be detected. The fact of publication (or lack thereof) in a peer reviewed journal thus will be a relevant, though not dispositive, consideration in assessing the scientific validity of a particular technique or methodology on which an opinion is premised.

Additionally, in the case of a particular scientific technique, the court ordinarily should consider the known or potential rate of error, and the existence and maintenance of standards controlling the technique's operation.

Finally, . . . [w]idespread acceptance can be an important factor in ruling particular evidence admissible, and a known technique which has been able to attract only minimal support within the community, may properly be viewed with skepticism. . . .

We conclude by briefly addressing what appear to be two underlying concerns of the parties and amici in this case. Respondent expresses apprehension that abandonment of "general acceptance" as the exclusive requirement for admission will result in a "free-for-all" in which befuddled juries are confounded by absurd and irrational pseudoscientific assertions. In this regard respondent seems to us to be overly pessimistic

about the capabilities of the jury and of the adversary system generally. Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence. . . .

Petitioners and, to a greater extent, their amici . . . suggest that recognition of a screening role for the judge that allows for the exclusion of "invalid" evidence will sanction a stifling and repressive scientific orthodoxy and will be inimical to the search for truth. It is true that open debate is an essential part of both legal and scientific analyses. Yet there are important differences between the quest for truth in the courtroom and the quest for truth in the laboratory. Scientific conclusions are subject to perpetual revision. Law, on the other hand, must resolve disputes finally and quickly. . . . We recognize that, in practice, a gatekeeping role for the judge, no matter how flexible, inevitably on occasion will prevent the jury from learning of authentic insights and innovations. That, nevertheless, is the balance that is struck by Rules of Evidence designed not for the exhaustive search for cosmic understanding but for the particularized resolution of legal disputes. . . .

The judgment of the Court of Appeals is vacated, and the case is remanded for further proceedings consistent with this opinion.

. . .

In *Daubert,* the Supreme Court held that the earlier *Frye* test for expert testimony had been superseded by Congress when it adopted the Federal Rules of Evidence in 1975. In the years that followed, the Supreme Court progressively tightened its permissive interpretation of the admissibility standard in the Federal Rules, giving trial judges considerable discretion to exclude both scientific methodologies and expert opinions that they determine fail to meet *Daubert*'s reliability and relevance tests. In 2000, Rule 702 was amended to codify the requirements articulated in *Daubert* and subsequent cases. The Federal Rules apply only in federal courts. State court rules of evidence vary—the *Frye* test continues to apply in some states—resulting in conflicting determinations as to the validity of controversial scientific evidence.

The history of Bendectin—which combined vitamin B6 and an antihistamine for the management of nausea and vomiting in pregnancy—illustrates the consequences of judicial decisions to admit questionable scientific evidence. Merrell Dow took the drug off the market 10 years before the Supreme Court's decision in *Daubert,* amid several multimillion dollar jury verdicts finding that it caused birth defects. A leading expert witness who testified for the plaintiffs in many Bendectin lawsuits, William McBride, was later found to have falsified data regarding the teratogenic effects of the drug. The FDA approved the same drug combination under a new brand name in 2015 after additional studies continued to demonstrate its safety and effectiveness.

Importantly, few cases are actually heard by a jury. Judges dispose of some cases, like *Daubert,* by granting summary judgment on the grounds that no reasonable jury could find in the plaintiff's favor. In most cases, the parties reach a settlement agreement based on their respective assessments of how a jury is likely to respond to the case. The rules of evidence play a crucial role in either instance, determining what evidence can be taken into account by the judge and jury and thus helping the parties assess the likely success of the plaintiff's claims. In addition to adjudicating procedural matters, such as the admissibility of evidence, judges are responsible for deciding questions regarding the standard to which the defendant's conduct is held and other substantive questions of law. In the sections that follow, we turn to the various causes of action available for holding individuals and businesses accountable for their harmful activities.

LIABILITY FOR NEGLIGENCE

We begin with the most common type of tort liability, negligence. Private plaintiffs may sue private defendants (or public defendants, though these cases are rarer because the doctrine of sovereign immunity protects government defendants, see chapter 3) for breaching the duty to exercise due care to avoid foreseeable and unreasonable harm to the person or property of others. Essentially, negligence law imposes a general duty on private parties to conduct their activities with reasonable care.

In the excerpt the follows, Dorit Reiss explores the intriguing possibility that parents who refuse to vaccinate their children could be liable for transmitting a vaccine-preventable disease. As Art Caplan wrote in a 2013 *Bill of Health* blog post,

> If you know the dangers of measles or for that matter whooping cough or mumps, and you still choose to put others at risk should you be exempt from the consequences of that choice? I can choose to drink but if I run you over it is my responsibility. I can choose not to shovel the snow from my walk but if you fall I pay. Why should failing to vaccinate your children or yourself be any different?

Does Caplan make a persuasive case for imposing liability or should a parent's right to rear their children as they see fit be treated differently?

Reiss reviews the five elements that plaintiffs are required to establish before they may hold a defendant legally responsible for negligence. All five elements of the prima facie case of negligence must be established

for the plaintiff's claim to be successful: duty, breach, causation-in-fact, proximate causation, and damages. Reiss also touches on the rationales for tort liability: compensation of injured parties (related to theories of corrective justice) and deterrence (the idea that imposing tort liability on one defendant will ultimately influence other potential defendants to exercise greater care). As you read the excerpt, consider what purposes would be served by requiring parents to pay damages to those who are harmed by their refusal to vaccinate. Would such an approach be consistent with public health's population perspective, prevention orientation, and commitment to social justice?

COMPENSATING THE VICTIMS OF FAILURE TO VACCINATE: WHAT ARE THE OPTIONS?*

Dorit Rubenstein Reiss

In 2000, an unvaccinated eleven year old with a fever was taken to a pediatrics practice in Germany. The boy infected six other patients with measles, including three infants who were too young to vaccinate. After a long, painful, and heartbreaking deterioration, two of them died from a rare but fatal complication of measles called subacute sclerosing panencephalitis (SSPE). Natalie, one of the infected babies, was eleven months old when she was exposed to measles in 2000. She recovered from the initial bout, but developed SSPE in 2007. She lost her ability to walk, talk, and eat unassisted. Natalie eventually died in 2011, after a long period of "wake coma." Micha, the other child, was even younger. Micha's initial exposure to the measles virus was at five months old, and his SSPE manifested in 2005. On June 13, 2013, he too died from SSPE.

During the years of slow deterioration the lives of both families were centered on the dying child. The families incurred expenses related to the child's care and to losing work time. They suffered indescribable mental anguish. If they had lived in the United States, where health insurance coverage is not as extensive as in Germany, they would likely have had substantial health care costs. Nothing can fully compensate these families for the suffering they went through; however, monetary compensation can help the families rebuild their lives and prevent additional suffering from the financial, on top of the human, losses they suffered. The natural source of such compensation is the parents whose choice to not vaccinate their children led to the infection that killed the victims. SSPE is rare, but other harms can derive from vaccine-preventable infectious diseases, including severe physical disability, brain damage, and death. When one family's choice to not vaccinate imposes those harms on another, compensation should follow. . . .

Our tort system is predicated on the idea that when an actor takes an unreasonable risk, and that risk harms another, those harmed should be compensated for their losses. There are legal (and moral) challenges in applying this philosophy to the situation of an unvaccinated child infecting another, but there are answers and solutions to those challenges, and the policy reasons for allowing compensation are powerful. . . .

* 2014. *Cornell Journal of Law and Public Policy* 23 (3): 595–633.

A COMMON LAW NEGLIGENCE CLAIM FOR FAILURE TO VACCINATE: CHALLENGES AND SOLUTIONS

To establish a case for negligence, the plaintiff must prove, with a preponderance of evidence, that: (1) the defendant had a duty of care, (2) that duty was breached, (3) [the defendant's breach actually caused the plaintiff's harm], (4) the harm was proximately caused by the breach (in the traditional formulation) or within the scope of liability (in the language used by the Third Restatement), and (5) there were legally cognizable damages. This section addresses each of these elements, explaining where they might be problematic for a suit against non-vaccinating parents whose child infected another child, and why, in spite of these problems, there is still a potential case for negligence.

The Problem of the No-Duty-to-Act Rule

There is no problem in suing a non-vaccinating parent for putting others at risk through their affirmative conduct. For example, taking a child to a "chicken pox party" and then sending that child to school, aware of the infection, can be tortious. Courts have long acknowledged negligent infection as a cause of action, so a parent who knew their child had a communicable disease could be liable for unreasonably exposing others. But alleging failure to vaccinate as itself the unreasonable conduct runs against the traditional rule in tort law that there is no liability for failure to act.

The distinction between misfeasance and nonfeasance—action and omission—is an old one and long established in common law, if not always the easiest to identify in practice. It focuses on whether the defendant created the risk (e.g., by driving—a situation of misfeasance) or whether the risk exists independent of the defendant's conduct. In a classic example of nonfeasance, the defendant saw someone drowning and did nothing to help, although she could have done so at negligible risk to herself. . . .

[O]ne can make an argument that non-vaccinating parents make a deliberate and conscious choice that at least exacerbates the risk to the plaintiff, if not actually creating it. . . .

Even if we . . . treat this as a classic nonfeasance situation, the discussion does not end. . . . The courts have the authority to create exceptions to the rule for policy reasons, and they have used that authority in the past. . . . For example, courts have created a duty for a psychiatrist to warn a potential victim of a patient. . . .

Duty and Breach: Is Acting Legally Acting Reasonably?

In relation to duty, a final question is the effect of statutory non-medical exemptions on the potential tort case: Does a state's choice to provide a legal exemption from school immunization requirements mean that the legislature has decided not to impose a duty in torts for parents using such an exemption? [Turning to the breach element, d]oes acting pursuant to a legal exemption mean a defendant is acting reasonably? . . .

In allowing religious or philosophical exemptions, the state is deciding which reasons justify allowing a child to attend school, even at the risk of exposing others. The child's right to an education and the interest of the state in having educated citizens are important considerations, and states may be willing to incur a broader risk to protect them. Those rights are not at stake when deciding whether to compensate those hurt by a failure to vaccinate. . . . The state may be willing to take the risk of higher rates of vaccine-preventable diseases on itself due to exemptions, but it is not clear it

is willing to impose the financial costs caused by the failure of others to vaccinate on otherwise blameless individual families. . . .

At any rate, acting legally is not necessarily acting reasonably. . . . [V]accinating is supported by a balance of the risks that would easily meet the test of the Hand formula: the burden of vaccinating—unpleasant with a very small risk—is easily smaller than the potential loss from not vaccinating—to the unvaccinated child and to others—times the probability of harm. For both those reasons, it should not be difficult to find that not vaccinating is a breach of duty. The non-vaccinating parent no doubt estimates the risks to be higher than described here. But the question is not how they estimate the risk, but how would a reasonable person in the community estimate it. . . . [V]accination rates currently stand at over 90%. This suggests that the community standard, and the expectation, is that parents will vaccinate their children.

In contrast, the reason the parent did not vaccinate will affect reasonableness. A parent who did not vaccinate because of a vaccine shortage or because of lack of access to healthcare or similar external arguments can raise those arguments to claim reasonableness of conduct. Similarly, a parent whose child has a medical condition that makes vaccinating inappropriate would also be treated as different from a parent not vaccinating based on personal choice alone. . . .

Causation: Identifying the Source

[W]ith modern tools, in at least some cases it will be possible to identify who the source of an infection was. These tools include drawing a timeline and tracking the contacts of the infected child as well as laboratory analysis. . . . It may be impossible to rule out other sources completely but that is not the standard; the plaintiff must demonstrate that other causes are less likely to have caused the infection. . . .

Proximate Cause: Who Can You Sue?

In some cases, it is impossible to trace who specifically infected the plaintiff, but possible to trace an outbreak to an index case. The question is: can a plaintiff sue an index patient even if it's unlikely that the index patient directly infected the plaintiff's child? If an index patient started an outbreak, there is no [factual] causation problem: without the initial failure to vaccinate the index case, the outbreak would not have happened and the plaintiff would not be hurt. However, it may be unfair to hold the index patient liable for policy reasons, and the courts have a tool for such situations.

Proximate cause—[also known as "scope of liability"]—is a liability-limiting device used to prevent liability for negligent actions from being too extensive. . . . The concern in allowing liability to reach back to an index case is that the liability of that person may be too extensive if the illness travels afar. This is similar to cases where the courts faced extensive liability from, for example, oil spill or fire. Here too, the determination will have to be on a case-by-case basis. . . . The time passage from the initial infection, the number of people in the community, and any connections between the index case and the plaintiff will affect the result. . . .

Damages: Is There Compensation?

Most private individuals do not have handy the kind of money required to cover expensive medical treatments or to pay substantial amounts in compensation for a death.

The way this is usually handled is through liability insurance. But many liability insurance policies do not currently cover infectious diseases caused by the individual insured, it seems. As a response to claims when an insured individual infected another with a sexually transmitted disease, many insurance companies adopted a "Communicable Diseases Exclusion." . . .

Should the claim therefore be abandoned? No. There are three potential solutions to the compensation issue. First, in some cases the non-vaccinating parents may be wealthy enough to cover the costs. Those cases alone justify having the option. The other options draw on the fact that anti-vaccination organizations have shown their ability to mobilize in order to achieve their goals before. If the courts accept a tort remedy, anti-vaccination organizations could help their members . . . by organizing and negotiating with insurance companies for liability insurance to cover these situations, or by mobilizing to change state law to prohibit the infectious diseases exclusion. After all, insurance is not set in stone, and the exclusion that was added in can be removed (and the insurance company is well-placed to calculate the appropriate pricing of the policy in this situation).

. . .

Reiss raises the possibility of holding vaccine-refusing parents liable for negligence, which requires a showing of fault. The plaintiff must establish that the defendant breached the duty to exercise due care. Due care generally requires that the defendant act as a reasonable person would have acted under the circumstances. As Reiss explains, this obligation is sometimes described using the Hand formula (named for the famous judge who first articulated it in 1947): due care requires the taking of a precaution whose burden is outweighed by the benefit in terms of an expected reduction in the cost of accidents. Commentators point to the Hand formula as an early articulation of cost-benefit analysis, which has come to play such an important role in administrative agencies' assessment of direct regulation (see chapter 6).

LIABILITY FOR DEFECTIVE PRODUCTS

Not all tort causes of action require a showing of fault. For example, courts have long recognized that defendants may be liable for harms caused by their abnormally dangerous activities (such as the use of explosives), even if they conducted those activities as carefully as possible. No-fault liability, referred to as *strict liability,* is sometimes justified in economic terms: the courts require parties who conduct certain inherently hazardous activities to internalize the costs regardless of whether they exercised due care. Strict liability is also thought to assign financial responsibility to the party with the greatest ability to insure losses and pass the costs along to consumers as a whole (the *best loss*

spreader), who may also be in the best position to prevent harm (the *least cost avoider*).

In 1963, the California Supreme Court ushered in a new form of strict liability known as products liability, which holds sellers of defective and unreasonably dangerous products strictly liable for harm caused to consumers or bystanders, regardless of how much care the seller had exercised in bringing the product to market. Shortly thereafter, prominent experts incorporated products liability into the influential, but non-binding, *Second Restatement of Torts*. In the ensuing years, most state supreme courts and legislatures adopted strict products liability. Over time, they articulated three distinct types, each with its own test for defectiveness of products: *manufacturing defects* (an individual item is defective if it fails to conform to the manufacturer's intended design), *design defects* (the design itself is defective if its risks outweigh its utility or it fails to conform to consumer expectations), and *warning defects* (the product is defective if the seller failed to warn consumers about known or knowable dangers).

The landmark decision excerpted below discusses the liability of asbestos manufacturers for the deaths of tens of thousands of workers—mostly men—who developed asbestosis and mesothelioma as a result of exposure on the job. The plaintiff brought negligence and strict liability claims arguing that the manufacturers failed to warn him about the dangers of working with asbestos. The court's decision paved the way for many additional suits for personal injury (brought by workers and their families, some of whom were exposed to asbestos fibers brought home on workers' clothing) and property damage (brought by property owners who were required to remediate asbestos in buildings) that continue today. As you read the excerpt, consider the differences between negligence and products liability. Is one approach more or less suited to public health purposes?

*BOREL V. FIBREBOARD PAPER PRODUCTS CORP.**

United States Court of Appeals for the Fifth Circuit
Decided September 10, 1973

. . . Clarence Borel, an industrial insulation worker, sued certain manufacturers of insulation materials containing asbestos to recover damages for injuries caused by the defendants' alleged breach of duty in failing to warn of the dangers involved in han-

* 493 F.2d 1076.

dling asbestos. Borel alleged that he had contracted the diseases of asbestosis and mesothelioma as a result of his exposure to the defendants' products over a thirty-three year beginning in 1936 and ending in 1969. The jury returned a verdict in favor of Borel on the basis of strict liability. We affirm. . . .

Borel said that he had known for years that inhaling asbestos dust "was bad for me" and that it was vexatious and bothersome, but that he never realized that it could cause any serious or terminal illness. Borel emphasized that he and his fellow insulation workers thought that the dust "dissolves as it hits your lungs." . . .

When asked about the use of respirators, Borel replied that they were not furnished during his early work years. Although respirators were later made available on some jobs, insulation workers usually were not required to wear them and had to make a special request if they wanted one. Borel stated that he and other insulation workers found that the respirators furnished them were uncomfortable, could not be worn in hot weather, and—"you can't breathe with the respirator." Borel further noted that no respirator in use during his lifetime could prevent the inhalation of asbestos dust. . . .

[Borel sued] eleven manufacturers of asbestos insulation materials used by him during his working career. . . . The plaintiff sought to hold the defendants liable for negligence, gross negligence, and breach of warranty or strict liability. The negligent acts alleged in the complaint were: (1) failure to take reasonable precautions or to exercise reasonable care to warn Borel of the danger to which he was exposed as a worker when using the defendant's asbestos insulation products; (2) failure to inform Borel as to what would be safe and sufficient wearing apparel and proper protective equipment and appliances or method of handling and using the various products; (3) failure to test the asbestos products in order to ascertain the dangers involved in their use; and (4) failure to remove the products from the market upon ascertaining that such products would cause asbestosis. The plaintiff also alleged that the defendants should be strictly liable in warranty and tort. . . . The defendants denied the allegations in the plaintiff's complaint and interposed the defenses of contributory negligence and assumption of risk.

The trial court submitted the case to the jury. . . . As to the negligence count, the jury found that all [but two of the defendants] . . . were negligent. . . . It found also, however, that Borel had been contributorily negligent. As to the strict liability count, the jury found that all the defendants were liable. . . . The defendants appealed.

At the outset, we meet the question whether the trial court properly instructed the jury on strict liability. . . . Under the [Second Restatement of Torts], liability may not be imposed merely because a product involves some risk of harm or is not entirely safe for all uses. Products liability does not mean that a seller is an insurer for all harm resulting from the use of his product. Rather, a product is "defective" under the Restatement only if it is "unreasonably dangerous" to the ultimate user or consumer. The requirement that the defect render the product "unreasonably dangerous" reflects a realization that many products have both utility and danger. The determination that a product is unreasonably dangerous, or not reasonably safe, means that, on balance, the utility of the product does not outweigh the magnitude of the danger. . . .

Here, the plaintiff alleged that the defendants' product was unreasonably dangerous because of the failure to give adequate warnings of the known or knowable dangers involved. . . . [A] seller has a responsibility to inform users and consumers of dangers

which the seller either knows or should know at the time the product is sold. The requirement that the danger be reasonably foreseeable, or scientifically discoverable, is an important limitation of the seller's liability. In general, the rule of strict liability subjects the seller to liability to the user or consumer even though he has exercised all possible care in the preparation and sale of the product. This is not the case where the product is alleged to be unreasonably dangerous because of a failure to give adequate warnings. Rather, a seller is under a duty to warn of only those dangers that are reasonably foreseeable. . . .

As the plaintiff has argued, insulation materials containing asbestos may be viewed as "unavoidably unsafe products." As explained in comment k to section 402A of the Restatement, "unavoidably unsafe products" are those which, in the present state of human knowledge, are incapable of being made safe for their ordinary and intended use. Strict liability may not always be appropriate in such cases because of the important benefits derived from the use of the product. . . . But, as comment k makes clear, even when such balancing leads to the conclusion that marketing is justified, the seller still has a responsibility to inform the user or consumer of the risk of harm. . . . The rationale for this rule is that the user or consumer is entitled to make his own choice as to whether the product's utility or benefits justify exposing himself to the risk of harm. . . . An insulation worker, no less than any other product user, has a right to decide whether to expose himself to the risk.

Furthermore, in cases such as the instant case, the manufacturer is held to the knowledge and skill of an expert. . . . The manufacturer's status as expert means that at a minimum he must keep abreast of scientific knowledge, discoveries, and advances and is presumed to know what is imparted thereby. But even more importantly, a manufacturer has a duty to test and inspect his product. The extent of research and experiment must be commensurate with the dangers involved. A product must not be made available to the public without disclosure of those dangers that the application of reasonable foresight would reveal. Nor may a manufacturer rely unquestioningly on others to sound the hue and cry concerning a danger in its product. . . .

[T]he defendants contend . . . that a product cannot be unreasonably dangerous if it conforms to the reasonable expectations of the industrial purchasers, here, the insulation contractors. The defendants assert, in effect, that it is the responsibility of the insulation contractors, not the manufacturers, to warn insulation workers of the risk of harm. We reject this argument. . . . [A] seller may be liable to the ultimate consumer or user for failure to give adequate warnings. The seller's warning must be reasonably calculated to reach such persons and the presence of an intermediate party will not by itself relieve the seller of this duty. . . .

The defendants' position is that they did not breach their duty to warn because the danger from inhaling asbestos was not foreseeable until about 1968 and that, in view of the long latent period of the disease, Borel must have contracted asbestosis well before that date. . . . But even if it is assumed that Borel's condition was attributable principally to his earlier exposures, the defendants argument . . . fails since there is ample evidence in the record that the danger of inhaling asbestos, including the disease of asbestosis, was widely recognized at least as early as the 1930s. . . . In these circumstances, we think the jury was entitled to find that the danger to Borel and other insulation workers from inhaling asbestos dust was foreseeable to the defendants at

the time the products causing Borel's injuries were sold. . . . [However, w]e cannot say that, as a matter of law, the danger was sufficiently obvious to asbestos installation workers to relieve the defendants of the duty to warn.

We next consider whether there was substantial evidence to support the jury's finding that each defendant was the cause in fact of injury to Borel. . . . In the instant case, it is impossible, as a practical matter, to determine with absolute certainty which particular exposure to asbestos dust resulted in injury to Borel. It is undisputed, however, that Borel contracted asbestosis from inhaling asbestos dust and that he was exposed to the products of all the defendants on many occasions. It was also established that the effect of exposure to asbestos dust is cumulative, that is, each exposure may result in an additional and separate injury. We think, therefore, that on the basis of strong circumstantial evidence the jury could find that each defendant was the cause in fact of some injury to Borel. . . .

We now turn to a consideration of the defensive issues raised in the trial court's charge. . . . [T]he defendants allege merely that Borel was contributorily negligent in failing to use a respirator. This form of contributory negligence amounts to a failure to discover a defect in the product or to guard against the possibility of its existence and is not a defense to a strict liability action. . . .

In reaching our decision in the case at bar, we recognize that the question of the applicability of [products liability] to cases involving "occupational diseases" is one of first impression. But though the application is novel, the underlying principle is ancient. Under the law of torts, a person has long been liable for the foreseeable harm caused by his own negligence. This principle applies to the manufacture of products as it does to almost every other area of human endeavor. . . .

. . .

Products liability has continued to evolve in the decades since *Borel*, with a trend away from truly strict liability. Initially, defenses to negligence, such as the argument that the plaintiff voluntarily assumed the risk of injury (assumption of risk) or failed to exercise due care to protect herself (contributory negligence) did not apply to strict liability claims. Over time, however, a growing number of courts became open to reducing the amount of plaintiffs' recovery based on these defenses. Tests for defectiveness incorporated into the *Third Restatement of Torts* have emphasized cost-benefit analysis reminiscent of negligence doctrine, and many jurisdictions have abandoned tests focused on consumer expectations in favor of risk/utility balancing.

In spite of reforms that have made products liability a less promising avenue for injured plaintiffs, the doctrine has had a lasting impact on consumer product safety. Tort liability can sometimes pave the way for direct regulation. Mounting products liability judgments in the 1970s were accompanied by a wave of legislative and regulatory reforms.

Once the door is opened to successful liability claims, businesses (and their insurers) often find that they prefer the certainty of comprehensive regulation to the unpredictability of tort judgments. In addition to variations from judge to judge and jury to jury in the outcome of cases, tort doctrine is almost exclusively a matter of state law, and thus varies among jurisdictions.

When the threat of liability brings industry representatives to the negotiating table with lawmakers, industry often demands that the new regulatory regime *preempt* state tort liability in much the same way that federal legislation may preempt state and local direct regulation (see chapter 6). In some cases, these demands have been met, in others they have not. In the next section, we explore the cross-cutting issue of preemption of tort claims, which is critically important in public health law. We then return to our discussion of tort causes of action.

PREEMPTION OF TORT CLAIMS

Tort doctrine is generally a matter of judge-made common law. Just like state and local statutes and regulations, state common law tort rules can be preempted by federal legislation. Moreover, state legislatures have the authority to preempt state common law. Judicial decisions supersede the actions of the legislature only where those decisions are based on constitutional interpretations. If, for example, a state's supreme court adopts a no-fault liability rule for the makers of defective products and the state legislature disagrees with this result as a policy matter, the legislature may pass a statute rejecting no-fault liability.

In cases where the legislature expressly preempts common law liability, the role of the judiciary is relatively straightforward. In many cases, however, the legislature is silent on the matter, or else it includes an express preemption provision, but also a so-called *savings* clause that carves out (or "saves") certain types of common law liability claims from preemption. In these situations, the courts must determine whether the legislature intended to preempt tort liability claims.

In the excerpt that follows, Catherine Struve discusses a thorny area of the law: preemption of state common law tort claims against drug and medical device manufacturers who comply with federal food and drug laws. As you read, consider the advantages and disadvantages of preemption from the perspective of industry, lawmakers, and public health advocates.

THE FDA AND THE TORT SYSTEM: POSTMARKETING SURVEILLANCE, COMPENSATION, AND THE ROLE OF LITIGATION*

Catherine T. Struve

Both the tort system and the FDA seek to protect consumers of medical products. The tort system provides compensation when a consumer is harmed by a defective product and sets incentives for companies to design safer products. The FDA imposes an elaborate system of prior restraint: Pharmaceuticals and some medical devices must undergo extensive testing and stringent risk/benefit analysis before the FDA will approve them for marketing.

Formerly, the FDA viewed its risk/benefit analysis as setting a floor but not a ceiling for product safety: FDA-approved products could be marketed, but the manufacturer might still incur liability if a court later decided that a product was defective or a warning was inadequate. This view has changed in recent years, however, as policymakers have stressed the need to bring innovative medical treatments to market. Some now argue that the FDA review process should set both a floor and a ceiling: FDA approval of a new product indicates not only that the product can be marketed, but that it should be; FDA rejection of a proposed product warning means not only that the warning is unnecessary, but that it could be counterproductive.

FDA officials who hold this view consider the tort system dangerous. The threat of tort liability, they warn, deters pharmaceutical companies and device makers from developing much-needed new technologies. Even if those innovations are merely delayed rather than abandoned altogether, the cost is felt not merely in financial terms but also in the suffering of people whose illnesses could have been treated with the new drug or device.

These critics argue that the tort system—and juries in particular—should not be permitted to determine product safety. Lay juries, it is claimed, are incapable of understanding the complex scientific and statistical evidence relevant to product safety; they are eager to help injured plaintiffs—especially when the defendant has deep pockets—and they overlook the many consumers who might benefit from the product; they award excessive compensatory damages, especially for pain and suffering; and they often compound the problem by awarding staggering sums in punitive damages. . . .

[O]pponents of the tort system overstate the case: Empirical data indicate that juries do better than their critics assert at handling technical issues, that juries are not as eager as some think to award damages against business defendants, and that punitive damages are awarded rarely in products liability suits (and mainly in cases involving egregious misbehavior). . . .

Permitting FDA approval to preclude the possibility of tort liability does more than ensure that product safety decisions are reserved to the FDA. Preemption of tort litigation removes the opportunity for litigation to aid the FDA in its goal of monitoring product safety. Preemption also denies compensation to persons harmed by an FDA approved product—even if they were harmed after a safety problem first surfaced but

* 2005. *Yale Journal of Health Policy, Law, & Ethics* 5 (2): 587–670.

before the FDA took regulatory action to remove the product from the market or to require additional warnings. . . .

. . .

In recent years, the Supreme Court has dramatically altered the tort liability landscape for FDA-regulated products, making it difficult for injured plaintiffs to prevail. In *Riegel v. Medtronic,* 552 U.S. 312 (2008), the Court effectively barred plaintiffs from suing the makers of FDA-approved medical devices. The following year, the Court held that a failure to warn claim against a brand-name drug maker was not preempted in *Wyeth v. Levine,* 555 U.S. 555 (2009). The Court then reached the opposite conclusion for generics, barring warning defect and design defect claims against generic pharmaceutical makers in *PLIVA, Inc. v. Mensing,* (2011) and *Mutual Pharmaceutical Co. v. Bartlett* (2013). The Court noted that the FDA requires generic manufacturers to adopt the drug formulation and warnings required for the innovator drug they are duplicating if they wish to take advantage of the abbreviated approval process available for generics. Were they to alter their formula or labeling in conformance with state court tort judgments, they would be in violation of FDA requirements. Lower courts had allowed such claims on the grounds that generic manufacturers have the option of withdrawing unsafe products from the market, but this reasoning did not sway the Supreme Court. The Supreme Court's decisions prompted FDA to consider revising the rules to allow generic manufacturers to add safety warnings, but rulemaking was stalled in 2016 after a congressional proposal to block it. The same year, Congress enacted the 21st Century Cures Act, which loosened the requirements for approval of new drugs and new uses for existing drugs.

LIABILITY FOR FRAUD AND UNFAIR TRADE PRACTICES

Thus far, we have considered negligence and strict liability. Now, we turn to the third major category of tort liability: intentional torts. Intentional torts cover many kinds of personal and property invasions (e.g., battery, false imprisonment, and trespass) carried out deliberately by the defendant. Unlike negligence and strict liability, intentional torts do not require the plaintiff to establish actual harm. Rather, a plaintiff may be awarded nominal damages (typically $1) and punitive damages (which are aimed at punishing the defendant, not compensating the plaintiff) even if the plaintiff cannot show any physical injury or property damage.

One of the more complex intentional torts, fraud, is the foundation for state and federal consumer protection statutes, which generally prohibit false and misleading advertising and other deceptive trade practices. The Federal Trade Commission Act does not provide a private cause of action for injured parties, but many state consumer protection laws do. Some state laws also provide for statutory damages (e.g., $1000 for each violation) to deter and punish defendants even in cases where plaintiffs cannot establish that they suffered financial harm.

Fraud-based causes of action—whether derived from the common law or from statutes—typically require the plaintiff to establish that he or she relied on the defendant's false, misleading, or deceptive representations, which can be difficult to prove. Reliance is a particularly difficult showing to make at the pleadings stage of litigation—before the discovery process of gathering evidence has begun. Nonetheless, courts have applied heightened pleading standards to fraud-based claims, requiring plaintiffs to plead sufficient facts to support reliance before proceeding with discovery. Recall that discovery has been a crucial part of the litigation process for plaintiffs seeking redress for public health harms. Internal industry documents obtained via discovery have played a significant role in shifting public opinion against industries responsible for public health crises. Halting litigation prior to the discovery phase thus represents a major victory for defendants, who are able to maintain secrecy surrounding their operations.

Fraud-based claims—and the heightened pleading requirements applied to them—are playing a particularly important role in litigation against the food and restaurant industries. We excerpt two cases here: one against a fast food corporation whose products are alleged to have contributed to heart disease and diabetes; and the other against a grocery corporation with a reputation for selling "natural" products that consumers perceive as healthy even though many of them are high in sugar and calories. How are the *Pelman* plaintiffs' claims different from those made by the *Gitson* plaintiffs? How are they similar?

*PELMAN V. MCDONALD'S CORP.**

United States Court of Appeals for the Second Circuit
Decided January 25, 2005

. . . [P]laintiffs Ashley Pelman and Jazlen Bradley, by their respective parents, . . . allege, on behalf of a putative class of consumers, . . . that defendant McDonald's

* 396 F.3d 508.

Corporation violated both § 349 and § 350 of the New York General Business Law, commonly known as the New York Consumer Protection Act, during the years 1987 through 2002.

Specifically, [their complaint] alleges that the combined effect of McDonald's various promotional representations during this period was to create the false impression that its food products were nutritionally beneficial and part of a healthy lifestyle if consumed daily. [It] alleges that McDonald's failed adequately to disclose that its use of certain additives and the manner of its food processing rendered certain of its foods substantially less healthy than represented. [It] alleges that McDonald's deceptively represented that it would provide nutritional information to its New York customers when in reality such information was not readily available at a significant number of McDonald's outlets in New York visited by the plaintiffs and others. The amended complaint further alleges that as a result of these deceptive practices, plaintiffs, who ate at McDonald's three to five times a week throughout the years in question, were "led to believe[] that [McDonald's] foods were healthy and wholesome, not as detrimental to their health as medical and scientific studies have shown, . . . [and] of a beneficial nutritional value," and that they "would not have purchased and/or consumed the Defendant's aforementioned products, in their entirety, or on such frequency but for the aforementioned alleged representations and campaigns." Finally, the amended complaint alleges that, as a result, plaintiffs have developed "obesity, diabetes, coronary heart disease, high blood pressure, elevated cholesterol intake, related cancers, and/or other detrimental and adverse health effects. . . . "

What is missing from the amended complaint, however, is any express allegation that any plaintiff specifically relied to his/her detriment on any particular representation made in any particular McDonald's advertisement or promotional material. The district court concluded that, with one exception, the absence of such a particularized allegation of reliance warranted dismissal of the claims under § 350 of the New York General Business Law, which prohibits false advertising. As to the exception—involving McDonald's representations that its French fries and hash browns are made with 100% vegetable oil and/or are cholesterol-free—the district court found that, while the amended complaint might be read to allege implicit reliance by plaintiffs on such representations, the representations themselves were objectively nonmisleading.

[Plaintiffs do not challenge the dismissal of their § 350 claims. Plaintiffs do, however, challenge] the district court's dismissal of the claims under § 349 of the New York General Business Law, which makes unlawful "deceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in this state." Unlike a private action brought under § 350, a private action brought under § 349 does not require proof of actual reliance. Additionally, . . . because a private action under § 349 does not require proof of the same essential elements (such as reliance) as common-law fraud, an action under § 349 is not subject to the pleading-with-particularity requirements [applicable to fraud claims].

Although the district court recognized that § 349 does not require proof of reliance, the district court nonetheless dismissed the claims under § 349 because it concluded that "plaintiffs have failed, however, to draw an adequate causal connection between their consumption of McDonald's food and their alleged injuries." Thus, the district court found it fatal that the complaint did not answer such questions as:

> What else did the plaintiffs eat? How much did they exercise? Is there a family history of the diseases which are alleged to have been caused by McDonald's products? Without this additional information, McDonald's does not have sufficient information to determine if its foods are the cause of plaintiffs' obesity, or if instead McDonald's foods are only a contributing factor.

> This, however, is the sort of information that is appropriately the subject of discovery. . . . So far as the § 349 claims are concerned, the amended complaint more than meets the [pleading requirements]. Accordingly, the district court's dismissal of . . . alleged violations of § 349 is vacated and the case is remanded for further proceedings consistent with this opinion.

. . .

Industry groups, plaintiffs' lawyers, and public health experts closely watched the *Pelman* case. Using the tobacco litigation as an example, attorneys sought to unearth internal documents that might help turn public opinion against the fast food industry and raise awareness of childhood obesity and related health problems. Jazlyn Bradley, one of the named plaintiffs, lived in an overcrowded apartment with no kitchen before moving to a homeless shelter. She testified that she ate at McDonald's as much as three times per day because it was cheap and accessible. The plaintiffs sought compensation for their obesity-related health conditions, a court order directing the defendant to improve its nutrition labeling, and funding from McDonald's for consumer education. Rehearing the case upon remand, the trial court denied certification of the class, finding that questions about causation and damages unique to each individual predominated over questions about the defendant's behavior that were common to the claims of the entire class. In the aftermath of the *Pelman* litigation, approximately half the states enacted statutes, known as Cheeseburger Bills, amending their consumer protection laws and tort doctrine to grant immunity to the food, beverage, and restaurant industries from lawsuits for conditions caused by long-term consumption of their products.

Like common law tort doctrine, consumer protection statutes vary from state to state. California arguably has the most plaintiff-friendly consumer protection laws in the country. For example, although the federal Food, Drug, and Cosmetic Act (FDCA) does not include a private cause of action allowing consumers to bring suit for violations, California's Sherman Act incorporates all aspects of the federal FDCA, subject to a private cause of action under the *unlawful* prong of the state's Unfair Competition Law (UCL). Additionally, the *unfair* prong of the UCL

provides a cause of action for unfair trade practices, like those prohibited by the New York law relied on by the *Pelman* plaintiffs. Similar to New York's consumer protection law, the unfair prong of the California UCL requires the plaintiff to establish actual reliance. The unlawful prong, however, is unique in that it does not require actual reliance.

Plaintiff-friendly consumer protection laws are among the factors that have contributed to a wave of litigation against food manufacturers and retailers in the United States District Court Northern District of California. So many suits have been filed in recent years that commentators have dubbed it the "food court." The federal court has jurisdiction because the plaintiffs and defendants are from different states (this is called *diversity jurisdiction,* in reference to the diversity of citizenship between plaintiffs and defendants, and is intended to protect out-of-state defendants from discrimination in state courts). When it comes to procedural matters, such as standing doctrine and pleading requirements, the federal court is governed by federal rules. The court applies the substantive law of the state, however. The case excerpted below, in which the court applies the Federal Rules of Civil Procedure to adjudicate the plaintiff's state law claims, demonstrates the power of heightened pleading requirements even with respect to consumer protection laws that are purposefully designed to be plaintiff-friendly.

*GITSON V. TRADER JOE'S CO.**

United States District Court for the Northern District of California
Decided March 14, 2014

. . . [T]he plaintiffs' case has two facets. First, the plaintiffs allege that the packaging and labeling on various Trader Joe's products violate California's Sherman [Food, Drug, and Cosmetic] Law, which adopts and incorporates the federal Food Drug & Cosmetic Act (FDCA). These alleged violations of the Sherman Law give rise to the plaintiffs' . . . cause of action for violations of the unlawful prong of the California Unfair Competition Law (UCL)[, which provides a private cause of action for consumers to enforce the California Sherman Law and other laws]. Second, apart from being unlawful under the Sherman Law, the plaintiffs allege that Trader Joe's labeling and packaging is misleading, deceptive, unfair and fraudulent [under] the UCL, the California False Advertising Law (CFAL) and the Consumers Legal Remedies Act (CLRA)]. . . .

[The plaintiffs, Amy Gitson and Deborah Ross, claim that they purchased Trader Joe's products that are] unlawfully and misleadingly labeled with the ingredient

* 2014 WL 1048640.

evaporated cane juice (ECJ) instead of sugar. . . . The plaintiffs allege that the use of the term evaporated cane juice rather than sugar or syrup on Trader Joe's French Village Mixed Berry Nonfat Yogurt, French Village Strawberry Nonfat Yogurt, Greek Style Vanilla Nonfat Yogurt, and Organic Chocolate Soy Milk violates [federal Food and Drug Administration (FDA) regulations that] prohibit manufacturers from referring to ingredients by anything other than their common and usual names. The [complaint] cites guidance and warning letters from the FDA indicating that the FDA policy "is that sweeteners derived from sugar cane syrup should not be declared as 'evaporated cane juice.'" Plaintiffs assert that they are health-conscious consumers seeking to avoid added sugars, and therefore "had they known that 'evaporated cane juice' was essentially the same thing as added sugar, they would not have purchased the Purchased Products."

The [complaint] also brings claims based on [23 additional products labeled as containing EJC] that the plaintiffs did not purchase, but which are, they claim, substantially similar to those for which they did, in that they "make the same label misrepresentations . . . as the Purchased Products and/or violate the same regulations." . . .

The plaintiffs bring this action on behalf of themselves and a class defined as: All persons in the United States or, in the alternative, all persons in the state of California who, within the last four years, purchased Defendant's food products . . . labeled with the ingredient, "Evaporated Cane Juice" or "Organic Evaporated Cane Juice." . . .

Trader Joe's argues that plaintiffs' claims should be dismissed because they fail to allege actual reliance on the products' alleged label misrepresentations. . . . To establish standing under the UCL, a person must have "suffered injury in fact and . . . lost money or property as a result of such unfair competition." . . . A plaintiff can satisfy the UCL's standing requirement by alleging that he or she would not have bought the product but for the alleged misrepresentation. . . . The plaintiffs have adequately alleged actual reliance because they read the label of the ECJ Products, believed that ECJ was not sugar but something "healthy" or preferable to sugar, and would not have bought the ECJ Products had they known that ECJ was added sugar. Therefore, the plaintiffs have standing to bring claims regarding the ECJ Products [that they purchased].

Trader Joe's argues that plaintiffs [do not have standing to pursue claims regarding substantially similar products, which they did not purchase]. I disagree. . . . [T]he best approach for cases involving unpurchased products in the class action context is one which focuses on whether the type of claim and consumer injury is substantially similar as between the purchased and unpurchased products. . . . Plaintiffs' theory is that the use of the term ECJ violates the state law requirement that only the common or usual name of an ingredient appear on the label, meaning that all of Trader Joe's products listing ECJ as an ingredient are misbranded in exactly the same way. Plaintiffs need not show that the Purchased Products and the unpurchased ECJ Products are *physically* similar to establish standing because the resolution of the claim will be identical for purchased and unpurchased products. . . . For instance, plaintiffs claim that they were misled by the improper use of the term "evaporated cane juice" on Greek Style Vanilla Nonfat Yogurt, and the injury suffered as a result of that misrepresentation is the same as the injury suffered by an individual who is misled by the use of the exact same term on French Village Yogurt Vanilla. . . . For those reasons, plaintiffs have adequately demonstrated standing, at least for purposes of surviving a motion to dismiss, on the Substantially Similar ECJ Products. . . .

> Accepting the allegations in the complaint as true, which the Court must do at this stage, it is plausible that a reasonable consumer whose food purchases are influenced by whether foods contain added sugars would be deceived by the term "evaporated cane juice." Accordingly, the Motion to Dismiss . . . is denied.

. . .

The plaintiffs in *Gitson* were allowed to proceed with their claims because they were able to testify that they had actually read the labels on Trader Joe's products and would not have bought those products if the labeling had indicated that "sugar" was one of the primary ingredients. The *Pelman* plaintiffs had difficulty making similar assertions because, for the most part, they were unable to point to specific advertisements on which they relied.

Pelman and *Gitson* were both class action suits; in each case, the named plaintiffs brought suit on behalf of a class of unidentified people who were similarly misled. Class actions provide an important mechanism for addressing population-level harms. They aggregate many claims that would be too small to merit the effort of any individual plaintiff (or attorney working on a contingency-fee basis). Judges sometimes adopt a looser approach to causation, assessing it at the class level, rather than requiring each plaintiff to establish causation individually. As Wendy Parmet notes,

> A population approach to tort law would . . . take a liberal attitude toward using class action and case consolidations to help make complex tort actions economically feasible for plaintiffs to bring, and to overcome some of the difficulties of establishing specific causation. After all, although epidemiological evidence cannot establish individualized causation, it is well suited to determine the risk a particular agent or product presents to an exposed population. (Parmet 2009, 229)

Litigation by public plaintiffs, suing in their parens patriae capacity or to enforce civil or criminal laws, provides another means for redress of population-level harms. We turn to this type of litigation in the next section.

TORT-BASED LITIGATION BY PUBLIC PLAINTIFFS

Federal, state, and city attorneys can also bring civil or criminal suits against the manufacturers and distributors of hazardous products such as asbestos, tobacco, lead paint, pharmaceuticals, and firearms. Because they represent the collective interest of the populace, government attor-

neys are well situated to use litigation for public health purposes. Before turning to examples of public nuisance suits and racketeering prosecutions brought by governmental plaintiffs, we begin with an overview of the various tools available to state attorneys general.

THE POTENTIAL FOR STATE ATTORNEYS GENERAL TO PROMOTE THE PUBLIC'S HEALTH: THEORY, EVIDENCE, AND PRACTICE*

Lainie Rutkow and Stephen P. Teret

In the United States, the chief legal officer of each state is known as the Attorney General. State Attorneys General (SAGs) can take a wide range of actions on behalf of their state and the public interest through law enforcement, litigation, investigatory activities, and law and policy reform work. . . . In recent years SAGs have successfully tackled numerous public health issues, including end-of-life care, alcohol policy, tobacco control, prescription drug abuse, Medicaid fraud, and hospital mergers. . . .

THE ABILITY OF STATE ATTORNEYS GENERAL TO PROTECT AND PROMOTE THE PUBLIC'S HEALTH

Litigation and Law Enforcement

Under their common law authority, SAGs have the power to use litigation as a tool to protect "the public interest" and will often rely on the doctrine of parens patriae ("parent of the country") to do so. Parens patriae authority allows an SAG to bring litigation to recover costs or damages incurred because of behavior that threatens the health, safety, and welfare of the state's citizenry. . . .

In addition to initiating and participating in civil litigation, SAGs play an important role in the enforcement of their state's criminal law. The scope of an SAG's authority in this area varies significantly among the states. . . .

Investigative Activities

SAGs' investigative activities can contribute to their litigation and law enforcement efforts, as well as to their law and policy reform work. This is because, in civil and criminal contexts, SAGs can conduct investigations into issues such as government misconduct, criminal activity, and issues of substantial public interest. For criminal investigations, most states grant their Attorney General the ability to issue subpoenas to obtain testimony or evidence. . . .

Law and Policy Reform

As a state's chief legal officer, an SAG is frequently called upon to provide advice to the governor and administrative agencies. This advice can pertain to any legal or policy

* 2011. *Saint Louis University Public Law Review* 30 (2): 267–300. Reprinted with permission of the Saint Louis University Public Law Review © 2011.

issue. A related, but separate, power involves an SAG's issuance of opinions. Opinions are solicited from an SAG by the governor or a state agency, with the expectation that the SAG will provide a written response. While an SAG's opinion is not legally binding, it [is generally] entitled to great weight both by officers of the state and by the courts. SAGs can, however, promulgate legally binding regulations or rules, using authority granted to them by the state.

In addition to utilizing their formal powers, SAGs can engage in advocacy to promote change. Some SAGs do this by using the "bully pulpit" of their office to make their views known or to bring attention to a particular issue. This can be accomplished by issuing press releases, granting interviews, or holding press conferences. . . . Finally, SAGs can use their collective force to engage in advocacy that targets an industry or company. . . .

Mediating Factors

Because most SAGs are elected, their actions may be swayed by the political will of the voters. This may make an SAG more or less likely to vigorously pursue a particular public health issue, depending on its expected popularity with the electorate. . . . [Additionally], SAGs may decide to tackle a particular public health issue because other SAGs around the country are focusing on a similar issue. SAGs can simultaneously learn from each other to bring about change in their states and use their collective presence to stimulate change at the federal level. . . .

PUBLIC HEALTH BENEFITS ACHIEVED BY SAGS

Tobacco Control Litigation and the Master Settlement Agreement

On May 23, 1994, Michael Moore, Mississippi's Attorney General, . . . filed a lawsuit against the tobacco industry to recoup the costs incurred by Mississippi's Medicaid program for treating persons with diseases and conditions related to smoking. Unlike previous cases, Moore's lawsuit focused on harms to the state (*i.e.*, Medicaid costs) rather than harms to individuals. He drew on the financial and personnel resources of the Mississippi Attorney General's office, and established contingency fee agreements with attorneys outside the SAG's office who had extensive experience with personal injury law. These additional attorneys brought their own financial resources and familiarity with lawsuits against industries engaging in harmful practices.

[After overcoming resistance from the state's governor, who had received political contributions from the tobacco industry, Moore and his colleagues lobbied the state attorney generals' offices in other states to file suit as well.] Other states increasingly recognized that this growing collection of lawsuits was sending a strong message to the tobacco industry, and by 1997, over forty SAGs had brought related lawsuits. . . .

Several months later, [the parties announced] the Master Settlement Agreement (MSA), [which] required the four major tobacco companies to pay $206 billion to the states over the course of twenty-five years. The states were permitted to use this money however they chose, and, in exchange, they would drop pending lawsuits against the tobacco industry. Among its many provisions, the MSA dissolved the industry-supported Tobacco Institute[, which disputed the scientific consensus regarding the harmful effects of tobacco use] and established the American Legacy Foundation, which promoted tobacco control activities. In addition, the MSA restricted "the advertising, marketing

and promotion of cigarettes," which included prohibitions against targeting young people and bans on outdoor cigarette advertising. . . .

Investigation into Deceptive Food Labeling Practices

In October 2008, a coalition led by food and beverage manufacturers, food retailers, and scientists announced a new program, [which] used a set of [industry-chosen] nutritional criteria, to determine whether an item could be deemed a "Smart Choice." . . . Shortly after the program was launched in 2009, the Smart Choices logo began appearing on sugary processed cereals such as Froot Loops, Cocoa Krispies and Frosted Flakes as well as ice creams and mayonnaise. . . .

Richard Blumenthal, Attorney General of Connecticut, . . . sought to determine if the Smart Choices program had violated Connecticut's consumer protection laws, which prohibit misleading and deceptive labeling. . . . On October 20, 2009, within days of the initiation of Blumenthal's investigation, Margaret Hamburg, FDA Commissioner, announced that FDA would renew its focus on front-of-package labels and take action against "labels that are false or that mislead consumers." . . . The Smart Choices program halted its operations on October 23, 2009. . . .

SAGS' CURRENT AND FUTURE ABILITY TO IMPROVE THE PUBLIC'S HEALTH

SAGs have repeatedly used their powers, in both traditional and novel ways, to improve the public's health. . . . Much can also be learned from examining instances in which an SAG has tried, unsuccessfully, to tackle a particular public health issue. Although the public health community may initially perceive these instances as failures, they can provide important insight for SAGs as they strategize and plan their future public health endeavors. . . .

. . .

In their *parens patriae* capacity, city and state attorneys have brought public nuisance suits against various industries to vindicate collectively held, common law rights to public health and safety. These rights do not impose affirmative obligations on the state. Rather, they impose negative obligations on private parties, which are enforced by government.

The more common type of nuisance claim is a land-based private nuisance. For example, a landowner might sue the owner of a neighboring hog farm producing noxious odors and other unpleasantness, arguing that her right to enjoy her own property is being infringed by the defendant's unreasonable use of his property. One kind of public nuisance claim is a modest extension of this private nuisance doctrine. Imagine the hog farm is affecting not just its neighbors, but an entire town. At a certain point, this property-based private nuisance becomes a public one simply by virtue of the large number of people affected. But there is also another kind of public nuisance claim unrelated to the

defendant's property use or the plaintiffs' property enjoyment. It is this broader kind of claim that has sparked controversy.

Public nuisance law and public health law share a common heritage in the police power of the state. At its core, public nuisance is a tool for addressing harms to the public. As described in the *Second Restatement of Torts,* the central element of public nuisance is an "unreasonable interference with a right common to the general public," including "interference with the public health, the public safety, the public peace, the public comfort or the public convenience." The cause of action dates back to medieval England, but advocates have given it new life by applying it to some of the most complex public health and environmental problems of our time: the costs of tobacco use, gun violence, the contamination of housing stock with lead paint, climate change, and opioid addiction.

Many courts have been unreceptive to public nuisance claims against product manufacturers and distributors. Advocates and commentators dispute whether the defendant's hazardous products or marketing practices interfere with "public rights." The stakes are high. If a plaintiff successfully establishes interference with a public right, the door is opened to more flexible doctrines of causation (allowing it to be established at the population, rather than individual, level) and fault (public nuisance is a type of quasi-strict liability focusing on the invasion of public rights rather than on the reasonableness of the defendant's conduct).

Critics of expansive public nuisance liability argue that a public right must be more than the mere aggregation of private interests. In theorizing a narrower conception of the public, some have relied on economic analysis, arguing that public nuisance law is designed to protect indivisible, non-excludable public goods, such as clean air and water. Others, including Donald Gifford, whose work is quoted in the opinion excerpted below, have attempted to define this "something more" in terms of public and private physical spaces. Are these limitations convincing?

*STATE OF RHODE ISLAND V. LEAD INDUSTRIES ASSOCIATION**

Supreme Court of Rhode Island
Decided July 1, 2008

In this landmark lawsuit, filed in 1999, the then Attorney General, on behalf of the State of Rhode Island, filed suit against various former lead pigment manufacturers and the

* 951 A.2d 428.

Lead Industries Association (LIA), a national trade association of lead producers formed in 1928. . . . [The trial,] spanning four months, became the longest civil jury trial in the state's history. This monumental lawsuit marked the first time in the United States that a trial resulted in a verdict that imposed liability on lead pigment manufacturers for creating a public nuisance.

On appeal . . . we conclude that the state has not and cannot allege any set of facts to support its public nuisance claim that would establish that defendants interfered with a public right or that defendants were in control of the lead pigment they, or their predecessors, manufactured at the time it caused harm to Rhode Island children.

In reaching this conclusion, we do not mean to minimize the severity of the harm that thousands of children in Rhode Island have suffered as a result of lead poisoning. Our hearts go out to those children whose lives forever have been changed by the poisonous presence of lead. But, however grave the problem of lead poisoning is in Rhode Island, public nuisance law simply does not provide a remedy for this harm. . . . This Court is powerless to fashion independently a cause of action that would achieve the justice that these children deserve. . . .

[In Rhode Island,] the state Attorney General is empowered to bring actions to abate public nuisances. . . . This Court has defined public nuisance as an unreasonable interference with a right common to the general public. It is behavior that unreasonably interferes with the health, safety, peace, comfort or convenience of the general community. Put another way, public nuisance is an act or omission which obstructs or causes inconvenience or damage to the public in the exercise of rights common to all. . . .

This Court recognizes three principal elements that are essential to establish public nuisance: (1) an unreasonable interference; (2) with a right common to the general public; (3) by a person or people with control over the instrumentality alleged to have created the nuisance when the damage occurred. After establishing the presence of the three elements of public nuisance, one must then determine whether the defendant caused the public nuisance. . . .

As the Restatement (Second) makes clear, a public right is more than an aggregate of private rights by a large number of injured people. Rather, a public right is the right to a public good, such as an indivisible resource shared by the public at large, like air, water, or public rights of way. Unlike an interference with a public resource, "[t]he manufacture and distribution of products rarely, if ever, causes a violation of a public right as that term has been understood in the law of public nuisance. Products generally are purchased and used by individual consumers, and any harm they cause—even if the use of the product is widespread and the manufacturer's or distributor's conduct is unreasonable—is not an actionable violation of a public right. . . . The sheer number of violations does not transform the harm from individual injury to communal injury" (Gifford 2003, 817). . . .

The term public right is reserved more appropriately for those indivisible resources shared by the public at large, such as air, water, or public rights of way. . . . The right of an individual child not to be poisoned by lead paint is strikingly similar to other examples of nonpublic rights cited by courts, the Restatement (Second), and several leading commentators. . . . In the words of one commentator: " . . . [E]xposure to lead-based paint usually occurs within the most private and intimate of surroundings, his or her own home. Injuries occurring in this context do not resemble the rights traditionally understood as public rights for public nuisance purposes" (Gifford 2003, 818).

The enormous leap that the state urges us to take is wholly inconsistent with the widely recognized principle that the evolution of the common law should occur gradually, predictably, and incrementally. Were we to hold otherwise, we would change the meaning of public right to encompass all behavior that causes a widespread interference with the private rights of numerous individuals. . . .

We conclude, therefore, that there was no set of facts alleged in the state's complaint that, even if proven, could have demonstrated that defendants' conduct, however unreasonable, interfered with a public right or that defendants had control over the product causing the alleged nuisance at the time children were injured. Accordingly, we need not decide whether defendants' conduct was unreasonable or whether defendants caused an injury to children in Rhode Island.

Although this [conclusion] technically render[s] moot the issue of whether or not the execution of a contingent fee agreement between the Attorney General and certain private law firms was appropriate, we have nevertheless decided to address the legal issues surrounding the permissibility *vel non* of such an arrangement. . . .

Prior to commencing [this] civil action, cognizant of the fact that there were not adequate resources to finance such a demanding and substantial civil case, [the] Attorney General had executed a contingent fee agreement with [two private law firms]. That agreement provided that, in return for their legal representation on behalf of the state in the lead paint litigation, Contingent Fee Counsel would be entitled to a fee reflecting 16 2/3 percent of any monies recovered.

During the course of this litigation, defendants sought a ruling by the Superior Court that the contingent fee agreement was unenforceable and void because, in defendants' view, said agreement (1) constituted an unlawful delegation of the Attorney General's authority and (2) was violative of public policy. . . .

Although we are keenly aware of the gravity of the issue and of the fact that thoughtful and potent policy-based arguments have been made on both sides of the issue, in the end we have concluded that, in principle, there is nothing unconstitutional or illegal or inappropriate in [this] contractual relationship. . . . Indeed, it is our view that the ability of the Attorney General to enter into such contractual relationships may well, in some circumstances, lead to results that will be beneficial to society—results which otherwise might not have been attainable. However, due to the special duty of attorneys general to "seek justice" and their wide discretion with respect to same, such contractual relationships must be accompanied by exacting limitations . . . [to ensure that] the Office of Attorney General retains absolute and total control over all critical decision-making in any case in which such agreements have been entered into.

. . .

The Rhode Island court, following Gifford's commentary, took a particularly restrictive view of public nuisance doctrine that is out of step with that of many other jurisdictions. In 2017, for example, a California appellate court upheld a $1.15 billion verdict against two companies that profited from lead paint sales. *People v. ConAgra Grocery Products Co.*, 17 Cal.App.5th 51 (2017). The funds, awarded to 10 city

and county governments who sued on a public nuisance theory, are to be used to abate lead hazards in homes. The California court's three-judge panel rejected the defendant's argument that a public right was not implicated by lead hazards in private homes:

> Interior residential lead paint that is in a dangerous condition does not merely pose a risk of private harm in private residences. The community has a collective social interest in the safety of children in residential housing. Interior residential lead paint interferes with the community's "public right" to housing that does not poison children. This interference seriously threatens to cause grave harm to the physical health of the community's children. . . . Residential housing, like water, electricity, natural gas, and sewer services, is an essential community resource.

In the *Purdue Pharma* opinion that appears below, a federal appeals court rejected a pharmaceutical company's effort to remove a public nuisance claim to federal court, which it likely perceived as less friendly to the state and county government's claims than the state courts would be. The court contrasts *parens patriae* litigation brought by the state attorney general and a county government from class action suits, which merely aggregate the claims of individual private parties. As you read the following excerpt, note how the judge views public nuisance doctrine and *parens patriae* litigation differently from the judges who rejected Rhode Island's claim against lead paint manufactures.

*PURDUE PHARMA V. KENTUCKY**

United States Court of Appeals for the Second Circuit
Decided January 9, 2013

The Commonwealth of Kentucky . . . through its Attorney General, and Pike County, Kentucky . . . commenced this action in Kentucky state court against Purdue Pharma, L.P.; Purdue Pharma, Inc.; Purdue Frederick Company, Inc.; Purdue Pharmaceuticals, L.P.; and P.F. Laboratories, Inc. . . .

Plaintiffs' state court complaint contained the following allegations. Purdue manufactures and sells OxyContin, an opioid analgesic drug used to manage pain. From 1995 to 2001, Purdue promoted OxyContin to health care providers as "less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications," despite knowing that such assertions were false or misleading. According to Plaintiffs, Purdue's actions prevented Kentuckians from accurately assessing the appropriate uses and risks of OxyContin, and caused physicians to overprescribe OxyContin, which resulted in widespread addiction and other adverse

* 704 F.3d 208.

consequences, including death and "the commission of criminal acts to obtain OxyContin." Kentucky, which covers health care costs for indigent and otherwise eligible residents under its Medicaid and Pharmaceutical Assistance Programs, bore significant additional costs as a result of Purdue's actions. Similarly, Pike County spent millions of dollars investigating, apprehending, prosecuting, and incarcerating persons who, "due to the fraudulently concealed addictive nature of OxyContin, have resorted to criminal means to continue their addiction."

The complaint indicated that the action was brought pursuant to the Kentucky Attorney General's authority under state statutory and common law, "including [his] *parens patriae* authority," to recover, *inter alia,* "all the costs the Commonwealth . . . incurred in paying excessive and unnecessary prescription costs"; "all the costs expended for health care services and programs associated with the diagnosis and treatment of adverse health consequences of OxyContin use"; and "all the costs consumers have incurred in excessive and unnecessary prescription costs related to OxyContin." . . . In addition to damages based on the Medicaid-related expenses described above, the complaint also sought civil penalties, attorneys' fees, and equitable and injunctive relief.

Purdue removed the action to federal court, asserting that Plaintiffs' claims . . . constituted a disguised "class action" removable under [the Class Action Fairness Act of 2005 (CAFA)]. Following transfer to the United States District Court for the Southern District of New York, Plaintiffs moved to remand, arguing that the District Court lacked subject-matter jurisdiction because all of their claims arose exclusively under state law, and the case otherwise failed to meet CAFA's requirements. The District Court agreed and granted Plaintiffs' motion to remand. . . .

Purdue seeks leave to appeal the District Court's remand order, insisting this case presents an "important" and "unsettled" question under CAFA—namely, whether *parens patriae* lawsuits brought by state attorneys general qualify as "class actions" under CAFA. . . . Because this action is not a "class action" within the meaning of CAFA, federal jurisdiction does not exist to hear this case, and Purdue's petition must be denied. . . .

CAFA expanded the jurisdiction of the federal courts to allow class actions originally filed in state courts that conform to particular requirements to be removed to federal district courts. In general, CAFA . . . confer[red] federal jurisdiction over certain class actions. . . . CAFA's reach, however, is limited in the first instance to actions that qualify as either a "class action" or a "mass action." . . . Actions that fail to fit into one of these two statutory categories will fall outside CAFA's jurisdictional orbit, regardless whether they meet the other prerequisites. . . .

To assert *parens patriae* standing, the State (or Commonwealth) must articulate a quasi-sovereign interest distinct from the interests of particular private parties, such as an interest in the health and well-being—both physical and economic—of its residents in general. The State may show such an interest by alleging injury to a sufficiently substantial segment of its population. However, if the State is only a nominal party without a real interest of its own—then it will not have standing under the *parens patriae* doctrine.

Here, Plaintiffs claim to bring this suit in both proprietary and *parens patriae* capacities, seeking: (1) restitution and reimbursement for damages suffered directly by the Commonwealth and the County as a result of, *inter alia,* unnecessary prescriptions costs and Medicaid claims paid out of the state treasury; (2) civil

penalties, fines and attorneys' fees; and (3) equitable and injunctive relief based on "quasi-sovereign interests" in protecting the health and safety of citizens. . . .

This suit . . . was filed not by a class representative on behalf of similarly-situated plaintiffs, but by the Attorney General on behalf of the sovereign. . . .

In sum, the District Court correctly determined that Plaintiffs' action is not a "class action" as defined in CAFA, and therefore the case was properly remanded. The petition for leave to appeal is denied.

. . .

In December 2015, Kentucky settled with Purdue Pharma for $24 million to be paid over eight years. In the years that followed hundreds of additional state, local, and tribal governments—as well as health plans that bear the significant medical costs associated with opioid use disorders and hospitals that bear the costs of uncompensated emergency care for uninsured overdose patients—filed similar suits against Purdue Pharma and other opioid manufacturers and distributors. More than 250 of these individual suits were consolidated via the multi-district litigation process and assigned to Judge Dan Polster of the United States District Court for the Northern District of Ohio for adjudication of procedural matters. In 2018, Judge Polster convened the parties for a series of meetings to discuss the settlement process. Geoff Mulvihill (2018), who covered these meetings for the Associated Press, noted that determining the amount of potential financial payments is just the tip of the iceberg:

> There's no way of knowing how much money a settlement would cost the pharmaceutical industry, if one is ever reached. In New York City's lawsuit filed [in early 2018] it asked for more than $500 million.
>
> To reach a settlement, the parties will need to figure out more than the price. How much of the settlement would be the responsibility of the name-brand manufacturers that do most of the opioid marketing? How much would be the responsibility of the companies that sell even more pills as generics? What about distributors and drug store chains, which are named in some of the lawsuits?
>
> And what about restrictions on how money in a settlement is spent? States used payments from the tobacco settlement to help balance budgets and for government services outside public health. In the opioids case, some negotiators might insist on provisions to prevent that from happening. Various governments want to use money to pay for emergency responders burdened by the crisis, as well as education and treatment programs.

Litigation is one among many tools for addressing the opioid crisis, a topic we'll return to in chapter 13.

The Class Action Fairness Act discussed in *Kentucky v. Purdue Pharma* is an example of tort reform. Although the Act's reforms are

purely procedural—allowing defendants to insist that class actions be adjudicated by federal, rather than state, courts—the statute is widely regarded as making it more difficult for class action plaintiffs to prevail. Because private plaintiffs are typically represented by lawyers who work on a contingency fee basis, procedural rules that make success less likely also make it harder to find lawyers willing to invest the considerable resources required to pursue litigation. Thus, even if the goals of litigation are not limited to obtaining financial compensation (e.g., obtaining access to information via the discovery process, raising public awareness of a party's responsibility for a public health crisis, or obtaining injunctive relief), the difficulty of obtaining compensation thwarts the litigation strategy at the outset. We will return to tort reform later in the chapter.

In addition to state and city plaintiffs, the federal government has sometimes brought suit to protect public health and the environment. The federal government, in litigation that spanned nearly two decades, used a law enacted to combat organized crime to seek judicial redress for the fraudulent activities of cigarette companies.

*UNITED STATES V. PHILIP MORRIS USA INC.**

United States Court of Appeals for the District of Columbia Circuit Decided May 22, 2009

The United States initiated this civil action under the Racketeer Influenced and Corrupt Organizations Act (RICO), in 1999. The government alleged that nine cigarette manufacturers and two tobacco-related trade organizations violated [provisions of RICO that] make it unlawful for "any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity" or to conspire to do so. The government alleged that Defendants violated and continued to violate RICO by joining together in a decades-long conspiracy to deceive the American public about the health effects and addictiveness of smoking cigarettes. . . .

After years of pretrial proceedings and discovery, the case went to trial in September 2004. The bench trial lasted nine months and included live testimony from 84 witnesses, written testimony from 162 witnesses, and almost 14,000 exhibits in evidence. The government presented evidence that the presidents of Philip Morris, Reynolds, Brown & Williamson, Lorillard, and American assembled together in 1953 to strategize a response to growing public concern about the health risks of smoking and jointly retained a public relations firm to assist in the endeavor. From the beginning they agreed that no cigarette manufacturer would "seek a competitive advantage by

* 566 F.3d 1095.

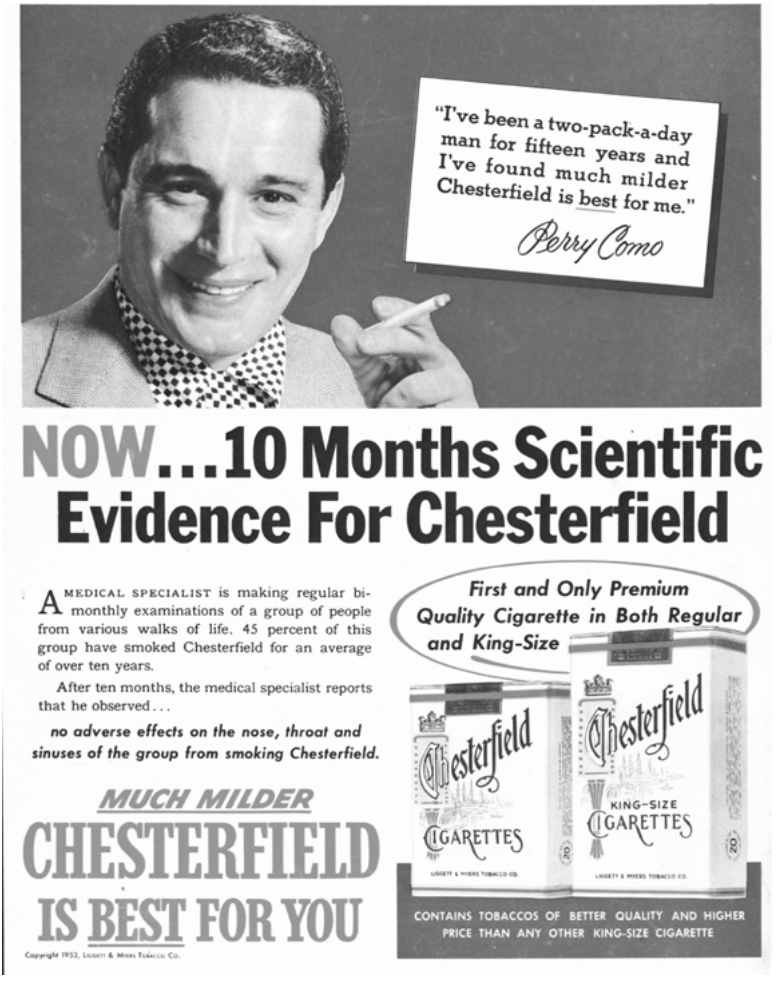

PHOTO 7.2. A cigarette advertisement extols misleading pseudoscientific evidence regarding the health effects of smoking.

inferring to its public that *its* product is less risky than others." . . . Acting on this agreement, the cigarette manufacturers jointly issued "A Frank Statement to Cigarette Smokers," published as a full-page advertisement in newspapers across the country on January 4, 1954. The Frank Statement set forth the industry's "open question" position that it would maintain for more than forty years—that cigarette smoking was not a proven cause of lung cancer; that cigarettes were not injurious to health; and that more research on smoking and health issues was needed. All of the Defendant manufacturers eventually joined this collective effort. . . .

Evidence at trial revealed that [during this time, Defendants] internally acknowledged as fact that smoking causes disease and other health hazards. In addition to the health hazards of smoking, the government presented evidence that Defendants intimately understood the addictiveness of nicotine and manipulated nicotine delivery in cigarettes to create and sustain addiction. . . . Evidence at trial suggested that despite this internal knowledge, for decades Defendants publicly denied and distorted the truth about the addictive nature of their products, suppressed research revealing the addictiveness of nicotine, and denied their efforts to control nicotine levels and delivery.

The government also presented evidence tending to show that Defendants marketed and promoted their low tar brands to smokers—who were concerned about the health hazards of smoking or considering quitting—as less harmful than full flavor cigarettes despite either lacking evidence to substantiate their claims or knowing them to be false. . . .

Regarding secondhand smoke, the government presented evidence suggesting that Defendants became aware that secondhand smoke poses a health risk to nonsmokers but made misleading public statements and advertisements about secondhand smoke in an attempt to cause the public to doubt the evidence of its harmfulness. . . .

In addition to these topics, the government also presented evidence to the district court regarding Defendants' targeted marketing to youth under twenty-one years of age and their denials of such marketing, as well as evidence concerning Defendants' employees and attorneys destroying documents relevant to their public and litigation positions and suppressing or concealing scientific research. . . .

The district court entered final judgment against Defendants on August 17, 2006, finding that they maintained an illegal racketeering enterprise and each Defendant participated in the conduct, management, and operation of the enterprise in violation of [RICO]. . . . The court concluded that [seven of the manufacturers] were reasonably likely to commit future RICO violations unless enjoined because they continued to make false and misleading statements at the time of trial, their businesses presented continuing opportunities to commit RICO violations, and their corporate leadership continued to consist of veteran employees with longstanding ties to the companies. . . . [T]he district court imposed injunctive remedies against [these] seven manufacturer Defendants. Specifically, the court ordered Defendants (1) to refrain from any acts of racketeering relating to the manufacturing, marketing, promotion, health consequences, or sale of cigarettes in the United States; (2) not to participate in the management or control of [the Tobacco Institute and other entities formed by the Defendants to further their public relations agenda], and not to reconstitute the form or function of those entities; (3) to refrain from making any material false, misleading, or deceptive representation concerning cigarettes that is disseminated to the United States public; (4) to cease using any express or implied health message or health descriptor for any cigarette brand, such as light or low tar; (5) to make corrective disclosures about addiction, the adverse health effects of smoking and secondhand smoke, their manipulation of cigarette design and composition, and light and low tar cigarettes; (6) to create document depositories providing the government and the public access to all industry documents disclosed in litigation; and (7) to provide their disaggregated marketing data to the government according to the schedule on which

they provide it to the Federal Trade Commission. The court also limited the sale and transfer of Defendants' brands, product formulas, and businesses to entities that either are subject to the injunctive order or will sell the brand, use the formula, or conduct the business exclusively outside the United States.

The district court denied the remainder of the government's requested injunctive relief, including its proposed national smoking cessation program, public education and counter-marketing campaign, and youth smoking reduction plan. The court also denied the government's requests that it appoint a monitor to investigate and restructure the Defendant companies, and that it order Defendants to make public all "health and safety risk information" about their products in their own files. [Defendants] appealed, raising numerous challenges to the finding of liability and the remedies imposed. . . .

As part of the remedial order, the district court ordered Defendants to disseminate "corrective statements" concerning the topics about which they had previously misled consumers. The court will determine the precise content of the statements at a future date after receiving proposals from the parties. . . . The remedial order sets out schedules for the manufacturer Defendants to follow in disseminating the corrective statements in cigarette package onserts, retail point-of-sale displays, newspapers, television, and their company websites. . . . Regarding the specific means of disseminating the statements, Defendants argue that cigarette package onserts violate the Labeling Act, that the point-of-sale displays are duplicative and impose severe burdens on retailers, and that requiring Defendants to make corrective statements in various media apart from existing advertising violates the First Amendment. . . .

[T]he district court ordered Defendants to "affix [corrective disclosures] to cigarette packaging, either on the outside of or within the outer cellophane wrapping around the package . . . in the same manner as certain Defendants, such as Philip Morris and Brown & Williamson, have utilized package onserts in the past [for promotional purposes]." Defendants object that the onserts violate the Federal Cigarette Labeling and Advertising Act (Labeling Act), which provides that "[n]o statement relating to smoking and health, other than the statement required by [the Labeling Act], shall be required on any cigarette package."

The Labeling Act defines a "package" as "a pack, box, carton, or container of any kind in which cigarettes are offered for sale, sold, or otherwise distributed to consumers." [According to the district court, a] package onsert is "[a] communication affixed to but separate from an individual cigarette pack and/or carton purchased at retail by consumers, such as a miniature brochure included beneath the outer cellophane wrapping or glued to the outside of the cigarette packaging."

These definitions show that the corrective statements in an onsert are not "statement[s] . . . on [a] package," but rather statements in a brochure attached to or included with a package, and thus are not prohibited by the plain language of the Labeling Act. . . . Moreover, the district court and the parties appear to have recognized the distinction between packages and onserts throughout the trial. . . .

[Regarding point-of-sale displays, w]e believe that the district court exceeded its authority by failing to consider the rights of retailers and crafting an injunction that works a potentially serious detriment to innocent persons not parties to or otherwise heard in the district court proceedings. Even though not explicitly bound by the terms of an injunction on pain of contempt, third parties may be so adversely affected by an injunction as to render it improper.

The district court also ordered each Defendant to publish the corrective statements on its corporate website, as a one-time full-page advertisement in thirty-five major newspapers, and as at least ten advertisements on a major television network over the course of one year. The court chose these media in order to "structure a remedy which uses the same vehicles which Defendants have themselves historically used to promulgate false smoking and health messages." . . .

The district court has not yet determined the content of the corrective statements. As the validity of its order relies on the commercial nature of the speech it burdens, the court must ensure the corrective disclosures are carefully phrased so they do not impermissibly chill protected speech. Consequently, the court must confine the statements to purely factual and uncontroversial information, geared towards thwarting prospective efforts by Defendants to either directly mislead consumers or capitalize on their prior deceptions by continuing to advertise in a manner that builds on consumers' existing misperceptions. . . .

The government and the intervenors [public health and tobacco control organizations] bring a cross-appeal challenging the district court's denial of additional remedies they sought against Defendants. . . .

The proposed remedies attempt to prevent and restrain future effects of past RICO violations, not future RICO violations, therefore they are outside the district court's authority . . . [A] remedy may not be justified simply on the ground that whatever hurts a civil RICO violator necessarily serves to prevent and restrain future RICO violations. If this were adequate justification, the phrase "prevent and restrain" would read "prevent, restrain and discourage," and would allow any remedy that inflicts pain. . . .

Only the intervenors appeal from the district court's denial of the government's proposed "youth smoking reduction targets" plan. Under that proposal, the court would require Defendants to reduce youth smoking by six percent each year for seven years, and if Defendants fail to meet an annual target, the court would assess them a $3,000 fine for each youth above the target who continues to smoke, a figure representing the "lifetime proceeds a Defendant could expect to earn from making its brands appealing" to youth. The district court denied this injunction because it was not tailored to prevent and restrain future RICO violations. . . . The youth smoking reduction proposal was not aimed at preventing Defendants from denying their youth marketing efforts but rather at restraining Defendants from marketing and selling to youth. . . . An injunction that would hold Defendants responsible for outcomes they could not control regardless of modifications in their behavior would not serve to prevent or restrain Defendants from committing future RICO violations. . . .

For the foregoing reasons, we affirm the district court's judgment of liability. . . . We also largely affirm the remedial order, including the denial of additional remedies sought on cross-appeal. . . .

. . .

The injunctive relief ordered by federal district court judge Susan Kessler in the RICO case against tobacco companies promises significant public health benefits. The remedy phase dragged on for more than a decade, however, with parties disputing every conceivable detail of the content, appearance, and placement of corrective disclosures. The

tobacco companies sponsored court-mandated corrective statements in television and newspaper advertisements from late 2017 through 2018. In mid-2018, a federal judge ordered the companies to post corrective statements on their websites, any social media campaigns they sponsor, and product packaging for a total of six two-week periods spread out over the course of two years. The tobacco RICO case also demonstrates that judicial remedies are subject to many of the same limitations that apply to the legislative and executive branches, including preemption and the First Amendment.

This case and others suggest that litigation is not necessarily a more expedient alternative to direct regulation, though it can be a crucial adjunct. Without the threat of liability, industry groups are less likely to support (or at least refrain from opposing) legislative and regulatory reforms. Absent discovery, the public may be less informed about industry practices aimed at manipulating their preferences and behavior. Without the common law mandate to take reasonable steps to monitor and improve safety, industry groups may grow complacent, declining to pursue safety innovations until lawmakers insist. The threat of liability is thus an important part of the public health law toolkit, but pro-defendant tort reform is rapidly eroding its foundations, as discussed in the next section.

TORT REFORM AND INDUSTRY IMMUNITY

Tort plaintiffs are often portrayed as money grubbing, opportunistic, and irresponsible. Groups that frequently find themselves defending against tort suits—including health care providers, product manufacturers, chemical companies, and others—have mounted a very successful campaign to get the public on their side. For example, many are familiar with the McDonald's hot coffee case. The plaintiff, Stella Leibeck, was ridiculed for being too stupid to realize that coffee is hot. Few are aware that she experienced third degree burns requiring skin grafts across her pelvic area because the coffee was heated to a significantly higher temperature than at other retailers—or that she repeatedly offered to settle the case for a tiny percentage of the damages the jury ultimately awarded her. Leibeck and plaintiffs in other high-profile cases have been turned into urban legends by industry and professional groups eager to convince the public to back tort reform.

Tort reform takes many forms. Some are procedural reforms, such as the Class Action Fairness Act at issue in the *Purdue Pharma* case excerpted above. Others cap damage awards, reducing incentive to sue

(and incentive to exercise caution). Some reforms, like the National Vaccine Injury Compensation Act mentioned in the introduction to this chapter and the Cheeseburger Bills inspired by the *Pelman* litigation, are industry-specific. The case that follows involves another industry-specific immunity statute, the Protection of Lawful Commerce in Arms Act, which was enacted by Congress after several state and city attorneys filed suit (a few of which were initially successful) against firearms manufacturers and distributors alleging that their distribution practices constituted a public nuisance.

*CITY OF NEW YORK V. BERETTA U.S.A. CORP.**

United States Court of Appeals for the Second Circuit
Decided April 30, 2008.

The action giving rise to this appeal was commenced on June 20, 2000, when the City filed a complaint against [manufacturers and wholesale sellers of firearms] seeking injunctive relief and abatement of the alleged public nuisance caused by the Firearms Suppliers' distribution practices. The City claimed that the Firearms Suppliers market guns to legitimate buyers with the knowledge that those guns will be diverted through various mechanisms into illegal markets. The City also claimed that the Firearms Suppliers fail to take reasonable steps to inhibit the flow of firearms into illegal markets. . . .

On October 26, 2005, the Protection of Lawful Commerce in Arms Act (PLCAA) became federal law. The PLCAA provides that any "qualified civil liability action that is pending on October 26, 2005, shall be immediately dismissed by the court in which the action was brought or is currently pending." A "qualified civil liability action" is

> a civil action or proceeding . . . brought by any person against a manufacturer or seller of a [firearm distributed in interstate or foreign commerce] . . . for damages, punitive damages, injunctive or declaratory relief, abatement, restitution, fines, or penalties, or other relief, resulting from the criminal or unlawful misuse of a [firearm distributed in interstate or foreign commerce] by the person or a third party.

On the day the PLCAA was enacted, the Firearms Suppliers moved to dismiss the Amended Complaint. . . . In its opposition to the Firearms Suppliers' motion to dismiss, the City . . . challenged the constitutionality of the Act on various grounds. The United States intervened to defend the constitutionality of the PLCAA. . . .

We . . . hold that the PLCAA is a valid exercise of the powers granted to Congress pursuant to the Commerce Clause and that the PLCAA does not violate the doctrine of separation of powers or otherwise offend the Constitution in any manner alleged by the City. . . .

The City advances four arguments on cross-appeal with respect to the constitutionality of the PLCAA: (i) the PLCAA is not a permissible exercise of Congress's power

* 524 F.3d 384.

PHOTO 7.3. An unloaded handgun. After several state and city governments sued firearms manufacturers and distributors, alleging that their marketing and distribution practices contributed to increased gun violence, Congress adopted the Protection of Lawful Commerce in Arms Act to immunize the industry from such suits. St. Louis Circuit Attorney's Office.

to regulate interstate commerce; (ii) the PLCAA violates basic principles of separation of powers by dictating the outcome of pending cases; and [iii] the PLCAA violates the First Amendment's guarantee of the right to petition the government to redress grievances through access to the courts. For the reasons that follow, we agree with the District Court that "[t]here is no violation of the United States Constitution." . . .

The City claims that the activity that the PLCAA concerns itself with—civil litigation against members of the gun industry for unlawful acts committed by third parties—is not commercial in nature and therefore is outside of Congress's regulatory power. . . . A foundation of the City's claim[, however,] is that New York City's strict limitations on gun possession are undermined by the uncontrolled seepage into New York of guns sold in other states. We agree that the firearms industry is interstate—indeed, international—in nature. . . .

[T]he City claims that the Act's mandate of dismissal of pending actions against firearms manufacturers violates [separation of powers] by legislatively directing the outcome of specific cases without changing the applicable law. The government, however, argues that [separation of powers] does not prohibit Congress from enacting statutes that set forth new rules of law applicable to pending cases, provided the new rule of law is also made applicable prospectively to cases commenced after enactment. We agree. . . .

[Finally, we conclude that the First Amendment] right to petition is not violated by a statute that provides a complete defense to a cause of action or curtails a category

of causes of action. The PLCAA immunizes a specific type of defendant from a specific type of suit. It does not impede, let alone entirely foreclose, general use of the courts by would-be plaintiffs such as the City. . . .

. . .

The Protection of Lawful Commerce in Arms Act (PLCAA) has shielded manufacturers and distributors from suits by public plaintiffs, as in the case above, as well as private individuals, such as survivors and families of those killed at Sandy Hook Elementary School when a shooter used a Bushmaster assault rifle manufactured by Remington to kill 26 people—most of them first graders—in less than five minutes. The plaintiffs sued Remington for common law torts and unfair trade practices. In 2016, a judge determined the claims were barred by the PLCAA. An appeal to the Connecticut Supreme Court was stalled by Remington's bankruptcy in 2018.

Tort-based litigation against firearms manufacturers and distributers promises compensation for victims, corrective justice for wrongdoers, and deterrence of others who might consider similar actions in the future. It also creates a political environment more favorable to direct regulation. Historically, the possibility that comprehensive safety regulation could include a provision preempting tort claims has been an important inducement to soften industry opposition to legislative action—on gun control and in other areas. In the case of the PLCAA, however, industry groups successfully lobbied Congress to preempt tort-based claims without replacing them with comprehensive gun control regulations. We will return to the topic of gun control in chapter 13.

In this area and many others, the costs and benefits of litigation as a tool for protecting the public's health continue to be hotly debated. As the cases presented in this chapter demonstrate, private plaintiffs and government attorneys are using causes of action that date back hundreds of years to address some of the most pressing problems of our time. The adaptability inherent in judge-made common law doctrines governing nuisance, negligence, and fraud offers many benefits for public health lawyers. At the same time, a decades-long public relations campaign by "frequent defendant" industries has successfully turned public opinion against litigation as a form of indirect regulation (Mulroy and Gadardian 2018). Plaintiffs seeking monetary damages are derided as greedy and lacking personal responsibility. Can litigation be preserved as part of the public health law toolkit in the face of political support for tort reform and a judiciary that is increasingly hostile to

claims by consumers? Should it be? Should public health advocates prioritize preserving tort litigation for its deterrent potential? Or should they focus on other battles over direct regulation, taxation, and spending?

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PHOTO 8.1. Patients wait to be seen at a clinic operated by the Taos County Cooperative Health Association, 1943. A poster in the waiting room urges mothers to weigh and measure their infants once a week and have them examined by a physician once a month. In the early 1940s, Taos County, New Mexico, had the highest infant mortality rate in the nation, with residents lagging behind in many other health indicators as well. Doctors and residents of the county developed the Cooperative Health Association with support from the federal Farm Security Administration and the University of New Mexico. More than one-third of the county's population joined the association, paying membership fees according to income, which covered about 15% of costs. A small staff of physicians, dentists, and nurses provided care in three clinics and the association also maintained contracts with area hospitals. Loomis, Charles P. 1945. "A Cooperative Health Association in Spanish Speaking Villages, or the Organization of the Taos County Cooperative Health Association." *American Sociological Review* 10 (2): 149–57. Photograph by John Collier for the Farm Security Administration.

CHAPTER EIGHT

Taxation, Spending, and the Social Safety Net

Political decisions about tax policy and spending priorities are deeply divisive. During the Obama administration, congressional Republicans temporarily shut down the federal government by refusing to approve a budget without defunding the Affordable Care Act (ACA). Later, in an effort to bar Medicaid reimbursements for health screenings and other services provided by Planned Parenthood clinics, they threatened to do so again. During the Trump administration, congressional Democrats, joined by some Republicans, voted no on budget proposals in an effort to resist the president's efforts to fund construction of a wall along the Mexican border and dismantle the Deferred Action for Childhood Arrivals (DACA) program. The result was a series of Continuing Resolutions to fund government operations temporarily while debate on a longer-term solution continued. In 2017, although the Republican Party enjoyed control over both houses of Congress and the presidency, it failed to garner a simple majority to repeal the ACA as it had long promised. As these examples demonstrate, disputes over taxation and spending strategies reflect conflicting notions of government's role in distributing resources, shaping the economy, and structuring our social order.

This chapter focuses on taxation and spending strategies for public health. Government revenue finances public health research and services. Taxes and conditions on government spending also influence the conduct of individuals, businesses, nonprofit organizations, and state

and local governments. Taxing and spending, therefore, operate as an indirect form of regulation.

We begin with taxation as an indirect form of regulation, with an emphasis on excise taxes for cigarettes and unhealthy food and beverages. Next, we discuss public health financing and the chronic underfunding of health departments, exacerbated in recent years by recession-driven budget cuts. We then turn to conditional spending as a regulatory strategy, with a focus on the particular legal and political issues raised by federal spending programs. We conclude with a case study on taxation and conditional spending strategies for ensuring access to health care and promoting integration of the public health and health care systems. We examine tax exemption requirements for nonprofit hospitals, favorable tax treatment of employer-based insurance, and penalties and subsidies to encourage the purchase of private insurance. We focus particularly on how Medicaid's status as a cooperative federalism spending program shapes opportunities for advocacy on behalf of low-income beneficiaries and the health care providers who serve them.

TAXATION AS INDIRECT REGULATION

In addition to direct regulation and indirect regulation via tort liability, policymakers often rely upon taxation as an indirect form of regulation. Policymakers have long used excise taxes and tax credits, deductions, and exemptions to influence the health-related behavior of businesses and individuals. In the excerpts that follow, Bruce Carruthers explains the politics of excise taxes and Jennifer Pomeranz discusses strategies for using excise taxes to prevent diet-related illnesses.

THE SEMANTICS OF SIN TAX: POLITICS, MORALITY, AND FISCAL IMPOSITION*

Bruce G. Carruthers

By encouraging some activities while discouraging others, governments use laws to shape individual and collective human behavior. The most extreme discouragement comes as outright legal prohibition, with severe penalties to be rigorously imposed on violators of the proscription. Moderate penalties combined with lax enforcement constitute a gentler way to discourage illegal activity. Yet there are other, even less strin-

* 2016. *Fordham Law Review* 84 (6): 2565–82.

gent ways to deal with unwanted behavior. Legal but morally problematic market-based activities can be discouraged through the price system: the imposition of a government tax raises prices and makes the taxed activity more expensive for participants to undertake. Depending on the price elasticity of demand, higher prices then reduce market activity. Examples of such problematic but legal activities in the United States include: alcohol consumption, tobacco consumption, and gambling. Other dubious activities that have been legalized very recently, or selectively, include consumption of marijuana (e.g., in Colorado) and use of sexual services (e.g., brothels in Nevada). Across all such disapproved, but still legal activities, the taxes imposed are simply known as "sin taxes." . . .

Contemporary economics is seldom concerned with sin and stigma. But economics does have a framework with which to analyze and even justify sin taxes. . . . [T]axes can be used to correct for externalities, a type of market failure. If consumption of a good or service entails social costs that are not fully reflected in the market price, then imposition of an excise tax can be socially beneficial. For example, if consumption of cigarettes causes damage to nonsmokers via secondhand smoke, then the market price of cigarettes will not reflect their full cost to people who neither bought nor sold the cigarettes. Similarly, if alcohol consumption involves social costs (including increased traffic accidents, fetal alcohol syndrome, and other problems associated with alcoholism) that are borne by people who do not consume alcohol, then the market price of alcohol is too low. Such a tax, sometimes called a "Pigouvian tax," can help "internalize" such externalities. Sin taxes face a number of complications. Whether they are imposed for moral, fiscal, or technical reasons, at some point higher taxes also increase the incentive to evade taxation and so can spur the growth of illegal or black market transactions. With too heavy of a fiscal burden, stigmatized legal activity shifts to where it becomes invisible to the state, and the state can neither track nor receive benefits from it. At the extreme, the ability of taxation to suppress activity has its limits. Ironically, governments acquire a financial interest in activity that they otherwise condemn: if alcohol consumption is too successfully reduced, the government may lose a valued source of tax revenue. In similar fashion, the profits generated by stigmatized activity are deemed "ill-gotten gains" and also can become stigmatized. Markets for such goods are often regulated in other ways that reflect concern about their broader social effects or their stigmatized status. For example, a regulatory agency may require producers and sellers to acquire a license to operate, or a statute may restrict buyers of such products by age (e.g., prohibitions against underage drinking and smoking). Although sin taxes are not the only way that public policy responds to or manages stigmatized activity, they will be my primary focus here.

Of course, taxes can also be used to signal positive social meanings, and not simply through nonimposition. In the political debates about welfare reform in the 1990s, for example, much was made of the virtues of "honest labor." In contrast to those who "chose" not to work and looked to government for financial support (thus participating in the culture of "welfare dependency"), the working poor were celebrated for their independence, uprightness, and sense of personal responsibility. So even as entitlement programs like Aid to Families with Dependent Children (AFDC) were abolished and overall social welfare supports were reduced, federal policy used the personal income tax system to reward the paid labor of the working poor. Expansion of the Earned Income Tax Credit (EITC) gave tax credits (not merely tax deductions) to low

income individuals based on their income level and number of children. In short, tax expenditures were used to mark and reward poor people who undertook paid labor. Similarly, home mortgage interest tax deductions reflect a widespread political consensus about the positive social value of individual home ownership. Other income tax measures reflect social approval of, among other things, entrepreneurship, charitable contributions, savings, and capital gains. The tax code can reflect both sin and virtue. . . .

When deployed as a fiscal burden that encumbers a particular activity, taxation can serve as a public marker of stigma. The tax publicly labels disapproved goods or services and can be imposed at exactly that point in the production chain where the good is created out of its constituent parts, or after its production and somewhere further downstream (perhaps when the good is sold, or the service provided, to consumers). Thus, as symbolic expressions of disapproval, excise taxes can be highly precise, differentiating sharply between good and bad commodities and even between the components of a commodity (e.g., glass, corn, wheat, rye, malted barley), and the commodity itself (e.g., bottled bourbon whiskey). . . .

The imposition of taxes on "luxuries" rather than "necessities" has implications for the perception of tax incidence. Luxury goods connote waste, excess, and discretionary consumption—a set of associations that certainly have shaped tax policy. . . . In addition, . . . luxuries generally are consumed by high-income individuals while necessities are consumed by everyone. This means that taxes on luxuries should be relatively "progressive" (so that higher income individuals pay higher consumption taxes), but taxes on necessities are more "regressive" in that lower-income individuals bear a proportionately higher burden. . . . [T]he imposition of excise taxes on stigmatized activity also has the effect of giving a precise measure to sinful activity: the more activity, the higher the tax, in exact proportion. . . . This occurs only when stigmatized activity involves the purchase or the use of market-based goods and services, both of which necessarily possess a market price. Depending on how it is imposed, whether in terms of value (e.g., as a percent added to the price), or some physical measure (e.g., per liquid gallon or per carton), a sin tax commensurates stigmatized activity. . . . And tax levels can differentiate between degrees of stigmatization within the same overall product category. For example, the alcohol taxes imposed on the purchase of beer or wine frequently are lower than those imposed on distilled spirits (so-called "hard liquor"). The latter beverage has a higher alcohol content and so is considered more problematic. . . .

[R]ather than avoid taxes, participants tarnished by stigma may actually seek out taxation because it can, in a sense, become a form of political protection. Consider the political power of U.S. prohibitionists who wanted to completely curtail the nonmedical consumption of alcoholic beverages and managed to do so during the Prohibition era (1920 to 1933). In consenting to be taxed both before and after Prohibition, distillers and brewers gave state and federal governments a good fiscal reason not to follow the prohibitionists and completely prohibit alcohol. And the higher the tax rates and the more lucrative and reliable the revenues, the stronger the reason not to follow the prohibitionists. This willingness to be taxed, however, hardly can explain the emergence of sin taxes. . . .

The imposition of taxes upon a particular type of transaction or commodity functions very much like an earmark. . . . Instead of generic revenue, the government

receives revenue from alcohol sales or revenue from cigarette sales, or taxes on casino gambling. . . . Otherwise identical legal tender becomes heterogeneous once it has been earmarked and placed into different budget categories. It is important to recognize that this is a different matter than the *incidence* of taxation, which concerns who bears the ultimate financial burden of a tax. If the party that directly pays a tax can pass the fiscal burden on to someone else (perhaps by charging higher prices to their customers), then the incidence is shifted elsewhere. . . .

How sin tax revenues are used creates another opportunity for earmarking, particularly when this helps to "launder" the revenues. . . . "Dirty" money may be "cleansed" by being earmarked to serve a virtuous social end. Perhaps tobacco revenues are spent on public health or to further children's education. . . . [For example, i]n 2005, twenty-six states earmarked their tobacco tax revenues, twenty-three states earmarked alcoholic beverage tax revenues, and fourteen states earmarked their tax revenues from gaming for purposes that included education, health, and welfare. For instance, the state of Alabama earmarked 32.4 percent of the tax revenues generated by the sale of liquor and wine for social and protective services and 40 percent of the revenues generated by beer sales for public schools and higher education. California earmarked 86.9 percent of taxes on the sale of cigarettes and tobacco products for a broad range of good works, including tobacco-related health education programs, disease research, environmental conservation, fire prevention, and indigent health care services. It is easier to tolerate sinful activities if they can be credibly used for good, and budgetary earmarks can tie particular taxes to particular expenditures. . . . The tax expresses disapproval while at the same time allowing the activity to proceed. On the destination or spending side, budgetary earmarks can further mitigate the stigma by ensuring that at least some sin tax revenues support valuable and praiseworthy public policies. Putting problematic revenues in tight linkage with legitimate activity creates a kind of halo effect. . . .

In the United States, the fiscal importance of "sin taxes" also has varied over time and across levels of government. At the federal level, sin taxes generally have declined in importance as a revenue source. . . . In 1902, for example, the federal government derived roughly 29 percent of its total revenues from a sales tax on alcoholic beverages and about 7.5 percent of revenues from sales taxes on tobacco. . . . By 1948, during the post-war economic boom and after expansion of the personal income tax system during World War II, sales of alcoholic beverages and tobacco products contributed only 4.7 percent and 2.7 percent, respectively[,] to federal government revenues. And twenty years later, the proportions were even smaller: 2.6 percent and 1.3 percent, respectively . . . At the start of both World Wars I and II, the U.S. government had to raise much greater sums of money than before, and, in addition to borrowing heavily, the only direction to go in was to impose new types of personal income, corporate income, excise, or estate taxes. . . . The historical pattern is not as simple for state government revenues. In 1902, state taxes on the sale of alcoholic beverages and tobacco products generated no revenue at all. Instead, state governments relied heavily on property-tax revenues. . . . Overall, these sin taxes generated zero state revenue at the outset of the twentieth century; their contribution then grew so that by mid century, they contributed a small but substantial amount of revenue. . . .

Even as sin tax collections vary over time, they also vary across states. Some states impose higher taxes on stigmatized transactions than others. In 2015, for example, the

tax rate on a gallon of distilled spirits was $12.80 in Alaska, $6.50 in Florida, and $8.55 in Illinois, whereas it was only $1.50 in Maryland and $2.28 in Colorado. Many states, including Alabama, Idaho, North Carolina, and Pennsylvania, directly control the sale of distilled spirits; accordingly, the state sets profit margins and also imposes fees and taxes. . . . The causes of these state-level variations have not been investigated thoroughly, but [researchers have] found that religious groups make a difference for sin taxes: U.S. states with larger Catholic populations tended to have lower alcohol taxes, while states with more Protestant fundamentalists were more likely to have state monopoly liquor stores (and less likely to have a state lottery). . . .

[T]he fiscal importance of sin taxes does not drive, in any mechanical fashion, the cultural or political salience of sin taxes. Indeed, once individual and corporate income taxes were put in place in response to wartime financial imperatives, excise taxes contributed relatively little to the federal budget. But the discussion of excise taxes imposed on sinful commodities nevertheless continued, and even intensified. The symbolic connection between stigmatized activity and the tax revenues that can arise out of them remained intact, even when sin tax revenues made a relatively small contribution to public finances. . . .

The power of the democratic state consists of its ability to mobilize and deploy material resources, but it also possesses considerable cultural power. Through its system of taxation, it renders the private economy legible, recognizes some of its moral features, and enacts with precision both approval and disapprobation. . . .

TAXING FOOD AND BEVERAGE PRODUCTS: A PUBLIC HEALTH PERSPECTIVE AND A NEW STRATEGY FOR PREVENTION*

Jennifer L. Pomeranz

. . . The greatest public health challenges of today stem from the increase in chronic diseases due to poor nutrition. . . . Food preferences are formed at an early age and continue to be shaped by taste, convenience, education, and influential marketing campaigns. In addition, peculiar price incentives in the United States encourage unhealthy food consumption. . . . Various public health interventions based on the government's taxing power have been proposed[, including] taxing specific individuals, products, nutrients, and ingredients. . . .

TAX THE PERSON

One proposed tax strategy is to tax people who are overweight, fail to lose weight, or who have diabetes. The rationale behind this type of tax is that people should take personal responsibility for their health. Under this theory, the government's role is to engage people to manage their own disease and take care of themselves in order to save on health care costs.

A tax that targets people based on physical characteristics would be difficult to administer and is likely to be ineffective and stigmatizing. The tax would also be espe-

* 2012. *University of Michigan Journal of Law Reform* 46 (3): 99–1027.

cially regressive for low-income individuals who are already overweight. There is significant scientific consensus that current weight loss methods, interventions, trials, and programs are not effective in helping people lose a meaningful amount of weight or maintain weight loss or a healthy body weight. Therefore, it cannot be expected that an overweight individual could lose enough weight to avoid the tax. Instead of deterring consumption, the tax would be a lifelong penalty for being overweight for a large percentage of the U.S. population. . . . Some believe that stigmatizing obese people positively influences their behavior, but research on the subject shows the opposite is true. . . .

Taxing the person in this case would be comparable to taxing people with lung cancer instead of taxing the tobacco products that caused the disease. . . . [T]axing the product is a better solution for public health, social justice, and equitable application of the law.

TAX THE PRODUCT

A second option is to tax a product associated with poor health outcomes in an effort to foster public health. . . . Tobacco, alcohol, and firearms are contributors to the leading causes of premature death in the United States, and all are subject to federal excise taxes. Public health advocates have focused on sugary beverages as the subject of state or local tax interventions because the health risks associated with sugary drink consumption are better established in the research . . . than the risks from any other food.

Rationale

Sugary beverage intake is associated with weight gain, overweight, and obesity and is an independent risk factor for diabetes and heart disease. The body does not compensate for caloric intake from sugary liquids by reducing intake of other forms of calories. This means that people do not eat less when they consume calories from sugary beverages, as they might if they consumed the same calories from whole foods. Sugary drink consumption is consistently associated with higher overall energy intake, and thus the association between consumption and weight gain is stronger than for any other food. These drinks are also the most consumed snack by adults and the largest source of added sugar in the diets of all Americans.

Public health advocates propose that states place excise taxes on sugary beverages to dissuade consumption and raise revenue that is earmarked for public health. . . . For sugary beverages, [the excise tax] would be imposed on the syrup or beverage manufacturer for beverages with added caloric sweetener. The goal of an excise tax is to increase the base price of the product. Conversely, a sales tax is imposed at time of payment, after most consumers have decided to make the purchase. A sales tax encourages consumers to buy larger containers and does not impact the cost of free refills. . . .

Unlike sales taxes, excise taxes are more amenable to earmarking, which is the dedication of revenue from a particular tax stream to a specific purpose. Excise taxes represent a significant revenue stream for the government, but many are earmarked for a specific fund related to the purpose of the tax. . . . For example, the funds could be redirected into low-income communities to correct the health disparities that result

from a lack of access to healthy food and health care services. The money could also be used to fund public health programs or to specifically subsidize healthier food, such as fruits and vegetables.

People with lower incomes spend a larger percentage of their income on food than people with higher incomes. Price elasticity varies among the population, with those at lower incomes reacting more to increased prices. If the goal of the tax is to reduce consumption, regressivity is minimized when the low-income group purchases less of the unhealthy item, thereby spending less of their income on it and potentially improving health outcomes. Earmarking the tax revenue for public health initiatives specifically to benefit low-income communities seeks to address regressivity concerns.

Policy Discussion

Advocates analogize the potential benefits of a sugary beverage tax to the successful use of taxation as a strategy in tobacco control. Tobacco taxes are credited with a reduction of smoking rates, especially in youth, and raising revenue to fund other tobacco control programs. Economists differ on the expected impact of sugary beverage taxes, but there seems to be a consensus that it could generate billions of dollars in revenue and reduce sugary beverage consumption to positively influence health. . . . Economists calculate that consumers may be more sensitive to price increases for sugary beverages than for tobacco. The price elasticity for tobacco is −0.25 to −0.50, which means [that a 10 percent increase in cigarette prices would result in a 2.5 to 5 percent decrease in cigarette smoking]. Conversely, the price elasticity for sugary beverages is approximately −0.8, so a 10 percent increase in price should reduce consumption by [about 8 percent]. Thus, compared to cigarettes, the demand for sugary beverages is more elastic, and the decline in consumption should be higher at lower tax rates.

Many economists calculate that a penny per ounce tax on sugary beverages is sufficient to reduce consumption. Other studies suggest that a higher tax would be necessary. One study examined states with existing sales tax rates on soft drinks, finding that the largest was 7 percent. . . . The researchers found these small taxes did not have a measurable impact on soft drink consumption or obesity among children in those states, so if reducing consumption is the goal, policymakers should consider higher taxes at the outset. If the tax gets implemented but primarily raises revenue and does not decrease consumption as expected, lawmakers could incrementally increase the tax until it reaches a deterrent level, as has been done with tobacco over the decades. Furthermore, even small excise taxes could generate revenue that can be earmarked for other obesity prevention efforts.

States with high tobacco tax rates and low smoking rates tend to also have minimum price laws for tobacco products, which could be a useful strategy for food taxes. Minimum price laws have proven necessary because tobacco manufacturers offer price discounts, coupons, and other promotions that bypass the purpose of the tax. . . . Sugary beverage manufacturers can be expected to employ similar strategies.

Finally, unlike for cigarettes, substitution by consumers of similarly unhealthy products is a concern when taxing food products. In addition to price, other factors may also impact consumers' substitution decisions, such as caffeine dependence or

whether they are seeking a snack, a sweet, or a thirst quencher. Possible outcomes of a sugary beverage tax include no substitution, substitution with zero calorie beverages, or substitution with caloric food or beverages. . . .

Excise Tax and SNAP

The Supplemental Nutrition Assistance Program (SNAP), formerly known as food stamps, provides money to low income persons to purchase food. There are few limitations on the use of this money; recipients can purchase all packaged food and beverages except alcohol and prepared food, e.g., rotisserie chicken. Recipients do not pay sales tax on food items purchased with SNAP dollars. Instituting an excise tax on sugary beverages, if passed on to consumers by manufacturers as anticipated, would increase the base price of the beverage. Thus, this type of tax would be passed on to SNAP recipients, unlike a sales tax with similar intent.

SNAP recipients purchase more sugary beverages than the general population, [Special Supplemental Nutrition Program for Women, Infants, and Children (WIC)] recipients, and higher income consumers. One study of scanner data estimated that at least 1.7 billion SNAP dollars were used to purchase sugary beverages in 2011. . . . New York City and several states have protested this use of government money and petitioned the United States Department of Agriculture (USDA) to consider piloting a change to the guidelines to remove sugary beverages from eligibility or to revise the nutritional requirements of SNAP purchases. The USDA has rejected these proposals. If it considers this in the future, and effectively reduces sugary beverage consumption, this policy would have had the potential to positively impact public health for the 46.2 million Americans currently receiving SNAP benefits. Excise taxes would also impact SNAP purchases by increasing the price of the product on the shelf, making them an effective tool for dissuading purchase for all consumers.

TAX THE NUTRIENT, CALORIE, OR INGREDIENT

Another policy option is to tax elements of the food: a specific nutrient, such as fat, caloric content, or an ingredient, such as added sugar. . . .

Fat

The world's first fat tax made headlines when instituted by Denmark in 2011. The media reported that Denmark's tax on saturated fat was intended to address diverse issues, including obesity and cardiovascular disease, and to close a budget gap. Saturated fat is, however, often naturally occurring in healthy and unhealthy food, and the tax applied whether or not the taxed product is considered healthy. In November 2012, the Danish government announced it was rescinding the country's fat tax because it was difficult to administer, politically disfavored, and encouraged citizens to cross the border to purchase foods covered by the tax (e.g., specialty cheeses).

Outdated dietary recommendations for the prevention and treatment of cardiovascular disease include advice to replace dietary fat with carbohydrates. Leading scientists have found that this replacement, particularly with refined carbohydrates, can negatively impact cholesterol, lead to insulin resistance, and increase the risk for obesity. One conclusion is clear: fat is not considered to be the primary driver of obes-

ity. Taxing fat to influence obesity outcomes in the United States would not be an advised strategy.

Calories

Enacting a tax based on calorie content is especially problematic from a health standpoint. Not all calories come with the same health benefits or detriments. Specific dietary components can individually impact nutritional health and weight gain. For example, . . . in one study researchers found that nut consumption was inversely related to weight gain while potato chip consumption was positively related despite the fact that one serving of nuts is 170 calories and one serving of potato chips is 160 calories. Also, consider that the Frosty, a frozen dessert product at Wendy's, is fewer calories than any of the restaurant's salads. However, it would be difficult to argue the dessert is the healthier option. . . .

Added Sugar

High consumption of processed carbohydrates, particularly sugary products, is associated with metabolic changes, weight gain, obesity, and diabetes. Research indicates that people with the highest sugar intake have the lowest micronutrient intake. The major source of added sugar in the American diet is derived from commercially sweetened products, including sugary beverages, grain-based desserts, dairy desserts, syrups, candy, and processed cereals for children. . . .

Economists at Iowa State University analyzed the difference among several added sugar taxing strategies, including taxing final products that contain added sugar and taxing sugar as an input at the manufacturer's production side. They found that the second strategy, taxing sugar as an ingredient, would more effectively reduce the demand for added sugar, impose less of a tax on consumers, and lead to the lowest welfare cost. This is because manufactures would substitute or reduce sugar in the production of the final products. . . .

. . .

Taxes are rarely a politically popular strategy. Once enacted, however, they are less vulnerable to legal challenge than direct regulations. The courts have given legislatures wide latitude to enact taxes regardless of their regulatory effects, as evidenced by the Supreme Court's decision to uphold the Affordable Care Act's individual mandate under Congress's taxation power, even though a majority of the Court found that the mandate exceeded Congress's power to regulate interstate commerce directly (see chapter 3). The authority of a particular government actor to impose a tax may be challenged, however. In 2018, for example, the Pennsylvania Supreme Court reviewed a suit by beverage manufacturers, distributors, and retailers arguing that the city of Philadelphia's authority to impose a tax on sugary drinks is preempted by state law. For a discussion of state preemption of local government authority see chapter 5.

In addition to the excise taxes discussed by Carruthers and Pomeranz, exemptions from state and local sales taxes and income tax deductions have hidden effects on the cost of goods and services. For example, most states and local governments exempt groceries from their generally applicable sales taxes, on the ground that they are necessities. Some jurisdictions have removed sugary drinks and candy from the general exemption for groceries as a back-door way of discouraging overconsumption while increasing revenue. Advocates have pushed to allow deductions or exemptions for additional items in recognition of their status as necessities (e.g., tampons, sanitary napkins, over-the-counter drugs and medical supplies) or in an effort to encourage consumption (e.g., gym memberships, sunscreen, insect repellant). Many jurisdictions designate specific days at the end of summer as "tax holidays" to ease the burden of purchasing school supplies and clothing. A few also have designated tax holidays for emergency preparedness items (e.g., weather radios, flashlights), home safety devices (e.g., smoke detectors, carbon monoxide monitors, and fire extinguishers), and energy efficient appliances. Tax holiday supporters often tout their role in stimulating the growth of local businesses in addition to encouraging the purchase of necessary or beneficial goods and services.

Of course, the principal purpose of taxation is to generate revenue to finance government activities. In the next section, we discuss public health financing, which supports the bedrock of basic public services (e.g., water, sanitation, education, and health care services) required to maintain healthy living conditions.

PUBLIC HEALTH FINANCING

Health departments are typically able to fund a small portion of their operations using earmarked funds generated by excise taxes and licensing fees collected from regulated businesses, such as hospitals and food service establishments. For the most part, however, health departments must rely on legislatures to allocate funding from general revenues.

The funds state and local governments allocate to public health vary dramatically depending on revenues, legislative priorities, and governance structure. State and local public health efforts are heavily dependent on federal funding, which also varies geographically. Most federal funding is awarded on a competitive basis, putting the onus on state and local agencies to advocate for their communities' needs. Other

funds are allocated more or less automatically based on population size or the incidence or prevalence of targeted conditions.

Grants to state and local governments make up about 75% of the budget of the U.S. Centers for Disease Control and Prevention (CDC). CDC funding was initially boosted by the ACA's establishment of the Prevention and Public Health Fund, but the new funding gradually became a replacement for—rather than a supplement to—regular appropriations. As a result, Republican proposals to eliminate the Prevention Fund in 2017 put 12% of CDC funding (much of it dedicated to supporting state and local health departments) at risk.

The following excerpt, from a report published annually by a bipartisan non-profit organization, examines trends in public health funding, with variations from state to state.

A FUNDING CRISIS FOR PUBLIC HEALTH AND SAFETY: A STATE-BY-STATE LOOK AT PUBLIC HEALTH FUNDING AND KEY HEALTH FACTS*

Trust for America's Health

A healthy United States is a strong United States. A prepared nation is a safe nation. But persistent underfunding of the country's public health system has left the nation vulnerable. . . . Ongoing federal fiscal austerity, including sequestration, has eroded the nation's ability to adequately prevent disease, respond to extreme weather events, and reduce disparities across communities at the time when the need is growing. At the same time, the nation's life expectancy rates are moving in the wrong direction. . . . [I]nsufficient funding has hampered the ability of the Centers for Disease Control and Prevention (CDC) and state and local health departments to keep pace with . . . new and continuing threats to the health of the American people and to fully fund prevention initiatives—which have been shown to save money and prevent illness and injury. . . . Budget cuts have occurred at all levels of the public health system from the smallest town to the most populous city as well as at the federal level. The country needs a long-term commitment to rebuild the nation's public health capabilities—not just to plug some of the more dangerous gaps but to make sure each community will be prepared, responsive and resilient when the unexpected occurs.

And the American public agrees. A survey of registered voters released in January 2017—conducted by the Trust for America's Health (TFAH)—found that nearly three-quarters (73 percent) of Americans support increasing investments to improve the health of communities. Yet, of the $3.36 trillion spent annually on healthcare in the United States each year, only 3 percent—$255 per person—goes to public health. . . .

* March 2018 Issue Report.

Federal dollars support a wide range of essential public health programs that aim to improve health, prevent diseases and injuries and prepare for potential disasters and major health emergencies. And, approximately 75 percent of CDC's budget is distributed to states, localities and other public and private partners to support services and programs. So when CDC's budget is reduced, the impact is experienced directly at the state and local levels as well. Such federal funding for states is based on a mixture of population-based formula grant programs (often determined by disease rates or other incidence formulas) and a series of competitive grants, where states apply and some states receive funding and others do not, due to insufficient funds. Because of federal funding limitations, many states submit competitive grant applications that are ultimately "approved but unfunded."

In Fiscal Year (FY) 2017, CDC's budget was $7.15 billion ($21.95 per person). Adjusting for inflation, CDC's core budget . . . has been essentially flat for the last decade. Of the roughly 75 percent of CDC funds that go to state and local communities, support ranges from a low of $5.74 per person in Missouri to a high of $114.38 per person in Alaska.

CDC spends $1.1 billion (only $4 per person) each year to prevent chronic diseases. Nearly half of all Americans have at least one chronic disease—most of which are preventable. More than 80 percent of annual healthcare expenditures (about $8,000 per person) is associated with chronic disease treatment. CDC's funding to prevent such illnesses with evidence-based programs have been cut by $66 million since 2015. . . .

State and local public health agencies and community-based organizations rely heavily on federal funding to support their public health activities, including chronic and infectious disease prevention, immunization services and other activities. For instance, according to ASTHO, about half of state public health spending comes directly from federal funds. When the government is operating under a continuing resolution (CR), [a temporary measure designed to avoid a government shutdown while legislators continue to debate the annual budget,] only a portion of the federal funds will be available to the state and local entities. For example, if a CR funds the government for 25 percent of the year, the public health grantee may receive, at most, 25 percent of their grant, and sometimes less. Short-term funding has long-term consequences. This limited funding (with no guarantee of continuation beyond the short-term CR) can cripple state and local public health programs that serve the public. If there are staff vacancies—such as epidemiologists, lab technicians, program coordinators or community health nurses—they are unlikely to be filled since new employees can only be guaranteed a few months of employment. Similarly, with only a portion of the full year funding, public health organizations are unable to purchase a full year of medical or other supplies. For example, it might be advantageous to purchase the majority of flu vaccines at the beginning of the year, but with only a partial percentage of full year funding, a public health department would be unable to purchase all the vaccines needed. . . .

[Almost half of state public health spending comes from federal funds, while one-quarter comes from state general revenue funds, with other state funds, fees, and fines making up the remainder. In FY 2014–15, the most recent year for which data is available, median state funding for public health was $35.77 per person and ranged from a low of $4.10 in Nevada to a high of $158.30 in Hawaii. Every state allocates and

reports its budget in different ways. States also vary widely in the budget details they provide. This makes comparisons across states difficult.]

Overall spending for public health by states has been declining. Based on a TFAH analysis (adjusted for inflation), 31 states made cuts to their public health budgets from FY 2015–2016 to FY 2016–2017. Only 19 states and Washington, D.C. maintained or increased their budgets, making it hard for states to compensate for reduced federal funding. Public health funding is discretionary spending in most states and, therefore, is at high risk for significant cuts during tight fiscal climates. State public health spending is actually lower in 2016–2017 than it was in 2008–2009, as some of the funding cuts that occurred during the Great Recession still have not been fully restored.

[Local public health expenditures from all sources of funding average about $55 per person.] Overall spending at local public health departments has also been decreasing. Since 2008, local health departments (LHDs) have lost 55,590 staff due to layoffs or attrition. In addition, about 25 percent of LHDs reported a lower FY 2016 budget than the previous year, with fewer LHDs reporting an increase in their budget for the current FY as compared to the previous year. While the number of LHDs experiencing budget cuts has decreased in recent years, most departments have not reported an increase in funding. However it is difficult to generalize about local health departments. There are about 2,800 local health departments (LHDs) in the United States. Some rural jurisdictions serve fewer than 1,000 residents, while the New York City Department of Health serves a population of about 8.55 million. Similarly, state and local funding for public health varies dramatically. Not only do various states structure their public health agencies differently[—]some are more centralized than others—but certain states and localities also put a higher priority on public health.

. . .

One reason that public health funding varies from state to state is that state governments have different approaches to tax policy. A state's history and political climate influence the mix of income taxes, property taxes, and sales taxes it collects. If political support for all forms of taxation is low, government services suffer.

CONDITIONAL SPENDING AND THE SOCIAL SAFETY NET

Many public health goals depend on government spending to support research, health education, and basic human needs such as food, housing, and medical care. Additionally, Congress can use its spending power to regulate the behavior of recipients indirectly by imposing conditions on federal funds.

In some cases, spending conditions apply to the use of federal funds only. For example, state and local government agencies and nongovernmental organizations are prohibited from using federal funds to engage in

lobbying. In 2012, Congress expanded the restrictions on advocacy applicable to the Department of Health and Human Services (HHS) and its grantees, clarifying that such funds may not be used to support "any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or Executive order proposed or pending before the Congress or any State government, State legislature or local legislature or legislative body" including "any activity to advocate or promote any proposed, pending or future . . . tax increase, or any proposed, pending, or future requirement or restriction on any legal consumer product, including its sale or marketing, including but not limited to the advocacy or promotion of gun control" (Waters and Vance 2012).

In other cases, Congress's conditions extend beyond how the recipient uses federal funds. For example, the Clean Air Act imposes various requirements on states' receipt of highway funds. If a state fails to submit an adequate implementation plan to achieve federally defined air quality standards or if the Environmental Protection Agency disapproves a state's plan or finds that it is not being implemented, the state may lose federal highway funds. Conditions of this sort must comport with the anti-coercion principle articulated by the Court in *NFIB v. Sebelius,* discussed in chapter 3.

Spending programs that are jointly administered by state and federal agencies may be more politically palatable than programs that are entirely federally run. For example, while Medicare is entirely financed and administered by the federal government (with the help of private contractors), Medicaid is jointly financed and administered by the federal government and the states. Cooperative state-federal programs provide federal oversight and funding while allowing flexibility for state governments to adopt strategies and levels of support that are best suited to each state's political climate and needs.

Conditional spending also allows Congress to influence the behavior of private actors. For example, the Supplemental Nutrition Assistance Program (SNAP, formerly known as Food Stamps) provides federal funding to state governments. Benefits are fully funded by the federal government, while administrative costs are split 50–50 with the state. In return, the state agrees to operate the program pursuant to federal requirements. Among those requirements are various rules that apply to vendors (grocery stores and other retailers who sell food) who participate in the program. In the excerpt that follows, Matthew Swinburne, an attorney with the Network for Public Health Law, describes SNAP reforms aimed at improving access to healthy foods.

PHOTO 8.2. 1918 United States Food Administration poster advertising corn as the "the food of the nation." During World War I, the Food Administration urged homemakers to substitute corn for wheat, in an effort to stabilize wheat prices. In recent years, public health advocates have pointed to generous subsidies for corn growers as a culprit in the ubiquitous presence of corn products that cheaply increase the calorie counts and shelf-life of many processed foods—including high-fructose corn syrup in everything from sodas and yogurts to salad dressings and breads, fillers in beef patties and chicken nuggets.

THE 2014 FARM BILL AND SNAP: IMPROVING THE DIETS OF LOW-INCOME AMERICANS?*

Mathew Swinburne

. . . Unfortunately, we live in a society where eating a healthful diet can be challenging largely because of the food system we have created. . . . From a production standpoint, we incentivize corn and soybeans, the primary ingredients in processed foods, by providing federal subsidies and crop insurance, while depriving farmers who grow fruits and vegetables of equivalent support. These policies are reflected in the fact that only 2 percent of our cropland is used to grow fruits and vegetables, while corn and soybeans account for more than 50 percent. Physical access to healthy food can also be a challenge. The USDA estimates that 23.5 million Americans live in *food deserts,* which are low-income communities without ready access to fresh, healthy, and affordable food. . . . And when fiscal barriers to a healthy diet are erected, they create the potential to broaden the racial disparities in diet-related illnesses . . . because of the simple fact that Hispanic Americans are approximately two and a half times more likely and black Americans almost three times more likely than their white counterparts to live below the poverty line. . . . The Supplemental Nutrition Assistance Program (SNAP) is a federal program that has the potential to affect the direction of our food system. SNAP, formerly known as food stamps, provides approximately 46.5 million low-income Americans with funds to purchase food. . . .

SNAP provides eligible low-income households with a monthly allotment of nutrition benefits to purchase food. These benefits are distributed on an Electronic Benefits Transfer (EBT) card which functions like a debit card. To administer this program the USDA's Food and Nutrition Service partners with state welfare agencies. The federal government provides 100 percent of the benefits funding and has established baseline requirements for numerous aspects of the SNAP program, including household eligibility requirements, benefit calculations, and vendor requirements. Each state is responsible for the administration of SNAP benefits within its jurisdiction. . . . To help minimize the economic burden of administering SNAP, the federal government also provides for 50 percent of the states' administrative costs.

With 46.5 million Americans spending approximately $70 billion dollars in SNAP benefits during 2014, food retailers are eager to participate in this program. . . . However, to access this large pool of customers, retailers must qualify for the program by meeting several federal standards. These standards include an evaluation of a store's food offerings and the business's integrity.

The Farm Bill has its roots in Franklin Delano Roosevelt's New Deal. In 1933, the Agriculture Adjustment Act (AAA) was passed in an effort to help America's struggling farms during the great depression. During this time there was a massive agricultural surplus that had drastically driven down the price of staple crops and products. The AAA provided subsidies for U.S. farmers to stop production of seven basic agricultural commodities: wheat, cotton, corn, hogs, rice, tobacco, and milk. The hope was that this measure would decrease the supply of these goods and as a result drive up staple crop

* 2015. *University of Maryland Law Journal of Race, Religion, Gender & Class* 15 (2): 329–60.

prices. Today, the Farm Bill has become an omnibus piece of legislation with a massive budget. The bill is reauthorized every 5–7 years and typically addresses a wide range of issues including commodity programs, conservation, rural development, crop insurance, and nutrition. Most important for this article, the Farm Bill's nutrition title deals with the reauthorization of the SNAP program and changes to its administration. The most recent Farm Bill, the Agriculture Act of 2014, . . . made two important changes to SNAP that have the potential to improve food security and healthy food access for low-income Americans. The first change is a modification of vendor requirements, which will require SNAP vendors to carry additional healthy options. The second change creates the Food Insecurity Nutrition Incentive (FINI) program, which will support a series of incentive programs, aimed at increasing fruit and vegetable consumption among SNAP beneficiaries. . . .

Vendors must meet specific standards to participate in the SNAP program. One of these standards requires that (1) vendors sell certain varieties of foods in each of the four staple categories, or (2) 50 percent of the store's retail sales must come from the sale of eligible staple foods. The eligible staple food categories include (1) poultry, meat, and fish; (2) bread and cereal; (3) vegetables and fruits; and (4) dairy products. Prior to the 2014 Farm Bill, vendors were required to carry at least three varieties in each of the staple food categories and had to provide perishable options in at least two of the food categories. Now, SNAP vendors must carry at least seven varieties in each of the staple food categories and provide perishable options in at least three of the categories. This change to the vendor standard has two intended outcomes: (1) decrease SNAP fraud by making it harder for unscrupulous vendors to enter the system, and (2) increase access to healthy food options. . . .

The change in vendor stocking requirements will have little effect on large food retailers like supermarkets, super stores, and grocers because these stores already carry a wide variety of the four staple food categories and likely have more than 50 percent of their sales from these items. . . . In theory, [the new stocking] standard could potentially increase healthy food access at [convenience stores and combination grocery/other (CGO) retailers (including drug stores, dollar stores, and general stores), which make up about two-thirds of SNAP retailers, account for about 12 percent of SNAP sales, and are often located] in underserved food deserts. But if SNAP vendors choose to leave the program as a result of the new standard, it will undercut the attempt to increase availability. Many vendors will have to deal with additional costs related to obtaining and stocking the newly required items, which include the expense of the items themselves, time required to secure the items, and durable equipment/refrigeration needed to store perishable goods. There are programs currently in place that help small storeowners transition to healthier food selections. . . . Hopefully, programs like the Healthy Corner Store Initiative [by the Food Trust, a nongovernmental organization that provides assistance with employee training, connections to food distribution channels, and infrastructure changes] will help limit any SNAP vendor attrition due to the new stocking requirement.

SNAP benefits can be spent on almost any food item; therefore, the purchase does not need to be a healthy item or one of the designated staple foods that vendors are required to carry under the new standard. . . . [S]tudies examining how individuals in low-income communities use convenience stores [suggest concerning shopping patterns].

Studies of youth shopping patterns reveal that the most popular purchases are energy-dense and nutrient-poor options including chips, candy, and sugar-sweetened beverages. Among adults, the patterns are similar: unhealthy items are purchased most often. This evidence indicates that shopping behaviors need to be changed—otherwise the new SNAP stocking requirement will simply result in healthy items sitting on the shelf.

Another aspect of low-income (and by extension, SNAP beneficiary) shopping behavior also needs to be examined. Low-income shoppers are acutely price-sensitive in their food shopping because of limited resources. Based on this restriction, these shoppers make complex calculations that address the need to maximize access to sale items from several stores, minimize transportation costs, extend the number of meals per dollar spent, and limit food waste. . . . [F]resh fruits and vegetables are often cut from the shopping list in order to stay on budget. . . . [This price-sensitivity] is exacerbated when dealing with small retailers who cannot offer nutritious items at the same low prices as supermarkets because they lack economies of scale and appropriate distribution networks. If SNAP beneficiaries perceive healthy food items as expensive luxuries at supermarket prices, how will they react to even higher convenience store prices? . . .

Overall, it appears that the new vendor standard is a small step towards improving the diets of SNAP beneficiaries, and additional interventions by public and private partners at all geographic levels—national, state and local—are required to ensure its effectiveness.

In addition to the new vendor standard, the Agriculture Act of 2014 also created the Food Insecurity Nutrition Incentive (FINI) program. FINI is a grant program designed to encourage fruit and vegetable purchases by SNAP beneficiaries through a financial incentive at the point of purchase. . . . These grants are provided to . . . nonprofit organizations, agricultural cooperatives, community health organizations, community-supported agriculture (CSA) programs, farmers' markets, and state, local, or tribal agencies . . . [to] support a diverse array of programs. For example, Heritage Ranch, Inc., in Hawaii received [a] grant to establish a new incentive program called Buy One Fresh/Get One Local. For every dollar a SNAP beneficiary spends on fruits and vegetables, Heritage Ranch will provide them with coupons of equal value that can be used for fresh local produce at participating farmers' markets, grocers, and CSAs. . . .

Despite the growth in SNAP utilization of farmers' markets, ensuring the use of these vendors [by SNAP recipients] is a critical challenge for FINI grantees. While FINI emphasizes use of direct to consumer marketing, there is an opportunity to expand outreach through the development of critical partnerships[, such as with] with health care providers. . . .

With an economic force of 74 billion dollars a year, SNAP has the potential to influence our food system and make healthy eating a reality for low-income Americans. . . . The 2014 Farm Bill and its changes to SNAP attempt to hone the program's focus on healthy food choices. . . . Although the new vendor standard and FINI require additional interventions, they are important catalysts in the evolution of our food system. Ignoring the public health challenge of creating a system that makes healthy food a real option for all Americans will only perpetuate the diet-related illness epidemic and its racial disparities.

• • •

Some state and local lawmakers have pushed for a more coercive approach to improving the nutrition of SNAP recipients. They have sought permission from the U.S. Department of Agriculture, which administers SNAP and other nutrition programs, to prohibit the use of SNAP benefits for sugary drinks or, alternatively, to restrict the use of SNAP benefits to a pre-determined list of healthy foods. Under the Obama administration, USDA repeatedly refused to grant a waiver allowing state or local governments to experiment with these approaches, based on concerns that restrictions would be difficult to administer and stigmatizing, and could put the political future of the SNAP program at risk. Is the paternalistic strategy of restricting SNAP benefits to healthier foods preferable? Or does it deprive families in low-income households from food choices that most others routinely make in life?

Some public health and environmental advocates have sought to reform another aspect of the Farm Bill: agriculture subsidies and crop insurance programs that favor grain and oilseed crops like corn and soy. These subsidies may artificially lower the prices of high-calorie processed foods (many of which contain high-fructose corn syrup) and meat (by subsidizing animal feed).

Unlike Medicare, Medicaid, and Social Security—which are established as *mandatory* spending programs that remain in place unless repealed by Congress, SNAP spending and farm subsidies must be affirmatively reauthorized by Congress on a periodic basis—typically every four years. This periodic reauthorization requirement opens up opportunities for reform that might otherwise succumb to congressional inertia. On the other hand, the reauthorization requirement makes *non-mandatory* spending programs vulnerable to expiration if a reauthorization measure fails to garner majority support within the majority party. In 2017, for example, a Republican-controlled Congress allowed the Children's Health Insurance Program (a non-mandatory spending program to cover children and families whose income levels are a little higher than the cut-offs used for Medicaid eligibility, discussed in more detail below) to expire, putting enrollees at risk until an agreement was reached in early 2018 to fund the program for six more years..

Federal spending has many hidden effects on what we eat, where we live, how we get from place to place, the quality of our environment, and our access to medical care. In the next section, we take a deeper dive into taxation and spending strategies in the health care sector.

TAXATION AND SPENDING TO ENSURE ACCESS TO HEALTH CARE

Few political issues are more contentious than government programs to ensure equitable access to affordable, high-quality health care. Many Affordable Care Act reforms operate through the tax system—including the requirement that individuals who can afford to do so purchase insurance or pay a tax penalty, tax credits to help low- and middle-income families purchase private insurance, and new requirements for tax-exempt hospitals. The ACA also uses spending programs, including the expansion of Medicaid and new federal grants, to support prevention and community health.

Many proposals to replace the Affordable Care Act also rely on taxation and spending strategies, with a preference for offering state governments and individual consumers maximum flexibility. In 2017, after eight years of campaign promises to repeal the ACA, some congressional Republicans proposed replacing the ACA's income-based premium assistance tax credits tied to the cost of health insurance with age-based credits unrelated to the cost of insurance. Others emphasized the benefits of deregulating the private insurance market to allow plans with lower premiums, higher deductibles, and lower coverage limits to proliferate. Coupled with health savings accounts, which allow individuals to accrue tax-free savings to be used for out-of-pocket health care expenses, these reforms would give patients more "skin in the game." When patients must pay for a greater share of health care costs out of their own pockets, they are likely to think twice about overusing medical services. Unfortunately, patients subject to high out-of-pocket charges are more likely to forgo recommended preventive services, seeking care only after their symptoms become unbearable.

A 2017 bill promoted as an ACA-repeal-and-replace plan was primarily devoted to dramatically restructuring federal Medicaid contributions, imposing a per-capita cap on federal spending, rather than covering a percentage of Medicaid spending that varies from state to state. Speaker of the House Paul Ryan had previously proposed converting Medicaid into a block grant program that would give states almost complete flexibility to use federal funds to increase access to health care in whatever way they see fit. Other Ryan proposals include converting Medicare into a system of subsidies for the purchase of private insurance plans sold on state-based exchanges—similar to the system established by the

PHOTO 8.3. A mother shops for fresh produce with her baby. Supplemental Nutrition Assistance Program benefits are redeemable for any food or nonalcoholic beverage product not intended to be consumed on the premises. In contrast, benefits provided through the Women, Infants, and Children (WIC) program are limited to a list of approved foods, including whole-grain bread and cereal products, fruits, vegetables, and low-fat dairy, that meet prescribed nutritional requirements. USDA.

Affordable Care Act. These proposals share an aim: to decrease the federal role in health care regulation by decreasing the proportion of health care costs that would be covered by federal spending over time. Many question, however, whether states, hospitals, long-term care facilities, and families can bear the costs these reforms would shift onto them.

Access to health care—for preventive care, disease management, and treatment of illness and injury—is an important public health goal and the ACA made health care more accessible for middle- and low-income Americans and those with preexisting conditions. The health care sector is also responsible for stewardship of medical resources (such as antimicrobials, which become less effective for everyone if misused) and ensuring community immunity through vaccination. For these reasons, the public health and health care sectors have always been interdependent, but their goals and administration have not always been well integrated.

The ongoing transformation of the health care sector has generated important opportunities to better serve public health goals. The World Health Organization and the Institute of Medicine have long argued for

enhanced integration between the health care and public health systems as a crucial component of health reform. The ACA includes several measures aimed at incorporating community health goals into health care operations. We begin with Sara Rosenbaum's analysis of requirements for tax-exempt hospitals to serve community health needs.

HOSPITALS AS COMMUNITY HUBS: INTEGRATING COMMUNITY BENEFIT SPENDING, COMMUNITY HEALTH NEEDS ASSESSMENT, AND COMMUNITY HEALTH IMPROVEMENT*

Sara Rosenbaum

In recent years growing attention has been paid to the role of hospitals in improving community health, not only providing medical care, but also serving as "health hubs" and as "intermediaries" in integrating health and economic mobility. This interest in promoting a stronger role for hospitals in community-wide health is the result of several developments.

The first development is the increased focus now being placed on social determinants of health. . . . Efforts to improve the social conditions that influence health necessitate a broad range of community actors, and as key institutions anchoring the communities they serve, hospitals emerge as a natural source of collaboration, leadership, and community support for broader health interventions. [For example,] Boston Children's Hospital's child health initiative . . . is aimed at not only treating serious illness but also at comprehensively addressing the underlying factors that affect the health of the city's children.

A second driver of change has been emanating from the health care system itself. Motivated by underlying social and economic conditions, as well as significant shifts in policy, the American health care system has begun to seriously confront a triple-threat situation: the highest per-capita health care spending in the world; relatively poor health outcomes; and significant racial, ethnic, and socioeconomic disparities in health and health care that leave burdened populations and communities vulnerable to preventable mortality and morbidity because of factors unrelated to either the need for services or the ability to benefit from high quality health interventions. This concern about excessive health care spending, poor health outcomes, and measurable disparities has led public and private insurers to place a growing emphasis on payment reforms designed to incentivize better and more efficient performance, such as incentives to reduce unnecessary and avoidable hospital inpatient readmissions. For hospitals serving communities with sizable populations facing health and social risks, achieving reduction in readmissions inevitably requires a focus on the underlying conditions of health, not only at discharge but generally. Similarly, payment reforms designed to foster overall efficiency, such as case payments, global payments, and capitation with opportunity for shared savings, aim to encourage integration of care and greater

* 2016. *Economic Studies at Brookings* 5 (March), www.brookings.edu/~/media/research/files/papers/2016/03/09-hospitals-as-community-hubs-rosenbaum/rosenbaum-pdf-layout-final.pdf.

alignment between medical care and community social services that may alleviate poor health. As hospitals respond to payment incentives that are becoming industry-wide norms, the public health imperative and the business imperative begin to converge.

A third development, which touches the two-thirds of all U.S. hospitals that operate as tax-exempt charitable organizations, is a series of significant shifts in recent years in the underlying legal framework that defines the relationship between hospitals and their communities. It is important to understand these shifts and their interaction because of their implications for hospital efforts to assume a broader presence on issues of upstream health matters, the role of hospitals within their communities, and the issues and challenges that remain.

THE BASIC COMMUNITY BENEFIT OBLIGATION OF TAX-EXEMPT HOSPITALS: ORIGINS AND EVOLUTIONS

Reflecting federal policy dating back to the original enactment of the federal income tax, § 501(c)(3) of the Internal Revenue Code confers tax-exempt status on organizations organized and operated for charitable purposes. The promotion of health is not an explicit charitable purpose under the Code; since 1956 however, the Internal Revenue Service (IRS) has recognized the promotion of health as the type of activity that would qualify as charitable when conducted by institutions that otherwise meet applicable federal requirements. Under IRS standards, the mere fact of a hospital's presence in a community does not confer a community benefit. Instead, hospitals must demonstrate that they are involved in activities recognized by the IRS as benefitting their communities.

Back and Forth on "Community Benefit" Requirements

Originally, in the 1950s, the IRS focused on activities that made the hospital's services accessible to community residents, with provision of charitable care to community residents as the defining hallmark of charitable status. In 1969, however, the IRS eliminated provision of charity care as a necessary precondition to tax-exempt status, adopting instead a more nebulous "community benefit" standard. This standard served to give hospitals broad discretion over what charitable activities they would pursue, such as research, health professions training, or general efforts to promote community health, while also qualifying for federal tax-exempt status. The IRS not only broadened the standard of community benefit to move away from the direct provision of free or discounted care but also provided little in the way of follow-on policy guidance and even less in the way of enforcement actions aimed at individual hospitals.

The early 2000s saw a renewed bipartisan focus, driven by the news coverage of the failure of many tax-exempt hospitals, on the conduct of these hospitals that, despite their poor performance in providing care to the underserved and poor, pursued aggressive and unreasonable billing and collection practices. In the Affordable Care Act (ACA), Congress amended the Internal Revenue Code to ban unreasonable billing and collection practices and added financial assistance for free or reduced cost care as a core requirement of all tax-exempt hospitals. Implementing federal regulations provide substantial guidance that addresses the basic elements of hospitals' financial assistance programs and practices. . . .

Clearer Rules for Community Hospitals

Nearly simultaneously with the ACA reforms, the IRS adopted a comprehensive and more explicit definition of what constitutes recognized hospital community benefit spending activities. This definition is captured in Schedule H, a special reporting document that all hospitals claiming tax-exempt status must file as part of the IRS's Form 990, which covers all charitable organizations.

Under Part I of Schedule H, the term "community benefit" now is defined by and encompasses financial assistance at cost, losses related to participating in Medicaid and other means tested government health programs, health professions education, community benefit operations, research, and a category of services known as "community health improvement." Instructions accompanying Schedule H define community health improvement as "activities or programs subsidized by the health care organization, carried out or supported for the express purpose of improving community health," and specify that such services must not generate inpatient or outpatient revenue, although nominal cost-sharing is permitted.

A New Emphasis on Building Communities

Part II of Schedule H also recognizes—separate and apart from community benefit—certain "community building" activities. These activities include physical improvements and housing, economic development, community support, environmental improvements, workforce development, and other activities that lie outside the basic IRS definition of community benefit. Taken together, these activities can be thought of as focusing much more on the upstream conditions of health rather than on patient services furnished by a hospital (or through grants to community providers) and offered in community locations. . . .

Under IRS policy, hospitals are permitted to count "community building" expenditures as a form of "community health improvement" activities—and thus as a form of community benefit. In order to do so, a hospital must describe "how its community building activities promote the health of the communities it serves." This policy thus effectively opens the door to greater involvement in upstream health activities on the part of tax-exempt hospitals as a form of community benefit spending. If the IRS uses this policy in a wise way, it could lead to nonprofit hospitals playing an increasingly important role in housing, education, and other key elements of a successful neighborhood. . . .

USING THE AFFORDABLE CARE ACT'S COMMUNITY HEALTH NEEDS ASSESSMENT REQUIREMENT

Beyond establishing financial assistance as a minimum obligation of all tax-exempt hospitals, the Affordable Care Act also made periodic community health needs assessments (CHNA) a basic requirement. The CHNA . . . requires nonprofit hospitals to conduct an assessment every three years of the health condition of their local community and produce a plan to address them. . . . In performing needs assessments, a hospital must take "into account input from persons who represent the broad interests of the community served by the hospital facility, including those with special knowledge of or expertise in public health." Assessments must be made "widely available to the public" and must be accompanied by annual "implementation strategies" "adopted" by the

hospital, whose purpose is "to meet the community health needs identified through the needs assessment." . . .

In conducting an assessment a hospital must define the community it serves in ways that do not exclude medically underserved, low income, or minority populations—living in the geographic areas from which the hospital facility draws its patients—because of their reliance on public insurance or their need for financial assistance. . . .

In assessing community health needs, the IRS requires that the hospital's assessment consider not merely the need for health care, but the "requisites for the improvement or maintenance of health status both in the community at large and in particular parts of the community." This must include the need to "prevent illness, to ensure adequate nutrition, or to address social, behavioral and environmental factors that influence health in the community." Needs must be prioritized, and resources for potentially meeting those needs must be identified. In other words, in framing the needs assessment process, the IRS focuses on the social determinants of health, not just health care services. . . .

Hospitals must accompany the community health needs assessment with an implementation strategy. The strategy is perhaps the most crucial portion of the needs assessment process. Unlike needs assessments, the IRS does not require that implementation strategies be made widely available to the public. . . . Hospitals' implementation strategies, however, must be attached to Schedule H or else must be available through a web link. . . .

The CHNA is potentially an important tool to encourage nonprofit hospitals to increase their efforts to work with local institutions to improve community health. But obstacles remain. . . . Although the ACA establishes needs assessment and implementation strategies as basic requirements for all tax-exempt hospitals, the legislation does not draw a legal connection between community benefit spending and the needs assessment and implementation strategy components of the law. But that means, as a legal compliance matter, that it would be permissible for hospitals to devote most or all of their community benefit spending to activities that directly relate to the hospital's own operations (such as financial assistance, Medicaid shortfalls, research, health professions education and training, or community benefit administration), rather than on activities actually identified as high priority community health investment matters as part of CHNA process.

. . .

Rosenbaum proposed that the IRS should redefine "community benefit" to align it more closely with community needs identified through the CHNA process. This approach would give hospitals greater incentive to invest in upstream community-building activities. Her analysis highlights the opportunities and challenges presented by growing integration of the public health and health care systems.

A hospital plays a significant role in its community's economy—as an employer of local residents and consumer of local supplies and services. It also has an economic stake in the health of its community. In addition to the requirements Rosenbaum describes (which apply to non-profit

hospitals), the Emergency Medical Treatment and Labor Act (EMTALA) mandates that all hospitals that operate an emergency department (ED) and accept Medicare payment must provide screening and stabilizing treatment for emergency medical conditions to all patients who present to the ED. If a patient is unable to pay, the hospital must bear the cost of mandated services. EMTALA provides a safety net of last resort to ensure that patients receive emergency care regardless of ability to pay. Hospitals are not required to provide preventive care or disease management services, but they may have an incentive to do so if they wish to avoid more expensive emergency care at a later date.

There are synergies between the health care and public health systems, but the economic interests of hospitals and the various third parties who pay for the vast majority of health care expenses (to which we turn in the excerpt that follows) in the health of the patients they serve do not align perfectly with public health goals. The health care system is traditionally driven by the needs of insured patients over the period of an annual budget, while public health must serve the needs of the entire community—and especially the most vulnerable—over the full life course.

The economic interest of health care providers and third-party payers in the health of the most vulnerable members of a community—for example, uninsured undocumented immigrants who are not eligible for public insurance programs—is attenuated at best. A hospital may be required to provide uncompensated emergency screening and stabilization services to these community members, but preventive care and disease management may be more expensive than occasional rescue care. For example, long-term management of chronic Hepatitis or HIV with medication can be more expensive than providing the rescue care mandated by law when a patient presents to the ED in crisis. Similarly, insurance companies and publicly funded programs like Medicare and Medicaid may be concerned that uncompensated care for uninsured patients increases health care prices for the insured, but these costs are indirect. The fact that an uninsured patient with a poorly managed infectious disease presents a greater risk of transmission to others (a disproportionate number of whom are likely to also be uninsured) is not easily integrated into the economic model of the health care industry.

Additionally, the economic interests of providers and payers tend to be focused on a short time horizon. Managing chronic conditions like diabetes, heart disease, or HIV to prevent complications may save money, but not always during the time period in which the patient is

covered by a specific insurer or resides within a specific hospital's catchment area. A provider or payer may lack economic motivation to provide years of preventive care to a patient who could move to another insurer or hospital by the time their condition would require costly emergency care. Many chronic disease complications will not unfold until a patient is covered by Medicare, at which point the costs are borne by taxpayers as a whole.

Finally, the fragmentary nature of the health care system makes integration with the public health sector challenging. Primary care physicians, specialty physicians, institutional providers, and the plethora of private insurers, self-insuring employers, and public programs operate independently rather than coordinating with one another. Despite this lack of coordination, payers and providers respond to financial incentives embedded in tax policy and reimbursement systems for public insurance programs, which are thus crucial levers for health reform.

In summary, hospitals' and insurers' growing interest in the social determinants of health creates opportunities to further public health goals. Yet, the imperfect match between public health goals and the economic interests of the health care industry demands vigilance.

The excerpts that follow focus on the role of third-party payers in the health care sector—including private insurance companies, employers who self-insure their employees' health care expenses, and public programs like Medicare and Medicaid. Unlike EMTALA, which obligates hospitals to provide care regardless of insurance status, the ACA relies primarily on insurance coverage to secure access to health care. The individual mandate functions as a tax on households that do not obtain qualified insurance even though it would be affordable for them to do so. Congress also included an employer responsibility provision that penalizes large employers who do not provide affordable insurance to their employees. Tax credits are available to subsidize the purchase of private insurance and keep out-of-pocket costs low for low- and middle-income families. Along with expanding enrollment in private insurance plans, the ACA regulates those plans to ensure that they offer adequate coverage and to limit underwriting based on pre-existing conditions and other health-status-related factors.

In addition to subsidizing private insurance, the ACA also expands eligibility for Medicaid, a cooperative-federalism spending program that covers low-income Americans. In the excerpt that follows, Nicole Huberfeld and Jessica Roberts contrast the political rhetoric surround-

PHOTO 8.4. Demonstrators call on Texas lawmakers to accept the ACA's Medicaid expansion at a rally in 2013. In *NFIB v. Sebelius* (see chapter 3), the Supreme Court made Medicaid expansion optional for states. Some Republican governors and state legislatures refused, leaving many residents uninsured and hospitals on the hook for uncompensated care. Photograph courtesy of TexasImpact via Flickr.

ing public financing of Medicaid (which they characterize as *visible* government assistance) with tax subsidies for private insurance (which they describe as *hidden* from public view). They argue that, despite the "myth of self-reliance" that dominates health reform discussions, vulnerability to illness, injury, and aging—and thus dependence on government assistance—is universal.

HEALTH CARE AND THE MYTH OF SELF-RELIANCE*

Nicole Huberfeld and Jessica L. Roberts

. . . Opponents of [the Affordable Care Act (ACA)] Medicaid expansion openly declared that providing health care to the "able-bodied" poor could encourage dependency. . . . In this rhetoric, politicians implicitly employ an ideal of self-reliance, a value long embedded in the American political psyche. . . .

In contrast, hidden government assistance—which is to say, subsidies funneled through the tax system—invites far less of what this Article will call "self-reliance

* 2016. *Boston College Law Review* 57 (1): 1–60.

scrutiny" than visible public assistance. Tax-free employer-provided benefits are rarely discussed as a government subsidy for purchasing health insurance. Likewise, [ACA tax credits to subsidize private insurance premiums for households with incomes between 100% and 400% of the federal poverty line have] garnered far less criticism than Medicaid expansion. In fact, Congress designed the ACA to push most people into private insurance—even when that insurance is highly subsidized by the government—because it seems more politically desirable. . . .

DIVIDED GOVERNMENT ASSISTANCE IN HEALTH CARE

The dividing line between visible public health insurance and hidden subsidies in private health insurance has facilitated a story of self-reliance for people who are in the private market, and that dividing line remains powerful even in the new era of universality in health insurance access and coverage. . . .

Visible Government Assistance

Direct federal funding is the most familiar form of government assistance because it is the most visible. The federal government has created various medical safety net programs since the New Deal, and today every American has a family member, friend, or coworker who benefits from them, particularly Medicare and Medicaid. . . . Combined, Medicare and Medicaid cover 37% of the nation's total population, 43% of the insured population, and represent approximately 35% of national health expenditures. . . .

Medicare is a national social insurance program that covers people aged sixty-five and over and those who are permanently disabled, regardless of their wealth, state of residence, or other status. . . . Medicare has been demonstrably successful in lifting most of our elderly population out of poverty caused by medical expenses. Despite being the closest thing Americans have to the oft-vilified "socialized medicine," Medicare is also politically popular. In fact, Congress intentionally removed medical care for the elderly from welfare-based state control due to effective lobbying by the elderly, who argued that they should not be subject to the whims of states' welfare-oriented programming, which was often financially inconsistent and sometimes punitive in attitude. Medicare thus created a national, universal approach to insuring the elderly by recognizing the commonly shared risk related to vulnerability in old age and creating a program that would respond at a low cost to beneficiaries' medical needs.

Medicare's universal approach does not allow for stigma. In part, this may result from the fact that people must have paid work-related taxes for forty quarters in order to automatically qualify for Medicare Part A at age sixty-five. For all of its universalism, Medicare is still a work-related program. But it also draws on the public's understanding and hope that all of us will become elderly, and none of us want to be impoverished when that day comes. Medicare draws on a principle of solidarity, the polar opposite of stigma, in addition to universality. In its inclusive approach to medical care, Medicare could be viewed as an exceptional program in America's pantheon of health care legislation and policy, which typically has drawn on the American ideal of self-reliance to create limited, non-universal benefits. . . .

In contrast, Congress designed Medicaid to facilitate health care access for specific groups deemed worthy of public assistance. Medicaid was enacted with the same pen stroke as Medicare, but the two programs are structurally and politically dissimilar.

Medicare is administered and funded entirely by the federal government (with the help of regional private contractors), and it is structured as federal spending subject to federal policy. In contrast, Medicaid has been considered a quintessential cooperative federalism program, a joint state-federal endeavor, underwritten and designed by the federal government but administered by each state with some state funding as well as state options to expand the program beyond the federal minimum requirements.

Medicaid differs dramatically from Medicare not only from governance and funding perspectives but also in the principles the program historically embodied. When Congress enacted Medicaid in 1965, the program covered only the "deserving poor," meaning the elderly, disabled, pregnant women, and children. The original Medicaid eligibility rules reflected the Elizabethan notion that only those blameless for their circumstances were worthy of aid. . . . The narrative of dependence as culturally undesirable is so strong, though, that at the same time "deserving" status rendered Medicaid enrollees worthy of redistributive federal assistance, it imposed stigma even beyond that typically attributable to poverty.

Further, states' fiscal policies have facilitated the prejudice Medicaid enrollees have faced. Historic efforts to address poverty through responsive governmental support show that states consistently have underfunded programs designed to assist the poor. In the case of Medicaid, this has meant low funding that leads to below-norm payment rates for providers. Low reimbursement rates have a signaling effect, hinting that states view these patients as not warranting health care providers' full efforts. . . .

[T]he ACA mandated expansion of Medicaid eligibility to all adults under age sixty-five with incomes up to 133% of the federal poverty level (FPL). For the first time, the expansion includes non-disabled, non-elderly, childless adults in Medicaid. The federal government completely funds the expansion through 2017, gradually decreasing the federal match to 90% by 2020 (the "supermatch"). Even when reduced in 2020, the supermatch is greater than the Medicaid funding states have received historically, which is tied to per capita income and ranges from no less than 50% to approximately 78% federal funding on the state dollar. . . . As with past Medicaid amendments, this expansion responded to state inability (or unwillingness) to cover low-income citizens who needed consistent access to health care. . . .

Hidden Government Assistance

[F]ederal tax policy has enabled broad access to health insurance coverage for decades, and for a large portion of the population, albeit indirectly through employer-based health insurance benefits. The hidden nature of tax benefits, in addition to the narrative that people who purchase private insurance are self-reliant, has rendered this form of subsidy for private health insurance less politically charged. . . .

[M]ost private health insurance is obtained as an employment benefit, and employees notoriously do not notice how much they and their employer contribute to their private insurance, let alone how much the federal government subsidizes that insurance through tax breaks. . . .

At the key moment after World War II when other nations were establishing national health care systems, national health insurance in the United States was defeated by a variety of factors, including political and ideological barriers, public ambivalence about appropriate methods for addressing medical expenses, and the American Medical Association's "socialized medicine" bugaboo.

Instead, health insurance as an employment benefit became an American phenomenon, wherein the federal government encourages employers to offer health insurance benefits by deeming them a business expense that is excluded from taxable income. Simultaneously, employees are encouraged to accept this benefit because the value of the health insurance coverage is excluded from taxable income. This subsidy system has been successful from the perspective that a majority of Americans obtain health insurance through their employers (53.9% of the population as of 2013). But this percentage has been decreasing through the last decade or more, in part giving rise to the high levels of uninsurance that precipitated the ACA's enactment.

The Congressional Budget Office (CBO) has called tax subsidies for employment-based health insurance the "largest single tax expenditure by the federal government." As of 2013, the CBO valued this tax subsidy at $248 billion, not including the tax deduction taken by self-employed individuals (valued at about $6 billion). Though rarely discussed as such, this tax subsidy is concrete financial support for access to health care through subsidized private health insurance. Yet when it is raised as part of health reform or other political conversations, rather than expressing concern regarding dependency or entitlement, the tax subsidy tends to be critiqued in terms of moral hazard (insurance overuse), unequal cost burdens (less affordable for lower wage earners), or fostering inefficiency (employers have no special expertise as health care intermediaries).

The ACA builds on the employment-based private health insurance system in a number of ways in an effort to achieve universal insurance coverage. For example, large employers (already highly likely to provide health insurance as an employment benefit) must pay a penalty if they do not offer health insurance at all or if the insurance they offer is unaffordable, and their employees purchase tax-subsidized insurance on an exchange. The ACA further fortifies employment-based insurance, especially for small employers (those with fewer than fifty employees, which are much less likely to offer health insurance benefits), by creating special mechanisms for small businesses to offer affordable health insurance benefits to their employees in small groups, which have historically had to pay higher premiums. These legislative provisions entrenched reliance on the employer-based, private insurance model by requiring certain employment benefits, which was historically deemed voluntary on the part of the employer. Further, the "individual mandate" facilitates this entrenchment by increasing the likelihood that an employee will accept the offered benefit rather than attempt to pocket additional salary.

The ACA also invigorated private health insurance markets by unifying the rules for individual and small group insurance unrelated to employer benefits. Before the ACA, individual health insurance plans were largely unattainable because insurers demanded very high premiums for such plans and the offered benefits were highly variable. The ACA increased access to a private insurance market that was elusive for most Americans by enabling access to individual insurance through health insurance exchanges, which standardize the minimum allowable benefits for Qualified Health Plans. The ACA also leveled the playing field by eliminating common exclusionary practices such as pre-existing condition clauses.

But leveling the playing field would not be enough to facilitate universal coverage without some kind of financial adjustment, as the individual and small group markets historically have been prohibitively expensive for low- and middle-income Americans.

Consequently, the ACA created federal tax subsidies for insurance premiums to everyone earning 100% to 400% of the FPL, or $11,770 to $47,080 for a one-person household. These new tax subsidies for health insurance are estimated to cost $45 billion in 2015 and are projected to increase to $91 billion by 2017 as implementation of the ACA gains momentum through upcoming open enrollment periods. These expenses further expand the hidden government assistance for private health insurance. . . .

Although the continued reliance on (employment-based) private health insurance is consistent with the narrative of American individualism, Congress expressed through the ACA implicit recognition that most low-to-middle income Americans simply cannot afford health insurance, even with the equalizing rules that the ACA imposes on private health insurers. Very few Americans can afford to purchase private health insurance on the open market, and the current subsidy numbers underline this fact. . . . Despite the common public narrative that private health insurance is consistent with American self-reliance, in reality almost everyone purchasing health insurance, whether individually or through an employer, is receiving some kind of federal government subsidy to be able to afford it.

In sum, the American government provides assistance obtaining health insurance coverage in two different ways: through highly visible direct benefits and through hidden tax subsidies. Despite the substantial similarities between the two models, particularly with respect to low-income populations, one has been stigmatized and attacked politically in a way the other has not. With respect to the poor and near-poor, this differentiation has created two perceived classes of individuals: undesirable dependents who rely on Medicaid and workers who deserve assistance in participating in the American dream. . . .

DEBUNKING THE MYTH OF SELF-RELIANCE

[A]ssuming that all individuals are autonomous stagnates reform because people are assumed to get what they deserve. This assumption constrains political power because any effort to change the status quo appears to either limit freedom or engage in redistribution. Alternatively, construing autonomy as a goal for public policy favors efforts to create equal opportunities for all Americans. According to the latter view, independence occurs when a person has access to basic resources allowing participation in both society's benefits and burdens. Lacking necessities, like food, shelter, and clothing, constrains the choices available to an individual. Pursuant to this framework, autonomy is not an assumed state of the human condition but rather an aspiration. Additionally, much like dependency and vulnerability, subsidy is also universal. Because dependency at varying points and to varying extents in our lives is inevitable, reliance on the government for support is likewise inevitable. . . .

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As Huberfeld and Roberts note, although Medicare and Medicaid were founded simultaneously, they are very different programs. Medicare is wholly federally funded and administered (with the help of private contractors who handle reimbursement pursuant to federal rules). Medicaid, however, is a spending program jointly funded and administered by

the federal government and the states. The cooperative federalism structure of the Medicaid program means that eligibility and coverage rules vary considerably from state to state (as highlighted by the refusal of many states to accept the ACA's Medicaid expansion, which the Supreme Court made optional in *NFIB v. Sebelius*). Reimbursement rates for providers also vary from place to place, but are generally much lower than those offered by Medicare or private insurers. Low reimbursement rates mean that Medicaid beneficiaries often struggle to access needed services despite being insured. In the following excerpt, Brietta Clark discusses how Medicaid's status as a spending program constrains opportunities for advocacy on behalf of beneficiaries and health care providers.

MEDICAID ACCESS, RATE SETTING, AND PAYMENT SUITS: HOW THE OBAMA ADMINISTRATION IS UNDERMINING ITS OWN HEALTH REFORM GOALS*

Brietta R. Clark

President Obama has recognized Medicaid as a critical component of ensuring health care access and thus made Medicaid expansion one part of the Affordable Care Act passed in 2010. Creation of the Medicaid program in 1965 has been one of the most important tools for saving lives and helping to fight health disparities due to income gaps and race discrimination. Today Medicaid continues to provide needed health care to our sickest and most vulnerable groups—extending the life of those with chronic conditions, and promoting better health for children, pregnant women, seniors and people with disabilities who otherwise might not be able to access care. While not perfect, it is a critical part of the health care safety net, which is why advocates have been arguing for its expansion for years.

While many laud the recent Medicaid expansion, they are also cautiously optimistic. Health care access for Medicaid beneficiaries depends on providers willing to treat them, yet many providers are severely restricting the number of Medicaid patients they see or are dropping out of the Medicaid program altogether, and the most common reason given is low reimbursement. Hospitals with emergency rooms have fewer options to avoid this problem because they have a duty to screen and stabilize anyone who comes to the emergency room, regardless of insurance status or ability to pay; however, these hospitals may try to limit acceptance of Medicaid patients for nonemergency services or look for other ways to cut expenses such as cutting services, relocating to more affluent communities, or closing, especially in the case of public hospitals.

Thus, existing threats to Medicaid access can be traced to state payment cuts, freezes, or changes in rate-setting methodology that dramatically reduce provider reimbursement, and shift greater financial risk onto health care providers. Payment

* 2012. *Howard Law Journal* 55 (3): 771–853.

rate cuts and freezes, in turn, have resulted from state and local budgetary pressures in difficult economic times, as well as federal pressure to contain Medicaid spending. Indeed, Congress gave the states significant flexibility in rate setting in order to encourage them to experiment with different payment and health delivery models that would reduce cost and deliver care more efficiently. Nonetheless, there are constraints on this flexibility. Congress has made clear, through the Medicaid Act and other legislation, that rates must be adequate to achieve other program goals, such as ensuring timely and equal access to quality care. The Medicaid Act also creates certain procedural requirements that states must follow in order to help ensure compliance—submitting rates for federal approval and giving the public adequate notice and opportunity to comment. In other words, although states have great flexibility in shaping a health care delivery and payment system that is more efficient and economical, they must do so in ways that respect federal access and quality protections.

Since Medicaid's enactment, providers and beneficiaries have brought payment suits challenging state rate cuts and rate-setting methodology as violating these requirements. In some cases, states ignore clear procedural requirements, making cuts without any consideration of access and quality factors. In other instances, the claim is that a state's process is inadequate because it does not consider the information necessary to ensure compliance with federal access and quality requirements. The U.S. Department of Health and Human Services (HHS), through its Centers for Medicaid and Medicare Services (CMS), is charged with oversight of the state rate-setting process. Until very recently, however, HHS has not exercised its rulemaking power to provide guidance to states, providers, or beneficiaries about the rate-setting process and criteria to be used to assess the sufficiency of rates, nor has CMS used its enforcement power to reject state rate cuts that violate federal law. This lack of explicit statutory or regulatory guidance has exacerbated concerns that states are abusing their flexibility to avoid complying with federal law and to implement cuts that jeopardize Medicaid access. This has made state processes and rates vulnerable to legal attack as arbitrary and inadequate.

The fate of Medicaid payment suits as a tool for protecting health care access and quality is uncertain for a number of reasons. First, the Supreme Court is currently considering providers' and beneficiaries' right to challenge state rate cuts in federal court and the level of review courts must apply to state cuts approved by the federal government. Second, the recent Medicaid expansion means that many more people will be eligible for Medicaid and will need providers, further exacerbating access concerns. Finally, despite the Obama Administration's renewed focus on Medicaid access problems and payment suits, it is sending conflicting signals about its commitment to enforce federal access and quality protections. . . .

[I]n some cases the underlying goals of cost and access may trigger legitimate and difficult policy questions that courts want to avoid, [yet] many payment suit cases reveal a different problem: states' abdication of their duties under federal law to consider the explicit statutorily required factors of access and quality, or to do any meaningful assessment of cost, access, and quality factors in rate setting. Such blatant disregard of the law results in cuts that are clearly illegal, as opposed to legal decisions based on difficult policy choices that may have unfortunate effects. . . .

The lack of federal regulatory guidance and administrative oversight in the rate review and approval process has created a regulatory void that enables states to

abuse their flexibility to make arbitrary rate-reductions. When coupled with federal pressure on states to reduce spending, enabling turns to encouragement. Although the Obama administration has gone the furthest so far in providing guidance to the states for rate-setting, its proposed rules continue to give states a great deal of discretion to design the rate-setting process and reviews of Medicaid access. Moreover HHS's recent reviews of state proposals to cut rates cast serious doubt over whether HHS will really be more proactive in its enforcement role than past administrations. Finally, and perhaps most disturbing, the Obama administration recently sided with states in their fight to remove one of the most important and reliable forms of consumer protection Medicaid beneficiaries have—the ability to challenge state illegal cuts and plan changes in federal court. The Obama administration urged the elimination of judicial review of rate setting, even as it entertained federal funding cuts to Medicaid that would shift more cost to the states and thus increase the likelihood of illegal cuts. . . .

The key to the promise of expanded access under Medicaid reform lies with federal regulators' commitment to enforcement of federal protections, but by this measure, the outlook is not very promising. Medicaid payment suits have provided a critical check on state illegality and the federal regulatory void that enables states to ignore federal law. Federal courts acknowledge the importance of deferring to state discretion and federal agency expertise to make policy decisions that require a balancing of cost, access, and quality goals—an essential part of the rate-setting process; but they have also taken seriously their obligation to prevent public law failures that could cause significant harm to Medicaid beneficiaries. The Medicaid expansion and recent regulatory activity by HHS reaffirm the important role that federal courts play in realizing the promise of reform.

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Shortly after Clark's criticism of the Supreme Court's restriction of private suits to enforce Medicaid law was published, the Court revisited the issue in the case excerpted below, further narrowing the options for Medicaid recipients and health care providers seeking to enforce federal Medicaid law against state governments.

*ARMSTRONG V. EXCEPTIONAL CHILD CENTER**

Supreme Court of the United States
Decided March 31, 2015

Justice Scalia delivered the opinion of the Court, except [with regard to the availability of a private right of action derived from § 1983].

We consider whether Medicaid providers can sue to enforce § 30(A) of the Medicaid Act.

Medicaid is a federal program that subsidizes the States' provision of medical services to "families with dependent children and of aged, blind, or disabled individuals,

* 135 S.Ct. 1378.

whose income and resources are insufficient to meet the costs of necessary medical services." 42 U.S.C. § 1396-1. Like other Spending Clause legislation, Medicaid offers the States a bargain: Congress provides federal funds in exchange for the States' agreement to spend them in accordance with congressionally imposed conditions.

In order to qualify for Medicaid funding, the State of Idaho adopted, and the Federal Government approved, a Medicaid "plan," which Idaho administers through its Department of Health and Welfare. Idaho's plan includes "habilitation services"—in-home care for individuals who, "but for the provision of such services, . . . would require the level of care provided in a hospital or a nursing facility or intermediate care facility for the mentally retarded the cost of which could be reimbursed under the State plan." § 1396n(c) and (c)(1). Providers of these services are reimbursed by the Department of Health and Welfare.

Section 30(A) of the Medicaid Act requires Idaho's plan to:

> provide such methods and procedures relating to the utilization of, and the payment for, care and services available under the plan . . . as may be necessary to safeguard against unnecessary utilization of such care and services and to assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area. . . . 42 U.S.C. § 1396a(a)(30)(A).

Respondents are providers of habilitation services to persons covered by Idaho's Medicaid plan. They sued petitioners—two officials in Idaho's Department of Health and Welfare— . . . claiming that Idaho violates § 30(A) by reimbursing providers of habilitation services at rates lower than § 30(A) permits. They asked the court to enjoin petitioners to increase these rates. . . .

The District Court entered summary judgment for the providers, holding that Idaho had not set rates in a manner consistent with § 30(A). The Ninth Circuit affirmed. It said that the providers had "an implied right of action under the Supremacy Clause to seek injunctive relief against the enforcement or implementation of state legislation." We granted certiorari.

The Supremacy Clause, Art. VI, cl. 2, . . . creates a rule of decision: Courts "shall" regard the "Constitution," and all laws "made in Pursuance thereof," as "the supreme Law of the Land." They must not give effect to state laws that conflict with federal laws. It is equally apparent that the Supremacy Clause is not the "source of any federal rights," and certainly does not create a cause of action. It instructs courts what to do when state and federal law clash, but is silent regarding who may enforce federal laws in court, and in what circumstances they may do so.

[In The Federalist No. 33, Alexander] Hamilton wrote that the Supremacy Clause "only declares a truth, which flows immediately and necessarily from the institution of a Federal Government." [This description] would have been grossly inapt if the Clause were understood to give affected parties a constitutional (and hence congressionally unalterable) right to enforce federal laws against the States. And had it been understood to provide such significant private rights against the States, one would expect to

find that mentioned in the preratification historical record, which contained ample discussion of the Supremacy Clause by both supporters and opponents of ratification. We are aware of no such mention, and respondents have not provided any. Its conspicuous absence militates strongly against their position. . . .

If the Supremacy Clause includes a private right of action, then the Constitution *requires* Congress to permit the enforcement of its laws by private actors, significantly curtailing its ability to guide the implementation of federal law. It would be strange indeed to give a clause that makes federal law supreme a reading that *limits* Congress's power to enforce that law, by imposing mandatory private enforcement—a limitation unheard-of with regard to state legislatures. . . .

Respondents contend that our preemption jurisprudence—specifically, the fact that we have regularly considered whether to enjoin the enforcement of state laws that are alleged to violate federal law—demonstrates that the Supremacy Clause creates a cause of action for its violation. They are incorrect. It is true enough that we have long held that federal courts may in some circumstances grant injunctive relief against state officers who are violating, or planning to violate, federal law. But that has been true not only with respect to violations of federal law by state officials, but also with respect to violations of federal law by federal officials. Thus, the Supremacy Clause need not be . . . the explanation. What our cases demonstrate is that, "in a proper case, relief may be given in a court of equity . . . to prevent an injurious act by a public officer."

The ability to sue to enjoin unconstitutional actions by state and federal officers is the creation of courts of equity, and reflects a long history of judicial review of illegal executive action, tracing back to England. It is a judge-made remedy, and we have never held or even suggested that, in its application to state officers, it rests upon an implied right of action contained in the Supremacy Clause. . . .

We turn next to respondents' contention that, quite apart from any cause of action conferred by the Supremacy Clause, this suit can proceed against Idaho in equity.

The power of federal courts of equity to enjoin unlawful executive action is subject to express and implied statutory limitations. "'Courts of equity can no more disregard statutory and constitutional requirements and provisions than can courts of law.'" *I.N.S. v. Pangilinan,* 486 U.S. 875, 883 (1988). In our view the Medicaid Act implicitly precludes private enforcement of § 30(A), and respondents cannot, by invoking our equitable powers, circumvent Congress's exclusion of private enforcement.

Two aspects of § 30(A) establish Congress's "intent to foreclose" equitable relief. First, the sole remedy Congress provided for a State's failure to comply with Medicaid's requirements—for the State's "breach" of the Spending Clause contract—is the withholding of Medicaid funds by the Secretary of Health and Human Services. 42 U.S.C. § 1396c. . . .

The provision for the Secretary's enforcement by withholding funds might not, *by itself,* preclude the availability of equitable relief. But it does so when combined with the judicially unadministrable nature of § 30(A)'s text. It is difficult to imagine a requirement broader and less specific than § 30(A)'s mandate that state plans provide for payments that are "consistent with efficiency, economy, and quality of care," all the while "safeguard[ing] against unnecessary utilization of . . . care and services." Explicitly conferring enforcement of this judgment-laden standard upon the Secretary alone establishes, we think, that Congress "wanted to make the agency remedy that it provided exclusive," thereby achieving "the expertise, uniformity, widespread consultation,

and resulting administrative guidance that can accompany agency decisionmaking," and avoiding "the comparative risk of inconsistent interpretations and misincentives that can arise out of an occasional inappropriate application of the statute in a private action." *Gonzaga Univ. v. Doe,* 536 U.S. 273, 292 (2002) (BREYER, J., concurring in judgment). The sheer complexity associated with enforcing § 30(A), coupled with the express provision of an administrative remedy, § 1396c, shows that the Medicaid Act precludes private enforcement of § 30(A) in the courts.

[Justice Sotomayor's dissent, which Justices Kennedy, Ginsberg, and Kagan joined,] agrees with us that the Supremacy Clause does not provide an implied right of action, and that Congress may displace the equitable relief that is traditionally available to enforce federal law. It disagrees only with our conclusion that such displacement has occurred here.

The dissent insists that, "because Congress is undoubtedly aware of the federal courts' long-established practice of enjoining preempted state action, it should generally be presumed to contemplate such enforcement unless it *affirmatively* manifests a contrary intent." But a "long-established practice" does not justify a rule that denies statutory text its fairest reading. Section 30(A), fairly read in the context of the Medicaid Act, "display[s] a[n] intent to foreclose" the availability of equitable relief. We have no warrant to revise Congress's scheme simply because it did not "affirmatively" preclude the availability of a judge-made action at equity.

Equally unavailing is the dissent's reliance on § 30(A)'s history. Section 30(A) was amended, on December 19, 1989, to include what the dissent calls the "equal access mandate," the requirement that reimbursement rates be "sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area." § 6402(a). There existed at the time another provision, known as the "Boren Amendment," that likewise imposed broad requirements on state Medicaid plans. Lower courts had interpreted the Boren Amendment to be privately enforceable under § 1983. From this, the dissent infers that, when Congress amended § 30(A), it could not "have failed to anticipate" that § 30(A)'s broad language—or at least that of the equal access mandate—would be interpreted as enforceable in a private action. Thus, concludes the dissent, Congress's failure to *expressly* preclude the private enforcement of § 30(A) suggests it intended *not to* preclude private enforcement.

This argument appears to rely on the prior-construction canon; the rule that, when "judicial interpretations have settled the meaning of an existing statutory provision, repetition of the same language in a new statute" is presumed to incorporate that interpretation. But that canon has no application here. . . . When Congress amended § 30(A) in 1989, this Court had already granted certiorari to decide, but had not yet decided, whether the Boren Amendment could be enforced through a § 1983 suit. Our decision permitting a § 1983 action did not issue until June 14, 1990—almost six months after the amendment to § 30(A). The existence of a granted petition for certiorari demonstrates quite clearly that the question whether the Boren Amendment could be privately enforced was unsettled at the time of § 30(A)'s 1989 amendment—so that if Congress was aware of the parallel (which is highly doubtful) the course that awareness would have prompted (if any) would not have been legislative silence but rather express specification of the availability of private enforcement (if that was what Congress intended).

Finally, the dissent speaks as though we leave these plaintiffs with no resort. That is not the case. Their relief must be sought initially through the Secretary rather than through the courts. The dissent's complaint that the sanction available to the Secretary (the cut-off of funding) is too massive to be a realistic source of relief seems to us mistaken. We doubt that the Secretary's notice to a State that its compensation scheme is inadequate will be ignored.

The last possible source of a cause of action for respondents is the Medicaid Act itself. They do not claim that, and rightly so. Section 30(A) lacks the sort of rights-creating language needed to imply a private right of action. *Alexander v. Sandoval,* 532 U.S. 275, 286–87 (2001). It is phrased as a directive to the federal agency charged with approving state Medicaid plans, not as a conferral of the right to sue upon the beneficiaries of the State's decision to participate in Medicaid. The Act says that the "Secretary shall approve any plan which fulfills the conditions specified in subsection (a)," the subsection that includes § 30(A). We have held that such language "reveals no congressional intent to create a private right of action." *Sandoval, supra* at 289. . . .

Spending Clause legislation like Medicaid "is much in the nature of a contract." The notion that respondents have a right to sue derives, perhaps, from the fact that they are beneficiaries of the federal-state Medicaid agreement, and that intended beneficiaries, in modern times at least, can sue to enforce the obligations of private contracting parties. We doubt, to begin with, that providers are intended beneficiaries (as opposed to mere incidental beneficiaries) of the Medicaid agreement, which was concluded for the benefit of the infirm whom the providers were to serve, rather than for the benefit of the providers themselves. More fundamentally, however, the modern jurisprudence permitting intended beneficiaries to sue does not generally apply to contracts between a private party and the government, . . . much less to contracts between two governments. Our precedents establish that a private right of action under federal law is not created by mere implication, but must be "unambiguously conferred," *Gonzaga University v. Doe,* 536 U.S. 273, at 283 (2002). Nothing in the Medicaid Act suggests that Congress meant to change that for the commitments made under § 30(A). . . .

. . .

In *Armstrong* and related cases, the Supreme Court has sharply limited private enforcement of federal Medicaid requirements, leaving recipients and health care providers who depend on the program vulnerable to spotty administrative enforcement by the underfunded Centers for Medicare and Medicaid Services. In 2018, Medicaid recipients sued HHS officials seeking a judicial declaration that HHS's approval of Kentucky's Medicaid plan, which included a waiver to impose a work requirement as a condition on eligibility, violated the federal Medicaid statute. The case will give the federal courts another opportunity to define the role of beneficiaries in enforcing federal Medicaid law. Unlike *Armstrong*, in which private citizens sued the state government, in this case the plaintiffs are asking the court to direct the federal agency to comply with federal statutory requirements.

As discussed above, the political future of Medicaid—and Medicare, which provides coverage to retirees over age 65 and people with disabilities—is also in doubt. Many lawmakers have expressed support for proposals to cap federal spending on Medicaid (by converting it to a block grant program) and Medicare (by converting it to a privatized voucher program). In both cases, the federal savings would come from shifting costs onto individuals, families, health care providers, and state governments.

In 2017, a Republican proposal to phase out the ACA's expansion of Medicaid eligibility and cut the ACA's subsidies for the purchase of private insurance met with political resistance. In addition to repealing key portions of the ACA, the proposal would have restructured Medicaid financing, imposing per-capita limits on federal support. Democrats decried the fact that there would be nearly 25 million more uninsured Americans by 2026 under the proposal. Fiscally conservative Republicans argued that the bill did not go far enough in repealing the ACA. Some Republicans from states where millions of people (as well as hospitals and other health care providers) have benefited from the ACA pointed out that the proposal failed to deliver on President Trump's promise to "cover everyone." The quandary congressional Republicans face as they seek to repeal and replace the ACA illustrates what a thorny issue health reform is and has always been.

Taxation and spending policies reflect government priorities about how resources should be distributed, which activities to encourage, and which to discourage. In this chapter and the ones that precede it, we have described the public health law toolkit, including direct regulation and deregulation (chapter 6), litigation and tort liability (chapter 7), and indirect regulation through taxation and spending. In the next part, we examine public health law within the context of the various silos that are used to organize public health science and practice: surveillance and research (chapter 9), infectious disease control (chapter 10), public health emergencies (chapter 11), noncommunicable disease prevention (chapter 12), and injury and violence prevention (chapter 13).

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PART FOUR

Public Health Law in Context

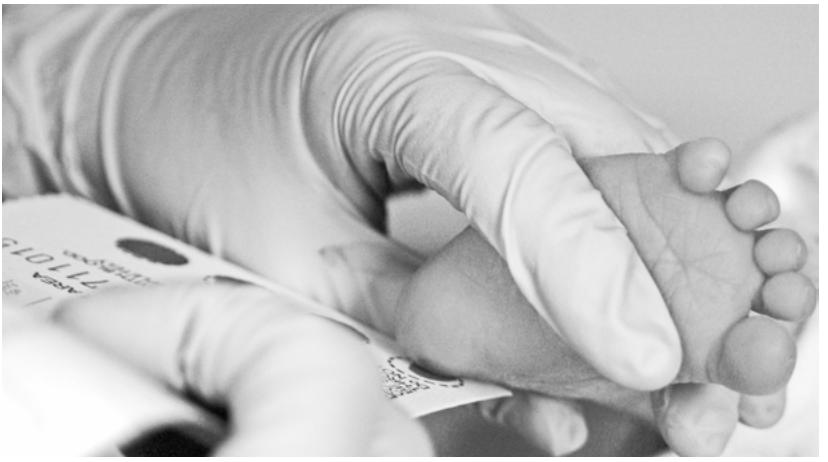

PHOTO 9.1. A newborn is tested for phenylketonuria using dried blood spots. Infants are routinely screened for phenylketonuria (a metabolic disorder that is fatal if untreated) and other serious but treatable genetic conditions. The dried blood spots produced by the testing process are often stored in deidentified form and used for purposes unrelated to the testing for which they were initially collected. The biosamples may be used to calibrate laboratory equipment, validate the accuracy of new screening tests, or for other kinds of research. Photograph by Eric T. Shelter for the U.S. Air Force, 2007.

CHAPTER NINE

Surveillance and Public Health Research

Privacy, Security, and Confidentiality of Personal Health Information

This chapter concerns two functions that form the bedrock of evidence-based public health law and policy: surveillance and research. To achieve collective benefits, public health officials systematically collect, store, use, and disseminate vast amounts of personal information, commonly in electronic form. Public health officials rely on this information to detect and investigate health hazards, understand health problems and develop innovative solutions, and inform, educate, and empower people in matters related to their health. This information is often personally identifiable and sensitive. Data may reveal information about a person's health status (e.g., mental illness, cancer diagnosis, HIV infection), behavior (e.g., sexual practices, gun ownership, or use of drugs, alcohol, or tobacco), and genetics (e.g., test results, family history), in addition to financial information.

Policymakers and judges must strike a difficult balance between individual interests in privacy and the collective benefits produced by public health data collection, use, and sharing. We begin with the rapid evolution of public health surveillance and research in response to new technologies. Next, we discuss the constitutional status of health information privacy. We discuss the two main regulatory frameworks that govern health information privacy at the federal level: the HIPAA Privacy Rule (regulating the use and disclosure of certain health information by certain entities) and the Common Rule (regulating federally funded research on human subjects). Finally, we present a case study of

the legal and ethical challenges presented by research on blood and tissue samples maintained in biobanks.

PUBLIC HEALTH SURVEILLANCE

Public health agencies cannot adequately protect the public unless they have a system of early detection and continuous monitoring of threats. In the absence of a strong public health information infrastructure, communities are vulnerable to diseases and injuries, particularly those that are novel, evolving, or not well understood. Surveillance is thus a fundamental public health activity that yields essential benefits. It also raises serious ethical concerns about privacy and autonomy. In the following excerpt, Michael Stoto describes the evolution of public health surveillance and the tension between public health needs and individual interests in privacy and confidentiality.

PUBLIC HEALTH SURVEILLANCE IN THE TWENTY-FIRST CENTURY: ACHIEVING POPULATION HEALTH GOALS WHILE PROTECTING INDIVIDUALS' PRIVACY AND CONFIDENTIALITY*

Michael A. Stoto

Surveillance, a core function of public health, is defined as "ongoing, systematic collection, analysis, and interpretation of health data essential to the planning, implementation, and evaluation of public health practice, closely integrated with the timely dissemination of these data to those who need to know" (Thacker and Berkelman 1988, 164). . . . [P]ublic health surveillance programs require a careful balance between the development of statistical and epidemiological data and knowledge that are essential to achieving population health goals and the protection of individuals' privacy and confidentiality rights.

Public health surveillance, as it is usually defined, includes two very different activities. *Case surveillance* focuses on individuals, or sometimes small groups of individuals, and serves to identify those with certain diseases and takes action to stop disease spread beyond these identified individuals. Historically, case surveillance has been used for communicable diseases capable of causing great harm to the entire population if allowed to spread. The loss of privacy involved with this type of surveillance has been justified in terms of disease averted. In contrast, *statistical surveillance* uses populations to identify differentials and trends that can inform public health policymaking, including the allocation of resources. Individuals need not be identified for the surveillance to serve its purpose, so data can be gathered either anonymously or with promises of confidentiality, thus not violating privacy rights. . . .

* 2008. *Georgetown Law Journal* 96 (2): 703–20.

Case surveillance and statistical surveillance have different goals and objectives, data sources, and methods. Over time, each approach has resolved the tradeoffs between population benefits and individuals' privacy and confidentiality rights in its own way. In recent years, however, new surveillance programs have been developed that combine, and sometimes confuse, the case and statistical approaches. Individual HIV case reporting, for instance, is advocated as a means of estimating the relative number of cases in different parts of the country in an effort to allocate federal resources. In some parts of the country, individually identified hospital emergency room records are transmitted to health departments, which use them in statistical analyses to detect disease outbreaks and covert bioterrorist attacks. Furthermore, individual case reports are increasingly utilized to monitor obesity, diabetes, and other non-communicable diseases. . . .

HISTORY OF PUBLIC HEALTH SURVEILLANCE

[Case surveillance programs focus] on identifying individuals with infectious diseases and taking action amongst the identified individuals to control disease outbreaks. . . . Control strategies traditionally include monitoring, contact tracing, treatment, and quarantine—indeed, before the development and widespread availability of antibiotics and vaccines in the twentieth century, this is most of what public health and medicine could do. Even after the advent of antibiotics, contact tracing . . . is still a common and effective public health tool. . . .

However, despite its successes, case surveillance may be causing more harm than benefit in some cases. For instance, screening before and during pregnancy and after birth for phenylketonuria, sickle cell disease, neural tube defects, substance abuse, and HIV-infection has been especially problematic. . . .

Over the course of the twentieth century, the primary cause of death shifted from infectious to chronic diseases; as a result the focus of surveillance shifted to populations rather than individuals. Monitoring populations required statistical analysis of data from birth and death certificates, as well as health surveys based on scientifically chosen sample surveys, such as the National Health Interview Survey (NHIS) and Behavioral Risk Factor Surveillance System (BRFSS).

Registries are another source of data for statistical surveillance programs. The National Cancer Institute (NCI) Surveillance, Epidemiology, and End Results (SEER) system, which operates fifteen population-based cancer registries covering approximately 26% of the U.S. population, uses active surveillance methods to record all incident cases of cancer as well as their treatments and outcomes. As a result, NCI is able to estimate cancer incidence and survival rates, something that is not possible for most chronic diseases.

Surveillance of occupational morbidity and mortality—developed in concert with new regulations on workplace safety regulation—and injury surveillance became more common in the 1990s as public health turned its attention to intentional and unintentional violence. A growing focus on health care quality in the early twenty-first century and attendant concerns about medical errors and iatrogenic injuries in recent years have led to intensified surveillance efforts, along with post-marketing surveillance for adverse effects of drugs and vaccines.

NEW APPROACHES TO DISEASE SURVEILLANCE THAT DEMAND A REEVALUATION OF THE BALANCE BETWEEN PROTECTING INDIVIDUALS' RIGHTS AND MAINTAINING THE EFFECTIVENESS OF DISEASE CONTROL PROGRAMS

When case-based surveillance was established as a public health function, the inherent loss of privacy was easily justified in terms of the benefits to those identified and, especially, the population at large. And for statistical approaches to surveillance, individuals' privacy was protected by releasing only aggregate numbers such as averages or proportions, as well as by suppressing small cells—that is, table entries representing fewer than five individuals. Three recent examples, however, have combined both individual and statistical approaches, upsetting the careful balance between the usefulness of the statistical and epidemiological information and the importance of individuals' privacy and confidentiality rights. . . .

HIV Reporting: A Case-Based Approach with a Statistical Purpose

Although it is a communicable disease, AIDS cannot easily be controlled by reporting individuals with HIV infection to health departments. By the time the infection becomes apparent, years may have passed in which the individual has already infected many others. Rather, the primary reason for requiring HIV case reporting is statistical, specifically to prepare estimates of the prevalence of the condition to guide the allocation of federal resources. This example raises two issues. The first issue is whether the loss of privacy involved in reporting someone who has HIV infection to public health authorities is justified by the public health benefits. The second issue is whether the statistical estimates derived from this surveillance system are accurate, and thus effective in achieving public health goals. If not, the justification for the loss of individual privacy is further undermined. . . .

Data from existing HIV case reporting systems . . . are incomplete in several important ways. . . . [T]he HIV reporting system collects data only from persons who choose to be tested and who do so at a non-anonymous testing site (i.e., where the HIV test result is linked with identifying information, including patient and provider names). . . . Because of this selectivity, HIV case reporting by name is unrepresentative of the larger population of infected persons. Further, because reported HIV cases could represent infections that are anywhere from a few weeks to a few years old, the data would reflect the time that individuals chose to be tested rather than when the individual became infected. As a result, HIV case reporting data provide only partial information about HIV prevalence, rather than information about HIV incidence, that is, new HIV infections. . . .

In conclusion, the value of the additional information that reporting individually identified HIV cases might provide either for the individual or in terms of more accurate statistical data or funding allocations is less than some would anticipate. In this context, the loss of privacy and confidentiality in reporting individual HIV cases to health departments may not be justified.

Syndromic Surveillance: Collecting Individual-Level Data to Detect Disease Outbreaks

Heightened awareness of the risks of bioterrorism since the September 11th attacks, coupled with a growing concern about naturally emerging and reemerging diseases

such as West Nile, SARS, and pandemic influenza, have led public health policymakers to realize the need for early warning systems. . . . Responding to this need, many health departments have developed "syndromic surveillance" systems, in which individually identified hospital emergency room records are analyzed statistically to detect possible disease outbreaks and covert bioterrorist attacks.

Syndromic surveillance, however, requires public health agencies to acquire large amounts of routine, individually identified health data before there is any indication of a disease outbreak. . . . The problem is that the legal structures that balance public health requirements with the protection of privacy and confidentiality do not contemplate surveillance systems that can be justified only in retrospect, that is, if they detect an outbreak. . . .

For instance, syndromic surveillance systems assume that during an attack or a disease outbreak, people will first develop symptoms, then stay home from work or school, attempt to self-treat with over-the-counter (OTC) products, and eventually see a physician with nonspecific symptoms, all days before they are formally diagnosed and reported to the health department. To identify such behaviors, syndromic surveillance systems regularly monitor existing data for sudden changes or anomalies that might signal a disease outbreak. Syndromic surveillance systems have been developed to include data on school and work absenteeism, sales of OTC products, calls to nurse hotlines, and counts of hospital emergency room (ER) admissions or reports from primary physicians for certain symptoms or complaints.

The possibility of earlier detection and more rapid response to a bioterrorist event has tremendous intuitive appeal, but there are practical concerns about the use of these systems in state and local public health practice. In statistical terms there is a relatively narrow window between what can be detected in the first few days and what is obvious. . . . Moreover, since the development and implementation of syndromic surveillance systems began in recent years, success in gaining access to personal health data has been mixed. Varying interpretations of the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule are at the heart of the problem. Although some argue that the Privacy Rule permits data owners to disclose protected health information to public health authorities, covered entities cite the rule in refusing to provide data to researchers and health departments. In addition to HIPAA, a variety of federal, state, and local public health laws enable, restrict, and otherwise influence the ability to share data for public health surveillance purposes. Concerns about protecting proprietary data also influence data sharing for public health purposes. . . .

Screening for Diabetes and Obesity: Case Reporting Applied to Non-Communicable Diseases

Although the focus of public health surveillance was originally on infectious diseases, population-level chronic disease surveillance has a long history. The analysis of vital statistics by cause of death was pioneered in the nineteenth century by William Farr in England and Lemuel Shattuck in the United States. And as indicated above, population-based surveys such as the National Health Interview Survey (NHIS) and the Behavioral Risk Factor Surveillance System (BRFSS) and registries such as the NCI's SEER system for cancer surveillance are long established. This sort of surveillance

system provides statistical data for the entire population as well as groups defined by demography, socioeconomic status, geography, and other factors.

Recent developments in chronic disease surveillance, however, have focused on individuals rather than populations. Rather than identifying trends and differentials between increasingly fine-grained populations, screening efforts seek to identify individuals with undetected chronic diseases such as diabetes. The anonymity and confidentiality traditionally used in the collection of statistical data on chronic diseases is no longer possible, raising questions about whether the benefits to the individuals concerned and to public health generally—which depend on the reliability of the screening programs and the interventions that follow—justify the loss of their privacy. . . .

In December 2005, the New York City Board of Health adopted a diabetes surveillance program that includes mandatory reporting of glycosylated hemoglobin to a registry established by the city's Department of Health and Mental Hygiene. Laboratories are required to report glycosylated hemoglobin levels, a measure of the degree to which an individual's diabetes is under control, along with the identity of the patient and the physician who ordered the test. . . .

Other programs attempt to identify individuals with an elevated risk of developing such diseases, such as obese and overweight children. For instance, as a result of a state law passed in 2003, public schools in Arkansas measure students' body mass index (BMI), and on this basis send annual confidential reports to parents of children who are obese or at risk of obesity. . . .

Although well established in theory, empirical evidence about the efficacy of programs that track individuals with diabetes, obesity, and other risk factors is lacking in practice. For instance, an evaluation three years after the Arkansas program began found . . . little evidence [of] changes in diet and activity patterns at home, or obesity levels. . . .

CONCLUSION

Ultimately, surveillance is a double-edged sword. The information from surveillance programs is critically needed to inform and guide public health policy and manage public health programs. However, all surveillance data derive from individuals' personal health information, meaning that their privacy and confidentiality are at risk. Therefore, before a surveillance program is initiated, a careful, case-by-case analysis balancing the benefits of the information for public health purposes and the rights of the individuals who are the subjects of the data is needed.

• • •

Stoto raises a key distinction between case surveillance—also referred to as *screening*—and statistical surveillance. We focus on the legal and ethical issues raised by screening in chapters 10 (infectious disease control), 12 (noncommunicable diseases), and 13 (injuries). In this chapter, we focus on what Stoto refers to as statistical surveillance: the collection and analysis of data for purposes of planning, implementing, and evaluating public health interventions.

Collection and use of aggregated or de-identified data raise fewer ethical or legal concerns. But some public health surveillance and research

programs rely on personally identifiable health information, requiring policymakers, public health lawyers, and judges to carefully balance individual interests in privacy, security, and confidentiality with the need for data-driven responses to public health threats.

PUBLIC HEALTH RESEARCH

Health research techniques are transforming rapidly. Enhanced computing capabilities have enabled increased collection and use of massive datasets. The enormous value of health information for research purposes must be balanced against the privacy of individuals whose data is collected and shared. We begin with an excerpt from an Institute of Medicine report on the importance of information-based health research.

THE VALUE, IMPORTANCE, AND OVERSIGHT OF HEALTH RESEARCH*

Institute of Medicine

. . . [P]rivacy and health research [are] complementary values. Ideally, society should strive to facilitate both for the benefit of individuals as well as the public. . . . Because a great deal of medical research falls under the purview of multiple federal regulations, it is important to understand how the various rules overlap or diverge. . . . [T]he definition of research has become quite complex under the various federal regulations, which make a distinction between research and some closely related health practice activities that also use health data, such as quality improvement initiatives. . . .

CONCEPTS AND VALUE OF HEALTH RESEARCH

Under both the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule and the Common Rule, "research" is defined as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." This is a broad definition that may include biomedical research, epidemiological studies, and health services research, as well as studies of behavioral, social, and economic factors that affect health.

Perhaps the most familiar form of health research is the clinical trial, in which patients volunteer to participate in studies to test the efficacy and safety of new medical interventions. But an increasingly large portion of health research is now information based. A great deal of research entails the analysis of data and biological samples that were initially collected for diagnostic, treatment, or billing purposes, or that were collected as part of other research projects, and are now being used for new research

* 2009. In *Beyond the HIPAA Privacy Rule: Enhancing Privacy, Improving Health through Research,* 111–52. Washington, DC: National Academies Press.

purposes. This secondary use of data is a common research approach in fields such as epidemiology, health services research, and public health research, and includes analysis of patterns of occurrences, determinants, and natural history of disease; evaluation of health care interventions and services; drug safety surveillance; and some genetic and social studies.

The Importance of Health Research

Like privacy, health research has high value to society. It can provide important information about disease trends and risk factors, outcomes of treatment or public health interventions, functional abilities, patterns of care, and health care costs and use. The different approaches to research provide complementary insights. Clinical trials can provide important information about the efficacy and adverse effects of medical interventions by controlling the variables that could impact the results of the study, but feedback from real-world clinical experience is also crucial for comparing and improving the use of drugs, vaccines, medical devices, and diagnostics. For example, Food and Drug Administration (FDA) approval of a drug for a particular indication is based on a series of controlled clinical trials, often with a few hundred to a few thousand patients, but after approval it may be used by millions of people in many different contexts. Therefore, tracking clinical experience with the drug is important for identifying relatively rare adverse effects and for determining the effectiveness in different populations or in various circumstances. It is also vital to record and assess experience in clinical practice in order to develop guidelines for best practices and to ensure high-quality patient care. . . .

The development of Herceptin as a treatment for breast cancer is a prime example of the benefits of research using biological samples and patient records. Many other examples of findings from medical records research have changed the practice of medicine as well. Such research underlies the estimate that tens of thousands of Americans die each year from medical errors in the hospital, and research has provided valuable information for reducing these medical errors by implementing health information technology, such as e-prescribing. This type of research also has documented that disparities in health care and lack of access to care in inner cities and rural areas result in poorer health outcomes. . . . These findings have all informed and influenced policy decisions at the national level. As the use of electronic medical records increases, the pace of this form of research is accelerating, and the opportunities to generate new knowledge about what works in health care are expanding.

Advances in health information technology are enabling a transformation in health research that could facilitate studies that were not feasible in the past, and thus lead to new insights regarding health and disease. As noted by the National Committee on Vital and Health Statistics [in 2007], "Clinically rich information is now more readily available, in a more structured format, and able to be electronically exchanged throughout the health and health care continuum. As a result, the information can be better used for quality improvement, public health, and research, and can significantly contribute to improvements in health and health care for individuals and populations." . . .

Science today is also changing rapidly and becoming more complex, so no single researcher or single site can bring all the expertise to develop and validate medical innovations or to ensure their safety. Thus, efficient sharing of information between institutions has become even more important than in previous eras, when there were fewer new therapies introduced. The expansion of treatment options, as well as the

escalating expense of new therapies, mandates greater scrutiny of true effectiveness, once efficacy has been demonstrated. This requires registries of patient characteristics, outcomes, and adverse events. Large populations are required to facilitate comparison of patient populations and to calculate risk/benefit estimates. . . .

Information-based research, such as research using health information databases has many advantages. It is often faster and less expensive than experimental studies; it can analyze very large sets of data and may detect unexpected phenomena or differences among subpopulations that might not be included in a controlled experimental study; it can often be undertaken when controlled trials are simply not possible for ethical, technical, or other reasons, and it can be used to study effectiveness of a specific test or intervention in clinical practice, rather than just the efficacy as determined by a controlled experimental study. It can also reexamine data accrued in other research studies, such as clinical trials, to answer new questions quickly and inexpensively. However, information-based research does have limitations. Often it has less statistical rigor than controlled clinical studies because it lacks scientific control over the original data collection, quality, and format that prospective experimental research can dictate from the start. In addition to these scientific limitations, because of its relational and often distant physical separation from the data subjects, and the sheer volume of the records involved, obtaining individual consent for the research can be difficult or impossible. . . .

THE CONSTITUTIONAL RIGHT TO INFORMATIONAL PRIVACY

The constitutional status of health information privacy depends heavily on the context in which that information is collected, stored, and used. In the case that follows, the Supreme Court considers several arguments for invalidating government-sponsored programs with purported public health purposes under the Due Process Clause of the Fourteenth Amendment. As discussed in chapter 4, these disputes often turn on the level of scrutiny the Court applies to the government's purpose and the extent to which its actions are likely to further that purpose.

*WHALEN V. ROE**

Supreme Court of the United States
Decided February 22, 1977

Justice Stevens delivered the opinion of the Court.

The constitutional question presented is whether the State of New York may record, in a centralized computer file, the names and addresses of all persons who have obtained, pursuant to a doctor's prescription, certain drugs for which there is both a lawful and an unlawful market. . . .

* 429 U.S. 589.

With an exception for emergencies, the Act requires that all prescriptions for Schedule II drugs [i.e., the most dangerous of the legitimate drugs] be prepared by the physician in triplicate on an official form. The completed form identifies the prescribing physician; the dispensing pharmacy; the drug and dosage; and the name, address, and age of the patient. One copy of the form is retained by the physician, the second by the pharmacist, and the third is forwarded to the New York State Department of Health in Albany. A prescription made on an official form may not exceed a 30-day supply, and may not be refilled.

[The state health department records data from prescription forms] on magnetic tapes for processing by a computer. Thereafter, the forms are returned to the receiving room to be retained in a vault for a five-year period and then destroyed as required by the statute. The receiving room is surrounded by a locked wire fence and protected by an alarm system. The computer tapes containing the prescription data are kept in a locked cabinet. When the tapes are used, the computer is run "off-line," which means that no terminal outside of the computer room can read or record any information. Public disclosure of the identity of patients is expressly prohibited by the statute and by a Department of Health regulation. . . .

A few days before the Act became effective, this litigation was commenced by a group of patients regularly receiving prescriptions for Schedule II drugs, by doctors who prescribe such drugs, and by two associations of physicians. [At trial, a]ppellees offered evidence tending to prove that persons in need of treatment with Schedule II drugs will from time to time decline such treatment because of their fear that the misuse of the computerized data will cause them to be stigmatized as "drug addicts." . . .

[W]e have frequently recognized that individual States have broad latitude in experimenting with possible solutions to problems of vital local concern. The New York statute challenged in this case represents a considered attempt to deal with such a problem. It is manifestly the product of an orderly and rational legislative decision. It was recommended by a specially appointed commission which held extensive hearings on the proposed legislation, and drew on experience with similar programs in other States. There surely was nothing unreasonable in the assumption that the patient-identification requirement might aid in the enforcement of laws designed to minimize the misuse of dangerous drugs. For the requirement could reasonably be expected to have a deterrent effect on potential violators as well as to aid in the detection or investigation of specific instances of apparent abuse. At the very least, it would seem clear that the State's vital interest in controlling the distribution of dangerous drugs would support a decision to experiment with new techniques for control. . . . It follows that the legislature's enactment of the patient-identification requirement was a reasonable exercise of New York's broad police powers. . . .

Appellees contend that the statute invades a constitutionally protected "zone of privacy." The cases sometimes characterized as protecting "privacy" have in fact involved at least two different kinds of interests. One is the individual interest in avoiding disclosure of personal matters, and another is the interest in independence in making certain kinds of important decisions. Appellees argue that both of these interests are impaired by this statute. The mere existence in readily available form of the information about patients' use of Schedule II drugs creates a genuine concern that the information will become publicly known and that it will adversely affect their reputa-

tions. This concern makes some patients reluctant to use, and some doctors reluctant to prescribe, such drugs even when their use is medically indicated. It follows, they argue, that the making of decisions about matters vital to the care of their health is inevitably affected by the statute. Thus, the statute threatens to impair both their interest in the nondisclosure of private information and also their interest in making important decisions independently.

We are persuaded, however, that the New York program does not, on its face, pose a sufficiently grievous threat to either interest to establish a constitutional violation.

Public disclosure of patient information can come about in three ways. Health Department employees may violate the statute by failing, either deliberately or negligently, to maintain proper security. A patient or a doctor may be accused of a violation and the stored data may be offered in evidence in a judicial proceeding. Or, thirdly, a doctor, a pharmacist, or the patient may voluntarily reveal information on a prescription form.

The third possibility existed under the prior law and is entirely unrelated to the existence of the computerized data bank. Neither of the other two possibilities provides a proper ground for attacking the statute as invalid on its face. There is no support in the record, or in the experience of the two States that New York has emulated, for an assumption that the security provisions of the statute will be administered improperly. And the remote possibility that judicial supervision of the evidentiary use of particular items of stored information [when a patient or doctor is accused of a violation] will provide inadequate protection against unwarranted disclosures is surely not a sufficient reason for invalidating the entire patient-identification program.

Even without public disclosure, it is, of course, true that private information must be disclosed to the authorized employees of the New York Department of Health. Such disclosures, however, are not significantly different from those that were required under the prior law. Nor are they meaningfully distinguishable from a host of other unpleasant invasions of privacy that are associated with many facets of health care. Unquestionably, some individuals' concern for their own privacy may lead them to avoid or to postpone needed medical attention. Nevertheless, disclosures of private medical information to doctors, to hospital personnel, to insurance companies, and to public health agencies are often an essential part of modern medical practice even when the disclosure may reflect unfavorably on the character of the patient. Requiring such disclosures to representatives of the State having responsibility for the health of the community . . . does not automatically amount to an impermissible invasion of privacy. . . .

A final word about issues we have not decided. We are not unaware of the threat to privacy implicit in the accumulation of vast amounts of personal information in computerized data banks or other massive government files. The collection of taxes, the distribution of welfare and social security benefits, the supervision of public health, the direction of our Armed Forces, and the enforcement of the criminal laws all require the orderly preservation of great quantities of information, much of which is personal in character and potentially embarrassing or harmful if disclosed. The right to collect and use such data for public purposes is typically accompanied by a concomitant statutory or regulatory duty to avoid unwarranted disclosures. Recognizing that in some circumstances that duty arguably has its roots in the Constitution, nevertheless New York's statutory scheme, and its implementing administrative procedures, evidence a

proper concern with, and protection of, the individual's interest in privacy. We therefore need not, and do not, decide any question which might be presented by the unwarranted disclosure of accumulated private data—whether intentional or unintentional—or by a system that did not contain comparable security provisions. We simply hold that this record does not establish an invasion of any right or liberty protected by the Fourteenth Amendment.

. . .

This foundational case has been read by the lower courts as proclaiming a narrow constitutional right to health information privacy under the substantive due process doctrine (see chapter 4). Ultimately, the Court upheld New York's program while emphasizing the strong security protections employed by the health department.

Whalen v. Roe involved an early prescription drug management program (PDMP), some version of which is now in place in all jurisdictions (see chapter 13). The primary purpose of these programs is interventional—to improve health care providers' and pharmacists' access to information about the patients under their care. The programs may also be accessible by law enforcement officers investigating a patient, pharmacist, or physician. For the purposes of a criminal investigation, law enforcement officers may be required to obtain a warrant or at least an administrative subpoena before accessing PDMP data. In *Oregon Prescription Drug Management Program v. ACLU Foundation of Oregon, Inc.*, 860 F.3d 1228 (9th Cir. 2017), however, a federal Circuit court held that Oregon's PDMP statute, which required a court order before state officials could disclose prescription monitoring information to law enforcement officers, was preempted by the federal Controlled Substances Act. The court held that the state's requirement that federal Drug Enforcement Agents must obtain a court order—and not merely an administrative subpoena as required under the Controlled Substances Act—to access PDMP data interfered with a scheme Congress established for federal investigation of drug crimes and undermined Congress's goal of strengthening law enforcement efforts to control traffic in illicit drugs.

Unlike in *Whalen v. Roe,* the plaintiffs in *Oregon Prescription Drug Management Program* brought Fourth Amendment claims. Fourteenth Amendment substantive due process claims typically turn on whether the individual interest at issue rises to the level of a fundamental right triggering heightened scrutiny. In contrast, the central inquiry under the Fourth Amendment is whether the challenged search violates the challenger's reasonable expectation of privacy. Although the trial court

found that access to PDMP data without a warrant violated the Fourth Amendment in *Oregon Prescription Drug Management Program,* the appellate court declined to reach the merits of that determination claim, based on a finding that the parties raising it lacked standing.

Laws that mandate or authorize collection, storage, and use of data from health care providers (including PDMPs, disease registries, and syndromic surveillance programs) are supported by two Fourth Amendment doctrines. First, the third-party doctrine holds that people have no reasonable expectation of privacy in information they voluntarily give to third parties. Because most surveillance programs involve collection of data from health care providers, laboratories, and pharmacies, the third-party doctrine counsels that the information is not protected from state intrusion. Second, the special needs doctrine holds that a warrant may not be required where special needs, beyond the need for law enforcement, render it impracticable. In *Ferguson v. City of Charleston,* 532 U.S. 67 (2001), the Court held that the special needs doctrine did not justify warrantless drug tests as part of a public hospital's collaboration with law enforcement officials to arrest women who tested positive for cocaine during prenatal care or labor. We discuss this case in chapter 13.

By focusing on whether a person has a "reasonable expectation of privacy," the Fourth Amendment can more flexibly respond to changes in technology, practices, and social norms. At the same time, framing-era practices are also important to resolving Fourth Amendment questions. As you read the excerpt below, consider the ways in which Wendy Mariner relies on each of these considerations to argue that health information privacy may be entitled to greater constitutional protection than the *Whalen* Court afforded.

RECONSIDERING CONSTITUTIONAL PROTECTION FOR HEALTH INFORMATION PRIVACY*

Wendy K. Mariner

Would you agree to allow your physician to give the state health department any of the following information about you personally or your children? A contagious disease, such as tuberculosis, gonorrhea, or HIV[?] A chronic disease, such as a cancer, asthma, or lupus[?] Blood sugar levels[?] Prescriptions for controlled substances[?] Immunizations[?] A newborn child's genetic anomaly[?] The cost of medical care[?] The outcome of medical treatment[?] The answer may be "it depends." Many people may not care at

* 2016. *Journal of Constitutional Law* 18 (3): 975–1054.

all whether the state has any or all of their medical information. For others, the answer depends on why the state needs specific information and what it does with that information. State health and social service departments routinely collect health information in all these categories from physicians, hospitals, laboratories, and pharmacies pursuant to various state reporting laws. They may also give the information, with or without personal identifiers, to federal and international agencies and private researchers. Few of these laws require individual consent to either the collection or the uses of a person's information. Should consent be required for any of these laws? What health information should be freely accessible to government and what should not?

These questions arise in the context of competing trends in the age of Big Data: the increasing social and commercial value of health information, and rising concerns about the loss of privacy. . . .

FRAMING THE QUESTIONS

Both the Universal Declaration of Human Rights and the International Covenant on Civil and Political Rights recognize privacy as a human right. Numerous international and regional conventions also contain privacy protections. In December 2013, amid concerns that surveillance adversely affects human rights, the United Nations General Assembly adopted [a resolution] calling on states to protect privacy both offline and online. . . . Pursuant to the Resolution, the High Commissioner for Human Rights prepared a report *The Right to Privacy in the Digital Age,* [which] was requested primarily in response to antiterrorism surveillance by the NSA and other nations' security agencies, but [its principles are generally applicable]. The Report summarizes basic principles governing the human right to privacy. First, "surveillance measures must not arbitrarily or unlawfully interfere with an individual's privacy, family, home or correspondence." [T]o be reasonable and not arbitrary, "any interference with privacy must be proportional to the end sought and be necessary in the circumstances of any given case." To be necessary, an intrusion on privacy must be "the least intrusive option available." These three concepts—legality, necessity, and proportionality—form the core principles of privacy protection in the human rights framework. . . . The United States Supreme Court is not in the habit of relying on international conventions to interpret constitutional provisions. Nonetheless, one might hear echoes of these principles in Chief Justice John Roberts' approach to evaluating whether police need a warrant to search the cell phone contents of an arrestee in *Riley v. California:* "by assessing, on the one hand, the degree to which it intrudes upon an individual's privacy and, on the other, the degree to which it is needed for the promotion of legitimate governmental interests." . . .

Health information offers a paradigmatic candidate for exploring whether and when U.S. constitutional law should protect privacy. Information about a person's health can be viewed as intensely personal and private, access to which the person has a moral and perhaps legal right to control. It can also be viewed as a valuable commodity that society needs in order to identify criminal suspects, investigate epidemics, calculate budgets, monitor the quality of care, develop social policy, and conduct biomedical and behavioral research. . . . [T]he question explored here is whether the U.S. Constitution may impose any limits on state-compelled collection or use of identifiable personal health information for civil—non-law enforcement—purposes, and if so, when and why.

Broad limits may impede important social advances. However, if health information is not protected at all, can there be protection for other types of information?

Several indicators suggest that now is an opportune time to revisit the parameters of constitutional protection for health information. First, with a financial push from the federal government, health information is being digitized at an increasing rate, while private sector internet services allow individuals to upload and monitor their own health information via multiple devices. All this feeds into Big Data, where predictive analytics can be used to identify higher quality, less costly health care and target individuals or groups for preventive or remedial interventions.

Second, the excitement over Big Data's potential to improve our lives is tempered by concerns that information can be misused to the detriment of many people, especially the disadvantaged. In this era, government agencies, including law enforcement and national security, can often obtain data collected by private entities. Acknowledging such concerns, the Obama Administration proposed new statutory and regulatory measures to protect the privacy of data held by private data custodians, intensifying debate on the extent to which individuals should be able to control access to their personal information. Moreover, members of Congress recently curbed the NSA's bulk data collection and other federal surveillance practices in order to limit privacy intrusions. Most importantly, the Supreme Court's recent Fourth Amendment decisions suggest that a majority of Justices may be considering a more sophisticated approach to determining when government agencies can access digital data. . . .

THE FOURTH AMENDMENT AND THE THIRD PARTY DOCTRINE

We might begin with the presumption that the Fourth Amendment does not apply when government compels an entity to produce another person's health information. In other words, such a search is an exception to the Fourth Amendment. Two lines of cases support this presumption. First, the third-party doctrine has effectively excised information obtained from third parties from Fourth Amendment protection. The third-party doctrine presumes that information held by third parties, like hospitals and health insurers, no longer qualifies as the person's "papers or effects" protected by the Fourth Amendment. Second, the special needs doctrine has created another exception, which has expanded to permit government invasions of privacy for increasingly questionable reasons. Thus, it is not surprising that most observers would assume that the Fourth Amendment does not protect health information to any cognizable degree. However, neither line of cases squarely addresses the question whether government can compel the production of personally identifiable health information for civil purposes. The third-party doctrine developed in the context of criminal procedure—investigations and prosecutions—which is the subject of most Fourth Amendment scholarship. Recent special needs cases have considered suspicionless searches for civil purposes, but such searches were bodily invasions—testing for unlawful drug use—not searches for data. Thus, it is worth reviewing the scope and limits of these doctrines to see whether or how they might apply to laws mandating the reporting of health information and whether there is room for any Fourth Amendment protection. . . .

The U.S. Supreme Court has certainly applied the Fourth Amendment in the civil context. Thus, it cannot be assumed that the Fourth Amendment offers no protection

to personal health information *solely* because the information is sought for purposes other than law enforcement.

Furthermore, demanding information directly from an individual certainly qualifies as a search of the person or his papers or effects. A compulsory reporting law would constitute a search or a seizure under the Fourth Amendment if the requirement were directed at the person whose information is demanded. Of course, health information is typically (although not always) held by a third party, such as a medical provider, a laboratory, an insurer, or (these days) an Internet server. . . .

[The Supreme Court's cases recognizing the third-party doctrine] suggest that a patient who voluntarily gives personal information to a health care provider has no Fourth Amendment claim against any action by government to obtain that information from the provider. After all, the patient has voluntarily provided the information, and the provider is using it in the course of business—treating the patient and billing for treatment.

A closer look at the third-party doctrine line of cases, however, reveals that they rely on facts that differ from mandatory reporting laws in several important respects. . . . [M]andatory reporting laws can be seen as government-compelled, continuous, suspicionless searches of an entire population's data, which [Supreme Court cases on the third-party doctrine] never considered. . . .

The NSA's bulk collection of data offers a contemporary analogy in the criminal context. The NSA relied on [the third party doctrine] to support the constitutionality of its program, but the legality, as well as the wisdom, of that program remains highly controversial. If [the third-party doctrine] is ultimately determined to not . . . justify bulk data collection for purposes of investigating terrorism, the third-party doctrine may prove to be fragile support for bulk data collection for civil purposes, too.

There is a striking similarity between civil surveillance programs and the NSA's bulk collection program. Both § 215 of the Patriot Act and most mandatory reporting laws require the ongoing suspicionless collection of data for future data mining. Yet one federal circuit court of appeals found the NSA's program was not authorized by the Act. Of particular interest is that court's discussion of what is "relevant" to an investigation. The court concluded that the word "relevant" in § 215 referred only to a particular investigation, not to the ongoing collection of all metadata just in case it might prove useful in the future. It found that "such an expansive concept of 'relevance' is unprecedented and unwarranted." *ACLU v. Clapper,* 785 F.3d 787, 812 (2d Cir. 2015).

Mandatory health data reporting laws are based on a similarly expansive concept of relevance. Substitute "medical research" for "criminal investigation," and the court's explanation could describe many health surveillance programs. For example, newborn screening databases are used primarily for research, and [all-payer databases (APDBs), which collect information about health insurance claims,] are used to analyze whether various approaches to health care are cost-effective. In some states, law enforcement can access PDMPs to obtain data about possible illegal drug users or prescribers. Ironically, the NSA collects less specific information about individuals than do health surveillance programs. The NSA collected metadata—only telephone numbers and email addresses—not the content of calls or emails. Surveillance programs collect names, addresses, test results, and a host of other details.

The relevance of the concept of "relevance" in civil surveillance programs lies in the justification for the initial data collection. . . . Data are sought for a reason. Usually data are said to be "needed" for a particular purpose, such as investigating the source

of an outbreak. For databases like PDMPs and ACDBs, however, the stated need is similar to the NSA's claims of relevance to an investigation. Of course, the NSA was looking for terrorists, not epidemics or data for medical research. Could this mean that ongoing data collection for criminal purposes violates a reasonable expectation of privacy, while doing the same for civil purposes does not?

A final difference between the third-party doctrine line of cases and mandatory health reporting laws lies in attitudes towards the information at issue. The third-party doctrine cases conclude that the person whose information is held by a third party has either voluntarily abandoned all control over the information or no longer has any legitimate property interest or reasonable expectation of privacy in the information. Neither of these presumptions completely squares with public attitudes about health information. As to the expectation of privacy, most patients expect that physicians, hospitals and insurers will not disclose identifiable data to the government unless the government has an independently justifiable basis for requiring the disclosure—beyond the mere fact that it exists in a medical record held by a third party. State and federal laws protecting the confidentiality of medical records, from the common law duty of confidentiality to the HIPAA Privacy and Security Rule, support protecting health information from unauthorized disclosure. Such laws reflect societal acceptance that the expectation of privacy is objectively reasonable. . . . As to voluntarily abandoning control over one's information, numerous scholars observe that almost all activities of daily life require people to trust their identifiable information with third parties, such as banks, cable service providers, and retailers. The overwhelming majority of Americans seek health care every year. Individuals have no choice but to allow their health care providers and insurers to hold identifiable information about them—increasingly in digital format.

These features of mandatory reporting laws—ongoing population-wide, suspicionless searches for civil uses and today's practical necessity of giving health information to third parties—contrast significantly with the assumptions underlying the third-party doctrine. The distinctions suggest that there may be room for Fourth Amendment protection of identifiable health data held by health, insurance or internet service providers—at least in some circumstances. . . .

The abandonment/consent rationale has lost most of its credibility in today's interdependent economy. Only those living "off the grid" can avoid providing detailed personal information to accomplish the most basic tasks of daily living. . . . [A]pplying the third-party doctrine to obtain information that a person cannot realistically avoid giving third parties is functionally the same as allowing the government to seize the information directly from the person. The Supreme Court's decisions in *Riley v. California* and *United States v. Jones* suggest some support for this conclusion. Justice Sotomayor, in an often-quoted concurrence in *Jones,* noted:

> [I]t may be necessary to reconsider the premise that an individual has no reasonable expectation of privacy in information voluntarily disclosed to third parties. This approach is ill suited to the digital age, in which people reveal a great deal of information about themselves to third parties in the course of carrying out mundane tasks. . . . I would not assume that all information voluntarily disclosed to some member of the public for a limited purpose is, for that reason alone, disentitled to Fourth Amendment protection.

The unanimous decision in *Riley* took this sentiment to heart, recognizing that digital technology and information pose new challenges to Fourth Amendment doctrines. The Court concluded that the police needed a warrant to search the arrested suspect's smart phone, because the phone's contents could not be considered part of an otherwise permissible warrantless search incident to an arrest.

The opinion described the vast amount of information that can be accessed through a cell phone. . . . Among the sensitive information mentioned is health information:

> [C]ertain types of data are also qualitatively different. An Internet search and browsing history, for example, can be found on an Internet-enabled phone and could reveal an individual's private interests or concerns—perhaps a search for certain symptoms of disease, coupled with frequent visits to WebMD.

Riley makes clear that the government may need some individualized suspicion to search the contents of a person's telephone, which is typically held remotely by third parties: "Our answer to the question of what police must do before searching a cell phone seized incident to an arrest is accordingly simple—get a warrant." . . .

CONCLUSION

[T]he Supreme Court's decisions in [*United States v.*] *Jones* (2012), *Riley* [*v. California*] (2014), and [*Los Angeles v.*] *Patel* (2015) have inspired hope among scholars who argue that the Fourth Amendment should be a more robust source of information privacy protection. Moreover, international reaction to surveillance is encouraging more attention to enforcing the human right of privacy.

Although this shift in outlook has focused on criminal investigations, it has implications for protecting privacy in the civil sphere. It may inspire challenges to a number of civil laws requiring health providers and insurers to report identifiable health information to the state. While the value of many such laws are beyond question, the rationale for their enactment no longer reflects either the specific purposes they serve in contemporary America or a coherent concept of privacy of medical information. A more nuanced approach to doctrine is in order, one that recognizes the reasonableness of expectations of privacy in health information and demands specific justification for compelling its disclosure to government in accordance with the principles governing the human right of privacy. This approach should distinguish important mandatory reporting laws from fishing expeditions, allow essential data collection, and preserve constitutional protection for essential aspects of privacy.

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Mariner argues that the Supreme Court can and should grant health information privacy greater constitutional protection. The enhanced privacy protection she proposes would have profound consequences for public health surveillance and research. Should the conflict between individual and collective interests in health information be resolved by recognizing stronger constitutional protection for privacy, or are there

other, more flexible ways to balance individual interests in privacy (and autonomy) against public health and safety goals?

Most commentators agree that public health surveillance and research programs pass constitutional muster under the Court's current precedents. Nonetheless, several state and federal statutes and regulations provide protection for the privacy, confidentiality, and security of health information, as discussed in the next section.

HEALTH INFORMATION PRIVACY LAWS

A patchwork of state and federal laws protect the privacy, confidentiality, and security of personal health information. Privacy is secured by common law tort doctrines that allow individuals to seek damages and injunctive relief from those who intentionally invade their privacy or breach a recognized duty of confidentiality (see chapter 7). Most states also have statutes governing the collection, storage, use, and disclosure of health information, some of which include a private cause of action for statutory damages to supplement enforcement by administrative agencies. The principal federal law relevant to health information privacy is the Privacy Rule promulgated by the Department of Health and Human Services pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA). HIPAA itself has very little to say about privacy. The statute does, however, include provisions aimed at encouraging adoption of electronic medical records, which raises privacy concerns. As a result, the statute directed HHS to promulgate rules to ensure that entities covered by HIPAA protect the privacy and security of certain health information. The HIPAA Administrative Simplification Rules are enforced by penalties administered by the HHS Office for Civil Rights, but they do not include a private cause of action. Below, we excerpt key provisions of the HIPAA Privacy Rule relevant to research and public health activities.

PRIVACY OF INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION (THE HIPAA PRIVACY RULE)

U.S. Department of Health and Human Services
Office for Civil Rights

45 CFR § 160.103 DEFINITIONS

Except as otherwise provided, the following definitions apply to this subchapter: . . .

Business associate . . . means . . . a person who: (i) On behalf of [a] covered entity . . . creates, receives, maintains, or transmits protected health information for a function or

activity . . . including claims processing or administration, data analysis, processing or administration, utilization review, quality assurance, patient safety activities. . ., billing, benefit management, practice management, and repricing; or . . . [p]rovides . . . legal, actuarial, accounting, consulting, data aggregation. . ., management, administrative, accreditation, or financial services to or for such covered entity . . . where the provision of the service involves the disclosure of protected health information. . . .

Covered entity means: (1) A health plan. (2) A health care clearinghouse. (3) A health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter. . . .

Health information means any information, including genetic information, whether oral or recorded in any form or medium, that: (1) Is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and (2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual. . . .

Protected health information means individually identifiable health information . . . that is: (i) Transmitted by electronic media; (ii) Maintained in electronic media; or (iii) Transmitted or maintained in any other form or medium. . . .

Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

§164.502 USES AND DISCLOSURES OF PROTECTED HEALTH INFORMATION: GENERAL RULES

(a) *Standard.* A covered entity or business associate may not use or disclose protected health information except as permitted or required by [provisions detailed below].

§164.512 USES AND DISCLOSURES FOR WHICH AN AUTHORIZATION OR OPPORTUNITY TO AGREE OR OBJECT IS NOT REQUIRED

A covered entity may use or disclose protected health information without the written authorization of the individual . . . or the opportunity for the individual to agree or object . . . in the situations covered by this section, subject to the applicable requirements of this section. When the covered entity is required by this section to inform the individual of, or when the individual may agree to, a use or disclosure permitted by this section, the covered entity's information and the individual's agreement may be given orally.

(a) *Standard: Uses and disclosures required by law*

(1) A covered entity may use or disclose protected health information to the extent that such use or disclosure is required by law and the use or disclosure complies with and is limited to the relevant requirements of such law. . . .

(b) *Standard: Uses and disclosures for public health activities*

(1) *Permitted uses and disclosures.* A covered entity may use or disclose protected health information for the public health activities and purposes described in this paragraph to:

(i) A public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, including, but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions; or, at the direction of a public health authority, to an official of a foreign government agency that is acting in collaboration with a public health authority;

(ii) A public health authority or other appropriate government authority authorized by law to receive reports of child abuse or neglect;

(iii) A person subject to the jurisdiction of the Food and Drug Administration (FDA) with respect to an FDA-regulated product or activity for which that person has responsibility, for the purpose of activities related to the quality, safety or effectiveness of such FDA-regulated product or activity. . . .

(iv) A person who may have been exposed to a communicable disease or may otherwise be at risk of contracting or spreading a disease or condition, if the covered entity or public health authority is authorized by law to notify such person as necessary in the conduct of a public health intervention or investigation . . .

(h) *Standard: Uses and disclosures for research purposes*

(1) *Permitted uses and disclosures.* A covered entity may use or disclose protected health information for research, regardless of the source of funding of the research, provided that:

(i) *Board approval of a waiver of authorization.* The covered entity obtains documentation that an alteration to or waiver, in whole or in part, of . . . individual authorization . . . for use or disclosure of protected health information has been approved by either:

(A) An Institutional Review Board (IRB), established in accordance with [relevant federal regulations]; or

(B) A privacy board that:

(1) Has members with varying backgrounds and appropriate professional competency as necessary to review the effect of the research protocol on the individual's privacy rights and related interests. . . .

(j) *Standard: Uses and disclosures to avert a serious threat to health or safety*

(1) *Permitted disclosures.* A covered entity may, consistent with applicable law and standards of ethical conduct, use or disclose protected health information, if the covered entity, in good faith, believes the use or disclosure:

(i)(A) Is necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public; and

(B) Is to a person or persons reasonably able to prevent or lessen the threat, including the target of the threat. . . .

. . .

Many privacy advocates have been critical of the HIPAA Privacy Rule. They point to its broad exceptions, its limited applicability, and the fact that it does nothing to regulate the collection of information. In the excerpt that follows, health law scholar Nicolas Terry questions whether

the HIPAA Privacy Rule is up to the challenges posed by massive datasets and increasingly sophisticated data-mining practices.

PROTECTING PATIENT PRIVACY IN THE AGE OF BIG DATA*

Nicolas Terry

. . . Beyond its generalized threat to privacy, big data poses an exceptional group of problems for health care, its providers, researchers, and patients. Rightly or wrongly, policymakers have agreed that patient information is deserving of elevated protection compared to other data (so-called health privacy exceptionalism). Yet, at the same time, the [federal government has] promoted the dramatic growth of electronic medical records (EMR) with the specific goal of increasing the collection of clinical data and its broad sharing. . . .

The ramifications of big data are manifold. . . . This battle has to be fought on three fronts. First, while HIPAA . . . provide[s] increasingly robust protections against unauthorized uses of health information by a relatively narrow set of traditional health care provider data stewards, it does almost nothing to regulate the collection of health data. This is because the HIPAA Privacy Rule is a misnomer. It is not a privacy rule because it only protects against data disclosure not against data collection. It is therefore more appropriately described as a confidentiality rule. In the world of big data this is like bringing the proverbial knife to a gunfight. . . .

Second, the United States has adopted a sector-based approach to data protection. . . . The health care sector and its stakeholders constitute an area considerably larger than the HIPAA-regulated zone. As a result, some traditional health information circulates in what may be termed a HIPAA-free zone. Further, the very concept of health sector specific regulation is flawed because health related or medically inflected data frequently circulates outside of the traditionally recognized health care sector. . . .

[Third,] neither current policy nor regulation provide the key component: a coherent choice architecture for dealing with appropriate patient decision-making regarding research use of personal or familial health data. . . .

BIG DATA AND HEALTH CARE DATA POOLS

Big data is beguiling. Like so many of the phenomena we confront in our information society, it promises benefits for almost no cost. If information can move around freely then transactions lose friction and everyone wins. We accept that transactional friction and related inefficiencies are major barriers to health care improving its woeful cost and quality issues. Add in the broadly expressed sentiment that increased application of information technologies is a potential solution. The almost inevitable conclusion is that health care should join the big data revolution. . . .

But big data is also big business with annual revenues approaching $34 billion. And those who aggregate and mine this data neither view their informational assets as

* 2012. *University of Missouri at Kansas City* 81 (2): 385–416.

public goods held on trust nor seem particularly interested in protecting the privacy of their data subjects. The truth lies in the opposite because the big data business model is selling information about their data subjects. . . .

The Big Data Model

Technically, "big data" refers both to the ability to store and aggregate . . . giant datasets and the availability of increasingly powerful data mining and analysis techniques. As explained by Steve Lohr [in a New York Times article from 2012], "[b]ig data is a shorthand label that typically means applying the tools of artificial intelligence, like machine learning, to vast new troves of data beyond that captured in standard databases."

Data aggregation and customer profiling are hardly news. . . . For example, Facebook sends user data to Datalogix, which matches them to data about customer purchases from stores in an effort to validate Facebook advertising. Similarly, retail operations like Amazon.com and Wal-Mart use sophisticated modeling to recommend purchases based on consumers' prior behavior. This pivot from mere profiling to behavioral tracking is critical. . . .

However, the big data phenomenon goes far beyond the enormity of traditional data pools and super-computer analysis. It also reflects a paradigm shift in data collection. [As described by Alistair in a blog post from 2012,] "In the old, data-is-scarce model, companies had to decide what to collect first, and then collect it," but "[w]ith the new, data-is-abundant model, we collect first and ask questions later."

Health care has two major intersects with big data. First, big data is touted as a way to improve health care, an issue that is explored below. Second, health data is viewed as a major source of big data. As to the latter, big data targets four large health care data pools: (1) drug and device data, (2) clinical data, (3) claims and related financial data, and (4) "patient behavior and sentiment data."

Big data will eventually pull from all four of these pools. However, in the short term, proprietary concerns likely will override any meaningful sharing of drug and device data by manufacturers or claims and related financial data by health care providers. In contrast, clinical data seems to have more of a will to find its way out and be included in big data. For a start, proprietary/commercial interests are likely to bend in the direction of exploitation rather than proprietary curation. Second, there is a powerful "sharing" meme increasingly surrounding clinical data and, whether directly or through function creep, much is destined to leak out.

Although the eventual migration of clinical data into big data is likely inevitable, it is quite a big ask at the moment. First, although privacy advocates view U.S. Department of Health & Human Services' (HHS) meaningful use subsidy program for EMRs as the final nail in the coffin of health privacy, the reality is rather different. Other than in a few vertically integrated health systems, clinical data remains quite fragmented while the current generation of EMRs is woefully limited. This is particularly the case with regard to the execution of tasks such as data sharing with patients or interoperability with the data systems of other providers. Second, EMR "leakage" is a health data risk that is actually covered by regulation. In 2009, HITECH introduced regulatory authority relating to accounting provisions for EMR data and limitations on the commercial exploitation of EMR data.

PHOTO 9.2. A physician reviews electronic medical records with a patient. Electronic recordkeeping has enabled faster, more accurate public health and medical research. It also creates significant concerns about the confidentiality and security of personal health information. Courtesy of Jerry Berger for Beth Israel Deaconess Medical Center.

Ironically, and likely only in the near-term, patients currently are the more likely source of the EMR clinical data that migrates into big data pools. . . . Patients will be encouraged (often by privacy advocates who view this activity as autonomy-satisfying "control") to download their records from HIPAA-protected EMRs. At that point, the patient-curated copy of the data loses its HIPAA protection and may be subject to exposure like other medically inflected data.

Legal Consideration of Big Data

Given its scale and the implications of its practices, the big data industry has managed to keep a relatively low legal profile. Overall, big data is lightly regulated. Only occasionally will an aggregator or broker fall afoul of some specific regulatory requirement, for example by failing to comply with the Fair Credit Reporting Act. Additionally, we have seen the occasional Federal Trade Commission (FTC) case brought against data aggregators who have failed to prevent unauthorized access to sensitive consumer information stored in their databases or data collectors who continued to collect information about consumers who had opted out of such. . . .

REFINING PRIVACY POLICY CHOICES

U.S. law generally has been more willing to make broad pronouncements about limitations on government intrusions into the lives of citizens than to protect them from commercial interests coveting their personal information. . . .

Awareness that the Government may be watching chills associational and expressive freedoms. And the Government's unrestrained power to assemble data that reveal private aspects of identity is susceptible to abuse. . . . Private tracking performed for commercial purposes is no less harmful. . . . Yet, even though the big data industry is creating a private surveillance model that is no less Orwellian than . . . governmental intrusions . . . private law privacy protections have been more modest and increasingly sector-based.

Core Privacy Models

Data protection regulation is not a monolith built around a single protective principle or rule. Rather, it is a multi-layered construct that can be built from a menu of choices, each of which, if legislated, would in some way constrict the movement of "private" data. The basic menu of choices for policymakers contains:

1. Processes or rules designed to reduce the value of data, thus making collection unlikely (or at least harmless). Such can be achieved, for example, by permitting collection of a type of data only if anonymized or by requiring de-identification prior to processing.

2. Rules that place formal limitations on data collection. Examples would include outright prohibitions on the collection of a particular type of data by particular classes of persons such as by the Genetic Information Nondiscrimination Act (GINA) or more amorphous prohibitions on the collection of data other than necessary for the transaction in question.

3. Formal limits on the processing of collected data. For example, the law might impose a restriction on using data for purposes other than those it was collected for or the sale of certain types of data (known as a market inalienability rule).

4. Security requirements specifying physical and technological barriers protecting collected data. Such barriers may be aimed at outsiders who would break into the data or insiders who would otherwise breach rules regarding access to or distribution of data.

5. Regulating or otherwise restricting the disclosure or distribution of collected information. For example, a confidentiality rule that requires certain defined classes of data custodians (such as "covered entities" under HIPAA/HITECH) to restrict access to collected data to specific persons or only to cases where the data subject has authorized the disclosure.

6. Breach notification. In cases where data has been put in jeopardy, such that there is a likelihood of unauthorized disclosure, the data custodian is under a duty to notify the data subject and usually some regulatory body.

. . . [E]xisting sector-based privacy protection of health information tends to pick from the later, less restrictive models [on this list]. HIPAA does have a security rule and . . . breach notification rules. But, notwithstanding the fact that it labels its primary data protection rule as a privacy rule, HIPAA/HITECH primarily relies on a confidentiality model.

HIPAA's confidentiality model has been much criticized. Further, much of its HITECH amelioration involved the adoption of breach notification, a relatively weak privacy model suggesting that the regulators are moving in the wrong direction. Nevertheless, as it exists today incorporating its HITECH tweaks and reflecting more serious enforcement, the HIPAA privacy rule is quite a powerful confidentiality rule. The

problem is that in the face of big data, even a good rule policing disclosures likely will prove insufficient. . . .

CONCLUSION

As EMRs and other HIT initiatives continue to generate vast pools of patient data and data analysis is hyped as the savior of health care, the necessity for a reformed privacy model will increase.

There has been a positive spirit of bipartisanship about HIT and health privacy over the past few administrations and the privacy of health information continues to be broadly embraced by a diverse group of stakeholders. . . . The imminent data takeover requires bipartisan reaction and urgent legislative action that will truly protect patients and their personal health information in the age of big data.

. . .

Terry discusses the importance of personal health information to researchers who use data to track trends, generate knowledge, and further the development and evaluation of health care and public health interventions. The HIPAA Privacy Rule's exception for research purposes relies on oversight by an institutional review board (IRB) or HIPAA privacy board. The framework governing IRBs was established in the National Research Act of 1974 and the Belmont Report drafted by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in 1979. These developments prompted HHS and the Food and Drug Administration to revise and harmonize regulations governing research involving human subjects. The Common Rule, excerpted below, was initially adopted in 1991 by 15 separate departments and agencies. A major revision was finalized in 2017 in the last days of the Obama administration. Identical text is codified in the various chapters of the Code of Federal Regulations applicable to the relevant agencies.

FEDERAL POLICY FOR PROTECTION OF HUMAN SUBJECTS (THE COMMON RULE)

U.S. Department of Health and Human Services

45 CFR §46.101 TO WHAT DOES THIS POLICY APPLY?

(a) Except as provided in [§46.104], this policy applies to all research involving human subjects conducted, supported, or otherwise subject to regulation by any federal department or agency which takes appropriate administrative action to make the policy applicable to such research. This includes research conducted by Federal civilian employees or military personnel. . . . It also includes research conducted, supported, or otherwise subject to regulation by the federal government outside the United States. . . .

§46.102 DEFINITIONS FOR THE PURPOSE OF THIS POLICY

. . . (e)(1) *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research:

(i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or

(ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. . . .

(4) *Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (for example, a medical record).

(5) *Identifiable private information* is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

(6) *An identifiable biospecimen* is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen. . . .

(l) *Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. . . .

§46.104 EXEMPT RESEARCH

(a) Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the [following categories] are exempt from this policy: . . .

(d)(4) Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(i) The identifiable private information or identifiable biospecimens are publicly available.

(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under [the HIPAA Privacy Rule]. . . .

§46.107 IRB MEMBERSHIP

(a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members (professional competence), and the diversity of the members, including race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and

welfare of human subjects. The IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments (including policies and resources) and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a category of subjects that is vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these categories of subjects.

(b) Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas. . . .

(d) No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB. . . .

§46.109 IRB REVIEW OF RESEARCH

(a) An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy. . . .

(b) An IRB shall require that information given to subjects (or legally authorized representatives, when appropriate) as part of informed consent is in accordance with §46.116. The IRB may require that information, in addition to that specifically mentioned in §46.116, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects. . . .

§46.111 CRITERIA FOR IRB APPROVAL OF RESEARCH

(a) In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

(1) Risks to subjects are minimized. . . .

(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. . . .

(3) Selection of subjects is equitable. . . .

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116. . . .

(7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects. . . .

§46.116 GENERAL REQUIREMENTS FOR INFORMED CONSENT

. . . (a)(1)Before involving a human subject in research covered by this policy, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative.

(2) An investigator shall seek such consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.

(3) The information that is given to the subject or the representative shall be in language understandable to the subject or the legally authorized representative.

(4) The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.

(5) Excerpt for broad consent obtained in accordance with paragraph (d) of this section:

(i) Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. . . .

(6) No informed consent may include any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

(b) *Basic elements of informed consent*. . . . [I]n seeking informed consent the following information shall be provided to each subject or the legally authorized representative:

. . .

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained. . . .

(d). . . . Broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens (collected for either research studies other than the proposed research or nonresearch purposes) is permitted as an alternative to the informed consent requirements in paragraphs (b) and (c) of this section. . . . [T]he following shall be provided to each subject or the subject's legally authorized representative [if asked to provide broad consent]:

(1) [A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained]; . . .

(2) A general description of the types of research that may be conducted with identifiable private information or identifiable biospecimens. This description must include sufficient information such that a reasonable person would expect that the broad consent would permit the types of research conducted;

(3) A description of the identifiable private information or identifiable biospecimens that might be used in research, whether sharing of identifiable private information or identifiable biospecimens might occur, and the types of institutions or researchers

that might conduct research with the identifiable private information or identifiable biospecimens;

(4) A description of the period of time that the identifiable private information or identifiable biospecimens may be stored and maintained (which period of time could be indefinite), and a description of the time that the identifiable private information or identifiable biospecimens may be used for research purposes (which period of time could be indefinite);

(5) Unless the subject or legally authorized representative will be provided details about specific research studies, a statement that they will not be informed of the details of any specific research studies that might be conducted using the subject's identifiable private information or identifiable biospecimens, including the purposes of the research, and that they might have chosen not to consent to some of those specific research studies;

(6) Unless it is known that clinically relevant research results, including individual research results, will be disclosed to the subject in all circumstances, a statement that such results may not be disclosed to the subject. . . .

. . .

The 2017 revisions to the Common Rule that appear in the excerpt above allow for broad consent when biological specimens are collected and stored for unspecified future research uses. We will return to this issue in our case study on biobanking below.

The Common Rule and provisions of the HIPAA Privacy Rule that govern research generally require the consent of human subjects or waiver of the consent requirement by an IRB or Privacy Board. In contrast, the HIPAA Privacy Rule and other state and federal laws governing public health practice activities such as screening and surveillance do not require consent. As a consequence, the distinctions between public health research and public health practice are crucial to assessing potential legal and ethical concerns. In 2010, the U.S. Centers for Disease Control issued the policy excerpted below to guide "CDC activities and CDC-supported activities carried out by state and local health departments and other institutions that conduct collaborative research with CDC."

DISTINGUISHING PUBLIC HEALTH RESEARCH AND PUBLIC HEALTH NONRESEARCH*

U.S. Centers for Disease Control and Prevention

. . . The practice of public health poses several challenges in implementing 45 CFR part 46 [The Common Rule]. Some public health activities can unambiguously be classified

* U.S. Centers for Disease Control and Prevention (2010).

as either research or nonresearch. For other activities the classification is more difficult, because 45 CFR part 46 does not directly address many public health activities. In addition, the statutory authority of state and local health departments to conduct public health activities using methods similar to those used by researchers is not recognized in the regulations. Appropriate protections applicable for activities occurring at the boundary between public health nonresearch and public health research are not readily interpretable from the regulations.

The regulations state that "research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." Obtaining and analyzing data are essential to the usual practice of public health. For many public health practice activities, data are systematically collected and analyzed. Scientific methods are used in both public health research as well as public health practice activities. Knowledge is generated in both cases. Furthermore, the extent to which knowledge is generalizable might not differ greatly in research and nonresearch. Thus, nonresearch and research activities cannot be easily defined by the methods they employ. Three public health activities—surveillance, emergency response, and evaluation—are particularly susceptible to the quandary over whether the activity is research or nonresearch.

The word "designed" in the regulatory definition of research is key for classifying public health activities as either research or nonresearch. The major difference between research and nonresearch lies in the purpose of the activity. The purpose of research is to generate or contribute to generalizable knowledge. The purpose of nonresearch in public health is to prevent or control disease or injury and improve health, or to improve a public health program or service. Knowledge might be gained in any public health endeavor designed to prevent disease or injury or to improve a program or service. In some cases, that knowledge might be generalizable, but the purpose of the endeavor is to benefit clients participating in a public health program or a population by controlling a health problem in the population from which the information is gathered. Classifying an activity as research does not automatically lead to review by an institutional review board (IRB) for the protection of human research participants. Once an activity is classified as research, three additional determinations must be made: 1. Is the activity research involving human participants? 2. If the activity is nonexempt research involving human participants, which institutions are engaged in research and are required to certify IRB approval? 3. If the activity is research involving human participants, does the research meet the criteria for exemption from 45 CFR part 46?

POLICY

Some surveillance projects, emergency responses, and evaluations are research involving human participants; others are not. Each project must be reviewed on a case-by case basis. Although general guidance can be provided to assist in classifying these activities as either research or nonresearch, no one criterion can be applied universally. The ultimate decision regarding classification lies in the purpose of the project. If the purpose is to develop or contribute to generalizable knowledge, the project is research. If the purpose is to prevent or control disease or injury or to improve a public health program, and no research is intended at the present time, the project is

nonresearch. If the purpose changes to developing or contributing to generalizable knowledge, then the project becomes research.

GUIDELINES FOR COMPLIANCE

General Attributes of Public Health Research

The purpose of the activity is to develop or contribute to generalizable knowledge to improve public health practice; intended benefits of the project can include study participants, but always extend beyond the study participants, usually to society; and data collected exceed requirements for care of the study participants or extend beyond the scope of the activity. Generalizable knowledge means new information that has relevance beyond the population or program from which it was collected, or information that is added to the scientific literature. Knowledge that can be generalized is collected under systematic procedures that reduce bias, allowing the knowledge to be applied to populations and settings different from the ones from which it was collected. Generalizable, for purposes of implementing the definition of research, does not refer to the statistical concept of population estimation, or sampling, which is collecting information from selected individuals in order to understand health in the population from which the sample came. Holding public health activities to a standard of studying every case in order to classify an activity as nonresearch is not practical or reasonable, nor is it necessary for nonresearch activities.

General Attributes of Nonresearch

The purpose of the activity is to identify and control a health problem or improve a public health program or service; intended benefits of the project are primarily or exclusively for the participants (or clients) or the participants' community; data collected are needed to assess or improve the program or service, the health of the participants or the participants' community; knowledge that is generated does not extend beyond the scope of the activity; and project activities are not experimental.

Other attributes, such as publication of findings, statutory authority. . ., methodological design, selection of participants, and hypothesis testing or generating, do not differentiate research from nonresearch, because these types of attributes can be shared by both research and nonresearch activities.

A nonresearch activity can develop or contribute to generalizable knowledge after the project is undertaken even though generating this knowledge was not part of the original purpose. In this case, because the purpose was not to develop or contribute to generalizable knowledge, the project is not classified as research at the outset. However, if subsequent analysis of identifiable private information is undertaken to develop or contribute to generalizable knowledge, the analysis constitutes human research that now requires further consideration under 45 CFR part 46.

If a project includes multiple components and at least one of those components is designed to develop or contribute to generalizable knowledge, then the entire project is classified as research unless the components are separable.

• • •

As the CDC's policy indicates, distinguishing public health practice from research is crucial because surveillance and other non-research activities generally do not require authorization from individual patients. Obtaining consent from each individual whose information is collected and shared as part of disease control efforts would be impractical and inconsistent with the obligation to protect the populace. Requiring patient authorization for public health surveillance activities would increase costs, delay policymakers' and regulators' access to crucial information, and result in partial data inadequate for public health needs.

For research, some have called for an expansion of consent requirements, while others have suggested that alternatives, such as participation agreements, should take the place of traditional informed consent in some cases. In 2015, HHS issued a notice of proposed rulemaking seeking public comment on proposed changes to the Common Rule. The proposal included a provision that would have required informed consent for secondary research on stored biospecimens (e.g., blood samples left over after clinical tests are run) even in cases where the researcher is not given any identifying information about the individual from whom the sample was taken. Many public health and academic organizations opposed the proposed change, arguing that additional hurdles would slow the progress of research without meaningfully adding to privacy protections. It was ultimately dropped from the final rule, which was published in 2017.

Traditionally, surveillance and research using de-identified or aggregated data have been considered to raise few ethical or legal concerns. Increasingly, however, patient advocates object to the use of de-identified biological samples and health information, expressing distrust of de-identification as a privacy safeguard. Their position also appears to be based on concerns that extend beyond privacy. For example, some patients advocate for property rights to control the use of their biological samples and share in any profits or other benefits. In the next section, we explore these issues through a case study on newborn dried blood spots.

CASE STUDY: BIOBANK RESEARCH AND SURVEILLANCE

Blood and tissue samples are routinely collected by health care workers to diagnose and monitor patients and screen populations for disorders. In some cases, these samples are maintained in biobanks after medical

testing is complete. New research tools have enabled research and surveillance using biospecimens that could hardly have been anticipated at the time the samples were collected. How should autonomy and privacy be balanced against the potential value of such research? Should researchers be required to contact individuals whose tissues were collected years or decades ago and obtain consent? When researchers collect new samples for biobanking, is a blanket consent agreement covering broadly defined uses in the future adequate to protect individual interests in privacy and autonomy? How can an individual be adequately informed about risks that cannot be anticipated at the time a sample is collected? Should biospecimens be considered de-identified so long as information about the individual is not stored with the specimen? Are samples that contain genetic material truly capable of being de-identified?

In the opinion excerpted below, a court grapples with the tension between patient autonomy and the value of information in a case concerning the storage and use of dried blood spots (DBS) collected for the purposes of newborn screening. Since the mid-twentieth century, health officials in many countries have mandated the collection of small amounts of blood from newborns (typically obtained via heel prick at two to nine days old) to test for the presence of potentially fatal but treatable metabolic disorders. Traditionally, de-identified samples were also used for limited research and validation purposes, primarily associated with developing new testing techniques for screening newborns. Over time, however, researchers began conducting other kinds of surveillance and research using DBS samples. For example, DBS samples contain maternal antibodies that can be used to monitor the prevalence of certain infections among women of childbearing years. When privacy advocates raised awareness among parents that health officials were maintaining vast biobanks covering virtually everyone born in their jurisdiction and (in some cases) selling access to the samples to researchers, some took legal action.

*BEARDER V. STATE**

Supreme Court of Minnesota
Decided November 16, 2011

At issue in this case is the interplay between [Minnesota's] newborn screening statutes and . . . Genetic Privacy Act. . . . Appellants are nine families with twenty-five children,

* 806 N.W.2d 766.

born between 1998 and 2008, whose blood was sampled and tested for heritable and congenital disorders as part of the State's newborn screening program. Appellants commenced an action against the State of Minnesota, the Department of Health, and the Commissioner of Health, alleging a violation of the Genetic Privacy Act. Appellants claim that the Genetic Privacy Act requires written parental consent before the Department may store newborn blood specimens collected through the newborn screening program or authorize public-health research to be conducted with those samples. The complaint was later amended to include various tort and constitutional claims. The State moved to dismiss or, in the alternative, for summary judgment. . . .

In 1965 Minnesota began to test newborns for certain metabolic disorders. The current program screens newborns for more than 50 disorders. Each year, more than 73,000 Minnesota newborns are screened; approximately 100 are discovered to have a confirmed disorder.

Newborn screening is conducted under the authority of the newborn screening statutes, which (1) require the Commissioner of Health to prescribe the manner of testing, recording, and reporting of newborn screening results; (2) require those who perform screenings to advise parents that the blood samples and test results may be retained by the Department of Health; and (3) permit parents either to decline to have their infants tested or to require destruction of the blood samples and test results following screening.

The newborn screening program requires certain individuals to collect blood samples from newborn children by the fifth day after birth. A sample consists of a few blood drops collected on a specimen card. The blood sample is sent to the Department within 24 hours of collection. Screening tests are then run on the blood sample.

Almost all of the screening tests analyze the blood sample for the presence of substances that indicate the possible presence of a disorder. The only test that analyzes the DNA or RNA of the blood is the second-level test for cystic fibrosis, which is performed only if the first test indicates the presence of a certain substance in the blood. The screening process typically uses 70% of the sample.

If a portion of the blood sample remains after the screening tests are completed, the sample is retained indefinitely unless there is a specific request to have it destroyed. As of December 31, 2008, there were more than 800,000 newborn screening samples in storage, dating back to samples taken as early as 1997. More than 50,000 blood samples have been used in studies for purposes beyond the initial screening of the newborn children. These studies have included developing new tests and assuring the quality of existing tests. Blood samples have also been used for studies unrelated to the newborn screening program. A blood sample is capable of being used for research for up to 20 years.

The State asserts that a federal law requires the Department to retain newborn screening test results for two years. After this two-year period, the test results are retained indefinitely unless the Department receives a request to destroy the results. The Department currently has electronic test results dating back to 1986 and "a small amount of paper records dating back to the 1960s." The appellants allege that the Department possesses more than 1.5 million screening test results.

The Department of Health contracts with Mayo Medical Laboratories to perform screening tests on newborn children's blood samples. This contract allows Mayo to use excess blood samples for studies unrelated to the newborn screening program if—in

addition to other requirements—the samples have been de-identified or Mayo has received written consent from the children's parent or legal guardian. The majority of the studies performed by outside research institutions use de-identified blood samples.

In 2006 the Legislature [adopted a law] regulating the treatment of genetic information. This amendment prohibits the collection, use, storage, or dissemination of a person's genetic information without the written informed consent of that person. . . .

Appellants argue that the Genetic Privacy Act requires the Department of Health to obtain informed consent before it may collect, use, store, or disseminate the blood samples that remain after newborn health screening is complete. The State argues that the Genetic Privacy Act does not limit the Department's handling of the samples because (1) blood samples received by the Department of Health are not "genetic information" under the Act, and (2) the newborn screening statutes "expressly provide" that the Department of Health may use, store, and disseminate the genetic information without first obtaining written informed consent.

Our first task is to determine whether the blood samples collected and stored by the Department are "genetic information," as that term is used in the Genetic Privacy Act, requiring the Department to obtain informed consent before it may use, store, or disseminate the blood samples that remain after the newborn health screening is complete. Appellants argue that the Genetic Privacy Act applies to blood samples because those samples contain information in the form of DNA. The State argues that the Genetic Privacy Act does not apply to blood samples because the Act treats those samples as biological *specimens,* not genetic *information*. . . .

We conclude that "genetic information" . . . includes the actual blood samples as "medical or biological" information. We also note that even if the Genetic Privacy Act did not define the blood samples themselves as "genetic information," those samples unquestionably *contain* genetic information. The Act limits the collection, use, storage, or dissemination of genetic information. It would be impossible to collect, use, store, or disseminate those samples without also collecting, using, storing, or disseminating the genetic information contained in those samples. . . . Unless otherwise expressly provided by law, the Department must have written informed consent to collect, use, store, or disseminate those samples.

Having concluded that the blood samples collected and stored by the Department are "genetic information" and subject to the restrictions of the Genetic Privacy Act, we turn to the question of whether the Department is exempted from those restrictions because they are "expressly provided" with authority to collect, use, store, and disseminate the information [because the Genetic Privacy Act requires] that "[u]nless otherwise expressly provided by law," the State must have written informed consent to collect, use, store, or disseminate genetic information. Thus, the Department may collect, use, store, or disseminate blood samples collected as part of the newborn screening program only to the extent expressly authorized by the newborn screening statutes. We examine each of the restrictions of the Genetic Privacy Act to determine the extent to which the newborn screening statutes give the Department the express authority to collect, use, store, or disseminate blood samples without written informed consent. . . .

Although the language of the newborn screening statutes do not explicitly state that the Department may collect blood samples, the statutes' provisions authorizing the

Department to conduct tests and providing for destruction of samples require that the Department be able to collect samples to be tested and destroyed. Despite the fact that this constitutes implied rather than express authorization, we conclude that the newborn screening statutes authorize the collection of blood samples to the extent necessary to allow the Department to conduct the tests expressly authorized by statute. . . .

The newborn screening statutes authorize the Commissioner to conduct "tests for heritable and congenital disorders," and require the Commissioner to "maintain a registry of the cases of heritable and congenital disorders detected by the screening program for the purpose of follow-up services." The newborn screening statutes therefore expressly authorize the Commissioner to use the blood samples without written informed consent only to the extent necessary to conduct tests for heritable and congenital disorders and conduct follow-up services. . . .

The newborn screening statutes require the Commissioner to "maintain a registry of the cases of heritable and congenital disorders detected by the screening program for the purpose of follow-up services." This language creates an express exception to the Genetic Privacy Act that allows the Commissioner to maintain blood samples from positive test results unless a child's parents object. . . .

The State argues that the newborn screening statutes provide two other express exceptions to the Genetic Privacy Act. First, it argues that the newborn screening statutes' requirement that the Commissioner "comply with a destruction request within 45 days after receiving it," authorizes the Commissioner to retain information for 45 days. But even if this provision authorizes the Commissioner to retain genetic information for 45 days before complying with a destruction request, it does not expressly provide for indefinite storage when no destruction request is received. [It] is silent on the question of how long genetic information may be retained, and therefore the statute cannot be an "express" exception to the Genetic Privacy Act's opt-in framework.

Second, the State argues that language in [the newborn screening statute] requiring "responsible parties" to advise parents "that the blood or tissue samples used to perform testing thereunder as well as the results of such testing may be retained by the Department of Health," expressly requires the Department to retain blood samples because if the Department were not allowed to do so, the statement would be false. . . . A requirement that "responsible parties" inform parents that blood samples may be retained *implies* that the Department is in fact authorized to do so, but it does not *expressly* authorize retention of those samples. Furthermore, the use of the word "may" indicates that blood samples might not be retained.

The Genetic Privacy Act's final restriction is on dissemination. The Act allows genetic information to be "disseminated only: (i) with the individual's written informed consent; or (ii) if necessary in order to accomplish purposes" for which informed consent was given. The newborn screening statutes expressly authorize the "reporting of test results." The Commissioner is also expressly authorized to contract with a private entity to perform the Department's functions. But there is no other source of law authorizing the dissemination of blood samples or genetic information beyond that expressly authorized for the reporting of newborn test results.

We conclude that the newborn screening statutes provide an express exception to the Genetic Privacy Act only to the extent that the Department is authorized to administer newborn screening by testing the samples for heritable and congenital disorders,

recording and reporting those test results, maintaining a registry of positive cases for the purpose of follow-up services, and storing those test results as required by federal law. The newborn screening statutes do not expressly authorize the Department to conduct any other use, storage, or dissemination of the blood samples.

Finally, we turn to the question of the appropriate remedy. The district court did not find a violation of the Genetic Privacy Act and held that the "remedy sought is not one the Court can impose." The court of appeals concluded that the use of blood samples of newborn children in studies unrelated to the newborn screening program would violate the Genetic Privacy Act, but held that appellants had presented no specific evidence that any of the children's blood had been so used. Because the district court concluded that the Department had not violated the Genetic Privacy Act, the court did not consider the availability of remedies to particular parties or whether any parties had established the facts necessary to show that their children's blood samples had been used, stored, or disseminated in violation of the Act. Because the record is insufficient to allow us to determine whether any of the appellants are entitled to remedies for such violation, we remand to the district court for further proceedings consistent with this opinion.

. . .

The Minnesota legislature responded to the state supreme court's ruling in *Bearder* by enacting new legislation directing the department of health to maintain blood spot samples that have all negative test results for 71 days. Those with a positive or abnormal test result are kept for two years to allow for follow-up testing and services. All test results are held for two years, in compliance with federal requirements, and then destroyed, unless parental consent to retain them is obtained. Parents may also consent to have the samples held for longer than the statutory time limits. The Minnesota Department of Health eventually settled the lawsuit and destroyed all DBS samples collected prior to the court's ruling.

Lawsuits filed by privacy advocates in two other states prompted similar regulatory changes—allowing individuals and their parents to request destruction of previously collected samples and requiring consent for newly collected samples. In Indiana, for example, parents may choose to sign a blanket authorization allowing their child's DBS sample to be used for research purposes for three years. In Texas, the state health department agreed to destroy all pre-existing DBS samples as part of a settlement agreement. In response to these suits and other concerns about DBS screening and research programs, federal legislation reclassified DBS research as research involving human subjects.

As discussed above, proposed changes to the Common Rule would have required affirmative consent to research prior to the use of DBS and other biobank samples, but those changes were discarded when the

final rule was promulgated in 2017. These proposals were prompted in part by renewed attention to the monetary value of some types of biological samples and inequities of past biospecimen uses such as the development of HeLa cells collected (without consent) from Henrietta Lacks.

As discussed above, the 2017 revised Common Rule permits researchers collecting new samples to obtain broad consent covering unspecified future uses. Are the disclosures required by §46.116(d) sufficient to ensure that biobank participants understand the scope of the consent they are granting? Some commentators have suggested that informed consent is an inappropriate paradigm for biobank research given that it is impossible to adequately inform a participant about the risks involved in unspecified future uses of technologies that may be unimaginable at the time of sample collection. These commentators have proposed an alternative approach emphasizing agreements to *participate* in biobank programs (rather than *consent* to research) with various mechanisms to ensure that the benefits of future uses are shared in an equitable manner.

The 2017 Common Rule also specifies that biobank participants may be informed that research findings will not be disclosed to them, even if those findings are clinically significant. Researchers may determine, for example, that a specific biospecimen indicates that the subject is at increased risk of developing a disease, such as cancer, dementia, or alcoholism. But it may not be feasible to return these findings to the individual, particularly if the specimen was collected long before the results were generated or if the biospecimen has been de-identified.

Note that the Michigan Supreme Court's opinion in *Bearder* requires consent for DBS research even when DBS samples are disconnected from any identifying information about the infant from which they were drawn. The public outcry over DBS research suggests that privacy, autonomy, and property rights may be implicated by the collection and storage of samples, even if they are not shared with others in a form that allows the sample to be linked to an identifiable individual using currently available technologies.

Public health surveillance and research implicate fundamental conflicts between individual interests in privacy and autonomy and collective needs for data to fuel effective public responses to pressing problems. Resolving these conflicts requires robust ethical analysis and legal protections, which should foster trust, transparency, and accountability. The information and understanding generated by public health surveillance and research form the basis for interventions to control the

spread of infectious disease, prepare and respond to public health emergencies, and prevent noncommunicable diseases, injuries, and violence. In the chapters that follow, we examine legal and ethical issues within the context of these silos of public health science and practice.

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PHOTO 10.1. A nurse gives a smallpox vaccination to a toddler at a local health department. CDC.

CHAPTER TEN

Infectious Disease Prevention and Control

This chapter examines the most ancient and enduring threat to the public's health—infectious diseases. The public health law toolkit for infectious disease prevention and control has evolved over centuries in response to scientific breakthroughs. For most of history, society's only response to epidemics was the crude separation of the sick from the well. In the nineteenth century, sanitarians influenced by early epidemiological studies sought to prevent epidemics through waste management, pollution control, housing regulations, and education about proper hygiene—innovations that continue to be mainstays of public health practice. In the early twentieth century, scientists developed medical countermeasures to prevent, detect, treat, and control the spread of infectious diseases, ushering in the agent (also known as microbial or germ) model of public health. Direct regulation to ensure uptake and safety of vaccinations and appropriate use of antimicrobials became a key focus of public health law. The social-ecological model that emerged at the turn of the twenty-first century has played a particularly important role in HIV prevention, highlighting the importance of privacy and anti-discrimination protections and other social supports to encourage infected individuals to learn their status, get treatment, and take precautions to avoid infecting others.

We begin this chapter with vaccination laws and policies aimed at securing community immunity. Next, we discuss screening to identify infected individuals so they can receive treatment and stop the spread of

infection to others. We discuss the potentially catastrophic consequences of antimicrobial resistance and related interventions to isolate infected individuals and ensure that they complete a full course of treatment. We conclude with a discussion of contact tracing and expedited partner therapy as strategies for increasing access to treatment and controlling the spread of disease.

Many of the topics in this chapter overlap with those covered in the next chapter on public health emergency preparedness and response. Public health authorities may rely on compulsory vaccination, screening, and treatment in response to a bioterror attack or emerging infectious disease outbreak. As a legal matter, civil confinement of individuals with tuberculosis to control the spread of antimicrobial resistance is closely related to quarantine of individuals exposed to more virulent and transmissible infections, such as Ebola. Here, our focus is on the management of routine infectious disease threats. We will address emerging infectious diseases with epidemic potential in chapter 11.

VACCINATION LAW AND POLICY: SECURING COMMUNITY IMMUNITY

Immunization protects individuals from illnesses that previously accounted for a large proportion of morbidity and mortality, particularly among children. It also protects the community as a whole. For any given individual, most vaccines are not foolproof. But if a sufficient percentage of the population is vaccinated, *community immunity* (also known as herd immunity) prevents the spread of disease from person to person, resulting in containment of occasional outbreaks (e.g., measles, pertussis) or even eradication of a disease altogether (e.g., smallpox, polio) (see figure 10.1).

Despite long-standing scientific consensus that the benefits of recommended vaccines clearly outweigh the risks, compulsory vaccination has, since its inception, roused popular resistance. The rate of complete immunization of school-age children in the United States is equal to or higher than that in most other developed countries. But high immunization rates nationally belie the public's vulnerability to vaccine-preventable disease. Unvaccinated and undervaccinated children represent a minority of the population as a whole, but they are often clustered geographically in communities that share a religious objection to vaccination, a preference for a "natural" lifestyle, or barriers to care. In such a community, if vaccination rates fall below the level required to maintain community

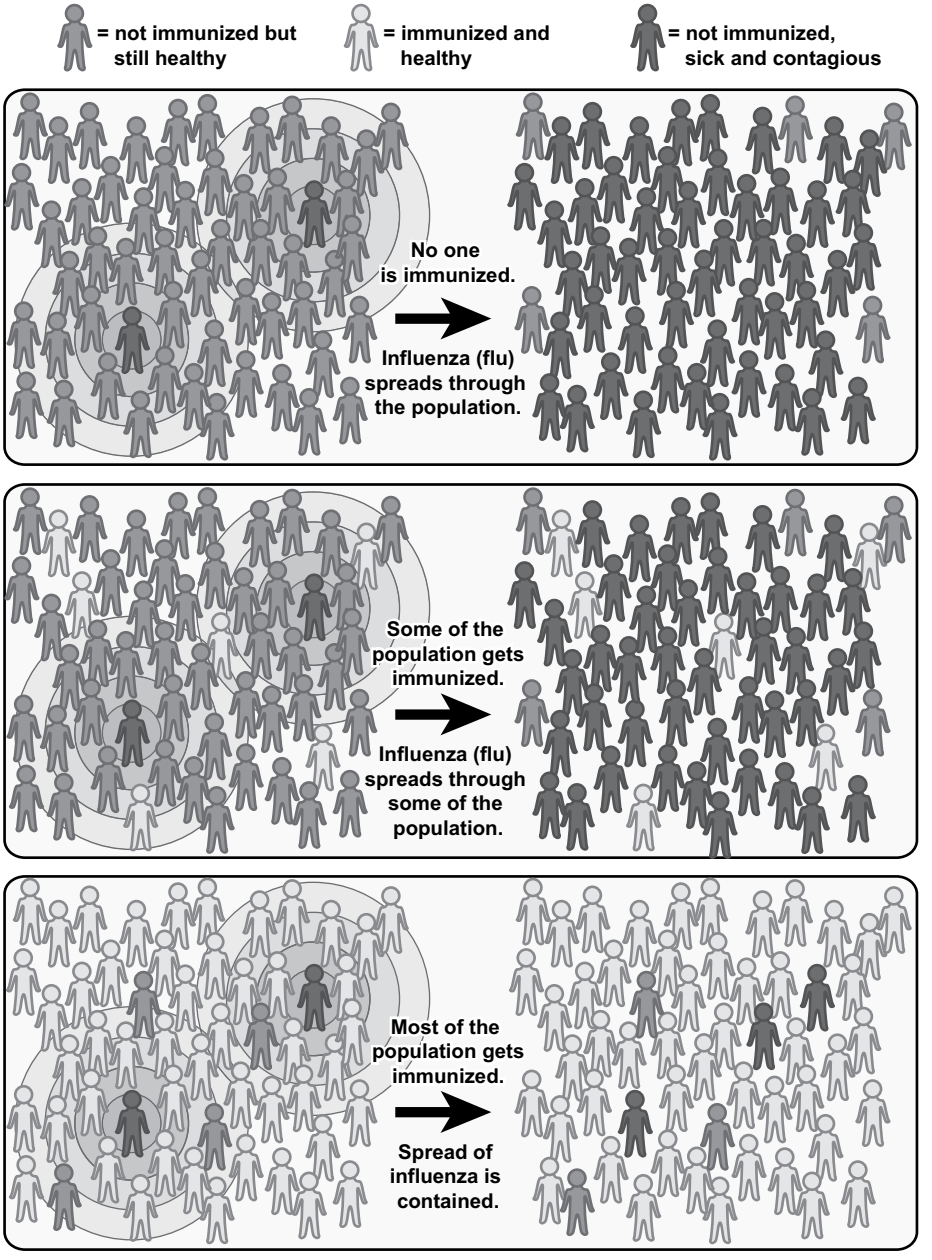

FIGURE 10.1. Community immunity. When a critical portion of a community is immunized against a particular disease, most members of the community are protected because there is little opportunity for a disease outbreak. In this illustration, the top box depicts a community in which no one is immunized against influenza and an outbreak occurs. In the middle box, a portion of the population is immunized, but it is not enough to confer community immunity. The bottom box shows that immunizing a critical portion of the population confers protection for most community members. Even those who are not immunized are protected because community immunity has been achieved and the spread of disease contained. Figure courtesy of National Institute for Allergy and Infectious Disease.

immunity (typically around 90% to 95%), the risk of an outbreak is increased. In an outbreak, unvaccinated individuals—including those who cannot be vaccinated safely because they are too young or have medical contraindications (e.g., allergies or cancer treatment)—are most at risk. But a small proportion of vaccinated individuals will also be at risk due to the imperfect effectiveness of the vaccine.

Community immunity is a public good. It is a shared resource that is—in economic terms—nonexcludable. If vaccination levels are above the community immunity threshold, everyone benefits, including those who did not contribute to the creation of the resource by accepting the small but real risk of an allergic reaction or other complication. A small percentage of individuals may safely refuse vaccination, free-riding on the community immunity created by others who are willing and able to accept the low risk of complications. Given that there are some individuals who, for medical reasons, cannot be vaccinated safely, the question becomes whether additional individuals who have a religious or philosophical objection to vaccination (or simply a preference not to undertake the risks that others do) can also be accommodated. Eventually, if enough individuals act solely out of self-interest, refusing to accept the risks of vaccination while continuing to benefit from the risks undertaken by others, the resource will be destroyed, to the detriment of all. This, in a nutshell, is the dilemma posed by vaccination policy, sometimes referred to as the "tragedy of the commons" (Hardin 1968).

In the excerpt that follows, Dorit Reiss and Lois Weithorn discuss why some parents refuse to vaccinate their children, the risks their decisions impose on their children and others, and legal tools for securing community immunity.

RESPONDING TO THE CHILDHOOD VACCINATION CRISIS: LEGAL FRAMEWORKS AND TOOLS IN THE CONTEXT OF PARENTAL VACCINE REFUSAL*

Dorit Rubenstein Reiss and Lois A. Weithorn

. . . Vaccines are literally lifesavers. They are our best defense against dangerous diseases that can lead to long-term disability or death, given that existing treatments cannot fully ameliorate many of these diseases once contracted. . . . Yet, some parents choose not to vaccinate their children because the parents are influenced by widely-disseminated and misleading characterizations of the risks of vaccines. . . . The

* 2015. *Buffalo Law Review* 63 (4): 881–980.

increase in non-vaccination rates is a problem, not just because children whose parents [forgo] vaccinations are at risk of contracting preventable diseases, but because their nonvaccination endangers others. . . .

VACCINES: BENEFITS AND RISKS

Over the past several decades, medical advances have led to the development of vaccines to prevent a growing list of diseases. Currently, the CDC's schedule recommends vaccination against fourteen diseases before children reach school age: diphtheria, hepatitis A, hepatitis B, Hib, influenza, measles, meningococcal disease, mumps, pertussis (whooping cough), pneumococcal, polio, rotavirus, rubella, tetanus, and varicella (chicken pox). . . .

Like every medical intervention—and in fact, everything in life—vaccines are not risk-free. We must always evaluate the risks together with the potential benefits. For example, a recent study examined the safety of MMR and MMRV, the two measles-containing vaccines. The study found that the risks of the vaccines included fever and febrile seizures—which, although "frightening to parents," generally do not cause long term harm. The vaccine can also cause temporary low platelet count in rare cases (about 1:40,000, according to the CDC), and very rarely (about 1.5 out of every million doses), a severe allergic reaction.

The measles infection itself can also cause low platelet count, fever, and febrile seizures. . . . The CDC estimates the rate of complications from measles at 30%. Those complications include death, encephalitis, pneumonia, deafness, and a rare but always fatal complication called subacute sclerosing panencephalitis (SSPE). . . .

Thus, although vaccines carry risks, those risks are quite small. Contrary to the claims of some nonvaccinators, documented risks do not include, for example, a greater likelihood of developing autism or leukemia. Furthermore, the documented risks are far smaller than the benefits of vaccines and the risks of not vaccinating. Generally, for any child except the few with medical contraindications, it is better to vaccinate—for that child, and for society. . . .

ANTI-VACCINATION: NUMBERS AND REASONS

The focus here is on parents who *choose* not to vaccinate because of concerns about or opposition to vaccinations. Thus, we do not focus on those children whose health status or particularized reaction to vaccines presents medically-recognized contraindications to some or all vaccines. In addition, we do not address circumstances in which parents who do not oppose vaccination fail to fully vaccinate their children because of practical obstacles (such as income or difficulty accessing health care professionals or settings). Fortunately, there now exist multiple mechanisms to help families pay for vaccinations. We recognize that for some families, practical barriers remain, although the evidence indicates that low-income children are not usually *un*vaccinated. Rather, because of access problems, they may be *under*vaccinated, that is, lacking some doses in a series. . . .

A recent cohort study by the Institute for Health Research at Kaiser Permanente [estimates that] 13.0% of children [are] undervaccinated because of affirmative parental decision not to vaccinate. This percentage includes unvaccinated children, partly-vaccinated children, and children on a delayed schedule. . . .

In a recent article, Hagood and Herlihy (2013) remind the reader that nonvaccinating parents differ in the bases and degrees of the commitment they manifest in their opposition to vaccines. . . . Hagood and Herlihy distinguish among Vaccine Rejector parents, Vaccine Resistant parents, and Vaccine Hesitant parents. "Vaccine Rejectors" are the parents who are entrenched in their opposition to vaccines, unwilling to consider information in opposition to their beliefs. They strongly believe that vaccines cause more harm than good, or that vaccines are part of "a conspiracy involving governments, health organizations and pharmaceutical companies." These parents typically distrust traditional medicine and are more likely to use alternative practices to respond to their children's health problems. . . . The second group is comprised of "Vaccine Resistant" parents. These parents are willing to consider information about the safety and efficacy of vaccines, though they still do not give their children all vaccines. . . . "Vaccine Hesitant" parents . . . have general anxiety about vaccines and have "heard things" that concern them about vaccines, but they may or may not be able to articulate a specific concern. If their fears are not addressed, their concerns may evolve into firmer opposition to vaccines. . . .

Why don't parents vaccinate? Research focusing on the nonvaccinating parent and postings provided by anti-vaccination websites identify the following reasons: safety concerns (including concerns about vaccine injuries, vaccine ingredients, and long term vaccine harms); underestimates of the risks of [vaccine-preventable] diseases; underestimates of vaccines' efficacy; distrust of government and doctors (in some cases rising to the level of belief in conspiracy theories); preference for alternative medicine linked to a professed belief in "natural" interventions or nonintervention; and a concern that vaccination policies violate their civil rights. . . .

RESPONDING TO THE NONVACCINATION CRISIS: POSSIBLE AVENUES OF POLICY REFORM

[S]tates have considerable constitutional leeway to impose requirements for childhood vaccines. This Part examines how the law can respond to the challenges presented by . . . nonvaccination. . . .

Choosing the Legal Tools to Promote Vaccination Compliance

In choosing the legal mechanisms to respond to nonvaccination trends, several considerations are relevant: effectiveness; compatibility with constitutional limitations on state power; social values; bioethical principles; political feasibility; cost; and efficiency. . . . [E]ven where it is constitutionally permissible to limit choices, states may prefer to seek compliance with vaccination policies through methods that restrict parental decisions as minimally as possible. . . . [P]arents are treated in law and ethics as surrogates representing children's interests, and are vested with the authority to consent or dissent in the child's place. As such, those values inherent in the doctrine of informed consent and respect for the role of parents in children's lives must be the starting place when considering reforms in public policy. . . . Furthermore, our nation was founded on principles that value and respect diversity and pluralism, including in personal secular and religious beliefs. As such, even where the First Amendment or related state constitutional provisions do not limit state action as infringements on

protected rights, policymakers may choose to promote, respect, or tolerate diversity and pluralism of secular and religious beliefs.

The normative questions about policy options have pragmatic aspects as well. Public health policy success typically depends on a substantial degree of voluntary cooperation. While cooperation can be compelled through a variety of means, some of which will be noted below, enforcement can be difficult, and costly, and individuals and institutions may find ways around legal policies that are not consistent with social norms. Thus, vaccination policies, to be most effective, should resonate with predominant social attitudes and values. To the extent that public education about the safety and benefits of vaccination policies can help shape those attitudes and values, such population-wide efforts are an essential component of policy responses, even where more coercive interventions are necessary to secure the compliance of those who cannot be persuaded. . . .

A Continuum of Legal Tools

Ordering Vaccination over Parental Objection. The most coercive way to increase childhood immunization rates is to force parents to vaccinate their children. Courts can order parents to do so, and have done so, on rare and unusual occasions. For example, in 1990, the city of Philadelphia faced a measles outbreak that centered on two churches whose members did not believe in vaccination (or modern medicine generally). Nine children died from measles during the outbreak, and ultimately a judge ordered vaccination of the children of the church members over parental objections. . . .

Criminalizing Nonvaccination. As in *Jacobson,* states can criminalize nonvaccination, attaching a criminal penalty. Criminal sanctions have been applied in the United States in this context even after *Jacobson,* although not recently. For example, in a number of cases, parents were sanctioned criminally for violating mandatory school attendance laws when they didn't vaccinate their children, and their children were denied access to school. Several other countries attach criminal sanctions to nonvaccination. For example, France requires children to be vaccinated against diphtheria, tetanus and polio—and attaches a criminal sanction. . . .

Conditioning Access to Services on Compliance with Vaccination Policies. Another mechanism for accomplishing a mandate is the conditioning of benefits, opportunities, or privileges, such as access to public or private services, on compliance with state requirements to vaccinate. . . . [T]his approach is universally applied in the United States, across the fifty states and District of Columbia, through school immunization requirements. Children are required to receive certain vaccines before they can attend public, and in most jurisdictions also private, school. . . . Most states qualify the right to attend school for those students who are granted exemptions and are unvaccinated: If there is an outbreak of a vaccine-preventable disease, exempted unvaccinated students are forced to stay home, not only until the end of the outbreak, but until the end of the period of infection risk. . . .

One obvious policy reform that would increase vaccination rates would be further reducing the availability of exemptions. . . . [A]pproximately twenty states permit philosophical or personal belief exemptions. Elimination of these exemptions—increased use of which is responsible for most of the rise in unvaccinated children in recent

years—would likely improve vaccination rates. Such elimination would, of course, render mandatory vaccination policies far more coercive in that the most commonly-used "escape valve" would be eliminated. . . . Somewhat less coercive than complete elimination of either category of exemptions would be narrowing the substantive breadth of the categories . . . although policymakers should be cognizant of the ways in which modifications to the language of the substantive requirements for religious exemptions might introduce possibly unconstitutional preferences for one religious group over another. . . .

Imposing Costs on Nonvaccinators. . . . In imposing [costs on those who choose not to vaccinate], government is, in essence, saying to nonvaccinators: "you are permitted to make your choice, but must pay the price." Such a legal policy does not *directly* constrain one's freedom to refuse, nor does it directly interfere with one's ability to take advantage of important services and benefits, such as access to school for school-age children. But, paying costs can influence choice, particularly when its consequences are powerfully and painfully felt.

Costs can be imposed through tort liability. For example, parents who choose not to vaccinate can be sued if their choice harms another. . . . [Alternatively, c]osts can be imposed on those who do not vaccinate via a no-fault mechanism. This method levies a tax or fee aimed at recouping the costs that nonvaccination imposes on the public purse. Or, those who do not vaccinate can be charged higher health insurance premiums as a way of imposing a cost on their refusals. . . .

Mandating Transparency. A different set of incentives would be through transparency: providing information to parents about vaccination rates and status. . . . At one extreme, states could require publications of the names of all the unvaccinated children in a school or daycare, directly exposing the identities of those children and their parents, with potentially stigmatizing consequences, while also warning others of the risk of contact, and thereby allowing others some measure of self-protection. We are not aware of any jurisdiction that uses such a method to encourage compliance. A less stigmatizing method that is already in use in some states, such as California, allows publication of rates of immunization in particular schools, preschools, and daycares. . . .

Procedural Tightening and Exemption Petitions. Research reveals that in jurisdictions where the procedures to obtain exemptions to vaccination policies are more "difficult," rigorous, tighter, or complex, exemption rates are lower, and vaccination rates are higher. . . . At one end of the continuum of "difficulty," the "easiest" procedures require parents only to . . . complete a fairly simple form. Somewhat more difficult are procedures that require a parent to draft a letter explaining the basis for the exemption request. . . . For example, some states require parents claiming a religious exemption to detail and explain their religious reasons (and some subject the explanation to an evaluation of sincerity). In some cases, the procedure is made more difficult by requiring parents to obtain the form at the health department rather than at the child's school. States have required notarization of exemption letters, or annual renewal of exemptions. Recently, . . . several states . . . added an educational requirement to their personal belief exemption—a parent must have a conversation with a doctor about the risks and benefits of immunization and the diseases before an exemption will be granted. . . .

Providing Positive Incentives for Vaccination. Provision of subsidies for compliance with vaccination recommendations constitutes one of the least coercive categories of tools. Such tools are already in use to help reduce health costs associated with vaccinating. . . .

Creation of additional incentives for vaccination may also encourage this preferred behavior. A jurisdiction could provide tax breaks for those who do vaccinate, consistent with policies currently in force in Australia. . . .

Persuading through Education. Finally, initiatives aimed at education comprise the least coercive set of tools. Substantial work is done [by private organizations] to educate parents about vaccines. . . . But the law can promote vaccine education as well. For example, legislators can add a module about immunization to an appropriate class in elementary or high school, teaching children the basic information about vaccines. . . .

CONCLUSION

Freedom of choice is a cherished American value. Just as important is promotion of the health of our population, particularly those who are young and vulnerable. . . . Making use of the available legal tools to improve childhood immunization rates can help protect children's health, reduce social costs, and free people from the burden of preventable diseases.

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In addition to the legal and policy approaches discussed in the excerpt above, policymakers can increase parents' confidence in vaccination by regulating vaccines to ensure that they are safe and effective. Policymakers also have a responsibility for ensuring that vaccines are available, accessible, and affordable for the vast majority of parents who desire to have their children vaccinated. These goals are not always in harmony. For example, tort liability offers a potential tool for ensuring vaccine safety. If an individual can prove that an unreasonably defective vaccine harmed her, courts can require the manufacturer to compensate her, creating an incentive for all manufacturers to ensure the safety of their products. There is a risk, however, that manufacturers will decide instead to avoid producing vaccines altogether because the financial benefits do not outweigh the liability risks. Many vaccines are a poor financial investment for private companies because they are expensive to develop and the market price may be too low to make a profit.

These forces led to critical vaccine shortages after a series of highly publicized jury verdicts against manufacturers in the 1980s. Congress responded by shielding manufacturers from tort liability and establishing a no-fault system to compensate individuals who suffer vaccine complications. The Vaccine Injury Compensation Program commits

public funds to compensate individuals who bear the costs of vaccination for the benefit of the population as a whole. Because manufacturers are shielded from the deterrent effect of liability, however, vaccine safety depends on direct regulation by the Food and Drug Administration.

Opponents of vaccination have criticized the program, arguing that it is additional evidence of the pharmaceutical industry's inappropriate influence over vaccination law and policy. Opponents also point to decisions by the court that administers the program as evidence that vaccines are indeed harmful. Their argument neglects the fact that decisions awarding compensation are based on a no-fault regime that is highly deferential to injured parties' claims and does not apply the rigorous evidentiary standards that govern typical court cases.

The constitutional status of compulsory vaccination is complex. Most legal experts agree that vaccination mandates, even those that do not recognize religious or philosophical exemptions, are constitutionally permissible. But there are no recent Supreme Court precedents directly on point and some critics argue that the Court's older precedents are no longer valid in light of intervening constitutional developments, including incorporation of the First Amendment to the states in 1940 (see chapter 4) and evolution of the Court's jurisprudence on privacy and bodily integrity.

The starting point for constitutional analysis of vaccination mandates is *Jacobson v. Massachusetts* (1895), excerpted in chapter 4, which upheld a vaccination mandate enforced via civil fines. As Reiss and Weithorn explain above, this approach is rarely employed in the United States today. Instead, most efforts to ensure community immunity condition school and day care attendance on vaccination status. Children in these settings are particularly likely to spread communicable diseases among themselves and to their family members and communities. In the case that follows, the Supreme Court rejected a due process challenge to an early school vaccination mandate.

*ZUCHT V. KING**

Supreme Court of the United States
Decided November 13, 1922

Justice Brandeis delivered the opinion of the Court.

Ordinances of the City of San Antonio, Texas, provide that no child or other person shall attend a public school or other place of education without having first presented

* 260 U.S. 174.

a certificate of vaccination. Purporting to act under these ordinances, public officials excluded Rosalyn Zucht from a public school because she did not have the required certificate and refused to submit to vaccination. They also caused her to be excluded from a private school. Thereupon Rosalyn brought this suit against the officials in a court of the State. The bill charges that there was then no occasion for requiring vaccination; that the ordinances deprive plaintiff of her liberty without due process of law by, in effect, making vaccination compulsory; and, also, that they are void because they leave to the Board of Health discretion to determine when and under what circumstances the requirement shall be enforced without providing any rule by which that board is to be guided in its action and without providing any safeguards against partiality and oppression. The prayers were for an injunction against enforcing the ordinances, for a writ of mandamus to compel her admission to the public school, and for damages. . . .

Long before this suit was instituted, *Jacobson v. Massachusetts* had settled that it is within the police power of a State to provide for compulsory vaccination. That case and others had also settled that a State may, consistently with the Federal Constitution, delegate to a municipality authority to determine under what conditions health regulations shall become operative. And still others had settled that the municipality may vest in its officials broad discretion in matters affecting the application and enforcement of a health law. A long line of decisions by this Court had also settled that in the exercise of the police power reasonable classification may be freely applied and that regulation is not violative of the equal protection clause merely because it is not all-embracing. In view of these decisions we find in the record no question as to the validity of the ordinance. . . . Unlike *Yick Wo v. Hopkins,* 118 U.S. 356 [(1886) (invalidating a regulation that was neutral on its face but administered in a racially discriminatory manner)], these ordinances confer not arbitrary power, but only that broad discretion required for the protection of the public health. . . .

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Since *Zucht*, the Supreme Court has addressed compulsory vaccination only in dicta. Nonetheless, the lower courts have regularly upheld the constitutionality of vaccination as a prerequisite for school attendance, rejecting arguments based on the First Amendment, equal protection, and due process. The case that follows is typical of these disputes.

*WORKMAN v. MINGO COUNTY BOARD OF EDUCATION**

United States Court of Appeals, Fourth Circuit
Decided March 22, 2011

Plaintiff Jennifer Workman filed this 42 U.S.C. § 1983 action against various West Virginia state and county officials, alleging that Defendants violated her constitutional

* 419 F. App'x 348.

rights in refusing to admit her daughter to public school without the immunizations required by state law. . . .

Workman is the mother of two school-aged children: M. W. and S. W. S. W. suffers from health problems that appeared around the time she began receiving vaccinations. In light of S. W.'s health problems, Workman chose not to vaccinate M. W.

Workman's decision not to allow vaccination of M. W. ran afoul of West Virginia law, which provides that no child shall be admitted to any of the schools of the state until the child has been immunized for diphtheria, polio, rubeola, rubella, tetanus, and whooping cough. However, Workman sought to take advantage of an exception under the statute, which exempts a person who presents a certificate from a reputable physician showing that immunization for these diseases "is impossible or improper or other sufficient reason why such immunizations have not been done." Thus, in an effort to enroll M. W. in the Mingo County, West Virginia, school system without the required immunizations, Workman obtained a Permanent Medical Exemption from Dr. John MacCallum, a child psychiatrist.

Dr. MacCallum recommended against vaccinating M. W. due to S. W.'s condition. [The] Mingo County Health Officer . . . approved the certificate and indicated that it satisfied the requirements for M. W. to attend school. . . . M. W. attended [a] pre-kindergarten program . . . for approximately one month in September 2007.

On September 21, 2007, the Superintendent of Mingo County Schools . . . sent a letter to . . . the acting head of the West Virginia Department of Health and Human Resources, stating that a school nurse had challenged Workman's certificate. [The acting head of the department recommended that Workman's medical exemption be denied whereupon a school official informed Workman that M. W. could no longer attend the pre-kindergarten program.]

M. W. did not attend school again until 2008, when she was admitted into a Head Start Program that accepted Dr. MacCallum's certificate. However, when M. W. aged out of that program, Mingo County Schools would not admit her; accordingly, Workman home-schooled M. W. . . .

In her complaint, Workman . . . sought a declaratory judgment, injunctive relief, and damages. Specifically, she alleged that Defendants' denial of her application for a medical exemption violated her First Amendment rights. She further alleged that Defendants' denial of her application for a medical exemption constituted a denial of Equal Protection and Due Process. . . .

Workman . . . argues that West Virginia's mandatory immunization program violates her right to the free exercise of her religion. The First Amendment provides that "Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof. . . ." The First Amendment [was] made applicable to the states by incorporation into the Fourteenth Amendment [in 1940].

Preliminarily, we note that the parties disagree about the applicable level of scrutiny. Workman argues that the laws requiring vaccination substantially burden the free exercise of her religion and therefore merit strict scrutiny. Defendants reply that the Supreme Court in *Employment Div., Dep't of Human Res. of Or. v. Smith,* 494 U.S. 872 (1990), abandoned the compelling interest test, and that the statute should be upheld under rational basis review. Workman counters that *Smith* preserved an exception for education-related laws that burden religion. We observe that there is a circuit split over the validity of this "hybrid-rights" exception. *See Combs v. Homer–Center School*

Dist., 540 F.3d 231, 244–47 (3rd Cir. 2008) (discussing circuit split and concluding [the hybrid rights] exception was dicta [in *Smith*]). However, we do not need to decide this issue here because, even assuming for the sake of argument that strict scrutiny applies, prior decisions from the Supreme Court guide us to conclude that West Virginia's vaccination laws withstand such scrutiny.

Over a century ago, in *Jacobson v. Massachusetts,* 197 U.S. 11 (1905), the Supreme Court considered the constitutionality of a statute that authorized a municipal board of health to require and enforce vaccination [and] held that the legislation represented a valid exercise of the state's police power, concluding "we do not perceive that this legislation has invaded *any right* secured by the Federal Constitution." *Id.* at 38 (emphasis added).

In *Prince v. Massachusetts,* 321 U.S. 158 (1944), the Supreme Court considered a parent's challenge to a child labor regulation on the basis of the Free Exercise Clause. *Id.* at 164, 64 S.Ct. 438. The Court explained that the state's "authority is not nullified merely because the parent grounds his claim to control the child's course of conduct on religion or conscience. Thus, he cannot claim freedom from compulsory vaccination for the child more than for himself on religious grounds." *Id.* at 166. The Court concluded that "[t]he right to practice religion freely does not include liberty to expose the community or the child to communicable disease or the latter to ill health or death." *Id.* at 166–67.

In this appeal, Workman argues that *Jacobson* dealt only with the outbreak of an epidemic, and in any event should be overruled as it "set forth an unconstitutional holding." Workman's attempt to confine *Jacobson* to its facts is unavailing. As noted by one district court, "[t]he Supreme Court did not limit its holding in *Jacobson* to diseases presenting a clear and present danger." *Boone v. Boozman,* 217 F.Supp.2d 938, 954 (E.D. Ark. 2002). Additionally, we reject Workman's request that we overrule *Jacobson* because we are bound by the precedents of our Supreme Court.

Workman also argues that because West Virginia law requires vaccination against diseases that are not very prevalent, no compelling state interest can exist. On the contrary, the state's wish to prevent the spread of communicable diseases clearly constitutes a compelling interest.

In sum, following the reasoning of *Jacobson* and *Prince,* we conclude that the West Virginia statute requiring vaccinations as a condition of admission to school does not unconstitutionally infringe Workman's right to free exercise. This conclusion is buttressed by the opinions of numerous federal and state courts that have reached similar conclusions in comparable cases.

Workman next argues that West Virginia's immunization requirement violates her right to equal protection. . . .

Regarding her as-applied challenge, Workman argues that the school system discriminated against her when [the school superintendent] inquired into the validity of her exemption. The district court found, however, that Workman presented "no evidence of unequal treatment resulting from intentional or purposeful discrimination to support her claim." Indeed, [the superintendent] submitted an affidavit in which he stated that "we had never dealt with a request for a medical exemption during my tenure as Superintendent. . . . " [Workman] points to no evidence of unequal treatment, and we see none. . . .

Regarding her facial challenge, Workman notes that the statute does not provide an exemption for those with sincere religious beliefs contrary to vaccination. She argues

that the statute therefore discriminates on the basis of religion. The district court ruled that, although a state may provide a religious exemption to mandatory vaccination, it need not do so. . . . The Supreme Court held as much in *Zucht v. King,* 260 U.S. 174 (1922). . . .

Here, Workman does not explain how the statute at issue is facially discriminatory; indeed, her complaint is not that it targets a particular religious belief but that it provides no exception from general coverage for hers. Following the Supreme Court's decisions in *Zucht* and *Prince,* we reject Workman's contention that the statute is facially invalid under the Equal Protection Clause.

Workman next argues that denying her a religious exemption from the mandatory vaccination statute violates her substantive due process right to do what she reasonably believes is best for her child. Workman asserts that, because the statute infringes upon a fundamental right it must withstand strict scrutiny. She contends that the statute fails strict scrutiny because West Virginia has no compelling interest to justify vaccinating M.W.

The Due Process Clause "provides heightened protection against government interference with certain fundamental rights and liberty interests." *Washington v. Glucksberg,* 521 U.S. 702 (1997). To determine whether an asserted right is a fundamental right subject to strict scrutiny under the Due Process Clause, a court must (1) consider whether the asserted right is deeply rooted in the Nation's history and tradition; and (2) require a careful description of the asserted liberty interest. Where a fundamental right is not implicated, the state law need only be rationally related to a legitimate government interest.

As in *Boone,* "the question presented by the facts of this case is whether the special protection of the Due Process Clause includes a parent's right to refuse to have her child immunized before attending public or private school where immunization is a precondition to attending school." *Boone,* 217 F.Supp.2d at 956. We agree with other courts that have considered this question in holding that Workman has no such fundamental right.

Indeed, the Supreme Court has consistently recognized that a state may constitutionally require school children to be immunized. *See Prince,* 321 U.S. at 166–67; *Zucht,* 260 U.S. at 176; *cf. Jacobson,* 197 U.S. at 31–32 (noting that "the principle of vaccination as a means to prevent the spread of [disease] has been enforced in many States by statutes making the vaccination of children a condition to their right to enter or remain in public schools."). This is not surprising given the compelling interest of society in fighting the spread of contagious diseases through mandatory inoculation programs. Accordingly, we conclude that Workman has failed to demonstrate that the statute violates her Due Process rights. . . .

In sum, we hold that . . . Workman's constitutional challenges to the West Virginia statute requiring mandatory vaccination as a condition of attending school are without merit. . . .

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Workman illustrates the difficulties plaintiffs face when they challenge state vaccination laws on First Amendment grounds. Vaccination man-

dates are almost exclusively adopted at the state and local level. Prior to 1940, the First Amendment did not apply to state and local governments because the Supreme Court had not incorporated it into the Fourteenth Amendment (see chapter 4). Thus, neither *Jacobson* (1905) nor *Zucht* (1922) addressed the argument that vaccination mandates run afoul of the First Amendment.

As in *Workman,* the lower courts have relied on the Supreme Court's dicta in *Prince v. Massachusetts,* 321 U.S. 158 (1944), and its holding in *Employment Div., v. Smith,* 494 U.S. 872 (1990), to uphold state and local vaccination mandates in the face of free exercise challenges. *Smith* held that "a law that is neutral and of general applicability need not be justified by a compelling governmental interest even if the law has the incidental effect of burdening a particular religious practice." The Court noted that any other approach

> would open the prospect of constitutionally required religious exemptions from civic obligations of almost every conceivable kind—ranging from compulsory military service to the payment of taxes to health and safety regulation such as manslaughter and child neglect laws, compulsory vaccination laws, drug laws, and traffic laws; to social welfare legislation such as minimum wage laws, child labor laws, animal cruelty laws, environmental protection laws, and laws providing for equality of opportunity for the races. The First Amendment's protection of religious liberty does not require this.

In 1993, Congress sought to minimize the impact of the Court's holding in *Smith* by adopting the Religious Freedom Restoration Act (RFRA). RFRA requires courts to apply strict scrutiny to laws of general applicability that substantially burden the exercise of religion. RFRA provides statutory, not constitutional, protection for religious freedom. As a result, Congress may circumvent RFRA's restrictions at any time. Thus, if Congress wished to adopt a federal vaccination law (assuming that could be justified as an exercise of a power enumerated in the Constitution), it could expressly state that RFRA did not apply to the vaccination mandate.

The federal RFRA does not restrict state or local action. In *City of Boerne v. Flores,* 521 U.S. 507 (1997), the Supreme Court held that Congress lacked authority to extend RFRA to the states. Several state legislatures have adopted their own versions of RFRA, however, which may apply to vaccination mandates unless the legislature specifies otherwise.

As discussed in chapter 4, vaccine-refusing parents, including the plaintiffs in *Workman,* have pointed to dicta in *Smith* suggesting that,

in some cases, a free exercise challenge to a neutral law of general applicability may trigger heightened scrutiny if it is combined with a claim based on other rights such as the right of parents to direct the education of their children or freedom of speech. As the *Workman* opinion notes, this hybrid rights theory is controversial among the circuit courts. It has been unsuccessful in the vaccination context thus far.

As Reiss and Weithorn note, although the First Amendment does not require states to offer exemptions for parents who object to vaccination on religious grounds, most states provide them. Exemption criteria and procedures vary. For example, New York's vaccination statute provides that it "shall not apply to children whose parent, parents, or guardian hold genuine and sincere religious beliefs which are contrary to" vaccination. New York State Public Health Law § 2164.9. Accompanying regulations specify that parents may submit a standard form or written and signed statement "stating that the parent, parents or guardian objects to their child's immunization because of sincere and genuine religious beliefs which prohibit the immunization of their child, in which case the principal or person in charge of the school may require supporting documents." New York Code, Rules and Regulations Title 10 Subpart 66–1.3(d). Several states offer exemptions for nonreligious (sometimes referred to as *philosophical*) objections to vaccination as well. For example, Michigan's statute states that "A statement signed by a parent or guardian to the effect that the child has not been immunized because of religious convictions or other objection to immunization" may be submitted in lieu of proof of immunization. In 2014, the Michigan Department of Community Health issued new regulations requiring certification "by the local health department that the individual received education on the risks of not receiving the vaccines being waived and the benefits of vaccination to the individual and the community" for all non-medical exemptions. Michigan Administrative Code 325.176(12).

California, West Virginia, and Mississippi are the only three states that do not recognize any non-medical exemptions. Of the three, West Virginia is the only state that has never offered a religious exemption. Mississippi's vaccination law was originally drafted to include a religious exemption, but the state's supreme court struck down the exemption on the grounds that it impermissibly discriminated against individuals who did not have a religious belief counter to vaccination. *Brown v. Stone,* 378 So. 218 (1979). Other state religious exemptions

have been struck down on the grounds that they violate the First Amendment's prohibition on establishment of a religion. Those states, including Arkansas, subsequently revised their religious exemption provisions to avoid requiring that a parent's objection be based on a "recognized" religion.

California permitted religious and philosophical exemptions for many years, but in 2015 (following a major measles outbreak that originated at Disneyland), the state legislature amended the law to remove all non-medical exemptions. The revised statute, excerpted below, is one of the most stringent school vaccination laws in the country.

CALIFORNIA EDUCATIONAL AND CHILD CARE FACILITY IMMUNIZATION REQUIREMENTS

CAL. HEALTH & SAFETY CODE § 120335

(b) The governing authority [of a school district or private school] shall not unconditionally admit any person as a pupil of any private or public elementary or secondary school, child care center, day nursery, nursery school, family day care home, or development center, unless, prior to his or her first admission to that institution, he or she has been fully immunized. The following are the diseases for which immunizations shall be documented:

(1) Diphtheria.
(2) Haemophilus influenzae type b.
(3) Measles.
(4) Mumps.
(5) Pertussis (whooping cough).
(6) Poliomyelitis.
(7) Rubella.
(8) Tetanus.
(9) Hepatitis B.
(10) Varicella (chickenpox).
(11) Any other disease deemed appropriate by the department, taking into consideration the recommendations of the Advisory Committee on Immunization Practices of the United States Department of Health and Human Services, the American Academy of Pediatrics, and the American Academy of Family Physicians. . . .

(e) The department may specify the immunizing agents that may be utilized and the manner in which immunizations are administered.

(f) This section does not apply to a pupil in a home-based private school or a pupil who is enrolled in an independent study program . . . and does not receive classroom-based instruction. . . .

CAL. HEALTH & SAFETY CODE § 120370

(a) If the parent or guardian files with the governing authority a written statement by a licensed physician to the effect that the physical condition of the child is such, or medical circumstances relating to the child are such, that immunization is not considered safe, indicating the specific nature and probable duration of the medical condition or circumstances, including, but not limited to, family medical history, for which the physician does not recommend immunization, that child shall be exempt from the requirements of [Section 120335].

(b) If there is good cause to believe that a child has been exposed to a disease listed in subdivision (b) of Section 120335 and his or her documentary proof of immunization status does not show proof of immunization against that disease, that child may be temporarily excluded from the school or institution until the local health officer is satisfied that the child is no longer at risk of developing or transmitting the disease.

CAL. HEALTH & SAFETY CODE § 120375

(a) . . . The immunization record of each new entrant admitted conditionally shall be reviewed periodically by the governing authority to ensure that within the time periods designated by regulation of the department he or she has been fully immunized against all of the diseases listed in Section 120335, and immunizations received after entry shall be added to the pupil's immunization record.

(b) The governing authority of each school or institution included in Section 120335 shall prohibit from further attendance any pupil admitted conditionally who failed to obtain the required immunizations within the time limits allowed in the regulations of the department, unless the pupil is exempted under Section 120270, until that pupil has been fully immunized against all of the diseases listed in Section 120335.

. . .

Lawsuits to invalidate the California law have been unsuccessful so far. The elimination of non-medical exemptions has led record numbers of parents to seek medical exemptions. California's medical board has pursued disciplinary action against at least one doctor whose certification of a medical exemption purportedly deviated from the standard of care.

SCREENING: LAW AND ETHICS

Vaccination plays a critical role in preventing many infectious diseases that once ravaged the population. But vaccinations are not yet available—and may never be available—for many communicable diseases. In such cases, and in cases where outbreaks occur despite vaccination programs, testing to detect the presence of an infection is important to disease control. In the previous chapter, we discussed clinical testing in the context of surveillance

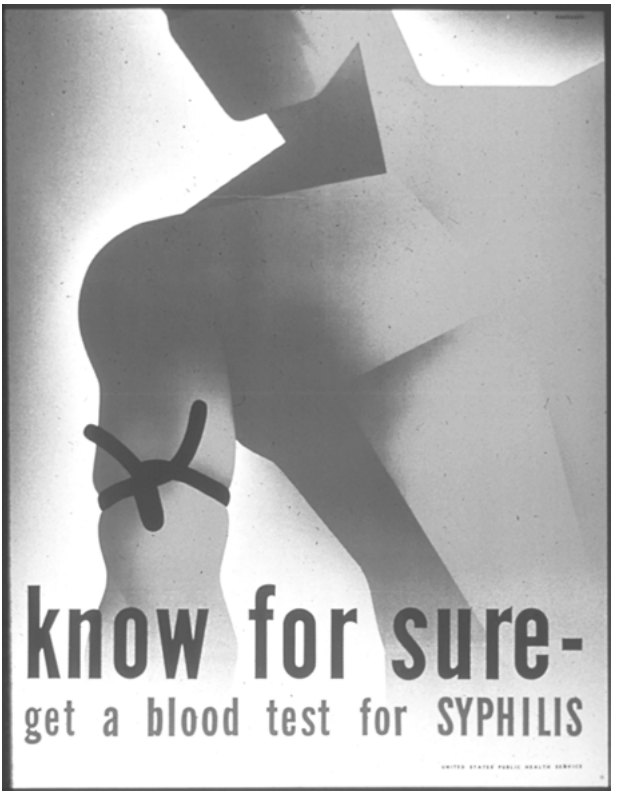

PHOTO 10.2. A World War II–era poster urges men to get tested for syphilis. U.S. Public Health Service.

aimed at monitoring trends in disease and injury. Here, our focus is on screening: the systematic application of a medical test to a defined population to identify individuals with specified conditions. Screening for infectious disease allows public health and health care professionals to offer education, counseling, and medical treatment. Treatment, of course, benefits the individual, but it can also reduce infectiousness.

Infectious disease screening is a basic tool of modern public health, but it can be intrusive and unjust. First, screening can be unreliable if the clinical test is technically deficient. If the test instrument is not sufficiently *sensitive,* it will fail to detect many cases of infection. If it is not sufficiently *specific,* it will produce false positives (i.e., persons will test positive although they are not actually infected). Even technically

adequate tests will have poor predictive value in populations with a low prevalence of infection. Screening in low-prevalence populations is likely to identify few cases of infection and many false positives. For example, early in the AIDS epidemic, Illinois mandated HIV screening as a condition of obtaining a marriage license, but soon discovered that it was highly cost-ineffective, uncovering few true positives and producing many false positive cases.

Second, screening can be intrusive unless the individual provides informed consent. Screening without informed consent undermines personal autonomy and bodily integrity. In addition, screening reveals sensitive medical information. If this information is passed on to others without the individual's permission, he may be subject to discrimination, bias, and social stigma as a result of his condition.

Third, screening may be unjust if it targets vulnerable populations. Suppose, for example, that tuberculosis screening were performed only on the homeless or syphilis screening were performed only on sex workers. Epidemiological studies may suggest that these groups are at increased risk, increasing the value of screening. But targeted groups could legitimately claim that the screening program is unjust because the classification it draws exacerbates preexisting stigmatization of vulnerable populations.

The excerpts that follow explore the law and ethics of screening. Scott Burris suggests that the social risks that attach to an HIV diagnosis threaten to undermine the benefits that could be gained by identifying infected individuals and offering them counseling and treatment to reduce the risk that they will spread the disease to others. The destigmatization strategy that he describes highlights privacy and antidiscrimination as important public health law tools for preventing the spread of HIV.

LAW AND THE SOCIAL RISK OF HEALTH CARE: LESSONS FROM HIV TESTING*

Scott Burris

To have the virus that causes AIDS, or the gene that predicts Huntingdon's, or a variety of other diseases that are particularly frightening, expensive, or stigmatized, is to face serious social as well as health threats. . . . The marginalization, sometimes even demonization, of people with diseases like tuberculosis and syphilis has been well doc-

* 1991. *Alabama Law Review* 61 (3): 831–96.

umented by historians. Today, the notion that diagnosis or treatment of such conditions can trigger social harms is widely accepted. It is likewise accepted that social risk can deter people with, or at risk of, threatening conditions from seeking care or from complying with public health directives. . . .

"THE ANTI-STIGMA PROJECT" DESCRIBED

There is no fundamental novelty in the stigmatization of HIV, nor in the recognition that stigma could interfere with the prevention of disease. Long before AIDS, states commonly had laws protecting the privacy of medical information reported to health departments, and the Supreme Court had suggested that such information enjoyed some constitutional protection. Yet, the social response to HIV has included an unprecedented amount of legal protection of the social status of the infected and those at risk. This response, which I refer to as "the anti-stigma-project," consists of a web of federal, state, and local laws to protect people with HIV from discrimination in employment, housing, and public accommodations; provisions in the federal and many state constitutions that have been interpreted in court to protect HIV-related medical information; and statutes in most states that variously protect medical privacy and limit HIV testing in the absence of informed consent. This project also has had a significant negative component: concerns about stigma have been consistently raised in opposition to other coercive legal measures, such as mandatory testing and a whole range of criminal laws directed at conduct that was thought to contribute to the spread of the disease.

The anti-stigma project can readily be justified in moral terms: it is unfair to mistreat people based on arbitrary and irrelevant differences and important, in civil society, to protect the privacy of sensitive personal information. More commonly, however, the anti-stigma project has been justified on utilitarian grounds: it has been argued that behavior that stigmatized or punished people with, or at risk of, HIV would reduce their willingness to cooperate with public health measures, frustrating, rather than assisting in the control of, the epidemic.

Disability Discrimination Law

Undoubtedly, the most significant legal development in the history of HIV was the treatment of HIV as a handicap as defined in statutes protecting disabled people from discrimination. This move began among litigators and judges, as lawyers representing people with HIV looked for sources of law that might protect their clients from the discrimination that began occurring almost as soon as the disease was identified. . . .

The statutory language defining handicap was usually quite broad. In Section 504 of the Federal Rehabilitation Act, for example, a "handicapped individual" was any person who "has a physical or mental impairment which substantially limits one or more . . . major life activities, . . . a record of such an impairment, or . . . is regarded as having such an impairment." The key legal question—whether Congress had intended to include communicable diseases within the definition—was settled by the Supreme Court in a 1987 case about a teacher with tuberculosis, *School Board of Nassau County v. Arline*[, 480 U.S. 273 (1987)]. [The Court noted] that the "isolation of the chronically ill and of those perceived to be ill or contagious appears across cultures and centuries, as does the development of complex and often pernicious mythologies about the nature, cause, and transmission of illness." . . .

The moral justification for the ruling was implicit rather than explicit, with a compassionate tone and a reliance on the self-evident odiousness of irrational fear, replacing moral exegesis.

The Court also justified its conclusion with reference to pragmatic concerns. Chief Justice Rehnquist, dissenting, argued that the decision represented an intrusion on the states' traditional authority to control communicable diseases. Justice Brennan's majority opinion countered (with a strong nod to HIV) that "because the Act requires employers to respond rationally to those handicapped by a contagious disease, the Act will assist local health officials by helping remove an important obstacle to preventing the spread of infectious diseases: the individual's reluctance to report his or her condition."

The complementary notions of rationality and unjustified fear are at the center of Brennan's approach to managing stigma through law. Much of the rhetorical and logical force of the opinion comes from his definition of the problem as the protection of the non-contagious from fear of contagion, which is axiomatically irrational, but which carries the implication that shunning the truly contagious is perfectly acceptable. The management problem for the law was to distinguish the two kinds of cases. The tool provided by the Court was the notion of "significant risk," which Brennan defined, with a pretense of precision, as a function of "(a) the nature of the risk (how the disease is transmitted), (b) the duration of the risk (how long is the carrier infectious), (c) the severity of the risk (what is the potential harm to third parties) and (d) the probabilities the disease will be transmitted and will cause varying degrees of harm."

In several later statutes, most notably the [Americans with Disabilities Act], Congress apparently adopted the Supreme Court's approach and affirmed the imputed intention to cover contagious diseases, including HIV, within the limits of "significant risk." In the course of the epidemic, this body of anti-discrimination law has been invoked again and again in response to discrimination in such areas as school admission, employment, medical care, housing, prison conditions, and insurance.

Privacy

The protection of privacy developed in two distinct strands. In the years after 1986, states began passing HIV testing and confidentiality laws in fulfillment of the social deal cut by public health officials on the use of HIV tests. At the same time, both state and federal courts began extending constitutional protection to HIV medical information, and recognizing a privacy interest in choosing to take or decline an HIV test. . . .

Politics being what they are, the laws did not always toe the pure anti-stigma line. Funeral directors, insurance companies, and other powerful players tended to get some degree of dispensation from the full force of the rules. Many exceptions were based explicitly or implicitly on the need to release information to protect others from a perceived significant risk of transmission or exposure. All things considered, however, HIV records acquired the sort of substantial privacy protection that people wrongly think all medical records enjoy.

Parallel to this was the development of constitutional privacy doctrine. The United States and many state constitutions have provisions that explicitly, or by judicial interpretation, protect the privacy of information collected or held by the government. Individuals whose HIV status was revealed by government officials used this existing body of law to win redress with considerable success. An exemplary case arose when a man with HIV, arrested on a minor charge, warned the officers frisking him to be careful because he had

"'weeping lesions'" and was HIV positive. The officers informed colleagues, who eventually warned the man's neighbors, resulting, by a roundabout but not unsurprising route, in his children being the subject of televised controversy at their school. The judge's opinion turned largely on the severity of HIV stigma:

> Society's moral judgments about the high-risk activities associated with the disease, including sexual relations and drug use, make the information of the most personal kind. Also, the privacy interest in one's exposure to the AIDS virus is even greater than one's privacy interest in ordinary medical records because of the stigma that attaches with the disease.

[*Doe v. Borough of Barrington,* 729 F. Supp. 376, 382 (D.N.J. 1990).]

The legal doctrine requires a "balancing" of the interest in privacy and the interest in disclosure, the latter being in most cases the prevention of transmission or the evaluation of the risk of an exposure. Judges and litigants in such cases have tended to evaluate demands for disclosure in terms similar to the significant risk analysis in anti-discrimination law. The mistreatment of the plaintiff and his family in *Doe* was unreasonable because none of the people who were warned were in real danger.

The judge in *Doe* also brought to bear the practical justification that privacy is a necessary condition for appropriate disclosure:

> Clearly, an arrestee's disclosure to police that he or she has AIDS is preferable to nondisclosure. . . . Police have more than "casual contact" with arrestee, increasing the likelihood that the disease can be transmitted. For example, by frisking an arrested person, police may come into contact with hypodermic needles. Thus, disclosure should be encouraged to protect police officers. Common sense demands that persons with AIDS be able to make such disclosures without fear that police will inform neighbors, employers, or the media.

Stigma as an Argument against Legislation

The handling of epidemics customarily involves social negotiation among the sick, the well, and the authorities. In a general way, then, it was not only plausible but eminently realistic for some to argue, and for health officials ultimately to conclude, that the response to the epidemic would have to be broadly acceptable to, and accommodate the preferences and needs of, the putative targets of control efforts. This is likely a truism of regulation in anything short of a police state. . . .

The argument has been raised against virtually every control measure made or proposed concerning HIV that involves any potential coercion at all. The roster includes not only more overt forms of control, such as quarantine and criminal prosecution of people with HIV, but also partner notification, premarital testing, and closure or regulation of sex clubs and bathhouses. The concern continues to arise in HIV policy deliberations at all levels.

• • •

The potential for public health interventions to exacerbate disease stigma is particularly concerning in cases where those interventions target groups that are socially marginalized, such as men who have sex with men, sex workers, injecting drug users, and people who are incarcerated. Epidemiological studies may indicate that these groups are at increased risk, but their socially vulnerable position and understandable mistrust of government authorities necessitate that public health officials tread carefully. Controversy over HIV screening of people who are incarcerated illustrates the complexity of managing disease risk among populations that are socially marginalized and particularly vulnerable to government control.

As one commentator (Hammett 2006) has noted,

> Despite the denials of many correctional administrators, sexual activity and illicit drug use do take place in prisons and jails. . . . Because of the general lack of condoms and sterile needles/syringes, such behavior may involve greater risk within correctional facilities than on the outside. . . . It has been estimated that in a given year, about 25% of all people in the United States who have HIV disease, about 33% who have HCV infection, and more than 40% who have tuberculosis disease will pass through a correctional facility that same year. This means that prisons and jails must be among the primary settings for interventions to prevent and treat infectious disease. . . . Nevertheless, the ethical problems and potential detriments of mandatory testing seem to outweigh the advantages. . . . [C]orrectional practices should reflect as much as possible those followed in the general community. . . . Creating a distinction on the basis of being incarcerated further stigmatizes inmates and undermines the important principle that correctional facilities are in fact part of the general community. . . . Within correctional facilities, the best policy is to offer and make readily available voluntary counseling and testing, with assurances that the results will remain confidential.

States and local laws and policies vary widely regarding HIV screening of incarcerated populations. CDC guidance, excerpted below, recommends routine screening of all inmates with an opportunity to opt out.

HIV TESTING IMPLEMENTATION GUIDANCE FOR CORRECTIONAL SETTINGS*

U.S. Centers for Disease Control and Prevention

. . . There are benefits to the community as well as the individual when a person learns of his or her HIV infection. Many people reduce their HIV risk behaviors to prevent transmission to their partners after being diagnosed with HIV infection, and they can begin the process of accessing care, treatment, and prevention services. Previous research has shown that men with a history of incarceration may avoid HIV testing while in the com-

* Centers for Disease Control and Prevention (2009).

munity and that inmates are more likely to receive voluntary HIV testing when prisons routinely provide (opt-out) HIV testing to everyone during the intake medical evaluation as opposed to prisons that rely on inmate-initiated (opt-in) requests for testing. Recent studies demonstrate that voluntary HIV testing is as cost-effective as other screening programs in health care settings in which HIV prevalence is as low as 0.1%. Since many incarcerated populations have a prevalence of diagnosed HIV infection {{gt}}1%, HIV screening in prisons and jails is a highly cost-effective public health strategy.

With opt-out HIV screening, the inmate is informed that an HIV test will be performed unless he or she declines the test. This process preserves public health and medical staff resources and greatly increases the proportion of inmates tested due to the streamlined consent and counseling processes. Opt-out screening also helps normalize HIV testing by making it a routine instead of an exceptional aspect of health care. . . . Opt-out HIV screening has the potential to identify many more HIV-infected individuals who are currently unaware of their HIV infection than opt-in screening does.

Benefits of adopting an opt-out HIV screening program

- Increases diagnosis of HIV infection;
- Preserves staff resources by streamlining the process;
- Reduces stigma associated with testing;
- Potentially diagnoses HIV infection earlier for the inmate; and
- Improves access to HIV clinical care and prevention services.

Basic principles of opt-out HIV screening

- HIV testing should be voluntary and free from coercion;
- Provide all inmates with information on HIV/AIDS and HIV testing upon entry into the facility;
- Screening should be performed only after notifying the inmate that an HIV test will be performed unless he or she declines (opts-out);
- Consent for HIV screening should be incorporated into the general informed consent (or other legal authorization) for medical diagnostic services;
- Separate written consent should not be required for HIV testing, unless required by state law; and
- Appropriate clinical care and support services to inmates diagnosed with HIV infection should be provided.

• • •

What are the benefits of routine testing of incarcerated individuals with opt-out? Is such an approach justified given that the general population is simply offered HIV testing and given the opportunity to consent or refuse?

ANTIMICROBIAL RESISTANCE: SUSTAINABLE MANAGEMENT OF A GLOBAL PUBLIC GOOD

It is impossible to overstate the number of lives saved by safe and effective antibiotic, antiviral, antifungal, and antiparasitic medications—

collectively known as antimicrobials. These drugs are unique, however, because their effectiveness can ultimately be overcome by the living pathogens (bacteria, viruses, fungi, parasites) they are designed to destroy. Microorganisms evolve rapidly because they replicate quickly and are able to transfer genetic material among themselves horizontally, rather than being limited to parent-offspring transfer. Particularly if an antimicrobial is administered at subtherapeutic levels insufficient to kill the pathogen (e.g., when low-dose antibiotics are used to promote rapid livestock growth or a patient with tuberculosis fails to complete a course of medication) the surviving organisms, which are resistant to the drug, proliferate. The spread of antimicrobial resistance is a complex global health crisis that demands innovative legal and policy interventions. Lawmakers can limit agricultural use through direct regulation, promote responsible treatment of infections by offering financial incentives to health care professionals, and raise public awareness through mandated disclosures and education campaigns. Antimicrobial resistance also raises ethical concerns discussed in the following excerpt.

THE ETHICAL SIGNIFICANCE OF ANTIMICROBIAL RESISTANCE*

Jasper Littmann and A.M. Viens

. . . Given the enormous importance of antimicrobial drugs for the functioning and delivery of modern health care, the progressive exhaustion of effective antibiotics presents health care professionals and policy makers with a distributive dilemma that raises complex moral questions of justice, especially how to fairly allocate antimicrobial resources. On the one hand, we may have to restrict the use of antibiotics as far as possible to ensure their continued effectiveness. On the other hand, we have not yet managed to ensure the provision of adequate access to antibiotics in many regions of the world, where the price of drugs is often prohibitive for patients and where over-the-counter sales have led to an unregulated and uncontrolled use of antibiotics. We are, therefore, faced with a situation in which we have to reduce the excessive use of antibiotics in some regions of the world while ensuring access in others. At the same [time], around half of the world's production of antibiotics are still used in animal and fish farming, which has created reservoirs for resistant bacteria and exacerbates the problem further. Efforts to make progress on these issues require us to raise, confront and enact some difficult ethical decisions that will affect the lives, relationships and personal projects of millions of people. . . .

* 2015. *Public Health Ethics* 8 (3): 209–24. By Permission of Oxford University Press.

WHY IS ANTIMICROBIAL RESISTANCE AN ETHICAL ISSUE?

[Antimicrobial resistance (AMR)] is putting current and future populations at substantial risk of injury, loss and death. It is going to require a redistribution of resources and a balancing of benefits and burdens, which in turn forces us to make a number of individual and collective sacrifices—often for people thousands of kilometers away and for future persons who have not come into existence yet. This will include questions about who is morally responsible for this predicament—and whether ascriptions of blame or sanctions should affect who should bear the costs of this problem. It is also going to require us to intentionally, and sometimes coercively, shape the institutional structures and individual behaviors of governments, corporations, scientists, clinicians and patients, which raises questions about important moral values such as solidarity, liberty, privacy, reciprocity, fairness and the common good. . . .

AMR and Risk

[E]xperts in global health and microbiology . . . predict the dawn of a post-antibiotic era, should we fail to act quickly and decisively. While models that predict the impact of AMR on future morbidity and mortality are—by their nature—speculative and dependent on a large number of uncertain variables, there appears to be broad consensus among experts that the effects of AMR are likely to be catastrophic in the near future, if we fail to take appropriate action. AMR will not only render the treatment of acute bacterial infections more difficult and costly—it will also increase the risk for medical procedures in which antibiotics are used prophylactically, such as surgical interventions or some types of chemotherapy. Allowing AMR to progress unchecked would thus lead to a situation where we might fall short of moral obligations to provide safe medical care, when standard invasive procedures carry high risks of complications or even death. In addition, AMR drastically increases the risk of a return of epidemic and pandemic outbreaks that could be treated with antibiotics in the past. Already, we are witnessing high levels of morbidity and mortality due to multi drug-resistant and extensively drug-resistant tuberculosis, with drug-resistant typhoid infections becoming more and more common as well. . . .

Responsibility for Acting

Due to the speed and scale with which we must react in order to avert a post-antibiotic age, we are also faced with what constitutes a proportional response and, crucially, who bears responsibility to act. While AMR is a complex challenge with numerous causes, it is the broad use of antimicrobials in health care and agriculture that is the driving force behind the emergence of drug resistance. This means that we are unlikely to find a solution to AMR without substantially changing the way we use antibiotics, and reducing the amount we consume. . . .

At the same time, however, we must remember that there may be no truly sustainable way of using antibiotics in the long-run, as micro-organisms have shown to be almost infinitely adaptable since the first introduction of antibiotics. This means that our struggle to keep abreast of AMR will most likely be a continuous and vicious cycle of resistance and obsolescence. . . . [U]nderstanding AMR as a slowly emerging disaster . . . emphasizes the need for policies that build resilience, and better prepare us for a world in which fewer effective anti-microbials are available. . . .

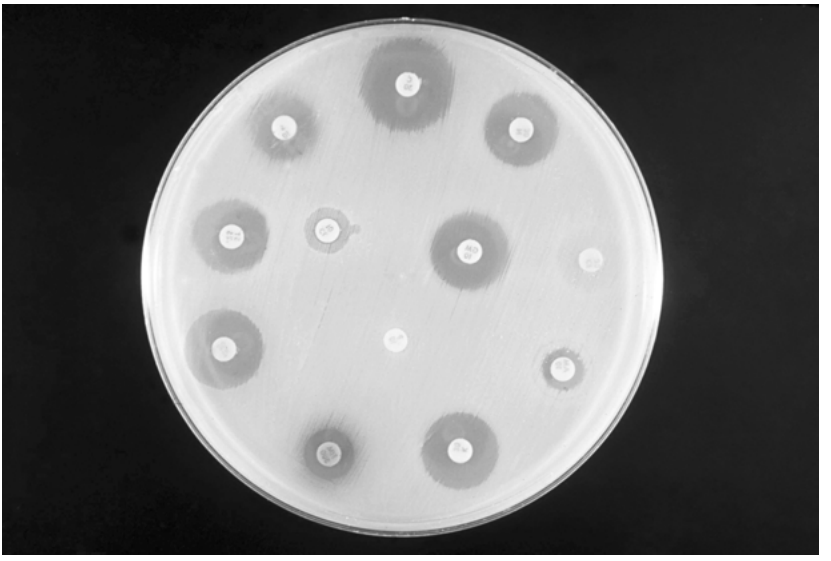

PHOTO 10.3. Antibiotic sensitivity of E. coli bacteria. The size of the "inhibition" zones surrounding each antibiotic-impregnated paper disk indicates the sensitivity of the bacteria to the antibiotic. U.S. Centers for Disease Control and Prevention.

Solidarity against AMR

There are no current or future persons who will not be affected by AMR. The risks and costs associated with this problem reflect a shared vulnerability we all have. This fact highlights the need for solidarity between persons, institutions and nation states in responding to AMR. . . .

Solidarity is important because it underlines the fact that we will only be able to effectively deal with AMR through collective and collaborative activities, but also because many of these population-level activities will often make it difficult to fulfil some individual-level preferences in order to achieve the public interest that arises out of mitigating AMR. This is not to understand AMR in simplistic terms as involving a conflict between liberty and the common good, or that population-level concerns should always win out over individual preferences. A focus on solidarity seeks to re-orient our ethical focus towards our common interests and vulnerabilities, individually and collectively, and how these considerations should make the distribution of health and risk a joint concern of all levels and sectors of our global society. . . .

AMR and Questions of Justice

[A]ny solution to the problem of AMR will require a fair balance of benefits and burdens among those affected by it. However, the global burden of infectious disease is distributed highly unevenly and low-income countries are disproportionately affected by AMR. This means that high-income countries will likely have to bear a much larger

share of the response, e.g., through developing new drugs and technologies, enhancing surveillance and reporting systems and conducting research in areas that may not be aligned with their current national priorities. . . .

MOVING FORWARD

Successful responses to the problem of AMR will not only be a scientific or medical undertaking, it must also be an ethical undertaking. . . . [E]very level of an AMR response strategy will inevitably involve making decisions with ethical implications. Reducing the use of antimicrobial drugs in humans and animals means instituting behavior-changing interventions and restricting their choices, which are likely to limit preferences and potentially subjecting people to elevated risks of complications or infection and financial costs. Improving surveillance and reporting systems increases concerns about confidentiality and privacy. Preventing and controlling the spread of drug-resistant infections, especially if we have AMR-related epidemics /pandemics, can involve the increased use of restrictive measures, raising questions about constraints on liberty and human right derogations. Promoting research and innovation into different preventative, diagnostic and therapeutic interventions will require us to make funding and allocation decisions that prioritize AMR over other important projects and policies. What these examples entail for policy makers, practitioners and researchers alike is that ethical decisions in AMR policy cannot be avoided—and if such policies are to have any kind of normative legitimacy, they can no longer be ignored either. . . .

. . .

In a proposal for an international legal framework to address antimicrobial resistance, Steven J. Hoffman and colleagues (2015) called for global collective action to harmonize efforts toward three goals:

> (i) access, to ensure that the prevention tools, diagnostics and therapies needed to reduce the infectious disease burden are available and affordable to everyone, everywhere; (ii) conservation, to reduce the need for antimicrobials and ensure their responsible use through prevention efforts, infection control, surveillance and appropriate prescriptions; and (iii) innovation, to develop the next generation of antimicrobials, vaccines, diagnostics and infection control technologies.

Moreover, they note, these goals are interdependent and must be addressed simultaneously.

> Without conservation and innovation, universal access will simply drive resistance and deplete existing stocks of effective antimicrobials. Conservation, if pursued alone, will constrict the market for antimicrobials, restrict investment and innovation in the field and hinder access. Innovation without conservation will waste new drugs and diminish the value of investments. Innovation without better access is inequitable. Like the legs of a tripod, each area needs the support of the other two.

One cause of antimicrobial resistance is incomplete treatment. When a patient takes antibiotics to treat tuberculosis (TB), for example, but does not complete the full course of treatment, the bacteria that cause the disease can develop resistance. In turn, the patient can spread the antibiotic-resistant strain of TB to other people. A patient may fail to complete a full course of antibiotic therapy for many reasons. In countries with inadequate regulation and enforcement, for example, antimicrobial medications may be counterfeit or substandard, failing to contain a full dose of the active ingredient. In other cases, unstable living conditions, lack of access to medical care, mental illness, or other conditions can impede a patient's ability to complete the course of treatment. One solution to antimicrobial resistance is directly observed treatment, which may be voluntary or compulsory, to ensure that the infected individual completes a full course of prescribed medication. We turn to this controversial issue in the next section.

ISOLATION AND COMPULSORY TREATMENT OF INFECTED INDIVIDUALS

Long before scientists understood the mechanics of how communicable diseases are transferred from person to person via microbes, societies employed one of the most basic tools for controlling the spread of disease. In modern parlance, *isolation* refers to separation of an infected individual from others. The related practice of *quarantine,* which will be addressed in the next chapter, refers to separation of those who may have been exposed, but have not yet tested positive for the infection. In many cases, individuals are willing to submit to isolation or quarantine for the benefit of others. Occasionally, however, due to lack of understanding, distrust of health care professionals or government officials, or self-interest, an individual may be unable or unwilling to comply, necessitating compulsory measures implemented via court order and law enforcement.

The advent of antimicrobial therapy has transformed the public health response to infectious disease. Treatment not only benefits individuals by ameliorating symptoms but also benefits society by reducing or eliminating infectiousness. But these benefits depend on individual compliance with the recommended course of treatment. In some cases, an individual may fail to appreciate the need for treatment due to lack of symptoms (e.g., many patients with sexually transmitted infections are asymptomatic but infectious and at risk for long-term complica-

tions). In other cases, initial doses of medication are sufficient to ameliorate the patient's symptoms—temporarily, at least—but inadequate to eliminate infectiousness. And in other cases, individuals struggling with substance use disorders mental illness, or lack of social support may be unable to complete a recommended course of treatment that requires taking oral medication at a consistent time each day for weeks or months. For particularly hard-to-treat infections such as multi-drug resistant tuberculosis, a course of treatment can last a year or more.

State intervention is sometimes necessary for the good of the individual and the public. Directly observed treatment (DOT, more commonly referred to as DOTS) entails supervision by a family member, peer advocate, community worker, or health professional to ensure the individual takes her medicine. Health officials may require the person to report to a specified location to receive the medication, to be visited by an observer at her home or place of work, or to be observed remotely via video chat. DOT can be accomplished voluntarily or through incentives (e.g., cash payments). Less often, however, public health officials can compel the individual to take medication if there is a risk to the public. And in very rare cases, health officials resort to confinement to ensure compliance with treatment (see chapter 11).

DOT is a highly effective and cost-efficient strategy for ensuring that infected individuals complete the full course of treatment. It can, however, infringe on personal liberty and privacy and should be deployed with care. As Bayer and Wilkinson (1995) suggest, public health authorities must determine

> the appropriate mix of clinic-based care and care provided by community-based outreach workers; the need for provision of housing for homeless patients; the need for drug and alcohol abuse treatment, and psychiatric services for those who are impaired; the part to be played by financial inducements for remaining in care; and the functions of court mandates and the ultimate threat of compulsory hospitalization for those who refuse to remain in treatment until cured.

Bayer and Wilkinson note that court mandates to participate in DOT are ultimately backed by the threat of compulsory hospitalization. Most state public health statutes authorize public health officials to mandate treatment for a contagious disease, whether or not the affected individual is competent to make treatment decisions. The courts have consistently affirmed the constitutionality of compulsory treatment. Although the right to refuse medical treatment is protected by the Constitution, the courts balance the individual's liberty interests against the state's

interest, generally permitting compulsory treatment where the individual poses a danger to himself or others and where treatment is medically appropriate. Civil confinement orders may be used to enforce compulsory treatment if necessary. As discussed in the next chapter, civil confinement can also be a tool for enforcing isolation and quarantine during public health emergencies.

Patients with communicable diseases who are unwilling or unable to comply with orders to isolate themselves or take recommended medications but do not otherwise require significant medical attention present a dilemma for the public health system. Hospital care is quite expensive and hospitals may not be well equipped to hold a patient against her will for a prolonged period. Are public health authorities justified in confining noncompliant patients in other settings? As the cases below—separated by more than 100 years—demonstrate, these questions may be resolved by a combination of constitutional doctrine and state statutory interpretation.

*KIRK v. WYMAN**

Supreme Court of South Carolina
Decided August 19, 1909

[The city of Aiken, South Carolina, found that Mary Kirk had contagious leprosy and required her to be isolated in the city hospital for infectious diseases. Kirk claimed that although she had leprosy, she was not dangerous to the community. In addition, she complained that the hospital where she was to be placed was really a "pesthouse, coarse and comfortless" and used for "incarcerating negroes having small-pox and other dangerous infectious diseases." She further objected to her isolation because of the odors coming from the city dumping ground near the hospital. She was granted a temporary injunction. The Board of Health appealed, claiming that she was a danger to community, that they had sought measures to improve the hospital and would eventually provide a private cottage for her, and that the city dump was located nearby but did not contain foul deposits.]

Municipal boards of health . . . are to be considered as deriving their authority to isolate infected persons . . . from section 1099 of the Civil Code, which provides:

> The said board of health shall have power and it shall be their duty to make and enforce all needful rules and regulations to prevent the introduction and spread of infectious or contagious diseases by the regulation of intercourse with infected places, by the arrest, separation, and treatment of infected persons, and persons who shall have been exposed to any contagious or infectious diseases. . . . They

* 65 S.E. 387.

> shall also have power, with the consent of the town or city council, in case of the prevalence of any contagious or infectious diseases within the town or city, to establish one or more hospitals and to make provisions and regulations for the management of the same. . . .

The principles of constitutional law governing health regulations by statute and municipal ordinance may be thus stated:

First. Statutes and ordinances requiring the removal or destruction of property or the isolation of infected persons, when necessary for the protection of the public health, do not violate the constitutional guaranty of the right of the enjoyment of liberty and property, because neither the right to liberty nor the right of property extends to the use of liberty or property to the injury of others. . . . The individual has no more right to the freedom of spreading disease by carrying contagion on his person, than he has to produce disease by maintaining his property in a noisome condition.

Second. The state must of necessity lodge the power somewhere to ascertain, in the first instance, and act with promptness, when the public health is endangered by the unhealthful condition of the person or the property of the individual; and the creation by legislative authority of boards of health, with the discretion lodged in them of summary inquiry and action, is a reasonable exercise of the police power. . . .

Third. Arbitrary power over persons and property could not be conferred on a board of health. . . . [B]oards of health may not deprive any person of his property or his liberty, unless the deprivation is . . . reasonably necessary to the public health; and such inquiry must include notice to the person whose property or liberty is involved, and the opportunity to him to be heard, unless the emergency appears to be so great that such notice and hearing could be had only at the peril of the public safety.

Fourth. . . . [T]he regulations and proceedings of boards of health are subject to judicial review. . . . In passing upon such regulations and proceedings, the courts consider, first, whether interference with personal liberty or property was reasonably necessary to the public health, and, second, if the means used and the extent of the interference were reasonably necessary for the accomplishment of the purpose to be attained.

Fifth. . . . [T]he courts must determine whether there is any real relation between the preservation of the public health and the [measure at issue]. If the statute or the regulations made or the proceedings taken under it are not reasonably appropriate to the end in view . . . the courts must declare them invalid. . . .

In applying these principles, it is to be borne in mind that the case under consideration is unusual, imposing upon the Aiken board of health a delicate and unpleasant duty. Miss Kirk is not only a lady of refinement, highly esteemed in the community, but she is quite advanced in years. The proceedings of the board show clearly their solicitude to treat Miss Kirk with courtesy and consideration. . . .

That Miss Kirk is afflicted with anaesthetic leprosy contracted while engaged in missionary work in Brazil is admitted. While there is a strong showing that the anaesthetic form of the disease is only slightly contagious, when the distressing nature of the malady is regarded, it is manifest that the board were well within their duty in requiring the victim of it to be isolated. The case then turns on whether, under the principles above stated, . . . the manner of the isolation was so clearly beyond what was necessary to the public protection that the court ought to enjoin it as arbitrary. . . . [T]here is hardly any danger of contagion from Miss Kirk, except by touch, or at least close personal

association. What is more important than these opinions is the uncontroverted fact that Miss Kirk has for many years lived in the city of Aiken, attended church services, taught in the Sunday school, mingled freely with the people in social life, resting on the opinion of Dr. Hutchinson, a distinguished London specialist, that her disease was not contagious, and in all that time there has been nothing to indicate that she has imparted the disease to any other person. Was there any necessity to send such a patient to the pesthouse? The board of health had established a strict quarantine of her dwelling, and there was no evidence that Miss Kirk had made any effort to violate it. The maintenance of this quarantine, we cannot doubt, afforded complete protection to the public. It is true the board could not be expected to maintain a permanent quarantine of a house in the heart of the city of Aiken; but the city council had agreed to build for the purpose of isolation a comfortable cottage outside of the city limits, which could have been completed in a short time.

There is some conflict in the affidavits as to the condition of the pesthouse; but it is not denied that it is a structure of four small rooms in a row, with no piazzas, used heretofore for the isolation of negroes with smallpox, situated within a hundred yards of the place where the trash of the city, except its offensive offal, is collected and burned. The smoke from this pile is blown through the house. The board of health, it is true, have made it less uncomfortable by painting and some other work; but . . . we are forced to the conclusion that even temporary isolation in such a place would be a serious affliction and peril to an elderly lady, enfeebled by disease, and accustomed to the comforts of life. Nothing but necessity would justify the board of health in requiring it, and we think . . . there was no good reason to conclude that such necessity existed.

IN RE *WASHINGTON**

Supreme Court of Wisconsin
Decided July 17, 2007

On May 19, 2005, Ruby Washington was evaluated for tuberculosis at [a tuberculosis (TB) clinic] operated by the City of Milwaukee Health Department. [After laboratory testing, she was diagnosed with TB and given medication.] Washington was living in a shelter and had no fixed address at the time. TB Clinic staff provided Washington with bus tickets to ensure that she would return for periodic directly-observed therapy. Washington did not show up for her next two appointments to receive her medication, and could not be located.

The Department issued Washington a directly-observed therapy and an isolation order on July 27, 2005, which it intended to serve upon Washington as soon as she could be located. On August 22, 2005, a nurse at the Medical Center informed the Department that Washington had been admitted to the hospital and was giving birth to a baby. The Department served the orders for treatment and isolation on Washington later that day, and requested that Washington stay at the Medical Center.

The next day, after Washington threatened to leave the Medical Center, the City of Milwaukee petitioned the circuit court under Wis. Stat. § 252.07(9) for enforcement of

* 735 N.W.2d 111.

the treatment and isolation orders. The Milwaukee Circuit Court . . . appointed an attorney from the State Public Defender's Office to represent Washington. Counsel for the parties reached a stipulation whereby Washington would remain confined at the Medical Center, at least until a status hearing on September 27, 2005, at which point the circuit court would assess the progress of Washington's treatment and her possible release from hospital confinement.

[At the hearing,] Counsel for the parties reached a second stipulation under which Washington would be released from confinement at the Medical Center, but would report to the TB Clinic at regular intervals to receive medication by directly-observed therapy, consistent with the July 27 order. Additionally, the stipulation required that Washington follow a nine-month treatment plan and live with her sister, Alwiller Washington, during that time. . . .

[Two days after the hearing, Washington's sister contacted the TB clinic to report that Washington had left her residence shortly after being released from the Medical Center and had not returned. A clinic manager named Irmine Reitl, accompanied by a city police officer, located Washington in a store parking lot.] In an affidavit to the court, Reitl averred that Washington "said many things that [Reitl] was unable to understand" and that Washington "seemed less than coherent in her thoughts."

[According to Reitl's testimony:]

> Ruby was crying and yelling while the police spoke to her. After a few minutes, Ruby was handcuffed and placed in a squad car. While in the police car, she continued to be agitated and was kicking her feet out of the squad car window and kicking the inside roof of the squad car, all the while loudly screaming, yelling and crying.

Washington received an assessment from the Medical Center and was transported to the [County Criminal Justice Facility (CJF)]. The City filed a "Motion of Contempt" with the circuit court seeking Washington's confinement to the CJF for noncompliance with the prior treatment order. Washington was held in the CJF pending a court hearing scheduled for October 3, 2005, on the City's motion.

On October 1, 2005, Washington was mistakenly released from the CJF and went missing. The October 3 hearing was adjourned because the City had yet to locate Washington. On the morning of October 5, Washington was found at the home of a friend, and was detained by police. She was taken to the Medical Center to be evaluated, and then held at a district police station for a period of hours.

Judge Fiorenza convened a hearing later that afternoon at which Washington contested the City's allegation that she was in violation of the treatment order. . . .

. . . Washington admitted that she stayed at a friend's house and not with her sister upon her release from the Medical Center on September 27. She also admitted that she had not taken her tuberculosis medication on October 2 as ordered because "[i]t had slipped [her] mind." Based on these statements, which the circuit court determined were admissions of noncompliance, the court found Washington to be in violation of the prior treatment orders. The circuit court concluded that, as a consequence, confinement was appropriate.

The City asked that Washington be confined to the CJF. The City stated that it "d[id] not believe that there [was] any facility . . . other than the [CJF] that would serve

the purpose of protecting the public health under these very unusual and extraordinary circumstances."

[Under the Wisconsin statue allowing confinement of a TB patient], the [Department of Health and Family Services [DHFS)] or local health officer must notify a court in writing of the confinement. . . . A law enforcement officer or other authorized person must transport, when necessary, the person subject to a confinement order . . . "to a facility that [DHFS] or [the] local health officer determines will meet the individual's need for medical evaluation, isolation and treatment." § 252.07(8)(b). A person may not be confined for more than 72 hours under § 252.07(8), excluding Saturdays, Sundays and legal holidays, "without a court hearing . . . to determine whether the confinement should continue." § 252.07(8)(c). Under Wis. Stat. § 252.07(9)(a),

> [t]he [DHFS] or a local health officer may petition any court for a hearing to determine whether an individual with infectious or suspect tuberculosis should be confined for longer than 72 hours in a facility where proper care and treatment will be provided and spread of the disease will be prevented.

The statute further provides that DHFS or a local health officer "shall include in the petition documentation that demonstrates all of the following": (1) the person has infectious tuberculosis, has noninfectious tuberculosis but is at a high risk of developing infectious tuberculosis or has suspect tuberculosis; (2) the person "has failed to comply with the prescribed treatment regimen . . . or that the disease is resistant to the medication prescribed" to the person; (3) "all other reasonable means of achieving voluntary compliance with treatment have been exhausted and no less restrictive alternative exists; or that no other medication to treat the resistant disease is available"; and (4) the person "poses an imminent and substantial threat to himself or herself or to the public health." § 252.07(9)(a)1.-4. A person confined under [the statute] "shall remain confined until the department or local health officer . . . determines that treatment is complete or that the individual is no longer a substantial threat to himself or herself or to the public health." If the person is to be confined for more than six months, "the court shall review the confinement every [six] months." Wisconsin Statute, § 252.07(9)(c). . . .

Washington does not challenge the circuit court's basis for ordering her confinement. . . . She asserts only that the court lacked authority under the statute to order confinement to the CJF. Washington first contends that a jail is not a "facility" as the term is used in § 252.07(9)(a), which authorizes confinement to a "facility where proper care and treatment will be provided and spread of the disease will be prevented."

Elsewhere in Wis. Stat. § 252.07 and in other sections of Chapter 252, "isolate" and "quarantine," or variants of these terms, are used rather than "confine." Section 252.07(1g)(c) defines "isolation" as "the separation from other persons of a person with infectious tuberculosis in a place and under conditions that prevent the transmission of infection." The term "quarantine" is not defined in Chapters 250 or 252. Webster's definition of "quarantine" is "to isolate as a precaution against contagious disease."

By contrast, the word "confine" has a somewhat different meaning than "isolate" or "quarantine." Webster's defines "confine" as "to keep in narrow quarters," listing

"imprison" as a synonym. "Confine" thus connotes not only isolation, but suggests something about the nature of the place to which a person may be isolated or quarantined that is consistent with placement in jail. Because the legislature in Wis. Stat. § 252.07(9)(a) did not use "isolate" or "quarantine," terms used frequently in § 252.07 and throughout Chapter 252, but used "confine" instead, we presume that the legislature was aware of the precise meanings of these terms and intended a different meaning by use of "confine." We conclude that, together, the commonly accepted meanings of "facility" and "confined" indicate that the legislature intended jail to be a permissible placement option under Wis. Stat. § 252.07(9)(a) for persons with noninfectious tuberculosis who are noncompliant with a prescribed treatment regimen, provided that "no less restrictive alternative exists" to such placement, and that the particular jail to which a person is to be confined is a place where proper care and treatment will be provided and spread of the disease will be prevented.

We find support for this interpretation in the legislative history of the statute. . . . In a memo addressed to the legislative drafting attorney critiquing an early draft of the proposal, a [state] official suggested that the revised statute include a definition of . . . "'facility' which could include something other than a health care facility. For example, if the person is incarcerated the facility would be a jail, which would be treating the person for [tuberculosis]." . . . The drafting attorney responded: "[P]lease note that I did not include a definition of 'facility' because I was unsure how the department wanted it defined *(other than to make sure it included a penal facility)*. I do not believe it's a problem to leave it undefined. *It would just take a rather broad dictionary definition*."

Washington contends that because the purpose of confinement for those with tuberculosis who have not complied with a treatment regimen is nonpunitive, Wis. Stat. § 252.07(9)(a) should be construed to preclude confinement to a jail in the absence of express statutory authorization for such a placement. We agree that the purpose of any placement is not to punish the noncompliant person for failing to follow a prescribed treatment regimen, but to provide treatment and to prevent him or her from infecting others. The statutory scheme ensures that jail is not a placement of first resort, but rather is permitted only in cases in which no less restrictive alternate placement is available. Additionally, the particular facility to which a person is to be confined, whether a penal institution or other type of facility, must be a place where proper care and treatment will be provided and spread of the disease will be prevented. . . .

If conditions at a particular jail (or other facility) are such that proper care and treatment would be unavailable, or contrary to the prevention of the spread of the disease, such a placement would not be authorized under § 252.07(9)(a). Whether a facility meets these requirements is a fact-intensive question and is addressed to the circuit court's discretion.

Washington next argues that if jail is a permissible place of confinement . . . confinement to jail is not permitted whenever some less restrictive placement is available. . . .

[She also] argues that the circuit court erred in considering the relative costs to taxpayers of different placements in making its confinement decision. She asserts that cost may not be considered in determining place of confinement because it is not one of the placement criteria set forth in Wis. Stat. § 252.07(9). . . .

Washington contends that the circuit court confined her to jail instead of the Medical Center based solely on its conclusion that the costs to local taxpayers of confinement to the Medical Center were too burdensome. We agree that the court's stated reasons for its placement decision were fiscal in part. However, we conclude the transcript of the circuit court hearing demonstrates that other factors, including the public health of the community and the treatment and care of Washington, were paramount.

The circuit court found that Washington posed a "huge health risk" to the community by repeatedly failing to take her medication for tuberculosis. The record shows that Washington had been previously treated for tuberculosis and was therefore at greater risk of developing a more dangerous, drug-resistant strain of the disease. The court concluded that Washington had a history of disappearing from sight, that the Department previously had great difficulty locating her, and that there was nothing in the record to show that she would voluntarily turn herself in to start taking her medicine again. When placed in the community under supervised conditions, Washington walked away from that placement. The court was concerned that Washington "cannot comply with Court orders." It heard testimony that if Washington were to escape custody yet again she would "certainly" become contagious within a month, perhaps in as soon as a week. The court was also concerned that tuberculosis could "become [resistant] to medications."

The circuit court did not want to confine Washington to jail, but felt it had no choice. . . .

Based on these considerations, we conclude that the order confining Washington to jail was not an erroneous exercise of the circuit court's discretion. . . . The circuit court reasonably concluded . . . that medical staff would not have been equipped to handle Washington's outbursts, and that the added security of jail was necessary to ensure that she would continue taking her medication and would not escape confinement. Factoring in taxpayer costs as well was not an erroneous exercise of discretion.

. . .

Can the difference in how Mary Kirk and Ruby Washington were treated by public health authorities be explained entirely by the medical facts? Could class bias have influenced how local officials and judges responded to the risks these two women posed and the acceptability of alternative approaches?

Courts are generally reluctant to adjudicate matters of budgetary allocations by the legislative and executive branches. And they are often particularly deferential to government activities to control communicable disease. Thus, public health officials generally have wide latitude to compel isolation and treatment, but have legal and ethical obligations to provide noncompliant patients with support and treatment in the least restrictive setting possible. For example, California guidelines for the civil detention of "persistently nonadherent" tuberculosis patients state that detention facilities should provide case management, discharge planning, twenty-four-hour security, recreation facilities, mental

health and substance abuse counseling, reasonable accommodation for social-cultural needs or disabilities, visiting privileges, and interpreter services. Ultimately, however, it is the legislature's responsibility to allocate sufficient resources to fulfill these obligations. Public health agencies must continue to prevent the spread of contagious disease even when they are chronically underfunded. As a result, individuals are often subjected to civil confinement under less-than-ideal conditions.

PARTNER NOTIFICATION AND EXPEDITED PARTNER THERAPY

Communicable diseases may put household members, sexual partners, needle-sharing partners, and other personal contacts at risk. This poses a legal and ethical dilemma for health professionals: whether to safeguard individual privacy or disclose the risk. This tension is especially pertinent with regard to sexually transmitted infections.

Public health statutes typically authorize officials to identify and notify sexual partners and other contacts at risk of infection. In many jurisdictions, health care providers are obligated to report the known sexual and needle-sharing partners of patients to the health department. Some states, encouraged by federal spending conditions, have adopted laws obligating providers to undertake a good faith effort to notify an HIV-infected patient's spouse of the risk of infection. Common law tort doctrines may also obligate health care providers to take reasonable steps to notify identifiable individuals who may be at risk due to a patient's infection.

In the excerpt that follows, Donna Hanrahan offers a hypothetical case study exploring ethical and legal concerns raised by contact tracing and partner notification in the age of social media.

HYPOTHETICAL: ROLE OF SOCIAL MEDIA IN HIV/AIDS TRACKING, CONTACT TRACING, AND PARTNER NOTIFICATION*

Donna Hanrahan

. . . The principle of confidentiality between physician and patient dates back to before the Hippocratic Oath. Nevertheless, the scope of confidentially is subject to limitations,

* Reprinted from "Privacy, Social Media, and Public Health: A Changing Landscape," Institute for Ethics and Emerging Technologies, December 5, 2013.

especially in cases where public welfare is endangered. Affirmative disclosure obligations have expanded throughout the years, and every state in the U.S. has some type of mandatory reporting of certain communicable diseases in place.

In addition to mandatory reporting, public health officials can exercise police authority to mandate contact tracing. Contact tracing is the process by which individuals who may have come into contact with an infected person are identified and later notified of potential exposure by a public health official without directly naming the infected individual. For the purposes of HIV/AIDS, this is generally limited to sexual partners or individuals involved in sharing intravenous needles. Despite its controversial nature due to privacy concerns, and potential deterrence of testing, it remains standard practice in nearly all states. . . .

It is not unprecedented for nontraditional methods to be used as a means of contact tracing as a last resort. Consider the example of Nushawn Williams in 1997. Williams, a 20-year-old male, was allegedly responsible for a "cluster" of HIV infections through sexual activity in Chautauqua County and New York City, despite knowledge of his HIV-positive status. Because of his self-declared intention of noncompliance, New York state and local health officials declared him a "clear and imminent danger to the public health," and released his identity to the news media, an untraditional outlet to inform the public about an alleged public health threat.

Now consider the following hypothetical involving an adult HIV-positive male who is unwilling to cooperate with public health officials. He refuses to disclose his contacts. . . . He also refuses to inform future sexual partners of his HIV status, will not use condoms during sexual activity, and continues to use popular social networking websites to seek out sexual partners.

Due to his refusal to assist in the identification of those exposed, and future noncompliance, the Department of Health and Human Services believes that social media could be of considerable use for the purpose of contact tracing to identify and notify individuals who may have been exposed. Taking into consideration the privacy implications of the proposed expansion of surveillance activities, would it be appropriate to incorporate social media into surveillance for the purpose of contact tracing?

There are two key conflicting principles in this hypothetical: 1) The privacy "right to be let alone" [of] the individual, and 2) the [contacts'] "right to know" of potential exposure. In other words, the state's fundamental authority to protect the population's safety and welfare is at odds with the individual's legally protected rights to autonomy, privacy, liberty, and property. Under the Millian harm principle, which holds that "the only purpose for which power can be rightfully exercised over any member of a civilized community, against his will, is to prevent harm to others," intervention and regulation on individual behavior is justified so long as it prevents harm and risk to others.

To intrude on individual liberties, the state must first demonstrate a rational and legitimate interest in intervention. Accordingly, one must assess the nature, duration, probability, and severity of risk at hand. In the case of HIV, there is a potentially high duration and magnitude of harm if exposed, so there is a clear rational interest for intervention. It can be argued that there is a duty for public health officials to warn exposed individuals. The population's reliance on the protection from the state implies an ethical obligation for the government to exercise its authority to ensure health and safety.

Generally, public health policy strives toward the least restrictive means of intervention to be exercised, to not unduly compromise the rights and liberties of an indi-

vidual. Accordingly, the use of online social network data without consent should be seen as permissible only as a last resort, rather than standard practice.

While it is often argued that individual liberty must be subordinated to protect the common public health good, it is important to weigh the incidental costs of implementing policies, such as decreased levels of public trust and deterrence of HIV testing. Consequently, the proposed policy of using online social network data in contact tracing may translate to reduced rates of public cooperation, which may make a community more vulnerable to public health harms.

. . .

Public health authorities have long been concerned with the control of sexually transmitted infections by tracing contacts and notifying partners so that they can take steps to protect themselves and others. Consistent condom use and other safer sexual practices reduce the risk of transmission. Treatment is also an important strategy for reducing infectiousness, even in cases where a cure is not yet available (e.g., HIV, chronic viral Hepatitis B).

For acute infections that can be cured by a relatively short course of antimicrobial therapy (e.g., chlamydia, gonorrhea, trichmoniasis), expedited partner therapy (EPT) has emerged as an important tool for facilitating access to treatment and controlling the spread of disease. EPT is especially useful for infections that are asymptomatic for many individuals who nonetheless remain infectious and at risk of long-term complications. For example, most women who are infected with gonorrhea are asymptomatic and are thus unlikely to seek out testing or treatment. But even if she is asymptomatic, a woman can spread the infection to others and is at risk for developing pelvic inflammatory disease, which causes infertility.

After asking a patient about his or her sexual contacts and taking steps to ensure that they are informed of their risk of infection, a health care provider may decide to prescribe the patient additional doses of antibiotics for the purpose of treating those partners. EPT facilitates treatment of the patient's sexual partners without requiring them to undergo a medical evaluation (which they may be unable or unwilling to do, especially if they are asymptomatic). It benefits the patient by protecting him or her from reinfection by an untreated partner. It benefits the partners by facilitating their treatment. And it benefits the community by rendering multiple individuals noninfectious.

The legal status of EPT is complicated and poorly understood by many health care providers. Antimicrobials are not federally controlled substances, so there are no federal restrictions on their prescription. In

some states, EPT may be barred by generally applicable laws governing the practice of medicine and prescriptions. In other states it is expressly permitted by statute, an example of which is reproduced below. EPT may also be limited by laws prohibiting insurance fraud if the prescription is written in the patient's name and paid for by the patient's insurance but is intended for use by another individual. EPT also raises ethical issues, which are addressed in the case study below.

EXPEDITED PARTNER THERAPY: CLINICAL CONSIDERATIONS AND PUBLIC HEALTH EXPLORATIONS*

Barry DeCoster and Lisa Campo-Engelsten

Dr. Eptor is facing Nick, an adolescent in the community emergency department (ED). Nick is 16, has been sexually active for about a year, has had three partners in the last six months, and has now noticed green penile discharge for about a week. Nick is otherwise healthy and has no other symptoms. Embarrassed about his symptoms, he drove alone for over two hours to Dr. Eptor's ED out of fear of being recognized. Based on Nick's clinical symptoms, Dr. Eptor is fairly confident of a diagnosis of *Neisseria gonorrhea* urethritis and prescribes 250 mg intramuscular (IM) ceftriaxone plus 1g azithromycin by mouth. He sends off Nick's specimen for Gram stain and culture.

Dr. Eptor is also concerned about Nick's partners. He recently overheard fellow physicians talk about prescribing a double dose of an antibiotic to cover a potential infection in a partner, something they called "expedited partner therapy." Dr. Eptor practices in a rural area and mostly deals with members of the local farming community. He has not seen an adolescent with a sexually transmitted infection (STI) in almost five years and generally feels uncomfortable working with this population of patients. . . .

Dr. Eptor struggles as he thinks about Nick and his three female partners. "How could I prescribe something to a person I have never met? What if one has an adverse reaction or doesn't respond to the medication?" Dr. Eptor knows that resistance to gonorrhea treatment has been increasing but he doesn't know the specific resistance profile for the area where Nick lives.

After some reflection, Dr. Eptor also becomes concerned that if he doesn't provide Nick with additional prescriptions, Nick's potentially asymptomatic partners might not ever seek care and could develop complications. Dr. Eptor doesn't want to be responsible for missing an opportunity to treat a subclinical infection in a young woman and risk her developing pelvic inflammatory disease (PID), which could compromise her fertility. He wonders about the scope of his public health role in this case and isn't sure whether the decision he makes will be compliant with his state's regulations and institution's guidelines and protected from a legal standpoint.

* 2016. *AMA Journal of Ethics* 18 (3): 215–28.

COMMENTARY

This case raises important ethical complexities. . . . Dr. Eptor has a clear duty to care for Nick, but this case raises ethical concerns about STI care as part of the broader scope of physicians' public health roles. Dr. Eptor knows that Nick's three female sexual partners are at a high risk of being infected. Does he have a duty to these women directly, even if they are not his patients? Do Dr. Eptor's duties to treat extend to the community at large?

Goals of Care and Ethical Responsibilities

These questions suggest different—possibly conflicting—goals of clinical bioethics and public health ethics. Clinical bioethics has traditionally focused on the ethical complexities at the micro level of primary care (i.e., the doctor-patient relationship) rather than at the macro level. Yet these dialogues are only partially helpful here for understanding what Dr. Eptor owes to Nick and Nick's sexual partners. . . . One way public health ethics differs from clinical ethics . . . is by prompting physicians to think about the needs of populations, not just individual patients, as ethically relevant to their decisions. In other words, from a public health perspective, physicians need to think about the problems facing populations, including social determinants of health; to think about prevention in addition to treatments and cures; and to seek ethically defensible responses that improve the health and well-being of populations. . . .

One response might be to say that Dr. Eptor has no duty except to his patient, Nick. Yet, even if we take this view, we must acknowledge that Nick faces a high likelihood of reinfection if he has sex again with any of these women before they are treated. So, Dr. Eptor's treatment of Nick's sexual partners could be an indirect way of providing *preventive* care to Nick.

Expedited Partner Therapy

One way to handle this situation is via expedited partner therapy (EPT), in which a physician prescribes treatment for a patient's sexual partners without seeing them. If Dr. Eptor were to follow his colleagues' lead by prescribing a "double dose" or multiple doses of antibiotics, he would have to make sure that Nick understands that the additional pills are to be shared with his partners. . . . This kind of semi-clandestine approach to treatment via double dosing has been common historically, albeit "not traditionally condoned." This subterfuge becomes unnecessary if Dr. Eptor practices in a state that has legalized anonymous prescriptions via EPT. In fact, only four states prohibit EPT. In states where anonymous prescriptions via EPT are legal, Dr. Eptor could write a prescription to Nick directly and to multiple unnamed prescription recipients to whom Nick could deliver the antibiotic. The CDC recommends EPT for all sexual partners in the last 60 days. This means EPT prescriptions can be written for as many partners as is appropriate. . . . Once filled, the prescription would be accompanied with literature on safety and how to contact a pharmacist if any of the women were to have questions.

Deciding Whether to Recommend EPT

There are several elements Dr. Eptor needs to consider in deciding whether to recommend EPT for Nick's partners. . . .

Is Nick reliable enough? Because EPT requires explicit conversations about taboo subjects, such as sex in general and STIs in particular, Dr. Eptor and Nick will have to have a frank discussion about whether Nick is prepared to take on the responsibilities of EPT. EPT is an appropriate alternative to the standard process of referring sexual partners to seek clinical attention, but it is not demanded of Nick. In this case, both Nick and Dr. Eptor must be reasonably certain that Nick is willing to and capable of contacting partners and of passing along both the medication and attached information. . . . Should Nick feel uncomfortable as a messenger for whatever reason, standard public health reporting systems remain the default.

Does the threat of antibiotic resistance make EPT unsafe? One important consideration is that an antibiotic-resistant strain of gonorrhea is on the rise, although Dr. Eptor is not sure if this is the case where Nick lives. In part, the threat posed by antibiotic resistance has shaped public health law: in some states, such as New York, EPT is legal only for chlamydia. A possible concern is that without proper follow-up testing, resistant strains of gonorrhea will likely spread, possibly even among people who have been treated for it before. . . .

In this case, Dr. Eptor could reasonably counsel Nick about risks of antibiotic-resistant strains of gonorrhea and plan for Nick to return for follow-up screening. If Nick tests negative, then Nick's treatment—and presumably Nick's partners' treatment via EPT—can probably be considered successful. If Nick tests positive for a resistant strain of gonorrhea, then Dr. Eptor will have to prescribe a different (IM) antibiotic to treat Nick and suggest the same for his partners, who would need to see doctors to receive it.

Obligations to Nick's partners. But what does Dr. Eptor know about or owe to Nick's female sexual partners? One ethical concern is that these women may believe that they have successfully treated their gonorrhea and thus see no need to seek follow-up treatment. If their STIs persist, however, one risk is that they could infect others. Another risk is that they might develop serious complications—such as [Pelvic Inflammatory Disease], which can lead to infertility or ectopic pregnancy—as a result of having what could turn out to be an untreated, subclinical STI. . . .

Recommendation. Although the use of EPT raises numerous ethical concerns from clinical and public health ethics points of view, we argue that Dr. Eptor would be acting responsibly from clinical and public health ethics points of view in prescribing EPT to Nick and his three partners, assuming it is legal in the state where they reside. EPT could benefit not only Nick but also his partners by providing them with treatments for their potential infections that are convenient (i.e., not requiring a visit with a health care provider) and possibly cost-free (i.e., covered by Nick or another third-party payer). Furthermore, it would enable Nick to take responsibility for his own health and the health of his sexual partners. Lastly, EPT helps Dr. Eptor contribute to the public health goal of reducing the transmission of STIs.

Additional decision: cost. If Dr. Eptor decides to prescribe EPT for Nick's partners, there remains the question about who should handle the cost of the medications. Given that these antibiotics are generally not expensive, Nick may choose to pay for his partners' medications out of pocket. Given the overall public health benefit and economic savings, one might argue that insurers ought to cover both Nick's and his partners' medications, but insurance policies vary in their coverage of EPT. Some state

programs, such as California's Medi-Cal program, explicitly prohibit payment of a patient's partners' medications through EPT. Here, we note there is further work to be done in advocating for policies that make EPT more accessible and thus increase its public health impact. . . .

MARYLAND EXPEDITED PARTNER THERAPY STATUTE

Maryland Code, Health Article, § 18-214.1

(a) The purpose of expedited partner therapy is to provide antibiotic therapy to any partner of a patient diagnosed with a sexually transmitted infection identified in subsection (b) of this section in order to:

(1) Contain and stop the further spread of the infection; and

(2) Reduce the likelihood of reinfection in the diagnosed patient.

(b) Notwithstanding any other provision of law, the following health care providers may prescribe, dispense, or otherwise provide antibiotic therapy to any sexual partner of a patient diagnosed with chlamydia or gonorrhea without making a personal physical assessment of the patient's partner:

(1) A physician licensed under [state law]

(2) An advanced practice registered nurse with prescriptive authority licensed under [state law].

(3) An authorized physician assistant licensed under [state law]; and

(4) A registered nurse employed by a local health department who complies with [relevant provisions of state law].

. . .

In this chapter, we have discussed the central importance of biological as well as social-ecological approaches to the control of infectious disease. The public generally has confidence in the capacity of science and technology to address threats to health. But, as we have seen, immunization, screening, and antimicrobial therapy are not sterile scientific pursuits; they are highly influenced by politics, law, and values. When these interventions are forced on unwilling individuals, we must balance the power and duty to safeguard collective well-being against individual claims to autonomy, bodily integrity, and privacy. Similar tensions arise from the equally contested public health interventions discussed in the next chapter on public health emergency preparedness and response.

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PHOTO 11.1. A father and child wait for help on the front steps of their home, surrounded by floodwaters. Photography by Jocelyn Augustino for FEMA.

CHAPTER ELEVEN

Public Health Emergency Preparedness and Response

In this chapter, we examine health and safety hazards whose scale, rapid onset, or unpredictability threatens to overwhelm routine public health capabilities. Public health emergencies include outbreaks of novel infectious diseases with high potential for morbidity or mortality for which medical countermeasures may be inadequate or unavailable (e.g., Ebola, highly pathogenic influenza, Zika). They also encompass public health impacts of chemical, biological, radiological, and nuclear (CBRN) exposures that result from intentional or accidental release (e.g., terrorist attacks, chemical leaks), as well as natural, industrial, and technological disasters (e.g., hurricanes, floods, earthquakes, dam failures, explosions). These events present diverse risks, but are united by a common need for advance planning, rapid detection, and effective response to mitigate and adapt to consequences.

The structure of this chapter follows the emergency management cycle, which organizes public and private sector efforts into several key phases: prevention, mitigation, preparedness, response, and recovery. We begin with an overview of public health emergency preparedness for a wide range of threats, with an emphasis on the growing federal role in coordinating prevention, preparedness, and response efforts. Next, we discuss federal and state laws governing emergency and disaster declarations and the special authority, regulatory flexibility, and financial assistance they trigger. We then turn to three crucial capabilities that may be deployed in response to specific types of emergencies. First, evacuation

and emergency sheltering, which may be necessary to mitigate the impacts of a natural disaster, technical failure, or chemical, nuclear, or radiological incident. Second, development and distribution of medical countermeasures (e.g., vaccines, antimicrobials, and supplies and staff needed to support their use) in response to a naturally occurring disease outbreak, bioterrorist attack, or widespread chemical, nuclear, or radiological exposure. Finally, the ancient public health powers of quarantine and isolation, which—along with less invasive measures such as travel restrictions and community containment strategies—provide vital tools for containing the spread of communicable disease outbreaks, particularly for pathogens with the potential to cause an epidemic.

ALL-HAZARDS PREPAREDNESS

Concerns about terrorism fueled major investments in public health emergency preparedness in the aftermath of the September 11, 2001 terror attacks, but the resulting infrastructure may also be deployed in response to naturally occurring communicable disease outbreaks, as well as natural and industrial disasters. This approach—referred to as all-hazards preparedness—allows for more efficient use of resources by developing capabilities to respond to a range of threats while also building basic infrastructure to meet routine needs. In 2011, CDC identified 15 core capabilities, which form the basis of its annual assessment of national, state, and local preparedness (see table 11.1).

At the turn of the twenty-first century, policymakers sought to modernize public health laws and invest in public health infrastructure to detect, monitor, and respond to emergencies. An unprecedented infusion of federal funding and legislative attention helped support a public health law renaissance under the banner of biosecurity. These efforts united national security, a core responsibility of the federal government, with public health, a core responsibility of state and local governments. Critics expressed concern, however, that the priorities of national security and public health can be at odds with each other. The narrower mission of national security—protecting the population from acute, large-scale threats—excludes much of what concerns public health, particularly its commitment to social justice and prioritizing the needs of the most vulnerable.

Some question whether efforts to prepare for and respond to bioterror attacks are well suited to build the community resilience needed to cope with naturally occurring disease outbreaks and natural disasters. For example, federal lawmakers across the political spectrum have

TABLE 11.1 CDC'S 15 PUBLIC HEALTH PREPAREDNESS CAPABILITIES

Community Resilience
Community preparedness is the ability of communities to prepare for, withstand, and recover from public health incidents in the short and long term, through engagement and coordination with emergency management, healthcare organizations and providers, community and faith-based partners, and state and local governments.
Community recovery is the ability to collaborate with community partners following an incident to plan and advocate for the rebuilding of public health, medical, and mental/behavioral health systems to a functioning level or better.
Biosurveillance
Public health laboratory testing is the ability to conduct rapid and conventional detection, characterization, confirmatory testing, data reporting, investigative support, and laboratory networking to address actual or potential exposure to all hazards, including chemical, radiological, and biological agents in clinical, food, and environmental samples.
Public health surveillance and epidemiological investigation is the ability to create, maintain, support, and strengthen routine surveillance and detection systems and epidemiological investigation processes, as well as to expand these systems and processes in response to public health emergencies.
Incident Management
Emergency operations coordination is the ability to direct and support a public health or medical incident by establishing a standardized, scalable system of oversight, organization, and supervision consistent with jurisdictional standards and practices and with the National Incident Management System.
Information Management
Emergency public information and warning is the ability to develop, coordinate, and disseminate information, alerts, warnings, and notifications to the public and incident management responders.
Information sharing is the ability to conduct multi-jurisdictional, multi-disciplinary exchange of health-related information and situational awareness data among all levels of government and the private sector in preparation for and in response to public health incidents.
Surge Management
Fatality management is the ability to coordinate with other organizations to ensure the proper recovery, handling, identification, transportation, tracking, storage, and disposal of human remains and personal effects; certify cause of death; and facilitate access to mental/behavioral health services to the family members, responders, and survivors.

(continued)

TABLE 11.1 *(continued)*

Mass care is the ability to coordinate with partner agencies to address the public health, medical, and mental/behavioral health needs of those affected by an incident and gathered together. This capability includes ongoing surveillance and assessment as the incident evolves.
Medical surge is the ability to provide adequate medical evaluation and care during events that exceed the limits of the normal medical infrastructure, and to survive a hazard impact and maintain or rapidly recover operations that were compromised.
Volunteer management is the ability to coordinate the identification, recruitment, registration, credential verification, training, and engagement of volunteers to support the public health agency's response.
Countermeasures and Mitigation
Medical countermeasure dispensing is the ability to provide medical countermeasures in support of treatment or prophylaxis to the identified population in accordance with public health guidelines and/or recommendations.
Medical materiel management and distribution is the ability to acquire, maintain, transport, distribute, and track medical materiel during an incident and to recover and account for unused medical materiel, as necessary, after an incident.
Non-pharmaceutical interventions are the abilities to recommend to the applicable lead agency and implement strategies for disease, injury, and exposure control, such as quarantine, social distancing, and hygiene.
Responder safety and health is the ability to protect public health agency staff responding to an incident and support the health and safety needs of hospital and medical facility personnel, if requested.

SOURCE: Adapted from Trust for America's Health. 2017. *Ready or Not? Protecting the Public's Health from Diseases, Disasters, and Bioterrorism,* 45–46.

NOTE: The United States Centers for Disease Control and Prevention (CDC) uses these 15 core capabilities in six domains to assess state and local public health preparedness and to assist health departments in their strategic planning.

supported the development of new medical countermeasures—such as anthrax and smallpox vaccines—and stockpiling for rapid deployment in case of emergency. These agent-specific strategies do nothing to protect the public from more common events such as natural disasters or measles outbreaks, however. They are less cost-effective than investment in basic public health infrastructure at the state and local level.

The report excerpted below offers an assessment of state and local public health emergency preparedness and emphasizes the need for more consistent attention to basic public health infrastructure and more stable mechanisms for funding emergency response efforts.

READY OR NOT? PROTECTING THE PUBLIC'S HEALTH FROM DISEASES, DISASTERS AND BIOTERRORISM*

Trust for America's Health

In the 16 years since the 9/11 and anthrax tragedies, the country has had countless reminders demonstrating the need for a sufficient response to the public's health needs during major incidents—be they caused by extreme weather events, disease outbreaks or a contaminated food supply. The 2017 Atlantic Hurricane Season was particularly historic. After Hurricane Harvey made landfall in Texas, it hovered over Houston for days—dropping several feet of rain that caused unprecedented flooding and sank the Earth's crust around Houston two centimeters. Harvey was followed by two Category 5 storms—Hurricanes Irma and Maria, which had a profound impact on many Caribbean nations, Puerto Rico, the Florida Keys and other areas in the region. Out West, rain was scarce as communities were ravaged by one of the worst wildfire seasons ever. The fast-moving blaze in California's wine country killed 43 people, scorched 250,000 square miles and destroyed 8,900 structures. . . .

Emergencies are a matter of when, not if; there is no reason to continue to be caught off guard when a new threat arises. The good news is that considerable progress has been made to effectively prepare for and respond to public health emergencies of all types and sizes, and much of what it takes to prepare for bioterrorism, major disease threats or major disasters is also essential to respond to [routine,] ongoing health threats. The bad news is that . . . public health and preparedness for all hazards are being undermined due to severe budget cuts and lack of prioritization. . . .

The primary source for state and local preparedness for health emergencies has been cut by about one-third (from $940 million in fiscal year [FY] 2002 to $667 million in FY 2017) and hospital emergency preparedness funds have been cut in half ($514 million in FY 2003 to $254 million in FY 2017). . . . Lack of available emergency funds has led to redirection of money from other priorities when a crisis hits. For example, delays in funding for the 2016 Zika response led to redirecting money from the Ebola response and from core state and local preparedness grants. This left most states with a weaker preparedness infrastructure that was not easily backfilled when emergency money was finally available. . . . Unstable funding leads to a cycle of hiring and firing of trained specialists—which often means the experts needed to respond are not on-staff or available when new crises hit.

Investments in improving preparedness . . . bolster health departments and the healthcare system overall—so they can better deal with ongoing needs like the opioid epidemic, foodborne diseases, water and lead safety, and other challenges communities regularly face. . . . A strategic modern biodefense also yields strong returns—investing in prevention and effective standing response capabilities helps avoid the costs in dollars and lives. . . .

While it is impossible to be 100 percent prepared for all emergencies, there are core basic capabilities that experts agree could be maintained to better protect the public from the range of possible concerns. In the past 15 years[, s]ome major advancements include: Integrated public health emergency operations planning and coordination;

* December 2017 Issue Report.

upgraded public health laboratories; more advanced development and manufacturing for vaccines and other medical countermeasures (MCMs); development of the Strategic National Stockpile, a federal repository of medical countermeasures, as well as an improved system to develop medical countermeasures more quickly; improved plans, resources and tactical capacity to rapidly deploy MCMs to the community; enhanced surveillance, epidemiologic investigations, situational awareness and information sharing mechanisms and communications; enacted legal and liability protections; advances in foodborne illness detection; animal health surveillance; increasing and upgrading public health staffing trained to prevent and respond to emergencies; improving systems for deployment of emergency medical and public health personnel; improvements in medical surge capacity, development of the National Disaster Medical System, Medical Reserve Corps, the HHS Operations Center, and emergency support function leadership in the Office of the Assistant Secretary for Preparedness and Response; and the Center for Medicaid and Medicare Service's release of Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers. Some major ongoing gaps include: Coordinated, interoperable, near real-time biosurveillance, including a sustained investment to maintain surveillance systems to more rapidly identify emerging threats; sufficient funding for the entire medical countermeasure strategy, including funding to continue research, development, purchase and distribution of vaccines, antiviral medications, diagnostics and antibiotics; chemical and radiation laboratory services; surge capacity within the healthcare system for a mass influx of patients, along with standards of care and in-place tiered systems of care for a range of threats; standing surge capacity abilities within the public health system to respond to multiple emergencies at the same time, particularly if multiple states are experiencing multiple emergencies simultaneously and one state cannot rely on out-of-state assistance; ongoing reductions in the public health workforce; and the ability to help communities—and especially their most vulnerable populations—become more resilient to cope with and recover from emergencies. . . .

[T]o ensure stronger baseline capabilities are in place and the system is more flexible and able to respond efficiently and effectively when new emergencies arise[, health and security experts recommend e]nsuring stable, sufficient health emergency preparedness funding to maintain a standing set of core capabilities so they are ready when they are needed. In addition, a complementary Public Health Emergency Fund is needed to provide immediate surge funding for specific action for major emerging threats. The current process of insufficient funding means there are long-standing gaps in the baseline system. Emergency supplemental budgets take time, cause delayed responses and cannot be used to backfill ongoing vulnerabilities in the response system. [Experts also recommend s]trengthening and maintaining consistent support for global health security as an effective strategy for preventing and controlling health crises. Germs know no borders as was recently seen with the Zika and Ebola outbreaks.

[There is also a need for] federal leadership before, during and after disasters—including senior leadership and coordination for a government-wide approach to health security, preparedness, response and recovery efforts. Clear federal leadership and an agreed upon framework of responsibilities—including fully utilizing authorities in existing law—can clarify roles, particularly in health emergency responses that cross federal agencies and involve domestic and international actions.

[Additionally, experts recommend support for innovation and modernization of infrastructure]—including a more focused investment strategy to support science and technology upgrades that leverage recent breakthroughs and hold the promise of transforming the nation's ability to promptly detect and contain disease outbreaks and respond to other health emergencies. For example, continuing investments in the modernization of near realtime, interoperable surveillance, such as syndromic surveillance; developing the next generation of medical countermeasures, including antivirals, vaccines and rapid diagnostic tests; and adopting wider use of advances in genomics to detect and contain outbreaks.

Recruiting and training a next generation public health workforce with expert scientific abilities to harness and use technological advances along with critical thinking and management skills to serve as Chief Health Strategist for a community [are also essential priorities]. The workforce should be able to lead health investigations; build plans to address problems; bring partners and resources together across the health sector and other affected sectors for increased collective impact; support community engagement; and communicate and effectively educate the public on how to reduce risk and better protect themselves, their families and their neighborhoods.

[Experts recommend r]econsidering health system preparedness for new threats and mass outbreaks[, including development of] stronger coalitions and partnerships among providers, hospitals and healthcare facilities, insurance providers, pharmaceutical and health equipment businesses, emergency management and public health agencies. More integrated approaches help leverage the strengths and coordinate activities across the public and private sectors, support regionalized health models and incentivize and speed the use of new technologies into practice. [Preparedness requires engagement of] partners to invest in building a broader community response strategy since all partners in a community are at risk and stand to benefit from more effective preparedness and response abilities.

[Prevention of] the negative health consequences of weather-related threats [is also a key priority]. As climate changes, the likelihood of unusual weather patterns and extreme weather events increase[s], water rises to unsafe levels and the insects and animals that spread disease move into new geographic locations. It is essential . . . to mitigate the impact of climate, weather and natural disasters on health problems, in addition to building the capacity to anticipate, plan for and respond to such . . . events.

[Experts also recommend s]upporting a culture of resilience so all communities are better prepared to cope with and recover from emergencies, particularly focusing on those who are most vulnerable. Sometimes the aftermath of an emergency situation may be more harmful than the initial event. Loss and suffering of loved ones, dislocation associated with housing damage, continuing environmental risks and post-traumatic stress have occurred in many recent emergencies. Certain populations such as older adults, people with disabilities, pregnant women, infants and those with limited resources are often at disproportionate risk. This must also include support for local organizations and small businesses—which are essential and inherent parts of communities—to prepare for and to respond to emergencies.

[Additionally, experts urge prioritization of] efforts to address one of the most serious threats to human health by expanding efforts to stop superbugs and antibiotic resistance. Outbreaks of new and/or difficult to treat infectious illnesses require a range

> of capacities from sophisticated and timely laboratory testing to epidemiologists to track potential exposures to immunizations and treatment.
>
> [Also essential is i]mproving rates of vaccinations for children and adults—which are one of the most effective public health tools against many infectious diseases. In spite of [the availability of] effective vaccines to prevent disease, there are significant sections of the population who are unprotected[,] leading to a number of recent outbreaks of preventable illnesses[, such] as measles and meningitis.
>
> [Finally, experts recommend f]ocusing on fixing the food safety system to better . . . address the potential risks in modern agricultural and food processing, sales and distribution approaches. State and local governments need the capacity to detect and contain foodborne outbreaks, using modern technology as well as traditional tools and personnel for both prevention and rapid response.

. . .

The *Ready or Not?* report highlights diminishing funding for emergency preparedness and response capabilities in recent years. Reduced funding reflects changing political priorities. Why might the types of large-scale events experienced in the years following 9/11 (e.g., hurricanes and outbreaks of Zika and Ebola as opposed to the mass-casualty bioterror attacks that policymakers feared) have led to a reduced commitment of resources?

The report also recommends more stable funding for public health emergency response, akin to funds set aside for natural disaster recovery. In 2016, for example, it took Congress seven months to appropriate funds to control the spread of Zika virus and deal with its effects. Partisan disagreements over funding for Planned Parenthood delayed the response throughout the spring and summer months while pregnant women in U.S. territories and Florida continued to be infected by the virus, causing devastating complications. The dispute illustrates the difficulties that result when emergency funding is allocated by Congress on an ad hoc basis, rather than being set aside in the Public Health Emergency Fund controlled by the Secretary of Health and Human Services, which was virtually empty when the Zika virus outbreak struck.

The *Ready or Not?* report also recommends enhanced federal leadership in public health emergency preparedness and response efforts. Undoubtedly, the tension between federal and state authority has led to significant failures in emergency preparedness and response. In the aftermath of events like Hurricane Katrina and the Ebola virus outbreak, commentators criticized government officials' lack of accountability and inadequate coordination across jurisdictions and among diverse sectors of government. But is federal leadership the right approach? In the next section, we turn to federal and state laws governing emergency declara-

tions, which play a crucial role in determining the relationship among local, state, and federal government actors during a crisis.

EMERGENCY DECLARATIONS: SPECIAL AUTHORITY, REGULATORY FLEXIBILITY, AND FINANCIAL SUPPORT

A complex array of federal and state laws governs declarations that trigger special government authority, regulatory flexibility, and financial support. The Stafford Act empowers the president to declare an emergency or major disaster, which triggers federal financial support to state and local governments and affected individuals and businesses. The state governor must first request assistance. The act defines *major disaster* as

> a natural catastrophe (including any hurricane, tornado, storm, high water, wind-driven water, tidal wave, tsunami, earthquake, volcanic eruption, landslide, mudslide, snowstorm, or drought) or, regardless of cause, any fire, flood, or explosion, in any part of the United States, which in the determination of the President causes damage of sufficient severity and magnitude to warrant major disaster assistance under this Act to supplement the efforts and available resources of States, local governments, and disaster relief organizations in alleviating the damage, loss, hardship, or suffering caused thereby.

This definition excludes many public health threats such as bioterrorism and infectious disease outbreaks.

Alternatively, the president may declare an *emergency,* which the Stafford Act defines as

> any occasion or instance for which, in the determination of the President, Federal assistance is needed to supplement State and local efforts and capabilities to save lives and to protect property and public health and safety or to lessen or avert the threat of a catastrophe in any part of the United States.

An emergency declaration authorizes the president to direct any federal agency to use existing authorities and resources to coordinate relief efforts and to assist state and local governments with health and safety measures.

Finally, under Sec. 319(a) of the Public Health Service Act, the Secretary of Health and Human Services may declare a *public health emergency* (regardless of whether state officials request assistance) upon a determination that "(1) a disease or disorder presents a public health emergency; or (2) a public health emergency, including significant outbreaks of infectious diseases or bioterrorist attacks, otherwise exists." Consequently, "the Secretary may take such action as may be appropriate to respond to the public health emergency, including making grants, providing awards for expenses, and entering into contracts and conducting

and supporting investigations into the cause, treatment, or prevention of a disease or disorder." A declaration does not necessarily make any additional funds available, however. When President Trump declared the opioid overdose epidemic a public health emergency, however, critics questioned whether it would have a meaningful impact without significant new funding. In addition to offering additional flexibility regarding funding, a public health emergency declaration also allows the secretary to waive federal regulations that could interfere with swift emergency response, including those aimed at securing patient privacy, access to emergency medical care, food and drug safety, and more.

In addition to federal declarations, state officials may declare a public health emergency to trigger assistance for local governments, authority to commandeer private resources and constrain individual liberty, and regulatory flexibility to facilitate rapid deployment of medical resources and personnel. State laws governing emergency declarations vary considerably, especially in how they define a public health emergency. Here, we reproduce a Florida statute enabling the state health officer to declare an emergency, issue health advisories, and quarantine or isolate individuals (which may be employed regardless of whether an emergency is declared).

FLORIDA PUBLIC HEALTH ADVISORIES, PUBLIC HEALTH EMERGENCIES, AND ISOLATION AND QUARANTINE STATUTE*

The State Health Officer is responsible for declaring public health emergencies, issuing public health advisories, and ordering isolation or quarantines.

(1) As used in this section, the term:

(a) "Isolation" means the separation of an individual who is reasonably believed to be infected with a communicable disease from individuals who are not infected, to prevent the possible spread of the disease.

(b) "Public health advisory" means any warning or report giving information to the public about a potential public health threat. Before issuing any public health advisory, the State Health Officer must consult with any state or local agency regarding areas of responsibility which may be affected by such advisory. Upon determining that issuing a public health advisory is necessary to protect the public health and safety, and prior to issuing the advisory, the State Health Officer must notify each county health department within the area which is affected by the advisory of the State Health Officer's intent to issue the advisory. The State Health Officer is authorized to take any action appropriate to enforce any public health advisory.

* Florida Statutes Annotated § 381.00315.

(c) "Public health emergency" means any occurrence, or threat thereof, whether natural or manmade, which results or may result in substantial injury or harm to the public health from infectious disease, chemical agents, nuclear agents, biological toxins, or situations involving mass casualties or natural disasters. Before declaring a public health emergency, the State Health Officer shall, to the extent possible, consult with the Governor and shall notify the Chief of Domestic Security. The declaration of a public health emergency shall continue until the State Health Officer finds that the threat or danger has been dealt with to the extent that the emergency conditions no longer exist and he or she terminates the declaration. However, a declaration of a public health emergency may not continue for longer than 60 days unless the Governor concurs in the renewal of the declaration. The State Health Officer, upon declaration of a public health emergency, may take actions that are necessary to protect the public health. Such actions include, but are not limited to:

1. Directing manufacturers of prescription drugs or over-the-counter drugs who are permitted under [the Florida Drug and Cosmetic Act] and wholesalers of prescription drugs located in this state who are permitted under [the Florida Drug and Cosmetic Act] to give priority to the shipping of specified drugs to pharmacies and health care providers within geographic areas that have been identified by the State Health Officer. . . .

2. Notwithstanding [the Florida Pharmacy Act] and [the Florida Drug and Cosmetic Act] and rules adopted thereunder, directing pharmacists employed by the department to compound bulk prescription drugs and provide these bulk prescription drugs to physicians and nurses of county health departments or any qualified person authorized by the State Health Officer for administration to persons as part of a prophylactic or treatment regimen.

3. Notwithstanding [state law governing professional licenses], temporarily reactivating the inactive license of [specified categories of] health care practitioners, when such practitioners are needed to respond to the public health emergency. . . .

4. Ordering an individual to be examined, tested, vaccinated, treated, isolated, or quarantined for communicable diseases that have significant morbidity or mortality and present a severe danger to public health. Individuals who are unable or unwilling to be examined, tested, vaccinated, or treated for reasons of health, religion, or conscience may be subjected to isolation or quarantine.

a. Examination, testing, vaccination, or treatment may be performed by any qualified person authorized by the State Health Officer.

b. If the individual poses a danger to the public health, the State Health Officer may subject the individual to isolation or quarantine. If there is no practical method to isolate or quarantine the individual, the State Health Officer may use any means necessary to vaccinate or treat the individual. Any order of the State Health Officer given to effectuate this paragraph shall be immediately enforceable by a law enforcement officer. . . .

(d) "Quarantine" means the separation of an individual reasonably believed to have been exposed to a communicable disease, but who is not yet ill, from individuals who have not been so exposed, to prevent the possible spread of the disease.

(2) Individuals who assist the State Health Officer at his or her request on a volunteer basis during a public health emergency are entitled to [benefits specified under state law, including a cap on damages for tort claims against volunteers]. . . .

PHOTO 11.2. Aedes aegypti mosquito. This species, which is common throughout much of the United States, is capable of spreading West Nile virus, Dengue fever, malaria, and Zika virus from person to person. Photograph by James Gathany for CDC.

(4) The department has the duty and the authority to declare, enforce, modify, and abolish the isolation and quarantine of persons, animals, and premises as the circumstances indicate for controlling communicable diseases or providing protection from unsafe conditions that pose a threat to public health, except [that isolation for the purpose of controlling the spread of sexually transmissible diseases and tuberculosis is governed by separate statutes]. Any order of the department issued pursuant to this subsection shall be immediately enforceable by a law enforcement officer. . . .

(6) . . . Any person who violates any rule adopted under this section, any isolation or quarantine, or any requirement adopted by the department pursuant to a declared public health emergency, commits a misdemeanor of the second degree [punishable by a definite term of imprisonment not exceeding 60 days or a fine not exceeding $500].

. . .

We will address quarantine and isolation—which, as the Florida statute excerpted above indicates, can be ordered by health officials regardless of whether an emergency has been declared—later in this chapter.

Florida's experience with emergency declarations in recent years is illustrative. In February 2016, for example, after nine travel-related cases of Zika virus infection were confirmed across four Florida counties, Governor Rick Scott signed an executive order directing the state health officer to declare a public health emergency in the affected counties. The order directed the health officer to follow CDC guidelines for controlling the spread of Zika virus and educating the public on prevention. Finally, the governor's order noted that the state secretary of agriculture was author-

ized to issue a declaration implementing mosquito abatement with the support of the state's Department of Environmental Protection and Commission for Fish and Wildlife Preservation. Relying on the definition of "public health emergency" found above, Florida officials have also issued declarations in response to the 2009 novel H1N1 pandemic, an epidemic of opioid overdose deaths (see chapter 13), and Hurricane Katrina.

EVACUATION AND EMERGENCY SHELTERING: MEETING THE NEEDS OF VULNERABLE POPULATIONS

Health officials may have to evacuate residents before, during, or after a natural or industrial disaster or terror attack. As government failures in the aftermath of disasters, such as Hurricanes Maria and Irma in 2017 and Hurricane Katrina in 2005, have demonstrated, ensuring a speedy evacuation to safe and sanitary shelters and providing for residents' needs are crucial to mitigating injuries and disease. The needs of vulnerable populations—such as the elderly, people living in poverty, and people with disabilities—demand particular attention. In the case that follows, a federal court adjudicated claims by residents of New York City with disabilities against the local government in the aftermath of Hurricane Irene. While the litigation was pending, another disaster, Hurricane Sandy, struck the city.

*BROOKLYN CENTER FOR INDEPENDENCE OF THE DISABLED V. BLOOMBERG**

United States District Court for the Southern District of New York
Decided November 7, 2013

The task of planning for, and responding to, emergencies and disasters is one of the most important, and challenging, tasks any government faces. Emergencies can take many forms . . . and a government . . . must be prepared for them to strike at almost any moment. Such preparedness requires considerable planning, resources to execute those plans, and a willingness to learn from experience and revise plans that do not sufficiently accomplish their goals. Even then, each emergency is different and, to some extent, unpredictable, and no amount of planning or resources can fully prepare a local government to respond to what may come. Moreover, ultimately, there are limits to what the government can do on its own: Not only must a local government be prepared, but its residents must also prepare themselves.

* 980 F. Supp. 2d 588.

[T]he question in this lawsuit . . . is whether in planning for, and responding to, emergencies and disasters, the City has adequately addressed the needs of people with disabilities. The Plaintiff class comprises all people with disabilities, as defined by the Americans with Disabilities Act (ADA), 42 U.S.C. § 12102, who are within the City and the jurisdiction served by the City's emergency preparedness programs and services. . . .

[The] mountain of evidence and argument [presented in this case] confirms that . . . while the City's emergency preparedness program adequately accommodates the needs of people with disabilities in some respects, it fails to do so in others. . . . Notably, there is no evidence that these failures are a result of intentional discrimination by the City against people with disabilities. But the ADA [and] the Rehabilitation Act . . . seek to prevent not only intentional discrimination against people with disabilities, but also—indeed, primarily—discrimination that results from "benign neglect." Moreover, these laws require that a government entity do more than provide a program on equal terms to those with and without disabilities; they require affirmative accommodations to ensure that facially neutral rules do not in practice discriminate against individuals with disabilities. . . . [T]he National Council on Disability, an independent federal agency, . . . has opined that the failure to address the specific vulnerabilities of people with disabilities in emergency planning "often leads to increased injury and death rates among this segment of the population during disasters."

The City's emergency preparedness program consists of numerous plans, guides, strategies, playbooks, scripts, and protocols [including] the Area Evacuation Plan, the Coastal Storm: Evacuation Plan, and the Coastal Storm: Sheltering Plan. . . . [The Office of Emergency Management] (OEM) is the City agency responsible for coordinating the City's emergency planning and responses to emergency situations. . . . The City has a Special Needs Coordinator, whose role it is to advocate within OEM for people with special needs and to provide guidance on incorporating the needs of people with disabilities into the City's emergency plans. . . . [F]rom August 2012 until at least the time of trial—a period that included Hurricane Sandy—[the City did not have a full-time Special Needs Coordinator, having failed to replace the previous coordinator]. . . .

One way in which emergency planners can help ensure that the needs of people with disabilities are incorporated sufficiently into emergency plans is to include people with special needs in the planning process. . . . The City maintains a Special Needs Advisory Group (SNAG), composed of approximately fifty representatives of agencies, service providers, and advocacy groups that represent and work with people with special needs. The group, which is chaired by the Special Needs Coordinator, meets quarterly to discuss emergency planning and to offer feedback and suggestions to the City. . . . The group has no decisionmaking authority and, indeed, has not even seen any of the City's emergency plans in their entirety. . . .

[The Fire Department of New York (FDNY)] is the lead City agency responsible for building evacuations. The [New York Police Department (NYPD)] is also involved in . . . canvassing buildings to identify and rescue those who may be unable to evacuate without assistance. . . . [A witness representing] FDNY testified that there was no need to plan specifically for the evacuation of people with disabilities, because the Fire Department "treat[s] everybody the same way. . . . [F]irefighters, paramedics and EMTs quickly assess the needs of the individual and transport them out of harm's way—whether to a hospital or other safe place—depending on the needs of the individual and

the dictates of the particular emergency situation." . . . There is little doubt that the FDNY and the NYPD are capable of rescuing individuals with disabilities from high-rise buildings under ordinary circumstances. It is less clear, however, that they would be able to do so during a large-scale evacuation, particularly one that occurs with little or no notice. The City does not require most high-rise buildings to maintain emergency evacuation devices for people with disabilities and, indeed, most buildings do not have them. . . .

Most of the City's public transportation . . . is inaccessible to people with disabilities. . . . To address these deficiencies, New York State's Metropolitan Transit Authority (the MTA) provides paratransit services—that is, accessible public transportation. . . . Unlike other forms of public transportation, however, paratransit ordinarily requires a user to reserve a ride at least twenty-four hours in advance. The City directs people with disabilities to continue to rely on paratransit in an emergency . . . The City's plans do not, [however], mandate that paratransit be available without reservations during an emergency; that it remain open for a certain amount of time after the issuance of an evacuation order; or even that it be available at all during an emergency. Nor may the City direct [paratransit] operations during an emergency: [they are] not run by the City but rather by the MTA, a public corporation chartered by the state, and the City has no agreement with the MTA to provide services during an emergency. . . .

[Under the Homebound Evacuation Operation (HEO), when someone calls 311 (the City's information hotline)] to inquire about assistance evacuating, the 311 representative determines which of three levels of assistance the caller requires. First, people who are capable of getting to the sidewalk in front of their building are transferred to MTA paratransit dispatchers. Second, for callers who can sit up unassisted for an extended period of time but cannot exit the building on their own, 311 dispatchers take their contact information and forward it to the FDNY. . . . If an evacuee does not answer the door, the FDNY evacuation team makes one attempt to contact the evacuee by phone and, if the evacuee cannot be reached, it moves on. Finally, those who are incapable of sitting up unassisted and must be transported on a stretcher are transferred to the Emergency Medical Service (EMS) . . . to be transported by ambulance to a hospital outside the evacuation zone. . . .

[T]here are several reasons to believe that the HEO could be insufficient to meet the needs of people with disabilities in future emergencies. . . . [T]he City does not inform the public about the existence of the HEO. . ., or that that Operation is available before—and, indeed, *only* before—a storm actually makes landfall. . . . [T]he HEO is triggered by a request for evacuation assistance. Some people with disabilities, however, may not be able to request such assistance. Moreover . . . 311 may be unreliable or unavailable during an emergency. The City has not even evaluated the capacity of 311 to assist those who might require evacuation assistance. Finally, and most fundamentally, it is hard to know whether, or how, the HEO could function in a no-notice emergency. . . . [T]he HEO was originally conceived as part of the Coastal Storm Evacuation Plan for use in emergencies with advance notice . . . As currently written, for example, the Operation ends at least six hours *before* an emergency actually strikes, and does not reactivate afterwards. . . .

Because people with disabilities often require accessible housing or other accommodations, they may be less able than those without disabilities to stay with friends, family, or neighbors during a disaster. . . . The City . . . has eight special medical needs

shelters (SMNSs), at least one of which is located in every borough. The SMNSs are intended to shelter individuals whose needs exceed the capability of the general shelters but who do not require hospitalization. . . . Evacuees seeking shelter are instructed to report first to an evacuation center. Once there, they undergo a basic intake process to evaluate their needs, after which they are either directed to a co-located shelter or transported to another shelter, an SMNS, or a hospital. . . .

Because of its awareness that not all shelters and evacuation centers are accessible . . . the City has adopted a "usability" standard. As the City's expert conceded, the concept of "usability" is not equivalent to the ADA's standard of accessibility. . . . The City's public information during Hurricane Sandy stated only that the shelters would have usable *entrances;* it made no commitment that the shelters would have usable . . . restrooms, or that the dormitories, food distribution areas, and other shelter areas would themselves be usable. . . . City officials testified that if a shelter was not sufficiently accessible, the City would provide accessible transportation to another shelter that was. But . . . the City has not assessed how many people might require accessible transportation . . . and, by extension, whether it would be able to provide such transportation. . . .

[P]eople with cognitive or sensory disabilities may require accommodations in order to effectively communicate with shelter staff, receive information, and navigate a shelter. . . . The City provides shelter staff with some training and guidance on communicating with people with disabilities. . . . And at the time of trial, OEM was developing a new video training course focused on interacting with people with disabilities. . . . [T]he City does not provide—or plan for—any other accommodations. Instead, the City relies on people with disabilities to find ways of communicating their needs without assistance. . . .

The City maintains a stockpile designed to provide . . . the "basic supplies" required to house and care for 70,000 people for seven days. . . . While the supplies provided to SMNSs include some items to accommodate people with disabilities, such as wheelchairs, accessible cots, and diabetic testing kits, the City's emergency plans do not call for such items to be provided to general shelters. . . . [T]he City does not stockpile power wheelchairs, chargers for such wheelchairs, walkers, ventilators, or prescription medications. Nor does the City have any memoranda of understanding with organizations that might be able to provide these items. . . .

Although the record indicates that at least some of the supplies required by people with disabilities are available at—or can, if needed, be procured by—the City's shelters, the City warns otherwise in its communications with the public. For example, one *Ready New York* guide cautions that "Shelters DO NOT have special equipment (e.g., oxygen, mobility aids, and batteries). Be prepared to bring your own." . . .

Days after [Hurricane Sandy hit], many residents still lacked power, and the City was concerned that people might be trapped in their homes. But the City's emergency plans did not account for this situation. . . . The City's first response was to coordinate a volunteer effort to canvas . . . homes in areas without power. The City did not, however, track where these volunteers had been, and it had no way of knowing which buildings had been reached. . . . [Ten days after the storm hit], the City undertook a more systematic canvassing operation of high-rise buildings . . . In six days of canvassing, the teams knocked on nearly 37,000 doors, approximately 13,000 of which were occupied; received nearly 1,000 food and water requests; and assisted with 35 medical

evacuations. [Nearly four weeks after the storm hit], . . . the City began canvassing buildings that were six stories or lower in which people remained without heat or electricity. . . . [N]one of these canvassing efforts was undertaken pursuant to a City emergency plan, as the City had no such plan. . . .

[According to the City's] Commodities Distribution Point Plan . . . after a large-scale emergency, the City may set up commodity distribution points to distribute, among other things, food, water, and ice for medication that must be kept cold. . . . [A]fter Hurricane Sandy, the City provided substantial assistance to those who required prescription medication. For example, volunteers handed out fliers listing pharmacies that were open and could expedite prescription requests. Some volunteers even contacted pharmacies on behalf of those who required medication refills. The City also partnered with the State Department of Health to provide a mobile pharmacy in areas . . . in which pharmacies were not yet reopened. These actions were not, however, taken pursuant to any emergency plan. The City does not, in fact, have any plan directing the provision of prescription medication assistance in the event of an emergency. . . .

Before and during Hurricane Irene, there was no closed captioning of the Mayor's press conferences; nor did the City use a sign language interpreter. In connection with Hurricane Sandy, the City drafted a policy [stating] that "American Sign Language interpreters shall be used, at a minimum, when the Mayor provides the public with critical and time-sensitive communications about a significant and imminent threat to public health and safety during a state of emergency." "Such situations," the policy continues, "[s]hall also require the City to issue a media advisory . . . formally request[ing] that networks provide open captioning and post written bullets on screen summarizing the Mayor's official statements." . . . [T]he City's plans do not require that the City provide information about shelter accessibility, accessible transportation, evacuation assistance, or any other information required by people with disabilities to respond to an emergency. And, indeed, during recent emergencies, the information relevant to people with special needs has often been incomplete, incorrect, or lacking entirely. . . .

In order to establish a violation of the ADA or the Rehabilitation Act, Plaintiffs must show that: (1) they are "qualified individuals" with a disability; (2) Defendants are subject to the ADA or the Rehabilitation Act; and (3) Plaintiffs "were denied the opportunity to participate in or benefit from [the City's] services, programs, or activities, or were otherwise discriminated against by [D]efendants, by reason of [their] disabilities." Here, there is no dispute that Plaintiffs are qualified individuals with disabilities (or organizations that advocate on their behalf and have standing to sue as organizations); that the City is subject to the ADA and the Rehabilitation Act; and that the City's emergency preparedness program is a service, program, or activity within the meaning of both statutes. The only issue, then, is whether Plaintiffs were denied the opportunity to participate in, or benefit from, the City's emergency preparedness and response program or were otherwise discriminated against by the City. . . .

Plaintiffs have proved that the City's plans for evacuations . . . are not in compliance with the [law]. . . . *[A]d hoc* accommodations are both legally inadequate and practically unrealistic. . . .

To be sure, the ADA does not require that *every* shelter be accessible. But the City cannot even identify which, or how many, of its shelters and evacuation centers are accessible. There is no way, therefore, for the City to ensure that there are sufficient

shelters and evacuation centers to meet the needs of people with disabilities or for it to direct people to accessible shelters and evacuation centers. . . .

[T]he City must do more than ensure that the buildings in which it locates its shelters are physically accessible; it must ensure that the services offered therein are also accessible. . . . Without the means to communicate at shelters, people with disabilities may be less able than others to access the services therein. . . .

Ordinarily, a public entity is not required "to provide to individuals with disabilities personal devices, such as wheelchairs; . . . or services of a personal nature including assistance in eating, toileting, or dressing." 28 C.F.R. § 35.135. This regulation, however, . . . does not apply "in special circumstances, such as where the individual is an inmate of a custodial or correctional institution." 28 C.F.R. Part 35, App. B (2005). An emergency constitutes a similar special circumstance. The purpose of the shelter system is to provide people with the goods and services they need to remain healthy, safe, and functional when an emergency has rendered them unable to provide these goods and services for themselves. The City may not provide people without disabilities the goods and services they require while withholding them from those with special needs. But [assuming] those who need such supplies are [able] to get them through the City's substantial requisition process, through which the City can obtain almost anything within forty-eight hours. . ., there is no reason the stockpile itself must contain these items. . . . The City's communication about the stockpile, however, is another matter. Although the record indicates that the City provides adequate supplies for people with disabilities in the shelter system, the City informs the public that it will not do so. This misinformation not only violates the requirement that people with disabilities must be able to obtain accurate information about the provision of accessible services, but also dissuades people with disabilities from attempting to use the shelter system. . . .

[In failing to provide people with disabilities meaningful access to its emergency preparedness program, the City] has deprived people with disabilities of what they are entitled to under the law, not to mention of the peace of mind that people *without* disabilities can have when it comes to the City's preparedness plans.

. . .

What impediments stand in the way of comprehensive planning for the needs of people with disabilities and other vulnerable populations in emergencies? What might the plaintiffs' goals have been in bringing litigation against the city? What are the advantages and disadvantages of litigation as a tool for achieving those goals?

In addition to highlighting the role of litigation in encouraging government officials to develop comprehensive and equitable emergency plans, *Brooklyn Center for Independence* provides a window into the complexities involved in emergency planning and response. Crises highlight the fundamental tension between individual and collective responsibility that pervades public health law. What responsibility does government have to prepare for and respond to an emergency? What aspects of an emergency situation justify shifting responsibility for assuring access to

basic necessities (e.g., food, water, prescription medications) from the individual to the government or from one level of government to another? Are these criteria adequately reflected in the definitions of *emergency* and *disaster* set forth in federal and state laws excerpted in the previous section?

As *Brooklyn Center for Independence* indicates, distribution of medical supplies and services is vital to an effective response. In the aftermath of a hurricane or other disaster, trauma care can mitigate the direct impacts. But indirect, and often hidden, health impacts may have an even greater population impact. Mental health services to address the psychosocial impacts of an event and routine care to ensure that treatment is not disrupted for those with chronic conditions should also be part of emergency planning.

MEDICAL COUNTERMEASURES: ENSURING SAFETY AND EQUITY IN TIMES OF CRISIS

While some argue that it is the individual's responsibility to stockpile sufficient supplies to meet basic needs and manage chronic conditions during an emergency, there is bipartisan support for government's role in developing and distributing specialized medical countermeasures. Biological, chemical, radiological, and nuclear incidents may require special vaccines, antimicrobials, or antidotes, some of which may be difficult or impossible for private individuals to obtain. These may include potassium iodide tablets to mitigate the effects of radiation, vaccines to protect against biological weapons such as smallpox or anthrax, or antiviral drugs that prevent complications from influenza. The excerpts in this section examine ethical and legal issues raised by development and distribution of specialized medical countermeasures. In an emergency, should safety regulations be relaxed to hasten access to new treatments? Who should receive vaccines, medicines, and supplies when not all can? In other words, how can society ensure equitable allocation of safe medical resources in conditions of scarcity?

When confronted with a novel disease, health care workers and policymakers may be forced to care for patients without sufficient evidence that available medical treatments are safe or effective. In many cases, the patient becomes a research subject and data is collected for the benefit of others who may be affected in the future. But in a rapidly developing epidemic, there may be cases in which unproven treatments could or should be provided to individuals who (for a variety of reasons) are

unable to participate in clinical trials. The following excerpt assesses the ethical issues raised by these situations.

EXAMINING THE ETHICS OF CLINICAL USE OF UNPROVEN INTERVENTIONS OUTSIDE OF CLINICAL TRIALS DURING THE EBOLA EPIDEMIC*

Seema K. Shah, David Wendler, and Marion Danis

The Ebola outbreak in West Africa began in the spring of 2014. By the end of 2014, it had caused the deaths of more than 6,000 people, and was difficult to contain. Ebola virus disease is a febrile illness characterized by profound vomiting and diarrhea, with extreme fluid and electrolyte loss. There is evidence that intravenous repletion of fluids and electrolytes can improve outcomes, although health infrastructure to provide this is not available in many places afflicted by the epidemic. Treatment and preventive interventions targeted to Ebola virus disease are still undergoing development and testing. Accordingly, the situation has prompted heated debate over whether it is acceptable to offer interventions with a limited evidence basis to patients outside of the context of research. In August 2014, an advisory panel to the World Health Organization [determined that it would be acceptable] to use unproven interventions that have been promising (in vitro and in animals) in clinical practice if certain conditions were met. Since then, however, several commentators have argued that unproven interventions should not be offered outside of clinical trials, with some contending it would be "a serious mistake" to do so. . . .

The existing debate . . . has primarily addressed whether treatments and vaccines that are in the development pipeline should be offered prior to regulatory approval. Although we agree with the general view . . . that unproven interventions may be provided if there is prior reason to believe the interventions might work, and the provision of the intervention involves collecting at least a minimal set of data [and thus can be evaluated under frameworks applicable to research], we consider two issues that have largely been missing from this debate. The first is that the interests of patients are not fully aligned with the interests of their providers and drug developers in this context. . . . The second is . . . that resource constraints facing providers, funders, and patients often counsel against offering unproven interventions.

BACKGROUND: IS IT PERMISSIBLE TO OFFER UNPROVEN INTERVENTIONS TO PATIENTS?

Some scholars argue that the rule of rescue is the main justification for providing access to unproven interventions. The rule of rescue provides that when we can help others significantly at relatively low cost to ourselves, we are obligated to do so. . . .

Some scholars have noted that the precautionary principle underlies our regulations governing unproven treatments. . . . The precautionary principle requires that regulators err on the side of caution and not make drugs available until it is known that they are sufficiently safe and likely to be effective. Yet the precautionary principle may

* 2015. *American Journal of Bioethics* 15 (4): 11–16.

have little force for patients who are terminally ill or have very limited options for survival, and this is reflected in many national regulations that permit expanded access to unproven therapies in certain cases. There is also some tension between what it might make sense for a terminally ill patient to try and what physicians, funders, and health systems should offer to that patient. . . . [T]here are resource constraints, concerns about offering patients false hope, and worries about how markets might be created that prey on the vulnerabilities of people who are dying. . . .

Providing access to unproven therapies can be justified on grounds of beneficence. . . . If interventions can help patients who are likely to face poor outcomes without any intervention, this is a good reason to provide those interventions. . . . [E]xisting frameworks for access to investigational therapies place conditions on access such as robust informed consent, community engagement, and fair allocation. They also emphasize that the following factors should be considered: The risk/benefit profile should be favorable, given the available evidence and alternatives to receiving treatment; safety data should be gathered; planning for what happens if drugs are not approved should occur in advance; and the interests of companies that provide drugs should be considered, but not to the extent that patients are exploited by having to pay for access to therapies that are unlikely to work.

TWO WAYS THE ISSUE OF ACCESS TO UNPROVEN INTERVENTIONS ARISES

In the context of the Ebola outbreak, the question of when it is permissible to offer patients unproven therapies [outside the context of clinical trials] arises in . . . two ways. First, . . . patients, physicians, health funders, and health systems [face tough questions] when considering whether to provide already approved or otherwise available interventions [whose effectiveness as an off-label treatment of Ebola is unproven]. . . . Second, [there are situations in which providing experimental drugs within the context of a research protocol is not feasible. T]he drug discovery pipeline may lead to either the production of drugs in quantities that are more than are needed for use in planned clinical trials, situations where experimental drugs were produced in insufficient quantities for clinical trials but still able to do some good for a few individuals (as was the case with the experimental drug ZMapp), or delays in the start of clinical trials for some reason that can lead to additional supply. Relatedly, all who need interventions (by one estimate, 30,000 people in the Ebola epidemic) will not be able to enroll in clinical trials. The facts that trials may need to be conducted in places with a reasonable amount of health care infrastructure, but that many patients are being treated in rural settings, suggest that compassionate use may be one way to expand access to populations that are relatively disadvantaged. . . .

Interventions Already Approved for Other Indications or Otherwise Available

Unlike the provision of interventions that are simultaneously going through clinical trials, interventions that are already approved for other indications or otherwise available do not threaten the drug development process. The two main considerations that suggest this category of interventions should be used in a limited fashion are their potential to do harm and resource constraints.

For instance, off-label interventions may be available in larger quantities than experimental drugs still in the development pipeline, but if they have significant side effects or a potential to cause harm without much expected benefit, it might not be advisable to use them outside of the context of clinical trials. . . . There may be other interventions that are more widely available, like bananas, which may have some biological plausibility [related to potassium replacement] and raise little concern about doing harm. Yet these interventions may not be likely to make much of a difference, so the time and effort required to provide them may be better spent in other ways. Finally, there may be interventions for which there is no evidence to support their use. Although there is less reason to offer patients interventions that have a weak evidence base, patients might request access to unproven interventions that have little evidence of net benefit, and a physician could reasonably choose to respect patient autonomy in such a situation.

Resource constraints may counsel against providing unproven interventions in some of these cases, however. There are significant and important limitations on resources for patients, funders, health systems, and providers. . . . A patient who is seriously ill might have limited time in which an intervention might work, and therefore does not have the time to try many different interventions that might conceivably be helpful. . . . Funders deciding what to provide in terms of aid to fight Ebola also have many competing options to choose among. They could fund projects to build infrastructure, develop research on experimental therapies and vaccines, facilitate the provision of health care workers to affected areas, and/or expand access to unproven interventions. . . . [H]ealth care providers . . . will have to care for multiple patients, with limited time and resources that can be devoted to each patient, which may prevent them from being able to offer certain kinds of interventions. Some interventions may also be very difficult to access in the clinical environment.

Additionally, health care providers may also have legitimate concern about maintaining trust in the medical profession. The practice of medicine was once colored by the public's perception of physicians as peddling goods that were unlikely to cure them. . . . Significantly, however, patients' and providers' interests may diverge in some cases; it may make sense for patients to try things with very little reason to believe that they will work, though it would be problematic and could undermine trust in the medical profession if physicians were to routinely offer unproven remedies without much reason to support their use. The need to maintain trust in the medical profession also puts extra pressure on the need to obtain informed consent and conduct community consultation before offering unproven interventions, whether in the context of a clinical trial or not. . . .

Extra Supply of Experimental Interventions [Offered Outside of Clinical Trials]

[R]esearch on experimental interventions is critical and offering unproven interventions outside of clinical trials should not interfere with the ability to conduct research. Access programs can be counterproductive; although they are intended to solve the problem of providing treatment when there are not sufficient data to know what to offer, [they risk undermining the generation of that knowledge].

It is also relevant to consider whether unproven *prevention* interventions, such as vaccines, should be offered. . . . The case for offering unproven vaccines to healthy

individuals is . . . a much harder case to make[, t]hough the case might be stronger [for] people at heightened risk of infection (such as health professionals treating Ebola patients). . . . [T]he need for rigorous evidence is arguably higher when the intervention is intended to be administered to large numbers of healthy individuals[. Additionally,] the numbers needed to show an effect . . . might make it more important to ensure compassionate use does not interfere with clinical trial enrollment.

CONCLUSION

We have argued that it may be problematic in some cases to provide access to unproven interventions outside of clinical trials because of the resource constraints facing providers, funders, health systems, and patients, and the need to maintain integrity of the medical profession. In particular, these actors should prioritize the provision of and further research into supportive care interventions that are effective against Ebola virus disease.

. . .

Shah and her coauthors discuss the special considerations raised by rapidly developing epidemics of diseases for which proven treatments are not available and not all of those affected may be enrolled in clinical trials. The excerpts that follow deal with a different scenario: emergency allocation of vaccines, medicines, and other resources known to be safe and effective where supplies are limited.

ALLOCATING VACCINES AND ANTIVIRAL MEDICATIONS DURING AN INFLUENZA PANDEMIC*

Carl H. Coleman

. . . The limited availability of vaccines and antiviral medications during a pandemic means that difficult decisions will have to be made about how to allocate these resources. Questions about allocating scarce life-saving resources are not, of course, unique to pandemic situations. For example, the demand for transplantable organs consistently exceeds the supply, and, as a result, complex regulatory systems have been developed to ensure that organs are allocated fairly and consistent with medical need. However, existing systems for allocating scarce resources like organs provide only limited guidance for the type of decisions that will arise during an influenza pandemic. First, during a pandemic, decisions will have to be made under crisis circumstances, in the face of social unrest as well as uncertain and evolving medical information. Regulatory systems will have to be flexible and responsive, and allocation criteria may have to be based on broad generalities rather than case-by-case assessments of individual needs. Second, unlike decisions about allocating organs, the impact of which is felt primarily by individual patients, decisions about allocating vaccines and antivirals will have significant implications for all of society. For example, because influenza

* 2009. *Seton Hall Law Review* 39 (4): 1111–24. Reprinted with permission of Carl H. Coleman.

is infectious, individuals denied access to vaccines or antivirals will not only have a greater likelihood of becoming ill and dying, but they will also have a greater chance of infecting other persons. Similarly, denials of care to essential service providers, such as health care workers or key government officials, may increase risks to third parties by undermining society's ability to mount an effective response to the pandemic. As a result, prioritization systems will have to take into account the externalities of treatment denials, in addition to the impact on the individuals seeking care.

While the details of national pandemic preparedness plans vary, the general approach taken to the question of allocating vaccines and antivirals is substantially similar. Overall, the primary goal is to save the most lives possible, while simultaneously reducing social disruption and economic losses. These are certainly valuable goals, particularly in the context of a crisis in which society's very existence may be threatened. Yet, underlying the decision to pursue these goals are several contestable value judgments that pandemic planners have not always made explicit. . . .

APPROACHES TO THE ALLOCATION OF VACCINES AND ANTIVIRAL MEDICATIONS IN NATIONAL PREPAREDNESS PLANS

[M]any countries have developed pandemic preparedness plans that explicitly address the allocation of vaccines and anti-viral medications. In the United States, the Department of Health and Human Services . . . issued guidelines for the allocation of both vaccines and antiviral medications [in 2009]. For vaccines, the guidelines divide individuals into target groups and then, within the target groups, into tiers: The target groups include: (1) persons who "maintain homeland and national security"; (2) persons who "provide health care and community support services"; (3) persons who "maintain critical infrastructure"; and (4) "the general population." The first tier within each group would receive top priority for vaccination. For the occupational groups—i.e., groups one through three—the first tier includes deployed forces, critical health care personnel, emergency medical service personnel, and fire and police officers. For the general population, tier one would be limited to pregnant women, infants, and toddlers, all of whom are expected to have a higher risk of dying during a pandemic. After individuals in the first tier of each group are vaccinated, supplies would be directed to persons in the second, third, fourth, and fifth tiers.

DHHS has also issued guidance for the use of antiviral drugs. Initial priorities would focus on efforts to contain or suppress initial pandemic outbreaks anywhere in the world and to provide post-exposure prophylaxis at the border to travelers entering the country. Then, the bulk of the stockpiled medications would be directed to persons infected with pandemic influenza who present themselves for care early in the course of their illness and who would benefit from antiviral medications. Other priorities include prophylaxis for health care workers, persons who have compromised immune systems, and persons living in residential settings such as nursing homes, prisons, and homeless shelters when outbreaks occur in those settings. The guidelines recognize that existing stockpiles will be insufficient to cover all of these categories, and conclude that, when supplies are limited, "treating all persons based on assessment of medical need is considered preferable to targeting certain priority groups for treatment." . . .

The DHHS guidance documents are intended to be advisory only. They do not purport to be binding on the state, local, and tribal planners who are the primary audience

of the documents. In fact, the vaccine guidance notes that "it is important that plans are flexible as the guidance may be modified based on the status of vaccine technology, the characteristics of pandemic illness, and risk groups for severe disease—factors that will remain unknown until a pandemic actually occurs."

Other countries' prioritization plans differ in some respects from the DHHS guidelines, but in general reflect similar considerations. . . .

ASSESSING THE PLANS: AGE, OCCUPATIONAL CATEGORIES, AND THE PRIMACY OF SOCIAL UTILITY CONSIDERATIONS

Existing prioritization plans share several common characteristics. [H]ere three features of these plans that . . . warrant greater attention [are highlighted]. First, the plans all seek to save the most lives possible without distinguishing between the value of lives based on individuals' ages. Second, they prioritize certain occupational groups, most commonly health care workers, but they often do not clearly define the contours of these categories. Finally, they reflect the general view that maximizing aggregate social welfare should be the primary consideration in allocation decisions, despite the potential impact of such an approach on socially disadvantaged groups. . . .

All Lives Are Equal, Regardless of Age

[A] serious weakness of treating all lives as inherently equal is that such an approach ignores commonly held intuitions about the implications of aging. . . . The idea that young people's lives are deserving of greater protection than the lives of older persons is sometimes referred to as the "fair innings" argument, which is based on the idea that everyone deserves to live through all the "innings," or phases, of life. . . . The fair innings argument reflects the view that fairness does not necessarily mean that everyone should have equal access to the same amount of resources, but that everyone should have an equal chance to live a complete life.

The pure version of the fair innings argument would give the greatest preference to the youngest members of society—i.e., infants—on the ground that they have the most years of life ahead of them. A variation of the argument . . . would balance the amount of time a person has left to live against the amount of time the person has already invested in living. With this "investment refinement" to the standard fair innings argument, a 20-year-old person would have greater priority than an infant. . . .

However, age-based prioritization systems also raise concerns of their own. First, even if we were to agree that the number of years a person has left to live is a relevant criterion for allocating vaccines and antivirals, age is not always an accurate proxy for life expectancy. Factors such as genetics, health status, and lifestyle also play important roles. . . . Second, any official policy that treats the lives of those closer to death as less deserving of protection creates the danger of reinforcing biases and discrimination against the elderly. . . .

Membership in Particular Occupational Categories Justifies Priority Access to Resources

Giving priority in resource allocation to essential health care workers is particularly justifiable if those individuals will have to assume greater-than-normal risks to their own health in order to carry out their job responsibilities. . . . Offering these workers

protection against infection may be a necessary incentive to get them to agree to work. In addition, providing access to vaccines and antivirals to individuals who expose themselves to life-threatening risks as part of the pandemic response effort can be justified by the ethical principle of reciprocity, which states that those who make sacrifices for the benefit of society have a greater claim to benefits from society in return.

Nonetheless, basing preferential treatment on specific occupational categories is problematic because the categories are inherently broad and may be difficult to contain within reasonable limits. For example, should the category of "health care worker" include only professionals with unique life-saving abilities, such as infectious disease specialists, or should it include anyone who works in a setting that provides health care—including, for example, janitorial staff or members of the billing department? If the goal is to ensure the continued functioning of hospitals and other health care providers, then arguably anyone necessary to the maintenance of that institution would have a claim to priority access. Yet, if anyone who works in a health care institution is entitled to priority, it will be hard to justify differential treatment for others who provide equally valuable societal benefits, such as day care providers, bus drivers, or sanitation workers. . . .

Promoting Aggregate Social Welfare and the Impact on Vulnerable Populations

A general concern with utilitarian-based approaches to the allocation of scarce life-saving resources is that they may conflict with other important societal values, particularly the values of equality and non-discrimination. . . . For example, developing a mechanism for delivering vaccines and antiviral medications to hard-to-reach rural populations will inevitably cost more than using those resources in concentrated urban settings. Sending resources to developing countries, and helping those countries deploy those resources in the absence of well-developed health care infrastructures, will entail similar inefficiencies. In general, many of the most vulnerable segments of society would suffer under a system that focuses primarily on the cost-effective deployment of resources. . . . The impact of utilitarian-centric resource allocation policies on vulnerable populations is particularly problematic in light of the fact that individuals who are economically and socially disadvantaged would probably suffer the greatest burdens of an influenza pandemic. . . .

Even the most ardent supporters of taking equality considerations into account in resource allocation decisions do not deny that maximizing social utility is an important ethical value. The question is ultimately one of balance. . . .

CONCLUSION

Existing plans for allocating vaccines and antivirals during a pandemic are rational responses to a problem with no ideal solution. . . . While no plan can perfectly resolve the competing considerations, it is essential that the trade-offs are made explicit and subject to broad public deliberation. . . .

• • •

Coleman suggests that many of the most commonly asserted bases for determining who should have access to scarce medical resources during an influenza pandemic have social justice implications. Unless policymakers steadfastly adhere to the notion that all lives are of equal worth—in the face of strong intuitive notions that the young should be given priority over those who have already enjoyed a long life, for example—they inevitably step onto a slippery slope leading to consideration of other proxies for life expectancy or worth, including health status and disability. The next excerpt explores these implications in more detail.

PLAYING GOD: THE LEGALITY OF PLANS DENYING SCARCE RESOURCES TO PEOPLE WITH DISABILITIES IN PUBLIC HEALTH EMERGENCIES*

Wendy F. Hensel and Leslie E. Wolf

[Several algorithms developed for allocating scarce medical resources in the event of a widespread public health emergency] explicitly exclude patients with particular physical or mental disabilities from treatment. In some cases, the disability in question is excluded because it negatively affects the likelihood that the medical intervention will be successful in the short-term. In others, however, the identified disabilities bear no discernable relationship to immediate treatment outcomes. Instead, individuals in these categories are precluded from critical care either because they will need resources for a prolonged period of use, are deemed to have a poor quality of life post-treatment, or otherwise have a limited long-term prognosis as a result of their disabilities. . . .

THE LEGALITY OF USING DISABILITY AS A FACTOR IN ALLOCATING SCARCE RESOURCES

[Disability rights laws reflect] the government's commitment to equality of opportunity for people with disabilities in even the most demanding of circumstances. The provision of health services is subject both to anti-discrimination laws and to judicial scrutiny even in times of public health emergencies. . . . Against this background, the categorical exclusion of individuals with specific disabilities from some scarce resources during a pandemic would almost certainly qualify as discrimination on the basis of disability. . . .

In response to such concerns, it is likely that proponents of the plans would point to precedent suggesting that medical treatment decisions are not cognizable under these statutes. . . . This position is not surprising in light of courts' understandable reluctance to second-guess complicated decisions made by health professionals in

* 2011. *Florida Law Review* 63 (3): 719–70.

their area of expertise. . . . The logic of these cases, however, would seem inapposite to an evaluation of the legality of protocols promulgated in advance of a pandemic, particularly those which categorically preclude access to care. . . . The cases declining to review medical treatment decisions generally require scrutiny of professional judgment rendered to a specific individual without predetermined limitations as to what care may be provided. Because the professional's decision pertains to and can be evaluated in the context of a particular patient and his actual need for treatment, it is necessarily based, at least to some extent, on an individualized determination as mandated by the ADA. It may be that once this threshold is crossed, the legitimacy and reasonableness of medical decisions are most appropriately evaluated in the context of state tort law and professional standards of care, rather than in the context of anti-discrimination laws.

In contrast, sweeping policies that preclude or significantly limit entire categories of people with disabilities from receiving medical care in advance of actual need necessarily are based on generalizations concerning status. Their legitimacy depends on whether scientific evidence establishes that no individual in the excluded class could possibly qualify for or benefit from the medical treatment at issue, or whether the exclusionary criteria is actually based on prejudicial stereotypes and myths. It is precisely this type of inquiry that Congress intended to reach through the ADA and the Rehabilitation Act, and such policies should be subject to judicial review. . . .

In addition to, or in lieu of, identifying specific disabilities to exclude from care, some protocols have used the patient's likely duration of need for the scarce resource as a factor in allocation decisions. The longer the patient is likely to need the intervention, such as a ventilator, the less likely he or she is to receive it in the first instance. . . . Following [the reasoning of disability law precedents], the durational limits would be discriminatory to the extent that their practical effect is to erect a significant hurdle between people with disabilities and scarce resources during a health emergency. If evidence suggests that individuals in the excluded categories have the potential to benefit from ventilator use but because of their disability "cannot be effectively treated" within the established durational limits, [precedent] would suggest such limitations are actionable under [federal disability laws]. Disability advocates may plausibly argue that they are not seeking additional substantive benefits, but instead a reasonable modification—an extension of time—to facilitate meaningful access to the same benefit. . . .

Some of the protocols allocate scarce resources among pandemic patients based on the medical professional's assessment of the individual's anticipated quality of life after treatment. . . . As history has demonstrated . . . medical professionals are not immune to the societal bias towards life with disabilities. . . . Because quality of life determinations are inherently subjective and may be based on biased assumptions concerning life with disabilities, they are unlikely to survive a challenge under the ADA or the Rehabilitation Act. . . .

[I]t is less clear whether limiting treatment more generally to those who are most likely to benefit from it would implicate the ADA. . . . The legality of this approach is likely to lie in the definition of "effectiveness" or "medical benefit" employed in the protocols. . . . To the extent that this evaluation is limited to the most basic question of whether a particular patient will survive or receive a physiological benefit from imple-

mentation of the scarce resource, using medical effectiveness or benefit as allocation principles would seem consistent with the ADA. . . . If there is scientifically sound data suggesting that the individual is unlikely to survive for an appreciable period of time despite access to the scarce resource, it would be reasonable to conclude they are not "qualified" for the benefit regardless of the source of the incapacity. . . .

There is no question that some preexisting disabilities will make it more difficult for individuals to fight and survive unrelated illnesses, and therefore, such standards will exclude some individuals with disabilities from receiving care. Nevertheless, such criteria are facially neutral and involve the individualized consideration missing from the categorical denials that run afoul of the ADA. Unlike subjective interpretations regarding quality of life, the use of medical effectiveness in this manner is not based on stereotypes, generalizations, or myths about disabilities. . . . In the absence of a strict first-come, first-served policy, the ability of the individual to immediately gain from implementation of the intervention or, more basically, to survive its application would seem to be the most neutral criteria, although nevertheless imperfect, for distributing resources in times of crises. . . .

It is not sufficient to conclude that the ADA and the Rehabilitation Act apply to the allocation protocols or to identify the discriminatory implications of some of their provisions. The protocols may nevertheless be lawful if they are "necessary" within the meaning of the ADA, such that the modification or removal of the identified criteria would constitute a fundamental alteration to the provision of emergent care in a pandemic. . . .

Proponents of the protocols are likely to argue that . . . [a]n emergency requires decisionmaking and assessment on short time frames with incomplete information. There is no question that a disability diagnosis is shorthand for myriad conditions experienced by the individual that may be relevant to treatment decisions. If the use of diagnostic categories is the only or even the best way to facilitate decisionmaking in situations requiring immediate action, courts may logically conclude that they are necessary to the efficient distribution of resources. By the same token, it would fundamentally alter the provision of care in public health emergencies to preclude their use. . . .

As for those protocol provisions that would more appropriately be challenged on the ground of disparate impact—quality of life, duration of need, duration of benefit, and medical effectiveness—the answer to whether they are necessary to providing health care in a public health emergency depends on whether the public health maxim of the greatest good for the greatest number is in fact a legitimate and primary goal of the state in times of crisis. . . .

[Even assuming that it is], it would be difficult to conclude that protocol criteria based on generalizations, stereotypes, or myths about people with disabilities are legally necessary to the effective administration of resources. Quality of life assessments, in particular, are unlikely to meet this standard. Even if the court endorses the legitimacy of the "greatest good" approach, the answer of which treatment provides the "greatest" result depends on a value assessment of the lives to be saved. There is no way to perform this assessment without reference to generalizations about life with disabilities, particularly in times of crisis when treatment decisions are likely to be made under time pressure. . . .

CONCLUSION

It is evident that advance planning for public heath emergencies must take place, and that it must be done within the parameters of antidiscrimination laws. These issues cannot await resolution by the courts—the application of these protocols will be made in the field when timing is critical. If these issues are not debated openly and collectively in advance, they are likely to be resolved covertly by individuals in times of crises. At the point of litigation, moreover, individuals with disabilities will already be irreversibly harmed. Jurors and the judiciary are likely to be more heavily influenced by the chaos surrounding a time of emergency and the need for the government to mount a quick response than they would be swayed by the civil rights of individuals at that time. The protection to be afforded, therefore, must come on the front end of the planning process.

A public health emergency will necessitate hard decisions. Public health authorities and medical professionals need clear guidance so that they can make good decisions under bad circumstances. For protocols to successfully alleviate some of the uncertainty in times of public health crises, moreover, their necessity must be understood and embraced by the public, particularly those who are likely to be most significantly impacted by them. The real power of [federal disability laws] lies not in their ability to punish misconduct, but in the guidance they provide in the development and implementation of equitable policies for people with disabilities. . . .

. . .

Hensel and Wolf conclude by raising a troubling question about how public health law functions during an emergency: Is the judiciary up to the task of protecting individual rights during times of public panic? They suggest that judicial review may be insufficient and urge policymakers and health officials to vet their emergency plans thoroughly, rather than relying on adjudication after the fact. This question also has important implications for judicial review of quarantine and related containment strategies, which are the focus of the next section.

QUARANTINE, CONTROLLED MOVEMENT, AND COMMUNITY CONTAINMENT STRATEGIES

The means by which tuberculosis, HIV, and many other infectious diseases are transmitted from person to person are well understood. They present serious risks, but policymakers have had time to consider how best to control the spread of infection and courts have adjudicated the extent to which constraints on personal liberty are permissible. Treatments—though imperfect and not universally accessible—are available.

Novel infectious diseases, particularly those with pandemic potential, present special challenges. As previous epidemics (e.g., severe acute respiratory syndrome (SARS) in southeast Asia and Canada, novel

H1N1 influenza in Mexico and the United States, and Ebola virus in West Africa) illustrate, policymakers can overreact. They can infringe on individual rights unnecessarily in response to the public's dread of an easily transmissible, potentially lethal disease for which medical countermeasures are unavailable. The following excerpt discusses the legal and ethical issues raised by quarantine and related containment strategies in the context of a rapidly developing epidemic.

FROM SARS TO EBOLA: LEGAL AND ETHICAL CONSIDERATIONS FOR MODERN QUARANTINE*

Mark A. Rothstein

. . . Quarantine is one of the most aggressive and controversial measures public health officials have at their disposal in attempting to control a disease outbreak, because restricting the movement of potentially large numbers of asymptomatic people raises serious legal and ethical concerns. . . . During the 1918–1919 Spanish flu pandemic, "nonpharmaceutical interventions," including quarantine, were successful in decreasing case fatality rates. During the SARS epidemic of 2003, quarantine was used extensively in several Asian countries and Canada. In the absence of a vaccine or effective treatment quarantine played a part in ending the epidemic. Similarly, during the Ebola epidemic of 2014 in West Africa, with no vaccine or widely available treatment, and a mortality rate of approximately seventy percent, social distancing measures, including quarantine, became a primary containment strategy. The social distancing measures included school closures and bans on public gatherings, including sports, shopping, and entertainment. The quarantines were both individually based and area-wide (or *cordon sanitaire*). . . . [T]he paradox of quarantine and other social distancing measures is that they may be effective in fighting a disease outbreak, but they can be applied too broadly, resulting in a variety of social harms, including economic disruption, personal isolation, and even violence. . . .

LEGAL AUTHORITY

Legislation

In the event of a public health emergency involving a communicable disease, state public health officials working with their local counterparts are responsible for determining whether and how to impose quarantine in accordance with the substantive and procedural requirements of state law. In most states, the authority to use quarantine and similar measures begins when the governor or other public official declares a public health emergency. . . .

Procedures for isolation and quarantine put an emphasis on responding to public health emergencies quickly. For example, the [the Model State Emergency Health Powers Act (MSEHPA)] permits the isolation and quarantine of individuals without

* 2015. *Indiana Health Law Review* 12 (1): 227–80.

notice for up to ten days pursuant to an administrative directive [if delay would significantly jeopardize limitation of disease transmission]. Notice of a judicial petition for an isolation or quarantine order must be given to affected individuals or groups within twenty-four hours, and hearings based on such a petition must be held within five days. . . . Among the drawbacks to mandatory quarantine are the need for public health departments to devote essential resources to litigation in a time of emergency, the lack of familiarity of trial court judges with the scientific issues in a quarantine petition, . . . the inability of many court systems to process timely appeals, and the nagging issue of how to deal with individuals who fail to comply with a court-ordered quarantine. . . .

[Both the MSEHPA and a]nother model law project, . . . the Turning Point Model State Public Health Act (TPMSPHA), [set forth] eight conditions and principles [that] apply to isolation and quarantine: (1) isolation and quarantine must use the least restrictive means necessary; (2) isolated individuals must be kept separately from quarantined individuals; (3) the health status of individuals in isolation and quarantine must be monitored regularly; (4) an individual in quarantine who becomes infected must be removed promptly to isolation; (5) isolation and quarantine must be terminated immediately when an individual no longer poses a substantial risk of transmitting an infection; (6) individuals must be supplied with adequate food, clothing, shelter, a means of communication, and competent medical care; (7) outside premises used for isolation and quarantine must be maintained in a safe and hygienic manner; and (8) to the extent possible, cultural and religious beliefs shall be respected. . . . [Pursuant to both model laws,] the government must appoint counsel without charge to those subject to quarantine. . . .

The federal government . . . also has limited authority to impose quarantine. This authority . . . is restricted to preventing communicable diseases from entering the country or crossing state lines. . . . [A]s of 2015, the CDC has twenty quarantine stations at points of entry and land border crossings, which represents a significant increase from the eight stations in place during the SARS outbreak of 2003. During the Ebola epidemic in 2014, CDC personnel at the airport quarantine stations screened international passengers. . . . [The Public Health Service Act (PHSA)] also authorizes the Surgeon General to isolate individuals with a communicable disease who attempt to cross state or national borders. The PHSA lists the following diseases for possible quarantine: cholera, diphtheria, infectious tuberculosis, plague, smallpox, viral hemorrhagic fever, and yellow fever. Pursuant to Executive Orders in 2003 and 2005, the following conditions were added: SARS and "influenza viruses that are causing, or have the potential to cause, a pandemic." . . .

The decentralized and fragmented nature of American public health law presents great challenges for coordination among federal, state, and local officials as well as among various agencies and private entities. . . . The enactment of appropriate legislation is only the first step in an effective public health response to infectious disease outbreaks; the laws must be implemented efficiently to achieve the desired results.

Case Law

The United States Supreme Court has explicitly upheld the exercise of broad quarantine powers by the states. The Supreme Court upheld the power of the state to enforce quarantine laws in the absence of a contrary federal law. . . . More recent state court decisions have upheld the authority of public health officials to confine individuals to prevent the transmission of infectious disease as long as certain criteria have been met.

PHOTO 11.3. U.S. Marines get their temperature checked as they return from building Ebola treatment units in rural Liberia, 2014. Individuals traveling to the United States from areas affected by Ebola were routinely screened for symptoms. Additional restrictions were imposed on some individuals, in spite of the fact that they were not symptomatic and thus not contagious, prompting litigation. Photograph by Craig Philbrick for the U.S. Army.

AN ETHICS FRAMEWORK

[F]our ethical considerations . . . should be evaluated in deciding whether to order a quarantine and, if so, the specifics of quarantine: . . . (1) necessity, effectiveness, and scientific rationale; (2) proportionality and least infringement; (3) humane supportive services; and (4) public justification.

Necessity, Effectiveness, and Scientific Rationale

"Necessity" means public health officials ought to impose quarantine only in the face of a demonstrable threat to public health. . . . The potential effectiveness of quarantine is related to the interval between exposure and the onset of illness. For infections with a short interval, such as the one to four days for influenza, there may be a narrower window to impose quarantine. For Ebola, with a two to twenty-one day incubation period, a longer quarantine has been used; indeed, the long quarantine period has been associated with many problems in Liberia and the United States. . . .

Proportionality and Least Infringement

"Proportionality" means the public health response is appropriate in light of the threat; in other words, there is a reasonable relationship between the burdens and the expected benefits. Not all events of infectious disease requiring social distancing measures justify using quarantine, the most coercive and intrusive measure. On the other hand, shelter in place or other measures may be insufficiently aggressive. . . .

When the initial Ebola cases spread to the United States, first in Dallas and then in New York City, public fears caused twenty-one states to impose a mandatory

twenty-one-day quarantine of all health care workers returning to the United States after treating Ebola patients in West Africa. . . . One consequence of states imposing twenty-one day quarantines was that essential health care workers were dissuaded from volunteering to serve in West Africa. Other important reasons for questioning these ad hoc state policies include possibly undermining the CDC's credibility and confusing the public by having different quarantine policies in each state. . . .

To be effective, any public health response to an infectious disease outbreak depends on the prompt clinical diagnosis of infected persons and the prompt imposition of isolation. In a mere two days, the time between when [the first U.S. Ebola case, Thomas Eric Duncan,] was mistakenly discharged from [a Dallas] hospital's emergency department and the time he was readmitted and placed in isolation, as many as 100 individuals had possible exposure. Counting the contacts of the health care workers who treated him, 177 people in Texas were placed in quarantine. Two of the nurses who treated Mr. Duncan in the final stages of his illness became infected and, after treatment at other institutions, completely recovered. . . . The entire, unfortunate episode . . . could and should have been prevented. It was unrealistic for the CDC to expect that every hospital would be able to treat Ebola patients without endangering the medical and nursing staff. Eventually, the CDC changed its policy and certified thirty-five hospitals nationwide as being prepared to treat Ebola patients. . . .

It should be remembered that the theory behind imposing quarantine is that some asymptomatic individuals may be infectious, and without quarantine they may expose others to the disease. This logic applies well with regard to many of the airborne diseases, such a[s] influenza and SARS. It is not the case with Ebola, because an asymptomatic individual is not infectious and neither is a patient in the earliest stage of infection when the most noteworthy symptom is the onset of fever. Individuals become infectious only when the viral load in their bodily fluids is extremely high, which occurs when the individuals become seriously ill and they release significant amounts of vomit, diarrhea, and blood. . . . Of crucial importance, fever *precedes* the infectious stage; it does not indicate the infectious stage. . . .

Notwithstanding any realistic risk of contagion from asymptomatic health care workers, some health care workers with possible Ebola exposure failed to limit their public contact during the twenty-one day period after their last known exposure. . . . Although there was no risk of transmission while they were asymptomatic or until days later if they became symptomatic, these brave and selfless health care workers still had an obligation to help prevent the spread of panic. . . . It is an interesting question of when scientifically unnecessary measures are appropriate to quell irrational public fears or when doing so "out of an abundance of caution" makes matters worse. . . .

Deciding whether quarantine is necessary and, if so, determining the appropriate length of quarantine, are only the first steps in tailoring quarantine to the specific public health conditions. Additional considerations include the type of quarantine (individual or area-wide), whether quarantine should be voluntary or mandatory, how many individuals should be quarantined, the criteria for inclusion or exclusion, and the appropriate locations for quarantine. The overall goal should be to adopt the least burdensome means necessary to accomplish the desired public health objective. Using narrowly tailored public health measures also leads to greater public support for the entire range of public health interventions needed in an epidemic. . . .

Humane Supportive Services

Public health officials need to be able to monitor the individuals in quarantine, a communication system must be established to connect the individuals in quarantine with health care providers, and a transportation plan is needed to take individuals who become ill to a hospital or other health care facility as soon as possible. In addition, clothing, bedding, and other personal items used by a patient placed in isolation may need to be removed and safely disposed of to prevent the infection of others, including individuals placed in quarantine at the same location. . . .

The financial effect on individuals in quarantine is also an important concern. During the SARS epidemic all of the affected countries realized that they needed to enact legislation prohibiting discrimination in employment against individuals in quarantine (and guaranteeing their reemployment) and to supply quarantined individuals with some form of income replacement. Without such protections many low-income and self-employed persons who were asymptomatic would feel compelled to violate quarantine and go to work. Unfortunately, few, if any, comparable legal protections currently exist in the United States, and it is questionable how rapidly such legislation could or would be enacted at either the federal or state level. . . .

Public Justification

The decision-making process used by public health officials and government leaders should be open, at least to the extent that the rationale for official action is clearly explained to the public. Decision makers should marshal the best available scientific evidence and expert opinion on the need for quarantine and then disclose the information in a timely and understandable manner. Good communication with the public may improve voluntary compliance and obviate the need for enforcement. . . .

[P]ublic justification involves the important relations among the government, the media (broadly defined), and the public. The 2009 H1N1 influenza epidemic provides an instructive case study, as it featured the convergence of a new presidential administration in Washington, a weak American economy, and a highly skeptical public whose fears and suspicions were stoked by cable news, social media, and a 24/7 news cycle. When the H1N1 influenza strain emerged in 2009, public health officials were quite concerned about a possible 1918–1919-type pandemic, inasmuch as the broad H1N1 influenza strain was the same. Yet, there were few hard facts or confident predictions available. In attempting to be candid and transparent, however, government admissions of uncertainty seemed to undermine public confidence rather than enhance it. . . . Political party affiliation was closely associated not only with trust in the government's pronouncements, but with the likelihood of taking the H1N1 vaccine. . . . In the future, public health officials should not only make the scientific case for public health action, but they must confront the reality that politicization of public health may undermine public support for any proposed action. . . .

CONCLUSION

Quarantine . . . raises in the starkest possible terms the fundamental ethical conflict of public health—the clash between individual and population rights and interests. In the United States, personal liberty is greatly valued and protected by law, although the Supreme Court has long held that liberty may be restricted through "reasonable

regulation" to protect the public health. Consequently, it will be a significant challenge for public officials and public health experts to convince large numbers of asymptomatic people of the necessity and moral imperative of their temporarily relinquishing a degree of their liberty for the possible benefit of the public's health.

. . .

Some argued that the CDC should have taken a more active leadership role in directing state and local responses to the threat of Ebola, but that may have been inconsistent with our federal system of government. As Rothstein describes, the CDC's quarantine authority is limited. The Public Health Service Act authorizes the CDC to detain, medically examine, and quarantine individuals traveling into the United States or between states if they are suspected of carrying communicable diseases specified in executive orders issued by the president. In early 2017, the Obama administration published revised regulations, excerpted below, governing CDC's exercise of this statutory authority.

CONTROL OF COMMUNICABLE DISEASES

U.S. Centers for Disease Control and Prevention

42 CFR § 70.1 GENERAL DEFINITIONS

As used in this part, terms shall have the following meaning: . . .

Apprehension means the temporary taking into custody of an individual or group for purposes of determining whether Federal quarantine, isolation, or conditional release is warranted. . . .

Communicable stage means the stage during which an infectious agent may be transmitted either directly or indirectly from an infected individual to another individual.

Conditional release means the temporary supervision by a public health official (or designee) of an individual or group, who may have been exposed to a quarantinable communicable disease to determine the risk of disease spread and includes public health supervision through in-person visits, telephone, or through electronic or Internet-based monitoring. . . .

Isolation means the separation of an individual or group reasonably believed to be infected with a quarantinable communicable disease from those who are healthy to prevent the spread of the quarantinable communicable disease. . . .

Precommunicable stage means the stage beginning upon an individual's earliest opportunity for exposure to an infectious agent and ending upon the individual entering or reentering the communicable stage of the disease or, if the individual does not enter the communicable stage, the latest date at which the individual could reasonably be expected to have the potential to enter or reenter the communicable stage.

Public health emergency as used in this part means:

(1) Any communicable disease event as determined by the Director with either documented or significant potential for regional, national, or international communicable disease spread or that is highly likely to cause death or serious illness if not properly controlled; or
(2) Any communicable disease event described in a declaration by the Secretary pursuant to 319(a) of the Public Health Service Act; or
(3) Any communicable disease event the occurrence of which is notified to the World Health Organization, in accordance with Articles 6 and 7 of the International Health Regulations, as one that may constitute a Public Health Emergency of International Concern; or
(4) Any communicable disease event the occurrence of which is determined by the Director-General of the World Health Organization, in accordance with Article 12 of the International Health Regulations, to constitute a Public Health Emergency of International Concern; or
(5) Any communicable disease event for which the Director-General of the World Health Organization, in accordance with Articles 15 or 16 of the International Health Regulations, has issued temporary or standing recommendations for purposes of preventing or promptly detecting the occurrence or reoccurrence of the communicable disease.

Qualifying stage is statutorily defined (42 U.S.C. 264(d)(2)) to mean:

(1) The communicable stage of a quarantinable communicable disease; or
(2) The precommunicable stage of the quarantinable communicable disease, but only if the quarantinable communicable disease would be likely to cause a public health emergency if transmitted to other individuals.

Quarantine means the separation of an individual or group reasonably believed to have been exposed to a quarantinable communicable disease, but who are not yet ill, from others who have not been so exposed, to prevent the possible spread of the quarantinable communicable disease.

Quarantinable communicable disease means any of the communicable diseases listed in an Executive Order, as provided under section 361 of the Public Health Service Act. . . .

Reasonably believed to be infected, as applied to an individual, means specific articulable facts upon which a public health officer could reasonably draw the inference that an individual has been exposed, either directly or indirectly, to the infectious agent that causes a quarantinable communicable disease, as through contact with an infected person or an infected person's bodily fluids, a contaminated environment, or through an intermediate host or vector, and that as a consequence of the exposure, the individual is or may be harboring in the body the infectious agent of that quarantinable communicable disease.

42 C.F.R. § 70.2 MEASURES IN THE EVENT OF INADEQUATE LOCAL CONTROL

Whenever the Director of the Centers for Disease Control and Prevention determines that the measures taken by health authorities of any State or possession (including

political subdivisions thereof) are insufficient to prevent the spread of any of the communicable diseases from such State or possession to any other State or possession, he/she may take such measures to prevent such spread of the diseases as he/she deems reasonably necessary, including inspection, fumigation, disinfection, sanitation, pest extermination, and destruction of animals or articles believed to be sources of infection.

42 C.F.R. § 70.5 REQUIREMENTS RELATING TO TRAVELERS UNDER A FEDERAL ORDER OF ISOLATION, QUARANTINE, OR CONDITIONAL RELEASE

(a) The following provisions are applicable to any individual under a Federal order of isolation, quarantine, or conditional release with regard to a quarantinable communicable disease: . . .

(1) Except as specified under the terms of a Federal conditional release order, no such individual shall travel in interstate traffic or from one State or U.S. territory to another without a written travel permit issued by the Director. . . .

42 C.F.R. § 70.6 APPREHENSION AND DETENTION OF PERSONS WITH QUARANTINABLE COMMUNICABLE DISEASES

(a) The Director may authorize the apprehension, medical examination, quarantine, isolation, or conditional release of any individual for the purpose of preventing the introduction, transmission, and spread of quarantinable communicable diseases, as specified by Executive Order, based upon a finding that:

(1) The individual is reasonably believed to be infected with a quarantinable communicable disease in a qualifying stage and is moving or about to move from a State into another State; or

(2) The individual is reasonably believed to be infected with a quarantinable communicable disease in a qualifying stage and constitutes a probable source of infection to other individuals who may be moving from a State into another State.

(b) The Director will arrange for adequate food and water, appropriate accommodation, appropriate medical treatment, and means of necessary communication for individuals who are apprehended or held in quarantine or isolation under this part.

42 C.F.R. § 70.12 MEDICAL EXAMINATIONS

(a) The Director may require an individual to undergo a medical examination as part of a Federal order for quarantine, isolation, or conditional release for a quarantinable communicable disease. . . .

(c) As part of the medical examination, the Director may require an individual to provide information and undergo such testing as may be reasonably necessary to diagnose or confirm the presence or extent of infection with a quarantinable communicable disease.

(d) Individuals reasonably believed to be infected based on the results of a medical examination may be isolated, or if such results are inconclusive or unavailable, individuals may be quarantined or conditionally released in accordance with this part.

42 C.F.R. § 70.13 PAYMENT FOR CARE AND TREATMENT

(a) The Director may authorize payment for the care and treatment of individuals subject to medical examination, quarantine, isolation, and conditional release. . . .

(b) Payment for care and treatment shall be in the CDC's sole discretion and subject to the availability of appropriations. . . .

42 C.F.R. § 70.14 REQUIREMENTS RELATING TO THE ISSUANCE OF A FEDERAL ORDER FOR QUARANTINE, ISOLATION, OR CONDITIONAL RELEASE

(a) A Federal order authorizing quarantine, isolation, or conditional release shall be in writing, signed by the Director, and contain the following information:

(1) The identity of the individual or group subject to the order;

(2) The location of the quarantine or isolation or, in the case of conditional release, the entity to who and means by which the individual shall report for public health supervision;

(3) An explanation of the factual basis underlying the Director's reasonable belief that the individual is in the qualifying stage of a quarantinable communicable disease;

(4) An explanation of the factual basis underlying the Director's reasonable belief that the individual is moving or about to move from one State into another or constitutes a probable source of infection to others who may be moving from one State into another;

(5) An explanation that the Federal order will be reassessed no later than 72 hours after it has been served and an explanation of the medical review of the Federal order pursuant to this part, including the right to request a medical review, present witnesses and testimony at the medical review, and to be represented at the medical review by either an advocate (e.g., an attorney, family member, or physician) at the individual's own expense, or, if indigent, to have representatives appointed at the government's expense;

(6) An explanation of the criminal penalties for violating a Federal order of quarantine, isolation, or conditional release; and

(7) An explanation that if a medical examination is required as part of the Federal order that the examination will be conducted by an authorized and licensed health worker, and with prior informed consent.

(b) A Federal order authorizing quarantine, isolation, or conditional release shall be served on the individual no later than 72 hours after the individual has been apprehended, except that the Federal order may be published or posted in a conspicuous location if the Federal order is applicable to a group of individuals and individual service would be impracticable.

(c) The Director shall arrange for translation or interpretation services of the Federal order as needed.

(d) Nothing in this section shall affect the constitutional or statutory rights of individuals to obtain judicial review of their Federal detention.

42 C.F.R. § 70.18 PENALTIES

(a) Persons in violation of this part are subject to a fine of no more than $100,000 if the violation does not result in a death or one year in jail, or both, or a fine of no more than $250,000 if the violation results in a death or one year in jail, or both, or as otherwise provided by law.

(b) Violations by organizations are subject to a fine of no more than $200,000 per event if the violation does not result in a death or $500,000 per event if the violation results in a death or as otherwise provided by law.

. . .

The regulations excerpted above govern quarantine, isolation, and conditional release to prevent the interstate spread of communicable diseases. Virtually identical provisions set forth at 42 C.F.R. § 71 apply to people arriving in the United States from foreign countries. Measures to control the international spread of disease are also subject to the requirements of the International Health Regulations, which the United States has accepted with the reservation that it will implement them in line with U.S. principles of federalism.

Although the revised CDC quarantine regulations stress cooperation with state and local authorities, federal agents are authorized to intervene directly in cases that threaten international or interstate spread of disease. The discretion the rules afford to federal agents to apprehend individuals reasonably believed to be infected with a quarantinable disease has aroused new concerns amid reports of discriminatory and abusive conduct by customs and border patrol agents even after they were ordered to halt enforcement of President Trump's sweeping ban on immigration from several predominantly Muslim countries.

As Rothstein notes, efforts to prevent the spread of Ebola virus outside West Africa focused on health care workers—many of them volunteers—who returned to their home countries after caring for Ebola-infected patients. Shortly after Kaci Hickox landed at Newark International Airport upon her return from working as a nurse in Sierra Leone, she was placed in quarantine. The previous day, news had broken that Craig Spencer, a physician who had returned to New York City from Guinea, was infected with Ebola and had become symptomatic shortly after riding public transportation and visiting with friends at a bowling alley. The threat of Ebola dominated news coverage at the time, and frightened constituents pressured government officials—some of whom were facing reelection within a matter of days—to take a more aggressive stance against returning health care workers and other travelers from West Africa. Two

days prior to Hickox's arrival, New Jersey governor Chris Christie announced a state Ebola preparedness plan that he described as going further than federal guidelines. Hickox was initially reported to have exhibited signs of fever upon landing in Newark. She was taken to an isolation tent in the parking lot of a hospital, where she used her phone to communicate to the world her displeasure with how she was being treated.

After it was confirmed that Hickox did not have a fever and was not symptomatic, New Jersey officials allowed her to travel home to Maine. There, Governor Paul LePage, who faced reelection in a matter of days, ordered state troopers to guard her home and follow her movements. The state health officer filed a petition in state court requesting that Hickox be subjected to various restrictions on movement amounting to a mandatory home quarantine with some allowance for activities outside the home that involved maintaining a distance of at least three feet from others. A temporary order was granted, but then modified by the court in the order reproduced below.

*MAYHEW V. HICKOX**

Maine District Court
Order Pending Hearing decided October 31, 2014

The State has requested that the court issue an order restricting Respondent's activities pending the final hearing on its Verified Petition for a Public Health Order [in which the State is requesting that the Respondent be ordered to undergo Direct Active Monitoring, coordination of any travel with public health authorities to ensure uninterrupted Direct Active Monitoring; controlled movement to include exclusion from long-distance commercial conveyances and local public conveyances; exclusion from public places and congregate gatherings; exclusion from workplaces (except to receive necessary health care); and exclusion from other public activities with the exception of non-congregate activities while maintaining a three-foot distance from others (e.g., walking or jogging in a park)]. This decision has critical implications for Respondent's freedom, as guaranteed by the U.S. and Maine Constitutions, as well as the public's right to be protected from the potential severe harm posed by transmission of this devastating disease. . . .

Maine Law authorizes a court to "make such orders as it deems *necessary to protect other individuals from the dangers of infection*" pending a hearing on a petition for a public health order. Me. Stat. tit. 22, § 811(3) (2014) (emphasis added). At this point in time, the only information that the Court has before it regarding the dangers of infection posed by Respondent, who has potentially but not definitely been exposed to the Ebola virus, derives from the Affidavit of Shiela Pinette, D.O., Director of the Maine

* No. CV-2014-36 (D. Me. Oct. 31, 2014) (order pending hearing).

Center for Disease Control and Prevention, together with the attachments from the U.S. Centers for Disease Control. In her affidavit, Dr. Pinette averred, *inter alia*:

> Ebola Virus Disease is spread through direct contact with the blood, sweat, vomit, feces and other body fluids *of a symptomatic person.* It can also be spread through exposure to needles or other objects contaminated with the virus. . . . *Individuals infected with Ebola Virus Disease who are not showing symptoms are not yet infectious.* Early symptoms of Ebola are non-specific and common to many other illnesses. Symptoms usually include: fever, headache, joint and muscle aches, weakness, diarrhea, vomiting, stomach pain, and lack of appetite. *Ebola may be present in an individual who does not exhibit any of these symptoms, because they are not yet infectious.*
>
> The incubation period for the virus, before it can be determined that a person does not have Ebola virus, is 21 days. A person who is infected with Ebola virus can start to show symptoms of the disease (become infectious) at any point during the incubation period. A person can test negative for Ebola virus in the early part of the incubation period and later become infectious and test positive. The Respondent remains at risk of being infected with Ebola, until the 21-day time period has [p]assed. The most common time of developing symptoms is during the second week after last exposure. Respondent entered that second week starting October 28, 2014. The surest way to minimize the public health threat is direct active monitoring and additional restrictions on movement and exposure to other persons or the public until a potentially exposed person has passed the incubation period. For Respondent that period expires November 10, 2014.
>
> Respondent is asymptomatic (no fever or other symptoms consistent with Ebola), as of the last check pursuant to her direct active monitoring this morning. Therefore the guidance issued by U.S. CDC states that she is subject to Direct Active Monitoring. Health care workers in the "some risk" category require direct active monitoring for the 21-day incubation period.
>
> Direct active monitoring means the [Maine CDC] provides direct observation at least once per day to review symptoms and monitor temperature with a second follow-up daily by phone. The purpose of direct active monitoring is to ensure that if individuals with epidemiologic risk factors become ill, they are identified as soon as possible after symptoms onset so they can be rapidly isolated and evaluated. Once a person is symptomatic they become contagious to others, and their infectiousness increases very quickly. . . .

Based on the information in this affidavit with attachments and arguments of counsel, the Court finds by clear and convincing evidence that an order is necessary. . . . [T]he court finds that ordering Respondent to comply with Direct Active Monitoring and to engage in the steps outlined below is "necessary to protect other individuals from the dangers of infection." The Court is aware that Respondent has been cooperating with Direct Active Monitoring and intends to continue with her cooperation. While this Court has no reason to doubt Respondent's good intentions, it is nevertheless necessary to ensure public safety that she continue to comply with Direct Active Monitoring until a hearing can be held on the State's Petition. The State has not met its burden at this time to prove by clear and convincing evidence that limiting Respondent's move-

ments to the degree requested [in the Verified Petition] is "necessary to protect other individuals from the dangers of infection," however. According to the information presented to the court, Respondent currently does not show any symptoms of Ebola and is therefore *not* infectious. Should these circumstances change at any time before the hearing on the petition—a situation that will most quickly come to light if Direct Active Monitoring is maintained—then it will become necessary to isolate Respondent from others to prevent the potential spread of this devastating disease.

For the foregoing reasons, the Court hereby orders that, pending the hearing on the petition, Respondent shall: (1) Participate in and cooperate with "Direct Active Monitoring" as that term is defined by the United States Centers for Disease Control in its October 29, 2014 *Interim U.S. Guidance for Monitoring and Movement of Persons with Potential Ebola Virus Exposure*. (2) Coordinate her travel with public health authorities to ensure uninterrupted Direct Active Monitoring; and (3) *Immediately* notify public health authorities and follow their directions if *any* symptom appears. . . .

The Court pauses to make a few critical observations. First, we would not be here today unless Respondent generously, kindly and with compassion lent her skills to aid, comfort, and care for individuals stricken with a terrible disease. We need to remember as we go through this matter that we owe her and all professionals who give of themselves in this way a debt of gratitude.

Having said that, Respondent should understand that the court is fully aware of the misconceptions, misinformation, bad science and bad information being spread from shore to shore in our country with respect to Ebola. The Court is fully aware that people are acting out of fear and that this fear is not entirely rational. However, whether that fear is rational or not, it is present and it is real. Respondent's actions at this point, as a health care professional, need to demonstrate her full understanding of human nature and the real fear that exists. She should guide herself accordingly.

. . .

Both Rothstein and *Mayhew v. Hickox* suggest that private individuals suspected of being exposed to a deadly infectious disease have an obligation to allay public fears, even though those fears may be irrational or based on misinformation. Simultaneously, public health officials have a responsibility to reassure the public by providing accurate information about risks and the government's response. Are public risk communication campaigns sufficient, however, given the extent to which politics has divided our society? As Rothstein notes, the public's perception of risk, trust in scientific expertise, and compliance with government recommendations are associated with political views and affiliations—as was the case during the H9N1 influenza epidemic, which struck shortly after a transition of power from the Bush administration to the Obama administration, and the Ebola outbreak, which coincided with the 2014 elections.

Many public health laws and policies depend on difficult value judgments that are highly susceptible to the improper influence of social and

cultural biases. Emergency preparedness and response efforts heighten underlying tensions between public and personal responsibility and between collective needs and individual interests. Government authority to prevent and respond to public health emergencies may enjoy broad public support in theory, but in practice emergency response actions may generate hotly contested disputes that must be resolved under conditions that are far from conducive to thoughtful deliberation.

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PHOTO 12.1. A woman tests her blood glucose level. Frequent self-monitoring by patients with diabetes is a crucial strategy for preventing potentially devastating complications, including vision loss and amputations. Nearly 30 million Americans have type-two diabetes. More than 85 million additional Americans are pre-diabetic. Without dietary changes and increased physical activity, 15% to 30% of them will develop diabetes within five years. Photograph by Amanda Mills for CDC.

CHAPTER TWELVE

Noncommunicable Disease Prevention

In the mid-twentieth century, when noncommunicable diseases (NCDs) and injuries eclipsed infectious diseases as the leading drivers of premature mortality and morbidity, public health law receded into the shadows. The behavioral model of public health (see chapter 1) that emerged in response to studies linking NCDs (e.g., lung cancer, skin cancer, coronary heart disease, and diabetes) to behaviors (e.g., smoking, tanning, unhealthy eating, and physical inactivity) relied principally on education and physician-patient counseling. The law had little relevance to these interventions. At the turn of the twenty-first century, however, law reemerged as an invaluable tool to promote the public's health in response to mounting evidence that modifiable environmental, economic, and social factors influence personal behaviors and lifestyles.

This chapter explores the role of direct regulation, tort liability, and taxation and spending strategies to prevent and control NCDs. We begin with the information environment that shapes individual choices about consumption of harmful products (e.g., tobacco, alcohol, meals high in calories and sodium, and sugary drinks) and constraints on government authority derived from the free speech rights of manufacturers and sellers. Next, we turn to regulation of products and the retail environment—an area where federal preemption often limits state and local authority. We then explore government efforts to create built environments conducive to physical activity. We also discuss the social environment, exploring how laws and policies influence social norms about

consumption. Finally, we present a libertarian critique of public health law's expanding focus on NCD prevention and ask whether concerns about a "nanny state" are valid or overstated.

THE INFORMATION ENVIRONMENT AND THE FIRST AMENDMENT

Health officials influence the information environment in three basic ways: (1) government speech can convey messages urging individuals to eat more fruits and vegetables, abstain from tobacco, reduce alcohol consumption, or adopt safer sexual practices, for example; (2) government can restrict advertising and promotion of unhealthy products; and (3) government can compel product manufacturers or retailers to disclose information or warnings about health and safety risks. We will discuss each type of intervention in turn.

The first type of intervention typically involves taxation and spending strategies to support education and marketing to encourage behavior change. When government speaks it faces few constitutional restrictions, as the opinion excerpted below illustrates.

*R. J. REYNOLDS V. SHEWRY**

United States Court of Appeals for the Ninth Circuit
Decided September 28, 2004

. . . The appellants, three tobacco companies, claim that California violated their First Amendment rights by imposing a surtax on cigarettes and then using some of the proceeds of that surtax to pay for advertisements that criticize the tobacco industry. The tobacco companies argue that this is a case of compelled subsidization of speech prohibited by the First Amendment. . . . California counters that the advertisements are government speech entirely immune from First Amendment attack. . . .

In 1988, California voters approved Proposition 99, a statewide ballot initiative also known as the "Tobacco Tax and Health Protection Act of 1988." The Act imposes . . . a 25-cent per-pack surtax on all wholesale cigarette sales in California. . . . Twenty percent of [funds generated by the surtax are allocated] "for appropriation for programs for the prevention and reduction of tobacco use, primarily among children, through school and community health education programs." In order to implement Proposition 99, the California Legislature directed the California Department of Health Services (DHS) . . . to develop a media campaign designed to raise public awareness of the deleterious effects of smoking and to effect a reduction in tobacco use . . . funded . . . exclusively from the proceeds of the surtax.

* 423 F.3d 906.

This case concerns certain advertisements the DHS produced as part of its Tobacco Control Program. According to the tobacco companies, the DHS concluded soon after the establishment of the Tobacco Control Program that a media campaign focused solely on presenting the health risks of tobacco use would be of limited utility in reducing the incidence of smoking in California, because people tend to "tune out" advertising that simply explains the health risks involved with tobacco use. Thus, the DHS concluded that, in order to carry out its mandate to encourage Californians to modify and reduce their use of tobacco, it would be necessary to launch a campaign to "denormalize" smoking, by creating a climate in which smoking would seem less desirable and less socially acceptable.

One method used by the DHS in this campaign has been to portray the tobacco industry itself as deceptive and as an enemy of the public health, or, in the companies' words, to attack not "the desirability of a product but . . . the moral character of [the] industry, accusing it of hypocrisy, cynicism and duplicity." The district court described these advertisements as follows:

> A recent round of television commercials features an actor playing a public relations executive for the fictional cigarette brand "Hampton," detailing for viewers his unseemly methods for getting people to start smoking. The ads end with the tagline, "Do You Smell Smoke?," implicitly referencing both cigarette smoke and a smoke-and-mirrors marketing strategy. Another ad portrays tobacco executives discussing how to replace a customer base that is dying at the rate of 1,100 users a day. Some of the ads end with images of mock warning labels such as: "WARNING: The tobacco industry is not your friend."; or "WARNING: Some people will say anything to sell cigarettes." Several spots suggest that tobacco companies aggressively market to children. In one particularly striking television ad entitled "Rain," children in a schoolyard are shown looking up while cigarettes rain down on them from the sky. A voice-over states "We have to sell cigarettes to your kids. We need half a million new smokers a year just to stay in business. So we advertise near schools, at candy counters. We lower our prices. We have to. It's nothing personal. You understand." At the conclusion, the narrator says, "The tobacco industry: how low will they go to make a profit?"

. . . [E]ach of the challenged advertisements is identified as "Sponsored by the California Department of Health Services." The tobacco companies do not claim that these advertisements contain any affirmatively false statements. . . . The district court explained that "there is substantial evidence, including published medical studies, indicating that the Proposition 99 programs, and the media campaign in particular, have been successful in achieving their goals." . . .

Chief Justice John Marshall famously stated that "the power to tax involves the power to destroy." *McCulloch v. Maryland,* 17 U.S. (4 Wheat.) 316, 431 (1819). According to the tobacco companies, however, this case involves neither an invalid exercise of the government's power to tax nor a claim that they have been destroyed by the government's speech. Rather, the companies claim a constitutional violation in the link between the excise tax and the government speech to which they object. . . .

The tobacco companies rely in large part upon one case: *United States v. United Foods, Inc.*, 533 U.S. 405 (2001). . . . In *United Foods,* the Court considered a federal program [that allowed a Mushroom Council established by the U.S. Department of Agriculture made up of industry-selected representatives] to impose mandatory assessments upon handlers of fresh mushrooms which can be used for projects of mushroom promotion, research, consumer information, and industry information. The Court held that by requiring the [petitioner] mushroom producer to contribute to generic advertisements for mushroom sales to which it objected, the government had put "First Amendment values . . . at serious risk" by "compell[ing] a discrete group of citizens [ ] to pay special subsidies for speech on the side that [the government] favors." *Id.* at 411.

Read broadly, and taken in isolation, this language might plausibly suggest that the tobacco companies have the right to object to the advertisements at issue here because they have paid "special subsidies" for the advertisements in the form of a tax that disproportionately affects them. Yet *United Foods* also makes clear that not every case in which the government mandates support for speech from a particular group necessarily creates a First Amendment violation. Most importantly, the Court specifically declined to address whether the same First Amendment analysis would apply to cases in which the speech produced was "government speech" that derived from the state itself and not the Mushroom Council. *See id.* at 416. . . .

Nothing in *United Foods* suggests that the compelled speech doctrine applies to situations where the government imposes an excise tax on private citizens and then uses the money to speak in the name of the government itself. No court has held otherwise. An otherwise valid tax for an otherwise valid purpose ordinarily must bind even those who object to the government's objective. In *Board of Regents of the University of Wisconsin System v. Southworth,* 529 U.S. 217, 229 (2000), the Court explained that:

> It is inevitable that government will adopt and pursue programs and policies within its constitutional powers but which nevertheless are contrary to the profound beliefs and sincere convictions of some of its citizens. The government, as a general rule, may support valid programs and policies by taxes or other exactions binding on protesting parties. Within this broader principle it seems inevitable that funds raised by the government will be spent for speech and other expression to advocate and defend its own policies.

. . . Paying a tax, even an excise tax, does not create a compelled form of association. When the government acts as a speaker it may espouse views that directly contradict those of taxpayers without interfering with taxpayers' freedom of expression. In a democracy based on majority rule, such a conclusion is inescapable. Government officials are expected as a part of the democratic process to represent and to espouse the views of a majority of their constituents. . . . If every citizen were to have a right to insist that no one paid by public funds express a view with which he disagreed, debate over issues of great concern to the public would be limited to those in the private sector, and the process of government as we know it radically transformed.

• • •

As *Shewry* indicates, the Constitution imposes few constraints on government-sponsored speech, even when it intentionally stigmatizes unhealthy products, the companies that sell them, and the individuals who consume them. Such campaigns do, however, raise ethical concerns, which we discuss later in this chapter.

Of course, public health officials' influence over the information environment is not limited to government-sponsored campaigns. Most people understand that government messages have a paltry effect on public attitudes and behaviors. There are just too many voices in the market for the government to have much influence. The business community speaks with particular force in the marketplace of ideas. Manufacturers of hazardous products spend billions of dollars on advertising and promotion designed to influence consumers to buy their products, often using sophisticated marketing techniques. Public health officials cannot hope to compete with these private purveyors of information through government speech alone. Consequently, regulation of commercial speech is an important public health strategy. Public health experts often advocate for restrictions on commercial advertising and mandates that compel manufacturers and sellers to disclose information and issue warnings about health and safety risks in advertising, on product packaging, and at the point of sale.

Advertising restrictions and disclosure mandates can take the form of direct regulation or indirect regulation through tort liability. Federal regulations, for example, prohibit tobacco companies from sponsoring sports events and mandate disclosure of nutrition facts on packaged food labels. Civil liability rules allow parties to hold manufacturers and retailers liable for misleading claims or failure to disclose pertinent information. For example, the federal government has sued tobacco companies for misleading claims and private parties have filed consumer protection actions against food manufacturers for deceptive labeling of sugar content (see chapter 7). However, government action—whether legislative, administrative, or judicial—must comport with the First Amendment's guarantee of free expression.

The cases excerpted below review the evolution of the commercial speech doctrine from the mid-1970s (when the Court for the first time applied the First Amendment to commercial speech) to today. The constitutional status of advertising restrictions and compelled disclosures remains uncertain, making this a dynamic and consequential area of the law. The Supreme Court continues to adjust its stance on commercial speech, as illustrated by *Sorrel v. IMS,* excerpted in chapter 4. In the

absence of clear guidance from the Supreme Court, the lower courts have taken divergent positions on disclosure mandates.

We begin with First Amendment constraints on advertising regulations. As discussed in chapter 4, restrictions on commercial speech are subject to an *intermediate scrutiny* test that falls somewhere between *rational basis review* (applied to most social and economic regulations) and *strict scrutiny* (applied to regulations that implicate noncommercial expression, infringe upon fundamental rights, or rely on suspect classifications). The intermediate scrutiny test for regulations that restrict commercial speech was developed by the Court in *Central Hudson Gas and Elec. Corp. v. Public Service Comm'n of N.Y.*, 447 U.S. 557, 566 (1980):

> At the outset, we must determine whether the expression is protected by the First Amendment. For commercial speech to come within that provision, it at least must concern lawful activity and not be misleading. Next, we ask whether the asserted governmental interest is substantial. If both inquiries yield positive answers, we must determine whether the regulation directly advances the governmental interest asserted, and whether it is not more extensive than is necessary to serve that interest

In *44 Liquormart, Inc. v. Rhode Island,* the Court applied this analysis to a state law prohibiting advertisements that feature the prices of alcoholic beverages. All nine justices agreed on the result, but no single rationale garnered majority support. Justice Stevens's opinion (on behalf of a plurality of four justices) applied the *Central Hudson* test in a way that was less permissive than in past cases. In particular, Stevens expressly disavowed an earlier case, *Posadas de Puerto Rico Associates v. Tourism Co. of Puerto Rico,* 478 U.S. 328 (1986), in which the Court had taken a more deferential stance toward commercial speech regulation. Notably, Justices Thomas and Scalia wrote separate concurrences rejecting the *Central Hudson* test in favor of the level of review least deferential to legislative judgments: strict scrutiny.

*44 LIQUORMART, INC. V. RHODE ISLAND**

Supreme Court of the United States
Decided May 13, 1996

Justice Stevens delivered the opinion of the Court. . . .

In 1956, the Rhode Island Legislature enacted two separate prohibitions against advertising the retail price of alcoholic beverages. The first applies to vendors licensed in

* 517 U.S. 484.

Rhode Island as well as to out-of-state manufacturers, wholesalers, and shippers. It prohibits them from "advertising in any manner whatsoever" the price of any alcoholic beverage offered for sale in the State; the only exception is for price tags or signs displayed with the merchandise within licensed premises and not visible from the street. The second statute applies to the Rhode Island news media. It contains a categorical prohibition against the publication or broadcast of any advertisements—even those referring to sales in other States—that "make reference to the price of any alcoholic beverages." . . .

Complaints from competitors about an advertisement placed by 44 Liquormart in a Rhode Island newspaper in 1991 generated enforcement proceedings that in turn led to the initiation of this litigation. . . . [After concluding that the advertisement's] implied reference to bargain prices for liquor violated the statutory ban on price advertising, the Rhode Island Liquor Control Administrator assessed a $400 fine. . . .

Advertising has been a part of our culture throughout our history. . . . It was not until the 1970's, however, that this Court held that the First Amendment protected the dissemination of truthful and nonmisleading commercial messages about lawful products and services.

In *Bigelow v. Virginia,* 421 U.S. 809 (1975), we held that it was error to assume that commercial speech was entitled to no First Amendment protection or that it was without value in the marketplace of ideas. The following Term in *Virginia Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748 (1976), we expanded on our holding in *Bigelow* and held that the State's blanket ban on advertising the price of prescription drugs violated the First Amendment. . . .

At the same time, our early cases recognized that the State may regulate some types of commercial advertising more freely than other forms of protected speech. Specifically, we explained that the State may require commercial messages to "appear in such a form, or include such additional information, warnings, and disclaimers, as are necessary to prevent its being deceptive," *Id.* at 772, n. 24, and that it may restrict some forms of aggressive sales practices that have the potential to exert "undue influence" over consumers.

Virginia Bd. of Pharmacy attributed the State's authority to impose these regulations in part to certain "commonsense differences" that exist between commercial messages and other types of protected expression. Our opinion noted that the greater "objectivity" of commercial speech justifies affording the State more freedom to distinguish false commercial advertisements from true ones, and that the greater "hardiness" of commercial speech, inspired as it is by the profit motive, likely diminishes the chilling effect that may attend its regulation. Subsequent cases explained that the State's power to regulate commercial transactions justifies its concomitant power to regulate commercial speech that is "linked inextricably" to those transactions. . . .

In *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of N.Y.*, 447 U.S. 557 (1980), we took stock of our developing commercial speech jurisprudence. In that case, we considered a regulation "completely" banning all promotional advertising by electric utilities. . . . Five Members of the Court recognized that the state interest in the conservation of energy was substantial, and that there was "an immediate connection between advertising and demand for electricity." *Id.*, at 569. Nevertheless, they concluded that the regulation was invalid because respondent commission had failed to make a showing that a more limited speech regulation would not have adequately served the State's interest. . . .

As our review of the case law reveals, . . . [w]hen a State regulates commercial messages to protect consumers from misleading, deceptive, or aggressive sales practices, or requires the disclosure of beneficial consumer information, the purpose of its regulation . . . justifies less than strict review. However, when a State entirely prohibits the dissemination of truthful, nonmisleading commercial messages for reasons unrelated to the preservation of a fair bargaining process, there is far less reason to depart from the rigorous review that the First Amendment generally demands. . . .

The First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good. That teaching applies equally to state attempts to deprive consumers of accurate information about their chosen products. . . . [Thus, w]e must review the price advertising ban with "special care," mindful that speech prohibitions of this type rarely survive constitutional review. . . .

[T]he State bears the burden of showing not merely that its regulation will advance its interest, but also that it will do so "to a material degree." . . . Accordingly, we must determine whether the State has shown that the price advertising ban will significantly reduce alcohol consumption.

We can agree that common sense supports the conclusion that a prohibition against price advertising . . . will tend to mitigate competition and maintain prices at a higher level than would prevail in a completely free market. Despite the absence of proof on the point, we can even agree with the State's contention that it is reasonable to assume that demand, and hence consumption. . ., is somewhat lower whenever a higher, noncompetitive price level prevails. However, without any findings of fact, or indeed any evidentiary support whatsoever, we cannot agree with the assertion that the price advertising ban will significantly advance the State's interest in promoting temperance.

Although the record suggests that the price advertising ban may have some impact on the purchasing patterns of temperate drinkers of modest means, the State has presented no evidence to suggest that its speech prohibition will *significantly* reduce marketwide consumption. . . . Moreover, the evidence suggests that the abusive drinker will probably not be deterred by a marginal price increase, and that the true alcoholic may simply reduce his purchases of other necessities.

In addition, . . . the State has not identified what price level would lead to a significant reduction in alcohol consumption, nor has it identified the amount that it believes prices would decrease without the ban. Thus, the State's own showing reveals that any connection between the ban and a significant change in alcohol consumption would be purely fortuitous.

As is evident, any conclusion that elimination of the ban would significantly increase alcohol consumption would require us to engage in the sort of "speculation or conjecture" that is an unacceptable means of demonstrating that a restriction on commercial speech directly advances the State's asserted interest. Such speculation certainly does not suffice when the State takes aim at accurate commercial information for paternalistic ends.

The State also cannot satisfy the requirement that its restriction on speech be no more extensive than necessary. It is perfectly obvious that alternative forms of regulation that would not involve any restriction on speech would be more likely to achieve the State's goal of promoting temperance. As the State's own expert conceded, higher

prices can be maintained either by direct regulation or by increased taxation. Per capita purchases could be limited as is the case with prescription drugs. Even educational campaigns focused on the problems of excessive, or even moderate, drinking might prove to be more effective. . . .

Relying on the *Central Hudson* analysis set forth in *Posadas de Puerto Rico Associates v. Tourism Co. of P.R.*, 478 U.S. 328 (1986). . . . Rhode Island first argues that, because expert opinions as to the effectiveness of the price advertising ban "go both ways," the Court of Appeals correctly concluded that the ban constituted a "reasonable choice" by the legislature. The State next contends that precedent requires us to give particular deference to that legislative choice because the State could, if it chose, ban the sale of alcoholic beverages outright. Finally, the State argues that deference is appropriate because alcoholic beverages are so-called "vice" products. . . .

[*Posadas*] held that, under the *Central Hudson* test, it was "up to the legislature" to choose to reduce gambling by suppressing in-state casino advertising rather than engaging in educational speech. *Posadas,* 478 U.S. at 344. . . . [O]n reflection, we are now persuaded that *Posadas* erroneously performed the First Amendment analysis. The casino advertising ban was designed to keep truthful, nonmisleading speech from members of the public for fear that they would be more likely to gamble if they received it. As a result, the advertising ban served to shield the State's antigambling policy from the public scrutiny that more direct, nonspeech regulation would draw. Given our longstanding hostility to commercial speech regulation of this type, *Posadas* clearly erred in concluding that it was "up to the legislature" to choose suppression over a less speech-restrictive policy. . . . [W]e conclude that a state legislature does not have the broad discretion to suppress truthful, nonmisleading information for paternalistic purposes that the *Posadas* majority was willing to tolerate. . . .

We also cannot accept the State's second contention, which is premised entirely on the "greater-includes-the-lesser" reasoning endorsed toward the end of the majority's opinion in *Posadas*. There, the majority stated that . . . "because the government could have enacted a wholesale prohibition of [casino gambling] it is permissible for the government to take the less intrusive step of allowing the conduct, but reducing the demand through restrictions on advertising." *Id.* at 346. The majority concluded that it would "surely be a strange constitutional doctrine which would concede to the legislature the authority to totally ban a product or activity, but deny to the legislature the authority to forbid the stimulation of demand for the product or activity through advertising on behalf of those who would profit from such increased demand." *Ibid.* . . . Further consideration persuades us that [this] argument should be rejected [because] it is inconsistent with both logic and well-settled doctrine. . . . Contrary to the assumption made in *Posadas,* we think it quite clear that banning speech may sometimes prove far more intrusive than banning conduct. . . . [T]he First Amendment directs that government may not suppress speech as easily as it may suppress conduct, and that speech restrictions cannot be treated as simply another means that the government may use to achieve its ends. . . .

Finally, we find unpersuasive the State's contention that, under *Posadas*. . ., the price advertising ban should be upheld because it targets commercial speech that pertains to a "vice" activity. . . . Our decision last Term striking down [a federal law prohibiting advertisements including the alcohol content of malt beverages] effectively rejected the very contention respondents now make. See *Rubin v. Coors Brewing Co.*, 514 U.S. at 478, 482, n. 2.

Moreover, the scope of any "vice" exception to the protection afforded by the First Amendment would be difficult, if not impossible, to define. . . . [A] "vice" label that is unaccompanied by a corresponding prohibition against the commercial behavior at issue fails to provide a principled justification for the regulation of commercial speech about that activity.

Because Rhode Island has failed to carry its heavy burden of justifying its complete ban on price advertising, we conclude that [these laws] abridge speech in violation of the First Amendment. . . .

. . .

As Justice Stevens notes, government officials have used a variety of tools to reduce alcohol consumption. Alcohol control prevents injuries and violence, protects families from financial insolvency, and prevents chronic disease. The alcohol industry has avoided federal advertising restrictions beyond standard consumer protection regulation of false or misleading advertisements. Some commentators credit the industry's voluntary compliance with a self-regulatory regime that restricts advertising targeted to under-age drinking. As *44 Liquormart* suggests, alcohol advertising regulations must carefully navigate First Amendment constraints.

In the next case, the Supreme Court considered state regulations targeting tobacco marketing. In a portion of the opinion not reproduced here, the Court determined that the state's cigarette advertising restrictions were preempted by federal law—an issue discussed later in this chapter. But at the time, federal law did not preempt cigar and smokeless tobacco products. The stage was thus set for a major First Amendment ruling on tobacco advertising.

*LORILLARD TOBACCO CO. V. REILLY**

Supreme Court of the United States
Decided June 28, 2001

Justice O'Connor delivered the opinion of the Court. . . .

In January 1999, pursuant to his authority to prevent unfair or deceptive practices in trade, the Massachusetts Attorney General promulgated regulations governing the sale and advertisement of cigarettes, smokeless tobacco, and cigars. . . . The regulations place a variety of restrictions on outdoor advertising, point-of-sale advertising, retail sales transactions, transactions by mail, promotions, sampling of products, and labels for cigars. . . . Before the effective date of the regulations, . . . members of the tobacco industry sued the Attorney General. . . .

[With respect to their First Amendment challenge,] Petitioners urge us to reject the *Central Hudson* analysis and apply strict scrutiny. Admittedly, several Members of the

* 533 U.S. 525.

Court have expressed doubts about the *Central Hudson* analysis and whether it should apply in particular cases. But here . . . we see no need to break new ground. . . .

Under *Central Hudson*'s four-part test for analyzing regulations of commercial speech, the Court must determine (1) whether the expression is protected by the First Amendment, (2) whether the asserted governmental interest is substantial, (3) whether the regulation directly advances the governmental interest asserted, and (4) whether it is not more extensive than is necessary to serve that interest. 447 U.S at 566. Only the last two steps of *Central Hudson*'s four-part analysis are at issue here. The Attorney General has assumed for purposes of summary judgment that petitioners' speech is entitled to First Amendment protection. With respect to the second step, none of the petitioners contests the importance of the State's interest in preventing the use of tobacco products by minors.

The third step of *Central Hudson* . . . requires that the speech restriction directly and materially advance the asserted governmental interest. This burden is not satisfied by mere speculation or conjecture. . . . We do not, however, require that empirical data come . . . accompanied by a surfeit of background information. . . . We have permitted litigants to justify speech restrictions by reference to studies and anecdotes pertaining to different locales altogether, or even, in a case applying strict scrutiny, to justify restrictions based solely on history, consensus, and "simple common sense."

The last step of the *Central Hudson* analysis complements the third step, asking whether the speech restriction is not more extensive than necessary to serve the interests that support it. We have made it clear that "the least restrictive means" is not the standard; instead, the case law requires a reasonable fit between the legislature's ends and the means chosen to accomplish those ends. . . .

The smokeless tobacco and cigar petitioners contend that the Attorney General's regulations do not satisfy *Central Hudson*'s third step. They maintain that although the Attorney General may have identified a problem with underage cigarette smoking, he has not identified an equally severe problem with respect to underage use of smokeless tobacco or cigars. . . . [Additionally, all of the petitioners] contend that the Attorney General cannot prove that advertising has a causal link to tobacco use such that limiting advertising will materially alleviate any problem of underage use of their products.

In previous cases, we have acknowledged the theory that product advertising stimulates demand for products, while suppressed advertising may have the opposite effect. The Attorney General relies in part on evidence gathered by the Food and Drug Administration (FDA) in its attempt to regulate the advertising of cigarettes and smokeless tobacco. The FDA promulgated the advertising regulations after finding that the period prior to adulthood is when an overwhelming majority of Americans first decide to use tobacco products, and that advertising plays a crucial role in that decision. . . . For instance, children smoke fewer brands of cigarettes than adults, and those choices directly track the most heavily advertised brands, unlike adult choices, which are more dispersed and related to pricing. Another study revealed that 72% of 6 year olds and 52% of children ages 3 to 6 recognized "Joe Camel," the cartoon anthropomorphic symbol of R.J. Reynolds' Camel brand cigarettes. After the introduction of Joe Camel, Camel cigarettes' share of the youth market rose from 4% to 13%. The FDA also identified trends in tobacco consumption among certain populations, such as young women, that correlated to the introduction and marketing of products geared toward that population.

The FDA also made specific findings with respect to . . . "the recent and very large increase in the use of smokeless tobacco products by young people and the addictive nature of these products. . . ." Researchers tracked a dramatic shift in patterns of smokeless tobacco use from older to younger users. . . . In particular, the smokeless tobacco industry boosted sales tenfold in the 1970s and 1980s by targeting young males. . . .

More recently . . . data on youth cigar use has emerged. . . . [T]he rate of cigar use by minors is increasing and, . . . in some States, the cigar use rates are higher than the smokeless tobacco use rates for minors. . . . After Congress . . . banned cigarette advertising in electronic media, television advertising of small cigars "increased dramatically in 1972 and 1973," "filled the void left by cigarette advertisers," and "sales . . . soared." . . . In the 1990s, cigar advertising campaigns triggered [another] boost in sales. . . .

On this record. . ., we are unable to conclude that the Attorney General's decision to regulate advertising of smokeless tobacco and cigars in an effort to combat the use of tobacco products by minors was based on mere speculation and conjecture.

Whatever the strength of the Attorney General's evidence to justify the outdoor advertising regulations, however, we conclude that the regulations do not satisfy the fourth step of the *Central Hudson* analysis. The final step of the *Central Hudson* analysis requires . . . a reasonable fit between the means and ends of the regulatory scheme. . . . The broad sweep of the regulations indicates that the Attorney General did not carefully calculate the costs and benefits associated with the burden on speech imposed by the regulations.

The outdoor advertising regulations prohibit any smokeless tobacco or cigar advertising within 1,000 feet of schools or playgrounds. In the District Court, petitioners maintained that this prohibition would prevent advertising in 87% to 91% of Boston, Worchester, and Springfield, Massachusetts. The 87% to 91% figure appears to include not only the effect of the regulations, but also the limitations imposed by other generally applicable zoning restrictions [that prohibit all outdoor advertising]. . . .

In some geographical areas, these regulations would constitute nearly a complete ban on the communication of truthful information about smokeless tobacco and cigars to adult consumers. . . . The Attorney General apparently selected the 1,000-foot distance based on the FDA's decision to impose an identical 1,000-foot restriction when it attempted to regulate cigarette and smokeless tobacco advertising. But the FDA's 1,000-foot regulation was not an adequate basis for the Attorney General to tailor the Massachusetts regulations. . . . The uniformly broad sweep of the geographical limitation demonstrates a lack of tailoring. In addition, the range of communications restricted seems unduly broad. . . . To the extent that studies have identified particular advertising and promotion practices that appeal to youth, tailoring would involve targeting those practices while permitting others. . . .

Massachusetts has also restricted indoor, point-of-sale advertising for smokeless tobacco and cigars. Advertising cannot be "placed lower than five feet from the floor of any retail establishment which is located within a one thousand foot radius of" any school or playground. . . . We conclude that the point-of-sale advertising regulations fail both the third and fourth steps of the Central Hudson analysis. . . . The 5 foot rule does not seem to advance [the goal of reducing youth exposure to advertising]. Not all children are less than 5 feet tall, and those who are certainly have the ability to look up and take in their surroundings. . . .

[Additional regulations of sales practices promulgated by the Attorney General] bar the use of self-service displays and require that tobacco products be placed out of the reach of all consumers in a location accessible only to salespersons. . . . [The District Court concluded that these restrictions implicate no cognizable speech interest. . . . The Court of Appeals recognized that self-service displays "often do have some communicative commercial function," but noted that the restriction in the regulations "is not on speech, but rather on the physical location of actual tobacco products." . . . Assuming that petitioners have a cognizable speech interest in a particular means of displaying their products, these regulations withstand First Amendment scrutiny.

Massachusetts' sales practices provisions regulate conduct that may have a communicative component, but Massachusetts seeks to regulate the placement of tobacco products for reasons unrelated to the communication of ideas. [According to *United States v. O'Brien,* 391 U.S. 367 (1968), non-content-based government regulation of communicative conduct is valid if (1) it furthers an important government interest, (2) it is unrelated to the suppression of free expression, and (3) the incidental restriction is no greater than essential to the furtherance of that interest.] We conclude that the State has demonstrated a substantial interest in preventing access to tobacco products by minors and has adopted an appropriately narrow means of advancing that interest.

Unattended displays of tobacco products present an opportunity for access without the proper age verification required by law. Thus, the State prohibits self-service and other displays that would allow an individual to obtain tobacco products without direct contact with a salesperson. It is clear that the regulations leave open ample channels of communication. . . .

Justice Thomas, concurring in part and concurring in the judgment.

[Massachusetts] seeks to suppress speech about tobacco because it objects to the content of that speech. We have consistently applied strict scrutiny to such content-based regulations of speech. . . .

Even if Massachusetts has a valid interest in regulating speech directed at children . . . it may not pursue that interest at the expense of the free speech rights of adults. . . . Massachusetts asserts a compelling interest in reducing tobacco use among minors. Applied to adults, an interest in manipulating market choices by keeping people ignorant would not be legitimate, let alone compelling. . . .

[I]t seems appropriate to point out that to uphold the Massachusetts tobacco regulations would be to accept a line of reasoning that would permit restrictions on advertising for a host of other products. . . . Respondents say that tobacco companies are covertly targeting children in their advertising. Fast food companies do so openly. . . . Moreover, there is considerable evidence that they have been successful in changing children's eating behavior. . . . To take another example, . . . [a]lthough every State prohibits the sale of alcohol to those under age 21, much alcohol advertising is viewed by children. Not surprisingly, there is considerable evidence that exposure to alcohol advertising is associated with underage drinking. . . .

Respondents have identified no principle of law or logic that would preclude the imposition of restrictions on fast food and alcohol advertising similar to those they seek to impose on tobacco advertising. In effect, they seek a "vice" exception to the First Amendment. No such exception exists.

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In his concurrence, Justice Thomas raised the specter of restrictions on food and beverage advertising to suggest that allowing tobacco restrictions would put the country on a slippery slope toward greater government control. Congress soundly rejected proposed Federal Trade Commission (FTC) regulations limiting advertisements targeting children for sugary foods and drinks in the late 1970s. Congress's harsh backlash against the FTC reverberated for decades in the agency's reluctance to take an aggressive stance toward advertising of harmful but lawful consumer products, even during relatively progressive administrations.

The federal government has largely eschewed advertising restrictions for products other than tobacco. Instead, it has relied on mandated disclosures of health and safety information. Federal law governs disclosures on packaged food and beverage products, such as the Nutrition Facts panels discussed in chapter 6. State and local governments have pioneered disclosure mandates for restaurants and other retailers. In the case that follows, the federal district court for the Southern District of New York discusses the standard of review applied to mandates to disclose factual and noncontroversial information under the Supreme Court's opinion in *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985). On appeal, the Second Circuit agreed with the district court's decision upholding New York City's mandate that chain restaurants post calorie counts on their menus. Because the lower court's opinion offers a more detailed assessment of the evidence presented by the City under the *Zauderer* standard, we have chosen to excerpt it, rather than the appellate court's opinion.

*NEW YORK STATE RESTAURANT ASSOCIATION V. NEW YORK CITY BOARD OF HEALTH**

United States District Court for the Southern District of New York
Decided April 16, 2008

. . . Food served in restaurants plays an increasingly large role in an individual's diet. It is estimated that one-third of daily caloric intake for all Americans comes from foods purchased outside the home. The parties . . . appear to agree that providing nutritional information in restaurants is likely to assist customers to make healthful food choices. Indeed, a number of fast food restaurants already provide a complete nutritional breakdown of their menu items in brochures, on posters, or online. The City has conducted a survey, however, indicating that few customers actually see the nutrient information in

* No. 08 Civ. 1000, 2008 WL 1752455, upheld 556 F.3d 114 (2d. Cir. 2009).

fast food restaurants such as McDonald's, Dunkin' Donuts and Burger King that presently disclose such information. To address this perceived deficiency [the New York City Board of Health adopted Regulation 81.50, which] requires covered restaurants to post caloric information on menus and menu boards in a font and format comparable to that used to display the name or price of the menu items. . . . Regulation 81.50 is mandatory for all chain restaurants of a certain size whether or not they presently disclose nutritional information on a voluntary basis. . . .

[The New York State Restaurant Association (NYSRA)] argues that Regulation 81.50 violates the First Amendment rights of its members to be free from compelled speech. The parties concede that Regulation 81.50 implicates only commercial speech, which is subject to less stringent constitutional requirements' than other forms of speech. . . . Regulation 81.50 only requires disclosure of calorie information in connection with a proposed commercial transaction—the sale of a restaurant meal. Thus, the category of speech affected by Regulation 81.50 falls squarely within the traditional definition of commercial speech. . . .

[*Zauderer v. Office of Disciplinary Counsel,* 471 U.S. 626 (1985) supplies] the proper standard of review in this case. Regulation 81.50 compels only the disclosure of "purely factual and uncontroversial" commercial information—the calorie content of restaurant menu items. Furthermore, . . . Regulation 81.50 attempt[s] to address a state policy interest by making information available to consumers, consistent with the First Amendment objective, with respect to commercial speech, of providing consumers with complete and accurate commercial information. Therefore, Regulation 81.50 passes constitutional muster as long as there is a "rational connection" between the disclosure requirement and the City's purpose in imposing it.

NYSRA argues that *Zauderer* [is] inapplicable, and that Regulation 81.50 should be evaluated using the analysis developed for "compelled speech." It is well established that the First Amendment generally does not allow the government to force a speaker to utter a message that is not its own. . . . NYSRA claims that Regulation 81.50 compels its members to promote the government's messages "that patrons must consider the caloric content of food when ordering in a restaurant, and that calories are the only nutritional criterion that patrons need to consider." . . .

Regulation 81.50 does not force any NYSRA member to take a position in any ongoing debate. It does not require any statement, express or implied, regarding the relative nutritional importance of calories or whether a food purchaser ought to consider this information, nor does it prevent any NYSRA member from contesting the City's views on these issues. The City is simply requiring restaurants to report "factual and uncontroversial" information—the number of calories in its products. Of course, it would be possible to recast any disclosure requirement as a compelled "message" in support of the policy views that motivated the enactment of that requirement. However, as discussed above, the mandatory disclosure of "factual and uncontroversial" information is not the same, for First Amendment purposes, as the compelled endorsement of a viewpoint. . . .

NYSRA further argues that [Regulation 81.50] should be analyzed under the four-part test set out in *Central Hudson,* a standard considerably more demanding than the "reasonable relationship" standard. . . . NYSRA seeks to justify increased scrutiny based on the "increasing recognition that commercial speech is of vital importance to First Amendment values." . . . The Second Circuit [has] made clear that *Central Hudson*

is not applied to factual commercial disclosure requirements[, except in] cases in which a state disclosure requirement is supported by no interest other than the gratification of "consumer curiosity."

The state's interest in preventing consumer "confusion" and "deception" is not limited to an interest in correcting affirmatively misleading statements and may include an interest in remedying consumers' ignorance or misinformation regarding the products they purchase. . . . The City cites evidence indicating that consumers tend to underestimate the calorie content of restaurant meals, sometimes significantly. . . .

NYSRA [argues] that the regulation does not directly advance the asserted government interest of reducing obesity, claiming that more research is needed on the relationship between calorie information and consumer behavior and that there is no evidence that Regulation 81.50 will be effective in lowering obesity rates.

The City submitted evidence indicating that weight gain results when calorie intake exceeds calorie expenditure, that the recent rise in obesity is in some part attributable to excess calorie intake, that even modest changes in calorie intake can affect weight, that record-keeping and self-monitoring of food and calorie intake are important components of weight-management programs, and that people tend to underestimate the calorie content of restaurant foods. The City also cites evidence that many consumers report looking at calorie information on packaged foods and changing their purchasing habits based on this information. The City further points out that, after the introduction of mandatory nutrition labeling on packaged foods, food manufacturers began to offer reformulated and "nutritionally improved" products—suggesting that consumer demand for such products is promoted by increased consumer awareness of the nutritional content of available food options. . . .

One cannot conclude with scientific certainty from the available evidence that a regulation of this type will ultimately be successful in combating obesity. But . . . conclusive proof is not required to establish a reasonable relationship between Regulation 81.50 and the City's interest in reducing obesity. Based on the evidence presented by the City, as well as common sense, it seems reasonable to expect that some consumers will use the [nutrition] information . . . to select lower calorie meals when eating at covered restaurants and that these choices will lead to a lower incidence of obesity. . . .

For the reasons stated herein, NYSRA has failed to show a likelihood of success on its . . . First Amendment claims. NYSRA's motion for a preliminary injunction is therefore denied.

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As *New York Restaurant Ass'n* indicates, *Zauderer*'s rational basis test is far more deferential to legislative judgments than the *Central Hudson* test. Rational basis review rarely invalidates government action. In contrast, regulation rarely survives the Court's increasingly vigorous scrutiny under *Central Hudson*. The fate of some of the most cutting-edge public health interventions to prevent noncommunicable disease thus turns on which test a court applies. The Supreme Court cases excerpted above (and others like them) have emboldened industry groups to challenge the continued validity of *Zauderer* as a carve-out from the strict

scrutiny that typically applies to regulations of speech. In the opinion that follows, the D.C. Circuit Court of Appeals used the *Central Hudson* test to invalidate cigarette graphic warning labels proposed by the FDA pursuant to a directive from Congress. In doing so, the D.C. Circuit broke with the Sixth Circuit, which had previously upheld the statutory graphic warnings provision under the *Zauderer* standard.

R. J. REYNOLDS TOBACCO COMPANY V. FDA*

United States Circuit Court for the District of Columbia Circuit
Decided August 24, 2012

The Family Smoking Prevention and Tobacco Control Act directed the Secretary of the U.S. Department of Health and Human Services to issue regulations requiring all cigarette packages manufactured or sold in the United States [and cigarette advertisements] to bear one of nine new textual warnings, as well as "color graphics depicting the negative health consequences of smoking" [comprising the top 50 percent of the front and rear panels of cigarette packages and 20 percent of the area of each cigarette advertisement]. Pursuant to this authority, the Food and Drug Administration (FDA) initiated a rulemaking proceeding through which it selected the nine images that would accompany the statutorily-prescribed warnings. Five tobacco companies challenged the rule, alleging that FDA's proposed graphic warnings violated the First Amendment. . . .

At the outset of the Proposed Rule, FDA asserted the government's "substantial interest in reducing the number of Americans, particularly children and adolescents, who use cigarettes and other tobacco products in order to prevent the life-threatening health consequences associated with tobacco use." . . . The agency explained that by "clearly and effectively convey[ing] the negative health consequences of smoking," the new warnings would discourage nonsmokers, particularly minors, from "initiating cigarette use," and encourage current smokers to quit.

[In its Final Rule,] FDA promulgated the final set of nine images . . . [and] also required each graphic image to bear the phone number of the National Cancer Institute's "Network of Tobacco Cessation Quitlines," which uses the telephone portal "1-800-QUIT-NOW."

FDA based its selection of the final images on an 18,000-person internet-based consumer study it commissioned. The study divided respondents into two groups: a control group that was shown the new text in the format of the current warnings (located on the side of cigarette packages), and a separate treatment group that was shown the proposed graphic warnings, which included the new text, the accompanying graphic image, and the 1-800-QUIT-NOW number. Each group then answered questions designed to assess, among other things, whether the graphic warnings, relative to the text-only control, (1) increased viewers' intention to quit or refrain from smoking;

* 696 F.3d 1205.

(2) increased viewers' knowledge of the health risks of smoking or second-hand smoke; and (3) were "salient," which FDA defined in part as causing viewers to feel "depressed," "discouraged," or "afraid."

In selecting these nine images, FDA reviewed and responded to over a thousand public comments. . . . Several comments—including comments from cancer researchers, nonprofits, and academics—criticized the single exposure study design, noting it prevented the government from assessing the long-term or actual effects of the proposed

PHOTO 12.2. Cigarette graphic warning labels. These graphic warning labels, selected by the FDA in 2011, would have occupied at least 20% of each cigarette advertisement and appeared on the top 50% of the front and rear panels of each pack of cigarettes. The agency withdrew the graphic warnings in 2012 amid a circuit split over their constitutionality.

warnings. Two of these comments recommended FDA conduct longitudinal research or post-market surveillance to assess actual long-term effects. FDA conceded the study did not permit it to reach "firm" conclusions about the "long-term, real-world effects" of the proposed warnings, but claimed the existing scientific literature "provides a substantial basis for our conclusion that the required warnings will effectively communicate the health risks of smoking, thereby encouraging smoking cessation and discouraging smoking initiation." Still other comments asserted that FDA's research study failed to provide

evidence that the proposed warnings would actually affect smoking rates, significantly affect consumers' knowledge of the risks of smoking, or bring about actual behavior change. . . . FDA summarily disagreed, stating that the images it selected would satisfy its "primary goal, which is to effectively convey the negative health consequences of smoking on cigarette packages and in advertisements," which can help "both to discourage nonsmokers . . . from initiating cigarette use and to encourage current smokers to consider cessation." . . .

Any attempt by the government either to compel individuals to express certain views, or to subsidize speech to which they object is subject to strict scrutiny. The general rule "that the speaker has the right to tailor the speech[] applies not only to expressions of value, opinion, or endorsement, but equally to statements of fact the speaker would rather avoid." This holds true whether individuals . . . or corporations are being compelled to speak.

This case contains elements of compulsion and forced subsidization. The Companies contend that, to the extent the graphic warnings go beyond the textual warnings to shame and repulse smokers and denigrate smoking as an antisocial act, the message is ideological and not informational. "[B]y effectively shouting well-understood information to consumers," they explain, "FDA is communicating an ideological message, a point of view on how people should live their lives: that the risks from smoking outweigh the pleasure that smokers derive from it, and that smokers make bad personal decisions, and should stop smoking." In effect, the graphic images are not warnings, but admonitions: "[D]on't buy or use this product." No one doubts the government can promote smoking cessation programs; can use shock, shame, and moral opprobrium to discourage people from becoming smokers; and can use its taxing and regulatory authority to make smoking economically prohibitive and socially onerous. And the government can certainly require that consumers be fully informed about the dangers of hazardous products. But this case raises novel questions about the scope of the government's authority to force the manufacturer of a product to go beyond making purely factual and accurate commercial disclosures and undermine its own economic interest—in this case, by making "every single pack of cigarettes in the country [a] mini billboard" for the government's anti-smoking message.

Even assuming the Companies' marketing efforts (packaging, branding, and other advertisements) can be properly classified as commercial speech, and thus subject to less robust First Amendment protections, a thorny question remains: how much leeway should this Court grant the government when it seeks to compel a product's manufacturer to convey the state's subjective—and perhaps even ideological—view that consumers should reject this otherwise legal, but disfavored, product? . . .

Courts have recognized a handful of "narrow and well-understood exceptions" to the general rule that content-based speech regulations—including compelled speech—are subject to strict scrutiny. There are two primary exceptions in the commercial speech context. First, "purely factual and uncontroversial" disclosures are permissible if they are "reasonably related to the State's interest in preventing deception of consumers," provided the requirements are not "unjustified or unduly burdensome." *Zauderer,* 471 U.S. at 651. Second, restrictions on commercial speech are subject to less stringent review than restrictions on other types of speech. For a statute burdening commercial speech to survive, the government must affirmatively prove that (1) its asserted interest is substantial, (2) the restriction directly and materially advances

that interest, and (3) the restriction is narrowly tailored. See *Central Hudson,* 447 U.S. at 566. While this test is not quite as demanding as strict scrutiny, it is significantly more stringent than *Zauderer*'s standard, which is akin to rational-basis review. . . .

FDA argues that *Zauderer*'s lenient standard of scrutiny applies to regulations that serve a different governmental interest: disclosure of the health and safety risks associated with commercial products. But by its own terms, *Zauderer*'s holding is limited to cases in which disclosure requirements are "reasonably related to the State's interest in preventing deception of consumers." . . . [I]n the absence of any congressional findings on the misleading nature of cigarette packaging itself, there is no justification under *Zauderer* for the graphic warnings. . . .

Moreover, the graphic warnings do not constitute the type of "purely factual and uncontroversial" information, or "accurate statement[s]," to which the *Zauderer* standard may be applied. The disclosures approved in *Zauderer* . . . were clear statements that were both indisputably accurate and not subject to misinterpretation by consumers.

The FDA's images are a much different animal. FDA concedes that the images are not meant to be interpreted literally, but rather to symbolize the textual warning statements. . . . But many of the images chosen by FDA could be misinterpreted by consumers. For example, the image of a man smoking through a tracheotomy hole might be misinterpreted as suggesting that such a procedure is a common consequence of smoking—a more logical interpretation than FDA's contention that it symbolizes "the addictive nature of cigarettes," which requires significant extrapolation on the part of the consumers. Moreover, the graphic warnings are not "purely" factual because—as FDA tacitly admits—they are primarily intended to evoke an emotional response, or, at most, shock the viewer into retaining the information in the text warning.

In fact, many of the images do not convey *any* warning information at all, much less make an "accurate statement" about cigarettes. For example, the images of a woman crying, a small child, and the man wearing a T-shirt emblazoned with the words "I QUIT" do not offer any information about the health effects of smoking. And the "1-800-QUIT-NOW" number, when presented without any explanation about the services provided on the hotline, hardly sounds like an unbiased source of information. These inflammatory images and the provocatively-named hotline cannot rationally be viewed as pure attempts to convey information to consumers. They are unabashed attempts to evoke emotion (and perhaps embarrassment) and browbeat consumers into quitting. While none of these images are patently false, they certainly do not impart purely factual, accurate, or uncontroversial information to consumers. Consequently, the images fall outside the ambit of *Zauderer.*

Because this case does not fall within the narrow enclave carved out by *Zauderer,* we must next determine which level of scrutiny—strict or intermediate—is appropriate. . . . Despite the contrary views of other circuits, our governing precedent makes clear that *Central Hudson* is the appropriate standard. . . .

Assuming FDA's interest in reducing smoking rates is substantial, we next evaluate whether FDA has offered substantial evidence showing that the graphic warning requirements "directly advance[] the governmental interest asserted." The government bears the burden of justifying its attempt to restrict commercial speech, and its burden is not light. . . .

FDA has not provided a shred of evidence . . . showing that the graphic warnings will "directly advance" its interest in reducing the number of Americans who smoke. FDA

makes much of the "international consensus" surrounding the effectiveness of large graphic warnings, but offers no evidence showing that such warnings have *directly caused* a material decrease in smoking rates in any of the countries that now require them. While studies of Canadian and Australian youth smokers showed that [graphic] warnings on cigarette packs caused a substantial number of survey participants to think—or think more—about quitting smoking, and FDA might be correct that intentions are a "necessary precursor" to behavior change, it is mere speculation to suggest that respondents who report increased *thoughts* about quitting smoking will actually follow through on their intentions. . . .

[In Canada in] 2001, the year the warnings were introduced, the national smoking rate dropped to 22 percent, and it further dropped to 21 percent in 2002. But the raw numbers don't tell the whole tale. FDA concedes it cannot directly attribute *any* decrease in the Canadian smoking rate to the graphic warnings because the Canadian government implemented other smoking control initiatives, including an increase in the cigarette tax and new restrictions on public smoking, during the same period. . . . FDA's Regulatory Impact Analysis (RIA) essentially concedes the agency lacks any evidence showing that the graphic warnings are likely to reduce smoking rates. . . . The RIA estimated the new warnings would reduce U.S. smoking rates by a mere 0.088%, a number the FDA concedes is "in general not statistically distinguishable from zero." . . .

FDA attempts to downplay the significance of the RIA by explaining that it "must be included in all federal rulemaking to improve the internal management of the Federal Government," and that it "was not intended to second-guess Congress's judgment regarding the value of new health warnings." FDA attempts to rehabilitate its findings by noting the analysis made only the "unremarkable point" that it is "difficult [to] determine with statistical precision the relative causal impact of the relevant contributing factors," particularly given the very small data sets to which FDA had access. But FDA cannot get around the First Amendment by pleading incompetence or futility. . . .

. . .

Two years after its decision in *R.J. Reynolds*, the D.C. Circuit reversed its holding that *Zauderer*'s more lenient standard applies only if the government's purpose is to correct deception. *American Meat Institute v. U.S Dep't of Agriculture*, 760 F.3d 18 (2014). By that time, however, FDA had withdrawn its proposed rule.

The controversy over *Zauderer*'s reach continues. In 2017, a New York appellate court rejected the Restaurant Association's challenge to a New York City mandate that sodium warnings appear on menus at chain restaurants. The provision, adopted by the New York City Department of Health and Mental Hygiene, requires chain restaurants to designate menu items containing more than 2,300 milligrams of sodium with a salt shaker icon. It also requires menus to include a disclosure that "high sodium intake can increase blood pressure and risk of heart disease and stroke." Also in 2017, a three-judge panel of the Ninth

Circuit Court of Appeals struck down San Francisco's sugary drink warning mandate for billboards and other outdoor advertisements (e.g., on transit shelters, vehicles, and stadiums). The first-of-its-kind measure, adopted by the city council, would require a text-only warning stating that "drinking beverages with added sugar(s) contributes to obesity, diabetes, and tooth decay." The warning would be required to occupy 20% of the space on the advertisement and would specify that it was "a message from the City and County of San Francisco." As of this writing, the case was scheduled for rehearing by the full court. The outcome of this litigation will turn on whether the courts apply *Zauderer* or *Central Hudson*.

The public health implications of *Zauderer*'s continued viability cannot be overstated. Heightened judicial review places a burden on regulators to prove that their chosen means will materially and directly advance the government's purpose. Underfunded agencies often lack the resources to conduct gold-standard studies to prove that disclosure will work before it is implemented. Furthermore, warnings are not designed to work in isolation. Their effectiveness depends on the interaction of point-of-sale disclosures with government-sponsored health education campaigns, and social-ecological strategies that facilitate healthier choices. Requiring regulators to prove that a disclosure mandate alone materially changes behavior is counter to good public health practice. Eliminating judicial deference to common sense legislative judgments may effectively halt innovation by state and local governments that cannot afford to rigorously test proposed interventions under experimental conditions prior to real-world implementation.

THE MARKETPLACE: PRODUCT AND RETAILER REGULATION

A multitude of federal, state, and local laws regulate harmful products and the businesses that manufacture and sell them. Regulators may dictate the composition of products (e.g., banning flavored cigarettes, limiting the alcoholic content of beer) or their configuration (e.g., prohibiting chain restaurants from giving away toys or other incentive items with meals for children that fail to meet nutritional standards). They may also use their licensing and zoning authority to influence the density of tobacco, alcohol, or fast food retailers in the marketplace. Licensing regulations can mandate certain practices (e.g., prohibiting food service establishments from selling sugary drinks in large containers or

requiring clerks to inspect identification cards for alcohol purchasers who appear to be under a certain age). Zoning authorities can also demand that developers set aside space for full-service grocery stores (or sidewalks or recreational paths, as discussed below) in return for approval of major development projects.

Tobacco control has been an important arena for product and retailer regulation. In the early 1970s, the federal government took an active role in tobacco control, pioneering restrictions on promotion and marketing as well as targeted product regulations. In 2009, Congress gave the FDA expansive new authority to regulate tobacco products. These regulations are not comprehensive, however, and state and local governments are left to fill important gaps.

Express savings clauses in federal tobacco statutes preserve significant state and local authority to implement tobacco control measures of their own. For example, states and localities may impose excise taxes on tobacco products or establish minimum prices (discussed in chapter 8), prohibit smoking in public places (discussed later in this chapter), raise the minimum age for tobacco purchases to 21, restrict the location and density of tobacco retailers, or even prohibit sales of menthol cigarettes (the only flavored cigarettes permitted under federal regulations) or all combustible tobacco products.

One state and local strategy that is gaining ground, prohibition of tobacco sales by pharmacies, was the subject of an equal protection case excerpted in chapter 4. In *Walgreen Co. v. San Francisco*, 185 Cal.App.4th 424 (Cal. App. 4th 2010), a state court invalidated San Francisco's first attempt to prohibit sale of tobacco by pharmacies on the grounds that the ordinance's exemption for general grocery stores and big box stores did not bear a rational relationship to the state's purpose. The city then passed an amended ordinance that eliminated the exemption. A large grocery store chain filed suit to assert its equal protection and substantive due process rights, but federal district court upheld the amended ordinance in *Safeway, Inc. v. San Francisco*, 797 F.Supp.2d 964 (N.D. Calif. 2011).

In addition to equal protection and due process challenges, retailers and manufacturers frequently assert that federal and state tobacco control laws preempt local ordinances regulating tobacco retailers. We discussed the deregulatory impact of federal preemption in chapter 3, where we excerpted *32–34 94th St. Grocery Corp. v. New York City Board of Health*, 685 F.3d 174 (2d. Cir. 2012), a case invalidating a local regulation mandating that tobacco retailers display health warnings at the point of purchase. Regulations restricting discounts and

coupons also have been challenged on First Amendment grounds. The opinion excerpted below is typical of these disputes.

*NATIONAL ASSOCIATION OF TOBACCO OUTLETS, INC. V. CITY OF PROVIDENCE**

United States Court of Appeals for the First Circuit
Decided September 30, 2013

. . . On January 5, 2012, the City of Providence adopted two ordinances concerning the sale of tobacco products. The Price Ordinance prohibits licensed retailers from "accept[ing] or redeem[ing], [or] offer[ing] to accept or redeem . . . any coupon that provides any tobacco products without charge or for less than the listed or non-discounted price," and from "sell[ing] tobacco products to consumers through any multi-pack discounts (e.g., 'buy-two-get-one-free' [offers])." The Flavor Ordinance prohibits most retailers from selling flavored tobacco products (other than cigarettes), such as flavored "cigars, pipe tobacco, snuff, chewing tobacco, dipping tobacco," and other flavored tobacco products. It provides that "[i]t shall be unlawful for any person to sell or offer for sale any flavored tobacco product to a consumer, except in a smoking bar."

The history of the Providence City Council's consideration of these ordinances demonstrates that they were designed to reduce youth tobacco use. . . . The testimony and data submitted to the City Council showed that (1) youth are particularly sensitive to tobacco price increases; and (2) such youth are vulnerable to non-cigarette flavored tobacco products. . . .

On February 13, 2012, shortly after the Council passed the ordinances, National Association filed suit in district court alleging . . . that both ordinances violated the First Amendment because they were impermissible regulations of commercial speech; that the Price Ordinance was preempted by the Federal Cigarette Advertising and Labeling Act, 15 U.S.C. § 1334(b), and that the Flavor Ordinance was preempted by the Family Smoking Prevention and Tobacco Control Act (FSPTCA), 21 U.S.C. § 378p(a)(2)(A); and that [the ordinances were also preempted by state law]. Both parties filed motions for summary judgment.

Along with its motion, the City submitted various affidavits, including a declaration from an economics expert concluding that "[e]xtensive economic research demonstrates that increases in cigarette and other tobacco product prices are highly effective in reducing cigarette smoking and the use of other tobacco products, particularly among young people," and another from a public health expert concluding that "the prohibition on the redemption of coupons and multi-pack discounts . . . would most likely have a real and measurable effect on smoking behavior," particularly in decreasing smoking among young people. The city also submitted a 2012 report of the Surgeon General confirming that "extensive use of price-reducing promotions has led to higher rates of tobacco use among young people than would have occurred in the absence of these promotions." As to the Flavor Ordinance, another declaration from a different public health expert concluded that the "[Flavor Ordinance] would

* 731 F.3d 71.

substantially reduce the sale of flavored tobacco products to underage consumers and would reduce the attractiveness of these products to underage consumers."

We first consider National Association's challenge to the validity of the Price Ordinance under the First Amendment. . . . Pricing information concerning lawful transactions has been held to be protected speech by the Supreme Court. *See Va. State Pharmacy Bd. v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 761–64 (1976). But the ordinance here does not restrict the dissemination of pricing information generally. Nothing in the Price Ordinance restricts retailers or anyone else from communicating pricing information concerning the lawful sale price of cigarettes. . . .

Nonetheless, National Association argues that certain sales practices have an "inherently expressive" component that implicates the First Amendment, and that this triggers *O'Brien* scrutiny. National Association relies on *Lorillard Tobacco Co. v. Reilly,* 533 U.S. 535 (2001). There, the Supreme Court concluded that the *O'Brien* test might apply to Massachusetts' regulations of certain tobacco sales practices, but ultimately held that these practices withstood First Amendment Scrutiny. The Supreme Court recognized that [certain provisions of the Massachusetts law] regulated conduct that "may have [had] a communicative component," *id.* at 569, because the regulated activity pertained to the display and dissemination of information to consumers. But *Lorillard* did not decide that the displays did in fact have a communicative component. . . . We therefore [hold] that the regulation of prices, without more, does not rise to the level of regulation of "inherently expressive" conduct subject to *O'Brien* scrutiny.

Finally, National Association argues that even if the restrictions on pricing do not violate the First Amendment, the ordinance's restriction on offers to accept these coupons or to engage in multi-pack discounting is barred by the First Amendment. We disagree. In *Central Hudson,* the Supreme Court made clear that "[t]he government may ban . . . commercial speech related to illegal activity." 447 U.S. at 563–64. . . . Here, the "offers" and other forms of allegedly commercial speech restricted by the Price Ordinance are offers to engage in unlawful activity; that is, sales of tobacco products by way of coupons and multi-pack discounts, which are banned by the Price Ordinance itself. The Price Ordinance does not violate the First Amendment.

National Association alternatively argues that both the Flavor Ordinance and the Price Ordinance are preempted by federal law. . . . We first consider the preemptive effect of the Labeling Act on the Price Ordinance. The purpose of the Labeling Act was to "establish a comprehensive Federal program to deal with cigarette labeling and advertising." The preemption provision of the Labeling Act provides that "[n]o requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this chapter." 15 U.S.C. § 1334(b). It is undisputed that the Price Ordinance is a "requirement or prohibition based on smoking and health." . . . Cases from other circuits interpreting § 1334(b) have held that "discounting" and "distribution of coupons" are "promotional" activities under the statute. We can assume, without deciding, that this is correct. . . .

In 2009, Congress enacted an exception to the § 1334(b) preemption provision that permits some [state and local] restrictions on promotional activity. This exception states that:

> Notwithstanding [§ 1334(b)], a State or locality may enact statutes and promulgate regulations, based on smoking and health, that take effect after the effective date of the [FSPTCA], imposing specific bans or restrictions on the time, place, and manner, but not content, of the advertising or promotion of any cigarettes.

15 U.S.C. § 1334(c)

Notably, § 1334(c) was enacted in response to a portion of the *Lorillard* Supreme Court decision, which held . . . that any tobacco advertising regulation motivated by concerns relating to smoking and health was preempted by the Labeling Act, even though the regulations merely "govern[ed] the location [i.e., place], and not the content, of [the] advertising." *Id.* at 548–49. National Association admitted at oral argument, and commentators have agreed, that this provision was designed to "essentially reverse" the *Lorillard* preemption ruling.

The 2009 amendment imposed two requirements for the exception: (1) the regulation must be content-neutral; and (2) it must be a regulation of the time, place, or manner of the advertising or promotion. . . . We read the "content" restricting provision as concerned with "content" relating to health claims or requiring specific health information. This is consistent with the overall purpose of the Labeling Act's preemption provision, which is to ensure that federal regulation in this respect is "not impeded by diverse, nonuniform, and confusing cigarette labeling and advertising regulations with respect to any relationship between smoking and health." 25 U.S.C. § 1331. . . . [T]he Price Ordinance merely regulates certain types of price discounting and offers to engage in such price discounting. It does not regulate "content" relating to health claims or warnings. The ordinance is content neutral. . . .

Section 14-303 regulates the "time, place, and manner" of how cigarettes may be purchased in the City of Providence. As such, the Ordinance falls into the category of conduct specifically excluded from preemption by Subsection 1334(c) and provides no conflict with the intended purpose of the Labeling Act regarding uniform cigarette labeling and advertising.

At the time of the 2009 enactment § 1334(c), minimum price laws were common. We are aware of no case after the 2009 amendments that has suggested that § 1334(b) of the Labeling Act was designed to preempt pricing regulations. . . . We see no material difference between price regulations generally and the regulation of multi-pack discounts and coupons. Price regulations, including regulations of price offers, are regulations concerning the "manner" of promotion, and are not preempted.

We next consider preemption of the Flavor Ordinance. National Association argues that the FSPTCA preempts the Flavor Ordinance, even though the relevant portion of the FSPTCA only regulates cigarette products, and the Flavor Ordinance only regulates non-cigarette tobacco products. National Association relies on 21 U.S.C. § 387p(a)(2)(A), which reads

> No State or political subdivision of a State may establish or continue in effect with respect to a tobacco product any requirement which is different from, or in addition to, any requirement under the provisions of this subchapter relating to *tobacco product standards,*

> premarket review, adulteration, misbranding, labeling, registration, *good manufacturing standards,* or modified risk tobacco products.

Id. (emphasis added). However, this provision was meant to prohibit state regulation narrowly and only with respect to the specified and limited areas listed in the statute. National Association contends that the Flavor Ordinance, by effectively banning flavored smokeless tobacco, imposes an additional "tobacco product standard" or "good manufacturing standard" in violation of this provision. . . .

The Flavor Ordinance makes it "unlawful for any person *to sell or offer for sale* any flavored tobacco product to a consumer, except in a smoking bar." It is not a blanket prohibition because it allows the sale of flavored tobacco products in smoking bars. Rather, it is a regulation "relating to" sales specifically allowed by the savings clause, which overrides the standards provision. . . .

The final issues concern National Association's argument that the Price Ordinance is preempted by state law, and its argument that both the Price Ordinance and Flavor Ordinance violate the Rhode Island Constitution in regulating tobacco licensing.

National Association argues that, while there is no express preemption, the Price Ordinance is impliedly preempted by state law because, in its view, Rhode Island law comprehensively regulates the offering and redemption of coupons and other discounts for tobacco products. It is true that, under Rhode Island law, the Price Ordinance would be preempted by state law if the Legislature intended that its statutory scheme completely occupy the field of regulation on a particular subject. It is also true that field preemption may be implied in the legislative scheme. However, there must be a clear indication that the General Assembly intended to occupy the field.

Here, it is apparent that the General Assembly has not occupied the field of tobacco regulation as it relates to pricing generally or coupons and multi-pack discounts in particular. National Association cites statutes that prohibit the sale of tobacco products to minors, the distribution of free tobacco products to minors, and unfair sales practices laws that bar misleading price advertising. We note also that the state sets minimum prices for the sale of tobacco products. But National Association cannot point to any text of these statutes that suggests an intent to occupy the field of tobacco price regulation. . . .

Because the Price Ordinance is an appropriate regulation of pricing, it falls outside the ambit of the First Amendment and is not the sort of regulation preempted by the Labeling Act. Moreover, because the Flavor Ordinance is an appropriate sales regulation that is expressly preserved by the FSPTCA, it also is not preempted. Neither ordinance, moreover, conflicts with state law because Rhode Island has not occupied the field of tobacco regulation. . . .

. . .

As *National Association of Tobacco Outlets* indicates, local product and retailer regulations must navigate a veritable minefield of potential preemption issues, including express and implied preemption by state and federal regulations.

The tobacco retailers' argument that prices are a form of expressive conduct protected by the First Amendment may seem like a stretch, but

similar arguments have been successful in other contexts. In *Hair Expressions Design v. Schneiderman*, 581 U.S. ___ (2017), for example, the Supreme Court held that a New York state law prohibiting retailers from imposing a surcharge on credit card sales restricts speech conveying price information and thus should be subject to scrutiny under the First Amendment. The Court rejected the position of the Second and Fifth Circuits that no-surcharge laws merely regulate economic conduct.

ALTERING THE BUILT ENVIRONMENT TO PROMOTE PHYSICAL ACTIVITY

Physical activity has many health benefits, including for cardiovascular health, mental health, diabetes, and related complications. Health care providers and schools have incorporated physical activity into their work with patients and students, but advice that puts the onus on the individual to change her behavior has a limited impact. Legal innovations (e.g., shared use agreements facilitating community access to school recreational facilities), zoning strategies (e.g., smart growth strategies to create walkable communities, including by requiring commercial developers to provide sidewalks or recreational trails), and spending strategies (e.g., investment in public transportation, bikeshare programs, and complete streets policies that make streets safe for pedestrians and cyclists) can help promote active living. In the excerpt below, the Supreme Court considered a Takings Clause challenge to a local government planning commission's imposition of conditions on a property owner's development permit. Particularly in communities where public recreational facilities are scarce, such conditions can play an important role in granting public access to privately owned property for recreational and transportation purposes.

*DOLAN V. CITY OF TIGARD**

United States Supreme Court
Decided June 24, 1994

Chief Justice Rehnquist delivered the opinion of the Court.

Petitioner challenges the decision of the Oregon Supreme Court which held that the city of Tigard could condition the approval of her building permit on the dedication of a portion of her property for flood control and traffic improvements. We granted certiorari to [determine] what is the required degree of connection between the exactions imposed by the city and the projected impacts of the proposed development.

* 512 U.S. 374.

PHOTO 12.3. The Nashua River Rail Trail, Groton, Massachusetts. Courtesy of Michael White via Wikimedia Commons.

The State of Oregon enacted a comprehensive land use management program in 1973. The program required all Oregon cities and counties to adopt new comprehensive land use plans that were consistent with the statewide planning goals. . . . Pursuant to the State's requirements, the city of Tigard, a community of some 30,000 residents on the southwest edge of Portland, developed a comprehensive plan and codified it in its Community Development Code (CDC). . . .

Petitioner Florence Dolan owns a plumbing and electric supply store located on Main Street in the Central Business District of the city. The store covers approximately 9,700 square feet on the eastern side of a 1.67-acre parcel, which includes a gravel parking lot. Fanno Creek flows through the southwestern corner of the lot and along its western boundary. . . .

Petitioner applied to the city for a permit to redevelop the site. Her proposed plans called for nearly doubling the size of the store to 17,600 square feet and paving a 39-space parking lot. . . . In the second phase of the project, petitioner proposed to build an additional structure on the northeast side of the site for complementary businesses and to provide more parking. . . .

The City Planning Commission granted petitioner's permit application subject to conditions imposed by the city's CDC[, which] required that petitioner dedicate the portion of her property lying within the 100-year floodplain for improvement of a storm drainage system along Fanno Creek and that she dedicate an additional 15-foot strip of land adjacent to the floodplain as a pedestrian/bicycle pathway. . . .

The Commission made a series of findings concerning the relationship between the dedicated conditions and the projected impacts of petitioner's project. First, the Commission noted that "[i]t is reasonable to assume that customers and employees of the future uses of this site could utilize a pedestrian/bicycle pathway adjacent to this development for their transportation and recreational needs." The Commission noted that the site plan has provided for bicycle parking in a rack in front of the proposed building and "[i]t is reasonable to expect that some of the users of the bicycle parking

provided for by the site plan will use the pathway adjacent to Fanno Creek if it is constructed." In addition, the Commission found that creation of a convenient, safe pedestrian/bicycle pathway system as an alternative means of transportation "could offset some of the traffic demand on [nearby] streets and lessen the increase in traffic congestion." The Commission went on to note that the required floodplain dedication would be reasonably related to petitioner's request to intensify the use of the site given the increase in the impervious surface. . . .

The Takings Clause of the Fifth Amendment of the United States Constitution, made applicable to the States through the Fourteenth Amendment, provides: "[N]or shall private property be taken for public use, without just compensation." One of the principal purposes of the Takings Clause is "to bar Government from forcing some people alone to bear public burdens which, in all fairness and justice, should be borne by the public as a whole." *Armstrong v. United States,* 364 U.S. 40, 49 (1960). Without question, had the city simply required petitioner to dedicate a strip of land along Fanno Creek for public use, rather than conditioning the grant of her permit to redevelop her property on such a dedication, a taking would have occurred. . . . On the other side of the ledger, the authority of state and local governments to engage in land use planning has [long been] sustained against constitutional challenge. . . . "Government hardly could go on if to some extent values incident to property could not be diminished without paying for every such change in the general law." *Pennsylvania Coal Co. v. Mahon,* 260 U.S. 393, 413 (1922). A land use regulation does not effect a taking if it "substantially advance[s] legitimate state interests" and does not "den[y] an owner economically viable use of his land." *Agins v. City of Tiburon,* 447 U.S. 255, 260 (1980). . . .

Under the well-settled doctrine of "unconstitutional conditions," the government may not require a person to give up a constitutional right—here the right to receive just compensation when property is taken for a public use—in exchange for a discretionary benefit conferred by the government where the benefit sought has little or no relationship to the property. . . .

In evaluating petitioner's claim, we must first determine whether the "essential nexus" exists between the "legitimate state interest" and the permit condition exacted by the city. If we find that a nexus exists, we must then decide the required degree of connection between the exactions and the projected impact of the proposed development. . . .

Undoubtedly, the prevention of flooding along Fanno Creek and the reduction of traffic congestion in the Central Business District qualify as the type of legitimate public purposes we have upheld. It seems equally obvious that a nexus exists between preventing flooding along Fanno Creek and limiting development within the creek's 100-year floodplain. . . . The same may be said for the city's attempt to reduce traffic congestion by providing for alternative means of transportation. . . .

The second part of our analysis requires us to determine whether the degree of the exactions demanded by the city's permit conditions bears the required relationship to the projected impact of petitioner's proposed development. . . .

We think a term such as "rough proportionality" best encapsulates what we hold to be the requirement of the Fifth Amendment. No precise mathematical calculation is required, but the city must make some sort of individualized determination that the required dedication is related both in nature and extent to the impact of the proposed development. . . .

We turn now to analysis of whether the findings relied upon by the city here . . . satisfied these requirements. . . . [B]ecause petitioner's property lies within the Central

Business District, the CDC already required that petitioner leave 15% of it as open space and the undeveloped floodplain would have nearly satisfied that requirement. But the city demanded more—it not only wanted petitioner not to build in the floodplain, but it also wanted petitioner's property along Fanno Creek for its greenway system. The city has never said why a public greenway, as opposed to a private one, was required in the interest of flood control.

The difference to petitioner, of course, is the loss of her ability to exclude others. . . . It is difficult to see why recreational visitors trampling along petitioner's floodplain easement are sufficiently related to the city's legitimate interest in reducing flooding problems along Fanno Creek, and the city has not attempted to make any individualized determination to support this part of its request. . . .

If petitioner's proposed development had somehow encroached on existing greenway space in the city, it would have been reasonable to require petitioner to provide some alternative greenway space for the public either on her property or elsewhere. But that is not the case here. We conclude that the findings upon which the city relies do not show the required reasonable relationship between the floodplain easement and the petitioner's proposed new building.

With respect to the pedestrian/bicycle pathway, we have no doubt that the city was correct in finding that the larger retail sales facility proposed by petitioner will increase traffic on the streets of the Central Business District. . . . Dedications for streets, sidewalks, and other public ways are generally reasonable exactions to avoid excessive congestion from a proposed property use. But on the record before us, the city has not met its burden of demonstrating that the additional number of vehicle and bicycle trips generated by petitioner's development reasonably relate to the city's requirement for a dedication of the pedestrian/bicycle pathway easement. . . . [T]he findings of fact that the bicycle pathway system "*could* offset some of the traffic demand" is a far cry from a finding that the bicycle pathway system *will,* or is *likely to,* offset some of the traffic demand. No precise mathematical calculation is required, but the city must make some effort to quantify its findings in support of the dedication for the pedestrian/bicycle pathway beyond the conclusory statement that it could offset some of the traffic demand generated.

Cities have long engaged in the commendable task of land use planning, made necessary by increasing urbanization, particularly in metropolitan areas such as Portland. The city's goals of reducing flooding hazards and traffic congestion, and providing for public greenways, are laudable, but there are outer limits to how this may be done. "A strong public desire to improve the public condition [will not] warrant achieving the desire by a shorter cut than the constitutional way of paying for the change." *Pennsylvania Coal,* 260 U.S., at 416. . . .

. . .

Dolan illustrates the difficulties local governments face when they use zoning authority to create public rights of way. In a similar case in 2014, the Supreme Court hindered federal government efforts to create a recreational trail through privately owned property. In *Marvin M. Brandt Revocable Trust v. United States,* 572 U.S. ___., the Court relied on statutory interpretation to resolve a dispute over ownership of a

disused railroad right of way. The federal government had granted an 83-acre parcel of land surrounded by a national forest to the Brandt family decades earlier, subject to a railroad easement. In 1983, Congress enacted a railbanking law to allow the U.S. Forest Service to convert rail lines to trails, resulting in thousands of miles of recreational trails spanning all 50 states. When the Forest Service sought to convert the rail corridor through the Brandt family's property into a recreational trail for hiking, biking, horseback riding, and cross-country skiing, the Court sided with the landowners, who refused to grant access.

Built environment strategies exemplify the social-ecological model that guides modern public health science and practice. But that model is at odds with deeply embedded cultural norms that view health as a matter of individual responsibility and place a premium on private property rights. Moreover, fiscal austerity has tightened state and local budgets, putting crucial investments in community infrastructure at risk. Measures such as the permit conditions imposed by the city in *Dolan* require private landowners—who benefit from public services and property protection in many ways—to contribute to projects that meet public needs, but zoning authorities must proceed with caution so as not to run afoul of the Supreme Court's takings jurisprudence.

PROMOTING HEALTHY NORMS ABOUT CONSUMPTION BY ALTERING THE SOCIAL ENVIRONMENT

The social-ecological model has revitalized many areas of public health practice and law. Even individually targeted strategies aimed at urging individuals to make healthier choices have been revamped in light of new insights about the influence of social norms on individual behavior. As discussed in *R.J. Reynolds v. Shewry,* excerpted above, straightforward education campaigns emphasizing the health risks of smoking, physical inactivity, imbalanced eating, and alcohol abuse are largely ineffective. The program at issue in *Shewry* made California a pioneer of the denormalization strategy for tobacco control. Denormalization efforts portray tobacco companies as unethical and manipulative and associate smoking with socially undesirable consequences (e.g., bad breath, impotence, wrinkled skin).

Social marketing campaigns are not the only component of the denormalization strategy. Law also shapes social norms. Laws prohibiting smoking in public spaces and laws mandating that private property owners enforce smoking bans in restaurants, bars, workplaces, and

other facilities protect nonsmokers from secondhand smoke, which is associated with health risks. Smoke-free laws also encourage smokers to quit by making it inconvenient to satisfy their addiction. Finally, smoke-free laws may discourage others—especially young people—from taking up smoking in the first place. When children are exposed to adults and teens who are smoking, they are more likely to view smoking as a normal activity. Smoke-free laws limit their exposure to secondhand smoke, while also limiting their exposure to the behavior of smoking.

Public health ethicists Ronald Bayer and Jennifer Stuber (2006, 49) have questioned whether tobacco denormalization is consistent with efforts to combat the stigma surrounding HIV and other conditions:

> Certainly there are people within the public health community who believe that they are stigmatizing a behavior and not smokers themselves, and for them this distinction is crucial. However, whether it is in fact possible to make such a distinction is an empirical question. . . . [C]ritics have voiced concerns, well known from the literature on AIDS, that stigmatization may in the end be counterproductive. But there are also antitobacco advocates who believe that to the extent that stigmatization limits smoking behavior, it is to be deployed rather than eschewed. For them, the moral question of how to balance the overall public health benefit that may be achieved by stigmatization against the suffering experienced by those who are tainted by "spoiled identities" is virtually never addressed. The issue becomes all the more pressing as stigmatization falls on the most socially vulnerable—the poor who continue to smoke.

Scott Burris (whose work on HIV destigmatization is excerpted in chapter 10) has argued that stigmatization is flatly unacceptable as a public health strategy, but tobacco denormalization does not amount to true stigma:

> One could argue that smokers are not really relegated to a "them" status, that smoking does not supplant all other traits and is not automatically or durably associated with a range of negative stereotypes. Or one could argue that it satisfies all the criteria of stigma in a formal way, but that in none of the domains is the effect serious enough to rise to the level of stigma. (Burris 2008, 187)

Similarly, Bayer (2008, 470) has described tobacco denormalization as "marginalization that can be shed," that "permits, even as its goal, the reintegration of those who have been shamed."

Ultimately, Bayer and Stuber (2006, 50) suggest that some forms of tobacco denormalization may be ethically appropriate while others may not be:

> [P]olicies and cultural standards that result in isolation and severe embarrassment are different from those that cause discomfort. Those that provoke

a sense of social disease are not the same as those that mortify. Acts that seek to limit the contexts in which smoking is permitted are different from those that restrict the right to work, to access health or life insurance, or to reside in communities of one's choice.

The extent to which the deployment of stigmatization exacerbates already-extant social disparities or has long-term counterproductive consequences for the effort to confront the epidemic of smoking-related morbidity must also be considered. And what is true for smoking may have broader applicability for other individual behaviors deemed unhealthy such as "overeating" and illegal drug use.

Bayer and Stuber warn that it may not be possible to distinguish between stigmatizing a behavior and stigmatizing the person who engages in it. In the next excerpt, bioethicist Daniel Callahan proposes stigmatizing obesity (a status), which he appears to conflate with behavioral choice.

OBESITY: CHASING AN ELUSIVE EPIDEMIC*

Daniel Callahan

Obesity may be the most difficult and elusive public health problem this country has ever encountered. . . . I call obesity elusive partly because of the disturbingly low success rate in treating it, but also because it requires changing the patterns, woven deeply into our social fabric, of food and beverage commerce, personal eating habits, and sedentary lifestyles. It also raises the most basic ethical and policy questions: how far can government and business go in trying to change behavior that harms health, what are the limits of market freedom for industry, and how do we look upon our bodies and judge those of others?

Obesity is ordinarily defined as an excess proportion of bodily fat and technically defined in terms of body mass index (BMI). . . . Around 35 percent of Americans are obese, and 67 percent are either obese or overweight. . . . But there is a disturbing twist in those findings: [only 35 percent of men and 42 percent of women describe themselves as obese, a number that] has remained essentially unchanged over the past 20 years . . . All of this helps[, in the words of another commentator,] "paint a picture of mass delusion in the United States about its rising weight." . . .

The public health field has deployed efforts in education, food labeling and advertising, food assistance programs, health care and training, transportation and urban development, taxation, and policy development. Most physicians do not discuss their patients' obesity with them, but various efforts are under way to make discussion of it a basic feature of primary care medicine. The aim is to catch those beginning to move into the overweight range early enough to prevent them from going any further. A number of corporations are using wellness programs and financial incentives to change the unhealthy habits of their employees.

* 2013. *Hastings Center Report* 43 (1): 34–40.

What difference have all these efforts made? The high and steady prevalence of obesity and excessive weight provides one answer to that question: not much. The statistical difference is hardly discernible. Nor is that the worst of it. Even when serious efforts in various weight loss programs are made, or individuals undertake their own effort, the success rate is abysmally low. The weight may come off for a time, but most people regain it after a few years. It is hard to know whether to laugh or cry when the most important studies of obesity count a 5 to 10 percent weight loss a "success," adding that even that much loss has a health benefit, not to be dismissed. . . . Bariatric surgery programs are now widely available, but their costs and assorted medical problems and side effects keep many from using them. . . .

It [is] necessary to find ways to bring strong social pressure to bear on individuals, going beyond anodyne education and low-key exhortation. It will be imperative, first, to persuade them that they ought to want a good diet and exercise for themselves and for their neighbor and, second, that excessive weight and outright obesity are not socially acceptable any longer. . . .

When I was first drawn to think about obesity, I could not help thinking about the success of the antismoking campaign of recent decades. That campaign went simultaneously after the supply side (the tobacco industry) and the demand side (individual smokers). As a smoker, I was at first criticized for my nasty habit and eventually, along with all the others, sent outside to smoke, and my cigarette taxes were constantly raised. The force of being shamed and beat upon socially was as persuasive for me to stop smoking as the threats to my health. I was also helped by the fact that others around me were stopping as well. If they could do it, so could I. . . . The campaign to stigmatize smoking was a great success, turning what had been considered simply a bad habit into reprehensible behavior.

Misled by the public health community's acceptance—and even enthusiastic embrace—of supply and demand measures against and outright stigmatization of smoking, I naively assumed that community would do the same against obesity. I had not realized that smoking was the exception—that the public health community generally opposes anything that looks like blaming the victim. This fact was surely evident in the struggle against HIV, as well as in other campaigns over the decades against the stigmatization of people with many other diseases. It has not been hard to find examples of stigmatization turning into outright discrimination, even (notoriously) in health care.

Why is obesity said to be different from smoking? Three reasons are common: it is wrong to stigmatize people because of their health conditions; wrong to think it will work well, or at all, with obesity; and counterproductive with the obese because of evidence that it worsens rather than improves their condition. Ethically speaking, the social pressures on smokers focused on their behavior, not on them as persons. Stigmatizing the obese, by contrast, goes after their character and selfhood, it is said, not just their behavior. Stigmatization in their case also leads demonstrably to outright discrimination, in health care, education, and the job market more generally. The obese are said to be lazy, self-indulgent, lacking in discipline, awkward, unattractive, weak-willed and sloppy, insecure and shapeless, to mention only a few of the negative judgments among doctors and nurses. . . .

While the public health community, and particularly those who take on obesity, have vigorously rejected deliberate efforts to stigmatize the obese, the fact of the

matter is that they are already stigmatized, and notably among health care workers. . . . Yet it is hard to imagine that much progress can occur toward solutions for obesity unless we bring some form of social pressure to bear against it. If we are left with nothing but the need to change almost everything about the way we live, more or less simultaneously, progress seems improbable. . . .

For any of those good goals to have real bite, it will be necessary to make just about everyone strongly want to avoid being overweight and obese. Education has not shown itself to be up to that task. Fear of illness has not, either. No technologies—surgery or pills—have made a major difference. . . . If this is a public health crisis—and surely it is—nothing less than an enhanced, edgier, population-directed strategy is needed. . . .

While obesity is not in any ordinary medical sense a contagious disease, it is subtly contagious in a social sense. When it is as common as is now the case, those who are overweight hardly notice that others are the same: it is just the way ordinary people look. We need them to notice the others and to want something different for themselves—and those others will be similarly motivated.

But can there be social pressure that does not lead to outright discrimination—a kind of stigmatization lite? That will, I concede, be a difficult line to walk, but it is worth a try. I would couch the social pressure in the following terms, finding ways to induce people who are overweight or obese to put some uncomfortable questions to themselves: If you are overweight or obese, are you pleased with the way you look? Are you happy that your added weight has made many ordinary activities, such as walking up a long flight of stairs, harder? Would you prefer to lessen your risk of heart disease and diabetes? Are you aware that, once you gain a significant amount of weight, your chances of taking that weight back off and keeping it off are poor? Are you pleased when your obese children are called "fatty" or otherwise teased at school? Fair or not, do you know that many people look down upon those excessively overweight or obese, often in fact discriminating against them and making fun of them or calling them lazy and lacking in self-control?

That last question in effect aims to make people acutely aware of pervasive stigmatization, but then to invoke it as a danger to be avoided: don't let this happen to you! If you don't do something about yourself, that's what you are in for. Many of the other questions invoke vanity as a value, or the good opinion of one's neighbors, friends, or fellow employees, or the risk of illness. Use all of them together, carrots and sticks. That will not much help most of those who are already overweight or obese. But beyond marginal improvements, most of them are already lost. They should surely not be neglected, but the important work is to be done with those not yet in that condition. . . .

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Callahan's proposal has been sharply criticized by academics and the media alike. Deb Burgard (a psychologist specializing in eating disorders who advocates for a "health at every size" approach to promoting body positivity and self-care) noted in an interview with NBC News that Callahan "must not have any contact with actual free-range fat people." Is denormalization of obesity akin to tobacco denormalization? Is it possible to denormalize behaviors (e.g., overeating), products

(e.g., sugary beverages), or corporations (e.g., fast food corporations) without stigmatizing people based on their size or appearance?

LIBERTARIAN CRITIQUES

In chapter 1, we examined the debate over public health law's expanding focus on NCD prevention and the social determinants of health. Here, we return to the libertarian critique with a focus on obesity.

WHAT (NOT) TO DO ABOUT OBESITY: A MODERATE ARISTOTELIAN ANSWER*

Richard A. Epstein

. . . [I]it is a sign of the prosperity of the United States and much of the developed world that talk of starvation has been displaced by an intense debate over its opposite—obesity—and what ought to be done about it.

The problems here proliferate at every level. First, there is the obvious question of how to define the condition. Next there is the tangle of questions over the source of obesity. Once we know its causes, how do we decide whether, and to what extent, it counts as a problem, as opposed to simply a state of affairs? Once its dangers are exposed, what, if anything should be done about it? That challenge potentially invites a number of private and public solutions, which could easily operate in tandem, to reduce the incidence and severity of obesity. Some approaches praise persuasion; others call for full disclosure; still others call for regulation, taxation, or new theories of liability. Some call for a full five-course meal. The issue operates in microcosm of the larger issues of health and human safety that buffet this and every other society. To what extent does society rely on the market, or some sense of individual and parental responsibility, and to what extent does society rely on a mix of government programs, some of which are coercive and others are not?

The lines are sharply drawn. It is much more likely that supporters of national health care will find good reasons for state intervention to counteract obesity than those who by and large favor private health care solutions. . . . The advocates of centralized solutions stress the difficulty ordinary individuals face on matters of cognition and self-control. . . . The effects of various products on human health are tricky to discern even with warning labels, and almost impossible to figure out without them. The ability of individuals to stick to diets or to exercise any other measure of self-control is notoriously weak, and in the minds of many counterproductive, so that perhaps a regime of taxation or regulation that moderates supply could operate as a useful backstop to, or a substitute for, the frailty of individual will, especially the will that cannot accurately discount future cravings to their present value.

* 2005. *Georgetown Law Journal* 93 (4): 1361–86. Reprinted with permission of the publisher, Georgetown Law Journal © 2005.

From the other side come the familiar rejoinders of those who are suspicious of government programs. They claim that governments have neither the incentives nor the knowledge to work any intelligent system of regulation, taxation, or liability. Ordinary individuals bear the consequences of ill-health first and foremost, and thus should be willing to take steps to advance their health by easing the strain of obesity. In addition, no system of upstream control, public or private, can fully take into account the tremendous variation in individual cases. Controlling obesity, this view urges, depends on person-specific knowledge of everything from body-type, age, and allergies, to food likes and dislikes, travel schedules, occupation, and so on. Any effort to develop centralized solutions will fail because the high level of variation across individual cases will defeat even a conscientious government that is consistently virtuous in the discharge of its public duties. . . . My own background presumption is more skeptical about government intervention. . . . As a firm believer in the decentralized view, I will argue here that the sound background presumption *against* government intervention has not been overcome. . . .

[A] large share of [the case for government intervention] rests on charges that a majority of Americans are overweight or obese. Critical to this account are the underlying definitions. Overweight persons are defined as individuals whose BMI (or body mass index) is over twenty-five. For obese persons, the BMI is over thirty. For those who want a frame of reference, a male with a height of six feet and a weight of 185 has a BMI of just under twenty-five, which means that he is not quite overweight, but close. The test makes no distinction between men and women. . . . and it does not account for differences in age. . . . The test makes no reference to levels of body fat. The muscular athlete and the couch potato of the same weight and size get the same BMI. . . . The steady upward trend in the BMI index is probably not evidence that more Americans than ever are putting on muscle mass doing weight-training in the gym. Rather, the percentage of overweight and obese people, by any definition, seems to be on the rise. Becoming overweight may be asking for trouble, for the condition is commonly associated with increases in type 2 diabetes, coronary heart disease, and hypertension.

What makes the issue so intractable is that the critics of government intervention are not necessarily defenders of obesity as a desirable state for any given person. Rather, their view is that individual means of control are likely to prove preferable. . . . The first source of uneasiness is the overwrought comparison of food with cigarettes. While cigarettes can be shunned altogether, people have to eat to live. . . . Even if we accept the figures on death and illness at face value, figuring out the right individual or social response is necessarily a good deal more difficult to achieve. . . .

The constant use of the term "epidemic" does more to inflame than inform. Whatever the problems with obesity, it is not a communicable disease, with the fears and pandemonium that real epidemics let loose in their wake. The attempts to describe it as a *public* health problem therefore expand the definition of public health to cover a wide range of decisions and actions that have none of the functions of public goods. There are no collective action problems, for I can go on a diet while you decide to binge, or the reverse. There is, accordingly, a vast difference in desirable social responses to pollution or plague on the one hand, where coercive collective action is indispensable, and to obesity, where different individuals can pursue different choices. . . .

It is sometimes said that obesity is a public issue because the collective provision of medical care in the United States means that individual decisions on health and fitness

have a profound effect on the public fisc to which all are forced to contribute. But here it is the social response, not the underlying set of choices, that introduces a public goods dimension into the mix. The problem could be reduced or eliminated by reversing the antecedent decision to socialize the expenses of health care through programs like Medicare and Medicaid. If we let insurers and employers have the right to draw distinctions on the grounds of weight, muscle mass or anything else, then the cross-subsidy problem will be largely eliminated because each person's rate will depend more on individual performance and not on the performance of others. The prices will not only change the distribution of burdens, but should create incentives to reduce the total size of the problem, which is an important consequence of prices that the champions of state intervention tend to overlook. It is only when universal access is the cardinal principle of health care that markets are sure to fail. But here doing nothing in the face of rising costs is not attractive, so it becomes fair game to support increased government regulation on anything that influences health care costs—for which obesity qualifies, as HHS duly notes. . . .

In light of the enormous attention that the question of obesity has generated, how should we respond? Individually, not collectively, seems the better approach. Better a bit of self-control than a ton of state initiatives. . . . The best recommendation: balanced diet and moderate exercise. I learned that in elementary school, even before I had heard of Aristotle. . . .

. . .

Epstein's approach exemplifies the individually focused personal responsibility norm that dominates social, cultural, and political responses to obesity. It is counter to all that public health stands for. The public readily understands communicable diseases and pollution as problems that no individual, acting alone, can address. The same cannot be said of NCDs and injuries. Yet NCDs and injuries are the leading drivers of premature mortality, morbidity, and disparities. These pressing problems are amenable to structural solutions achieved collectively through the democratic process. But interventions to alter the information, retail, built, and social environments often require significant investment of public funds and regulations that industry resists powerfully. Meanwhile, behavioral interventions that put the onus on individuals to make better choices without making it easier for them to do so offer a politically palatable, if largely ineffective, alternative.

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PHOTO 13.1. Firearms on display at a gun show in Houston. Courtesy of M & R Glasgow via Flickr.

CHAPTER THIRTEEN

Injury and Violence Prevention

In common parlance, we refer to many injuries, particularly road traffic injuries, as "accidents." This term lulls us into thinking that injuries are an unavoidable product of happenstance. But the evidence suggests that at the population level, injuries can be predicted and sharply reduced through a public health approach. Injuries and violence take a devastating toll on our society. Although noncommunicable diseases kill more Americans than injuries, injury deaths disproportionately affect young people, increasing the number of life-years lost. Unintentional injuries cause the largest number of deaths among those aged one to 44. Unintentional injuries, suicide, and homicide are the three leading causes of death for teenagers and adults under age 35.

Public health takes a social-ecological approach to preventing injuries (e.g., from car crashes, suicide, drug overdose, and firearms) and violence (e.g., intimate partner violence, community violence, child maltreatment, sexual violence). Whereas lawyers and judges tend to focus on punishing individual wrongdoers for negligence or intentional harm and compensating those who are injured, injury epidemiologists look for modifiable environmental factors. For example, a narrow approach to preventing distracted driving deaths punishes the distracted driver and allows the victim to hold him liable for damages. In contrast, a broader view would consider individual factors (e.g., driver intoxication, distraction, or seat belt use) and also the vector of injury (e.g., a noncollapsible steering wheel column that is more likely to injure the

driver's chest), the physical environment (e.g., a roadway design that makes collisions between motor vehicles and pedestrians or cyclists more likely), and the social environment (e.g., social norms regarding seat belt use and distracted driving, and the affordability of safer vehicles). Epidemiologist William Haddon developed the seminal framework for identifying factors that contribute to injury. The so-called Haddon Matrix plots factors according to their timing (pre-event, event, post-event) and focus (host, agent or vector, physical environment, social environment) to identify potential interventions. The systematic scientific study of injuries and violence allows policymakers to see beyond the intuitive view of these events as a matter of misfortune or individual blame. At the population level, events that may seem to be the result of bad luck or being in the wrong place at the wrong time become predictable and preventable.

Like noncommunicable disease prevention, injury and violence prevention calls for interventions that threaten the interests of powerful industries. Firearms, motor vehicle, and other product manufacturers resist direct regulation and tort liability. Often, they do so by appealing to the culturally resonant notion that injuries are a matter of personal responsibility. As an alternative to regulations that would hurt their profits, they call for behavioral interventions aimed at urging individuals to make better choices (e.g., drinking alcohol "responsibly," driving safely, storing firearms out of the reach of children).

Injuries occur in many contexts, triggering distinct, but overlapping, legal regimes. For example, federal occupational safety regulations and state workers' compensation laws address workplace injuries. Consumer product safety regulation and tort liability rules (see chapter 7) prevent household injuries (e.g., falls, burns, unintentional poisonings) as well as workplace, motor vehicle, and sports injuries. Here, we focus on the three leading causes of injury deaths in the United States: motor vehicle crashes, firearms, and drug overdoses (which public health experts classify as poisoning injuries).

We begin with motor vehicle crashes, focusing on criminal laws mandating the use of helmets, seat belts, and child safety seats and common law rules holding manufacturers liable for vehicles that are not sufficiently crashworthy. Next, we turn to firearms, which are associated with violence, unintentional injuries, and suicide but are notoriously difficult to regulate in the United States due to the Supreme Court's evolving Second Amendment jurisprudence. Finally, we address drug overdoses, which have surged due to an epidemic of heroin, fentanyl,

and prescription opioid abuse, shortening average life expectancy for certain demographic groups in some geographic areas.

MOTOR VEHICLE SAFETY

Motor vehicle crashes—including collisions with pedestrians and cyclists—are the leading cause of injury death among children and young adults aged five to 24. Scientists' earliest efforts to apply the principles of disease epidemiology to injuries focused on motor vehicle safety. The Haddon Matrix was developed for precisely this purpose in the years following World War II as motor vehicle travel became ubiquitous and safety regulations lagged behind the dramatic rise in traffic fatalities.

Some injury prevention strategies regulate—and, in some cases, criminalize—unsafe behavior. Libertarians criticize laws requiring vehicle operators and passengers to use helmets, seat belts, or child safety seats. Motorcycle helmet laws have been particularly controversial. Evidence strongly supports their effectiveness in reducing fatalities. Yet libertarian groups (such as the "Freedom of the Road" organization that supported the plaintiff in the following case) repeatedly brought suit to invalidate helmet laws under federal and state constitutional doctrines.

*BENNING V. STATE**

Supreme Court of Vermont
Decided January 28, 1994

In 1989, plaintiff Benning was cited for a violation of [Vermont Statutes Annotated, Title 23, § 1256] for operating a motorcycle without wearing approved headgear. However, the Caledonia County State's Attorney dismissed the citation because he found the statute vague and was unable to establish the elements necessary to prosecute the crime. Plaintiffs subsequently filed suit, seeking to have § 1256 declared unconstitutional and to have the State enjoined from further enforcement of the statute. Plaintiffs make three arguments based solely on the state constitution: (1) the statute is repugnant to the tenor, spirit and intent of the Vermont Constitution; (2) the statute is void for vagueness; and (3) the statute denies plaintiffs equal protection of the laws. We address each contention in turn.

Section 1256 was enacted in 1968, and states in full: "No person may operate or ride upon a motorcycle upon a highway unless he wears upon his head protective headgear reflectorized in part and of a type approved by the commissioner. The headgear shall be equipped with either a neck or chin strap." Within a year of its enactment, the

* 641 A.2d 757.

statute came under challenge in *State v. Solomon,* 260 A.2d 377 (1969). . . . [W]e upheld the validity of § 1256 against arguments that the statute exceeded the scope of the state's police power and violated the Due Process Clause of the Fourteenth Amendment to the United States Constitution. This Court concluded then that § 1256 was "directly related to highway safety" because an unprotected motorcycle operator could be affected by roadway hazards, temporarily lose control and become a menace to other motorists. The Court also concluded that "self-injury may be of such a nature to also invoke a general public concern." 260 A.2d at 380. . . .

In this case, plaintiffs attempt to distinguish their attack on § 1256 from *Solomon* on the grounds that *Solomon* was decided solely on federal constitutional grounds, whereas they challenge § 1256 on state constitutional grounds. . . . [T]he Vermont Constitution may afford greater protection to individual rights than do the provisions of the federal charter. Plaintiffs argue vigorously that this is a circumstance of greater protection.

Plaintiffs base this argument almost entirely on Chapter I, Article 1 of the Vermont Constitution, which provides: "That all men are born equally free and independent, and have certain natural, inherent, and unalienable rights, amongst which are the enjoying and defending life and liberty, acquiring, possessing and protecting property, and pursuing and obtaining happiness and safety. . . . "

Plaintiffs argue that both safety and liberty are among the "natural, inherent, and unalienable rights" guaranteed by the Article. As to safety, plaintiffs argue that the text gives individuals, not the government, the power to determine what is necessary for personal safety. Plaintiffs claim that they have a liberty interest in operating a motorcycle without a helmet, and since the purpose behind the statute is to protect the safety of the motorcycle operator, it offends their right to determine their own safety needs. . . .

We find sparse help for plaintiffs in the text of Article 1 and in our decisions construing this text. . . . The article expresses fundamental, general principles that underlie more specific statements of rights and powers set forth elsewhere in the Constitution. . . . Given the nature of Article 1, it is not surprising that we can discover no instance where this Court has struck down an act of the Vermont Legislature solely because of a violation of Article 1. The main reason is found in *State v. Carruth,* 81 A. 922 (1911), in which the defendant claimed that Article 1 gave him the right to shoot a deer on his land out of season, despite a criminal statute to the contrary. Concerning Article 1, this Court wrote: "Many things contained in the bill of rights found in our State Constitutions 'are not, and from the very nature of the case cannot be, so certain and definite in character as to form rules for judicial decisions; and they are declared rather as guides to the legislative judgment than as marking an absolute limitation of power.'" 81 A. at 923.

The specific words on which plaintiffs rely lack the specificity that would show the presence of concrete rights applicable to these circumstances. Plaintiffs' right to pursue and obtain safety does not suggest the government is powerless to protect the safety of individuals. Indeed . . . the individual pursues safety through governmental action. The juxtaposition of safety and happiness is consistent with a general statement of principle rather than an enforceable right. . . .

We are willing to give a broad reading to the term "liberty," but it is a vast expansion of the term to find within it a right to ride helmetless on public highways. Thus,

even if we were to interpret Article 1 as a specific, enforceable constraint on state regulatory action, the wording falls short of supporting plaintiffs' case. . . .

At the center of plaintiffs' argument is the assertion that Vermont values personal liberty interests so highly that the analysis under the federal constitution or the constitutions of other states is simply inapplicable here. In support of this contention, plaintiffs rely on political theorists, sociological materials and incidents in Vermont's history. Without detailing this argument, we find it unpersuasive not because it overvalues Vermont's devotion to personal liberty and autonomy, but because it undervalues the commitment of other governments to those values. . . . Certainly, if there was a heightened concern for personal liberty, there is no evidence of it in the text of the Constitution. Many states have constitutional provisions very similar to Article 1. . . .

[W]e reject the notion that this case can be resolved on the basis of a broad right to be let alone without government interference. We accept the federal analysis of such a claim in the context of a public safety restriction applicable to motorists using public roads. We agree with Justice Powell, recently sitting by designation with the Court of Appeals for the Eleventh Circuit, who stated:

> [T]here is no broad legal or constitutional "right to be let alone" by government. In the complex society in which we live, the action and nonaction of citizens are subject to countless local, state, and federal laws and regulations. Bare invocation of a right to be let alone is an appealing rhetorical device, but it seldom advances legal inquiry, as the "right"—to the extent it exists—has no meaning outside its application to specific activities. The [federal] Constitution does protect citizens from government interference in many areas—speech, religion, the security of the home. But the unconstrained right asserted by appellant has no discernable bounds, and bears little resemblance to the important but limited privacy rights recognized by our highest Court.

Picou v. Gillium, 874 F.2d 1519, 1521 (11th Cir. 1989).

We are left then with the familiar standard for evaluating police power regulations—essentially, that expressed in *Solomon.* Plaintiffs urge us to overrule *Solomon* because it was based on an analysis of the safety risk to other users of the roadway that is incredible. In support of their position, they offered evidence from motorcycle operators that the possibility of an operator losing control of a motorcycle and becoming a menace to others is remote. On the other hand, these operators assert that helmets make a motorcycle operator dangerous. Plaintiffs also emphasize that even supporters of helmet laws agree that their purpose is to protect the motorcycle operator, not other highway users.

We are not willing to abandon the primary rationale of *Solomon* because of plaintiffs' evidence. The statute is entitled to a presumption of constitutionality. Plaintiffs are not entitled to have the courts act as a super-legislature and retry legislative judgments based on evidence presented to the court. Thus, the question before us is whether the link between safety for highway users and the helmet law is rational, not whether we agree that the statute actually leads to safer highways. The *Solomon* reasoning has been widely adopted in the many courts that have considered the constitutionality of motorcycle helmet laws. We still believe it supports the constitutionality of § 1256.

> There are at least two additional reasons why we conclude § 1256 is constitutional. . . . Although plaintiffs argue that the only person affected by the failure to wear a helmet is the operator of the motorcycle, the impact of that decision would be felt well beyond that individual. Such a decision imposes great costs on the public. As Professor Laurence Tribe has commented, ours is "a society unwilling to abandon bleeding bodies on the highway, [and] the motorcyclist or driver who endangers himself plainly imposes costs on others." This concern has been echoed in a number of opinions upholding motorcycle helmet laws. . . . Whether in taxes or insurance rates, our costs are linked to the actions of others and are driven up when others fail to take preventive steps that would minimize health care consumption. We see no constitutional barrier to legislation that requires preventive measures to minimize health care costs that are inevitably imposed on society.
>
> A second rationale supports this type of a safety requirement on a public highway. Our decisions show that in numerous circumstances the liability for injuries that occur on our public roads may be imposed on the state, or other governmental units, and their employees. It is rational for the state to act to minimize the extent of the injuries for which it or other governmental units may be financially responsible. The burden placed on plaintiffs who receive the benefit of the liability system is reasonable. . . .
>
> As a result, we reiterate our conclusion that § 1256 "in no way violates any of the provisions of our state and federal constitutions." *Solomon,* 260 A.2d at 380.

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As *Benning* indicates, helmet and seat belt laws that criminalize unsafe behavior by vehicle operators and passengers raise paternalism concerns similar to those raised with respect to noncommunicable disease prevention. In both cases, public health and safety advocates often invoke health care costs to argue that seemingly self-regarding behavior affects the community as a whole. These arguments are vulnerable to the counterargument that such externalities are induced by the policy choice to finance health care costs collectively, which libertarians view as ill advised.

Critics have also raised equity concerns about policy enforcement of seat belt laws and other motor vehicle safety laws. State legislatures have two enforcement options: (1) *primary enforcement*, whereby the safety offense (e.g., failure to wear a seat belt or failure to repair a burnt-out taillight) is a sufficient basis for a police officer to initiate a traffic stop; or (2) *secondary enforcement,* whereby the safety offense can only be enforced if the officer had another reason to initiate the stop. In the 1990s and early 2000s, safety advocates successfully urged the majority of states to adopt primary enforcement seat belt laws. Policy surveillance studies indicate that primary enforcement reduces motor vehicle fatalities. Nonetheless, critics assert that primary enforcement affords greater

authority and discretion to law enforcement officers, increasing the opportunity for racially biased policing.

Other injury prevention measures focus on vehicle and roadway safety. These interventions are less likely to be viewed as regulating purely self-regarding behavior, but may nonetheless raise issues about the proper balance between personal and collective responsibility. The next case represents one of the first court decisions identifying lack of crashworthiness as a product defect leading to strict products liability. The court raises serious public policy concerns about leaving such matters to juries.

*DAWSON V. CHRYSLER CORP.**

United States Court of Appeals for the Third Circuit
Decided September 11, 1980

This appeal from a jury verdict and entry of judgment in favor of the plaintiffs arises out of a New Jersey automobile accident in which a police officer was seriously injured. The legal questions. . ., governed by New Jersey law, are relatively straight-forward. The public policy questions, however, which are beyond the competence of this Court to resolve and with which Congress ultimately must grapple, are complex and implicate national economic and social concerns. . . .

On September 7, 1974, Richard F. Dawson, while in the employ of the Pennsauken Police Department, was seriously injured as a result of an automobile accident that occurred in Pennsauken, New Jersey. As Dawson was driving on a rain-soaked highway, responding to a burglar alarm, he lost control of his patrol car—a 1974 Dodge Monaco. The car slid off the highway, over a curb, through a small sign, and into an unyielding steel pole that was fifteen inches in diameter. The car struck the pole in a backwards direction at a forty-five degree angle on the left side of the vehicle; the point of impact was the left rear wheel well. As a result of the force of the collision, the vehicle literally wrapped itself around the pole. The pole ripped through the body of the car and crushed Dawson between the seat and the "header" area of the roof, located just above the windshield. The so-called "secondary collision" of Dawson with the interior of the automobile dislocated Dawson's left hip and ruptured his fifth and sixth cervical vertebrae. As a result of the injuries, Dawson is now a quadriplegic. He has no control over his body from the neck down, and requires constant medical attention.

Dawson, his wife, and their son brought suit . . . against the Chrysler Corporation, the manufacturer of the vehicle in which Dawson was injured. . . . The plaintiffs' claims were based on theories of strict products liability and breach of implied warranty of fitness. They alleged that the patrol car was defective because it did not have a full, continuous steel frame extending through the door panels, and a cross-member running through the floor board between the posts located between the front and rear

* 630 F.2d 950.

doors of the vehicle. Had the vehicle been so designed, the Dawsons alleged, it would have "bounced" off the pole following relatively slight penetration by the pole into the passenger space.

Expert testimony was introduced by the Dawsons to prove that the existing frame of the patrol car was unable to withstand side impacts at relatively low speed, and that the inadequacy of the frame permitted the pole to enter the passenger area and to injure Dawson. The same experts testified that the improvements in the design of the frame that the plaintiffs proposed were feasible and would have prevented Dawson from being injured as he was. According to plaintiffs' expert witnesses, a continuous frame and cross-member would have deflected the patrol car away from the pole after a minimal intrusion into the passenger area and, they declared, Dawson likely would have emerged from the accident with only a slight injury.

In response, Chrysler argued that it had no duty to produce a "crashproof" vehicle, and that, in any event, the patrol car was not defective. Expert testimony for Chrysler established that the design and construction of the 1974 Dodge Monaco complied with all federal vehicle safety standards, and that deformation of the body of the vehicle is desirable in most crashes because it absorbs the impact of the crash and decreases the rate of deceleration on the occupants of the vehicle. Thus, Chrysler's experts asserted that, for most types of automobile accidents, the design offered by the Dawsons would be less safe than the existing design. They also estimated that the steel parts that would be required in the model suggested by the Dawsons would have added between 200 and 250 pounds to the weight, and approximately $300 to the price of the vehicle. It was also established that the 1974 Dodge Monaco's unibody construction was stronger than comparable Ford and Chevrolet vehicles. . . .

The jury . . . returned a verdict in favor of the plaintiffs. In answers to a series of special interrogatories, the jurors concluded that (1) the body structure of the 1974 Dodge Monaco was defective and unreasonably dangerous; (2) Chrysler breached its implied warranty that the vehicle would be fit for use as a police car; (3) as a result of the defective design and the breach of warranty, Dawson sustained more severe injuries than he would have incurred had Chrysler used the alternative design proposed by Dawsons expert witnesses; (4) the defective design was the proximate cause of Dawson's enhanced injuries; and (5) Dawson's failure to use a seatbelt was not a proximate cause of his injuries. The jury awarded Mr. Dawson $2,064,863.19 for his expenses, disability, and pain and suffering, and granted Mrs. Dawson $60,000.00 for loss of consortium and loss of services. After the district court entered judgment, Chrysler moved for judgment notwithstanding the verdict or, alternatively for a new trial. The court denied both motions. . . . We affirm. . . .

[T]he controlling issue in the case is whether the jury could be permitted to find, under the law of New Jersey, that the patrol car was defective. . . . [T]he New Jersey Supreme Court summarized its state's law of strict liability as follows:

> If at the time the seller distributes a product, it is not reasonably fit, suitable and safe for its intended or reasonably foreseeable purposes so that users or others who may be expected to come in contact with the product are injured as a result thereof, then the seller shall be responsible for the ensuing damages. . . .

The determination whether a product is "reasonably fit, suitable and safe for its intended or reasonably foreseeable purposes" is to be informed by what the New Jersey Supreme Court has termed a "risk/utility analysis." Under this approach, a product is defective if "a reasonable person would conclude that the magnitude of the scientifically perceivable danger as it is proved to be at the time of trial outweighed the benefits of the way the product was so designed and marketed." The court . . . identified seven factors that might be relevant to this balancing process: (1) The usefulness and desirability of the product its utility to the user and to the public as a whole. (2) The safety aspects of the product the likelihood that it will cause injury, and the probable seriousness of the injury. (3) The availability of a substitute product which would meet the same need and not be as unsafe. (4) The manufacturer's ability to eliminate the unsafe character of the product without impairing its usefulness or making it too expensive to maintain its utility. (5) The user's ability to avoid danger by the exercise of care in the use of the product. (6) The user's anticipated awareness of the dangers inherent in the product and their avoidability, because of general public knowledge of the obvious condition of the product, or of the existence of suitable warnings or instructions. (7) The feasibility, on the part of the manufacturer, of spreading the loss by setting the price of the product or carrying liability insurance. . . .

Chrysler maintains that . . . the Dawsons did not present sufficient evidence from which the jury reasonably might infer that the alternative design that they proffered would be safer than the existing design, or that it would be cost effective, practical, or marketable. In short, Chrysler urges that the substitute design would be less socially beneficial than was the actual design of the patrol car. In support of its argument, Chrysler emphasizes that the design of the 1974 Dodge Monaco complied with all of the standards authorized by Congress in the National Traffic and Motor Vehicle Safety Act of 1966 . . . and . . . accompanying regulations.

Compliance with the safety standards promulgated pursuant to the National Traffic and Motor Vehicle Safety Act, however, does not relieve Chrysler of liability in this action. For, in authorizing the Secretary of Transportation to enact these standards, Congress explicitly provided, "Compliance with any Federal motor vehicle safety standard issued under this subchapter does not exempt any person from any liability under common law." 15 U.S.C. s 1397(c). . . .

On the basis . . . of the evidence presented respectively by the Dawsons and by Chrysler, we conclude that the record is sufficient to sustain the jury's determination, in response to the interrogatory, that the design of the 1974 Monaco was defective.

Although we affirm the judgment of the district court, we do so with uneasiness regarding the consequences of our decision and of the decisions of other courts throughout the country in cases of this kind. . . . Congress, in enacting the National Traffic and Motor Vehicle Safety Act, provided that compliance with the Act does not exempt any person from liability under the common law of the state of injury. The effect of this provision is that the states are free, not only to create various standards of liability for automobile manufacturers with respect to design and structure, but also to delegate to the triers of fact in civil cases arising out of automobile accidents the power to determine whether a particular product conforms to such standards. . . .

The result of such arrangement is that while the jury found Chrysler liable for not producing a rigid enough vehicular frame, a factfinder in another case might well hold

> the manufacturer liable for producing a frame that is too rigid. . . . Under these circumstances, the law imposes on the industry the responsibility of insuring vast numbers of persons involved in automobile accidents. . . .
>
> Inasmuch as it was the Congress that designed this system, and because Congress is the body best suited to evaluate and, if appropriate, to change that system, we decline today to do anything in this regard except to bring the problem to the attention of the legislative branch.

. . .

The question of whether and when federal motor vehicle safety standards preempt common law tort claims continues to plague the judiciary and auto manufacturers. In 2011, for example, in *Williamson v. Mazda Motors of American, Inc.*, 562 U.S. 323, the Supreme Court held that a federal regulation that allowed manufacturers to install either a lap-and-shoulder belt or a lap belt alone in a rear seat did not preempt state tort claims alleging that all seats should have lap-and-shoulder belts. Injury prevention experts, industry groups, and policymakers continue to debate the pros and cons of allowing tort liability rules to develop alongside direct consumer product regulation.

In addition to vehicle safety, injury epidemiologists also focus on roadway safety. For example, traffic calming (narrowing traffic lanes and installing speed bumps) and separation of motor vehicle from cycling lanes reduce the risk of collision. The complete streets policies discussed in chapter 12 are designed to improve roadway safety, in addition to promoting more active forms of transportation to prevent noncommunicable disease. These policies are primarily facilitated by taxation and spending. Zoning regulations may also be used to encourage private developers to contribute to safer, healthier built environments, raising the potential for takings challenges.

FIREARM INJURIES AND GUN CONTROL

Firearms impose an enormous toll on American society. Intentional firearm injuries (homicides) cause the second-highest number of injury deaths among 15 to 24 year olds. Suicide by firearm is the third leading cause of injury deaths among children aged 10 to 14 and among adults 35 and older. Unintentional firearm injuries kill hundreds of Americans each year, including young children who fail to appreciate the danger.

These deaths are preventable. Yet gun control measures are among the most controversial public health regulations due to a mix of cultural

reverence for guns (especially in rural areas where hunting and target shooting are favored pastimes), industry influence, and the special status of the right to bear arms in the U.S. Constitution.

Many gun deaths, especially unintentional injuries, could be prevented by simple, well-understood safety devices, such as child safety locks and devices that clearly indicate whether a round is present in the chamber. In spite of the readily preventable danger they present, firearms are almost wholly exempt from product safety regulation. Federal law prohibits certain types of guns, such as short-barrel shotguns, which are notoriously inaccurate and easy for criminals to conceal. But there are no federal design safety standards applicable to domestically manufactured firearms. The U.S. Consumer Products Safety Commission is prohibited from regulating firearms and ammunition and the Bureau of Alcohol, Tobacco, and Firearms does not impose design standards.

In light of these significant regulatory gaps, many experts support tort liability to prompt safer practices by firearm and ammunition manufacturers and distributors. As the following case demonstrates, however, plaintiffs face numerous challenges under existing tort doctrine. *McCarthy v. Olin Corp*. arose out of an infamous incident of gun violence. Colin Ferguson opened fire on a Long Island Rail Road commuter train during the evening rush hour on December 7, 1993. Using two 15-round magazines, Ferguson killed six passengers and wounded 19 more. As he attempted to load a third magazine, passengers tackled him to the ground.

In criminal proceedings, Ferguson was convicted of several counts of murder and attempted murder, and was sentenced to 300 years in prison. Separately, victims and their families filed civil suits against the railroad and other parties, asserting negligence. Carolyn McCarthy, whose husband and son were among the victims, also filed suit against the manufacturers of the handgun, magazines, and bullets Ferguson used. The Court of Appeals decided the case shortly after McCarthy took office as a U.S. congresswoman, having run on a gun-control platform.

The majority in McCarthy sustained dismissal of the plaintiffs' complaint, finding it deficient with respect to the duty element of the negligence cause of action, the defectiveness element of the products liability claim, and the proximate cause element applicable to both. Judge Guido Calabresi, a prominent legal scholar and former dean of Yale Law School, dissented. In his seminal 1970 book *The Costs of Accidents,* Calabresi pioneered the economic analysis of tort doctrine. He argued that tort

doctrines rooted in cost-benefit analysis could deter unreasonably harmful conduct by potential tortfeasors, rather than focusing solely on achieving corrective justice by compensating victims. This prevention-oriented view of the rationale for tort liability is roughly compatible with the public health perspective.

*MCCARTHY V. OLIN CORP.**

United States Court of Appeals for the Second Circuit
Decided July 16, 1997

Plaintiffs include two surviving victims and the estate of one deceased victim of the December 7, 1993 assault on the 5:33 p.m. Long Island Railroad commuter train. The bullets used in the shootings were Winchester "Black Talon" hollowpoint bullets, designed to enhance the injuries of their victims. . . . The complaint [against Olin Corporation, the manufacturer of the bullets,] asserted causes of action in the negligent manufacture, advertising and marketing of a product that was unreasonably designed and ultrahazardous, the making of an unreasonably dangerous product and strict liability in tort. . . .

The Black Talon is a hollowpoint bullet designed to bend upon impact into six ninety-degree angle razor-sharp petals or "talons" that increase the wounding power of the bullet by stretching, cutting and tearing tissue and bone as it travels through the victim. . . . Although the bullet was originally developed for law enforcement agencies, it was marketed and available to the general public. In November 1993, following public outcry, Olin pulled the Black Talon from the public market and restricted its sales to law enforcement personnel. Colin Ferguson allegedly purchased the ammunition in 1993, before it was withdrawn from the market. . . .

To state a cause of action for a design defect, plaintiffs must allege that the bullet was unreasonably dangerous for its intended use. A defectively designed product is one which, at the time it leaves the seller's hands, is in a condition not reasonably contemplated by the ultimate consumer. This rule, however, is tempered by the realization that some products, for example knives, must by their very nature be dangerous in order to be functional. The very purpose of the Black Talon bullet is to kill or cause severe wounding. Here, plaintiffs concede that the Black Talons performed precisely as intended by the manufacturer and Colin Ferguson. Sadly it must be acknowledged that many products, however well-built or well-designed[,] may cause injury or death. Guns may kill; knives may maim; liquor may cause alcoholism; but the mere fact of injury does not entitle the person injured to recover[;] there must be something wrong with the product, and if nothing is wrong there will be no liability. . . .

Appellants . . . argue that under the risk/utility test analysis applied by New York courts, appellee should be held strictly liable because the risk of harm posed by the Black Talons outweighs the ammunition's utility. . . . The purpose of risk/utility

* 119 F.3d 148.

analysis is to determine whether the risk of injury might have been reduced or avoided if the manufacturer had used a feasible alternative design. However, the risk of injury to be balanced with the utility is a risk not intended as the primary function of the product. . . . There is no reason to search for an alternative safer design where the product's sole utility is to kill and maim. Accordingly, we hold that appellants have failed to state a cause of action under New York strict products liability law. . . .

The crux of appellants' negligence theory is that Olin negligently marketed and placed the Black Talon ammunition for sale to the general public. Appellants argue that because of the severe wounding power of the bullets, Olin should have restricted sales to law enforcement agencies, for whom the bullet was originally designed. They also argue that Olin should have known that their advertising, which highlighted the ripping and tearing characteristics of the bullet, would attract "many types of sadistic, unstable and criminal personalities." . . .

New York courts do not impose a legal duty on manufacturers to control the distribution of potentially dangerous products such as ammunition. Accordingly, although it may have been foreseeable by Olin that criminal misuse of the Black Talon bullets could occur, Olin is not legally liable for such misuse. . . .

It is the responsibility of courts in fixing the orbit of duty, to limit the legal consequences of wrongs to a controllable degree and to protect against crushing exposure to liability. To impose a duty on ammunition manufacturers to protect against criminal misuse of [their] product would likely force ammunition products—which legislatures have not proscribed, and which concededly are not defectively designed or manufactured and have some socially valuable uses—off the market due to the threat of limitless liability. . . .

Although appellants are the victims of a horrible tragedy, under New York law, they have failed to state a cause of action upon which relief can be granted—in sum, New York law does not afford them a remedy. . . .

Circuit Judge Calabresi, dissenting. . . .

Could a New York jury find that there was an undue risk of harm, if not in producing Black Talons, then in advertising them for use by (and selling them to) the general public? Put differently, could a jury find that the benefit gained by making Black Talons available to the public was outweighed by their potential harm. I believe that a reasonable jury could so find. . . .

The fact that the New York legislature has not chosen to forbid the distribution of Black Talons in no way alters the conclusion that the defendant may have been negligent in marketing them to the general public. There are all sorts of situations in which the general distribution of an object is legal, but the decision to market and sell it to certain persons is nonetheless negligent because it poses an undue risk of harm. When fireworks were legal, it was still negligent to market and sell them to children. Similarly, even in the absence of a statute, serving alcohol to intoxicated adults is negligent. . . . Selling tanks to the armed forces is fine; selling them to the general public is, I would think, clearly negligent. . . .

In the instant case, . . . a possible alternative design does exist. It consists of the elimination of the extra-destructive "talons." The proposed Restatement contains a remarkably relevant discussion:

> Several courts have suggested that the designs of some products are so manifestly unreasonable, in that they have low social utility and high degree of danger, that liability should attach even absent proof of a reasonable alternative design. In large part the problem is one of how the range of relevant alternative designs is described. For example, a toy gun that shoots hard rubber pellets with sufficient velocity to cause injury to children could be found to be defectively designed within the rule of § 2(b). Toy guns that do not produce injury would constitute reasonable alternatives to the dangerous toy. Thus, toy guns that project ping pong balls, soft gelatin pellets, or water might be found to be reasonable alternative designs to a toy gun that shoots hard pellets. However, if consideration is limited to toy guns that are capable of causing injury, then no reasonable alternative will, by hypothesis, be available. In that instance, the design feature that defines which alternatives are relevant—the capacity to injure—is precisely the feature on which the user places value and of which the plaintiff complains. If a court were to adopt this characterization of the product, it could conclude that liability should attach without proof of a reasonable alternative design. The court would condemn the product design as defective and not reasonably safe because the extremely high degree of danger posed by its use or consumption so substantially outweighs its negligible utility that no rational adult, fully aware of the relevant facts, would choose to use or consume the product.
>
> Third Restatement of Torts § 2 cmt. d.
>
> It is worth noting that courts and commentators have been wrestling with the questions of what is a relevant safer alternative design, and whether entire categories of products can be deemed defective in the absence of an alternative design, with increasing frequency in recent years. . . . The New York Court of Appeals has yet to confront the issue, and should be given the opportunity to do so here.

. . .

Tort claims against gun manufacturers and distributors have become even more difficult for plaintiffs since *McCarthy* was decided. In particular, the Protection of Lawful Commerce in Arms Act has immunized manufacturers from liability in many instances (see chapter 7). Notably, the tort liability rules that courts use to bar most claims against the firearms industry do not rely on the Second Amendment. They represent policy choices made by legislatures and judges.

Other types of regulation, especially at the state and local level, target gun owners and sellers, prohibiting certain types of sales and imposing background checks and other procedural requirements. The future of these regulations and others—such as laws prohibiting concealed carry of firearms—is uncertain following the Supreme Court's decision in *D.C. v. Heller* holding that the Second Amendment protects an individual's right to keep a loaded handgun in his home. Justice Stevens,

writing in dissent, argued the majority's holding was a departure from long-standing precedent.

*DISTRICT OF COLUMBIA v. HELLER**

Supreme Court of the United States
Decided June 26, 2008

Justice Scalia delivered the opinion of the Court. . . .

The District of Columbia generally prohibits the possession of handguns. It is a crime to carry an unregistered firearm, and the registration of handguns is prohibited. Wholly apart from that prohibition, no person may carry a handgun without a license, but the chief of police may issue licenses for 1-year periods. District of Columbia law also requires residents to keep their lawfully owned firearms, such as registered long guns, "unloaded and dissembled or bound by a trigger lock or similar device" unless they are located in a place of business or are being used for lawful recreational activities.

Respondent Dick Heller is a D.C. special police officer authorized to carry a handgun while on duty at the Thurgood Marshall Judiciary Building. He applied for a registration certificate for a handgun that he wished to keep at home, but the District refused. He thereafter filed a lawsuit . . . seeking, on Second Amendment grounds, to enjoin the city from enforcing the bar on the registration of handguns, the licensing requirement insofar as it prohibits the carrying of a firearm in the home without a license, and the trigger-lock requirement insofar as it prohibits the use of "functional firearms within the home." . . .

The Second Amendment provides: "A well regulated Militia, being necessary to the security of a free State, the right of the people to keep and bear Arms, shall not be infringed." In interpreting this text, we are guided by the principle that the Constitution was written to be understood by the voters; its words and phrases were used in their normal and ordinary as distinguished from technical meaning. Normal meaning may of course include an idiomatic meaning, but it excludes secret or technical meanings that would not have been known to ordinary citizens in the founding generation.

The two sides in this case have set out very different interpretations of the Amendment. Petitioners and today's dissenting Justices believe that it protects only the right to possess and carry a firearm in connection with militia service. Respondent argues that it protects an individual right to possess a firearm unconnected with service in a militia, and to use that arm for traditionally lawful purposes, such as self-defense within the home. . . .

The first salient feature of the operative clause is that it codifies a "right of the people." The unamended Constitution and the Bill of Rights use the phrase "right of the people" two other times, in the First Amendment's Assembly-and-Petition Clause and in the Fourth Amendment's Search-and-Seizure Clause. The Ninth Amendment uses very similar terminology ("The enumeration in the Constitution, of certain rights,

* 554 U.S. 570.

shall not be construed to deny or disparage others retained by the people"). All three of these instances unambiguously refer to individual rights, not "collective" rights, or rights that may be exercised only through participation in some corporate body.

Three provisions of the Constitution refer to "the people" in a context other than "rights"—the famous preamble ("We the people"), § 2 of Article I (providing that "the people" will choose members of the House), and the Tenth Amendment (providing that those powers not given the Federal Government remain with "the States" or "the people"). Those provisions arguably refer to "the people" acting collectively—but they deal with the exercise or reservation of powers, not rights. . . .

What is more, in all six other provisions of the Constitution that mention "the people," the term unambiguously refers to all members of the political community, not an unspecified subset. . . . This contrasts markedly with the phrase "the militia" in the prefatory clause[, which] consisted of a subset of "the people"—those who were male, able bodied, and within a certain age range. . . .

We move now from the holder of the right—"the people"—to the substance of the right: "to keep and bear Arms." Before addressing the verbs "keep" and "bear," we interpret their object: "Arms." . . . Some have made the argument, bordering on the frivolous, that only those arms in existence in the 18th century are protected by the Second Amendment. We do not interpret constitutional rights that way. Just as the First Amendment protects modern forms of communications and the Fourth Amendment applies to modern forms of search, the Second Amendment extends, prima facie, to all instruments that constitute bearable arms, even those that were not in existence at the time of the founding.

We turn to the phrases "keep arms" and "bear arms." . . . [T]he most natural reading of "keep Arms" in the Second Amendment is to "have weapons." . . . At the time of the founding, as now, to "bear" meant to "carry." . . . When used with "arms," however, the term has a meaning that refers to carrying for a particular purpose—confrontation. . . . Although the phrase implies that the carrying of the weapon is for the purpose of "offensive or defensive action," it in no way connotes participation in a structured military organization. . . .

The phrase "bear Arms" also had at the time of the founding an idiomatic meaning that was significantly different from its natural meaning: "to serve as a soldier, do military service, fight" or "to wage war." . . . But it *unequivocally* bore that idiomatic meaning only when followed by the preposition "against," which was in turn followed by the target of the hostilities. . . .

In any event, the meaning of "bear arms" that petitioners and Justice Stevens propose is *not even* the (sometimes) idiomatic meaning. Rather, they manufacture a hybrid definition, whereby "bear arms" connotes the actual carrying of arms (and therefore is not really an idiom) but only in the service of an organized militia. No dictionary has ever adopted that definition, and we have been apprised of no source that indicates that it carried that meaning at the time of the founding. . . .

Justice Stevens places great weight on James Madison's inclusion of a conscientious-objector clause in his original draft of the Second Amendment: "but no person religiously scrupulous of bearing arms, shall be compelled to render military service in person." He argues that this clause establishes that the drafters of the Second Amendment intended "bear Arms" to refer only to military service. It is always perilous to

derive the meaning of an adopted provision from another provision deleted in the drafting process. In any case, what Justice Stevens would conclude from the deleted provision does not follow. It was not meant to exempt from military service those who objected to going to war but had no scruples about personal gunfights. . . . Thus, the most natural interpretation of Madison's deleted text is that those opposed to carrying weapons for potential violent confrontation would not be "compelled to render military service," in which such carrying would be required. . . .

Putting all of these textual elements together, we find that they guarantee the individual right to possess and carry weapons in case of confrontation. This meaning is strongly confirmed by the historical background of the Second Amendment. . . . Between the Restoration and the Glorious Revolution, the Stuart Kings Charles II and James II succeeded in using select militias loyal to them to suppress political dissidents, in part by disarming their opponents. . . . These experiences caused Englishmen to be extremely wary of concentrated military forces run by the state and to be jealous of their arms. They accordingly obtained an assurance from William and Mary, in the Declaration of Rights (which was codified as the English Bill of Rights), that Protestants would never be disarmed: "That the Subjects which are Protestants, may have Arms for their Defence suitable to their Conditions, and as allowed by Law." This right has long been understood to be the predecessor to our Second Amendment. It was clearly an individual right, having nothing whatever to do with service in a militia. . . . And, of course, what the Stuarts had tried to do to their political enemies, George III had tried to do to the colonists. In the tumultuous decades of the 1760's and 1770's, the Crown began to disarm the inhabitants of the most rebellious areas. That provoked polemical reactions by Americans invoking their rights as Englishmen to keep arms. . . .

The prefatory clause reads: "A well regulated Militia, being necessary to the security of a free State. . . ." In *United States v. Miller,* 307 U.S. 174, 179 (1939), we explained that "the Militia comprised all males physically capable of acting in concert for the common defense." That definition comports with founding-era sources. . . . Petitioners take a seemingly narrower view of the militia, stating that "[m]ilitias are the state- and congressionally-regulated military forces described in the Militia Clauses (art. I, § 8, cls. 15–16)." Although we agree with petitioners' interpretive assumption that "militia" means the same thing in Article I and the Second Amendment, we believe that petitioners identify the wrong thing, namely, the organized militia. . . . [T]he ordinary definition of the militia as all able-bodied men. . . . Finally, the adjective "well-regulated" implies nothing more than the imposition of proper discipline and training.

The phrase "security of a free State" meant "security of a free polity," not security of each of the several States as the dissent [argues]. . . . It is true that the term "State" elsewhere in the Constitution refers to individual States, but the phrase "security of a free State" and close variations seem to have been terms of art in 18th-century political discourse, meaning a "'free country'" or free polity. . . .

We reach the question, then: Does the preface fit with an operative clause that creates an individual right to keep and bear arms? It fits perfectly, once one knows the history that the founding generation knew and that we have described above. That history showed that the way tyrants had eliminated a militia consisting of all the

able-bodied men was not by banning the militia but simply by taking away the people's arms, enabling a select militia or standing army to suppress political opponents. . . .

Justice Stevens places overwhelming reliance upon this Court's decision in *Miller,* 307 U.S. 174. "[H]undreds of judges," [Stevens writes,] "have relied on the view of the Amendment we endorsed there," and "[e]ven if the textual and historical arguments on both sides of the issue were evenly balanced, respect for the well-settled views of all of our predecessors on this Court, and for the rule of law itself . . . would prevent most jurists from endorsing such a dramatic upheaval in the law." And what is, according to Justice Stevens, the holding of *Miller* that demands such obeisance? That the Second Amendment "protects the right to keep and bear arms for certain military purposes, but that it does not curtail the Legislature's power to regulate the nonmilitary use and ownership of weapons."

Nothing so clearly demonstrates the weakness of Justice Stevens' case. *Miller* did not hold that and cannot possibly be read to have held that. The judgment in the case upheld against a Second Amendment challenge two men's federal indictment for transporting an unregistered short-barreled shotgun in interstate commerce, in violation of the National Firearms Act. It is entirely clear that the Court's basis for saying that the Second Amendment did not apply was *not* that the defendants were "bear[ing] arms" not "for . . . military purposes" but for "nonmilitary use." Rather, it was that the *type of weapon at issue* was not eligible for Second Amendment protection: "In the absence of any evidence tending to show that the possession or use of a [short-barreled shotgun] at this time has some reasonable relationship to the preservation or efficiency of a well regulated militia, we cannot say that the Second Amendment guarantees the right to keep and bear *such an instrument*." 307 U.S., at 178 (emphasis added). "Certainly," the Court continued, "it is not within judicial notice that this weapon is any part of the ordinary military equipment or that its use could contribute to the common defense." *Ibid.* . . .

This holding is not only consistent with, but positively suggests, that the Second Amendment confers an individual right to keep and bear arms (though only arms that "have some reasonable relationship to the preservation or efficiency of a well regulated militia"). Had the Court believed that the Second Amendment protects only those serving in the militia, it would have been odd to examine the character of the weapon rather than simply note that the two crooks were not militiamen. . . .

We may as well consider at this point (for we will have to consider eventually) *what* types of weapons *Miller* permits. Read in isolation, *Miller*'s phrase "part of ordinary military equipment" could mean that only those weapons useful in warfare are protected. That would be a startling reading of the opinion, since it would mean that the National Firearms Act's restrictions on machineguns (not challenged in *Miller*) might be unconstitutional, machineguns being useful in warfare in 1939. . . . The traditional militia was formed from a pool of men bringing arms "in common use at the time" for lawful purposes like self-defense. . . . We therefore read *Miller* to say only that the Second Amendment does not protect those weapons not typically possessed by law-abiding citizens for lawful purposes, such as short-barreled shotguns. . . .

It should be unsurprising that such a significant matter has been for so long judicially unresolved. For most of our history, the Bill of Rights was not thought applicable

to the States, and the Federal Government did not significantly regulate the possession of firearms by law-abiding citizens. . . . It is demonstrably not true that, as Justice Stevens claims, "for most of our history, the invalidity of Second-Amendment-based objections to firearms regulations has been well settled and uncontroversial." For most of our history the question did not present itself.

Like most rights, the right secured by the Second Amendment is not unlimited. . . . [C]ases, commentators and courts [have] routinely explained that the right was not a right to keep and carry any weapon whatsoever in any manner whatsoever and for whatever purpose. . . . Although we do not undertake an exhaustive historical analysis today of the full scope of the Second Amendment, nothing in our opinion should be taken to cast doubt on longstanding prohibitions on the possession of firearms by felons and the mentally ill, or laws forbidding the carrying of firearms in sensitive places such as schools and government buildings, or laws imposing conditions and qualifications on the commercial sale of arms.

We also recognize another important limitation on the right to keep and carry arms. *Miller* said, as we have explained, that the sorts of weapons protected were those "in common use at the time." 307 U.S., at 179. We think that limitation is fairly supported by the historical tradition of prohibiting the carrying of "dangerous and unusual weapons." . . .

It may be objected that if weapons that are most useful in military service—M-16 rifles and the like—may be banned, then the Second Amendment right is completely detached from the prefatory clause. But as we have said, the conception of the militia at the time of the Second Amendment's ratification was the body of all citizens capable of military service, who would bring the sorts of lawful weapons that they possessed at home to militia duty. It may well be true today that a militia, to be as effective as militias in the 18th century, would require sophisticated arms that are highly unusual in society at large. Indeed, it may be true that no amount of small arms could be useful against modern-day bombers and tanks. But the fact that modern developments have limited the degree of fit between the prefatory clause and the protected right cannot change our interpretation of the right.

We turn finally to the law at issue here. As we have said, the law totally bans handgun possession in the home. It also requires that any lawful firearm in the home be disassembled or bound by a trigger lock at all times, rendering it inoperable.

As the quotations earlier in this opinion demonstrate, the inherent right of self-defense has been central to the Second Amendment right. The handgun ban amounts to a prohibition of an entire class of "arms" that is overwhelmingly chosen by American society for that lawful purpose. The prohibition extends, moreover, to the home, where the need for defense of self, family, and property is most acute. Under any of the standards of scrutiny that we have applied to enumerated constitutional rights, banning from the home the most preferred firearm in the nation to "keep" and use for protection of one's home and family would fail constitutional muster. . . .

We must also address the District's requirement (as applied to respondent's handgun) that firearms in the home be rendered and kept inoperable at all times. This makes it impossible for citizens to use them for the core lawful purpose of self-defense and is hence unconstitutional. . . .

Apart from his challenge to the handgun ban and the trigger-lock requirement respondent asked the District Court to enjoin petitioners from enforcing the separate licensing requirement "in such a manner as to forbid the carrying of a firearm within one's home or possessed land without a license." . . . Before this Court petitioners have stated that "if the handgun ban is struck down and respondent registers a handgun, he could obtain a license, assuming he is not otherwise disqualified," by which they apparently mean if he is not a felon and is not insane. Respondent conceded at oral argument that he does not "have a problem with . . . licensing" and that the District's law is permissible so long as it is "not enforced in an arbitrary and capricious manner." We therefore assume that petitioners' issuance of a license will satisfy respondent's prayer for relief and do not address the licensing requirement.

Justice Breyer has devoted most of his separate dissent to the handgun ban. He says that, even assuming the Second Amendment is a personal guarantee of the right to bear arms, the District's prohibition is valid. He first tries to establish this by founding-era historical precedent, pointing to various restrictive laws in the colonial period. These demonstrate, in his view, that the District's law "imposes a burden upon gun owners that seems proportionately no greater than restrictions in existence at the time the Second Amendment was adopted." Of the laws he cites, only one offers even marginal support for his assertion. A 1783 Massachusetts law forbade the residents of Boston to "take into" or "receive into" "any Dwelling-House, Stable, Barn, Out-house, Ware-house, Store, Shop or other Building" loaded firearms, and permitted the seizure of any loaded firearms that "shall be found" there. That statute's text and its prologue, which makes clear that the purpose of the prohibition was to eliminate the danger to firefighters posed by the "depositing of loaded Arms" in buildings, give reason to doubt that colonial Boston authorities would have enforced that general prohibition against someone who temporarily loaded a firearm to confront an intruder (despite the law's application in that case). . . . Justice Breyer points to other founding-era laws that he says "restricted the firing of guns within the city limits to at least some degree" in Boston, Philadelphia, and New York. Those laws provide no support for the severe restriction in the present case. . . .

Justice Breyer moves on to make a broad jurisprudential point: He criticizes us for declining to establish a level of scrutiny for evaluating Second Amendment restrictions. He proposes, explicitly at least, none of the traditionally expressed levels (strict scrutiny, intermediate scrutiny, rational basis), but rather a judge-empowering "interest-balancing inquiry" that "asks whether the statute burdens a protected interest in a way or to an extent that is out of proportion to the statute's salutary effects upon other important governmental interests." After an exhaustive discussion of the arguments for and against gun control, Justice Breyer arrives at his interest-balanced answer: Because handgun violence is a problem, because the law is limited to an urban area, and because there were somewhat similar restrictions in the founding period . . . [the handgun ban is constitutional]. QED.

We know of no other enumerated constitutional right whose core protection has been subjected to a freestanding "interest-balancing" approach. The very enumeration of the right takes out of the hands of government—even the Third Branch of Government—the power to decide on a case-by-case basis whether the right is *really worth* insisting upon. A constitutional guarantee subject to future judges' assessments of its usefulness is no constitutional guarantee at all. . . .

> Justice Breyer chides us for leaving so many applications of the right to keep and bear arms in doubt, and for not providing extensive historical justification for those regulations of the right that we describe as permissible. But since this case represents this Court's first in-depth examination of the Second Amendment, one should not expect it to clarify the entire field. . . .
>
> We are aware of the problem of handgun violence in this country. . . . The Constitution leaves the District of Columbia a variety of tools for combating that problem, including some measures regulating handguns. . . . But the enshrinement of constitutional rights necessarily takes certain policy choices off the table.

. . .

Because the District of Columbia is a subsidiary of the federal government, *Heller* did not present the question of whether the Second Amendment's right to bear arms was implicit in the concept of ordered liberty such that it is incorporated into the Fourteenth Amendment's Due Process Clause (see chapter 4). Two years after *Heller,* the Supreme Court answered this question in the affirmative, applying the Second Amendment to the states in *McDonald v. Chicago,* 561 U.S. 742. Many open questions remain under the Second Amendment, including whether the individually held right to maintain a gun in one's home for self-defense recognized in *Heller* and *MacDonald* extends to a right to carry a gun outside the home. In 2017, over vehement objections from Justices Thomas and Gorsuch, the Supreme Court declined to take up a case that might have resolved an ongoing split among the federal circuit courts on this question.

As in other areas of injury prevention, efforts to prevent firearm injuries focus on altering the vector of injury (e.g., limiting access to bullets designed to inflict maximum damage) and the physical and social environment (e.g., limiting the density of gun retailers and requiring a cooling-off period for purchases, making it harder to obtain a firearm in the heat of the moment). As restrictions on access to guns and ammunition have faced greater legal obstacles, experts have placed greater emphasis on the importance of safe firearm storage, especially in homes with children.

The American Medical Association and other groups encourage physicians to discuss gun safety with parents, just as they discuss household chemicals, car seats, bike helmets, and other risks. In 2011, Florida prohibited physicians from asking patients about gun ownership. In *Wollschlaeger v. Florida,* a three-judge panel of the Eleventh Circuit issued three successive opinions rejecting a physician's First Amendment challenge to the law before granting his petition for the court to rehear the case en banc.

*WOLLSCHLAEGER V. FLORIDA**

United States Court of Appeals for the Eleventh Circuit
February 17, 2017

. . . Shortly after [Florida's Firearms Owners' Privacy Act (FOPA)] was enacted in 2011, a number of doctors and medical organizations filed suit in federal court against various Florida officials, challenging some of the Act's provisions as unconstitutional. . . . [T]he district court held that FOPA's record-keeping, inquiry, anti-discrimination, and anti-harassment provisions violated the First and Fourteenth Amendments, and permanently enjoined their enforcement. The state officials appealed, and a divided panel of this court issued three opinions—each using a different First Amendment standard of review—upholding the challenged provisions of FOPA. We voted to rehear the case en banc. . . .

[A]pplying heightened scrutiny as articulated in *Sorrell v. IMS Health, Inc.*, 564 U.S. 552 (2011), we agree with the district court that FOPA's content-based restrictions—the record-keeping, inquiry, and anti-harassment provisions—violate the First Amendment as it applies to the states. And because these three provisions do not survive heightened scrutiny under *Sorrell,* we need not address whether strict scrutiny should apply to them. We also conclude, this time contrary to the district court, that FOPA's anti-discrimination provision—as construed to apply to certain conduct by doctors and medical professionals—is not unconstitutional. . . .

As part of their medical practices, some doctors routinely ask patients about various potential health and safety risks, including household chemicals, drugs, alcohol, tobacco, swimming pools, and firearms. A number of leading medical organizations, and some of their members, believe that unsecured firearms in the home increase risks of injury, especially for minors and those suffering from depression or dementia.

In an effort to prevent and reduce firearm-related deaths and injuries, particularly to children, the American Medical Association "encourages its members to inquire as to the presence of household firearms as a part of childproofing the home and to educate patients to the dangers of firearms to children." [A policy] enacted by the AMA in 1989 . . . "supports increasing efforts to reduce pediatric firearm morbidity and mortality by encouraging its members to (a) inquire as to the presence of household firearms as a part of childproofing the home; (b) educate patients to the dangers of firearms to children; (c) encourage patients to educate their children and neighbors as to the dangers of firearms; and (d) routinely remind patients to obtain firearm safety locks, to store firearms under lock and key, and to store ammunition separately from firearms[.]"

The American Academy of Pediatrics and the American Academy of Family Physicians—as well as their Florida chapters—follow a similar approach. They "recommend that pediatricians incorporate questions about firearms into the patient history process and . . . have policies stating that firearm safety education to patients is a necessity."

In 2011, the Florida Legislature learned that a pediatrician in Ocala had reportedly told a mother that she would have to find a new physician for her child due to her

* 848 F.3d 1293.

refusal to disclose information about firearm ownership in the family home. The pediatrician explained that he asked all of his patients the same questions "in an effort to provide safety advice in the event there was a firearm in the home." He also said that he asked other similar questions, such as whether there was a pool in the home, to give safety advice to parents. The mother felt that the question "invaded her privacy," but the record is silent as to whether she ultimately answered the questions posed to her about firearms.

The Florida Legislature also learned, anecdotally, about five other incidents in which patients complained that doctors and medical professionals had asked unwelcome questions or made purportedly improper comments regarding their ownership of firearms. A state representative said that his daughter's pediatrician inquired if he owned a firearm, and then asked him to remove the firearm from the home. An email described how a mother "was separated from her children while medical personnel . . . interrogated" them about firearm ownership and put information about such ownership in their medical records. One doctor refused to treat a child because he wanted to know if there were firearms in the home. . . .

A representative of the National Rifle Association reported that a child would not be examined if the parent refused to answer questions about firearms in the home. That same representative testified at a subcommittee hearing that "[q]uestioning patients about gun ownership to satisfy a political agenda . . . needs to stop."

Based on these six anecdotes, the Florida Legislature enacted FOPA. . . . The record-keeping provision states that a doctor or medical professional "may not intentionally enter any disclosed information concerning firearm ownership into [a] patient's medical record" if he or she "knows that such information is not relevant to the patient's medical care or safety, or the safety of others." The inquiry provision states that a doctor or medical professional "should refrain from making a written inquiry or asking questions concerning the ownership of a firearm or ammunition by the patient or by a family member of the patient, or the presence of a firearm in a private home" unless he or she in "good faith believes that this information is relevant to the patient's medical care or safety, or the safety of others[.]" The anti-discrimination provision states that a doctor or medical professional "may not discriminate against a patient based solely" on the patient's ownership and possession of a firearm. The anti-harassment provision states that a doctor or medical professional "should refrain from unnecessarily harassing a patient about firearm ownership during an examination."

Through its use of a relevancy standard, FOPA's record-keeping and inquiry provisions prevent doctors and medical professionals from asking *all* patients . . . whether they own firearms or have firearms in their homes, or from recording answers to such questions. In the panel's view, such inquiries (and record-keeping) are appropriate only if the doctor or medical professional has "some particularized information about the individual patient, for example, that the patient is suicidal or has violent tendencies[.]" So a doctor or medical professional violates FOPA if he or she gives all new patients an intake questionnaire which asks about firearms in the home.

FOPA provides that violations of the record-keeping and inquiry provisions, among others, "constitute grounds for disciplinary action" by Florida's Board of Medicine. Another Florida statute, as amended by FOPA, states that "violating *any* of the provisions" of FOPA "*shall* constitute grounds for which . . . disciplinary actions . . . may be taken." . . .

It is undisputed that the individual plaintiffs, as doctors, wish to say and do what they believe FOPA prevents them from saying and doing. They filed affidavits in the district court explaining that they routinely ask all patients (or their parents) about firearm ownership in order to assess safety risks, and some believe that "information about firearm safety is always relevant to a patient's preventive care." Due to the challenged provisions of FOPA, and in order to avoid discipline by the Board of Medicine, these doctors are engaged in self-censorship. Against their professional judgment, they are no longer asking patients questions related to firearm ownership, no longer using questionnaires with such questions, and/or no longer maintaining written records of consultations with patients about firearms. . . .

The record-keeping, inquiry, and anti-harassment provisions of FOPA are speaker-focused and content-based restrictions. They apply only to the speech of doctors and medical professionals, and only on the topic of firearm ownership. Even if the restrictions on speech can be seen as viewpoint neutral—a point we need not address—that does not mean that they are content-neutral. "[A] speech regulation targeted at specific subject matter is content based even if it does not discriminate among viewpoints within that subject matter." *Reed* [*v. Town of Gilbert, Ariz.*, 135 S.Ct. 2218, 2230 (2015)]. "Innocent motives," moreover, "do not eliminate the danger of censorship presented by a facially content-based statute, as future government officials may one day wield such statutes to suppress disfavored speech." *Id.* at 2229. . . .

According to the state officials, the First Amendment is not implicated because any effect on speech is merely incidental to the regulation of professional conduct. . . . [W]e do not find the argument persuasive. We concur with the Third Circuit's assessment that the "enterprise of labeling certain verbal or written communications 'speech' and others 'conduct' is unprincipled and susceptible to manipulation." *King* [*v. Governor of New Jersey,* 767 F.3d 216, 228 (3d Cir. 2014)].

The Ninth Circuit [adopted the view that when a person is exercising judgment with respect to a particular client he is engaging in the practice of a profession and his speech is incidental to the conduct of the profession such that his First Amendment interests are diminished] in a case upholding a California law prohibiting mental health practitioners from providing sexual orientation change efforts (SOCE) therapy—meant to change a person's sexual orientation from homosexual to heterosexual—to children under the age of 18. *See Pickup v. Brown,* 740 F.3d 1208, 1225–29 (9th Cir. 2013). Importantly, however, the law in *Pickup* . . . did not restrict what the practitioner could say or recommend to a patient or client. *See id.* at 1223 (explaining that the California law did not prevent mental health providers "from expressing their views to patients, whether children or adults, about SOCE, homosexuality, or any other topic" or from "recommending SOCE to patients, whether children or adults"). The *Pickup* panel, therefore, concluded that the law "regulate[d] conduct" even though it covered the verbal aspects of SOCE therapy. *See id.* at 1229.

There are serious doubts about whether *Pickup* was correctly decided. As noted earlier, characterizing speech as conduct is a dubious constitutional enterprise. In any event, *Pickup* is distinguishable on its facts and does not speak to the issues before us. To the extent that *Pickup* provides any relevant insight, it recognizes that "doctor-patient communications *about* medical treatment receive substantial First Amendment protection," *id.* at 1227, and is therefore consistent with our approach.

A more analogous—and more persuasive—Ninth Circuit case is *Conant v. Walters,* 309 F.3d 629 (9th Cir. 2002), which struck down, on First Amendment grounds, a federal policy which threatened doctors with revocation of their DEA prescription authority if they recommended the medicinal use of marijuana to their patients. The Ninth Circuit recognized that doctor-patient speech (even if labeled professional speech) is entitled to First Amendment protection, and invalidated the policy because it was content- and viewpoint-based and did not have the requisite "narrow specificity." *See id.* at 637–39. In so doing, the Ninth Circuit rejected the government's paternalistic assertion that the policy was valid because patients might otherwise make bad decisions. *See id.* at 637. . . .

In sum, we do not think it is appropriate to subject content-based restrictions on speech by those engaged in a certain profession to mere rational basis review. If rationality were the standard, the government could—based on its disagreement with the message being conveyed—easily tell architects that they cannot propose buildings in the style of I. M. Pei, or general contractors that they cannot suggest the use of cheaper foreign steel in construction projects, or accountants that they cannot discuss legal tax avoidance techniques, and so on and so on.

We now turn to FOPA's record-keeping, inquiry, and anti-harassment provisions. Because these provisions fail to satisfy heightened scrutiny under *Sorrell,* they obviously would not withstand strict scrutiny. We therefore need not decide whether strict scrutiny should apply.

Under *Sorrell,* the state officials "must show at least that the [provisions] directly advance[] a substantial governmental interest and that the measure[s] [are] drawn to achieve that interest. There must be a 'fit between the legislature's ends and the means chosen to accomplish those ends.'" 564 U.S. at 572. And "[u]nlike rational basis review, th[is] . . . standard does not permit us to supplant the precise interests put forward by the State with other suppositions." *Edenfield v. Fane,* 507 U.S. 761, 768 (1993). . . .

The first interest asserted by the state officials is protecting, from "private encumbrances," the Second Amendment right of Floridians to own and bear firearms. We accept that the protection of Second Amendment rights is a substantial government interest, but nevertheless conclude that FOPA's record-keeping, inquiry, and anti-harassment provisions fail to satisfy heightened scrutiny.

The first problem is that there was no evidence whatsoever before the Florida Legislature that any doctors or medical professionals have taken away patients' firearms or otherwise infringed on patients' Second Amendment rights. This evidentiary void is not surprising because doctors and medical professionals, as private actors, do not have any authority (legal or otherwise) to restrict the ownership or possession of firearms by patients (or by anyone else for that matter). The Second Amendment right to own and possess firearms does not preclude questions about, commentary on, or criticism for the exercise of that right. So . . . there is no actual conflict between the First Amendment rights of doctors and medical professionals and the Second Amendment rights of patients that justifies FOPA's speaker-focused and content-based restrictions on speech.

We note that since 1989 Florida has made it a misdemeanor to fail to secure firearms which are obtained or possessed by minors without supervision and the general

questioning of patients about firearm ownership is consistent with this state policy on firearm safety. The Florida Legislature has recognized that "a tragically large number of Florida children have been accidentally killed or seriously injured by negligently stored firearms; that placing firearms within the reach or easy access of children is irresponsible, encourages such accidents, and should be prohibited; and that legislative action is necessary to protect the safety of our children."

Even if there were some possible conflict between the First Amendment rights of doctors and medical professionals and the Second Amendment rights of patients, the record-keeping, inquiry, and anti-harassment provisions do "not advance [the legislative goals] in a permissible way." *Sorrell,* 564 U.S. at 577. The record here demonstrates that some patients do not object to questions and advice about firearms and firearm safety, and some even express gratitude for their doctors' discussion of the topic. The record-keeping, inquiry, and anti-harassment provisions do not provide for such patients a means by which they can hear from their doctors on the topic of firearms and firearm safety, and that is problematic under heightened scrutiny.

In "the fields of medicine and public health . . . information can save lives." *Sorrell,* 564 U.S. at 566. Doctors, therefore, "must be able to speak frankly and openly to patients." *Conant,* 309 F.3d at 636. Florida may generally believe that doctors and medical professionals should not ask about, nor express views hostile to, firearm ownership, but it "may not burden the speech of others in order to tilt public debate in a preferred direction." *Sorrell,* 564 U.S. at 578–79.

The second interest, say the state officials, is the protection of patient privacy, i.e., keeping private facts away from the public eye. We recognize that protection of individual privacy is a substantial government interest, but that is not enough to sustain the three provisions at issue given other privacy protections in Florida law and the record before us.

One of the FOPA provisions that has not been challenged states in relevant part that patients "may decline to answer or provide any information regarding ownership of a firearm . . . or the presence of a firearm in the domicile of the patient or a family member of the patient." So any patients who have privacy concerns about information concerning their firearm ownership can simply refuse to answer questions on the topic. . . .

Injuries are the leading cause of death and morbidity among children older than one year, adolescents, and young adults. As a result, the American Medical Association and the American Academy of Pediatrics each recommend that doctors and pediatricians routinely ask patients about firearm ownership, and educate them about the dangers posed to children by firearms that are not safely secured. These policies, however, do not justify FOPA's speaker-focused and content-based restrictions on speech. There is no claim, much less any evidence, that routine questions to patients about the ownership of firearms are medically inappropriate, ethically problematic, or practically ineffective. Nor is there any contention (or, again, any evidence) that blanket questioning on the topic of firearm ownership is leading to bad, unsound, or dangerous medical advice. . . .

The anti-discrimination provision is of a slightly different caliber, as it prohibits discrimination "against a patient based solely" on his or her ownership and possession of a firearm. [This provision] does not, on its face, implicate the spoken or written word. . . .

> To discriminate generally means to treat differently and here we can uphold FOPA's anti-discrimination provision by construing it to apply to non-expressive conduct such as failing to return messages, charging more for the same services, declining reasonable appointment times, not providing test results on a timely basis, or delaying treatment because a patient (or a parent of a patient) owns firearms. When [the anti-discrimination provision] is limited in this way, there is no First Amendment problem. . . .

. . .

Wollschlaeger illustrates the complex relationship between public health and First Amendment protection for freedom of expression. By protecting the free speech rights of physicians in this case (and others on matters regarding reproductive health), courts protect patients' access to information about how to keep themselves and their family members safe and healthy. In other cases (such as those upholding state regulations prohibiting harmful psychotherapy practices that purport to convert the patient's sexual orientation) imposing evidence-based restrictions on the practices of health care providers may be necessary to protect the public's health.

DRUG OVERDOSE

Health authorities are alarmed by skyrocketing rates of opioid overdose since the turn of the century. Many trace the rise to aggressive marketing of prescription opioids for chronic pain, which resulted in oversupply and diversion to recreational users. As prescription opioids have become harder to obtain, some addicted users have switched to heroin. In turn, heroin may be mixed with (or even replaced by) fentanyl, a powerful drug used for surgical anesthesia, which masks the dilution of heroin and increases the risk of overdose.

Public health experts classify drug overdoses as poisonings, which are considered to be injuries. Distinguishing between intentional and unintentional overdose can be difficult, but many public health interventions are equally applicable to either scenario. Rather than focusing on punishing illicit drug users or education programs that urge individuals to abstain, public health takes a broader view. Interventions include regulation of drug manufacturers and health care professionals, incentives to adopt safer prescribing practices, and deregulation and public spending to facilitate access to naloxone (a drug that can reverse the effects of opioid overdose if administered quickly) and medication-assisted treatment.

Surveillance of drug prescriptions is vitally important to overdose prevention. Prescription drug monitoring programs (PDMPs) established in all but one state allow prescribers and health authorities to track patient

prescriptions, combatting doctor shopping. But information gathered for public health purposes may be of interest to others as well. When law enforcement officers seek test results and other information about at-risk patients for the purposes of criminal prosecution, they generally must obtain a search warrant. In some cases, health authorities seek to secure personal health information from police intrusion. In *Oregon Prescription Drug Management Program v. DEA*, 860 F.3d 1228 (9th Cir. 2017), for example, state authorities successfully obtained a court order declaring that they need not grant federal Drug Enforcement Authority agents access to the database without a warrant. In the case that follows, however, a hospital run by a state university collaborated with law enforcement to identify and punish patients who tested positive for illicit drugs. The program exemplifies the traditional, punitive approach to substance-use disorders that is now disfavored by most public health experts.

*FERGUSON V. CITY OF CHARLESTON**

Supreme Court of the United States
Decided March 21, 2001

Justice Stevens delivered the opinion of the Court.

In this case, we must decide whether a state hospital's performance of a diagnostic test to obtain evidence of a patient's criminal conduct for law enforcement purposes is an unreasonable search if the patient has not consented to the procedure. More narrowly, the question is whether the interest in using the threat of criminal sanctions to deter pregnant women from using cocaine can justify a departure from the general rule that an official nonconsensual search is unconstitutional if not authorized by a valid warrant.

In the fall of 1988, staff members at the public hospital operated in the city of Charleston by the Medical University of South Carolina (MUSC) became concerned about an apparent increase in the use of cocaine by patients who were receiving prenatal treatment. In response to this perceived increase, as of April 1989, MUSC began to order drug screens to be performed on urine samples from maternity patients who were suspected of using cocaine. If a patient tested positive, she was then referred by MUSC staff to the county substance abuse commission for counseling and treatment. However, despite the referrals, the incidence of cocaine use among the patients at MUSC did not appear to change.

Some four months later, Nurse Shirley Brown, the case manager for the MUSC obstetrics department, heard a news broadcast reporting that the police in Greenville, South Carolina, were arresting pregnant users of cocaine on the theory that such use harmed the fetus and was therefore child abuse. Nurse Brown discussed the story with MUSC's general counsel, Joseph C. Good, Jr., who then contacted Charleston Solicitor

* 532 U.S. 67.

Charles Condon in order to offer MUSC's cooperation in prosecuting mothers whose children tested positive for drugs at birth. . . .

The task force that Condon formed included representatives of MUSC, the police, the County Substance Abuse Commission and the Department of Social Services. Their deliberations led to MUSC's adoption of a 12-page document entitled "POLICY M-7," dealing with the subject of "Management of Drug Abuse During Pregnancy." . . .

The first section, entitled the "Identification of Drug Abusers," provided that a patient should be tested for cocaine through a urine drug screen if she met one or more of nine criteria. It also stated that a chain of custody should be followed when obtaining and testing urine samples, presumably to make sure that the results could be used in subsequent criminal proceedings. The policy also provided for education and referral to a substance abuse clinic for patients who tested positive. Most important, it added the threat of law enforcement intervention that "provided the necessary 'leverage' to make the policy effective." That threat was, as respondents candidly acknowledge, essential to the program's success in getting women into treatment and keeping them there.

In 1990 . . . the policy was modified at the behest of the solicitor's office to give the patient who tested positive during labor, like the patient who tested positive during a prenatal care visit, an opportunity to avoid arrest by consenting to substance abuse treatment.

If the pregnancy was 27 weeks or less, the patient was to be charged with simple possession. If it was 28 weeks or more, she was to be charged with possession and distribution to a person under the age of 18—in this case, the fetus. If she delivered "while testing positive for illegal drugs," she was also to be charged with unlawful neglect of a child. Under the policy, the police were instructed to interrogate the arrestee in order "to ascertain the identity of the subject who provided illegal drugs to the suspect." Other than the provisions describing the substance abuse treatment to be offered to women who tested positive, the policy made no mention of any change in the prenatal care of such patients, nor did it prescribe any special treatment for the newborns.

Petitioners are 10 women who received obstetrical care at MUSC and who were arrested after testing positive for cocaine. [They filed this suit challenging the policy's validity on the theory that warrantless and nonconsensual drug tests conducted for criminal investigatory purposes were unconstitutional searches]. Respondents include the city of Charleston, law enforcement officials who helped develop and enforce the policy, and Representatives of MUSC[, a state hospital whose staff are government actors. Respondents argued that the searches were reasonable under the "special needs" doctrine, even absent consent, because they were justified by special non-law-enforcement purposes.]

On the understanding "that MUSC personnel conducted the urine drug screens for medical purposes wholly independent of an intent to aid law enforcement efforts," the appellate court concluded that the interest in curtailing the pregnancy complications and medical costs associated with maternal cocaine use outweighed . . . a minimal intrusion on the privacy of the patients. . . .

We granted certiorari to review the appellate court's holding on the "special needs" issue. [We] assume for purposes of our decision—as did the Court of Appeals—that the searches were conducted without the informed consent of the patients. . . .

Because the hospital seeks to justify its authority to conduct drug tests and to turn the results over to law enforcement agents without the knowledge or consent of the

patients, this case differs from the four previous cases in which we have considered whether comparable drug tests "fit within the closely guarded category of constitutionally permissible suspicionless searches." *Chandler v. Miller,* 520 U.S. 305, 309 (1997). . . . [In previous cases upholding drug tests for railway employees involved in train accidents, Customs Service employees seeking promotion to sensitive positions, and high school students participating in interscholastic sports,] we employed a balancing test that weighed the intrusion on the individual's interest in privacy against the "special needs" that supported the program. As an initial matter, we note that the invasion of privacy in this case is far more substantial than in those cases. . . . The reasonable expectation of privacy enjoyed by the typical patient undergoing diagnostic tests in a hospital is that the results of those tests will not be shared with nonmedical personnel without her consent. In none of our prior cases was there any intrusion upon that kind of expectation.

The critical difference between those [previous] drug-testing cases and this one, however, lies in the nature of the "special need" asserted as justification for the warrantless searches. In each of those earlier cases, the "special need" that was advanced as a justification for the absence of a warrant or individualized suspicion was one divorced from the State's general interest in law enforcement. . . . In this case, however, the central and indispensable feature of the policy from its inception was the use of law enforcement to coerce the patients into substance abuse treatment.

Respondents argue in essence that their ultimate purpose—namely, protecting the health of both mother and child—is a beneficent one. . . . In [previous cases,] however, we did not simply accept the State's invocation of a "special need." Instead, we carried out a "close review" of the scheme at issue before concluding that the need in question was not "special," as that term has been defined in our cases. In this case, a review of the M-7 policy plainly reveals that the purpose actually served by the MUSC searches "is ultimately indistinguishable from the general interest in crime control." . . .

While the ultimate goal of the program may well have been to get the women in question into substance abuse treatment and off of drugs, the immediate objective of the searches was to generate evidence for law enforcement purposes in order to reach that goal. . . . Because law enforcement involvement always serves some broader social purpose or objective, under respondents' view, virtually any nonconsensual suspicionless search could be immunized under the special needs doctrine by defining the search solely in terms of its ultimate, rather than immediate, purpose. Such an approach is inconsistent with the Fourth Amendment. . . .

Justice Scalia, dissenting. . . .

[I]t is not the function of this Court—at least not in Fourth Amendment cases—to weigh petitioners' privacy interest against the State's interest in meeting the crisis of "crack babies" that developed in the late 1980's. I cannot refrain from observing, however, that the outcome of a wise weighing of those interests is by no means clear. The initial goal of the doctors and nurses who conducted cocaine testing in this case was to refer pregnant drug addicts to treatment centers, and to prepare for necessary treatment of their possibly affected children. When the doctors and nurses agreed to the program providing test results to the police, they did so because (in addition to the fact that child abuse was required by law to be reported) they wanted to use the sanction of arrest as a strong incentive for their addicted patients to undertake drug-

addiction treatment. And the police themselves used it for that benign purpose, as is shown by the fact that only 30 of 253 women testing positive for cocaine were ever arrested, and only 2 of those prosecuted. It would not be unreasonable to conclude that today's judgment, authorizing the assessment of damages against the county solicitor and individual doctors and nurses who participated in the program, proves once again that no good deed goes unpunished.

. . .

Commentators have noted the contrast between how lawmakers responded to the crack cocaine epidemic of the 1980s and how they are currently addressing the opioid epidemic. In a video essay from 2016 for *PBS NewsHour,* legal scholar Ekow Yankah expressed the hope that "we can learn from our meanest moments":

> Faced with a rising wave of addiction, misery, crime and death, our nation has linked arms to save souls. Senators and CEOs, Midwestern pharmacies and even tough-on-crime Republican presidential candidates now speak with moving compassion about the real people crippled by addiction.
>
> It wasn't always this way. Thirty years ago, America was facing a similar wave of addiction, death and crime, and the response could not have been more different. Television brought us endless images of thin, black, ravaged bodies, always with desperate, dried lips. We learned the words crack baby. Back then, when addiction was a black problem, there was no wave of national compassion. . . . Blacks would just have to pull themselves out of the crack epidemic. Until then, the only answer lay in cordoning off the wreckage with militarized policing.
>
> Today, police chiefs facing heroin addiction are responding not by invoking war, but by trying to save lives and get people into rehab. . . . One former narcotics officer said: "These are people. They have a purpose in life, and we can't look at it any other way." But he couldn't quite put his finger on just what had changed. His words reflect our collective self-denial. It is hard to describe how bittersweet many African-Americans feel witnessing this. Glad to be rid of a failed war on drugs? Yes, but also weary and embittered. When the faces of addiction had dark skin, the police didn't see sons and daughters, sisters and brothers. . . . We don't have to wait until a problem has a white face to answer with humanity.

The opioid overdose epidemic has prompted decisive action. Dozens of cities and states have sued opioid manufacturers, alleging they negligently marketed drugs with high abuse potential for treatment of chronic pain and downplayed the addiction risks (see chapter 7). A suit filed by Chicago led to an agreement by Pfizer to adopt a voluntary code of opioid marketing in 2016. A federal budget deal voted into law in early 2018 committed $6 billion over two years to address opioid use, but policymakers and advocates continue to debate how that money

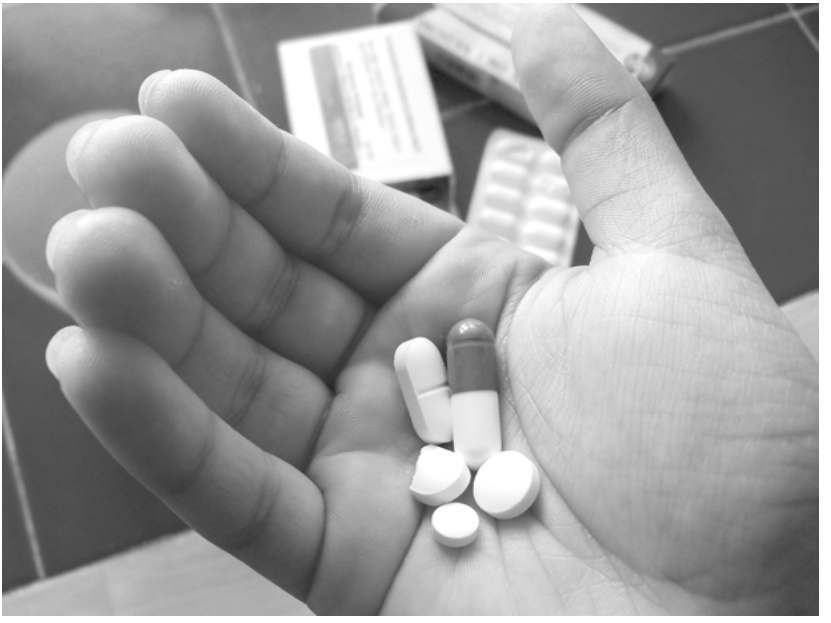

PHOTO 13.2. A woman holds a handful of pills. Opioid prescriptions quadrupled in the United States between 1999 and 2016. More than 115 Americans die each day of an opioid overdose. About 40 percent of opioid overdose deaths in the US involve prescription drugs. Courtesy of Kiran Foster via Flickr.

should be spent. President Trump and Attorney General Jeff Sessions have advocated for a law-and-order crackdown relying on criminal prosecutions for sale and possession of opioids. Public health advocates argue for expanded access to medication-assisted treatment for people with substance-use disorders and harm-reduction strategies—such as safe consumption facilities and naloxone access initiatives—which aim to prevent overdose deaths without necessarily disrupting opioid use. They also warn that harsh restrictions on opioid prescriptions create barriers for patients with chronic pain while diverting people with substance-use disorders from prescription opioids to heroin and fentanyl.

Beginning with Florida in 2011, several states have declared opioid-related public health emergencies. In Massachusetts, a 2014 declaration enabled the state health commissioner to expand naloxone access and accelerate mandatory prescription monitoring. Governor Deval Patrick's administration also sought to restrict the prescribing and dispensing of opioid drugs with high abuse potential, which had been approved by the FDA. In the next opinion, a federal court reviewed those restrictions.

*ZOGENIX V. BAKER**

United States District Court for the District of Massachusetts
Decided on March 17, 2015

In an effort to combat prescription drug abuse, the Commonwealth of Massachusetts . . . has sought to regulate the use and handling of Zohydro ER, which is a Food and Drug Administration–approved opioid painkiller. Plaintiff Zogenix, Inc., which markets and sells Zohydro, has challenged many of these regulations as preempted by federal food and drug laws. Last year, I enjoined the Commonwealth from enforcing two preliminary forms of its regulations. The Commonwealth has now issued final regulations that largely conform to my previous orders, but Zogenix continues to challenge some of the restrictions, as well as the overall scheme. [The amended] complaint alleges . . . that the regulations are preempted by federal food and drug laws [and] that they violate the Equal Protection Clause, . . . the Contracts Clause, . . . the Dormant Commerce Clause. Defendants now move to dismiss for lack of subject matter jurisdiction and failure to state a claim upon which relief can be granted.

Hydrocodone, the active ingredient in Zohydro, is an opioid painkiller. Hydrocodone drugs have long been available in the United States, but they are usually sold as combination drugs with acetaminophen. Acetaminophen has high liver toxicity, so overuse of hydrocodone-acetaminophen combinations can cause liver damage. Zohydro, which does not include acetaminophen, is a pure hydrocodone drug—the only one on the market today. Although it is formulated to provide pain relief over a twelve-hour period when used as instructed, users may immediately feel the full opioid high (without suffering ill effects from acetaminophen) by inhaling or injecting crushed Zohydro pills.

Since the United States Food and Drug Administration (FDA) approved Zohydro on October 25, 2013, it has been sold throughout the United States and in Massachusetts. It is subject to schedule II controls under both the federal and Massachusetts Controlled Substances Acts, which are the most restrictive controls available for an FDA-approved drug. Yet, because Zohydro contains no ingredients to deter abuse (i.e., it is not an "abuse resistant formulation"), Commonwealth officials have worried that these controls are insufficient to protect against further opioid abuse.

In the spring of 2014, Massachusetts Governor Deval Patrick declared opioid abuse and overdoses to be a public health emergency. With this announcement he authorized, and the Department of Public Health (DPH) issued, an emergency order that banned the prescribing, ordering, dispensing, or administration of Zohydro. Zogenix sued, contending that federal law preempted the emergency order and seeking a preliminary injunction. On April 15, 2014, I enjoined enforcement of DPH's emergency order.

On April 22, 2014, the Commonwealth's Board of Registration in Medicine (BORIM) promulgated an emergency regulation requiring an individually licensed prescriber to take certain steps before prescribing Zohydro, including supplying a letter of medical necessity confirming that other pain management treatments had failed. Similarly, on May 6, 2014, the Commonwealth's Board of Registration in Pharmacy (BORIP) promulgated two Zohydro-related regulations. The first, which I will call the "pharmacist-only" regulation, stated that "[a] certified pharmacy technician, pharmacy technician,

* No. 14-11689-RWZ, 2015 WL 1206354.

pharmacy technician trainee, or pharmacy intern may not handle [Zohydro]." The second contained a host of prerequisites a pharmacist must satisfy before dispensing Zohydro. Zogenix again moved for injunctive relief from these regulations on federal preemption grounds. I allowed that motion in part, enjoining the letter of medical necessity requirements. . . .

On or about July 3, 2014—nearly contemporaneously with my last injunction—BORIM, BORIP, and [the Board of Registration of Physicians Assistants (BOROPA)] issued new, "final" regulations concerning Zohydro. Among other changes, the new BORIM and BOROPA regulations omitted the troublesome language that formed the basis for my second injunction. Where formerly other pain management treatments must have "failed" before a physician or physician assistant could prescribe Zohydro, the new regulations merely required that other pain management treatments be deemed "inadequate." . . . The new BORIP regulations changed the "pharmacist-only" handling regulation to allow both pharmacists and pharmacy interns to handle Zohydro. Certified pharmacy technicians, however, were still prohibited from doing so. On the defendants' motion, I lifted the injunction on August 28, 2014.

On September 15, 2014, Zogenix filed [an amended complaint focusing] on the effect that the BORIP handling regulations will have on pharmacists' ability to distribute Zohydro. . . . Defendants . . . argue that Zogenix cannot challenge the gubernatorial public health emergency declaration because that declaration, standing alone, does not affect Zogenix. But Zogenix concedes that it is not asking the court to enjoin . . . the gubernatorial declaration itself—it is challenging only the final regulations. . . .

Zogenix first contends that the final BORIP regulations are preempted by the federal Food, Drug, and Cosmetic Act (FDCA), again arguing that they "constitute an effective ban on Zohydro." According to Zogenix, the regulations preventing certified pharmacy technicians from handling Zohydro "are unconstitutional because they make it so difficult to dispense Zohydro ER that pharmacists are unlikely to do so," with the effect being that pharmacies "will likely [be] bar[red] . . . from stocking Zohydro ER at all." . . .

Zogenix's position is essentially the same as when it sought injunctive relief against the "pharmacist-only" BORIP regulation last year. As I explained there, the issue is one of obstacle preemption, which occurs when, under the circumstances of the particular case, the challenged state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress. . . . Resolving the obstacle preemption question requires me to . . . assess whether the regulations prevent the accomplishment of the FDCA's objective that safe and effective drugs be available to the public.

On the record before me last summer, I could not allow Zogenix's motion to enjoin the "pharmacist-only" BORIP regulation because Zogenix had not offered sufficient evidence of the regulations' effect on Zohydro's availability. But I did not foreclose the possibility that a more detailed submission, informed by a record of enforcement, might show whether an obstacle to the FDCA's objectives exists. Zogenix may be able to show, through survey evidence or third-party discovery from pharmacies and physicians, that Massachusetts pharmacies are not stocking its drug because of handling difficulties caused by the regulations and that their failures to stock the drug are affecting physicians' prescribing practices. Zogenix has alleged such facts in its Complaint, and I must take those allegations as true at this stage. . . . The defendants' motion to dismiss this count is therefore denied.

Zogenix's Equal Protection Clause claim is premised on the BORIP regulations treating Zohydro differently from similarly situated drugs. . . . To the extent that Zogenix contends that the BORIP handling regulations contravene the Equal Protection Clause, the regulations must do so by treating certain regulated individuals or regulated classes differently (*e.g.*, by prohibiting certified pharmacy technicians, pharmacy technicians, and pharmacy technician trainees from handling Zohydro while allowing pharmacists and pharmacy interns to do so). Although Zogenix may feel some economic effects from these regulations, they do not directly contravene its equal protection rights. Zogenix therefore does not have standing, on its own, to assert an equal protection claim. . . .

Zogenix concedes that Zohydro "is the first single-entity hydrocodone product available on the market [and] the first extended release hydrocodone product." There are necessarily no comparable products, and no baseline from which to measure regulatory departures, if Zohydro is unique in these (or other) material ways. The complaint's failure to do more than conclusorily state that Zohydro is "similarly situated [to unspecified other] extended-release/long acting opioid medications on the market" is insufficient to survive defendants' motion to dismiss.

The Contracts Clause of the United States Constitution provides that "No state shall . . . pass any . . . law impairing the Obligation of Contracts." U.S. Const. art. I, § 10. But, despite this sweeping language, the Supreme Court has recognized that states may enact laws and regulations that impair private contracts if they are acting to protect basic interest[s] of society. To determine whether a state law or regulation contravenes the Contracts Clause today, "the threshold inquiry is whether the state law has, in fact, operated as a substantial impairment of a contractual relationship." *Energy Reserves Grp., Inc. v. Kansas Power & Light Co.*, 459 U.S. 400, 411 (1983). If so, "the State, in justification, must have a significant and legitimate public purpose behind the regulation, such as the remedying of a broad and general social or economic problem." *Id.* Health and safety, for example, are paradigmatic examples of legitimate public purposes. *Houlton Citizens' Coal. v. Town of Houlton,* 175 F.3d 178, 191 (1st Cir. 1999). "Upon finding a legitimate public purpose, the next step ordinarily involves ascertaining the reasonableness and necessity of the adjustment of contract obligations effected by the regulation." *Id.* That a regulation is under-inclusive and only partially addresses the legitimate public purpose does not render it unreasonable or unnecessary.

Zogenix alleges that the BORIP regulations impair two of its contractual relationships: those with wholesalers that supply Zohydro to Massachusetts pharmacies, and those with Inflexxion, a company that it retained to track abuse patterns for Zohydro within Massachusetts. I assume, without deciding, that the BORIP handling regulations will impair these contracts. Yet, Zogenix still has not stated a claim for violation of the Contracts Clause [because] the regulations are directed at achieving the Commonwealth's legitimate public purpose. That the regulations are under-inclusive because they fail to restrict access to other opioids does not make them unreasonable. . . . Zogenix's Contracts Clause claim is dismissed.

The Dormant Commerce Clause doctrine, which is implicit in Article I, § 8 of the United States Constitution, holds that state and local laws are unconstitutional if they place an undue burden on interstate commerce. The Dormant Commerce Clause, like the Commerce Clause itself, applies to "[a]ll objects of interstate trade," including

pharmaceutical products. *City of Philadelphia v. New Jersey,* 437 U.S. 617, 622 (1978). The Supreme Court "has adopted what amounts to a two-tiered approach to analyzing state economic regulation under the Commerce Clause." *Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.*, 476 U.S. 573, 578–79 (1986). First, "[w]hen a state statute directly regulates or discriminates against interstate commerce, or when its effect is to favor in-state economic interests over out-of-state interests, [the Court has] generally struck down the statute without further inquiry." *Id.* at 578. But, if a statute has only indirect effects on interstate commerce and regulates evenhandedly, it is reviewed under a less stringent standard. Under that test, courts employ a balancing approach whereby they examine whether the state's interest is legitimate and whether the burden on interstate commerce clearly exceeds the local benefits. *Pike v. Bruce Church, Inc.*, 397 U.S. 137 (1970). . . .

There are no allegations that the BORIP handling regulations discriminate against out-of-staters or purport to regulate conduct outside Massachusetts' borders. . . . It does not contravene the dormant commerce clause for a state merely to regulate the distribution within its borders of a product that travels in interstate commerce. And, although Zohydro's theory about national pharmacies refusing to dispense Zohydro may be sufficient to show a burden on interstate commerce, the speculative and threadbare allegations in the complaint are insufficient to meet the pleading requirements. Despite having information on which national pharmacies order its drug and despite serving three different complaints in this case, Zogenix has not described a single example of a national pharmacy refusing to dispense Zohydro—let alone an example of a national pharmacy refusing to dispense Zohydro because of the BORIP handling regulations.

Even assuming that the BORIP handling regulations place some minimal burden on interstate commerce, Zogenix's Dormant Commerce Clause claim would still fail as a matter of law because that burden is outweighed by the regulations' putative benefits, *i.e.*, promoting public health and safety. Zogenix contends that the facts have not developed in a way that Zohydro presents a risk to public health in the first place, but that misses the point of the *Pike* test. Under *Pike,* it is the *putative* local benefits that matter, not whether these benefits actually come into being at the end of the day. . . . Zogenix's Dormant Commerce Clause claim is therefore dismissed.

. . .

Zogenix highlights the difficulties states face when they take a more aggressive approach toward health and safety regulation than federal regulators. The court rejected Zogenix's constitutional arguments, but was receptive to its preemption challenge. The FDA's decision to approve Zohydro was controversial. Governor Patrick attempted to reverse that decision within the borders of Massachusetts by regulating health care providers and pharmacies. In response to successive district court judgments, the Patrick administration watered down its initial regulations, shifting from a total ban to burdensome administrative requirements and, finally, to less burdensome requirements.

The opioid epidemic has mobilized a multi-level, multi-sector governmental response similar to what emerged in the mid-twentieth century to prevent motor vehicle fatalities. Public opinion polls suggest that the public favors a similarly aggressive response to firearm deaths, but industry influence and the Supreme Court's evolving Second Amendment jurisprudence have forestalled meaningful action. In all three instances, policymakers and regulators have struggled to balance individually focused strategies (e.g., helmet laws, gun owner liability for failing to keep weapons secure, criminalization of drug possession) with social-ecological strategies that emphasize collective responsibility (e.g., crashworthiness standards for motor vehicles, licensing that limits the density or location of gun retailers, litigation to require pharmaceutical companies to compensate state and local governments for the harms caused by their irresponsible marketing practices). The same dynamic is apparent in each of the silos we have explored—infectious disease control, emergency preparedness, and noncommunicable disease prevention. The population perspective implicit in public health science, practice, and law runs counter to the individualistic orientation of the American legal system. This tension comes to the fore in debates over the long-standing commitment of public health to social justice. We turn to this issue in the next chapter.

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PHOTO 14.1. A demonstrator protests the police shooting of Jamar Clark. The Black Lives Matter movement has highlighted the impact of racism on the lives of Black people in the United States and around the world. In addition to being far more likely to be the victim of a police shooting, African Americans experience disproportionate rates of infant mortality, HIV, hypertension, homicide, and many other health problems. Courtesy of Tony Webster.

CHAPTER FOURTEEN

Health Justice

Public health science, practice, and law vastly improved the health and well-being of populations during the late nineteenth and twentieth centuries, contributing to dramatic increases in life expectancy. A white female born in the United States in 1900 could expect to live a little less than 49 years. A Black female born the same year could expect to live an average of just 32.5 years. By 2000, average life expectancy at birth had risen to nearly 77 years and racial disparities in life expectancy had narrowed slowly over the course of the century. In 2000, the disparity in life expectancy between non-Hispanic whites and Blacks was about five years for females and seven for males.

The story of public health in the United States in the twenty-first century may be more complex. On average, a person born in the United States can expect to live a shorter life than one born in any other country with similar per capita gross domestic product. In 2015, average life expectancy at birth in the United States was nearly 80 years old, but there was a marginal decline for the first time in decades. This very small decline is not necessarily indicative of a longer-term trend, but it is concerning. Among white middle-aged Americans, reductions in cancer and heart disease mortality have been offset by sharp increases in drug overdoses, suicide, and alcohol-related liver disease—dubbed "deaths of despair" by economists Anne Case and Angus Deaton (2017). Disparities between white and Black Americans have largely

stagnated, while disparities based on income and formal educational attainment have widened. American men with the highest incomes can expect to live almost 15 years longer than those with the lowest. For women, the gap is a little over 10 years. American adults with at least a high school diploma or equivalent can expect to live almost a decade longer than those without. Obtaining a bachelor's degree or higher adds an additional four years of life for men, two for women.

We face numerous challenges, but they are surmountable. In a 2016 study of the association between income and life expectancy, for example, Raj Chetty and his co-authors found that the decreased longevity associated with living in a low-income household is mitigated by living in a city with higher average household income and educational attainment. Chetty et al. postulated that "[t]here are many potential explanations for why low-income individuals who live in affluent, highly educated cities live longer. Such areas may have public policies that restrict smoking or greater funding for public services, consistent with higher levels of local government expenditures in these areas" (Chetty et al. 2016, 1764). This theory is bolstered by a growing body of research that links a wide range of laws and policies to better health outcomes.

Health outcomes are distributed in readily identifiable patterns indicative of embedded injustice. The expanding toolkit of legal and policy interventions presented in this reader promises to alter those patterns. Yet our nation is deeply divided over how to respond. At a time when stark disagreements about the role of government in securing the public's health dominate headlines, some commentators have questioned whether commitment to social justice should be explicitly championed as a defining feature of public health.

The first editions of this reader and the text that accompanied it argued that social justice is foundational to public health law and ethics. Here, we renew our commitment to that notion—both as a description of the work public health does and as a normative assertion about the work it must do. In this chapter, we showcase the efforts of public health scientists, legal scholars, ethicists, and activists to chart a path for public health to respond to worsening health outcomes and stagnant and widening health disparities. We focus on health justice as a framework for guiding public health law. We also draw on work generated by three related social justice movements that have highlighted racial disparities in health: environmental justice, reproductive justice, and food justice. We begin with a call for public health to return to its roots.

THE EXODUS OF PUBLIC HEALTH: WHAT HISTORY CAN TELL US ABOUT THE FUTURE*

Amy L. Fairchild, David Rosner, James Colgrove, Ronald Bayer, and Linda P. Fried

. . . Since the 1960s, public health practitioners have struggled with their identities as scientists and activists. Although issues of socioeconomic disparities and inequality have become a part of the public health agenda, we remain uneasy with forming political alliances even as our initiatives have been challenged by a host of activists. . . . Understanding the potential for setting forth an ambitious charge as the field moves into the twenty-first century will require careful consideration of the current social backdrop, particularly as it relates to how we define the relationship between science and action.

A CALL TO ACTION

The mission of public health has its roots in the mid-nineteenth century, when physicians, housing reformers, advocates for the poor, and scientists trained in new techniques of chemistry and civil engineering came together to fight problems growing out of urbanization, industrialization, and large-scale immigration. This coalition transformed the nation's economy and environment and, in turn, its health. . . .

Amid alarm over the "conditions of the poor," civic leaders around the nation launched investigations into the social and environmental, as well as the individual, causes and consequences of disease. In Chicago, social reformers in Hull House focused on living conditions as the reason for the declining health and well-being of workers, women, and children. In Boston, charity workers looked at the slums in which the Irish lived as the source of disease. In Philadelphia, New York, and Boston, reformers focused on housing as a cause of the city's physical, social, and moral decline. These efforts mirrored the work of reformers and social critics in Europe, who saw in the relationship between poverty and disease the foundation for a call for radical social change. . . .

Perhaps most remarkable was the degree to which public health served as both an organizing and a unifying concept. . . .

THE RETREAT OF PUBLIC HEALTH

If epidemics were a hallmark of the crowded, centralized cities of the East Coast during the nineteenth century, then cancers and other chronic illnesses became the paradigmatic conditions that plagued the twentieth century. The first part of that century saw fundamental changes in land use and transportation that improved health in many respects but created new hazards and new diseases. Exposures to synthetic materials, the creation of a huge marketing industry that promoted toxic materials for consumer uses (e.g., lead paints and tobacco), and air, water, and soil pollution led to an epidemiological revolution as infectious diseases gave way to chronic conditions.

Ironically, in the wake of these social and epidemiological transformations, the public health community embraced bacteriology, with its focus on the laboratory rather

* 2010. *American Journal of Public Health* 100 (1): 54–63.

than the social and environmental context, as an authoritative science that did not require political alliances: science spoke for itself. Departments of public health shed sanitation, housing reform, and even hospital care. The interdisciplinary alliance that lent power to public health splintered, with profound consequences for the subsequent evolution of the field. . . .

In 1940, the American Public Health Association passed a resolution codifying the standard repertoire of services that local health departments should provide, what became known as the "basic 6." Although there was interstate variation, by and large the responsibilities of health departments were narrowed to six areas: collecting data on vital statistics; controlling communicable diseases via methods such as outbreak investigations, contact tracing, partner notification, and (rarely) isolation and quarantine; ensuring environmental sanitation (e.g., with respect to municipal water supplies); providing laboratory services for the diagnosis of illnesses by private doctors, hospitals, and other clinicians; offering maternal, infant, and child health services; and providing education, via brochures, posters, and other mass media, to promote healthy behaviors. Thus, at the same moment that it prioritized objective science over social reform and alliances with relatively powerful progressive constituencies such as labor, charity, social welfare organizations, and housing reformers, the field was marginalized and left with no political base. . . .

By the beginning of the Cold War . . . the idea of public health as a sweeping enterprise was all but moribund. . . . Hospital construction and clinical, as opposed to population-based, research had become a national priority. At the same time, some of the sanitary activities for which health departments had been responsible, such as garbage collection, air pollution control, and noise abatement, were pulled under the aegis of other professions and government agencies. It was now medicine that was positioned to protect the nation's health. . . .

[V]oices of public health professionals in academia and state or local health departments were strikingly absent throughout the years of congressional testimony regarding the place of public health within a national health plan. Public health ceded medical care to insurance companies, hospitals, physicians, and other interest groups that did not understand (or actively opposed) the role public health could or should play in postwar America.

Science and medicine became great levelers, allowing public health professionals to ignore social factors—including the racial segregation, poverty, inequality, and poor housing that had been the traditional foci of public health reformers only thirty years before—and explain disease without any of the disruptive implications of a class analysis. . . . The Progressive Era emphasis on social welfare and urban reform became ideologically dangerous when class analysis lost status within the intellectual community and was even equated with anti-Americanism in the context of the affluent society of the McCarthy era.

New medical technologies—antibiotics, vaccines, psychotropic medications, and a host of other clinical interventions—provided apolitical means of attacking disease without disrupting the social order. . . .

Public health thus reframed science as a practice that stood outside of politics and the social reform efforts that had defined public health in the nineteenth century. Although public health departments could claim the right to conduct surveillance for

[non-infectious] diseases, it was unclear whether they could claim the authority to intervene on the basis of any evidence of harm they gathered. . . .

THE BROADER STRUGGLE

Social, cultural, and institutional changes provide the backdrop to the waning authority of public health that began in the years after World War II. In the 1950s, the rise of medical authority went hand in hand with the ascendance of the hospital as the center of treatment and research. Power was consolidated in corporate interests and given force by a general cultural ethos of mass consumption and market-driven health care. In the 1970s, a powerful discourse of personal responsibility for health and disease placed blame on individuals and implicitly absolved corporations that marketed harmful products such as cigarettes and lead paint and polluted the nation's water and air.

An influential 1974 report by Marc Lalonde, the Canadian minister of health, signaled a new focus on health promotion in the industrialized democracies: it was time to focus on changing risky behaviors. In a similar vein, John Knowles, former president of the Rockefeller Foundation, argued in a widely discussed article that "[t]he solution to the problems of ill health in modern American society involves individual responsibility." Knowles set a critical tone for subsequent policy, which placed the blame for American morbidity and mortality on "careless habits" and individual "indulgence in 'private' excesses."

An increasing focus on individual health promotion and disease prevention intersected with social movements concerned with issues of race, gender, sexuality, and medical authority, all of which challenged the public's trust in expert judgments. This emphasis was given force by revelations regarding the 40-year history of unethical practices involved in the Tuskegee syphilis study, as well as by the ill-fated plan of the Centers for Disease Control and Prevention in 1976 to protect the nation from swine flu. These developments contributed to deep fissures in the field of public health.

The great social epidemiologist Thomas McKeown argued that radical social change would be necessary to alter the profile of social suffering. Jack Geiger, working with civil rights organizations such as the Congress of Racial Equality, traveled to Mississippi to establish health centers for impoverished African Americans; Lorin Kerr's work with the United Mine Workers forced black lung disease in Appalachia onto the national agenda; and many in the American Public Health Association pressed for strong alliances with women's organizations, civil rights groups, and peace activists.

Yet, although they may have represented the social conscience of public health, these individuals were rarely able to alter power relationships on a broader scale. At the same time, others in the field openly opposed any role outside of public health science in addressing the health concerns of the nation. For example, epidemiologist Kenneth Rothman argued that, as a science, public health had no advocacy role in social debates; it might document the effects of poverty on health, for example, but it had no mandate to attack poverty.

BACK TO THE FUTURE

In the view of critics, public health professionals have, over the course of a century, defined their mandate ever more narrowly and shrunk from political engagement with

powerful interests such as corporations and business that created unhealthful environments. They failed to confront medical specialists interested in defining preventive interventions as clinical and hence as reimbursable. This critique was made perhaps most memorably by Paul Cornely in a 1970 address to the American Public Health Association. Newly elected as the group's first African American president, Cornely leveled a blistering attack on what he saw as the complacency of his profession. It had been "a mere bystander" to the profound changes in the health care system that had taken place in the 1960s; its members wasted their time on "piddling resolutions and their wordings." Public health, he charged, remained "outside the power structure." Cornely's address was a clarion call for more aggressive action against a host of health problems integral to modern industrial society. . . .

For many decades, the field has been constrained by self-imposed limitations and, all too often, has avoided engagement with those who challenge complacency and existing power relationships. The histories of tobacco, lead poisoning, and HIV bear all of the marks of the more-than-century-long history of modern public health, although in mirror image. Forsaking its early ideology, commitments, and crusading spirit, public health became unwilling or uncertain about how to use science to challenge powerful corporate interests, deeply entrenched moral beliefs, or profound social inequalities linked to gender, race, and class. Yet, as different institutions, organizations, and communities mobilized in the name of public health, the field was pressed to join the coalitions making headway against HIV and the tobacco and lead industries, reasserting the radical role that public health had played in the late nineteenth and early twentieth centuries.

The current economic calamity, affecting the health and well-being of hundreds of millions of people around the world, provides the chance to rethink fundamental assumptions about our country's economic and social system. Public health is positioned to reclaim its place as part of an emerging reform movement. The future will present new challenges, from global warming and industrial pollution to bioterrorism and universal health care. We can either accommodate the status quo or confront political and economic power in the name of the public's health.

Public health must go "back to the future" and integrate power and agency into our models for promoting the public's health. History sensitizes us to the interplay of the varied social, political, and economic forces that positioned public health at different moments in time, regardless of the areas of responsibility the field claimed. History demands that we understand not only the forces that shaped public health action in the past but also the current forces that will shape the potential and limits of what we can do as professionals committed both to science and to its application.

. . .

In response to the wide-ranging health problems exacerbated by the 2008 financial crisis, Fairchild and her co-authors urge public health leaders to reclaim the powerful combination of scientific inquiry and social activism that characterized the Sanitarian movement of the nineteenth century. They point to the success of activists who worked in broad coalitions to fight HIV and the tobacco and lead industries in the

late twentieth century while many public health advocates sat on the sidelines.

As public health advocates seek to integrate power and agency into the social-ecological model for promoting the public's health, they might look to three interrelated social justice movements that emerged in the late twentieth century, each of which highlighted the health impacts of racism: environmental justice, reproductive justice, and food justice. Our next excerpt provides a case study on community organizing, demonstrations, legal action, and political action as strategies for protecting the population of Chester, Pennsylvania, from environmental threats to health.

JUSTICE FROM THE GROUND UP: DISTRIBUTIVE INEQUITIES, GRASSROOTS RESISTANCE, AND THE TRANSFORMATIVE POLITICS OF THE ENVIRONMENTAL JUSTICE MOVEMENT*

Sheila Foster

The environmental justice movement . . . has emerged from a primarily local, grassroots response to the presence and continued siting of hazardous waste facilities in poor communities and communities of color. For the last two decades, these communities have fought back against the injustice they perceive permeates environmental decision-making. . . .

What is the *injustice* they experience? What is the *justice* they seek? There is no clear-cut answer to such questions, especially given the diversity of the various local struggles. . . . By studying the movement at its source and talking to those actually leading these struggles, we can begin to understand the normative content of their claims of injustice and their corresponding struggle for justice. . . .

ENVIRONMENTAL INJUSTICE IN CHESTER, PENNSYLVANIA

Chester, Pennsylvania is an urban city of 39,000 residents. Located along the Delaware River, approximately fifteen miles southwest of Philadelphia, Chester is a small enclave of people of color within predominantly white Delaware County. While Delaware County, excluding Chester, is only 6.2% African American, Chester is 65% African American. The median family income in Chester is 45% lower than in Delaware County and its 25% poverty rate is more than three times the rate in Delaware County. Unemployment and crime are high in Chester, as is the rate of health problems. Chester has a mortality rate 40% higher than the rest of Delaware County, as well as the state's highest child mortality rate.

Waste facilities that once promised needed jobs have instead brought many forms of pollution. From 1986 to 1996, the Pennsylvania Department of Environmental Pro-

* 1998. *California Law Review* 86 (4): 775–842. Reprinted with permission of the California Law Review.

tection (DEP) issued seven permits for commercial waste facilities in Delaware County, five of which were in Chester. All of the municipal waste and sewage in Delaware County is processed in Chester, even though only 7.5% of the county population lives in Chester. Moreover, over 60% of the waste-processing industries in Delaware County are located in Chester.

Living in Chester today can best be described as an assault on the senses—a toxic assault. During the summer, the stench and noise force residents to retreat into their dwellings. . . . The residents were most irritated by the huge trucks that would rumble through their neighborhoods at all times of the day and night, disturbing their sleep and their children's recreational time, and damaging the overall character and peace of their community. Noise and vibration from the constant stream of waste trucks have caused the foundations of nearby houses to crack and property values to plummet. Residents have felt imprisoned in their own community. Only later would they fully appreciate the damaging effects these facilities might have on the health of their community. "We are not against profit or gain, but we want to gain in our own areas," said one resident, "we want to live."

The recent incursion of waste treatment facilities into Chester began in the late 1980s. . . . In 1988, despite objections from many Chester residents, and without their input, the DEP granted a permit for the operation of the Westinghouse Resource Recovery Facility. The Westinghouse incinerator is one of the largest in the country and is permitted to burn over 2,000 tons of trash per day. As well as burning 100% of Delaware County's own waste, the incinerator draws trash from three surrounding states—Delaware, New Jersey, and New York—and as far away as Ohio to feed its massive burners. . . . The Westinghouse incinerator not only brought trucks and dust, but also odor and, according to residents, possibly more illness. Adults in the neighborhood experienced respiratory problems and their children missed more school than usual due to unexplained illness. The Westinghouse incinerator and Abbonizio Recycling operate in a community already surrounded by older industries such as Witco Chemicals, Scott Paper, British Petroleum, Sunoco Oil, and a twenty-year-old sewage treatment facility owned by Delaware County Regional Water Control (DELCORA). . . .

The presence of these facilities may pose a grave health risk to the Chester residents. When President Clinton issued his Executive Order on Environmental Justice, the United States Environmental Protection Agency (EPA) chose Chester as the subject of a six-month cumulative risk assessment. This study, released in the fall of 1994, found unacceptable cancer and non-cancer risks, such as kidney and liver disease and respiratory problems, from the pollution sources in Chester. The EPA also concluded that (1) blood lead levels in Chester's children are unacceptably high, with more than 60% of the children's blood samples above the Center for Disease Control (CDC) recommended maximum level; and (2) air emissions from facilities in and around Chester account for a large component of the cancer and non-cancer risk to the citizens of Chester. Peter Kostmayer, then head of the EPA Mid-Atlantic Region, said that although there was a correlation between the facilities in Chester and poor health in the community, causation was difficult to prove scientifically, due to other compounding factors. Nevertheless, the clustering of facilities in Chester heightens the perception that the community's poor health status is linked to the surrounding waste processing facilities. . . .

As with many urban areas in which toxic waste facilities are located, Chester's history as a former industrial haven helped to shape its destiny. . . . Chester suffered from

the post-war flight of its manufacturing industry overseas and the flight of middleclass whites to surrounding suburban neighborhoods. Between 1950 and 1980, 32% of the jobs in Chester disappeared. During the same time period, the African-American population increased from 20% to 65%.

Chester is now one of the most economically depressed communities in Pennsylvania. Predictably, social decline soon followed on the heels of the economic decline. Chester's school district is one of the worst in the state. Chester also has the highest crime rate in the state. Desperation accompanied this economic and social decline, as evidenced by the city government "[e]ncourag[ing] everything and anything to come to town to provide jobs." . . .

[T]he situation in Chester seems partly the result of its unique political history: a corrupt Republican political machine that has long controlled many aspects of local decision-making, and some behind-the-scenes political machinations. Peter Kostmayer, former head of the EPA Mid-Atlantic Region, recalled hearing from a DEP official that "there were political figures and their allies that had financial investments in Chester" and supported Chester as a home to the waste industry. A close examination of the present scenario in Chester, including the issuance of waste treatment facility permits, seems to corroborate this assessment. . . .

As many studies document, commercial waste facilities are disproportionately located in poor communities of color. This disparate impact and its empirical basis have provided substance to claims of environmental racism and environmental injustice. Highlighting the empirical results, even without legal imprimatur, has been an important political rallying point for environmental justice advocates.

But the weight placed on empirical studies as the defining characteristic or indicia of environmental injustice has also imperiled the progress of the movement. . . . Although focusing on the national distributive inequities provided a starting point for inquiring about the injustice, it provided little else in the way of a substantive understanding of environmental racism. . . . [T]he hidden assumption underlying empirical work on environmental racism is that racism is a specific thing whose effects can be neatly isolated. Limiting the concept of environmental racism to discrete and measurable discriminatory acts fosters an incomplete understanding of racism and injustice. . . .

Environmental justice is often regarded as the equitable distribution of environmental risks and benefits. It also encompasses the concept of environmental equity, which holds that all populations should bear a fair proportion of environmental contamination and health risks. These conceptions of environmental justice, . . . heavily reliant upon a distributive paradigm, are too monolithic. Injustice manifests itself in different ways for different social groups and can be seen and measured along a number of axes. Conceptualizing social harm only in distributive terms leaves different measures of injustice unnoticed and unheeded.

THE STRUGGLE FOR ENVIRONMENTAL JUSTICE IN CHESTER, PENNSYLVANIA

In the early 1990s, Chester's residents banded together to fight back against what they viewed as an all-out attack on their community's quality of life and health. . . . The DEP was on the verge of permitting an infectious medical-waste sterilization plant

next to the Westinghouse incinerator. . . . [At town meetings,] residents aired their complaints about the facilities—odors, dust, noise, and trucks carrying trash to the facilities. Industry and government representatives offered responses such as, "Do you think your government would do something wrong to you? Do you think [we would allow this facility if it did not] meet all of the federal and state regulations?" At least one resident found the attitude of the representatives condescending. Zulene Mayfield stood up, introduced herself, and told the representatives, "I can't understand why you bright, college-educated people can't come down here and tell a better lie than what you're telling. . . . [W]e are people from probably the worst school district in the state and we can see [and] understand these lies. . . . " Zulene got up and left. From that point on, Zulene attended the weekly meetings of concerned residents of Chester. Eventually, Chester Residents Concerned About Quality of Life (CRCQL) formed, with Zulene at the helm.

The initial meetings with industry and government officials foreshadowed a pattern of stonewalling that emerged every time the community sought information and solutions from industry and government. . . . Eventually, the residents . . . decided to sit all facility and government representatives together and "watch them point fingers at each other," instead of telling the residents to go talk to someone else. . . . The confrontational dynamic expected at the meeting never materialized. Government and industry representatives seemingly agreed to divulge as little information as possible. . . .

The government and industry officials' conduct at the meetings exemplified the ways in which the decision-making process had excluded the residents all along—as if they did not matter. Moreover, it seemed as though various tactics were employed to keep the residents in the dark about issues fundamentally affecting their health and quality of life. For instance, one of the barriers residents initially faced was an inability to understand the highly technical language the facility representatives used. When a resident attempted to speak in an open meeting to a Westinghouse representative about the *incinerator,* the representative immediately corrected the resident, telling her that it was a *resource recovery facility.* This tactic played on the lack of sophistication of the Chester residents and effectively silenced them. As one resident remarked, "Every meeting we left feeling like our tail was between our legs, because they always tried to make us think that what *was* happening *was not* happening." Believing that "intelligence" is an "equalizer," CRCQL members sought to familiarize themselves and other Chester residents with the terminology and technology of the facilities. Nevertheless, even as the residents educated themselves, government and industry representatives continued to ignore them. Meetings with facility representatives were completely unsatisfactory; the residents felt unacknowledged and unheard. . . .

On a cold day in December 1992, the residents held their first protest, focusing on one of the most visible and audible invasions into their city—the trucks carrying waste to the Westinghouse incinerator. . . . [T]en to fifteen residents, mostly senior citizens, lined Thurlow Street in Chester to stop the trucks from reaching their destination. . . . Westinghouse finally responded after residents physically refused to let the trucks take their load to the Westinghouse facility for up to two hours. Westinghouse's chief financial officer flew to Chester during the protest to meet with the residents. After hearing their story, Westinghouse officers agreed to build a new road for the trucks hauling trash to the incinerator. Although the new route was built only one block away,

the residents felt this protest was a success. For the first time since they had begun to stand up and voice their opinions, they felt empowered. . . .

Despite the message of resistance sent by the protests, in July 1993, the DEP issued a permit for the construction and operation of yet another facility in Chester. The community learned that Midlantic BioWaste Systems Inc., a subsidiary of Thermal Pure Systems, planned to build an infectious medical waste sterilization plant next to the Westinghouse incinerator. The proposed facility's operators planned to sterilize medical-chemotherapeutic waste through a process called autoclaving. They would then package and ship the waste to a landfill. For Chester residents, this was the last straw. . . . CRCQL mobilized the Chester residents and gathered more than 500 signatures in opposition to the project. . . .

Unfortunately, the residents then uncovered an even more entrenched barrier—local politics. All of the city council members except for the mayor sent a letter to the governor and to the DEP asking them to expedite the permitting of Thermal Pure. Not surprisingly, the DEP granted Thermal Pure's permit. . . . In Pennsylvania, as in other states, permit applicants must publish formal notice of their proposed facility in local newspapers to give the public an opportunity to comment on and learn about the facility. However, this requirement often provides inadequate notice to, in particular, low-income communities, where literacy levels are low, and it is unlikely that many citizens will become aware of or read the official notice. For instance, as happened in Chester, it is not uncommon for notice of a permit application to be placed in a minuscule space at the back of the local newspaper. Once again, the residents felt the decision-makers had excluded them. . . .

A Philadelphia public interest lawyer, Jerome Balter, read an article about the Chester protest and decided to call CRCQL. . . . Through Baiter's efforts, the residents discovered yet another weapon in their fight against the facilities—legal action. . . . Balter appealed the Thermal Pure permit on CRCQL's behalf. . . . In February 1995, the [state trial court] . . . declared that the Thermal Pure permit was invalid. . . . To CRCQL's amazement, their victory and the closure of Thermal Pure was short-lived. . . . In November 1995, the Pennsylvania Supreme Court overturned the commonwealth court ruling by a vote of 5–0, allowing Thermal Pure to reopen. . . .

The decision exists under a cloud of illegitimacy for many Chester residents. According to CRCQL, the supreme court . . . may have been influenced by the firm responsible for the recent proliferation of waste sites in Chester. Pennsylvania Supreme Court Justice Stephen Zappala is the brother of a partner in Russell, Rea, and Zappala, owners of most of the facilities located in Chester. Justice Zappala recused himself from the Chester case, but CRCQL believes he "exercised his influence." . . . While this accusation has yet to be proven, the appearance of impropriety sounded the death knell for CRCQL's belief that the law would provide justice for people like themselves. . . . Jerome Balter, in contrast, believes the community relied too heavily on the legal system. "There is a reliance on legal action, and no matter how much the lawyer says 'don't count on it,' they count on it."

CRCQL learned a powerful lesson: While legal action brings much needed attention to environmental justice struggles, legal strategies rarely address what is, in essence, a larger political and structural problem. As the struggle surrounding the *Thermal Pure* case illustrates, lawsuits take place in a forum in which the resources of private corporations and government entities far outweigh community resources. Given their

experience with the Pennsylvania Supreme Court, the Chester community is unlikely to rely solely on legal strategies in the future. In fact, the group realizes that legal strategies, even hopeful ones like the Title VI action they are currently pursuing [claiming that the DEP violated federal regulations mandating that any jurisdiction receiving federal EPA money "shall not use criteria or methods of administering its program which have the *effect* of subjecting individuals to discrimination because of their race, color, national origin, or sex . . . "], are merely "another stone in David's sling," a way to bolster their *political* struggle for empowerment and inclusion.

In late 1994, CRCQL became aware of yet another potential hazard targeted for their community. Soil Remediation Systems (SRS) recently had filed a permit application with the DEP to construct a soil incineration facility in Chester. Once again, the community mobilized. Petitions, protests, and a well-attended public hearing sent the message to SRS and the DEP that the community did not want another facility. . . .

Fortunately, CRCQL had gained powerful allies by this time. In 1992, after decades of Republican party reign that kept "tight control over the city's votes by controlling public funds in such a way that every government function was delivered as a personal favor," the Democratic party overthrew the Republicans in what CRCQL calls "one of the most impressive political campaigns in the city's history." CRCQL benefited from this change of leadership: the group convinced all five members of the city council to oppose the SRS permit. Moreover, CRCQL, in a meeting with the Secretary of the DEP, convinced the agency to delay the decision until the EPA completed its health study of Chester. Despite the public outcry, the opposition by the city council, and the EPA's troubling conclusions in its health assessment of Chester, the DEP granted the SRS permit.

As the political tide turned in CRCQL's favor, group members shifted the focus of their political actions. Instead of "reacting to the actions of the industries and the government" and "trying to convince the power brokers to act on their behalf," the residents moved proactively to "cut these industries off at the pass." CRCQL again rallied the residents to the cause. CRCQL's first successful step in this direction was to convince the city council to amend the zoning code so that waste management industries would face more difficulty when attempting to site facilities in Chester. The group then canvassed the city for signatures for a petition to amend the zoning ordinance. They collected 3,000 signatures and presented them to the city council. The council commenced to drag its feet until CRCQL confronted it and said, "If every meeting we have to call all 3,000 people and tell them the ordinance is not signed, we will do that."

In June 1994, the city council passed an ordinance requiring any waste company hoping to locate in Chester to prove that the operation of its proposed facility would not increase overall pollution levels in the city. SRS failed to meet the burden of proof under the ordinance. As a result, SRS lost its DEP permit because it could not get a building license from the city and, thus, failed to break ground by the permit's specified deadline. As one CRCQL member remarked, "Finally, the government was forced to react to the residents, instead of the other way around."

[Following acts of racial intimidation against Zulene and other members, CRCQL sought to expand its coalition. An environmental justice retreat CRCQL held at Swarthmore College grew into] the Campus Coalition Concerning Chester (C4). . . . According to Zulene, CRCQL wanted to get people the decision-makers could "relate to"; if not parents then "let's get the children," the group reasoned. The goal was to "educate the

kids and let the kids go home" and ask their parents the kinds of questions confronting the Chester community.

By broadening CRCQL's base, Zulene and other members felt they could both build a more politically sustainable partnership, as well as "take the focus off" CRCQL as an African-American organization. Thus far, according to Zulene, the partnership with C4 has been "wonderful"—educating people on campus, in Chester, and in surrounding communities. . . . [For example, i]n the summer of 1995, CRCQL and C4 conducted a door-to-door health survey of Chester, which helped to document the poor public health of the community and to bolster the residents' claims of environmental damage. . . .

Despite . . . setbacks, CRCQL has created a venerable legacy—it is now a political force to be reckoned with in Chester. What began as a small group of residents concerned with their quality of life and their health has grown into an organization with the power to engage decision-makers on issues that fundamentally affect the residents' material livelihood. Indeed, CRCQL's biggest victory may be that it is a cohesive, healthy group and is still fighting in coalition with C4. A self-taught community organizer, Zulene Mayfield recognizes that the importance of CRCQL's struggle goes beyond the individual victories and defeats in their campaign against the toxic facilities in Chester. "Historically, black people haven't realized the power they have. The people who have realized it, who have the knowledge, have to teach the others. We have to start using our own power."

PURSUING ENVIRONMENTAL JUSTICE: SITING PROCESS REFORMS, STRONG PARTICIPATORY DEMOCRACY, AND TRANSFORMATIVE POLITICS

The Chester experience suggests that distributive paradigms of justice are merely a starting point in understanding the phenomenon of environmental injustice. CRCQL began its struggle out of concern about the accumulation of hazardous waste facilities in their community and the effects those facilities had on the community's quality of life—the trucks, dust, noise, and odor. As their efforts to find out more about the facilities in their community progressed, their struggle became more multi-faceted. In the end, their resistance was as much about the legitimacy of decision-making processes which fundamentally affect their lives as it was about the outcomes of those processes. . . .

As Chester illustrates, the very social and structural constraints that operate in the larger world continue to constrain individuals in the environmental decision-making process. Because of their economic, social, and political isolation, Chester residents, like other low-income people of color, feel that they are viewed and treated as marginal to decision-making processes. In addition, a disparity in available resources persists in communities such as Chester because they [lack specialized knowledge pertinent to the issues involved]. Moreover, though many federal and state environmental laws promise participatory decision-making, Chester illustrates the failure of such laws to include disaffected communities in environmental decisions. . . .

[T]he mainstream environmental movement has constructed a notion of environmentalism which fails to address the material concerns of low-income communities of color. Grassroots environmental justice activists recognize this neglect and hope to construct a new meaning of environmentalism. . . . The notion of "environment" for

environmental justice groups and networks has come to mean "home" and "community." These are the places that need to be preserved and protected from pollutants and other harms. This "community preservation" principle recognizes that the harms resulting from the disenfranchisement of the most vulnerable communities from environmental decision-making are not only health-related, but include non-health-related consequences—such as the reduction of community cohesion and socioeconomic damage, resulting from the loss of businesses, homes, and schools. . . .

Indeed, the next phase in the transformation of environmental justice participants, and their local communities, lies in forging partnerships and networking with grassroots organizations across substantive areas. . . . Only the future will prove whether, and to what extent, [networks of activists] can consolidate the power of varied local organizations such as CRCQL and implement an agenda for environmental and social justice for society's most vulnerable members. Until then, the success of groups such as CRCQL suggests that the goal is not out of reach. . . .

. . .

Foster's analysis of the environmental justice movement in Chester suggests that social justice demands more than a fair distribution of burdens and benefits. Justice also requires participatory parity—equal respect, recognition, and voice for all community members. Procedural protections—such as the notice and comment rulemaking process followed by the state environmental protection agency prior to permitting new waste processing facilities—may not be sufficient to ensure participatory engagement by African Americans, who have been actively discouraged and even prohibited from participating in governance throughout American history.

Next, we turn to reproductive justice, a movement that has been linked to environmental justice since its inception. The reproductive justice framework emerged from a meeting of American women of color at a 1994 United Nations development conference in Cairo. The conference was explicitly focused on the interdependence of economic development, environmental protection, and women's rights as human rights. In the excerpt below, Loretta Ross, a key figure in the movement, describes reproductive justice.

UNDERSTANDING REPRODUCTIVE JUSTICE*

Loretta Ross

. . . Reproductive Justice is a positive approach that links sexuality, health, and human rights to social justice movements by placing abortion and reproductive health issues

in the larger context of the well-being and health of women, families and communities because reproductive justice seamlessly integrates those individual and group human rights particularly important to marginalized communities. We believe that the ability of any woman to determine her own reproductive destiny is directly linked to the conditions in her community and these conditions are not just a matter of individual choice and access. For example, a woman cannot make an individual decision about her body if she is part of a community whose human rights as a group are violated, such as through environmental dangers or insufficient quality health care. Reproductive justice addresses issues of population control, bodily self-determination, immigrants' rights, economic and environmental justice, sovereignty, and militarism and criminal injustices that limit individual human rights because of group or community oppressions. . . .

The theory of reproductive justice was created because women of color were looking for a way to articulate the needs of our communities. SisterSong's three core reproductive justice principles developed since our founding in 1997 reflect the theory and practice we collectively learned and shared. We believe that every woman has the human right to: Decide if and when she will have a baby and the conditions under which she will give birth. Decide if she will not have a baby and her options for preventing or ending a pregnancy. Parent the children she already has with the necessary social supports in safe environments and healthy communities, and without fear of violence from individuals or the government. . . .

We must end the separation of abortion rights from other social justice, reproductive rights and human rights issues because it is difficult—if not impossible—to mobilize communities in defense of abortion rights if abortion is taken out of the context of empowering women, creating healthier families, and promoting sustainable communities. By shifting the definition of the problem to one of reproductive oppression rather than a singular focus on protecting the legal right to abortion, SisterSong offers a more inclusive and catalytic vision of how to move forward in building a new movement for women's human rights. . . .

Reproductive justice calls for an integrated analysis, a holistic vision and comprehensive strategies that push against the structural and societal conditions that control our communities by regulating our bodies, sexuality, labor and reproduction. It demands that we work across social justice movements to build a united struggle for universal human rights. It allows us to pursue a vision that will protect and determine our complete physical, mental, spiritual, political, economic, and social well-being. In order to turn reproductive justice into action, we must develop new leaders, organize our youth, and educate our community leaders. . . .

We stand at a critical time in which to consider the pro-choice movement's future direction. The implications for women's lives are increasingly acute in light of the extreme political conservatism sweeping the nation from all quarters and affecting reproductive and sexual health policies on all levels—ranging from the U.S. President and the Supreme Court, to state legislatures and local school boards and foreign policies. Moreover, assaults upon the civil and human rights of communities of color and other disenfranchised members of our society continue to rise within our nation's policies and the rapidly changing political climate. As such, we believe it is essential to utilize the reproductive justice frame as a means to unite women and their communities, be relevant to communities of color, and link to advocates from the nation's capital

to the grassroots in order to develop proactive strategies to protect and preserve our lives.

. . .

Ross's reminder that individuals are embedded in communities and individual health is inextricable from community health lends itself to the communitarian perspective of public health. She issued her call for networked advocacy by and for women of color and their communities in 2006. It rings with renewed urgency in the aftermath of the 2016 election. Building a coalition among a diverse array of women's rights, women's health, civil rights, immigrant rights, LGBT rights, disability rights, reproductive justice, environmental justice, and health justice advocates to resist the fiscally and socially conservative agenda of the Trump administration presents many challenges and opportunities for effective advocacy. Today's advocates are drawing lessons from the history of coalition-building efforts during the 1960s and 1970s. In the next excerpt, Christopher Curran and Marc-Tizoc Gonzales link the efforts of food justice activists in Oakland, California, to the city's long history of racial justice advocacy focused on self-sufficient access to food, health care, and other basic necessities.

FOOD JUSTICE AS INTERRACIAL JUSTICE: URBAN FARMERS, COMMUNITY ORGANIZATIONS AND THE ROLE OF GOVERNMENT IN OAKLAND, CALIFORNIA*

Christopher J. Curran and Marc-Tizoc González

Urban farming may be the latest evolution in the long struggle for interracial justice in Oakland, California. This broad movement for food justice has arisen due to an impending community health crisis; communities of color have long faced disproportionate rates of cancer, diabetes, and illnesses associated with lack of access to nutritious food and other forms of environmental racism. . . .

The city of Oakland has long served as an incubator of working class revolutionary movements that have coalesced around racial identity. While its neighbor across the bay, San Francisco, is known for the countercultural movements made famous by the Beat generation of the 1950s and the hippies of the 1960s, [and] the adjoining city of Berkeley became the epicenter of student-led resistance to the Vietnam War and other manifestations of American military aggression, Oakland has been home to less privileged revolutionaries fighting for something much more basic: survival.

Oakland is now considered one of the most ethnically diverse cities in the United States, but the current state of diversity is a relatively recent phenomenon. . . . [T]he

* 2011. *University of Miami Inter-American Law* Review 43 (1): 207–32. Reprinted by permission.

militarization of the economy during World War II opened up large numbers of shipyard jobs that were filled by Black sharecroppers from the South. As Oakland's Black population increased quickly, the city's banks and industries responded by adopting informal practices called "redlining," whereby investment and services were diverted away from predominantly Black neighborhoods, causing property values to fall. Then, as economic pressures and racial tensions increased with the loss of shipyard jobs after World War II, the city of Oakland adopted a policy of recruiting new police officers from the Deep South. Many of these white police hires brought racist attitudes and violent tactics with them.

Bobby Seale and Huey P. Newton formed the Black Panther Party [in Oakland] in 1966 as a call for organized Black nationalism and weapons training in defense against rampant police brutality. Much less publicized in the initial media reports at the time, however, were the neighborhood social programs at the core of the Panthers' Ten-Point Program calling for "Land, Bread, Housing, Education, Clothing, Justice and Peace," and exemption from the draft for Black men.

The Panthers established a free breakfast program for children in 1969, and within a year the program was running in cities throughout the United States and reaching more than 10,000 children. The Panthers implemented a series of initiatives called Survival Programs under the slogan "survival pending revolution." Melvin Dickson, one of the early Black Panthers and organizer of the Party's food programs, describes his reasons for setting up the free breakfast program as extending beyond the goal of meeting his community's need for sustenance. A deeper need, as he saw it, was self-determination of a type that would not be achieved by charity. . . .

When the Panthers founded an Intercommunal Youth Institute as an alternative model for education, Dickson set up a school gardening program to educate children about where food comes from and give them a stake in growing it themselves. In establishing the garden program, Dickson drew on his family's experiences growing food during his youth in West Memphis, Arkansas. As he tells it, members of his Southern Black community were skilled farmers "out of need, long before going back to the land became popular in the counterculture movement." By drawing on this tradition of growing food and making a public connection between the goals of providing sustenance and resisting oppression, Dickson and the other early Panthers took a step beyond reacting to injustice and toward creating a society that meets the basic needs of its members.

The Panthers captured the attention of the nation, and of the authorities. Calling the Panthers "the greatest threat to the internal security of the country," FBI Director J. Edgar Hoover maintained a campaign to violently intimidate the Panthers in an attempt to undermine and discredit their Marxist ideology and objectives. By the late 1970's, with many in the party leadership in jail, on the run, or dead, and with group unity weakened by internal disagreements between those who favored a reformist approach and those who advocated more radical revolutionary tactics, the Panthers disbanded.

The Panthers' influence, however, remains strong, though it is not always credited. While Melvin Dickson was not the first to introduce the idea of gardens in schools, gardens similar to the one tended at the Intercommunal Youth Institute were in place by 2008 in more 3,849 of California's 9,223 public schools. . . . The current level of support is the result of widespread public and bipartisan support. . . . Based on studies

that have shown children who grow fruits and vegetables are more likely to develop preferences for eating them and that nutrition is closely linked to cognitive development, the California legislature enacted a series of . . . bills beginning in 1999 to support school gardens. . . .

Despite the mainstreaming of school gardens in California, the future of this and other innovative programs is less than secure due to the state's budget crisis. Notwithstanding the efforts of successive generations of Oaklanders to build autonomous communities, the number of Oakland's small grocery stores has gradually dwindled to the point that many residents now live in "food deserts"—urban areas with limited access to fresh, healthy produce but with an abundance of liquor stores and fast food. West Oakland in particular, with an average household income of $20,000 per year and where 35 percent of the residents do not have easy access to a car to travel the distance it takes to find a grocery store, is afflicted by this lack of access to nutritious food. The incidence of diabetes in West Oakland is three times higher than in the rest of Alameda County. . . .

West Oakland is home to a diffuse range of organized and unorganized groups that have responded to the current slow-motion crisis of food insecurity. City Slickers Farms is a group of urban farms and gardens that organized in 2000 and offers sliding scale food stands, educational programs, and training programs to teach low-income West Oakland residents how to grow food in their backyards. Oakland residents who worked with City Slickers Farms went on to form the People's Grocery in 2002, launching a "Collards & Commerce" youth program to employ and train youth in urban gardening, business, cooking, and nutrition workshops, as well as to run a grocery store on wheels called the Mobile Market. Another organization, Mo' Better Foods, was created in 1998 by David Roach to encourage Black farmers and develop markets for their produce in Oakland. Roach is the son of a part-time sharecropper from Texas and believes in changing eating habits while simultaneously preserving and strengthening the traditional food culture of the Black community. One of his current projects is to build an urban farm in Oakland based on the noninstitutional "educational park" model developed by Dr. Martin Luther King, Jr. These are just three of a growing network of urban agriculture programs in Oakland that have a philosophy based on food justice—the race-conscious movement that "asserts that no one should live without enough food because of economic constraints or social inequalities" [in the words of Althea Harper in a 2009 Food First Development Report].

The collective voice of food justice activists and new urban farmers has made an impression on Oakland's city government; in 2006, the City Council unanimously passed [a resolution authorizing the mayor's] Office of Sustainability to develop an Oakland Food Policy and Plan to produce 30 percent of Oakland's food needs within the city and immediate region. . . . Oakland's Food Policy Council is one of numerous food policy councils established across the country at the state, local, and regional level. . . . The Oakland Food Policy Council has undergone a multi-year process of formation, fundraising, and recruitment of members. . . . [Its recommendations] include a "fresh food financing fund" to help and encourage small business owners who want to sell healthy food[, and] changes to Oakland's zoning code to facilitate sustainable urban agriculture and remove legal obstacles to the practice. . . .

Food justice activists would do well to lobby hard for the funding of studies to yield empirical data on urban agriculture. If such studies strongly substantiate its potential

to reduce emissions, urban farmers can seize the moment to garner support for their cause as a politically feasible measure to further multiple goals relating to climate change, food security, and neighborhood revitalization all at once. In contrast to the divisiveness exhibited in the debate over carbon trading, urban agriculture can become a unifying force. . . .

In the struggle to provide for themselves and their communities, Oaklanders continue to draw on their roots; food justice activist and soul food chef Bryant Terry has hosted grub parties to share food and discussions about community health in the same room where the Black Panthers first debuted their free breakfast programs more than forty years ago. Due to the richness of its political organizing culture and the increasing collective expertise in sustainable food production, Oakland is becoming a model city for innovative approaches to urban agriculture. With a healthy degree of political pressure and well-timed lobbying supported by sufficient empirical research, there may be an opening for urban agriculture programs to marshal greatly increased levels of state support if they can be presented as a tool to reduce greenhouse gas emissions. . . . The underlying goal of food justice activists, however, is not simply to popularize urban agriculture as an emissions cutting measure, but to promote the practice of growing food in cities as a way to engender a fundamental shift in how our human society exists in relation to the natural cycles that govern our farms and ourselves. Whether increased support for urban agriculture in Oakland comes from the city government, the state, the nonprofit sector, or from no source other than individual neighborhood residents who make the decision to create community around the cultivation of food, it is undeniable that a powerful movement for food justice is gaining ground.

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The environmental justice, reproductive justice, and food justice movements share a common focus on community-level determinants of health and well-being. The relationship between health and place is a new frontier of social epidemiology and public health. As bioethicist Lisa Eckenwiler (2016) argues:

> [H]ealth justice demands the creation and sustenance of places that nurture care; allow for bodily integrity, mobility, and autonomy; and promote equity. . . .
>
> Ethical placemaking calls, first, for nurturing relations of care and interdependence. Ecological subjects are not so much self-reliant as embedded in relationships and, most importantly, those that help sustain us over time given our shared and variable fragility. Placemaking should support societies' obligations to provide the conditions in which people can care and be cared for. . . .
>
> Ethical placemaking also aims to ensure bodily integrity for ecological subjects[, which] requires access to health care services, green space, and nutritious food; freedom from violence and threats of violence; and protection from exposure to unsafe work conditions, weak infrastructure, and industrial pollutants. . . . Comprehensive neighborhood interventions aspire to address these concerns. . . .

> Ethical placemaking should contribute to autonomy, not interpreted in terms of individual self-reliance but in the relational sense that perceives individuals as originating and persisting within relations of care and interdependence and as flourishing given ongoing opportunities for self-directed thought and action. . . .
>
> Equity is at the moral center of place-based interventions for health. . . . [M]ost placemaking efforts in public health target entrenched health inequities and the particular social and physical conditions underlying them. . . .
>
> More generally, though, place-based interventions should be understood as efforts to promote health justice, or the capability to be healthy for all people. Given the importance of place for health, in other words, governments and other agents (the for-profit sector, lenders, and ordinary individuals) have responsibilities to create the conditions necessary for all people to be and endure in at least a minimally good—but, optimally, flourishing—life.

Public health laws and policies created and implemented through community action are at the heart of efforts to achieve health justice. Communities can act collectively to create safe and appealing green spaces and public thoroughfares; to ensure access to safe housing, fresh produce, and high-quality health care; to build school and work environments that support health and safety; and to secure public goods like breathable air, clean water, effective antimicrobials for treatable infections, and community immunity for vaccine-preventable illnesses. Public health law provides the tools—direct regulation, deregulation, litigation, taxation, and spending strategies—that communities use to create the conditions required for people to be healthy and flourish. In this and many other respects, law itself acts as a social determinant of health and a tool for achieving—or denying—health justice.

In our final excerpt, Emily Benfer highlights the role of law and legal advocacy in achieving health justice. Benfer's approach differs from, but is not incompatible with, the vision of health justice we have presented.

HEALTH JUSTICE: A FRAMEWORK (AND CALL TO ACTION) FOR THE ELIMINATION OF HEALTH INEQUITY AND SOCIAL INJUSTICE*

Emily A. Benfer

. . . Premised on fundamental principles of equity, health justice requires that all persons have the same chance to be free from hazards that jeopardize health, fully

* 2015. *American University Law Review* 65 (2): 275–352.

participate in society, and access opportunity. Health justice addresses the social determinants of health that result in poor health for individuals and consequential negative outcomes for society at large. . . .

ACHIEVING HEALTH JUSTICE

Health justice requires a regulatory and jurisprudential approach that consistently and reliably considers the health ramifications of judicial and legislative decision making. . . . Policies, laws, and social structures must anticipate, and be designed to mitigate, the effects of socioeconomic inequality and the social determinants of poor health. Equally important, health justice requires the development of laws and policies that prevent health inequity and increase individual capability. . . .

The problems of health inequity and social injustice are complex in nature and require an interdisciplinary and interprofessional response that engages all fields of expertise, including law, medicine, public health, social work, organizing, communications, historical studies, urban planning, education, and business, among others. At a minimum, in the quest for health justice, society as a whole must hold itself to a higher standard and commit to (1) developing primary prevention policies; (2) prohibiting, amending, or repealing laws adversely affecting health; (3) ending discrimination and racial bias; and (4) listening to, engaging, and developing affected communities.

Develop Primary Prevention Policies

The development of primary prevention policies to address conditions that disproportionately affect low-income and minority individuals must be prioritized, especially when the root cause and viable solutions are apparent. [For example, i]n many cases, health conditions related to indoor environmental hazards are a function of building and property maintenance. Only complete abatement of lead paint will guarantee protection of children from the devastating, life-altering consequences of lead poisoning. Federal and local governments must appropriate funds and invest in the elimination of environmental hazards, such as lead remediation efforts that remove lead-based paint and lead-contaminated soil in residential communities and areas that children frequent. . . . Equally important, the government and tenants must have access to penalties and remedies that will motivate property upkeep, maintenance, and repairs. . . . Companies responsible for manufacturing and selling lead-based paint with actual and constructive knowledge that it was harmful must be held accountable and required to invest in lead abatement. . . .

Address Laws That Negatively Affect the Health of Marginalized Populations

States must monitor legislation and correct any potentially deleterious effect on low-income and minority populations, especially the penalization of people who are victims of crime, impoverished, minority, or disabled. To do this effectively and before the harm occurs, states must (1) evaluate how a law might be applied, intentionally or inadvertently, to the disadvantage of marginalized individuals; and (2) examine the potential health effects on the entire population, paying special attention to marginalized individuals. Failure to take these precautionary and corrective measures will result in

a law that either perpetuates the issue legislators seek to address, or creates new ones. . . .

Ultimately, to prevent the lasting damage and poor health outcomes resulting from longstanding bias, discrimination, and segregation, federal and local governments, members of the legal system, members of academia, as well as communities and individuals, must commit to collaboratively developing robust and affirmative measures that address implicit bias and prevent its collateral negative effects.

Empower Communities and Individuals

Communities and individuals experiencing the negative consequences of injustice and health inequity firsthand are best positioned to identify the major challenges to overcoming inequity and to evaluate the viability of proposed solutions. The community-based participatory approach allows affected individuals to interact with policymakers while identifying issues and developing strategies that address social determinants of poor health. . . .

Community mobilization at the local level is a critical and proven component to improving health outcomes. Interventions and investments that affect the entire community have a greater likelihood of reducing health inequities than attempts to change individual behavior. For example, increased investment in healthy housing on a community-wide level can lead to housing stability, less strain on families, and decreased violence. Overall, this type of investment in a community results in the reduction of social inequity and improved community health and bonded communities that are better able to recognize, respond to, and fight off detrimental environmental and community health threats. Mobilized communities have higher political and community participation and are positioned to influence resource allocation. In contrast, the absence of community cohesion can have negative consequences, such as increased violence, decreased participation in democracy and reduced investment in education. These interventions can be conducted through community organizing, direct outreach, and investment in the development of communities. . . .

CONCLUSION

The status quo can only be improved by holding our laws and policies, our communities, and ourselves to a higher standard—one of health justice. Failure to respond to the flagrant injustice plaguing low-income communities and the resulting poor health outcomes impacts all of us. . . . As Dr. Martin Luther King, Jr. wrote, all persons "are caught in an inescapable network of mutuality, tied in a single garment of destiny. [Thus,] whatever affects one directly affects all indirectly."

We must make it our first priority to achieve health justice and insist on the elimination of health inequity and social injustice, especially of the kind that results in dangerous health consequences for minorities and people living in poverty. When individual human beings commit to these ideals, health justice will be realized. Only then will all individuals have the ability to access opportunity, achieve what they see as their responsibility and agency to do, and realize their fullest potential. Especially in this single garment of destiny, every human being should have that chance.

• • •

Benfer does not shy away from expressly condemning the injustice inherent in health disparities. She also uses the language of opportunity. Other scholars, such as Stephen Woolf and Jason Purnell (2016), advocate for collective action to reduce health disparities, but they also suggest that the rhetoric of opportunity may be more appealing across the political spectrum than language that calls out injustice and inequity:

> Median household income in the United States has been stagnant for 2 decades, a period when wealth shifted dramatically to the upper class. Widening income inequality and the endangered middle class are now topics of public discourse. Meanwhile, the public health literature has documented a steepening health gradient based on socioeconomic status. The adverse consequences of having low education and income have intensified. Life expectancy has decreased for whites of low socioeconomic status. . . . The health implications of this trend are concerning, especially at a time when the number of financially stressed households is increasing. . . .
>
> Recent health care delivery and financing reforms . . . have created a business case for providers and payers to address community conditions that drive population health outcomes, for which they are now accountable, and that increase costly overutilization of hospital services. . . . A more holistic view is that everyone seeks a good life. Health is an essential component, but a good life also involves productive work, emotional and spiritual well-being, supportive social relationships, and a clean and safe environment. Domains that shape a good life include health, education, employment, income, housing, the environment, safety, and so on. These sectors have typically worked in silos to improve outcomes, but growing concerns about inequities ([e.g.,] in academic achievement, jobs, home loans, police treatment) are drawing public attention to the same root causes. . . . Inequity, a term that can engender political controversy, is giving way to the language of opportunity and the more positive, bipartisan message that everyone deserves a fair chance at the American dream.

As the excerpts above indicate, the tensions and complexities that have long characterized public health law and ethics are evident in current debates. Threats to defund safety net programs that keep millions of children and families out of poverty, skyrocketing rates of opioid overdose, the mounting burden of diabetes, surging suicide rates, increasingly common outbreaks of vaccine-preventable diseases, the looming danger of antimicrobial resistance, and the wide-ranging impacts of climate change contribute to a growing sense of unease about the future. Most agree that these problems warrant a response, but there is deep disagreement about what that response should be. When must individual interests give way to meet collective needs for health and justice? What is the proper balance between individual and collective responsibility for health? What

conditions trigger a mutual obligation to offer assistance to those in need? Should collective action be achieved through public governance subject to the Constitution's requirement of equal protection or private charitable organizations that enjoy the freedom to help whomever and however they see fit? To what extent should good health and a long life be included among the prizes for doing well financially?

The health justice framework we have adopted in this volume unites the science, politics, law, and ethics of public health. Social epidemiology has generated powerful insights about the influence of embedded injustice on health and longevity. We cannot ignore the implications of those insights for the scope of public health law and policy. The expansion of public health law to address noncommunicable diseases, injuries, and the social determinants of health necessitates particular attention to legal and ethical constraints derived from individual rights. But collective action to ensure the conditions required for people to be healthy and secure is the legitimating purpose of government. Limiting the scope of public health law in the face of so much preventable death and suffering would be profoundly unjust.

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