CHAPTER 4

# Population Health and Federalism: Whose Job Is It?

> It is one of the happy incidents of the federal system that a single courageous state may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country.
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> —*New State Ice Co. v. Liebmann*, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting)

What do infectious epidemics, hurricanes, cigarettes, and handguns have in common? First, each can harm the health and well-being of multiple populations. Second, the source of each of these threats extends beyond the boundaries of any single locality or state, yet each of these public health threats affects different regions differently. Third, optimal interventions for each of these threats would include local, statewide, national, and perhaps international components. Yet, in the United States, efforts to protect diverse populations from each of these dangers are hampered by uncertainty and confusion as to whether the job belongs primarily to the federal government or to the states.

Sometimes, as evident in the bungled response to Hurricane Katrina in 2005, poor communication and coordination between federal and state officials is the cause of the problem.[1] Sometimes, as was also true when Katrina struck, public health protection is jeopardized by constitutional doctrines that raise doubts as to the authority of each level of government

to act.[2] Not surprisingly, private interests threatened by public health regulations have become adept at playing the federalism game, challenging state regulations for intruding on the federal government's jurisdiction while questioning federal regulations as violating states' rights. Although such inconsistency may be expected from regulated interests, it is more problematic when it appears in judicially created doctrines.

The uncertainty caused by federalism is not new. In the early years of the Constitution it was generally assumed that the states, acting through their so-called police powers, were the legal entities authorized to protect public health. Indeed, courts in the nineteenth century often asserted that if the matter at hand was a public health regulation, it clearly belonged to the states.[3] Nevertheless, the federal government became involved with public health quite early on. For example, in 1796, Congress authorized the federal government to impose maritime quarantines.[4] Very shortly thereafter, Congress enacted a law to support the distribution of the newly discovered smallpox vaccination.[5] Ever since, both the states and the federal government have undertaken an active, if inconsistent, role in protecting population health.

What is new today is the degree to which uncertainties over federalism threaten to disable both the states and the federal government from undertaking public health measures. Also new is the lack of weight given to the population health issues at hand when courts decide the boundaries of federalism. In effect, the formalities of federalism, rife with their own complexities, now threaten to overshadow the ability of any government to effectively protect the health of its populations. These formalities may also undermine the fundamental principles federalism was meant to serve. A population-based perspective that recalls that protection of population health is a vital goal of governments and law as well as the centrality of populations to legal analysis holds the potential for improving public health protection and revitalizing the law of federalism.

## The Role of the Police Power

Federalism, it has been said, is the great genius of American constitutionalism. By splitting the "atom of sovereignty," the framers of the Constitution created a governmental structure in which power is shared, diffused, and

checked.[6] As a result, multiple jurisdictions are available to address pressing public problems and protect individual and minority interests. Both the empowering and the limiting aspects of federalism are relevant to protecting population health.

Traditionally, public health protection was assumed to fall within the province of the states.[7] This is because under the structure established by the framers and enshrined in the Constitution, the federal government is a government of limited, albeit impressive, authority. It can only exercise those powers granted to it by the Constitution, including the powers enumerated in Article I, Section I granting Congress the power to "regulate Commerce with foreign Nations, and among the several States and with the Indian Tribes," to "lay and collect Taxes, Duties, Imposts and Excises, to pay the debts and provide for the common Defense and general Welfare of the United States," and to make all laws "which shall be necessary and proper for carrying into Execution the foregoing Powers."

Although the Constitution's preamble states that the document was executed to promote the general "welfare," the Constitution does not explicitly give the federal government any authority to protect public health or to regulate in order to further the general good. This point is sometimes noted in connection with the Tenth Amendment, which expresses the "truism" that "the powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people."[8]

Thus the Constitution reserves to the states the authority not given to the federal government. Under traditional constitutional theory, this authority includes the power to protect the public's health and welfare. This point was expressed famously by Chief Justice Marshall in 1824, when he stated that "inspection laws, quarantine laws, [and] health laws of every description" are among the mass of powers that continued to reside with the states after the Constitution's ratification.[9]

As discussed in chapter 2, these diffused and difficult to define powers are known as the police powers, a term that derives from the ancient Greek *polis* for political community. Throughout the nineteenth century, the police powers were often identified by courts with the protection of public health and safety as well as morals. In numerous cases courts relied on a simplistic equation between public health and the police powers to decide the constitutionality of a state law that was charged with exceeding the

state's jurisdiction. For example, when Chief Justice Marshall upheld a state law authorizing the erection of a dam on a stream used for interstate commerce, he noted that the dam would improve the health of the inhabitants of the stream's banks.[10] Likewise several decades later, the Supreme Court upheld an inspection fee imposed on vessels arriving at the port of New Orleans on the theory that the state could take measures to protect the city from the importation of deadly diseases.[11]

This simple identification of public health with the states' police powers was always riddled with exceptions and subject to potential problems. Most notable was the overlapping and increasingly important scope of federal authority. Although the Constitution does not grant the federal government any public health powers per se, it quickly became accepted that those powers that Article I grants to the federal government are "plenary" and can be used to achieve public health goals.[12] The earliest example of this may have been the 1796 act authorizing the establishment of maritime quarantines.[13] This law, which was enacted after vigorous congressional debates over the scope of federal authority, demonstrates vividly how Congress could use its Article I commerce powers to tackle a public health problem. The 1965 amendments to the Social Security Act, which created the Medicaid and Medicare programs and provided health insurance to millions, provide more modern and far-reaching examples of Congress's use of one of its enumerated powers (to tax and spend) to achieve a goal that might traditionally have been thought of as within the states' police powers.[14]

The 1796 quarantine act illustrates another conceptual obstacle for any effort to divide the world of legal powers along neat federal or state lines. Although maritime quarantines are core public health laws in that they are instituted to prevent diseases from being imported, they are also often motivated by concerns about the impact of disease on commerce and tariff revenue. Similarly, many if not most laws that an observer might reflexively call a public health law result from mixed motivations. Laws also tend to have myriad effects. Thus the placement of commercial laws on one side of the federalism divide and public health laws on the other side is not quite as simple, or sensible, a task as it may at first appear.

Nevertheless, for many decades, the inherent difficulty of determining whether a law was or was not about public health did not present a significant impediment to either federal or state efforts to enact public health

regulations. From the New Deal until the 1990s, the Supreme Court adopted a highly deferential stance toward both state and federal laws that either appeared to protect public health or purported to do so. Recognizing the problematic nature of drawing fine lines between Congress's power under Article I and the states' police powers, and concluding that the allocation of power and responsibility could be best dealt with by the political process, the Supreme Court settled on a doctrinal approach that essentially provided no federalism-based limitations on congressional action.[15] As a result, the federal government was able to establish a broad range of regulations and programs that aimed either directly or indirectly at public health. The enactment of the Occupational Safety and Health Act,[16] the National Childhood Vaccine Program,[17] and the Food Drug and Cosmetic Act,[18] all gave lie to the traditional view that the protection of population health generally belongs to the states as opposed to the federal government.

Yet, states continued to be key players in population health protection. Even as the federal government's involvement in the area grew, with the apparent blessing of the New Deal and post-New Deal Supreme Courts, state and local governments continued to provide the bulk of direct, core public health activities (such as surveillance, restaurant inspection, and medical licensing).[19] In addition, although some state public health activities were found to be unconstitutional under federalism-based theories designed to protect interstate commerce, such holdings were relatively few until the mid-1980s. Until then, the ability of both the state and federal governments to protect public health was rarely limited by questions of federalism. Today questions abound.

## Limits on State Action—the Dormant Commerce Clause

Since the mid-1980s, decisions rendered under both the so-called negative or dormant commerce clause as well as the doctrine of preemption have increasingly challenged the states' ability to protect population health. Although each doctrine is distinct, both demonstrate the dangers that judicial enforcement of federalism can present for population health.

Consider first the evolution of the dormant commerce clause doctrine. The doctrine itself dates back to the early days of the nineteenth century,

when the Constitution's grant to Congress of authority to regulate commerce was understood as depriving states of the same power.[20] Under this exclusive powers approach, jurists assumed that because the Constitution vested the power to regulate interstate commerce with the Congress, it effectively took any such powers away from the states. Thus state regulations of interstate commerce were deemed to be unconstitutional, even though there is no language in the Constitution to that effect. (Hence, the negative commerce clause.) On the other hand, because courts deemed the protection of public health to be solidly within the core of the states' police powers, a state regulation would be held constitutional and not an impermissible regulation of interstate commerce if the law were viewed as a public health law. As a result, the characterization of a law as a public health law was extremely important to the determination of the law's constitutionality. In that sense, the early dormant commerce clause doctrine recognized the importance of public health to legal decision making.

By the mid-nineteenth century, however, the exclusive powers approach came under pressure. Courts recognized that some state regulation of interstate commerce was desirable or at least inevitable.[21] Moreover, courts perceived that states might use putative public health measures as a pretext for interfering with interstate commerce.[22] As a result, alternative rationales were offered to justify federalism boundaries under the dormant commerce clause.

One highly influential rationale explained the dormant commerce clause doctrine as embodying the Constitution's disdain for discrimination and favoritism between the states.[23] Seeking to protect commerce from the evils of state protectionism and balkanization, this theory found state laws that appeared either facially or by their impact to discriminate against out-of-state economic interests as unconstitutional. In other words, state laws that were viewed as protectionist were found to violate the Constitution.

Initially this approach did not present a major hurdle for state public health laws. Although state laws that purported to protect public health were occasionally found unconstitutional because of their discriminatory nature or the whiff of protectionism that surrounded them, courts generally maintained a relatively deferential stance toward laws enacted in the name of public health.[24] For example, although striking down a municipal ordinance that required milk to be pasteurized within five miles of the city as protectionist, the Supreme Court reminded lower courts that a state has

an "unquestioned power to protect the health and safety of its people."[25] A few years later, in upholding an injunction against a newspaper publishing advertisements for optometrists, the Supreme Court cautioned that "the Constitution when conferring upon Congress the regulation of commerce . . . never intended to cut the States off from legislating on all subjects relating to the health, life, and safety of their citizens, though the legislation might indirectly affect the commerce of the country."[26]

This deference to the states' police power eroded after the Supreme Court settled on a two-tiered analysis for determining whether state laws, including those that purport to protect health or safety, violate the dormant commerce clause. Today, courts treat as per se unconstitutional those state laws that "directly regulate[] or discriminate[] against interstate commerce."[27] On the other hand, state laws that have a less direct or only an incidental impact upon commerce fall into the second tier and are usually subject to the so-called *Pike* balancing test that asks whether the state law is legitimate and whether the burdens it places on commerce outweigh its local benefits.[28] Although the first tier of the analysis would seem to create the greater obstacle for legal interventions designed to protect public health, in fact, both tiers may pose problems for legal measures aimed at protecting population health.

The first and perhaps seminal case applying the first tier was *City of Philadelphia v. New Jersey*,[29] in which the Supreme Court considered a challenge to a New Jersey law that prohibited the importation of most "solid or liquid waste which originated or was collected outside the territorial limits of the State."[30] In an opinion by Justice Stewart, the Supreme Court found the statute unconstitutional, stating that "where simple economic protectionism is effected by state legislation, a virtually *per se* rule of invalidity has been erected."[31] Moreover, the Court continued, the question of whether the statute was intended to address an environmental problem was not relevant to the statute's constitutionality. As long as the state used discriminatory means, the statute was effectively assured of being found unconstitutional, even if the statute addressed a legitimate or pressing problem, such as solid waste disposal.

In announcing this per se rule, Justice Stewart had to discuss quarantine laws that had long been considered constitutional. Overlooking the fact that quarantines also applied to persons as well as to goods, Justice Stewart described the quarantine exception to the dormant commerce clause as a

very narrow one that applies only when laws ban the importation of noxious articles that pose an immediate hazard to the state that institutes the quarantine. Justice Stewart noted that "there has been no claim here that the very movement of waste into or through New Jersey endangers health, or that waste must be disposed of as soon and as close to its point of generation as possible."[32]

Responding in dissent, Justice Rehnquist stressed the severity of the environmental and health problems posed by solid waste and argued that the majority failed to give the state adequate leeway to address those dangers.[33] Yet in emphasizing the state's very real interests in protecting its population, and in noting the historic breadth of the quarantine power, the justice failed to consider the burdens that New Jersey was potentially imposing on other states' efforts to protect their own populations. Thus neither the majority nor the dissent recognized that *Philadelphia* presented a key question for public health federalism: which level of government—state or federal—is best suited to protect the health of multiple populations?

Had the justices asked that question, they might well have concluded that in the case at hand, a federal solution was preferable. But that would only have led them to another also critical question: in the absence of an effective federal response, how much leeway should be given to state efforts to address problems that could theoretically be better addressed at the federal level? As will be discussed, a population-based approach will tend to err in upholding such state laws, at least against federalism-based attacks, not only because they may at times improve the health of populations but also because they can provide data for understanding how population health issues should and should not be addressed.[34] In *Philadelphia*, however, neither the majority nor dissent asked such questions. Instead, the majority offered a formulaic per se test and the dissent nostalgically preached the virtues of the letting states solve their own problems.

Despite the Court's failure to consider the population health issues immanent to the case, the per se test adopted in *Philadelphia* did not itself represent a major blow to many contemporary public health laws. Since the development of techniques other than quarantine to prevent the spread of most epidemics, few public health problems require legal interventions as overtly discriminatory against interstate commerce as was the New Jersey solid waste law.

Nevertheless, the Court's approach in *Philadelphia* presaged a significant hurdle for public health protection as well as a major departure from a population perspective. The difficulty lies in part from the Court's expansive interpretation of protectionism in subsequent cases. For example, in *C. &. A. Carbone, Inc. v. Town of Clarkstown*,[35] the Supreme Court applied the *Philadelphia* approach to a municipal ordinance that required all solid waste within the town to be deposited at a local waste transfer station. In contrast to the statute at issue in *Philadelphia*, this ordinance did not bar the importation of any goods, it simply required a particular procedure to occur before the disposal of any local waste. Moreover, as Justice Souter astutely noted in his dissent, the ordinance served to help finance the local transfer station by guaranteeing it a steady supply of waste to process.[36] And, of course, by helping finance the station, the ordinance helped ensure the sanitary disposal of the waste. Thus the ordinance could be viewed as a sanitary law, among the most well-accepted exercises of the police power. The *Carbone* majority, however, applied *Philadelphia* and viewed the ordinance as discriminatory against out-of-state interests because it required local producers of waste to use or pay for the local transfer station. So understood, the law was seen as protectionist and hence per se unconstitutional. In effect, the majority found that the ordinance's efficacy in addressing the waste disposal problem was not germane to the constitutional question.

More recently, the Supreme Court has appeared to reverse course and grant public health protection somewhat greater weight in dormant commerce clause cases. In *United Haulers Association, Inc. v. Oneida-Herkimer Solid Waste Management Authority,* the Supreme Court upheld a "flow control" ordinance quite similar to the one struck down in *Carbone*, with one exception.[37] According to the majority opinion, authored by Chief Justice Roberts, the flow ordinance in *United Haulers Association* favored a public, rather than a privately owned, waste transfer station.[38] The Court found that distinction critical because "unlike [a] private enterprise, government is vested with the responsibility of protecting the health, safety, and welfare of its citizens."[39]

Rhetorically, the Court's opinion in *United Haulers Association* appears to adopt a population perspective by recognizing the importance of using law affirmatively to protect the health of populations. Indeed, the Court even suggests that government has such a duty. The opinion also appears

to appreciate that states and local governments were traditionally responsible for overseeing the safe disposal of waste.[40]

Nevertheless, the impact of *United Haulers Association* on the first tier of the Supreme Court's dormant commerce clause jurisprudence remains unclear. Although the distinction between a publicly controlled and privately controlled waste transfer station is not trivial from the perspective of an approach to law that emphasizes the government's affirmative role in promoting health, it is nevertheless relatively narrow and does not provide any cushion for state laws that regulate the private sector. Hence, the interests of commerce by the private sector continue to trump population health, at least when regulations can be said to discriminate against interstate commerce. Moreover, the Court's opinion in *United Haulers Association* adheres to a rigid formalism that privileges the nominal distinction between public and private entities, without paying any attention to whether the regulation at issue does in fact benefit—or is even designed to benefit—the health of populations. Indeed, the opinion is remarkable for its blindness to the empirical world.

The preference in contemporary dormant commerce clause doctrine for formalism and the concomitant neglect of empirical considerations is also evident in a series of cases that relate to what is known as extraterritoriality. Since 1982, the Supreme Court has expressed concern about state laws that have an extraterritorial effect and impose legal obligations on out-of-state activities.[41] According to the Court, by regulating out-of-state activities these laws inappropriately and almost always unconstitutionally burden interstate commerce because they subject economic entities to multiple and potentially inconsistent regulations.[42]

As a result, lower courts have treated extraterritorial laws as falling within the first tier and have applied a per se rule, thereby invalidating state laws that seek to regulate the distribution of harmful material by the Internet (including child pornography and cigarettes).[43] Strikingly, these cases give little or no weight to the population health impact of their decisions. Nor do the cases consider the possibility that different populations experience public health problems differently and therefore may, at times, benefit from a local or state regulation. Finally and most problematically from a population health perspective, these cases often fail to appreciate, never mind incorporate, public health methodologies. In demanding a singular approach to complex problems and by preventing states from

developing new and varied solutions, these cases threaten to thwart society's ability to test and analyze different approaches to public health problems. In effect, the cases fail to understand that empirical verification requires the existence of populations facing different conditions and the testing of different solutions. Or, to put it most simply, the courts fail to grasp that we cannot know whether a particular approach to a public health problem, be it cigarette smoking or drunk driving, works unless we can compare its impact to that of different approaches in relatively similar populations. By shutting down the "laboratories of democracy," courts undermine everyone's ability to make informed judgments about the efficacy of regulations.

Theoretically, empirical evidence about the health impact of a regulation should play a greater role when courts review regulations in the second tier; in other words, when courts review laws that are not thought to be protectionist or do not impose direct regulations on interstate commerce. According to settled doctrine, these laws are subject to the *Pike* test and are upheld as long as the burdens placed on interstate commerce do not clearly exceed the local benefits obtained by the laws.[44] According to the Supreme Court, in undertaking this test courts should respect a state's goals.[45]

Often courts do appear to value a state's attempt to protect population health. After rejecting the application of the per se rule to public entities in *United Haulers Association*, for example, the Supreme Court upheld the flow control ordinance under the *Pike* test. According to the Court, the ordinance passed the test because any "incidental" impact on interstate commerce would not exceed the ordinance's public benefits, which were said to include helping finance waste disposal and encouraging recycling and the proper disposal of hazardous materials.[46] In reaching this conclusion, the Court asserted that it would not rigorously review state police power actions.

At times, however, the Court has appeared to do just that. For example, in *Kassel v. Consolidated Freightways Corp.*, the Court struck down an Iowa law that limited the length of "doubles," or twin trucks, to sixty feet.[47] Although the state claimed that the law was designed to prevent highway accidents, the Supreme Court, in a plurality opinion by Justice Powell, concluded that the state had not proven that the statute would in fact benefit

safety. In undertaking this review, Justice Powell granted little or no deference to the state's claim that the regulation would protect public health. Instead, his analysis suggested that as long as the safety claim could not be proven, the burdens placed on interstate commerce, which were far easier to observe, would be decisive. In effect, as under the first tier of analysis, Justice Powell prioritized free trade over population health without providing any rationale of why he was doing so and without offering any methodology for balancing, as the *Pike* test purports to do, a regulation's health effects against its impact on commerce. Indeed, the Court's inability to explain how to conduct such a balancing test in any rigorous or even understandable fashion has led justices with such divergent views as Justices Brennan and Scalia to condemn the test.[48]

The *Kassel* plurality's approach to analyzing state laws that are not obviously protectionist or extraterritorial in their reach can have devastating consequences for efforts to use the law to promote public health. For example, in *Consolidated Cigar Corp. v. Reilly*, a Massachusetts law that required warning labels on cigar packages was found unconstitutional by the Court of Appeals for the First Circuit under the *Pike* test.[49] The court never explained why the burdens on interstate commerce that resulted from the labeling requirement outweighed the health benefits the state sought to achieve under the regulation. Indeed, the opinion is striking for its lack of rigorous analysis.

Unless the reluctance of the Court in *United Haulers Association* to rigorously review police power actions is applied more broadly, and consistently, the *Pike* test may continue to inhibit efforts by states to use their law to protect the health of populations. As the economy becomes more complex and interrelated, local state laws inevitably pose a greater burden on interstate commerce. Consider, for example, state laws that require physicians to be licensed. These laws have been considered an appropriate exercise of the states' police power for well over a hundred years.[50] Decades ago, they had no obvious or discernable effect upon interstate commerce because it was difficult, if not impossible, to envision how a physician could practice medicine across state lines. By the late twentieth century, the development of telemedicine suggested that these very traditional laws could indeed pose problems for interstate interests. By the dawn of the twenty-first century and the rise of the Internet, laws that block the practice of medicine over the Internet may seem to stand in the way of commerce.

At the same time, public health studies are increasingly demonstrating the national, indeed global, nature of many public health problems. From cigarettes to avian influenza, motor vehicle injuries to HIV, it is no longer plausible to believe that public health protection can succeed if it is limited to interventions that do not touch on out-of-state interests. Nor can broad social determinants of health be effectively addressed without affecting commerce beyond the state's borders. Thus, the protection of population health increasingly requires efforts that cross state lines and affect out-of-state interests. Unfortunately, the current, formalistic doctrine, which is uninformed by the concerns, perspectives, and methodologies of public health, does not provide a solution. As a result, despite the traditional identification of the police powers with public health and the Supreme Court's frequent paeans to states' rights, the contemporary dormant commerce clause doctrine creates a formidable and inconsistent barrier to using law to protect the health of populations.

## Federal Authority to Protect Public Health

The increasing difficulty that states face in attempting to regulate on behalf of public health and the increasing interstate nature of health problems argue for expanding the federal government's role in protecting population health. The federal government, after all, has more resources than the states to deal with public health threats. Moreover, only the federal government can enact regulations that explicitly extend across state lines and address interstate (as well as international) threats. Indeed, in contrast to the states, the federal government is not limited by the Court's dormant commerce clause doctrine. Rather, it is directly empowered by the Constitution to enact laws that regulate interstate commerce, even if such laws restrain or burden interstate commerce. Hence, to the extent that public health regulations implicate interstate commerce, as they increasingly do, it appears sensible to assume that the federal government should assume primary responsibility for public health protection at least within the United States.[51]

To a large extent, that has already happened. Throughout the twentieth century the federal government's involvement in matters relating to public health expanded greatly.[52] The process began in 1906 with the enactment

of the Food and Drug Act,[53] and accelerated during the New Deal as the federal government became more involved in numerous aspects of the economy and the Supreme Court adopted an extremely broad interpretation of Congress's authority under both the commerce clause and the tax and spend clause.[54] This not only opened the door for enhanced federal involvement in such core New Deal projects as workers' rights and financial security, matters that indirectly affect the health of broad populations, but also ultimately in more traditional public health activities, such as the regulation of product safety or the quality of air and water, and even to a degree, the practice of medicine.[55] Today, not only does the federal government provide a large share of funding for state public health agencies, it has also come to dominate many core public health activities that once resided solely with the states.[56]

The breadth of federal regulation in areas that were previously left to the states has led to the increasing displacement, or preemption, of state laws. Under the supremacy clause, federal laws trump conflicting state laws.[57] In addition, when Congress acts pursuant to its Article I authority, it may chose to preempt either some or all state laws related to the field.[58] However, statutory language pertaining to preemption is notoriously ambiguous, especially about whether Congress intends to preempt private tort actions.[59] In addition, federal statutes can be found to preempt state action even in the absence of any specific federal statutory language, either because a state regulation conflicts with federal policy or because the federal regulation of the issue is so pervasive as to evidence Congress's attempt to occupy the entire field.[60]

In recent years, industries regulated by states or subject to state tort actions have increasingly relied on preemption as a defense.[61] Moreover, federal agencies, such as the Food and Drug Administration (FDA), have recently taken a new and more expansive view of the preemptive effect of their regulations.[62] Although the Supreme Court has repeatedly asserted a presumption against preemption of state health and safety laws, meaning that preemption should not be found in the absence of clear statutory language mandating it,[63] neither the Supreme Court nor the lower courts have consistently adhered to that approach, resulting in new obstacles for state efforts to protect population health.[64] For example, in 2008 in *Rowe v. New Hampshire Motor Transport Association*, the Supreme Court found that the Federal Aviation Administration Authorization Act of 1994 preempted the

state of Maine's efforts to prevent shipping companies from delivering tobacco products to minors.[65] In so doing, the Court refused to find or imply any "public health exception" to the sweep of federal preemption.[66] The same day, the Court also found that the Medical Device Acts Amendments of 1976 preempted state tort actions brought against defective medical devices that had been subject to premarketing approval by the FDA.[67]

A few weeks later an equally divided Court affirmed without opinion a lower court ruling upholding a Michigan law barring drug claims except when the manufacturer has defrauded the FDA.[68] However, Chief Justice Roberts, who has thus far been a strong supporter of preemption, did not participate in that case, leaving it unclear as to how the Court will rule in future cases about the preemption of drug liability claims. Whatever the Court ultimately concludes about the preemptive impact of FDA regulations, it is likely that state efforts to protect population health will continue to face the hurdle of federal preemption. As will be discussed, from a population-based approach this is problematic to the extent that preemption is unaccompanied by effective federal population health interventions, as may be the case with an overly expansive finding of FDA preemption.

The growth of federal involvement in traditional state public health activities, as well as the increasing tendency of regulated industries to assert preemption claims, stands in stark contrast to a series of Supreme Court decisions in the 1990s that appeared to restrict the scope of federal authority under the commerce clause.[69] Although, as we shall see, the Court has recently pulled back from the so-called new federalism approach heralded by these cases, uncertainty continues to cloud federal efforts to protect population health.

Without doubt the key case was *United States v. Lopez*, decided in 1995.[70] As previously noted, since the New Deal courts had read the federal government's authority under the commerce clause broadly to allow Congress to regulate almost anything, from homegrown wheat to racial discrimination.[71] In fact, between 1936 and 1995 the Supreme Court denied every challenge brought under the commerce clause to a federal regulation of private sector activity.

*Lopez* affirmed such a challenge. The federal statute at issue was the Gun-Free School Zones Act, which made it a federal crime to possess a firearm within a thousand feet of a school.[72] In declaring this statute unconstitutional, Chief Justice Rehnquist, writing for a 5–4 Supreme Court

majority, emphasized both the limits on Congress's power under the commerce clause and the Court's role in reviewing congressional oversteps. Perhaps most significantly for population health, the Court stated that when, as in the case before it, Congress attempts to regulate a noncommercial activity by claiming that it affects interstate commerce, the effect must be substantial and the Court must conduct an independent review that does not rely exclusively on the assertions or findings of Congress.[73] Without such stringent oversights, the Court stated, Congress's power under Article I would be transformed into "a general police power of the sort retained by the States."[74] Interestingly, in suggesting that Congress's authority under the commerce clause had to be read narrowly to preserve a domain for the states and their police power, the Court did not consider the narrowing effect that decisions under the dormant commerce clause had on just such authority.

*Lopez* was followed in 2000 by *United States v. Morrison*,[75] in which the same 5–4 majority that prevailed in *Lopez*, found that Violence Against Women Act[76] unconstitutional because Congress was regulating a matter (gender-based violence) that was not commercial in nature and did not substantially affect commerce. Once again, the Court gave little or no deference to Congress's findings of an impact on commerce, essentially ignoring what Justice Souter termed a "mountain of data" showing the effects of violence against women on interstate commerce.[77]

Five years later, however, the Supreme Court, again by a 5–4 vote, appeared to reverse direction. In *Gonzales v. Raich*, a majority of the Supreme Court held that Congress had the authority to prohibit the possession or use of medical marijuana that was to be used intrastate and in accordance with California law.[78] In distinguishing *Lopez* Justice Stevens, writing for the majority, emphasized two factors. First, in contrast to the Gun-Free School Zone Act, the federal Controlled Substances Act at issue in *Gonzales* regulated "quintessentially" economic activity.[79] Moreover, the act created a comprehensive regulatory scheme, which the majority believed needed to be assessed for its overall effect on commerce. This latter point was critical to Justice Scalia, who in a concurring opinion, argued that Controlled Substances Act's application to medical marijuana was constitutional not because the locally grown marijuana affected commerce but because Congress had the power under the "necessary and proper" clause to prohibit the possession and use of intrastate marijuana

in order to safeguard a larger regulatory scheme of interstate activity.[80] Justice Scalia emphasized that only when federal regulation of wholly intrastate activities is necessary for the success of a broader, interstate regulatory scheme is it constitutional.

In dissent, Justice O'Connor painted a very different picture. Central to her understanding of the case, was the "role of States as laboratories. The States' core police powers have always included authority to define criminal law and to protect health, safety, and welfare of their citizens."[81] Hence rather than focusing on the totality of the federal statute and how it related to interstate commerce, Justice O'Connor began with the premise that laws relating to health and safety ought generally to belong to the states. She then found that federal laws that intrude on the state's authority should be reviewed stringently to determine whether they had a sufficient nexus to interstate commerce to warrant federal intervention. To look at the federal law as a whole the way the majority did was, according to Justice O'Connor, "tantamount to removing meaningful limits on the Commerce Clause."[82]

Although the majority's holding in *Gonzales* suggests that, at least for now, the Court is unwilling to extend *Lopez* and strike down comprehensive federal statutes (at least when they prohibit socially unacceptable drugs), the deep division of the *Gonzales* Court shows that the lines between federal and state authority remain in flux. Moreover, the majority decision depended on the fifth vote of Justice Scalia, whose approach to the case emphasized the narrowness of the majority's holding. Critically, none of the justices considered the public health implications of the ruling as critical to the outcome. Indeed, to all but Justice Scalia, who focused on the broader regulation at issue, the formalities of federalism were not only dispositive, they were all that mattered.

A similar formalism and disregard for the population health ramifications of federal law is evident in a series of decisions limiting Congress's ability to use the commerce clause to impose obligations upon state governments. In *New York v. United States*, the Supreme Court struck down a federal law requiring states to develop plans for disposing of low level radioactive waste.[83] In the later case of *Printz v. United States*, it struck down a requirement that local law enforcement officials conduct background checks on gun purchasers.[84] In both cases, the Court read the Tenth Amendment as limiting Congress's ability to use the commerce clause to

"commandeer" or place affirmative obligations on the states. Vital to each decision was the majority's contention that the Framers envisioned the states to be separate and sovereign entities.

These no-commandeering decisions may have a greater impact on population health than either *Lopez* or *Gonzales.* Precisely because Congress has been sensitive to the traditional role that states have played regarding population health, many federal laws that aim to protect public health follow a cooperative federalism model, setting federal parameters and obligations on states, which are entrusted with actually enforcing the policy at hand. The no-commandeering cases question this federal reliance on the states. Moreover, these decisions may make it difficult for the federal government, which lacks a large, dispersed public health workforce, to work with and through the states to respond rapidly to a public health emergency, such as an influenza pandemic. This point was presciently made by Justice Stevens in his pre-September 11 dissent in *Printz*: "Matters such as the enlistment of air raid wardens, the administration of a military draft, the mass inoculation of children to forestall an epidemic, or perhaps threats from international terrorists, may require a national response before federal personnel can be available to respond."[85]

The federal government's ability to protect population health would be further jeopardized if the federal courts were to constrain the federal government's ability to use its power to tax and spend in order to achieve population health goals. Since the New Deal, the Supreme Court has interpreted Congress's so-called spending power broadly to achieve goals including public health protection that are not themselves enumerated in Article I.[86] In addition, the Court has affirmed that Congress can attach conditions to the money that it gives states.[87] In other words, when it pays the bills, Congress can commandeer states, but only within some limits.

To ensure that Congress does not use its economic clout to purchase away the role of the states, the Supreme Court has articulated some outer limits on Congress's power to attach conditions to grants to states. In *South Dakota v. Dole,* which upheld a federal law requiring states receiving federal highway funds to establish twenty-one as the legal drinking age, Justice Rehnquist identified two key requirements for Congress's use of the spending power to impose conditions on states.[88] First, Congress must be unambiguously state the conditions that states must meet in return for receiving the desired federal funds. Theoretically, this permits states to

reject the funds and ignore the federal mandate. Second, conditions placed on a state must be reasonably related to the programs the federal government funds. In other words, Congress can require states to set twenty-one as the drinking age because underage driving leads to highway accidents on federally funded roads. But Congress probably could not use federal highway funds to require states to change the licensing requirements for physicians. For that requirement, Congress would probably have to use some of its health care dollars.

Thus far, the combination of this broad, albeit ambiguous, interpretation of the spending clause and an almost unlimited budget has meant that Congress still enjoys a relatively unfettered ability to spend in the name of public health and establish standards and priorities for states to follow to obtain federal funds. Such diverse federal programs as the Medicaid and bioterrorism prevention programs all follow that model. Countless other programs could be named.

Congress's ability to use its spending powers so broadly, however, is not without critics. In *Dole* itself, Justice O'Connor in dissent expressed a different understanding of the spending clause, one that saw Congress's ability to achieve regulatory goals via that clause as limited to those categories in which Congress otherwise has regulatory power under the Constitution.[89] More recently, the Supreme Court has emphasized that Congress must provide states with clear notice before providing for private enforcement of federally imposed conditions.[90] Moreover, some lower courts, and many critics, have argued with force and passion that the federal spending power needs to be reined in, lest the very concept of state sovereignty be eviscerated. [91] This argument, which is increasingly gaining attention, may well portend the next direction for the new federalism. If so, the federal government's ability to protect the health of populations will face dire threats.[92] Astonishingly, this may occur even as courts circumscribe the ability of states to respond to public health problems.

## A Population Health Federalism

The discussion thus far has focused on the problems the Supreme Court's federalism jurisprudence has posed for either state or federal laws that purport to protect public health. Of course, imposing those hurdles is only

problematic from a population perspective if the laws thwarted actually promote population health. Undoubtedly, that is not always the case. For example, it seems unlikely that the Gun-Free School Zone Act at issue in *Lopez* had much public health significance given that the problem it addressed was already the subject of relatively similar laws in many states.[93] Likewise, it is questionable whether federal requirements that public schools receiving federal funds use an abstinence-only approach to sex education protect the health of minors.[94]

From the vantage point of population-based legal analysis, however, contemporary federalism jurisprudence is troubling not simply because it erects obstacles to particular federal statutes that purport to protect public health (indeed from a public health perspective such statutes should often be struck down if they use public health as a pretext), but for two other reasons as well. First, current federalism doctrine fails to consider the population health impact of either particular decisions or the doctrine writ large. Second, the doctrine neither values nor incorporates an understanding of the relationship between federalism and populations. In effect, the Court has constructed a highly formal doctrinal apparatus to determine how to allocate authority between multiple and overlapping jurisdictions without noticing that federalism implicates the interaction of different populations and thus can be better understood by adopting a population perspective.

The Court's failure to consider the population health impact of its jurisprudence is both obvious and highly problematic. Whereas a hundred years ago the Court gave great weight to whether a statute could be viewed as a public health statute—leading to the simplistic division of the regulatory world into those matters that fell within the police power and those that did not—the Court today has moved to the opposite extreme, in which the question of whether a regulation relates to population health is often irrelevant. Although the Court still claims that a state's public health goals are relevant to the application of the *Pike* test, they are not consistently treated as such. As noted earlier, federal judges sometimes appear to pay far more attention to a regulation's burdens on commerce than to its potential population health effects. Moreover, courts are apt to discount or disregard empirical evidence relating to a statute's population health impact, while accepting almost at face value claims relating to the burdens a statute imposes on commerce. Thus not only do the federal courts now

frequently ignore public health claims in particular cases, they also sometimes reject, ostensibly as beyond their competence, the empirical and epidemiological evidence that public health can provide in support or refutation of particular public health statutes. As a result, federalism decisions are rendered with little or no consideration of whether they will improve or harm population health. Nor do courts give thought to whether a determination that a particular matter can be addressed by a different branch of government is empirically sound.

Different rationales can be given for this neglect. One obvious defense is that population health is a value exogenous to the principles to which courts must adhere when determining questions of federalism. Or, to put it another way, public health protection is a matter for the legislatures, not constitutional courts. When deciding constitutional questions, defenders of today's doctrinal approach argue, courts must be bound by the text and history of the Constitution's framing.[95]

A full refutation of this approach to constitutional interpretation is well beyond the bounds of this discussion. Nevertheless, it is worth recalling that such text-based arguments should have little weight when the matter at hand is the dormant commerce clause, which itself lacks any textual basis. That nontextual doctrine is a part of our constitutional tradition, both because there are valid reasons for limiting state burdens on interstate commerce and because history has granted it legitimacy. That historic record, however, does not support the exclusion of public health considerations from analysis in either dormant commerce clause causes or cases concerning Congress's Article I powers. As noted, the Court's earliest federalism cases relied on a rough and ready identification between the police power and public health to determine the appropriate boundaries between federal and state action. The fact that we now can recognize the sloppiness of that analysis, and have more sophisticated social science and empirical tools to assess regulations, does not necessitate that we ignore the role once given to public health. Instead, it provides an opportunity to improve the quality of the analysis. Thus if courts want to remain faithful to precedent and early understandings of the Constitution, they will not neglect population health's import to federalism. They will instead give it weight while utilizing contemporary methodologies.

More important, excluding population health as a value from the Court's federalism analysis substitutes an empty formalism for a realistic

engagement with the rationales for federalism. In both its dormant commerce clause and its Article I analysis, the Supreme Court has moved toward a seemingly complex but highly formulaic mode of analysis that relies on ready-to-use tests (per se or not per se, commercial or not commercial) and abstract values such as the dignity of the states in lieu of a meaningful discussion as to why the Constitution provides for, and we continue to appreciate, federalism.

In fact, the division of powers between the states and federal governments is not simply the result of historical circumstance (though they are partially that). Nor do doctrines that lack a clear textual basis, such as those applying the so-called dormant commerce clause, deserve our adherence solely on grounds of textual fidelity. Instead, federalism merits respect and continues to resonate in the twenty-first century precisely because it provides an important way of solving various problems of political governance, as evident by the fact that other parts of the world, such as Europe, are working toward their own form of federalism.[96]

Before the U.S. Constitution was adopted, political theory assumed that "a state with more than one independent sovereign power within its boundaries was a violation of the unity of nature; it would be like a monster with more than one head, continually at war with itself."[97] Federalism defied that convention and created a political system with multiple sovereignties. Most obviously, this allowed for multiple centers of powers, complimenting the checks and balances usually identified with the separation of powers. As James Madison noted in the *Federalist Papers,* this division of power provided a "double security" for the people.[98]

In its recent federalism decisions, the Supreme Court has emphasized this power-limiting aspect of federalism. Concurring in *Lopez,* Justice Kennedy pointed to "the theory that two governments accord more liberty than one" to justify the imposition of limits on Congress's reach, stating that federalism's ability to enhance liberty "requires for its realization two distinct and discernable lines of political accountability: one between the citizens and the Federal Government; the second between the citizens and the States."[99] Likewise in *New York v. United States,* Justice O'Connor cited the need for clear lines of political accountability as one rationale for prohibiting Congress from commandeering the states.[100]

There is no doubt that federalism can and does appropriately serve to enhance accountability, thereby safeguarding liberty, but an overly strict

interpretation of federalism-based limits on the operation of governments obscures federalism's concurrent capacity to invigorate governments' ability to carry out those functions for which they were constituted. Indeed, the ingenuity of federalism is that it not only provides multiple forums to check power and protect liberty understood as the negative freedom from government restraint, but that it also provides multiple forums to exercise power and promote positive forms of liberty, including those associated with public health protection.

This vision of federalism is most clearly discernable in the Constitution's creation of a federal government that has direct regulatory authority and is not reliant on the states. Indeed, this critical aspect, which Justice O'Connor cited in *New York v. United States*, was actually defended in the *Federalist Papers* as a way to prevent the federal government from being as weak as it was under the Articles of Confederation.[101] As John Jay asserted in the *Federalist Papers*, such a weak government could not carry out those very functions for which governments are formed, such as protecting the safety of the people.[102]

American federalism was thus designed in large measure to establish a strong but limited national government that had the capacity to deal with threats that were beyond the ability of individual states to carry out. In the age of the Framers, foreign armies posed the most obvious threats. But by the 1790s, when Congress was debating the enactment of a national quarantine law, it had already become clear that health threats could also require a national response. Today, when pandemics can travel around the world in a matter of hours, the need for federal intervention in the prevention of infectious diseases is as evident as is the need for federal protection against foreign enemies. More broadly, as we have come to understand the role that interstate and international commerce play in creating the social determinants of health, the need for a federal response is even clearer. Our federalism permits an adequate federal response by giving Congress plenary powers to deal with matters pertaining to international and interstate commerce and by permitting Congress to use its vast spending powers to work with states as well as private entities to undertake a wide array of public health activities, some of which may require relative uniformity between the states and some of which Congress can and does support while permitting significant variation between the states.

Federalism, however, also helps ensure the well-being of populations by maintaining states as smaller governmental entities with the capacity

to safeguard the health of different populations. Although it is a cliché, it remains true that state governments, closer to the people, are often more able to respond quickly and innovatively to particular health problems. This is not simply because the costs of enacting legislation are less at the state level, but also because the very possibility of fifty plus jurisdictions increases the likelihood of novel and innovative interventions. Any one intervention may not be well designed and it may indeed impose unjustifiable costs on the economy or civil liberties. But a state's experience with it can teach us something about the interaction between law and the health problem at hand, because, as Justice Brandeis observed so long ago, states can and do serve as "laboratories," in which different approaches to a problem can be attempted.[103] By creating fifty plus locations for population health interventions, federalism provides multiple opportunities for communities to undertake efforts to address the threats they face and deem problematic. Often, such state efforts provide a model for other states, or the federal government, to follow or refrain from following. In either case, the interventions can increase our understanding about how to safeguard the health of populations and perhaps provide the only opportunity we may have to actually compare, and thereby learn about, the efficacy of different interventions. Moreover, the very fact that state public health laws impose costs on interstate commerce creates political pressure for Congress to respond by devising national solutions.[104]

That one of the rationales for federalism is its ability to enhance the ability of both the states and the federal government to protect public health and safety implies that courts should not ignore the population health impact of federalist decisions. Cases such as *Lopez* that purport to limit Congress's power to preserve the sovereignty of states without considering why state sovereignty matters have the analysis backward. Likewise, decisions that restrict the states' police power without undertaking any consideration of whether the regulation at issue could indeed protect the health of the states' occupants fail to appreciate that the police power is one of the reasons why there are states.

The question remains, however, what it would mean to incorporate public health into a federalism analysis. Most clearly, as has already suggested, it would entail a meaningful consideration of the impact of particular federalism decisions and rules on the health of varying populations, particularly those within and without a state. This would demand a rejection of formalistic and categorical reasoning in favor of an approach far

more accepting of empirical evidence. Second, applying a public health perspective to federalism doctrine would require adopting the population perspective that is not only the core of public health but also so vital to federalism. As a result, federalism, the constitutional doctrine most closely associated with the shifting relationships between groups, would begin to take groups or populations seriously.

As discussed, the population perspective postulates that populations matter, in other words, that individuals act differently and are affected when they are in populations. Likewise the perspective emphasizes the interdependency of individuals within a population as well as the fact that populations are not fixed. They are multiple and contingent.

These postulates can enrich federalism. First, they help to clarify why states matter. States matter not only because they are historic remnants nor just because they serve the federalist goal of safeguarding liberty. They also matter because they provide one important way in which to situate and recognize individuals within groups. Once we recall the obvious, that states are made of groups of people, we are reminded of the seemingly self-evident but easily ignored point that different groups have different attributes. They differ with respect to the risks they face, the preferences they form, and the paths they choose. These points should matter when courts determine whether a particular regulation should fall within the province of the states or the federal government.

For example, the populations of different states and even within states vary widely with respect to numerous health issues. Government statistics show that the overall incidence of cancer among men in 2002 varied from over 640 per 100,000 in Rhode Island to only 441.1 per 100,000 in Arizona.[105] On the other hand, in 2002, the death rate from heart disease among women varied from 116.6 to 161.6 per 100,000 in states such as Minnesota and Wyoming to 219.3 to 275.5 per 100,000 in states such Alabama and Arkansas.[106] Similar population differences can be found between states with respect to a wide variety of health conditions. Careful review of such data can give rise to hypotheses about the different factors that can help explain the different rates of disease between states. A review may suggest, for example, that the population of different states face significantly different exposures to environmental hazards.[107]

On the other hand, for many health issues, the happenstance of state boundaries may have little relevance. Airborne infectious diseases, such as

pandemic influenza, can cross state lines with rapid speed, making it foolish to assign to the states the responsibility to respond to such diseases. Perhaps more important, many health issues affect population groups that are not best defined by state residency, but rather by other factors, including socioeconomic status, race or ethnicity, or even occupation. Here, the allocation of responsibility to states may make little sense. The existence of these population differences are and should be treated as relevant to the federalism question. As the Supreme Court appreciated long ago in the now-discarded *Cooley* case, local conditions do exist and often do cry out for local interventions.[108] Appreciating when population factors do and do not correlate with the political divisions we know as states can help federalism analysis to differentiate when it makes sense to allocate authority at a state level and when it does not. Of course, such an undertaking necessarily requires a willingness to forgo formalism and engage with the messy, contingent world of empirical epidemiology.

Likewise, the population perspective reminds us that not only are we all in multiple populations, but that different populations develop different social norms that may or may not be expressed in positive law and that help determine individual risks to disease and mortality. Federalism reflects this understanding by allowing for multiple forums in which citizens may come together as citizens to enact laws to shape and influence their environment.

Under the dormant commerce clause, such a population-based approach might counsel the abandonment of *Philadelphia's* per se test as well as a willingness to review more thoroughly state claims to be enacting on behalf of the police power. Such a review would require courts to dare to face the empirical world of epidemiology and public health. And it might just lead to the invalidation of some state laws that would today survive scrutiny by a judiciary reluctant to immerse itself in a world of inconclusive reports and confusing statistics. But such a review would also reduce the chances that regulations with the potential to protect a population's health will be thrown out simply because of the costs they impose on commerce. In effect, it would create a public health exception to free trade somewhat similar to that which theoretically exists under the World Trade Organization system.[109] It would also signal the important point that the state police power does matter.

At the same time, incorporating a population perspective into the determination of Congress's Article I powers would counsel that courts apply a pragmatic approach. Under this approach, courts would accept the New Deal's perception that there can be no strict division between commerce and public health. Both are inextricably tied to each other. This is not only because matters of commerce affect health and health affects commerce, but also because both are important and essential to the body politic for similar reasons: they are part of what is necessary to enable communities to flourish. Hence Congress's power necessarily implies the power to affect public health.

Yet, under population-based legal analysis, the recognition of the interrelationship between commerce and public health would not dictate adoption of the New Deal Court's laissez faire approach to federal power. To the contrary, population-based legal analysis emphasizes that one of the goals of federalism is to preserve governments' ability to improve the well-being of populations. This suggests that when Congress uses its Article I powers in a way that undermines the ability of states to develop effective, well-targeted interventions, in other words, when Congress degrades the ability of states to protect the health of their populations without offering an equally effective federal tool—for example, by preempting the state's ability to regulate the delivery of tobacco products to minors——courts should be wary.[110] Most obviously, in such situations courts should construe congressional statutes narrowly to preclude excessive preemption of state initiatives. At times, such an approach might lead courts to find that Congress has violated Article I by enacting laws in the name of commerce that in fact cannot be understood as anything other than attempts to address matters that are best left to the police power. Given the deep interconnections between commerce and health, such cases would be rare. They would, however, differ from *Gonzales*, *Lopez*, and many of the Court's other recent federalism cases because they would depend not upon an abstract regard for federal authority or state sovereignty but rather the ability of a population to achieve particular health objectives.

## Notes

1. Select Bipartisan Committee to Investigate the Preparation for and Response to Hurricane Katrina, *A Failure of Initiative, The Final Report of the Select Bipartisan*

*Senate Committee to Investigate the Preparation for and Response to Hurricane Katrina*, http://katrina.house.gov/full_katrina_report.htm (last visited October 10, 2008).

2. Erin Ryan, *Federalism and the Tug of War Within: Seeking Checks and Balance in the Interjurisdictional Gray Area*, 66 MD. L. REV. 503, 525–27 (2007).

3. *E.g.*, Willson v. Black Bird Creek Marsh Co., 27 U.S. (2 Pet.) 245, 251 (1829).

4. Michael S. Morgenstern, *The Role of the Federal Government in Protecting Citizens from Communicable Diseases*, 47 U. CIN. L. REV. 537, 541–44 (1978).

5. James G. Hodge, Jr. & Lawrence O. Gostin, *School Vaccination Requirements: Historical, Social and Legal Perspectives*, 90 KY. L.J. 831, 844 (2001/2002).

6. Saenz v. Roe, 526 U.S. 489, 504 n. 17 (1999).

7. James G. Hodge, *Implementing Modern Public Health Goals through Government: An Examination of New Federalism and Public Health*, 14 J. CONTEMP. HEALTH L. & POL'Y 93, 94 (1997).

8. U.S. CONST. amend X; United States v. Darby, 312 U.S. 100, 124 (1941).

9. Gibbons v. Ogden, 22 U.S. (9 Wheat. 1) 207 (1824).

10. Willson v. Black Bird Creek Marsh Co., 27 U.S. (2 Pet.) 245 (1829).

11. Morgan's S.S. Co. v. Louisiana Bd. of Health, 118 U.S. 455 (1886).

12. M'Culloch v. Maryland, 17 U.S. (4 Wheat.) 316 (1819).

13. An Act for the Relief of Sick and Disabled Seamen, Ch. 77, 1 State. 605 (1798). For a history of early federal involvement in communicable disease control, see Morgenstern, *supra* note 4, at 541–44.

14. Pub. L. 89–97, 79 Stat. 290 (1965).

15. *E.g.*, United States v. Darby, 312 U.S. 100 (1941).

16. Pub. L. 91–596, 84 Stat. 1590 (1970).

17. Pub. L. 99–660, 100 Stat. 3756 (1986).

18. Ch. 675, 52 Stat. 1042 (June 25, 1938).

19. NATIONAL ACADEMY OF SCIENCES, THE FUTURE OF THE PUBLIC'S HEALTH IN THE 21ST CENTURY 105 (2003).

20. Gibbons v. Ogden, 22 U.S. at 209.

21. *E.g.*, Cooley v. Board of Wardens, 53 U.S. (12 How.) 299, 300 (1851).

22. *E.g.*, Brimmer v. Rebman, 138 U.S. 78, 83 (1891).

23. H.P. Hood & Sons, Inc. v. Du Mond, 336 U.S. 525, 539 (1949).

24. *E.g.*, Dean Milk Co. v. City of Madison, 340 U.S. 349 (1951).

25. *Id.* at 354.

26. Head v. New Mexico Bd. of Exam'rs in Optometry, 374 U.S. 424, 428 (1963).

27. Brown-Forman Distillers Corp. v. New York State Liquor Auth., 476 U.S. 573, 579 (1986).

28. Pike v. Bruce Church, Inc., 397 U.S. 137, 142 (1970).

29. 437 U.S. 617 (1978).

30. *Id.* at 618 (quoting N.J. State. Ann. § 13:17–15 (West Supp. 1978)).

31. *Id.* at 624.

32. *Id.* at 628.

33. *Id.* at 632–633 (Rehnquist, J., dissenting).

34. *See* text accompanying notes 103–04 *infra*.

35. 511 U.S. 383, 390 (1994).

36. *Id*. at 425 (Souter, J., dissenting).

37. 550 U.S. 124, 127 S. Ct. 1786 (2007).

38. 127 S. Ct. at 1794–95. The dissent, in contrast, argued that the facility in *Carbone* was effectively a public entity, even if it was nominally owned by a private party. *Id*. at 1803 (Alito, J., dissenting).

39. *Id*. at 1795.

40. *Id*. at 1796.

41. Edgar v. Mite Corp., 457 U.S. 624 (1982). *See also* Brown-Forman Distillers Corp. v. New York State Liquor Auth., 476 U.S. 573 (1986).

42. Healy v. The Beer Inst., 491 U.S. 324, 336 (1989). The Court may have reined in this doctrine somewhat in Pharmaceutical Research & Mfrs. of Am. v. Walsh, 538 U.S. 644 (2003) (upholding Maine's Medicaid Prescription Drug Program).

43. *E.g.*, Santa Fe Natural Tobacco Co. v. Spitzer, 2001 U.S. Dist. LEXIS 7548 (S.D.N.Y. 2001) *rev'd sub nom* Brown and Williamson Corp. v. Pataki, 320 F.3d 200 (2d Cir. 2003); American Library Ass'n v. Pataki, 969 F. Supp. 160 (S.D.N.Y. 1997).

44. 397 U.S. 137, 142 (1970).

45. Bibb v. Navajo Freight Lines, Inc., 359 U.S. 520, 524 (1959).

46. United Haulers Assoc., Inc. v. Oneida-Herkimer Solid Waste Mgmt. Auth., 127 S.Ct. at 1797.

47. 450 U.S. 662 (1981).

48. CTS Corp. v. Dynamics Corp. of Am., 481 U.S. 69, 95 (1987) (Scalia, J., dissenting in part and concurring in part); 450 U.S. at 678–706 (Brennan J., dissenting).

49. 218 F.3d 30 (1st Cir. 2000), *aff'd in part, rev'd in part sub nom*. Lorillard Tobacco Co. v. Reilly, 533 U.S. 525 (2001).

50. Dent v. West Virginia, 129 U.S. 114 (1889) (upholding medical licensing law against Fourteenth Amendment challenge).

51. For a discussion of the importance of global approaches to public health, see chapter 10, *infra*.

52. LAWRENCE O. GOSTIN, PUBLIC HEALTH LAW: POWER, DUTY, RESTRAINT 155–61 (2d. ed. 2008).

53. Pure Food Act, Ch. 3915, 34 Stat. 768 (1906).

54. United States v. Darby, 32 U.S. 100 (1941); Charles C. Steward Mach. Co. v. Davis, 301 U.S. 548 (1937).

55. 312 U.S. at 100; NLRB v. Jones & Laughlin Steel Corp., 301 U.S. 1 (1937); 301 U.S. at 548.

56. Susan Wall, *Transformations in Public Health Systems*, 17 HEALTH AFFAIRS 69 (1998).

57. U.S. CONST. ART. VI, CL. 2.

58. For example, the Employee Retirement Income Security Act of 1974, known as ERISA, explicitly precludes state regulation of self-insured employee benefit plans, including health plans, leaving states with only limited authority over employer-provided health insurance. *See* 29 U.S.C. § 1144 (a)(2000).

59. For a discussion of some of the reasons why this might be the case, see Roderick M. Hills, Jr., *Against Preemption: How Federalism Can Improve the National Legislative Process,* 82 N. Y. U. L. Rev. 1, 10–16 (2007).

60. Geier v. Am. Honda Motor Co., Inc. 529 U.S. 861, 884 (2000).

61. Stacy Allen Carroll, *Federal Preemption of State Products Liability Claims: Adding Clarity and Respect for State Sovereignty to the Analysis of Federal Preemption*, 36 Ga. L. Rev. 797, 800 (2002); Jean Macchiaroli Eggen, *The Normalization of Product Preemption Doctrine*, 57 Ala. L. Rev. 725, 726 (2006); Lars Noah, *Reconceptualizing Federal Preemption of Tort Claims as the Government Standards Defense,* 37 Wm. & Mary L. Rev. 903, 905 (1996).

62. *Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products*, 71 Fed. Reg. 3, 922, 3, 933–36 (Jan. 24, 2006) (to be codified at 21 C.F.R. pts 201, 314, 601).

63. Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996).

64. *E.g.*, 529 U.S. at 861.

65. 552 U.S.__, 128 S.Ct. 989 (2008) (construing 49 U.S.C. § 14501(c)(1)).

66. *Id.* at 996.

67. Riegel v. Medtronic, Inc., 552 U.S. __, 128 S.Ct. 999 (2008).

68. Warner-Lambert Co. v. Kent, __ U.S. __, 128 S.Ct. 1168 (2008) (*aff'd mem*).

69. See note 61, *supra.*

70. 514 U.S. 549 (1995).

71. Heart of Atlanta Hotel, Inc. v. United States, 379 U.S. 241 (1964); Wickard v. Filburn, 317 U.S. 111 (1942).

72. Pub. L. 101–647, 104 Stat. 4789, 4844–845 (1990).

73. 514 U.S. at 562–65.

74. *Id.* at 567.

75. 529 U.S. 598 (2000).

76. P.L. 103–322, 108 Stat. 1941 (1994).

77. 529 at 628 (Souter, J., dissenting).

78. 545 U.S. 1 (2005).

79. *Id.* at 2210.

80. *Id.* at 33, 36 (Scalia, J., concurring).

81. *Id.* at 42–43 (O'Connor, J., dissenting).

82. *Id.* at 45.

83. 505 U.S. 144 (1992).

84. 521 U.S. 898 (1997).

85. *Id.* at 940 (Stevens, J., dissenting).

86. Charles C. Steward Mach. Co. v. Davis, 301 U.S. 548, 590 (1937).

87. New York v. United States, 505 U.S. 144 (1992).

88. 483 U.S. 203 (1987).

89. *Id.*

90. Arlington Central School Dist. Bd. of Educ. v. Murphy, 548 U.S. 291 (2006).

91. *E.g.*, Virginia Dep't of Educ. v. Riley, 106 F. 3d 559, 570–72 (4th Cir. 1997) (en banc); United States v. Sabri, 183 F. Supp. 2d 1145, 1155–159 (D. Minn. 2002),

*rev'd in part*, 326 F. 3d 937 (8th Cir. 2003), *aff'd mem*. 541 U.S. 600 (2004); Lynn A. Baker & Michael N. Berman, *Getting Off the Dole: Why the Court Should Abandon Its Spending Doctrine and How a Too-Clever Congress Could Provoke It to Do So*, 78 IND. L. J. 459, 471–74 (2003).

92. Nicole Huberfeld, *Clear Notice for Conditions on Spending, Unclear Implications for States in Federal Healthcare Programs*, 86 N.C.L. REV. 441, 476 (2008).

93. 514 U.S. at 581.

94. 42 U.S. C. § 710. *See* Christopher Trenholm et al., *Impacts of Four Title V, Section 510 Abstinence Education Program, Final Report* (2007), http://aspe.hhs.gov/hsp/abstinence07/report.pdf (last visited Mar. 3, 2008).

95. *Cf.* ANTONIN SCALIA, A MATTER OF INTERPRETATION: FEDERAL COURTS AND THE LAW 37–41 (Amy Gutmann ed., 1997) (offering a textualist theory of statutory and constitutional interpretation).

96. Ryan, *supra* note 2, at 24–25.

97. GORDON S. WOOD, THE CREATION OF THE AMERICAN REPUBLIC, 1776–1787 345–46 (1969).

98. THE FEDERALIST No. 51, at 291 (James Madison) (Clinton Rossiter ed., 1999).

99. 514 U.S. at 568, 576 (Kennedy, J., concurring).

100. 505 U.S. at 168–69.

101. THE FEDERALIST No. 15 (Alexander Hamilton) (Clinton Rossiter ed., 1999).

102. THE FEDERALIST No. 3 (John Jay) (Clinton Rossiter ed., 1999).

103. New State Ice Co. v. Liebmann, 285 U.S. 262, 311 (1932) (Brandeis, J. dissenting).

104. This argument is compatible with Hills's argument that state regulations can help to place health and safety issues on Congress's agenda. *See* Hills, *supra* note at 59, at 19–20.

105. U.S. Cancer Statistics Working Group, *United States Cancer Statistics:* 1999–2002 *Incidence and Mortality Web-Based Report* (2005), http://www.cdc.gov/cancer/npcr/uscs (last visited Oct. 10, 2008).

106. Centers for Disease Control and Prevention, *Women and Heart Disease Fact Sheet, Death Rates for Diseases of the Heart per 100,000 Women, 2002*, http://www.cdc.gov/DHDSP/library/fs_women_heart.htm (last visited Oct. 10, 2008).

107. *See* American Lung Association, *The State of the Air 2005*, http://environment.about.com/od/healthenvironment/a/stateofair.htm (last visited Oct. 10, 2008).

108. Cooley v. Board of Wardens, 53 U.S. (12 How.) 299, 319–20 (1852).

109. *See* David P. Fidler, *A Globalized Theory of Public Health Law*, 30 J.L. MED. & ETHICS 150, 157 (2002). For a further discussion, see chapter 10, *infra*.

110. *E.g.*, Rowe, 128 S.Ct. at 989.