The Courts and Public Health

The Courts and Public Health: Caught in a Pincer Movement

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Public health practitioners are familiar with the general outlines of legal authority and with judicial standards for reviewing public health regulations. What may not be as familiar are 3 emerging judicial doctrines that pose considerable risks to public health initiatives.

We explain the contentious series of judicial rulings that now place health departments' broad grant of authority in jeopardy. One doctrine invokes the First Amendment to limit regulatory authority. The second involves the Supreme Court's reinterpretation of federalism to limit both federal and state public health interventions. The third redefines the standard of evidence required to support regulations.

Together, these judicial trends create a pincer movement that places substantial new burdens on the ability of health departments to protect health. (*Am J Public Health.* 2014;104:392–397. doi:10.2105/AJPH.2013.301738)

THE YEAR 2013 WAS NOT KIND to efforts to use law to protect public health. In July the Appellate Division of the New York Supreme Court affirmed a lower-court ruling enjoining New York City's innovative ban on the sale of large sugary sodas.[1] A few months earlier, the Food and Drug Administration (FDA) announced that it would not appeal a federal appeals court ruling striking down regulations requiring graphic warning labels on cigarette packages.[2] Although the fates of both New York's ban on large sugary sodas and the graphic warning labels remain uncertain—the city is appealing the Appellate Division's decision, and the FDA is revisiting its regulatory options—these decisions are emblematic of a worrisome development for public health. Despite a growing body of research demonstrating the powerful role that law can play in public health protection,[3] adversaries of public health laws have won several high-profile court challenges. Their victories have helped to shift legal doctrine in ways that present new dangers for public health law.

Three emerging judicial doctrines pose the greatest risk to public health initiatives, especially those targeting noncommunicable diseases. One doctrine invokes the First Amendment to limit regulatory authority. The second involves the Supreme Court's reinterpretation of federalism to limit both federal and state public health interventions. The third redefines the standard of evidence required to support regulations. Together, these judicial trends create a pincer movement that places substantial new burdens on the ability of health departments (HDs) to protect health.

THE FIRST AMENDMENT

Historically, the First Amendment created little problem for public health. That has changed as a result of 2 separate developments, one in public health and the other in constitutional law.

Public health's collision course with the First Amendment emerged in response to the epidemiological transition to lifestyle, or noncommunicable, diseases, as well as growing threats to population health from dangerous products. Lacking political support and legal authority for banning dangerous products such as cigarettes, public health policymakers have increasingly focused their regulatory strategy on what they view as less restrictive interventions—regulating advertising and mandating the disclosure of health-related information. These approaches are often praised for enhancing consumer knowledge and choice but are now being challenged as restricting free speech.

Before 1975, governments had wide leeway to control the marketing and labeling of dangerous products because the First Amendment was not applied to so-called commercial speech. Then, in *Bigelow v. Virginia*, a case concerning a state ban on the promotion or advertising of abortion services, the Supreme Court ruled that commercial speech was entitled to First Amendment protection.[4] Still, the Court initially made clear that government had greater leeway in regulating commercial speech than other forms of speech. The Supreme Court's approach was explained in 1980, in *Central Hudson Gas & Electric Corp v. Public Service Commission*,[5] which offered a 4-part test, asking whether (1) the speech is truthful and related to legal products, (2) the asserted government interest is substantial, (3) the regulation "directly advances" the asserted government interest, and (4) the regulation is no more extensive than necessary to serve the government interest.[6] If the answer to all questions is yes, the law is constitutional.

Subsequently, *Zauderer v. Office of Disciplinary Counsel* upheld a law

requiring the disclosure of attorneys' fee information on print advertisements.[7] The Court there stated that disclosure laws "reasonably related to the State's interest in preventing deception" are constitutional as long as they are not unduly burdensome,[8] noting that disclosure laws "trench more narrowly" than laws banning speech.[9]

Initially, *Central Hudson* and *Zauderer* seemed to suggest that public health regulations were constitutional even if they touched upon speech, as long as they were well crafted and evidence based. Policymakers often relied on this framework both because they believed that laws requiring the disclosure of information about public health risks are more respectful of autonomy than laws limiting the sale or use of dangerous products and because such laws are often more politically viable.

Over time, however, the Supreme Court's approach to commercial speech changed. For example, in 2001 in *Lorillard v. Reilly*, the Court found that several provisions of Massachusetts regulations governing the marketing of cigars and smokeless tobacco failed the *Central Hudson* test.[10] According to the Court, the state demonstrated neither that its regulation of outdoor advertising was no more extensive than necessary nor that point-of-sale regulations would be effective in preventing minors from using tobacco products. *Thompson v. Western States Medical Center* quickly followed,[11] in which the Court struck down a federal law exempting compounding pharmacies from the FDA's drug approval process if they did not advertise.[12] Because the exemption from regulation depended on compounders' willingness to forgo advertising, the Court ruled that the law burdened speech. The law also failed the *Central Hudson* test in part because the Court thought that the government could have protected the public from the dangers of compounding pharmacies (which became very evident in the recent nationwide outbreak of fungal meningitis traced to a compounding pharmacy) by banning compounding.[13] Thus, although public health practitioners may see marketing regulations as less restrictive than product bans, they are now more constitutionally suspect.

In both *Lorillard* and *Western States*, the Supreme Court applied the *Central Hudson* test with a rigor approaching strict scrutiny, the most stringent form of judicial review, traditionally applicable under the First Amendment to restrictions on noncommercial speech. When strict scrutiny is used, state laws are almost always overturned. In *Sorrrell v. IMS Health, Inc*,[14] the Court went further, striking down Vermont's data-mining law prohibiting pharmacies from disclosing physician prescription records for marketing purposes. According to the Court, the prohibition based the definition of disfavored speech on the speaker and content, and therefore was "presumptively invalid."[15] The fact that the speech was commercial made no difference to the outcome. The Court stated that its conclusion would have been the same if it had applied either *Central Hudson* or strict scrutiny.[16]

As a result of these developments, public health laws that once would have been assumed to be constitutional now face serious First Amendment challenges. For example, the Second Circuit Court of Appeals recently relied on *Sorrell* to overturn a conviction for promoting the off-label use of drugs.[17] To the court, the ban on off-label promotion was precisely the type of speaker and content discrimination *Sorrell* condemned.

Equally ominous for public health, in *RJ Reynolds Tobacco Co. v. FDA*, the Court of Appeals for the District of Columbia relied on *Sorrell* in ruling that FDA regulations requiring graphic warning labels on cigarette packages were unconstitutional because the government could not show that they were closely tailored to reducing tobacco usage.[18] In its decision, the court concluded that the labels were not aimed at preventing deception but rather at influencing consumer behavior. The court also expressed skepticism

> that the government can assert a substantial interest in discouraging consumers from purchasing a lawful product, even one conclusively linked to adverse health consequences.[19]

RJ Reynolds conflicts with an earlier Sixth Circuit decision upholding the regulations.[20] Despite this conflict, the Obama administration was clearly worried about the regulations' fate before the Supreme Court; in March the Justice Department announced that it would not ask the high court to overrule the D.C. Circuit's decision.[21] Instead, FDA will "undertake research to support new rulemaking."[22] Whether it will now be able to develop rules that are strong enough to reduce cigarette use remains to be seen.

FEDERALISM

Traditionally, the legal doctrines underpinning federalism secured the ability of both state and federal governments to protect the nation's health. Under well-established principles, the states were presumed to have broad police powers allowing them to protect their residents' health, and the federal government was thought to possess robust authority under the Constitution's Commerce and General Welfare clauses to enact nationwide legislation.

Times have changed. In the past 25 years, the Supreme Court has issued a series of decisions limiting the reach of the federal government. Concomitantly, courts have frequently ruled that federal law preempts, or overrides, state public health laws. Hence both state and federal public health laws are vulnerable to federalism-based constitutional challenges.

The Court's Commerce Clause jurisprudence began to change in the 1990s when it overturned federal laws that required state enforcement because they unconstitutionally commandeered the states.[23] Then the Court began to look closely at federal laws that relied on Congress's power to regulate matters that substantially affect commerce, finding for example, that the possession of guns near schools did not substantially affect commerce and could not be prohibited by Congress.[24] Last year a majority of the Court found that Congress lacked authority

under the Commerce Clause to impose the individual insurance mandate under the Affordable Care Act.[25] Nonetheless, the Court upheld the mandate as a constitutional exercise of congressional power to tax and spend.

For public health law, however, recent limitations on Congress's spending authority may be even more deleterious than the Court's recent commerce clause jurisprudence. Many federal public health laws rest not on Congress's commerce authority but on its power to spend for the general welfare, because Congress attaches numerous health-related conditions on states' receipt of federal funds. Until last year, no such law had ever been found to exceed Congress's authority. But in 2012, in its Affordable Care Act decision, 7 justices found that Congress's requirement that states expand their Medicaid programs or risk losing their existing federal Medicaid dollars was unconstitutionally coercive.[26] The Court's analysis—there was no majority opinion—raised more questions than it answered, leaving the fate of other federal spending laws uncertain.

Although public health practitioners may be tempted to read the Supreme Court's federalism cases as evincing respect for state public health powers, the story is more complex. As the Court has tightened its review of federal authority, it has also shown an increasing willingness to strike down state laws under preemption, a doctrine that holds that state laws that conflict with or are precluded by federal laws violate the Constitution's Supremacy Clause.

Because preemption depends on Congress's intent in enacting specific statutes,[27] the Court's preemption jurisprudence is notoriously difficult to assess. But despite a supposed presumption against preemption of state health laws (based on respect for the states' traditional police powers),[28] many state civil actions and health regulations have been preempted. For example, the Supreme Court has held that federal law preempts state claims against generic drug and medical device makers.[29] In *Lorillard*, the Court held that federal law preempts state cigarette-marketing regulations.[30]

Not surprisingly, regulated industries often use preemption to challenge state public health laws. For example, the food industry has argued, with mixed success, that the Nutrition Education and Labeling Act preempts actions related to food labeling brought under state consumer protection laws,[31] as well as public health regulations requiring calorie labeling.[32] Even though many of these claims have failed, the possibility of preemption and the uncertainty surrounding it create a significant legal risk for state public health policymakers.

THE COURTS AND PUBLIC HEALTH

Recent cases suggest that judges continue to struggle with the nature of the epidemiological evidence that underlies most public health initiatives. Two recent opinions particularly impose evidentiary standards that if widely followed portend perhaps unachievable burdens on public health agencies that would constrain agencies' broad grant of authority. These high-visibility opinions, especially combined with the other trends we describe, demonstrate increasing skepticism about how public health works and establish evidentiary standards so strict that many regulations are vulnerable.

Take *RJ Reynolds*.[33] The majority opinion narrowly defined the government's asserted interest as reducing smoking rates. As the dissent noted, this construction overlooked the FDA's interest in correcting decades of false and misleading advertising. Having limited the government's interest to a narrow objective, the majority ruled that the evidence produced did not convincingly demonstrate that the graphic warnings would actually reduce smoking (the government's directly asserted interest).

Almost from the beginning, the majority dismissively characterized the government's evidence as "questionable social science."[34] The court concluded that the government did not provide substantial evidence to demonstrate that the means (graphic warnings) were narrowly tailored to achieve a substantial governmental goal (reducing smoking). The majority stated that

> FDA has not provided a shred of evidence . . . showing that the graphic warnings will "directly advance" its interest in reducing the number of people who smoke. . . . FDA offered no evidence showing that such warnings have *directly caused* a material decrease in smoking rates in any of the countries that now require them [emphasis in original].[35]

The majority's disdain for the FDA's evidence shows a fundamental misunderstanding of the science behind epidemiology. First, the majority did not take into account the time lag needed to estimate changes in behavior. Australia's plain-packaging law was enacted in 2011, yet it was included in the majority's list of countries with restrictive laws that did not directly reduce smoking rates. Even mentioning the Australian experience disregards the time needed for adopting plain packaging, collecting and analyzing data, and reporting any changes in smoking rates. Demanding to see behavioral change in such a short time frame for an addictive substance is an unrealistic and impossible scientific burden.

Second, the majority opinion evinced minimal understanding of attribution. For example, the court dismissed studies showing intentions to quit, despite considerable social scientific evidence that intentions to act predict subsequent behavior change.[36] More importantly, the court's understanding of the factors involved in smoking cessation was unidimensional (i.e., 1 factor, graphic images, must lead to a particular result), when in fact smoking cessation results from multiple factors. In requiring proof that action X (graphic warnings) causes response Y (reduced smoking rates), the court ignored that most behavior is multifactorial. No 1 factor determines an individual's tobacco use.

Graphic warning labels, for instance, represent just 1 type of mass-reach intervention targeting large audiences through multiple channels.[37] A truncated listing of possible cessation interventions would include stand-alone education campaigns and multicomponent strategies.[38] At best, the

court's requirement that HDs isolate 1 intervention among them as the direct cause would mandate sophisticated research methods, perhaps even randomized controlled trials, that have not been used in public health systems research. Instead, "public health interventions rely on cross-sectional studies, quasi-experimental designs, and time-series analyses" to show statistically significant correlations between X and Y, rather than causal relationships.[39] In this sense, legal and epidemiological causation reflect differing constructs, which the court did not consider. Because another Court of Appeals reached the opposite conclusion,[40] it is premature to say that the *RJ Reynolds* case augers a radical departure from the current deference standard, undermining public health. But in light of the importance of the D.C. Circuit to regulatory policy, and similar opinions on environmental issues, the opinion is troubling.[41]

Recent judicial rulings striking down New York City's ban on large sugary drinks likewise misconstrue the evolving nature of public health threats and the appropriate governmental response. In *New York Statewide Coalition v. New York City Department of Health*, the trial court overturned regulations that limited the size of sugary drinks to 16 ounces.[42] Among other issues, petitioners challenged the rule as being beyond the board of health's broad grant of authority. The court agreed, refusing to defer to the agency's expertise. Tracing the history of legislation applicable to the board, the court suggested that its powers should be read more broadly when applied to communicable rather than chronic diseases. The court reached this conclusion despite broad language in the city charter giving the board power to "prevent the spread of disease within the City" and to control chronic diseases.[43]

On appeal, the appellate court upheld the trial court's decision, relying on a separation-of-powers argument.[44] Although the appellate decision did not deal directly with the trial court's limitations on regulating noncommunicable diseases, it made 2 statements that will be equally troubling for public health practitioners. First, the court stated that the board lacked regulatory authority because "soda consumption cannot be classified as a health hazard *per se*" [emphasis in original].[45] Like the *RJ Reynolds* decision, this places a potentially insuperable burden on regulating noncommunicable diseases. Once again, it shows a fundamental misunderstanding of health risks and causation. Few (if any) causes can be defined as a health hazard per se. Even bacteria in food—in small quantities—are usually harmless. Indeed, it is hard to think of anything that the board regulates that would be considered a per se health hazard.

Second, the court held that the board did not bring any special expertise in shaping the rule because "[t]he deleterious effects (e.g., obesity) associated with excessive sugar consumption are well-known."[46] It is difficult to reconcile that interpretation with either the history of public health interventions or the legislature's determination when it established the board that public health would best be served if an expert body exercised regulatory authority.

Both decisions question public health officials' authority to promulgate regulations when the legislature has not acted or has been unable to reach a consensus. In limiting that authority, the opinions disregard both the initiatives public health officials must develop to reflect changing disease patterns and the technical expertise needed to address the obesity epidemic. Although the challengers characterized the ban as "an exercise in futility on practical and scientific grounds"[47] because it was too limited to have an effect on obesity rates, a major flaw in the analysis is the assumption that "unless public health does everything, it can do nothing."[48] In essence, the opinions reflect the view that public health should only respond to infectious diseases, not to the chronic diseases the country now faces.

POLICY AND PRACTICE IMPLICATIONS

These recent doctrinal developments may seem arcane, but they may have significant and potentially adverse implications for public health policy and practice. For instance, business groups and their allies have made no secret of their desire to convince courts that restrictions on product marketing conflict with the First Amendment, and they have waged a long-term litigation campaign to roll back laws and regulations they deem intrusive. The ongoing litigation designed to unravel the Affordable Care Act is just 1 manifestation of a broader effort, even though HDs continue to prevail in most cases reviewing their actions (especially routine enforcement activities). Taken together, the 3 judicial trends we outline here constitute an increasingly skeptical stance toward public health and a mutually reinforcing pincer movement restricting the range of permissible regulatory practice. From a policy perspective, the pincer movement represents a creative and sustained attack on governmental authority (on public health specifically and on the administrative state more generally).

Although one might argue that these trends are inchoate, are not doctrinally related, and rely on selected cases, the context in which the cases have emerged supports our assessment. Beyond litigation challenging the authority of federal, state, and local public health agencies to act,[49] threats to public health include denialism (i.e., opposing public health's scientific validity)[50] and the unrelenting decrease in public funding. As a result, it seems undeniable that public health is on the political and judicial defensive.

By providing a platform for continued challenges, these judicial trends are also likely to strengthen public health's opponents, encouraging further litigation over reasonable public health initiatives. At a minimum, opponents will begin citing these cases to support further judicial restrictions on public health authority. For example, judicial skepticism about public health evidence may spur the antivaccination movement to revive its scientifically illegitimate challenges to essential vaccination strategies.[51] The

courts' unwillingness to defer to public health laws may also adversely influence how courts rule on other innovative public health regulations, such as menu-labeling laws and bans on trans fats. Both the FDA's oversight of food and pharmaceutical companies and the Environmental Protection Agency's ability to protect the environment appear to be especially imperiled.[52]

A potential consequence is increasing the costs that HDs face in both compiling records that can satisfy judicial review and responding to litigation. These burdens may impede HDs' ability to protect health, thereby undermining the public's trust in these agencies and facilitating the shift of public health responsibility to the private sector.

One overriding facet of these developments is the courts' disrespect for other branches of government. Even in upholding the Affordable Care Act's individual mandate, Chief Justice John Roberts betrayed his disdain for the elected branches, stating, "It is not our job to protect the people from the consequences of their political choices."[53] This disdain for the policy decisions of the other branches represents a fundamental threat to public health protection, which, after all, is what we, as a society, do to establish the conditions by which we can be healthy.[54]

GOVERNMENTAL PUBLIC HEALTH'S RESPONSE

The public health community cannot assume that these trends will subside through new judicial appointees or congressional action. Along with an ideological climate suspicious of government's ability to solve problems, powerful political and economic interests have supported the development of these troubling doctrines. Despite the supposed separation between the courts and politics, history has shown repeatedly that the courts seldom stray far from public opinion. In the long run, public health laws will be most secure in court only if and when the public believes that laws can provide effective and appropriate solutions to health problems they care about.

In the meantime, the range of responses is frustratingly narrow and partially beyond the public health community's direct control. Instead, public health officials and national organizations must work with their attorneys to develop alternative litigation strategies that incorporate new ways of building the evidentiary base for judicial consideration.

Scientific evidence that may have been sufficient a few years ago must now be bolstered through even more rigorous methods and presentation. Although public health practitioners cannot control how the courts set the burden of proof to support regulations, agencies can augment existing data collection and analytical methods to present scientifically robust evidence that can withstand the higher scrutiny now imposed. If HDs supply courts with the strongest possible evidence, judges may find little room to ignore the obvious.

Even with such evidence, public health practitioners must proceed with caution, and on advice of counsel, in selecting legal tools for public health protection. Laws that once looked legally safe, such as those requiring the disclosure of information about a product's risks, may no longer be the safest tactic from a litigation perspective. Public health policymakers may therefore want to consider other legal strategies. For example, in light of Chief Justice Roberts's opinion upholding the Affordable Care Act's individual mandate through Congress's taxing power, taxes may now prove to be more legally secure, if less politically viable, than laws taking other forms.

The judicial trends we describe are legally dubious, reflect scientific illiteracy, and threaten the population's health. The disconnect between judicial understanding of what constitutes sufficient scientific evidence to justify public health regulation and how public health practitioners view the same evidence is vast, as is the distance between the courts' respect for public health and the public's expectation that government will keep it safe. But whatever its shortcomings, this is the legal climate that public health practitioners face, and for which they must prepare, if they are to carry out their mission. ■

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Human Participant Protection

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Impact of Alabama's Immigration Law on Access to Health Care Among Latina Immigrants and Children: Implications for National Reform

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We conducted in-depth interviews in May to July 2012 to evaluate the effect of Alabama's 2011 omnibus immigration law on Latina immigrants and their US- and foreign-born children's access to and use of health services.

The predominant effect of the law on access was a reduction in service availability. Affordability and acceptability of care were adversely affected because of economic insecurity and women's increased sense of discrimination. Nonpregnant women and foreign-born children experienced the greatest barriers, but pregnant women and mothers of US-born children also had concerns about accessing care.

The implications of restricting access to health services and the potential impact this has on public health should be considered in local and national immigration reform discussions. (*Am J Public Health.* 2014;104:397–405. doi: 10.2105/AJPH.2013.301560)

IN THE ABSENCE OF RECENT national immigration reform, state legislatures have increasingly proposed measures to address local immigration issues. Since 2007, legislators have put forth more than 1300 immigration-related bills and resolutions annually.[1] Most of these failed to become