HEALTH LAW, ETHICS, AND HUMAN RIGHTS

New York City's War on Fat

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In February, a federal appeals court handed public health officials in New York City an important victory in their ongoing war on obesity and chronic disease.[1] In the past 3 years, the New York City Board of Health and Mayor Michael R. Bloomberg have pioneered three uses of the law to combat these health threats in new ways. In order to reduce the prevalence of poorly controlled diabetes, the city has required laboratories to report test results indicating elevated levels of glycated hemoglobin to a citywide registry. To reduce the rate of heart disease, the board of health has banned the use of artificial trans fat in food-service establishments in the city. Finally, the board has required that chain restaurants post calorie information on menu boards; the February court ruling affirmed its right to do so.

These initiatives have attracted wide attention and many imitators. Ten local governments, one state, and Puerto Rico have adopted bans on trans fat, and 17 states have considered such bans.[2,3] Six local governments and one state have adopted menu-labeling laws[4,5]; seven others and 19 states have considered such legislation.[6] Federal menu-labeling bills have been introduced in both houses of Congress.[7,8] Notwithstanding these developments, critics have derided the "nanny mayor" for intruding into patient privacy, consumer choice, and the freedom of speech of restaurant owners.[9]

This article, which examines the legal issues and policy lessons arising from New York City's experience, focuses on the trans fat and menu-labeling regulations. These issues exemplify the challenges involved in extending justifications for invoking the coercive power of the state — which traditionally has been invoked by public health authorities primarily to combat infectious disease — to the "new frontier" of the prevention of obesity and chronic disease.[10]

THE POLICY CONTEXT

New York City is home to approximately 2 million overweight and 1 million obese adults.[11] Diabetes has been diagnosed in nearly 10% of overweight adults and 18% of obese adults in the city,[11] and an estimated 200,000 residents have undiagnosed diabetes.[12] Hospitalization costs for New Yorkers with diabetes topped $481 million in 2003, three quarters of which was paid by Medicaid and Medicare.[12] Coronary heart disease, which is associated with trans fat consumption,[13] was responsible for 23,000 deaths in 2004.[14]

Diet is a major focus of epidemiologic investigations into these problems. Nationally, Americans obtain one third of their daily caloric intake from restaurant meals, and a 2007 survey of customers of chain restaurants in New York City showed that one third purchased meals containing more than 1000 calories.[15]

TWO NEW PUBLIC HEALTH LAWS

BAN ON TRANS FAT

On December 5, 2006, the board of health imposed a two-stage phase-out of trans fat in all of the city's food-service establishments, enforceable through fines.[16] Restaurants initially were given until July 1, 2007, to ensure that most oils, shortenings, and margarine contained less than 0.5 g of trans fat per serving. Because restaurants expressed concerns about meeting this deadline, the board added a grace period. In early October 2007, the city inspected 504 restaurants and found 96% to be in compliance with the first-stage ban.[17] Violators received fines (from $200 to $2,000), which could be challenged through administrative hearings.

In the second phase, which ended on July 1, 2008, restaurants were required to transition all foods (except packaged foods sold in the manufacturer's original package) to formulations including less than 0.5 g of trans fat per serving. The board implemented a grace period until October 1, 2008, and it provided educational resources to restaurant owners about how to transition to healthier fats.

MENU LABELING

In December 2006, the board of health voted unanimously to require restaurants that had chosen to make calorie information publicly available on or after March 1, 2007, to post it on menus and menu boards.[18] The regulation, which applied to approximately 10% of restaurants in New York City, was enforceable through fines after an initial grace period.

The rule was to go into effect on July 1, 2007, but its implementation was postponed after the New York State Restaurant Association (NYSRA) sued the board of health. The NYSRA argued that New York's regulation was preempted by federal law and violated restaurant owners' rights of free speech. In September 2007, a federal district court granted summary judgment in favor of the NYSRA on the preemption claim.[19] However, its decision turned on the fact that the board had applied its regulation only to restaurants that voluntarily made disclosures regarding calories; the court suggested that a mandatory regulation could be permissible.

On October 24, 2007, the board reintroduced a revised rule that applies to any restaurant in New York City that is part of a chain with 15 or more outlets nationally that serve standardized portions.[20] This rule requires posting of calories on all menu boards, menus, and display tags on food items in close proximity to the menu item. After a public comment period, the board adopted the revised rule on January 22, 2008.[20]

In February 2008, the NYSRA again sought to block implementation of the regulation, making the same two claims. The district court ruled in favor of the board in April and refused to delay enforcement of the regulation while the NYRSA appealed the decision to the Second Circuit Court of Appeals.[21] In response to the court's request for the Food and Drug Administration (FDA) to state its position on the preemption claim, the FDA filed a brief supporting the board's stance on both claims in late May.[22] In February 2009, the Second Circuit held in favor of the board of health.[1]

LEGAL ISSUES

STATUTORY PREEMPTION

The major issue in the menu-labeling litigation has been whether New York City's regulation is preempted by the federal Nutrition Labeling and Education Act of 1990 (NLEA). Preemption is the constitutional principle that the federal government may preclude state and local regulation on a particular subject if Congress has authority to regulate that area, it has done so, and the state action is inconsistent with the federal scheme. Judicial analysis of preemption claims focuses on determining whether Congress intended to preclude the particular state or local action at issue when it passed the federal statute.[23]

Congress's intent in enacting the NLEA was to provide information about nutrition on the labels of most foods and to strengthen the FDA's authority to regulate claims that might be made about nutrients in food. The NLEA requires that labels on food products include nutrition information, but it exempts meat and dairy products and food served in restaurants.[24] It further specifies that food purveyors who voluntarily make "claims" about nutrition on their products must do so in conformance with applicable FDA regulations.[25]

Two statutory provisions address federal preemption.[26] The first declares that no state or local government may impose requirements for nutrition labeling that differ from those of the NLEA, except for requirements regarding nutrition labeling of restaurant food. The second prohibits states and localities from regulating the voluntary "claims" that restaurants make about nutrition in a way that differs from the NLEA's requirements, except for laws concerning the ability of restaurants to make claims about nutrients that are associated with an increased health risk.

In the first round of litigation, the district court held that the menu-labeling regulation violated the second preemption provision because it required that the calorie disclosures be made on menus, but the federal rules give restaurants making claims about nutrient content flexibility in how they communicate nutrition information.[19] In the second round, the NYSRA argued that the revised ordinance was preempted because it still attempts to regulate "claims" about nutrition. The district court, however, held that a statement about a nutrient amount is not a "claim" when it is a mandated factual disclosure.[21] Under the first preemption provision, the judge said, federal preemption is not triggered by a local nutrition-labeling rule that applies only to foods that are exempt from the NLEA's labeling requirements, such as restaurant food.

The arguments on appeal focused on what constitutes a "claim." The court accepted the FDA's view, expressed in existing FDA regulations and an amicus brief filed in the case, that a quantitative statement such as "100 calories" is a "claim" when state or local law requires it to be made in the product labeling. The court further agreed that menu boards should be considered part of the labeling of restaurant food.[1]

CONCERNS ABOUT FREE SPEECH

The NYSRA has also argued that both versions of the menu-labeling regulation violate the First Amendment by impermissibly compelling restaurants to convey that "calorie information is the only relevant nutritional criterion to consider when making food selections" — a message with which they disagree.[27] It has further argued that the regulation is not narrowly tailored to achieving the government's objective, because restaurants can and do communicate information about nutrition in a variety of ways aside from menu boards. The board of health responded that the regulation requires restaurants only to disclose a fact (not to urge any particular message), that posting the information on menu boards is the most effective way to reach consumers, and that restaurants are free to include additional information if they so choose.[28]

The district court rejected the NYSRA's arguments.[21] It noted that although commercial speech was entitled to First Amendment protection, regulations compelling disclosure of "factual and uncontroversial" information will be upheld as long as they are reasonably related to the government's interest in promoting consumer awareness and protecting the free flow of complete and accurate information — a requirement that was satisfied.[29-31] Jurisprudence on free speech makes a careful distinction between requiring disclosure of simple facts and forcing a speaker to express a viewpoint.

On appeal, the NYSRA argued that the lower court should have applied a tougher standard of review. The Second Circuit rejected this argument on the basis of settled case law, and it held that the menu-labeling regulation was reasonably related to the goals of reducing consumer confusion and promoting informed decision making to reduce obesity.[1]

LESSONS LEARNED

CONSENSUS BUILDING

New York City's antifat initiatives appear to be on fairly solid legal ground, despite the controversy they have generated. New York's experience — in court and in the rule-making process — offers some lessons about policymaking at the frontier of public health law that may be useful to lawmakers in other jurisdictions.

One lesson relates to the importance of building public consensus in favor of new public health laws. The board of health had the luxury of rulemaking without having to build a legislative consensus; it only had to subject the proposed rule to a period of public notice, hearings, and comment. Perhaps as a result, its consensus-building performance was not optimal. Surprisingly, the board reportedly did not consult with the NYSRA or other key stakeholders before proposing the menu-labeling rule. It is certainly not clear that such meetings would have changed the restaurant industry's views, but this lack of consultation could have derailed the proposal if the lawmaking process had been legislative rather than administrative.

The board appears to have taken the notice-and-comment process seriously, however. It reviewed more than 2200 public comments on the draft menu-labeling regulation (99% of which supported the proposed rule) and 2287 comments on the proposal regarding trans fat (95% of which were positive), and it modified the regulations in response.[18,32]

One helpful step that the city took to build support for its rule making was to try a voluntary phase-out of trans fat before moving to a mandate. In 2005, the health department sent letters to 20,000 restaurants and 14,000 food suppliers in New York City asking them to stop using trans fat and offering technical assistance.[33] It trained more than 7000 persons in how to make the switch, but it found that there was no reduction in the use of trans fat nearly a year later. Being able to say that a less coercive policy had been tried and had failed doubtless bolstered the case for a regulation.

Another beneficial move was the city's attempt to gauge public acceptance of menu labeling through polling. It studied the results of a 2005

national poll that showed that 83% of adults wanted information about nutrition to be available in restaurants.[34] A statewide telephone poll conducted shortly before the menu-labeling law went into effect showed that 80% of New Yorkers supported expansion of the law to cover the entire state.[35] These findings probably reassured the board that its moves were not so far out in front of public opinion as to threaten its institutional legitimacy. Although the menu-labeling ordinance is opposed by the restaurant industry — something the city probably could not have avoided even with greater consultation with industry representatives — it enjoys broad public support.[36]

THE SCIENCE BASE

New York City's ability to defend its initiatives both politically and legally was greatly strengthened by the thoroughness of its investigations, conducted before the rule-making process, into the need for and likely effectiveness of the proposed interventions. A key element in judicial analysis of First Amendment claims and other legal challenges to public health laws is examination of the extent to which the interventions are likely to advance the government's stated purpose. Thorough documentation of the data providing support for a proposed public health law can not only minimize public backlash, but also build a bulwark against legal challenges.

To support the proposed ban on trans fat, the board marshaled data indicating that heart disease is the leading cause of death in New York City and estimating that up to 23% of coronary heart disease events could be avoided by replacing trans fat with alternatives.[16] The science base linking the consumption of trans fat to coronary heart disease is highly persuasive, and it includes an Institute of Medicine recommendation that such consumption be minimized.[32,37]

The board's announcement of the menu-labeling rule included a review of scientific literature on consumer errors in estimating calorie content and the unavailability of information about nutrition in restaurants.[38] Nutrition labels have strong face validity as a mechanism for encouraging more healthful food choices,[31,39] and both the FDA and the Institute of Medicine have recommended that calorie information be made available in restaurants.[40,41] The empirical evidence supporting labels, however, is currently fairly thin. Studies of the effects of food labels on purchasing have shown mixed results, with some studies showing a decreased likelihood of purchasing unhealthful items[42,43] or a reduction in calories purchased[15] and others showing that labels in restaurants did not change most patrons' food selections.[44-46] However, a September 2008 survey showed that 84% of New Yorkers who had seen the new menu labels reported being surprised by the calorie counts and 73% reported that the information affected their purchasing behavior.[36]

In the litigation, the NYSRA submitted an expert affidavit criticizing the evidence supporting the menu-labeling rule as emanating from studies with low methodologic rigor.[47] In response, the board of health emphasized the scientific evidence for each link in the causal chain connecting menu labeling to reductions in obesity: patrons underestimate the caloric value of restaurant food, caloric intake in restaurants is high, and excess caloric intake drives obesity. However, when it came to providing direct evidence that nutrition labeling prompts the lower intake of calories, it could point to data from only one restaurant chain and from surveys examining hypothetical ordering choices in restaurants.[28,43]

This exchange between the NYSRA and the board of health raises the question of what level of evidence should be required in order to implement a public health–oriented legal intervention and sustain it against legal challenges. The board criticized as unreasonable the suggestion that evidence must emanate from a randomized, controlled trial before an intervention could be implemented, noting that few public health interventions could have satisfied this standard.[28] Indeed, courts generally will require only a reasonable basis for a policymaker's belief that a public health law will be effective, although some types of legal claims, particularly challenges to free speech, will provoke a more searching judicial inquiry. The available data regarding consumers' use of information about nutrition is sufficient to meet the reasonableness standard, but stronger, direct evidence of efficacy may be required to satisfy tougher standards of judicial review.

CONCLUSIONS

New York City's initiatives exemplify the view that traditional justifications and methods for combating infectious disease should be applied

to chronic health conditions[48] and that "the forceful application of law" can be a potent tool for combating chronic disease.[49] They show the potential impact of bold action by local governments. They also illustrate the dangers of a decentralized approach to public health lawmaking; a patchwork of state and local laws creates compliance challenges for restaurant chains and sparks preemption battles for the governments that are implementing the rules. Both the promise and the pitfalls of this approach will be amplified as other localities and states experiment with public health laws inspired by New York City's example in the years to come.

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