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The Deregulatory State

Lawrence O. Gostin
Georgetown University Law Center, gostin@law.georgetown.edu

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Lawrence O. Gostin
The Linda D. and Timothy J. O’Neill Professor of Global Health Law
Georgetown Law
gostin@law.georgetown.edu

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The Deregulatory State

by Lawrence O. Gostin

Public health can be achieved only through collective action. Individuals acting alone cannot protect themselves from work hazards, unsafe or ineffective vaccines and pharmaceuticals, impure food and water, a polluted environment, or epidemics. Only a well-regulated society can secure the essential conditions for health. Yet in this country, successive administrations have eroded health and safety protections. The consequences include deaths in the mining industry, lead in toys, industrial solvents in toothpaste, harmful bacteria in peanut butter and spinach, and unsafe and ineffective pharmaceuticals (such as COX-2 inhibitors and non-statin cholesterol medications).

The “Deregulatory State” is a result of a conservative campaign that has created and reinforced deep-seated concerns about overbearing government. The political dialogue used to describe agency action is pejorative and effective: “big government,” “centralized,” “top-down,” and “bureaucratic.” This anti-government narrative has set the terms of the debate about the role of government in protecting the public from market excesses and failures.

The Deregulatory State takes many subtle forms, including self-policing, so that industry discloses and corrects its own safety violations; incapacitating, so that agencies are starved of expertise and resources; devolving, so that residual regulation is focused at the local level; preempting, so that the federal government denies states the authority to protect their citizens; and privatizing, so that government functions are conducted by “for-profit” or voluntary entities. In this column, I will focus on two broad categories of deregulation: federal preemption and privatization.

Regulatory Vacuums through Preemption

Congress has the power to preempt, or supersede, public health regulation at the state level, even if the state is acting squarely within its police powers. Federal preemption may seem like an arcane doctrine, but it has powerful consequences for the public’s health and safety. The Supreme Court’s preemption decisions can effectively foreclose meaningful state regulation and prevent people from turning to the courts for legal redress. Preemption has had antiregulatory effects on issues ranging from tobacco control to occupational health and safety, motor vehicle safety, and employer health care plans. From 2001 to 2006, Congress enacted twenty-seven statutes that preempt state health, safety, and environmental policies, demonstrating the potential breadth of federal power to override state public health safeguards.

The Bush administration has vigorously advocated preemption to invalidate state public health efforts in both amicus curiae briefs and preambles to agency rules. On February 20, 2008, the Roberts Court handed the administration a victory in two major preemption cases. In _Rowe v. New Hampshire Motor Transport Association_, the Court held that a federal transportation statute pre-empted Maine’s laws designed to prevent minors from buying cigarettes on the Internet. In _Riegel v. Medtronic, Inc._, the Court ruled that manufacturers are immune from tort liability for medical devices, such as implantable defibrillators or heart pumps, that received pre-market approval and meet Food and Drug Administration specifications.

The Court just heard another FDA preemption case on whether tort liability can be based on fraud for misrepresenting or withholding information from the agency during the approval process. And next term, the Court will decide whether FDA drug approval preempts personal injury suits. In effect, the executive and judicial branches are dismantling a long-standing civil justice safety net for consumers and patients who suffer from industry misconduct left unchecked by federal and state regulations.

Outside the courtroom, multiple agencies charged with protecting public health, safety, and the environment have systematically pushed for preemption through administrative rulemaking. Federal agencies have inserted preemptory language in preambles to rules governing everything from seatbelt placement (this from the National Highway Traffic and Safety Administration) and mattress flammability (the Consumer Product Safety Commission) to drug labeling (the FDA) and railroad safety (the Railroad Administration). This troubling trend is made all the more worrisome by the administration’s failure to provide an opportunity for public comment on the preemption language in rule preambles.

This sweeping preemption of state regulation and tort actions has created regulatory vacuums. Instead of advocating devolution or otherwise supporting state authority to protect the public’s health, the federal government has consistently derailed state regulation. At the same time, it has dismantled federal safety standards, leaving a large regulatory abyss. For example, even after the Supreme Court ruled that the Environmental Protection Agency had the power to regulate heat-trapping gases emitted by automobiles, the agency not
only refused to regulate but also prevented California from filling the regulatory gap.\(^5\)

Thus, the public remains unprotected prospectively because the federal government both declines to regulate and suppresses state efforts to do so. And the public is unprotected retrospectively because of the Court's invalidation of state tort law. In short, the public is left to fend for itself.

**Trusting the Private Sector**

Privatization, understood broadly, is the government's abdication of responsibility for health governance by assigning public functions to the private sector. It can happen directly, when the state contracts out governmental functions to industry (such as in mental health care, prisons, or child welfare services). Or it can happen indirectly, when the state withdraws financial and political support for critical agency functions, cooperates with industry in setting and enforcing standards, or simply allows companies to self-regulate.

**Agency incapacity.** Government can avoid stringent regulation simply by starving agencies of funds or making them rely on industry largess for resources. The FDA offers a classic case study of how the White House and Congress can weaken a once powerful agency. The FDA is responsible for the safety of approximately 80 percent of food sold and all human drugs, vaccines, and medical devices. All told, it regulates 25 percent of all consumer spending—about $1 trillion per year. Yet Congress has steadily either reduced funding or held it constant, even as the FDA's functions have expanded vastly, and public concern for food, drug, and medical devices has increased. The FDA's resource shortfalls have resulted in inadequate inspections, a dearth of scientists, inability to speed the development of new therapies, and neglect of food and drug imports. For example, the FDA now carries out 78 percent fewer food inspections than thirty-five years ago and inspects food manufacturers on average only once every ten years. The agency needs twice its current level of funding to be properly equipped to fulfill its mission.\(^6\) The FDA is also hampered by the lack of clear regulatory authority, organizational problems, and a scarcity of postapproval data about drugs' risks and benefits.\(^7\) Just as troubling, the FDA's major source of funding for drug approvals is user fees from pharmaceutical companies, which invites criticism about the agency's close relationship with industry.

**Self-policing.** As part of the trend against state regulation, agencies have developed self-policing programs that shift the burden of regulatory compliance from government to industry. The Occupational Safety and Health Administration’s “Voluntary Protection Program” exempts participating firms from routine inspection and eschews formal adjudication. With the virtual nonenforcement of violations under this program, industry's abysmal record of safety compliance is not surprising. OSHA has repeatedly failed to prosecute firms with a long history of safety violations, even in the face of debilitating injuries and deaths caused by employer negligence.\(^8\) Similarly, the Department of Veterans Affairs’ “Medical Errors” program asks hospitals to self-disclose dangerous forms of malpractice, and the EPA’s “Greenlights” recognizes and rewards firms for self-disclosing and correcting safety violations. But industry has only mild incentives to self-police, and researchers say they do so only if agencies increase inspections and compliance.\(^9\)

**Self-regulation.** In an increasingly deregulated state, industry representatives, rather than government, have initiated much contemporary "regulatory" activity. Forms of industry self-regulation include codes of conduct, collaborative agreements, accreditation, information disclosure, and ratings. These programs govern a wide array of domains, including worker and product safety, consumer protection, environmental management, fire prevention, and advertising (such as for tobacco and alcoholic beverages). Perhaps the most prominent recent illustration of self-regulation is the decision by food and beverage manufacturers to limit sales in schools and curb advertising to children. But more often than not, self-regulation occurs in response to pressure by government or advocacy groups. For example, the food and beverage industries announced their schools and advertising policies shortly after the publication of Federal Trade Commission reports highlighting their deceptive practices and the risks of obesity.

Because they are not in a position to defend themselves and their families, members of society need the protection of the state. If the government drastically reduces regulation and enforcement and leaves core government duties to the private sector, current and future generations will suffer. Indeed, it was in recognition of the palpable harms of the free market that health, safety, and environmental regimes and civil justice systems emerged. They have evolved over a long period to work synergistically in their protective effect; the whole system is now under serious threat.


3. Rowe v. N.H. Motor Transport Ass'n, No. 06-457 (February 20, 2008).


