9-13-2018

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of documents from the Sugar Research Foundation demonstrated that the sugar industry successfully sought to deflect the concerns of health-conscious consumers from sugar to fat.[5] Many countries have curtailed advertising aimed at young people by the food industry. Tax policies are increasingly being used to reduce consumption of sugar-sweetened beverages in U.S. jurisdictions and elsewhere, but the American Beverage Association has vigorously opposed these efforts, including by supporting state preemption. A San Francisco policy that is currently being adjudicated would support the potential use of warning labels on sugar-sweetened beverages.

An audio interview with Dr. Healton is available at NEJM.org

The table presents potential provisions that could result from litigation or voluntary settlements with these industries and provisions contained in the MSA. Combined with tobacco use, these epidemics (excluding climate change, for which U.S. data are unavailable) cause nearly one third of all U.S. deaths. The trajectory of these major public health problems could be altered by reducing industry manipulation of science and lobbying for policies against the public interest; compensating public coffers for money spent combating these epidemics and redirecting funds to prevention; and using public education, product warnings, and price increases to reduce use of harmful products. By using these strategies, state AGs could strengthen their consumer-protection roles as guardians of the health of the public.

Disclosure forms provided by the author are available at NEJM.org.

From the New York University College of Global Public Health, New York.

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DOI: 10.1056/NEJMp1802633

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Pharmaceuticals are consuming increasingly large portions of U.S. state budgets, and high prices are preventing patients from getting, and adhering to, essential medicines. In mid-May 2018, President Donald Trump announced a heavily hyped but relatively modest federal plan to bring down drug prices. Meanwhile, several states are moving forward with their own solutions, and Maryland's approach is particularly ambitious. In 2017, responding to notorious cases such as the 5000% increase in the cost of Daraprim (pyrimethamine) and the 10-fold increase in the cost of EpiPens (epinephrine auto-injectors), Maryland enacted a statute that prohibits manufacturers from "price gouging" on any "essential off-patent or generic drug" (see box).

But in April 2018, a panel of the federal Fourth Circuit Court of Appeals overturned the statute. The two-judge majority reasoned that the state could not regulate the prices charged by manufacturers, because they sold to wholesalers in transactions that occurred "wholly" out of state.[1] The court invoked the "dormant commerce clause," the legal doctrine holding that the Constitution implicitly restricts states from interfering with interstate commerce, even when Congress has been silent regarding the activity in question.

One judge dissented, arguing that the Maryland law targets only the prices paid for products that reach Maryland buyers. Manufacturers could simply earmark their Maryland-bound transactions and price them to comply with that state's laws.

Similarly, the Supreme Court has recognized that states are free to impose greater or lesser tort liabilities on drugs approved by the Food and Drug Administration (FDA). In the U.S. constitutional system, states are the "laboratories of democracy" that have the power to regulate on virtually any subject.[2] As the dissent noted, "numerous States impose safety, quality, and labeling restrictions on goods sold by out-of-state manufacturers through out-of-state distributors to in-state consumers."[1]

In some ways, the Maryland decision echoes the historic *Lochner* decision of 1905, in which the Supreme Court invoked a "liberty of contract" to strike down a New York law regulating the number of hours per week that bakers could work.[3] In the *Lochner* era, the Supreme Court routinely and creatively invented constitutional provisions to undermine progressive state laws. Today, this sort of judicial meddling is widely condemned as contrary to democracy and federalism. Like the liberty of contract invoked in *Lochner*, the dormant commerce clause is not explicitly laid out in the Constitution itself.

The dormant commerce clause arises only from a sense of the framers' larger purpose: to create a single economic union, in which states would not exercise protectionism to favor local producers. Yet the Maryland law is not protectionist. It is not as if Maryland burdened drug makers in New Jersey and Virginia in order to favor their Maryland competitors, which is the paradigmatic violation. The Supreme Court has struck down such an arrangement when New York tried to favor local milk producers by prohibiting out-of-state producers from undercutting their prices. The Court has also struck down laws that pegged local beer prices to those offered in other states, because such laws could cause manufacturers to raise their prices in other states. Here, Maryland used no such interstate price peg.

Maryland's statute also avoids conflict with federal patent law, which purposefully gives inventors a monopoly as an incentive. High prices are part of the design of that federal regime, and states cannot interfere with that goal. In contrast, the Maryland law focuses on generic drugs.

Maryland's HB 631, "An Act concerning Public Health — Essential Off-Patent or Generic Drugs — Price Gouging — Prohibition"

Where consumers have no meaningful choice about an important drug and there is a lack of competition, the statute prohibits "price gouging":

- Targeting "unconscionable" price increases, defined as "excessive and not justified by the cost of producing" or expanding access to the drug;
- Applying only to generic medications (for which all exclusive marketing rights and patents have expired); and
- Applying only to essential medicines, as designated by the World Health Organization or the Maryland Secretary of Health;

The law authorizes the Attorney General to petition a court to restore money to consumers, require manufacturers to provide the drug at the last permissible price, and order civil penalties.

The State of Maryland has asked that all the judges on the Fourth Circuit sit together to review the case. The U.S. Supreme Court may also do so. Either court could reverse the panel decision. Congress could also authorize states to experiment.

If all else fails, the state legislature may try to craft another solution that avoids the panel's opinion. One approach would be to regulate prices charged to consumers and payers within the state and allow economic forces to work their way up the supply line to the price-gouging manufacturers. If a retailer is unable to sell at an exorbitant price, then wholesalers and manufacturers will be unable to charge unreasonably high prices in the first place.

In 2003, the U.S. Supreme Court unanimously upheld a different sort of pharmaceutical statute in Maine.[4] Maine linked its Medicaid and uninsured self-pay markets by imposing a prior-authorization requirement on expensive drugs sold in its Medicaid system unless manufacturers agreed to pay a rebate to subsidize private purchases. By targeting transactions within the state, this law reached the manufacturers regardless of their out-of-state wholesalers.

Under any such policy, it will remain difficult and contentious to determine what is and is not an "unconscionable" price and to set the amount of any required rebate. Without a more comprehensive system of value-based pricing, an ad hoc approach will only generate more litigation. More important, small states acting alone run the risk that the manufacturer may just walk away, refusing to sell at a cut rate. But that's the nature of a bargain with a monopolist.

A better approach, I would argue, is to bring more generics into the market, creating options for states and buyers, which will drive down prices. Although the FDA approved a record number of generics in 2017,[5] there are still cases in which the FDA has authorized no competitors to a given product, leaving pharmaceutical companies with effective monopolies. Some potential competitors are barred in the United States, even though the products are working safely and effectively in Canada and Europe. National borders are, in this sense, harming American patients and payers. Transnational regulatory reciprocity would increase competition and drive down prices.

In May 2018, Vermont passed a law tasking a state agency with designing a program for importing drugs from Canada, but such a move also requires federal approval. Giving some preliminary credence to this approach, in July 2018, Secretary of Health and Human Services Alex Azar directed the FDA to establish a working group on drug importation as a means of fighting generic price hikes.

A promising solution is found in an initiative led by Intermountain Healthcare and involving several major hospital groups and the Department of Veterans Affairs. Announced in January 2018, this nonprofit consortium will use a novel contracting mechanism to manufacture essential generic drugs. When progress is stymied by politics and the courts, innovation may find another path.

Disclosure forms provided by the author are available at NEJM.org.

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This article was published on August 8, 2018, at NEJM.org.

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DOI: 10.1056/NEJMp1805432

Limiting State Flexibility in Drug Pricing

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Throughout the United States, escalating drug prices are putting immense pressure on state budgets. Several states are looking for ways to push back. Last year, Massachusetts asked the Trump administration for a waiver that would, among other things, allow its Medicaid program to decline to cover costly drugs for which there is limited or inadequate evidence of clinical efficacy.[1] By credibly threatening to exclude such drugs from coverage, Massachusetts hoped to extract price concessions and constrain the fastest-growing part of its Medicaid budget.

In late June, however, the Centers for Medicare and Medicaid Services (CMS) denied Massachusetts' request.[2] On the same day, the agency issued a memorandum clarifying that, under requirements included in the Omnibus Budget Reconciliation Act of 1990, state Medicaid programs are legally obliged to cover all drugs approved by the Food and Drug Administration (FDA) — including those approved under the agency's less rigorous accelerated-approval pathway.[3]

Many of these drugs — including some with uncertain efficacy — are very expensive. Take, for example, Exondys 51 (eteplirsen), which was approved for the treatment of Duchenne's muscular dystrophy on the basis of a trial that involved 12 boys and used a surrogate end point. The drug's label states that "a clinical benefit of Exondys 51 has not been established," yet the retail price of the drug is about $300,000 per year. State Medicaid programs don't pay full price — that same 1990 legislation entitles them to a discount that today amounts to at least 23% of the drug's average sales price. Even so, drugs like Exondys 51 are straining state budgets.

To reduce the burden of high-cost, low-value drugs, Massachusetts has proposed establishing a closed formulary, in which certain drugs can be excluded from coverage. The Trump administration might have been expected to welcome the proposal. At least rhetorically, it is committed to reducing drug prices. And closed formularies are ubiquitous in private insurance and public health care programs alike. The Veterans Health Administration uses one, and Medicare Part D plans can exclude certain products.

So why not let Massachusetts try a closed formulary for Medicaid? CMS's letter to the state doesn't say. It is silent on what exactly is deficient about Massachusetts' request. The letter does claim that CMS "would be willing to consider" a closed formulary — but only if Massachusetts both gives up the steep discounts that it's entitled to by law and demonstrates that its Medicaid spending won't increase because of the changes.

Together, these requirements create an insuperable obstacle to any closed formulary. Under CMS's