VIEWPOINT

Legal Challenges to State Drug Pricing Laws

Theodore T. Lee, BA
Yale Law School, Yale University, New Haven, Connecticut.

Aaron S. Kesselheim, MD, JD, MPH
Program On Regulation, Therapeutics, and Law (PORTAL), Division of Pharmacoepidemiology and Pharmacoeconomics, Department of Medicine, Brigham and Women's Hospital, Harvard Medical School, Boston, Massachusetts.

Amy Kapczynski, JD
Collaboration for Research Integrity and Transparency (CRIT), Yale Law School, New Haven, Connecticut.

Corresponding Author: Theodore T. Lee, BA, Yale Law School, Yale University, 127 Wall St, New Haven, CT 06511 (theodore.lee@yale.edu).

In recent years, growth in spending on prescription drugs has been fueled by high prices of new therapeutic products, increases in the prices of available brand-name drugs, and substantial price increases for a small fraction of older generic drugs.[1] These trends have attracted significant scrutiny from policy makers. High drug prices create health risks as well as financial risks for patients. Survey findings suggest that 24% of patients with cancer do not fill prescriptions because of factors related to costs,[2] and one-third of nonelderly patients with cancer changed their prescription drug use (such as skipping doses or taking less medication) for financial reasons.[3] Insurers, facing budgetary crises due to rising prices, have in many cases imposed higher premiums and higher out-of-pocket costs on patients.

While the federal government has yet to enact major reforms, in 2017 some states passed laws intended to help manage and shed light on pharmaceutical prices. Most of these state legislative efforts have been challenged in court by industry associations that seek to invalidate these laws and stop them from going into effect. In this Viewpoint, we review the legal arguments that industry has raised in Maryland and Nevada, 2 of the earliest states to encounter legal challenges to their drug price reform laws.

Maryland and Nevada Laws

The Maryland law prohibits certain price increases for essential generic (off-patent) drugs. It also applies to drug-device combinations used to deliver off-patent drugs, such as the epinephrine autoinjector (EpiPen).[4] Manufacturers must justify price increases of more than 50% in a 1-year period to the state's attorney general. The attorney general then has the option to sue the manufacturer or wholesale distributor to stop any "unconscionable" price increase, restore excess payments to patients and third-party payers, and impose penalties.

The Nevada law imposes reporting requirements on certain manufacturers of drugs essential for the treatment of diabetes.[5] Companies that increase prices by more than the previous year's medical inflation, or by double medical inflation over the previous 2 years, must provide information to the state government on drug production costs, marketing costs, profits from the drug, information about patient assistance programs, the price of the drug, and the aggregate amount of any rebates provided. The law directs the state to publish an annual report based on these disclosures with information about price increases, the reasons for those increases, and the effects of those increases on prescription drug spending.

Commerce Clause Challenges

In lawsuits challenging the Nevada and Maryland laws, industry has invoked the "dormant" commerce clause, a constitutional doctrine that prohibits states from engaging in economic protectionism. A key motivation for giving Congress power over interstate commerce was to prevent states from favoring local goods. Accordingly, under this doctrine, states cannot discriminate against nor unduly burden interstate commerce. For example, the Supreme Court struck down a New York law that required out-of-state milk companies to buy dairy from out-of-state farmers at the same price paid to New York dairy farmers if they wanted to sell in New York.[6]

Challenges from industry have used this doctrine to argue that Maryland's law directly regulates drug prices in other states, because supply chains are complex and typically involve intermediaries in other states. However, the doctrine is not so expansive. States may not formally set prices in other states (as New York did), but the Maryland law does not do that: It only constrains the prices of drugs sold in the state. While reducing prices in one place can have incidental effects in another, the Supreme Court has rejected similar arguments as too indirect and speculative. In a 2003 case, the Court upheld a Maine law that required manufacturers selling in the state to enter into a rebate agreement with the state or meet a set of prior authorization requirements, even though nearly all sales to distributors occurred outside Maine.[7] The Maryland law similarly only requires that commerce within the state be conducted on the state's terms.

In Nevada, industry similarly claims that the new law burdens interstate commerce by indirectly influencing prices in other states. The claim here is even weaker than the one in Maryland, since Nevada is imposing transparency and not direct pricing requirements. Industry has also argued that the law would force disclosure of trade secrets and in this way affect commerce in other states. Even if trade secrets were affected (unlikely, as discussed below), courts give deference to states when claims are made that regulatory actions cause excessive indirect burdens. Many valid state regulations affect businesses that operate nationally, because it is generally accepted that states are the primary regulators in many domains. Trade secret law is an example: It is primarily state law and differs state to state. States also frequently pass laws that regulate pharmaceuticals and that differ state to state; for example, states are currently passing laws to address the opioid crisis. These differences surely have out-of-state effects, but this has never been thought to generate constitutional problems.

In September 2017, the trial court dismissed the dormant Commerce Clause arguments in the Maryland case. The similar challenges to Nevada's law, which have not yet been adjudicated, likely will fail because they are weaker still.

Patent Challenges

Industry challengers have also asserted that state laws that affect the prices of patented drugs conflict with federal patent law. When federal and state law conflict, federal

law preempts state law. In a controversial 2007 decision, *BIO v DC*,[8] a federal appeals court struck down a Washington, DC, law that penalized companies that priced their patented drugs 30% more than the price in the United Kingdom, Germany, Canada, or Australia, asserting that it interfered with the objectives of federal patent law.

The law in Maryland has so far escaped challenge on this basis, even though it formally applies to drug-device combinations, which could be patented. While Nevada's law has been challenged on this theory, it is more broadly written than the law struck down in *BIO v DC*, providing the state with strong arguments in its defense. The logic of *BIO v DC* is that states cannot target patent holders in a way that interferes with their abilities to make maximal use of their federal patent rights. Pharmaceutical and biotechnology industry associations have argued that the Nevada law has an analogous effect because it triggers reporting requirements if growth in prices exceeds medical inflation. However, in contrast to the District of Columbia law, the Nevada law requires only disclosure of information, not curbs on prices. It is difficult to see how a general reporting requirement applying to the drug industry could be understood to conflict with federal patent law.

Furthermore, the Nevada law is a general one and addresses its disclosure requirements to both generic and patented diabetes drugs. The District of Columbia law specifically targeted patented medicines and did not seek to regulate a broader field—a distinction that the *BIO* court suggested might make a difference. It is well accepted that states have general powers to regulate price gouging, to impose taxes and surcharges, and to regulate industries via laws of general application, such as consumer protection and products liability law. Laws of these kinds regularly affect the financial returns associated with patented products.

Trade Secrecy Challenges

Because the Nevada law requires disclosure of certain business information, pharmaceutical and biotechnology industry associations have also argued that it conflicts with the law of trade secrets, which protects company trade secrets from disclosure to competitors. While lawmakers may obligate companies to disclose trade secrets to regulators, when they mandate disclosure of such secrets to the public they may need to provide compensation, under the clause of the Constitution that protects private property from government "takings."

However, the information requested by Nevada likely does not involve genuine trade secrets. Trade secrecy law is very fact-specific: To be a trade secret, a piece of information must be secret and must be economically valuable to a competitor if disclosed. Most of the information requested under the Nevada law is neither central to drug companies' business models nor comprehensively secret (companies already disclose some of this information). Therefore, manufacturers can likely fulfill their obligations under the law without disclosing trade secrets.

Nevada's law might also be interpreted to give companies the chance to protect any legitimate trade secrets by entering into confidentiality agreements with the state and making the requisite fact-intensive showing. A more robust defense of transparency laws—which would permit more information to be shared with the public—is also possible: States can argue that even if trade secrets are implicated, they have legitimate and important public interests in making drug prices and related information transparent and in this way justify the disclosure. Because Nevada's transparency law can be construed to have little or no influence on genuine trade secrets, and because there are significant public interests served by making prices, production costs, rebates, and similar information public, the law is likely to be upheld against this challenge.

Conclusions

In the federal system of the United States, states have significant power to regulate commerce and protect consumers within their territory. The United States relies on states to respond to local priorities and to serve as "laboratories of democracy" when new policy challenges emerge. States are now taking this step in the context of drug prices, and, to date, when federal courts have addressed the issue they have rejected industry's attempts to stifle this innovation. Even though these early decisions are being appealed, this review of the key issues at stake suggests that other states have a sound legal basis to take similar and even more expansive action to restrain drug prices and impose transparency requirements.

ARTICLE INFORMATION

Published Online: February 12, 2018. doi:10.1001/jama.2017.20952

Conflict of Interest Disclosures: All authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest. Mr Lee reported that from 2012 to 2015 he worked as a management consultant at Bain & Company, which serves a variety of clients in the health care industry, and that during that period he worked on strategy and operations projects for pharmaceutical companies, medical device companies, health care providers, and pharmacy benefit managers. He did not receive compensation for this work beyond the salary paid by Bain & Company. No other authors reported disclosures.

Funding/Support: Dr Kesselheim's work is funded by the Laura and John Arnold Foundation, with additional support from the Harvard Program in Therapeutic Science and the Engelberg Foundation. Dr Kesselheim reports grants from the FDA Office of Generic Drugs and Division of Health Communication outside the submitted work (2013-2016). Ms Kapczynski is funded in part by the Laura and John Arnold Foundation, through a research grant to Yale University to support the Collaboration for Research Integrity and Transparency (CRIT).

Role of the Funders: The funders had no role in the preparation, review, or approval of the manuscript or the decision to submit the manuscript for publication.

REFERENCES

1. Kesselheim AS, Avorn J, Sarpatwari A. The high cost of prescription drugs in the United States: origins and prospects for reform. *JAMA*. 2016;316(8):858-871.

2. Zafar SY, Peppercorn JM, Schrag D, et al. The financial toxicity of cancer treatment: a pilot study assessing out-of-pocket expenses and the insured cancer patient's experience. *Oncologist*. 2013;18(4):381-390.

3. Zheng Z, Han X, Guy GP Jr, et al. Do cancer survivors change their prescription drug use for financial reasons? findings from a nationally representative sample in the United States. *Cancer*. 2017;123(8):1453-1463.

4. Md Code Ann, Health–General, §§2-801–2-803.

5. SB 539, 2017 Nev Stat, ch 592.

6. *Baldwin v G.A.F. Seelig Inc*, 294 US 511 (1935).

7. *Pharmaceutical Research and Manufacturers of America v Walsh*, 538 US 644 (2003).

8. *Biotechnology Industry Organization v District of Columbia*, 496 F3d 1362 (Fed Cir 2007).