Legal Challenges of Rx Drug Laws Passed in 2017 Will Shape Future States' Cost Containment Legislation

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To date, more than 150 bills to rein in prescription drug costs have been introduced or approved in state legislatures across the country. As these legislative successes grow, it is important to examine how the first generation of state drug cost containment laws passed in 2017 are weathering legal challenges by the pharmaceutical industry, as these court decisions will shape states' future drug policies.

Last year, California, Maryland, and Nevada approved important drug cost laws. There was also a seminal US Supreme Court decision that appears at first glance unrelated to state prescription drug cost policy, but it cracked open the door to wholesale importation of lower-cost prescription drugs from Canada.

Supreme Court Enabled Importation of Patent-Protected Goods

In May 2017, the Supreme Court cleared the way for wholesale importation of drugs from Canada. The court[1] ruled against the US firm Lexmark and in favor of an ink cartridge recycler, Impression Products. Impression purchased Lexmark's toner cartridges from abroad, refilled, and resold them at prices below Lexmark's US brand price in the United States.

The court determined that because Lexmark sold its products overseas, the overseas purchasers were not legally bound by Lexmark's US patent rights when they resold those products, and the US purchaser of the overseas recycled toner cartridges was similarly not bound by Lexmark's US patent given they had purchased the product from an entity other than the original manufacturer. Bottom line, the court found that patent rights did not apply once the product entered the international marketplace.

Had the decision gone the other way and favored Lexmark, states' efforts to import brand-name prescription drug products into the United States from overseas wholesalers would likely face a legal challenge under patent law – even though such importation is allowed under a very narrow provision of the Food, Drug, and Cosmetic Act.

Maryland's Generic Drug Price Gouging Bill

The second significant legal action in 2017 was passage of Maryland's drug anti-price-gouging law (SB 631) in May, which was championed by the state's attorney general. This landmark legislation prohibits makers of essential drugs from raising prices to "unconscionable" levels. The law applies to off-patent and generic drugs manufactured by three companies and all drugs on the World Health Organization's list of "essential medicines" – considered to be the minimum pharmaceutical treatments needed for a basic health care system.

The Maryland law allows the state's Medicaid agency to inform the attorney general about drugs that cost at least $80 and have a wholesale cost increase of 50 percent or more in 12 months. The attorney general can use the agency information or it can independently identify essential generic and off-patent

drugs that undergo an "unconscionable" price increase. An "unconscionable" price increase is defined as an excessive price hike that is not justified by changes in production and for which consumers have no meaningful treatment alternative.

If the attorney general does not find an adequate explanation for the price increase, the issue can be referred to the state court, which can decide if penalties should be imposed on a manufacturer. The law gives the court three specific remedies to impose on manufacturers:

- Roll back the price to an earlier, lower level;
- Compensate all Maryland purchasers and insurance companies that paid the "unconscionable" price for the drugs; or
- Impose civil penalties of up to $10,000 for each violation.

The pharmaceutical industry attempted to block the law and filed a legal challenge in the US District Court for Maryland,[2] claiming numerous violations of constitutional law. Notably, the court allowed implementation of the law to proceed, finding that the industry's concerns did not meet the legal standards of harm required to impose an immediate injunction. As of mid-March, the appeal was still pending.

In its challenge, the industry argued that the state's new law conflicts with the Dormant Commerce Clause (DCC),[3] which the court dismissed, finding that the anti-gouging law did not affect industry oper-ations in other states in any meaningful way that would exceed the public benefit of the law to Maryland residents. The industry also alleged the law violates constitutional due process requirements because the standard of "unconscionable" price increases was overly vague. The court found that this issue required further exploration, and the case remains under appeal.

There are several interesting aspects in the industry's legal filings in the Maryland anti-gouging case that may be relevant for future state health policy and legislation. In its original filing, the industry argued that the law violated the DCC because the industry had no meaningful way to limit or end its drug sales in Maryland in order to avoid the law. The industry argued that a drug company cannot simply redesign its drug sale supply chain to boycott a particular state in order to avoid state regulation.

If this industry assertion is true – that manufacturers cannot control the supply chain and intentionally avoid sales in states with regulations they oppose – state policymakers should be comforted that any new drug cost policy they create will not create drug shortages in their states. Therefore, industry arguments that a state law addressing drug costs will create drug shortages in the enacting state appears wholly untrue.

Interestingly, during oral arguments on the Maryland case in January, industry lawyers argued that direct price controls would not violate the DCC, but establishing thresholds for what constituted "exorbitant" price increases would violate the DCC because, unlike price controls, limits on excessive price increases would unduly burden interstate commerce and a company's national operating procedures.

Industry arguments against Maryland's anti-gouging law appear to actually support a new Maryland drug cost control proposal recently introduced in 2018 (S. 1023), which would establish an all-payer, drug reimbursement rate-setting commission for high-cost drugs. This all-payer system would appear to meet the industry's definition of a policy that does not violate the DCC.

Several states now have price-gouging legislation modeled on Maryland's law pending.

Nevada's Transparency Law

Nevada's drug transparency law (SB 539), enacted in 2017, has several innovative provisions to contain drug costs. The law requires the state to post a list of all essential anti-diabetes medicines, and the drugs' makers also have to report annually the costs of manufacturing and marketing each product, in addition to other details. Additionally, each year the state will identify products with price increases exceeding the medical consumer price index in the past 12 months or twice the increase in the previous 24 months. Makers of those drugs must report additional information that justifies or explains their price increases. Nevada's law makes all manufacturer-supplied information public.

The law also requires:

- Reporting of pharmaceutical sales representatives and the free goods or compensation provided by each sales representative to Nevada-licensed providers;
- Pharmacy benefit managers to report the dollar value of manufacturer drug rebates collected; and
- All non-profit patient groups that are active in Nevada to publicly report all sources of financial support. The intent is to make it more publicly transparent when patient groups have financial interests in aligning with and lobbying on behalf of the pharmaceutical industry.

The industry's challenge to Nevada's transparency law alleges a number of federal law violations.[4] Specifically, the industry argues:

- Manufacturer reporting of company pricing decision data violates federal patent holder rights to price their produces without constraint and is thus preempted by federal patent law;
- The data required to be reported are proprietary and the intended public disclosure of that information violates trade secret law and results in the taking of property without compensation (the Takings Clause of the Fifth Amendment);
- The Nevada law violates the DCC because public disclosure of trade secrets in Nevada will over-ride trade secret laws of other states (and most states had trade secret protection legislation before the federal law was enacted in 2016);[5] and
- The new law presents such a danger to the industry that it should not be allowed to be implemented until all related issues have been litigated.

To date, the federal appeals court has decided that the law does not present a threat of harm sufficient to warrant an injunction, so Nevada's law has gone into effect. All the issues are under litigation in the appeals court.

California's Transparency Law

Enacted in October 2017, the California price transparency law (SB17) applies to all drugs (brand-name and generic) with a wholesale acquisition cost of at least $40. When the price of these drugs increases more than 16 percent in the prior 12 months or 32 percent in the preceding 24 months, manufacturers are required to report a variety of data about their business operations and costs – to the extent that the information is otherwise public. The industry is challenging[6] the law in three areas:

- **Violation of the DCC**. The industry alleges that reporting otherwise public information to the state is an undue burden on its interstate operations. They maintain that the reporting threshold itself is simply regulating the price manufacturers can set in states outside of California (even though the state law does not set any prices, but requires some amount of transparency on prices of the manufacturers' choice).

- **Violation of free speech**. This argument is complicated, but the law requires reporting of (otherwise public) information when prices increase above a certain level. The industry argues this compels manufacturer to disclose (or "speak") information that the manufacturer would otherwise choose not to share. The industry also argues that compelling this speech is tantamount to forcing a manufacturer to say that its business activity has a negative social impact, which they otherwise would choose not to say. Even if a required action was considered "speech," the law only requires information that is otherwise public – information that the manufacturer has already chosen to disclose.
- **Violation of due process**. The industry argues that the law fails to provide due process because it is not clear to the industry over what period of time a total price increase is calculated, which is the trigger for reporting. Does the law intend that months before the enactment are counted when figuring the time period of a price increase? This lack of clarity, and the risk of manufacturer penalties arising from failure to accurately report, constitute impermissible vagueness of the law, resulting in loss of due process rights, it argues. However, the law became effective in January 2018 and many manufacturers appear to be reporting any price increase to health care payers, whenever it occurs, since its enactment. The question of when price justification reporting is required will be sorted out by the executive branch agency charged with implementation of the law.

Conclusion

States have broken important new ground to ensure drug affordability and access to life-changing pharmaceutical treatments and to push the industry to lower costs. It is not clear that the industry will prevail in its challenge of recent state laws that provide a significant public benefit, but currently all eyes are on these legal challenges. The legal decisions issued in the months ahead will shape how states proceed with future drug cost containment policies. But, as is evidenced by the numerous proposed bills across the nation, state legislatures will continue to propose strategies to lower the cost of critical medications.

For more information about the latest state drug cost containment legislation across the country, visit NASHP's Legislative Tracker page.

Notes

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1. US Supreme Court docket # 15, 1189, Impression Products v Lexmark International Inc.
2. Association for Accessible Medicines v Brian Frosh Case 1:17-cv-01860
3. NASHP has a paper explaining the Dormant Commerce Clause and its relation to state regulation of industry, here
4. Nevada law SB 539. Case #2:17-cv-02315, Pharmaceutical Manufacturers of America and Biotechnology Innovation Organization v Sandoval.
5. The Dormant Commerce Clause is the subject of another NASHP paper that can be found here.
6. US District Court, Case # 2:17-01323, Pharmaceutical Manufacturers of America v Brown.