PHARMACEUTICAL PRICE-GOUGING: AN ANALYSIS OF MARYLAND'S EFFORTS TO REGULATE UNCONSCIONABLE INCREASES IN THE PRICES OF GENERIC DRUGS

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INTRODUCTION

Few people in modern American history have attained the notoriety of "PharmaBro" Martin Shkreli. In August of 2015, he acquired the exclusive rights to a drug called Daraprim for $55 million through his company Turing Pharmaceuticals. Daraprim, which has been off-patent since 1953, is a drug primarily used to treat toxoplasmosis in newborn babies and HIV patients. No generics had entered the market due to high barriers to entry, and after acquiring Daraprim, Turing put it on a closed distribution and removed it from wholesalers and pharmacies. Very soon after, Turing raised the price of Daraprim from $13.50 a pill to $750 a pill—an increase of over 5,000%—and Martin Shkreli became the "Most Hated Man in America."[1]

Cases of pharmaceutical companies raising off-patent drug prices by obscene amounts routinely make headlines, and are almost always met with public outrage because of the intense and undue burden they place upon patients, insurance providers, and the government. This paper analyzes one new regulatory effort, Maryland's HB 631, to curb price-gouging of generic drugs. The law will be examined in terms of its legality and efficacy through an exploration of the following:

- Public health and economic ramifications;
- Constitutional issues in the law's regulatory mechanism;
- The policy context and regulatory environment in which the law is operating.

[1] Merle, R. (2017, March 8). Martin Shkreli's long, strange tale could end with a decade in prison. *The Washington Post*.

HISTORY

Legislative History: Hatch-Waxman Act

The generic drug legal space is rife with complicated processes, checkpoints, and hurdles. The modern regulatory environment for generics was largely created in 1984 with the Drug Price Competition and Patent Restoration Act—commonly known as the Hatch-Waxman Act—which seeks to preserve drug innovation through patent-term restoration policies while also increasing competition in the marketplace through the introduction of generics.[2] This section will focus on these latter provisions, which provide the backbone of the regulatory process for the entry of generics into a market.

Under Hatch-Waxman, the active compounds in pioneer drugs, known as new molecular entities (NME's), receive a "data exclusivity" period of five years, during which no generic drugs can enter the market.[3] If a drug is patent-protected, then this exclusivity period is extended until the life of the patent.[4] After the exclusivity period expires,[5] generics can enter the market by submitting an Abbreviated New Drug Application (ANDA), named so because the generic is not required to conduct clinical and preclinical trials.[6] From here, the regulatory process becomes complicated and task-intensive. In order to be listed in the FDA's approved list of drugs, the so-called "Orange Book," a generic must prove bioequivalence, meaning that the drug "performs in

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[2] Mossinghoff, G. J. (1999). Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process. *Food and Drug Law Journal.*

[3] Grabowski et al. (2017). Pharmaceutical Patent Challenges: Company Strategies and Litigation Outcomes. *American Journal of Health Economics.*

[4] It is here that the patent-term restoration provisions kick in. Many pioneer drugs see their realized patent life shortened because patents are often filed early on in the development process; Hatch-Waxman provides a maximum five year extension on the exclusivity for cases like these.

[5] Potential generic entrants can also attempt to enter the market *before* the exclusivity period expires by using what is known as a "paragraph IV challenge," where they assert that their drug does not infringe on the brand name drug's patent, or that the brand name drug's patent is invalid.

[6] Mossinghoff, G. J.

the same manner as the innovator drug."[7] After conducting studies to prove bioequivalence, the generic drug must then prove bioavailability parity—the rate of absorption of the generic drug must be comparable to the original. The drug then must undergo multiple chemical reviews and label reviews before it can be approved.[8]

Price-Gouging

The Martin Shkreli saga ended with the pharma magnate eventually going to jail, but not for his price-gouging of Daraprim; he was instead convicted for running a Ponzi-like scheme at a hedge fund he managed. In fact, what he did at Turing with Daraprim was completely legal, and not entirely uncommon. Valeant Pharmaceuticals, for example, increased the price of two drugs treating a rare disorder called Wilson's Disease by 5,785% and 3,162%.[9] Another company, Rodelis, increased the price of a multi-drug resistant tuberculosis medication by 2,060%.[10] Indeed, a report by the Government Accountability Office found that from 2010-2015, 315 generic drugs experienced an "extraordinary price increase—a price increase of at least 100 percent."[11]

Over the last decade, drug companies and industry groups have poured $2.3 billion into lobbying efforts in Washington.[12] As a result, according to a joint report by the Yale School of Public Health and the Yale Law School, "the federal government has failed to take—and many policymakers have not even considered—meaningful steps to curb drug prices."[13] In the absence of federal action on this issue, some states have created policies of their own to combat

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[7] Ibid.
[8] Ibid.
[9] U.S. Senate, Special Committee on Aging. (2016).
[10] Ibid.
[11] United States, Government Accountability Office. (2016, August). *Generic Drugs Under Medicare*.
[12] Berman et al. (2017, August). *Curbing Unfair Drug Prices: A Primer for States* (Issue brief).
[13] Ibid.

pharmaceutical price-gouging. In April of 2017, Maryland passed a law, HB 631, that was considered by many to be a model for other states. HB 631 prevented any drug manufacturer or distributor from "engaging in price-gouging in the sale of any off-patent or generic drug."[14] Price-gouging, or an "unconscionable increase" was given a very specific definition by the Maryland legislature:

> "... 'unconscionable increase' means a price increase that is excessive, and not justified by the cost of producing the drug or expanding access to it, and that results in consumers having no meaningful choice about whether to purchase the drug at an excessive price, because of the importance of the drug to their health, and insufficient competition in the market for the drug."[15]

Violators of this law would be subject to fines of up to $10,000 per violation, with enforcement duties falling upon the office of the Maryland Attorney General.

Predictably, the law was met with resistance from the pharmaceutical industry, which immediately challenged the statute in court. The case, *Association for Accessible Medicines v. Frosh*, made its way up to the U.S. Fourth Circuit Appeals Court, where the court ruled in a 2-1 decision that the law was unconstitutional. The state moved to have the case heard *en banc* by the full panel of judges on the court but was denied. In October of 2018, Maryland Attorney General Brian Frosh filed a petition for a writ of certiorari with the Supreme Court.[16]

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[14] Public Health - Essential Off-Patent or Generic Drugs - Price Gouging - Prohibition
[15] Public Health - Essential Off-Patent or Generic Drugs - Price Gouging - Prohibition
[16] Frosh et al. (2018, October). *Petition for a Writ of Certiorari to the Supreme Court of the United States: Frosh v. Association for Accessible Medicines*. Cockle Legal Briefs.

ANALYSIS

The Argument for HB 631

The Maryland law regulates a very particular type of pharmaceutical business model; indeed, while rising drug prices are a problem in a variety of pharmaceutical sectors, HB 631 only targets exploitation of dysfunction in the generic drug market, as outlined in a report by the U.S. Senate Special Committee on Aging. In its analysis of the generics industry, the Committee found that several companies purposely built their operations around the following five core elements:

- The company would acquire a *sole-source*, off-patent drug for which there was only one manufacturer;
- This drug was the *gold standard* for the condition it treated;
- Critically, the company purchased a drug that serviced a *small market*;
- After purchasing the drug, the company restricted consumer access to it by pulling it from normal pharmacies and wholesalers and putting it on a *closed distribution* loop;
- Once these elements were in place, the company *drastically increased the price* of the drug so as to make a windfall profit.[17]

From an economic perspective, this is a creative (if rather Machiavellian) way to game to the market. Capitalism operates such that competition keeps prices down, but this innovative business model essentially forms monopolies around decades-old therapies; in the absence of any competition, the company is free to raise prices astronomically, and in the absence of any regulation, the company does so *legally*.

[17] U.S. Senate, Special Committee on Aging.

Maryland's price-gouging law was formed in response to the negative ethical implications and economic impacts of this business model. Drastic price hikes in the generic industry represent a life-threatening burden on patients—for example, 24% of cancer patients do not fill prescriptions because of excessive prices.[18] Furthermore, the design of the above business model insidiously conspires to impose a special burden upon people afflicted by rare, "orphan" diseases with small patient bases. One witness before the Senate Committee described how her treatment for Wilson's disease—which affects only about 2,000 to 3,000 Americans—spiked so suddenly that her out-of-pocket costs increased by over $10,000 per year.[19] Another witness described how she faced a $360,000 bill for the use of a Daraprim to save her two-month-old infant from a case of toxoplasmosis.[20] This kind of testimony makes clear the ethical case for curbing this kind of price-gouging; it is disturbing to see patients at their most vulnerable beset with astronomical medicine bills threatening their course of treatment.

Price-gouging also carries with it a host of negative economic effects. In many cases, the state covers a significant portion of the expenses for prescription drugs through programs such as Medicare and Medicaid.[21] Price hikes thus represent a *de facto* tax upon citizens as states struggle to reconcile their role in providing essential health coverage in the face of rising costs. The economic implications extend to the private insurance market as well; faced with claims for increasingly expensive drugs, insurance companies have resorted to "increasing premiums, deductibles, and out-of-pocket drug payments," or worse, denying claims all together, thus further threatening patient security.[22]

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[18] Lee et al. (2018). Legal Challenges to State Drug Pricing Laws. *JAMA.*
[19] U.S. Senate, Special Committee on Aging.
[20] Ibid.
[21] Berman et al.
[22] Ibid.

Buttressing the economic and ethical arguments in support of HB 631 are the distinctly American, capitalistic tendencies against monopolistic behavior. The Sherman Antitrust Act expressly prohibits "monopolization, attempted monopolization, or conspiracy or combination to monopolize" when said conduct unreasonably restrains trade.[23] The FTC is charged with regulatory power in potential violations of the Sherman Antitrust Act and related anti-competitive legislation. However, the FTC does not intervene "without evidence of a conspiracy among competitors or other anti-competitive actions that sustain the increased price,"[24] and in most pharmaceutical price-gouging cases, there is nothing insidious besides the price hike itself. Rarely do pharmaceutical companies engage in behavior that would exclude competitors[25]; instead, lack of competition arises from the lack of incentives to undergo the FDA's intense approval process and be the second entrant into a small generic drug market. Indeed, the business models pursued by HB 631's target companies operate fairly and legally within the regulatory framework of the generics market; companies like Turing and Valeant follow all of the rules of the FDA, and raise their prices because their legal monopoly status gives them no reason not to.

But by creating conditions in which competition is non-existent—even if the steps in the process to do so were legal—this brand of price-gouging goes against the *spirit* of laws such as the Sherman Antitrust Act. Indeed, the language of the Maryland law operates on the same principles as, say, regulation against predatory pricing. In *Utah Pie Co. v. Continental Baking Co.* the Court held that there must be a clear marginal-cost economic or competitive basis for lower prices in order for the action to not be considered predatory pricing.[26] HB 631 operates in a

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[23] Sherman Antitrust Act. § 2 (1890).
[24] Alpern et al. (2015). High-Cost Generic Drugs—Implications for Patients and Policymakers. *New England Journal of Medicine.*
[25] Ibid.
[26] *Utah Pie Co. v. Continental Baking Co.* (1967).

similar fashion, dictating that a price-increase must be "justified by the cost of producing the drug or expanding access to it."[27] Even in the absence of FTC or congressional action to combat predatory behavior, there seems to be a basis in existing pro-competitive statutes for regulation against price-gouging.

The Argument Against HB 631

In its suit against the state of Maryland, the Association for Affordable Medicines (AAM) asserted two constitutional challenges to HB 631: that it violated the extraterritoriality prong of the dormant commerce clause and that it is unconstitutionally vague.[28]

The dormant commerce clause of the constitution places a "constraint on the power of the States to enact legislation that interferes with or burdens interstate commerce."[29] Coming out of this is the extraterritoriality principle, which states that a "state may not regulate commerce that takes place wholly outside of the State's borders, whether or not the commerce has effects within the state."[30] Statutes directly controlling out-of-border commerce are invalid, regardless of whether the extraterritorial reach is expressly written or intended by the legislature or if it is a "practical effect" of the statute.[31]

In *AAM v. Frosh*, the appellate court held that even while HB 631's provisions were only triggered when a drug was available for sale in Maryland, the act "directly regulates the prices charged for prescription drugs in out-of-state transactions."[32] The court based this conclusion on the assessment that the legislation would target transactions that occur outside of the state of Maryland because the wording of the act targets manufacturers and distributors—almost none of

[27] Frosh et al.
[28] *Association for Accessible Medicines v. Frosh.*
[29] Ibid.
[30] Ibid.
[31] Ibid.
[32] Ibid.

whom are headquartered in, operate in, or manufacture in Maryland.[33] Indeed, the majority of these drugs are sold in Maryland through resale or consumer retail, but HB 631 instead puts its regulatory focus on price changes "in the initial sale of the drug," thereby directly regulating the transactions of wholesale distributors and manufacturers which occur entirely outside of the borders of Maryland.

Maryland's defense to this conclusion is that the out-of-state pricing effects are merely "upstream impacts of a state regulation" and not the direct regulation that the dormant commerce clause requires. But the court holds that HB 631's regulatory mechanism constitutes a price control mechanism; instead of merely creating an upstream pricing disturbance because of an in-state regulation, it creates a change in manufacturers' pricing schemes that comes independently of "natural market forces."[34] By consequence, the "practical effect" of the Maryland Law is that Maryland places a price control on an out-of-state transaction—which is expressly prohibited by the extraterritoriality principle—thus rendering the law invalid.

The court did not rule on the AAM's claim of unconstitutional vagueness because the law was already invalidated for violating the dormant clause. The vagueness claim is important, though, because it asserts that the "unconscionable increase" standard was too inconsistent and reliant on post hoc enforcement by the Attorney General in order for the regulated parties to know clearly what their obligations were. The Supreme Court has set the precedent in cases such as *FCC v. Fox* that regulators must provide fair and clear notice of the exact duties a regulated group has before imposing regulations on them[35]; the enforcement mechanism of HB 631, wherein the Attorney General would file suit against companies in violation of the law, would

[33] Ibid.
[34] Ibid.
[35] *FCC v. Fox Television Stations.* (2009).

mean that such duties would be made evident only *after the fact*, subject to law enforcement's discretion in its exercise of the penalty as opposed to a clear, prior communicated standard.

In a memorandum of law in support of their preliminary injunction, the AAM also claims that HB 631 would pose a significant threat to the public interest. The Association asserts that the law would "introduce enormous uncertainty and business risk for generic drug manufacturers,"[36] leading to the potential risk of companies withdrawing from marketing their medicines in the Maryland market, or worse yet, declining to make generic medicines altogether. Such actions would be an unintended negative externality of the law, with detrimental public health consequences for the state of Maryland.

Evaluating the Current System

In balance, then, it seems that the clear economic and ethical principles in favor of curbing price-gouging are countered by legal arguments that make meaningful regulation of the pharmaceutical industry difficult. The current infrastructure of the pharmaceutical distribution system is nationwide in scale; companies manufacture medicines in one state and then sell it to wholesalers at a *national* level, who then sell it to distributors who resale it to local retailers, hospitals, and pharmacies.[37] Absent any federal action on this issue, it is difficult for states to find policy strategies that meaningfully combat price-gouging; constitutional constraints make it impractical to rely on state-level legislation to regulate a national-level problem.

The simple solution would be to lobby for more federal oversight on this issue, but such a perspective ignores the dysfunction in a system which allows such excesses in the first place—a system in which competition is inhibited and disincentivized. Indeed, per each additional entrant

[36] Memorandum of Law in Support of Plaintiff's Motion for Preliminary Injunction.
[37] Ibid.

in a generic drug market, drug prices decrease by 20%, and yet, pharmaceutical companies report consistent barriers to entry and inhibitors to competition.[38]

The largest such barrier is the bloated nature of the FDA approval process for generics. As of 2015, the median approval time for an ANDA was 43 months, with more than half the applications taking upward of four years.[39] Furthermore, there is increased demand in generic entry; in the last 3 years alone, the number of ANDA submissions has risen from 539 to 1,306.[40] Faced with such an immense workload, the FDA has fallen into a cavernous backlog, with 4,036 generic drug applications awaiting approval as of July 1, 2018.[41] The inefficiency of this approval system is compounded by the significant costs to be borne by ANDA applicants, with each submission facing "FDA fees well in excess of $70,000."[42]

In light of this, there is a certain twisted genius to the business model pioneered by Shkreli and other "price-gougers"—it makes sense to target drugs with small markets because potential competitors will be deterred from entering the cumbersome FDA approval cycle just to access such a small base of potential customers as the second or third entrant. As such, we see that the regulatory environment today is *permissive* to price-gouging; because of the complicated calculus that a company must undertake to decide whether to attempt to penetrate a market at such a high entry cost, players who make the first move and take a small drug market hostage have free reign to raise prices as much as they want to make a windfall profit.

[38] United States, Government Accountability Office.
[39] U.S. Senate, Special Committee on Aging.
[40] Association for Accessible Medicines, & IQVIA.
[41] The Latest on the ANDA Review Backlog.
[42] U.S. Senate, Special Committee on Aging.

CONCLUSION AND RECOMMENDATION

The policy problem at the core of *AAM v. Frosh* is one of national significance. If the Supreme Court grants certiorari to this case, then it will place pharmaceutical price-gouging at the center of the national debate. In the end, we could see a realist versus formalist showdown in the court, where the economic and ethical implications of price-gouging are placed in stark opposition to the constitutional challenges posed by attempting state-level legislation on a problem of national scale. The court currently has a formalist majority, suggesting a victory for pharmaceutical companies, but price-gouging on life-saving medicines generally garners such universal discomfort that this case may not be decided on strictly ideological lines.

Ultimately, though, even if Maryland's law is upheld, it is an insufficient, surface-level patching to a hole that extends deeper into the system than this legislation can feasibly cover. All Maryland's law does is provide penalties for companies that have recognized and capitalized on opportunities to increase their profits that are borne out of inefficiencies in the current market structure. This method of after-the-fact regulation does nothing to address the institutional problems that create an environment where price-gouging can occur in the first place. Instead, policymakers should turn their attention to fixing these enabling factors. Legislation to provide more resources to the FDA to work through their backlog is in order, as well as legislation that further incentivizes generic entry into markets with smaller patient bases.

There is the potential for legislative innovation here—for example, expedited review for ANDA submissions to markets with only one generic drug would attract entrants to that market and thus lower prices. Indeed, with the cost of entry being reduced, the prospect of entering a market is not tempered by fears of a drawn-out and expensive approval process. This policy would also need to be accompanied by other legislative measures; special incentives for generic

drugs entering markets with small patient bases would help effectively defeat the business model of many price-gouging companies from the bottom up. After these structural changes were implemented, Congress could look into giving more explicit guidance to the FTC on exercising its antitrust regulatory power to prevent maneuvers by pharmaceutical companies to corner segments of the markets. Ultimately, though, the focus of new policy initiatives should be adjusting the infrastructure of the pharmaceutical industry such that market entry by generics—and by extension, competition—is increased. Indeed, natural market forces are often far more effective checks than imposed, post hoc regulations.

The issues brought upon by pharmaceutical price-gouging are both troubling and pressing, couched in ethical and economic relevance. It is incumbent upon regulators and policymakers to take action in a way that restores competitive balance and thus mitigates the worst excesses of this essential, life-saving industry.

Endnotes

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