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## Note

### **I Get By with a Little Help from My 750-Dollar-Per-Tablet Friends: A Model Act for States to Prevent Dramatic Pharmaceutical Price Increases**

*Alexander Walsdorf\**

Imagine being a low-income worker in poverty or living paycheck to paycheck.<sup>1</sup> Maybe you are an independent contractor or flex employee and have no job security. Perhaps you have no savings or emergency funds to reach into if the unexpected happens. Now, further imagine having HIV/AIDS and needing medication to prevent and treat fatal parasitic infections. This medication is far from cheap, costing \$13.50 per pill at wholesale. Your insurance—assuming you have it—covers most of the cost, but you still are left to pay a certain amount of out-of-pocket costs. What would you do if the price of that medication skyrocketed over 5000% to now cost \$750 per pill?

When Turing Pharmaceuticals acquired the U.S. marketing rights for Daraprim, a drug that, among many other uses, prevents parasitic infections such as toxoplasmosis in people living with HIV/AIDS, this nightmarish scenario became a reality for

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1. As of 2015, there were 43.1 million people living in poverty in the United States. BERNADETTE D. PROCTOR ET AL., U.S. CENSUS BUREAU, INCOME AND POVERTY IN THE UNITED STATES: 2015 at 12 (Sept. 2016), <http://www.census.gov/content/dam/Census/library/publications/2016/demo/p60-256.pdf>.

many.<sup>2</sup> The Turing case is just one example of a decades-long practice of dramatic—some would say predatory—price increases of various lifesaving drugs in the pharmaceutical industry.<sup>3</sup> Regardless of whether these price hikes are morally repugnant, they are perfectly legal. Further, the expense of researching, developing, and bringing drugs to market requires and justifies subsequent high retail costs.<sup>4</sup> If pharmaceutical companies will not profit from their efforts, why should they bother at all?

Federal law not only permits dramatic price increases in pharmaceuticals, but effectively aids pharmaceutical companies in doing so. Through the interplay between federal intellectual property and antitrust law, pharmaceutical companies have wide latitude to price their drugs as they see fit. Patent and intellectual property law promotes innovation,<sup>5</sup> which is realized by granting the inventor or patent holder a limited monopoly.<sup>6</sup>

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2. For more information on Turing Pharmaceuticals' acquisition of Daraprim, and its notorious ex-CEO Martin Shkreli, see Anna Almendrala, *What the Daraprim Price Hike Actually Does to Health Care*, HUFFPOST (Sept. 23, 2015), [https://www.huffingtonpost.com/entry/daraprim-price-turing-shkreli\\_us\\_560063cee4b00310edf82060](https://www.huffingtonpost.com/entry/daraprim-price-turing-shkreli_us_560063cee4b00310edf82060).

3. Another example of dramatic price increases is Mylan's increase of the price of its EpiPen, an autoinjector to be used immediately after an allergic emergency. Mylan increased the price of an EpiPen two-pack from \$100 in 2009 to more than \$600 in 2016. For more background information on EpiPen's price hike, see Nathan Bomey, *5 Things We Learned from EpiPen Price Hike Hearing*, USA TODAY (Sept. 22, 2016), <https://www.usatoday.com/story/money/2016/09/22/epipen-congress-hearing-mylan/90827270>; see also Anne Harding, *6 Insane Examples of Prescription Drug Price Increases*, HEALTH.COM (Sept. 25, 2015), <http://www.health.com/mind-body/6-insane-examples-of-prescription-drug-price-increases>.

4. Estimates suggest it costs on average \$2.6 billion to bring a drug to market. *Cost to Develop and Win Marketing Approval for a New Drug Is \$2.6 Billion*, TUFTS CTR. FOR STUDY DRUG DEV. (Nov. 18, 2014), [http://csdd.tufts.edu/news/complete\\_story/pr\\_tufts\\_csdd\\_2014\\_cost\\_study](http://csdd.tufts.edu/news/complete_story/pr_tufts_csdd_2014_cost_study) [hereinafter TUFTS CTR.]. *Contra* Jason Millman, *Does It Really Cost \$2.6 Billion to Develop a New Drug?*, WASH. POST (Nov. 18, 2014), <https://www.washingtonpost.com/news/wonk/wp/2014/11/18/does-it-really-cost-2-6-billion-to-develop-a-new-drug> (compiling various studies on how much it costs to bring a drug to market, the largest estimate being five billion dollars).

5. U.S. CONST. art. I, § 8. Known as the Copyright Clause, this section of the U.S. Constitution authorizes Congress "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." *Id.*

6. Stephan Kinsella, *"The" Purpose of Patent Law*, CTR. FOR STUDY INNOVATIVE FREEDOM (Dec. 6, 2010), <http://c4sif.org/2010/12/the-purpose-of-patent-law>.

However, granting limited monopolies contradicts the commonsense notion that antitrust law should regulate the conduct of businesses and promote fair competition for the benefit of consumers.<sup>7</sup> Consumers do not benefit when they have to pay more than 5000% more per pill for a lifesaving prescription drug than they did two years ago.

Little has been done—or even proposed—to prevent dramatic price increases for prescription drugs. Meanwhile, the few safeguards that do exist have had little success. The Hatch-Waxman Act, which was designed to ensure generic competition of pharmaceutical drugs with their brand-name counterparts, has only had limited success.<sup>8</sup> Some state governments have attempted to increase generic competition through enactment of their own competition laws or have attempted to directly regulate the sales price of patented drugs;<sup>9</sup> the Supremacy Clause and preemption by the Patent Act often prohibits such efforts. Lastly, while politicians at the federal level have proposed legislation to prohibit price increases of pharmaceutical drugs, no meaningful legislation has come to pass.<sup>10</sup>

What can be done to prevent dramatic price increases in the pharmaceutical industry? This Note provides an answer in light of the absence of meaningful options.<sup>11</sup> Part I of this Note discusses the economics of the pharmaceutical industry and how patent law protects economic interests. It then explores the existing mechanisms in place designed to keep the price of pharmaceuticals low, including the Hatch-Waxman Act and antitrust scrutiny by the Federal Trade Commission (FTC) and Congress. It also examines the various proposals presented by federal and state legislators to control soaring pharmaceutical prices. Part II addresses the pitfalls of various federal proposals to control rising drug prices and also explains why Patent Act preemption constrains states from regulating drug pricing. Part III advocates for states to adopt this Note's proposed Model Act—or some variation of it—which would allow states to directly prohibit and

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7. See *Guide to Antitrust Laws*, FTC, <https://www.ftc.gov/tips-advice/competition-guidance/guide-antitrust-laws> (last visited June 18, 2018).

8. See, e.g., Aaron S. Kesselheim & Jonathan J. Darrow, *Hatch-Waxman Turns 30: Do We Need a Re-Designed Approach for the Modern Era?*, 15 YALE J. HEALTH POL'Y L. & ETHICS 293, 319 (2015).

9. See *infra* Part II.A.2.

10. See *infra* Part I.B.

11. President Trump has signaled his willingness to reduce the prices of pharmaceutical drugs. It seems unlikely he would accomplish this feat without congressional support, however, which to date has yet to appear.

regulate dramatic price increases of pharmaceutical products. Part IV addresses counterarguments and concerns about the legality and possible preemption of this Note's proposed Model Act. Ultimately, this Note illustrates the need for a carefully crafted solution to rectify dramatic pharmaceutical price increases. It proposes legislation that addresses the problem in a way that conforms with existing federal and state law.

## I. THE UNITED STATES' EMPHASIS ON PATENT PROTECTION FOR DRUG DEVELOPMENT

Despite various intervention and enforcement mechanisms and the recent influx of regulatory proposals, dramatic pharmaceutical price increases have occurred for decades.<sup>12</sup> The cost of researching, developing, and bringing a new drug to market incentivizes pharmaceutical companies to exploit their patents and set prices however they see fit. Section A briefly addresses the high cost of drug development. Section B discusses the roles of federal patent and antitrust laws to protect the economic interests of the pharmaceutical industry. Section C discusses the Hatch-Waxman Act, a federal mechanism to reduce drug prices by increasing generic competition with name-brand drugs. Finally, Section D examines a variety of other proposals designed to control soaring drug prices.

### A. A PRECURSOR TO PHARMACEUTICAL PRICING: THE MASSIVE PRICE TAG AND RISK OF DRUG DEVELOPMENT

Estimates vary on how much it costs to develop and bring a new pharmaceutical drug to market. One estimate predicts it costs anywhere between five-hundred million dollars and two billion dollars,<sup>13</sup> while others predict it can cost anywhere between \$2.5 billion<sup>14</sup> and five billion dollars.<sup>15</sup> Without needing to

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12. *Competitive Problems in the Pharmaceutical Drug Industry: Hearing Before the Subcomm. on Antitrust, Monopolies & Bus. Rights of the S. Comm. on the Judiciary*, 100th Cong. 1–2 (1987) (demonstrating that price increases in the pharmaceutical industry have occurred since, at least, the mid-to late-1980s, giving Congress at least thirty years to enact legislation preventing such occurrences).

13. A study conducted by the FTC found that drug development cost \$521 million for one large drug manufacturer, while it cost over \$2 billion for another. Christopher P. Adams & Van V. Brantner, *Estimating the Cost of New Drug Development: Is It Really \$802 Million?*, 25 HEALTH AFFAIRS 420, 427 (2006).

14. See TUFTS CTR., *supra* note 4.

15. Matthew Herper, *The Cost of Creating a New Drug Now \$5 Billion, Pushing Big Pharma to Change*, FORBES (Aug. 11, 2013), <https://www.forbes.com>

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settle on a specific dollar amount, it is universally agreed that new drug development requires huge sums of capital to research, develop, and bring a drug to market.<sup>16</sup>

The risks of bringing a new drug to market increase its costs. A compilation of the Food and Drug Administration's (FDA) drug development and approval process found that the overall probability of success of a new pharmaceutical drug being approved by the FDA was a mere eight percent.<sup>17</sup> That same compilation found that it took, on average, 7.6 to 19 years to research, develop, receive FDA approval, and bring a drug to market.<sup>18</sup> Some may argue the need to recoup the investment, in addition to earning a profit in this risky endeavor, justifies pharmaceutical price tags.

## B. FEDERAL MECHANISMS TO PROTECT THE ECONOMIC INTERESTS OF DRUG DEVELOPMENT

Federal law protects drug developers' economic interests in new drug development. This Section explores how the Patent Act and federal antitrust law operate to keep the price tag of pharmaceuticals high. Part IV discusses these principles specifically as they apply to the proposed Model Act.

### 1. The Patent Act

Enacted in 1790,<sup>19</sup> the Patent Act<sup>20</sup> benefits the public and protects inventors by encouraging inventors to disclose new technology in return for a limited-duration monopoly on their intellectual property.<sup>21</sup> The limited-duration monopoly lasts for a period of twenty years from the application filing date, after which

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[.com/sites/matthewherper/2013/08/11/how-the-staggering-cost-of-inventing-new-drugs-is-shaping-the-future-of-medicine](http://www.fda.gov/oc/ohrt/2013/08/11/how-the-staggering-cost-of-inventing-new-drugs-is-shaping-the-future-of-medicine).

16. See Millman, *supra* note 4 (explaining that a \$2.6 billion price tag on a new drug development is a fair estimate).

17. *The Drug Development and Approval Process*, INDEPENDENT INST., [http://fdareview.org/03\\_drug\\_development.php](http://fdareview.org/03_drug_development.php) (last visited June 18, 2018).

18. *Id.*

19. *The U.S. Patent System Celebrates 212 Years*, U.S. PATENT & TRADE-MARK OFFICE (Apr. 9, 2002), <https://www.uspto.gov/about-us/news-updates/us-patent-system-celebrates-212-years>.

20. 35 U.S.C. §§ 1–376 (2012).

21. See Chandra Nath Saha & Sanjib Bhattacharya, *Intellectual Property Rights: An Overview and Implications in Pharmaceutical Industry*, 2 J. ADVANCED PHARMACEUTICAL TECH. & RES. 88, 88 (2011) (“Intellectual property rights (IPR) have been defined as ideas, inventions, and creative expressions based on which there is a public willingness to bestow the status of property. IPR provide certain exclusive rights to the inventors or creators of that property,

it enters the public domain, free for anyone to use.<sup>22</sup> Patent law promotes progress in science and technology. To obtain a patent, the scientific discovery or technology must be new,<sup>23</sup> useful,<sup>24</sup> and nonobvious.<sup>25</sup> Obtaining a patent on new technology “involves the discovery of scientific knowledge and technical know-how, as well as the development of products and processes that are conceptually new.”<sup>26</sup>

The Patent Act plays an integral role in the pricing of pharmaceuticals. Pharmaceutical patent holders—and patent seekers—argue that patent law should protect their interests in new drug developments that meet the new, useful, and nonobvious requirements.<sup>27</sup> The claim is that the law should protect those companies who need to recoup the high cost of drug development by allowing them to charge high prices during the period they hold effective monopolies.<sup>28</sup> Without patent protection, anyone could use and profit from new drugs without having to spend the money or incur the risk that drug development entails.<sup>29</sup> This could lead to a collective-action problem, as few companies would invest millions or billions of dollars over a period of 7.6 to 19 years without having patent protection preventing others from piggybacking on their efforts.

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in order to enable them to reap commercial benefits from their creative efforts or reputation.”). While patents, trademarks, and copyrights are included under the umbrella term of intellectual property, this Note will focus primarily on patents and their implication in the pharmaceutical industry.

22. 35 U.S.C. § 154.

23. *Id.* § 102.

24. *Id.* § 101.

25. *Id.* § 103.

26. Tallam I. Nguti, *Patent Law: Doctrinal Stability—A Research and Development Definition of Invention Is Key*, 20 VAL. U. L. REV. 653, 654 (1986).

27. See Alison Kodjak, *Tighter Patent Rules Could Help Lower Drug Prices, Study Shows*, NPR (Aug. 23, 2016), <https://www.npr.org/sections/health-shots/2016/08/23/491053523/tighter-patent-rules-could-help-lower-drug-prices-study-shows> (“Companies spend billions of dollars researching drugs and ushering them through FDA approval . . . They wouldn’t do that unless they could charge supercompetitive prices to make up for those investments.”).

28. Austin Frakt, *How Patent Law Can Block Even Lifesaving Drugs*, N.Y. TIMES (Sept. 28, 2015), <https://www.nytimes.com/2015/09/29/upshot/how-patent-law-can-block-even-lifesaving-drugs.html>.

29. See *id.*

## 2. The Role of Antitrust Law

The FTC is the federal agency tasked with enforcing federal antitrust law.<sup>30</sup> The FTC “takes action to stop and prevent unfair business practices that are likely to reduce competition and lead to higher prices, reduced quality or levels of service, or less innovation.”<sup>31</sup> Examples of prohibited anticompetitive behavior include “activities like price fixing, group boycotts, and exclusionary exclusive dealing contracts or trade association rules.”<sup>32</sup> The FTC enforces federal antitrust law to promote and protect competition at both the distribution and manufacturing levels of the pharmaceutical chain.<sup>33</sup> The Agency’s policy states that “[i]n pharmaceutical product markets, price generally decreases as the number of generic competitors increases.”<sup>34</sup> Thus the FTC promotes the entrance of generic drugs into the market place to compete with name-brand labels.<sup>35</sup>

## 3. The Problem with Protecting Economic Interests

The intersection between federal patent law and antitrust law becomes problematic when pharmaceutical companies like Mylan and Turing dramatically increase their drug prices. Patent law protects inventions by excluding competitors from the market for a limited time,<sup>36</sup> effectively granting the ability to exclude others in a monopolistic way. In situations where a patent holder has no existing competition, the ability to exclude any potential competition all but ensures a monopoly in effect.<sup>37</sup> In-

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30. FTC, COMPETITION ISSUES IN THE DISTRIBUTION OF PHARMACEUTICALS 2 (2014), [https://www.ftc.gov/system/files/attachments/us-submissions-oecd-other-international-competition-fora/pharmaceuticals\\_us\\_oecd.pdf](https://www.ftc.gov/system/files/attachments/us-submissions-oecd-other-international-competition-fora/pharmaceuticals_us_oecd.pdf) [hereinafter FTC, COMPETITION ISSUES]. Among other things, the FTC seeks to influence competition policy and promote competitive practices by studying markets and marketing practices, as well as advocate for competition policy to the Congress as it considers adopting laws and regulations. *Id.*

31. *Anticompetitive Practices*, FTC, <https://www.ftc.gov/enforcement/anticompetitive-practices> (last visited June 18, 2018).

32. *Id.* These practices are generally grouped into two types: “agreements between competitors, also referred to as horizontal conduct,” and “monopolization [of the market by one company], also referred to as single firm conduct.” *Id.*

33. *See id.*

34. FTC, COMPETITION ISSUES, *supra* note 30, at 6.

35. *See id.* at 6–7.

36. *See* 35 U.S.C. § 154 (2012).

37. *See* Carolyn Y. Johnson & Catherine Ho, *How Mylan, the Maker of EpiPen, Became a Virtual Monopoly*, WASH. POST (Aug. 25, 2016), <https://www.washingtonpost.com/business/economy/2016/08/25/7f83728a-6aee-11e6-ba32>



versely, the competing principle of antitrust law seeks to promote and protect competition. That purpose directly contradicts federal patent law's grant of exclusion.<sup>38</sup> It is within this conflicting framework of federal law that various mechanisms have been proposed to ease the tension and place a restraint on pharmaceutical prices.

### C. A MECHANISM TO CONTROL DRUG PRICES THROUGH INCREASED GENERIC COMPETITION: THE HATCH-WAXMAN ACT

In September 1984, Congress passed the Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Act.<sup>39</sup> Hatch-Waxman created a regulatory scheme governing the approval of generic drugs by the FDA. The Act aimed to encourage innovators to invest in the research and development of new drugs on one hand, and "increase generic drug competition in the pharmaceutical drug market, thereby lowering drug prices and consumer costs for drugs" on the other.<sup>40</sup> Hatch-Waxman attempts to improve the number of generic drugs in the market by prohibiting "reverse payments": agreements between brand-name drug manufacturers and generic drug manufacturers, whereby the brand-name manufacturer pays the generic manufacturer to keep its drugs out of the

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-5a4bf5aad4fa\_story.html ("Mylan benefited from factors including failed competitors, patent protections and laws requiring allergy medications in schools. Having a virtual monopoly has facilitated the rapid price hike. Mylan reached \$1 billion in sales for the second time last year.").

38. Lara J. Glasgow, *Stretching the Limits of Intellectual Property Rights: Has the Pharmaceutical Industry Gone Too Far?*, 41 IDEA: J.L. & TECH. 227, 231 (2001) ("It is when intellectual property rights are utilized beyond their rightful scope that intellectual property law is no longer in balance with anti-trust law, but rather in direct conflict. In situations where intellectual property rights are used to obtain unwarranted market power, or to interfere with competition beyond what is enabled by the law, antitrust law must step in to curtail the potential excessive cost to the consuming public.").

39. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. §§ 355, 360(cc) (2012), 35 U.S.C. §§ 156, 271, 282 (2012)), amended by Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) (commonly known as the Hatch-Waxman Act); see also *Legislative and Regulatory Responses to the FTC Study on Barriers to Entry in the Pharmaceutical Marketplace: Hearing Before the S. Comm. on the Judiciary*, 108th Cong. 8, 14 (2003) [hereinafter 2003 Hearing] (statement of Daniel E. Troy, Chief Counsel, FDA) (explaining the impetus and importance of the Hatch-Waxman Act); Colleen Kelly, *The Balance Between Innovation and Competition: The Hatch-Waxman Act, The 2003 Amendments, and Beyond*, 66 FOOD & DRUG L.J. 417, 417 (2011).

40. Kelly, *supra* note 39.

market.<sup>41</sup> Reverse payments remove competition in the market, allowing brand-name manufacturers to maintain the high price of their brand-name products for longer than normally permitted under their patent rights.<sup>42</sup> The FTC has stated that it will litigate against reverse-payment schemes to protect consumers from anticompetitive conduct that raises prices and diminishes drug choices.<sup>43</sup>

A recent report concluded that Hatch-Waxman has successfully promoted generic drug competition. At the time of the Act's passage in 1984, "only approximately 35% of brand-name blockbuster drugs had generic counterparts, while today, virtually all brand-name blockbuster drugs have generic counterparts."<sup>44</sup> Still, the issue is far from settled; scholars continue to debate the Act's success in ensuring competition by promoting generic drugs in the marketplace.<sup>45</sup>

#### D. OTHER FEDERAL ATTEMPTS TO CONTROL DRUG PRICES

Although proposed by various members of Congress over the past decade, the federal government has yet to enact any of the recommended legislation to increase generic competition and

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41. 21 U.S.C. § 355(b)(2)(A)(iv); *see also* Henry N. Butler & Jeffrey Paul Jarosch, *Policy Reversal on Reverse Payments: Why Courts Should Not Follow the New DOJ Position on Reverse-Payment Settlements of Pharmaceutical Patent Litigation*, 96 IOWA L. REV. 57, 57 (2010) ("In a reverse-payment settlement, the generic drug company agrees not to enter the market for some period of time and the patent holder agrees to give it something of value—often quarterly cash payments."). The FTC has found that reverse payments are prevalent in the pharmaceutical industry, finding that sixty-six such agreements occurred from 2004 through 2009. FTC, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS 4 (2010), <https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf> [hereinafter FTC, PAY-FOR-DELAY]. The FTC has also found that such agreements delay entry of generic competitors to the market for an average of seventeen months. *Id.* The FTC attempts to litigate and advocate against reverse-payment agreements and estimates that these agreements will cost consumers an estimated thirty-five billion dollars over the next ten years. *Id.* at 2, 5–6.

42. FTC, PAY-FOR-DELAY, *supra* note 41, at 4.

43. *Id.* at 5–6; *Anticompetitive Practices*, *supra* note 31.

44. WENDY H. SCHACHT & JOHN R. THOMAS, CONG. RESEARCH SERV., R41114, THE HATCH-WAXMAN ACT: A QUARTER CENTURY LATER 5 (2012).

45. *Compare* Butler & Jarosch, *supra* note 41 (arguing that "the effects of reverse payments are not obvious, can be procompetitive, and that a presumption of anticompetitive effect is thus unwarranted"), *with* Emily Michiko Morris, *The Myth of Generic Pharmaceutical Competition Under the Hatch-Waxman Act*, 22 FORDHAM INTELL. PROP., MEDIA, & ENT. L.J. 245, 250 (2012) (arguing that "the Hatch-Waxman Act's single-minded fixation on generic manufacturers as if they were direct competitors for brand-name pharma is misguided at best").

lower drug prices. This Section briefly discusses four such proposals, including the oft-discussed option of parallel importation.

### 1. Prescription Drug Importation

In 2009, Senator Byron Dorgan, a Democrat from North Dakota, cosponsored the Pharmaceutical Market Access and Drug Safety Act of 2009.<sup>46</sup> The bill sought to amend the Federal Food, Drug, and Cosmetic Act to allow for the importation of prescription drugs to increase competition, thus lowering drug prices.<sup>47</sup> Specifically, the bill would have allowed American consumers to import lower-priced, FDA-approved drugs from other countries.<sup>48</sup> Despite offering immediate relief to consumers from soaring drug prices via international competition, the bill died in Congress.<sup>49</sup>

### 2. The Prescription Drug Affordability Act

In 2015, Senator Bernie Sanders, an Independent from Vermont, proposed the Prescription Drug Affordability Act of 2015,<sup>50</sup> which sought to “ensure greater affordability of prescription drugs.”<sup>51</sup> The bill proposed to give the Secretary of Health and Human Services the power to negotiate lower drug prices on behalf of Medicaid beneficiaries, allow pharmacists and wholesalers to import prescription drugs, block reverse payments from brand-name drug manufacturers to generic drug manufacturers, and require more reporting by pharmaceutical companies.<sup>52</sup> The bill, referred to a congressional committee on September 10, 2015, died in committee.<sup>53</sup>

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46. See Pharmaceutical Market Access and Drug Safety Act of 2009, S. 525, 111th Cong. (2009).

47. See *id.*

48. *Id.*

49. *S. 525 (111th): Pharmaceutical Market Access and Drug Safety Act of 2009*, GOVTRACK, <https://www.govtrack.us/congress/bills/111/s525> (last visited June 18, 2018).

50. Prescription Drug Affordability Act of 2015, S. 2023, 114th Cong. (2015).

51. *Id.*

52. *Id.*

53. *S. 2023 (114th): Prescription Drug Affordability Act of 2015*, GOVTRACK, <https://www.govtrack.us/congress/bills/114/s2023> (last visited June 18, 2018).

### 3. Medicaid Generic Drug Price Fairness Act of 2015

On May 18, 2015, Senator Sanders proposed the Medicaid Generic Drug Price Fairness Act of 2015.<sup>54</sup> The bill sought to amend title XIX (Medicaid) of the Social Security Act to increase rebates of generic drugs.<sup>55</sup> Cosponsored by six other senators,<sup>56</sup> the bill attempted a modest reform to current pharmaceutical pricing to provide relief for consumers. The bill also died in committee.<sup>57</sup> The failure of this bill to make it past the Finance Committee demonstrates the unlikelihood that Congress will ever enact this—or an equivalently simple—measure.<sup>58</sup>

### 4. Parallel Importation

Parallel importation gained traction as a viable option to combat the rising cost of prescription drugs as a result of the

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54. Medicaid Generic Drug Price Fairness Act of 2015, S. 1364, 114th Cong. (2015).

55. The proposed bill would amend

[T]itle XIX (Medicaid) of the Social Security Act to increase the amount of rebate with respect to each generic drug in the manner that the rebate for a dosage form and strength of a single source drug or an innovator multiple source drug is increased, except as provided in special application rules, including a special rule for certain noninnovator multiple source drugs.

*S.1364 – Medicaid Generic Drug Price Fairness Act of 2015*, CONGRESS.GOV, <https://www.congress.gov/bill/114th-congress/senate-bill/1364> (last visited June 18, 2018).

56. Senators Sherrod Brown (D-OH), Mazie Hirono (D-HI), Richard Blumenthal (D-CT), Al Franken (D-MN), Elizabeth Warren (D-MA), and Sheldon Whitehouse (D-RI) cosponsored the bill along with Senator Sanders. *S.1364 - Medicaid Generic Drug Price Fairness Act of 2015*, CONGRESS.GOV, <https://www.congress.gov/bill/114th-congress/senate-bill/1364/cosponsors> (last visited June 18, 2018).

57. *Id.*; *S. 1364 (114th): Medicaid Generic Drug Price Fairness Act of 2015*, GOVTRACK, <https://www.govtrack.us/congress/bills/114/s1364> (last visited June 18, 2018). As discussed, the numerous proposed and yet to be enacted pieces of legislation demonstrate the disagreement over how to promote generic competition and decrease drug prices, whether a partisan bill or not. But with Republican majority in both houses of Congress and a GOP president, it is possible the federal government may enact some legislation. A Kaiser Family Foundation survey found that more Republicans were angry about drug prices than about Obamacare. Paul Demko & Sarah Karlin, *GOP Candidates Stuck on Drug Prices*, POLITICO (Dec. 1, 2015), <https://www.politico.com/story/2015/11/drug-costs-gop-candidates-prescriptions-216292>. Republicans are also part of the huge majorities that back strong government measures to make drug prices more affordable. *Id.* Time will tell if the Republicans will enact legislation to promote generic drug competition.

58. Numerous other bills were proposed in 2017 alone, but did not gain traction. See Ron Lanton III, *The Current State of Drug Price Legislation*, SPECIALTY PHARMACY TIMES (Nov. 16, 2017), <https://www>

wide support it received from President Trump and legislators.<sup>59</sup> Parallel importation allows goods to be “produced genuinely under protection of a trademark, patent, or copyright, placed into circulation in one market, and then imported into a second market without the authorization of the local owner of the intellectual property right.”<sup>60</sup> Essentially, parallel importation allows consumers to directly import drugs from another country at a much cheaper price without violating the intellectual property rights of the patent holder in the United States. Congress has yet to seriously consider this option. Various members of Congress often cite safety concerns as the biggest reason why they do not support current parallel-importation proposals.<sup>61</sup> The FDA itself has stated that “there are significant safety concerns related to allowing the reimportation of non-bioequivalent products” into the United States.<sup>62</sup> Until bioequivalent products from other countries can meet the FDA’s strict requirements regarding health and safety, parallel importation likely remains an unobtainable solution.

As briefly summarized above, Congress has yet to address the rising costs of pharmaceutical products. Its failure to pass the Pharmaceutical Market Access and Drug Safety Act, the Prescription Drug Affordability Act, and Medicaid Generic Drug Price Fairness Act demonstrates congressional inability or unwillingness to enact meaningful legislation to reduce soaring drug prices. On January 11, 2017, Congress had yet another chance to take a step toward combatting rising drug prices.<sup>63</sup> Senator Amy Klobuchar, a Democrat from Minnesota, introduced a simple amendment to the congressional budget to allow

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.specialtypharmacytimes.com/publications/specialty-pharmacy-times/2017/november-2017/the-current-state-of-drug-price-legislation.

59. See David Nather, *Trump’s Health Care Plan Takes (Another) Page from the Democrats*, STAT (Mar. 2, 2016), <https://www.statnews.com/2016/03/02/trump-health-care-plan>.

60. KEITH E. MASKUS, PARALLEL IMPORTS IN PHARMACEUTICALS: IMPLICATIONS FOR COMPETITION AND PRICES IN DEVELOPING COUNTRIES 2 (2001), [http://www.wipo.int/export/sites/www/about-ip/en/studies/pdf/ssa\\_maskus\\_pi.pdf](http://www.wipo.int/export/sites/www/about-ip/en/studies/pdf/ssa_maskus_pi.pdf).

61. See Zach Carter & Ryan Grim, *Cory Booker and a Bunch of Democrats Prove Trump Right on Big Pharma*, HUFFPOST (Jan. 12, 2017), [https://www.huffingtonpost.com/entry/democrats-rush-to-prove-trump-right-on-big-pharma\\_us\\_5877edd4e4b0b3c7a7b05c29](https://www.huffingtonpost.com/entry/democrats-rush-to-prove-trump-right-on-big-pharma_us_5877edd4e4b0b3c7a7b05c29).

62. Alicia Mundy, *FDA Questions Reimportation of Drugs*, WALL ST. J. (Dec. 9, 2009), <https://www.wsj.com/articles/SB126036822300483431>.

63. *S. Amdt. 178 to S. Con. Res. 3*, CONGRESS.GOV, <https://www.congress.gov/amendment/115th-congress/senate-amendment/178/text> (last visited June 18, 2018).

parallel importation of drugs from Canada<sup>64</sup>—which is currently illegal under federal law.<sup>65</sup> However, the Senate voted the amendment down.<sup>66</sup> Many who voted no, including prominent New Jersey Democrat Cory Booker, cited the amendment’s lack of consumer protections and deficient safety standards.<sup>67</sup> Even though it was a purely symbolic, nonbinding measure that would not have had the force of law if enacted,<sup>68</sup> the fact that the Senate “voted against reducing drug prices” represents yet another example of Congress’s inaction in the war against rising drug prices.<sup>69</sup> Its current failure offers little hope for any legislation designed to combat rising drug costs.

But why has Congress refused to enact any legislation aimed at lowering drug prices? It might soon, as President Trump has expressed support for allowing parallel importation of drugs from other countries as well as allowing Medicare to negotiate prescription drug prices.<sup>70</sup> However, it seems certain that the pharmaceutical lobby will continue to impede such measures.<sup>71</sup> Drug lobbyists spent at least two-hundred million

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64. *Id.*

65. See Marvin A. Blumberg, *Information on Importation of Drugs Prepared by the Division of Import Operations and Policy*, FDA, <https://www.fda.gov/ForIndustry/ImportProgram/ucm173751.htm> (last updated Sept. 25, 2015).

66. Carter & Grim, *supra* note 61.

67. *Id.* (“Any plan to allow the importation of prescription medications should also include consumer protections that ensure foreign drugs meet American safety standards. I opposed an amendment put forward last night that didn’t meet this test.”).

68. Louis Jacobson, *Viral Image About Democratic Senators and “Big Pharma” Is Misleading*, POLITIFACT (Jan. 18, 2017), <http://www.politifact.com/truth-o-meter/statements/2017/jan/18/other-98/viral-image-about-democratic-senators-and-big-phar> (“The vote was more symbolic than substantive. It was an amendment to a Senate budget resolution, which is a non-binding [sic] measure that doesn’t get signed by the president or become law . . . . So the measures shouldn’t be oversold as direct action.”).

69. See Carter & Grim, *supra* note 61.

70. Nather, *supra* note 59.

71. When discussing how much money Medicare could save if it negotiated drug prices, President Trump said, “We don’t do it . . . . Why? Because of the drug companies.” Sarah Kliff, *Donald Trump Endorses an Idea Liberals Love: Letting Medicare Negotiate Drug Prices*, VOX (Jan. 26, 2016), <https://www.vox.com/2016/1/26/10835000/trump-medicare-drug-prices>.

dollars each of the past nine years seeking to influence legislators.<sup>72</sup> In 2016 alone, lobbyists contributed more than sixty million dollars to members of Congress and candidates.<sup>73</sup> While exploring the reasons why Congress continues to oppose reducing exorbitant drug prices lies outside the scope of this Note, the amount of money drug companies spend on lobbying would seemingly be an influential factor. Even if enacted, however, it is unlikely that the measures discussed above would sufficiently restrict dramatic price increases of pharmaceuticals.

## II. ISSUES WITH PROPOSED STATE SOLUTIONS TO COMBAT DRAMATIC PRICE INCREASES OF PHARMACEUTICALS

As discussed in Part I, federal legislators have proposed various methods to limit soaring pharmaceutical prices, but to date have failed to enact any meaningful legislation. This Section addresses various states' attempts to regulate this crisis.

### A. STATE-LEVEL REGULATION

Given the federal government's inaction, individual states have enacted their own laws in an attempt to curb the rising costs of pharmaceuticals. However, the legislative efforts, at least to date, arguably do not go far enough to address the soaring prices of drugs—whether because the laws are limited in scope, ineffective, or preempted by federal law.

#### 1. States' Attempts To Control Drug Prices Through Transparency Legislation

In 2017, the California State Legislature enacted a new bill titled Health Care: Prescription Drug Costs.<sup>74</sup> Among other things, the bill requires:

[A] manufacturer of a prescription drug with a wholesale acquisition cost of more than \$40 that is purchased or reimbursed by specified purchasers, including state agencies, health care service plans, health insurers, and pharmacy benefit managers, to notify the purchaser of an increase in the wholesale acquisition cost of a prescription drug if the increase in the wholesale acquisition cost for a course of therapy, as defined, exceeds a specified threshold.<sup>75</sup>

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72. *Pharmaceuticals/Health Products*, OPENSECRETS.ORG, <https://www.opensecrets.org/lobby/indusclient.php?id=h04> (last visited June 18, 2018).

73. *Id.*

74. S.B. 17, 2017–2018 Sess. (Cal. 2017).

75. *Id.*

The California Legislature intended to make “pharmaceutical pricing as transparent as the pricing in other sectors of the health care industry.”<sup>76</sup> Much to the chagrin of the pharmaceutical lobby, California’s Governor Jerry Brown signed the bill into law in October of 2017.<sup>77</sup>

California is not alone in its efforts to combat rising drug prices through transparency legislation. As of June 2017, thirteen other states introduced or passed transparency bills designed to compel drug companies to release information relating to costs and pricing.<sup>78</sup> While the covered drugs, reporting requirements, and public-disclosure exemptions vary from state to state, compelling companies to publicly disclose their costs in order to justify their price tags could lead to reduced drug prices; at least that is the goal.<sup>79</sup> However, whether transparency in pricing alone can reduce and prevent dramatic pharmaceutical price increases has yet to be seen, and more time is needed to see the effects of these legislative efforts.

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76. *Id.* Upon signing the bill California Governor Jerry Brown advocated that “Californians have a right to know why their medical costs are out of control, especially when pharmaceutical profits are soaring . . . . This measure is a step at bringing transparency, truth, exposure to a very important part of our lives, that is the cost of prescription drugs.” April Dembosky, *California Governor Signs Law to Make Drug Pricing More Transparent*, NPR (Oct. 10, 2017), <https://www.npr.org/sections/health-shots/2017/10/10/556896668/california-governor-signs-law-to-make-drug-pricing-more-transparent>.

77. Dembosky, *supra* note 76 (“The drug lobby fiercely opposed the bill . . . hiring 45 firms to try to defeat it and spending \$16.8 million on lobbying against the full range of drug legislation.”).

78. AARON BERMAN ET AL., YALE GLOBAL HEALTH JUSTICE PARTNERSHIP, *CURBING UNFAIR DRUG PRICES: A PRIMER FOR STATES 15–17* (2017); *see also* Lydia Ramsey, “*More Is Possible*: A Bunch of States Are Taking on High Drug Prices, and It Could Start Hitting Drugmaker Profits”, *BUS. INSIDER* (June 4, 2017), <http://www.businessinsider.com/states-with-drug-pricing-transparency-bills-2017-6/#maryland-is-tackling-generic-drug-price-hikes-1>.

79. BERMAN ET AL., *supra* note 78, at 14 (“Understanding what prices are and how they are set will allow both patients and regulators to make more informed decisions about whether prices are excessive, and introduce some rationality and evidence into pricing debates. In the current environment, manufacturers’ arguments are frequently based on exaggerated and unsubstantiated claims.”). For example, proposed legislation in Washington state would require a covered manufacturer to report an economic justification for a qualifying price increase in a covered drug. H.B. 1541, 65th Leg., Reg. Sess. (Wash. 2017). This would, presumably, have the effect of limiting unjustified pricing increases.



## 2. States' Attempts To Control Drug Prices Through Price Restrictions

In addition to drug-transparency laws, states have introduced or enacted legislation designed to address unfair price increases of pharmaceuticals. As of 2017, twelve states—including New York, Maryland, and Ohio—either proposed or enacted such fair-pricing legislation.<sup>80</sup> Similar to the drug-transparency bills, the fair-pricing bills varied widely in what they covered: whether they applied only to generic drugs, brand-name drugs, or both; the types of pricing they implicated; if there are reporting or price-justification requirements; and if there is a private right of action.<sup>81</sup> Some of the enacted laws seem promising, albeit potentially limited in scope.<sup>82</sup>

For example, New York's statute only requires review of pharmaceutical conduct once its Medicaid expenditures surpass

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80. See BERMAN ET AL., *supra* note 78, at 18–19.

81. *Id.*

82. It is worth noting that none of the existing state proposals or legislation preempt this Note. Legislation aimed at transparency does not provide any avenue for states to actually lower drug prices. Rather, transparency laws (might) allow a state to bring a claim against manufacturers for noncompliance with reporting requirements. See, for example, Vermont's Prescription Drug Cost Containment statute. VT. STAT. ANN. tit. 18, § 4635 (2018). See also BERMAN ET AL., *supra* note 78, at 15–17. Additionally, of the fair drug-pricing bills that have been introduced by states since 2015, the majority have either failed to become enacted or are currently stuck in legislative committees. See *id.* at 18–19; see also S.B. 925, 2017 Sess. (Conn. 2017); H.B. 5930, 2017 Sess. (Conn. 2017); H.B. 2983, 190th Gen. Court (Mass. 2017); S.B. 3088, 217th Leg. (N.J. 2017); H.B. 2387, 2017 Sess. (Or. 2017); H.B. 161, Reg. Sess. 2017–2018 (Pa. 2017); S.B. S.1048, 189th Gen. Court (Mass. 2015). Further, state legislation that has been enacted is either limited in scope or otherwise does not go far enough to meaningfully regulate pharmaceutical behavior: Maryland's legislation is limited to generic drugs only, while New York's legislation applies only to generic drugs or the amount to be spent by the state's Medicaid program. See BERMAN ET AL., *supra* note 78, at 18–19; *infra* notes 83–84. Additionally, Nevada's legislation is limited to diabetes medication. S.B. 539, 79th Sess. (Nev. 2017). For an additional roundup of current state-level legislative actions, see *Prescription Drug Cost Workgroup*, NAT'L ACAD. FOR STATE HEALTH POL'Y (Apr. 11, 2017), <https://nashp.org/wp-content/uploads/2016/09/2017-Rx-Legislation-Tracker-4.11.pdf>. This Note attempts to apply to all pharmaceutical conduct—not just conduct relating to generic drugs or Medicaid expenditures. It seeks to extend farther and be more comprehensive than any current legislative effort. The biggest advantage this Note provides, as discussed in Part IV.A, *infra*, is its attempt to address patent preemption head-on. No current state effort does so.

a certain budgetary threshold—it does not implicate the expenditures of residents who do not use Medicaid.<sup>83</sup> Maryland’s legislation, on the other hand, applies to off-patent or generic drugs only.<sup>84</sup> The impact of these fair-pricing bills has yet to be seen.

Although limited in scope, New York and Maryland’s legislation has, to date, survived all legal challenges. The same cannot be said for all similar efforts. For example, Maine enacted the Maine Pharmacy Act in 2013. The Act sought to “lower the cost of medicines for state residents” by permitting them “to purchase prescription drugs through a broker from pharmacies . . . licensed in Canada, the U.K., New Zealand and Australia.”<sup>85</sup> Additionally, the District of Columbia passed the Excessive Pricing in Sales of Prescription Drugs Act in 2005.<sup>86</sup> The Act outlawed drug manufacturers from selling patented prescription drugs for an excessive price.<sup>87</sup> Both Acts immediately drew ire from the pharmaceutical industry, who quickly challenged the legislation in court. Indeed, both the District of Columbia’s and Maine’s meaningful attempts at cost-reducing legislation were preempted by federal patent law.<sup>88</sup>

#### B. THE PATENT ACT, SUPREMACY CLAUSE, AND PREEMPTION

State proposals to control soaring drug prices can attract preemption challenges, particularly under federal patent law. At the same time, preemption of a state’s ability to implement legislation to regulate pharmaceutical pricing and protect consum-

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83. See S. 2007-B, N.Y. S. (N.Y. 2017), <http://legislation.nysenate.gov/pdf/bills/2017/S2007B>; see also Julie Appleby, *New York State Wants Its Prescription Drug Money Back—Or Else*, KHN (May 22, 2017), <https://khn.org/news/new-york-state-wants-its-prescription-drug-money-back-or-else>.

84. See H.B. 631, 2017 Reg. Sess. (Md. 2017), [http://mgaleg.maryland.gov/2017RS/Chapters\\_noln/CH\\_818\\_hb0631e.pdf](http://mgaleg.maryland.gov/2017RS/Chapters_noln/CH_818_hb0631e.pdf).

85. Ed Silverman, *Judge Strikes Down Maine Law for Importing Prescription Medicines*, WALL ST. J. (Feb. 25, 2015), <http://blogs.wsj.com/pharmalot/2015/02/25/judge-strikes-down-maine-law-for-importing-prescription-medicines>.

86. D.C. CODE ANN. § 28-4553 (West 2005).

87. *Id.* The full text of the Act reads: “It shall be unlawful for any drug manufacturer or licensee thereof, excluding a point of sale retail seller, to sell or supply for sale or impose minimum resale requirements for a patented prescription drug that results in the prescription drug being sold in the District for an excessive price.” *Id.*

88. See *Biotechnology Indus. Org. v. District of Columbia*, 496 F.3d 1362, 1374 (Fed. Cir. 2007) (“[W]e conclude that [D.C. Code § 28-4553] is preempted by federal patent law.”); Silverman, *supra* note 85. This Note seeks to address the obstacle of preemption head on.

ers within its borders limits the state's power and raises important federalism concerns.

### 1. Preemption of States' Pharmaceutical Pricing Legislation: The Supremacy Clause

Federal preemption over states' abilities to enact laws derives from the Supremacy Clause of the Constitution. The Supremacy Clause states:

This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.<sup>89</sup>

"It is a familiar and well-established principle that the Supremacy Clause invalidates state laws that interfere with, or are contrary to, federal law."<sup>90</sup> However, this principle can be at odds with "the presumption that state and local regulation of health and safety matters can constitutionally coexist with federal regulation."<sup>91</sup> The presumption that state regulation of health and safety matters can coexist with federal regulation is a particularly strong.<sup>92</sup> Such state regulation is usually considered to be under the sole jurisdiction of the states' police power, as "[s]tates traditionally have had great latitude under their police powers

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89. U.S. CONST. art. VI, cl. 2.

90. *Hillsborough Cty. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 712 (1985).

91. *Id.* at 716.

92. *Id.* ("Appellee must thus present a showing of implicit pre-emption of the whole field, or of a conflict between a particular local provision and the federal scheme, that is strong enough to overcome the presumption that state and local regulation of health and safety matters can constitutionally coexist with federal regulation."). This presumption applies for areas of traditional state police power as well. See *Gobeille v. Liberty Mut. Ins. Co.*, 136 S. Ct. 936, 946 (2016) ("The Court in the past has 'addressed claims of pre-emption with the starting presumption that Congress does not intend to supplant state law,' in particular state laws regulating a subject of traditional state power." (citation omitted)); *De Buono v. NYSA-ILA Med. & Clinical Servs. Fund*, 520 U.S. 806, 814 (1997) ("[The act] clearly operates in a field that 'has been traditionally occupied by the States.' Respondents therefore bear the considerable burden of overcoming 'the starting presumption that Congress does not intend to supplant state law.'" (citations omitted)).

to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons.”<sup>93</sup> Regardless of this strong presumption, if a conflict between a state law and a federal law exists, the federal law predominates.<sup>94</sup>

Courts generally presume that a state law is not preempted. However, express or implied preemption may overcome that presumption.<sup>95</sup> Starting with this presumption, courts will look to congressional intent, determined by the plain language of the statute, the statutory framework surrounding the statute, and the “structure and purpose of the statute as a whole.”<sup>96</sup> Express preemption occurs when the federal law or regulation expressly states that it preempts any state law.<sup>97</sup> Express preemption of the entire field “will be inferred where ‘the field is one in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject.’”<sup>98</sup> Correspondingly, if Congress did not include express preemptive language, “Congress’[s] intent to pre-empt all state law in a particular area may be inferred where the scheme of federal regulation is sufficiently comprehensive to make reasonable the inference that Congress ‘left no room’ for supplementary state regulation.”<sup>99</sup> This is known as field preemption. Additionally, implied preemption also exists “where state regulation actually conflicts with federal law, or where state regulation ‘stands as an obstacle to the accomplishment and execution’ of Congress’s purposes.”<sup>100</sup> This is known as conflict preemption.

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93. *Metro. Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 756 (1985), *overruled in part on other grounds*, *Ky. Ass’n of Health Plans v. Miller*, 538 U.S. 329 (2003) (internal quotation marks omitted).

94. *See id.* at 749 (noting that the preemption doctrine “protects against state interference with policies implicated” by federal law).

95. *Id.* at 738, 747–48 (noting that express or implied congressional intent determines whether the state law is preempted); *see also* *Malone v. White Motor Corp.*, 435 U.S. 497, 504 (1978) (“Often Congress does not clearly state in its legislation whether it intends to pre-empt state laws; and in such instances, the courts normally sustain local regulation of the same subject matter unless it conflicts with federal law or would frustrate the federal scheme, or unless the courts discern from the totality of the circumstances that Congress sought to occupy the field to the exclusion of the States.”).

96. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 486 (1996) (citations omitted).

97. *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977) (discussing express preemption).

98. *Hillsborough Cty. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 713, (1985) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

99. *Id.*

100. *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 547 (1992) (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)).

Preemption often prohibits state law from regulating the pharmaceutical field, making it impossible for states to regulate pricing.

## 2. Preemption in Practice

Recall the District of Columbia's Excessive Pricing in Sales of Prescription Drugs legislation,<sup>101</sup> designed to outlaw drug manufacturers from selling patented prescription drugs for an excessive price.<sup>102</sup> The pharmaceutical industry quickly challenged the legislation, and the case made its way up to the Court of Appeals for the Federal Circuit in *Biotechnology Industry Organization v. District of Columbia*.<sup>103</sup> The Federal Circuit decided the case on conflict preemption grounds, finding that the Act conflicted with the purposes of federal patent law.<sup>104</sup> The court found that the Act's purpose of penalizing manufacturers who set their prices at excessive levels limited those manufacturers' ability to exercise their full patent rights granted to them on their pharmaceutical products—namely, their right to set their own prices however they saw fit.<sup>105</sup> The court stated that the “economic rewards during the period of [patent] exclusivity are the carrot. . . . Upon grant of the patent, the only limitation on the size of the carrot should be the dictates of the marketplace.”<sup>106</sup> The court acknowledged that states have general police power within their borders, but noted that state laws are preempted by federal law when they interfere or conflict with federal laws.<sup>107</sup>

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101. *Supra* notes 86–87.

102. *Id.* The Act defined “excessive” as: “where the wholesale price of a patented prescription drug in the District is over 30% higher than the comparable price in any high income country in which the product is protected by patents or other exclusive marketing rights.” See D.C. CODE ANN. § 28-4554 (West 2005).

103. 496 F.3d 1362 (Fed. Cir. 2007).

104. *Id.* at 1374 (noting the goals of the D.C. statute may be worthwhile, but they were “contrary to the goals established by Congress in the patent laws” and were thus preempted).

105. *Id.* (“By penalizing high prices—and thus limiting the full exercise of the exclusionary power that derives from a patent—the District has chosen to re-balance the statutory framework of rewards and incentives insofar as it relates to inventive new drugs.”).

106. *Id.* at 1372 (quoting *King Instruments Corp. v. Perego*, 65 F.3d 941, 950 (Fed. Cir. 1995)).

107. *Id.* at 1373 (stating “the District has general police powers” but that those powers “must yield” to Congressional intent).

The District of Columbia legislation is not the only state<sup>108</sup> law struck down by the courts on preemptive grounds. Recall that the Maine legislature introduced the Maine Pharmacy Act (MPA) in 2013.<sup>109</sup> The Act sought to “expand[ ] the definition of a ‘mail order prescription pharmacy’ under the [MPA] to include an entity located outside of the United States that dispenses prescription medications by mail or carrier from a facility not located in this State to a pharmacy or to a patient who resides in this State,” effectively allowing parallel importation of pharmaceuticals from countries such as Canada.<sup>110</sup> In determining the legality of the Act, the federal district court noted that “Congress has created a complex regulatory scheme covering the importation of pharmaceuticals into the United States,”<sup>111</sup> such as by enacting the Federal Food, Drug, and Cosmetic Act (FDCA).<sup>112</sup> The FDCA prohibits any “new drug” from being introduced or imported into commerce that has not received FDA approval.<sup>113</sup> The court cited Eighth Circuit case law<sup>114</sup> and concluded “that the FDCA occupies the field of importation of pharmaceuticals

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108. Although not a state, the court in *Biotech* made it clear that the preemption doctrine certainly applies to the District of Columbia. *See id.* at 1371–73. In fact, Congress has a long, sometimes controversial history of exerting its will on the District of Columbia. *See* Aaron C. Davis & Peter Jamison, *Congress Once Ran the Local D.C. Government. GOP Signals That It May Do so Again*, WASH. POST (Jan. 30, 2017), [https://www.washingtonpost.com/local/dc-politics/congress-once-ran-the-local-dc-government-gop-signaling-it-may-do-so-again/2017/01/30/814f89a2-e71f-11e6-bf6f-301b6b443624\\_story.html](https://www.washingtonpost.com/local/dc-politics/congress-once-ran-the-local-dc-government-gop-signaling-it-may-do-so-again/2017/01/30/814f89a2-e71f-11e6-bf6f-301b6b443624_story.html).

109. ME. REV. STAT. ANN. tit. 32, § 13731 (2013).

110. *An Act to Facilitate the Licensing of International Mail Order Prescription Pharmacies by the Maine Board of Pharmacy: Hearing on L.D. 171 Before the J. Standing Comm. on Labor, Commerce, Research and Econ. Dev.*, 126th Legis., 1st Sess. (Me. 2013) (statement from Senator Troy Jackson, Assistant Majority Leader), <http://www.mainelegislature.org/legis/bills/getTestimonyDoc.asp?id=1095>; *see* Silverman, *supra* note 85.

111. *Oullette v. Mills*, 91 F. Supp. 3d 1, 10 (D. Me. 2015).

112. 21 U.S.C. §§ 301–399 (2012).

113. *Id.* § 355(a).

114. The court quoted in relevant part:

That Congress created a special procedure for authorizing importation of prescription drugs from Canada supports our conclusion that the preexisting system established by the [FDCA] does not permit such importation. While it is true that no federal statute by its express terms bans importation of prescription drugs from Canada, such an explicit country-by-country prohibition is unnecessary to accomplish the task. By creating the comprehensive regulatory system described above, Congress has effectively precluded importation of these drugs absent the sort of special authorization contemplated by 21 U.S.C. § 384.

*Oullette*, 91 F. Supp. 3d at 10 (citing *In re Canadian Imp. Antitrust Litig.*, 470 F.3d 785, 790 (8th Cir. 2006)).

from foreign countries,”<sup>115</sup> preempting the Act pursuant to the Supremacy Clause.

To briefly recap, the federal government appears unable or unwilling to combat rising drug costs.<sup>116</sup> State legislation attempting to restrain drug pricing has either lacked significant enforcement power and therefore had limited success (California), or courts have ruled the legislation preempted by federal law (District of Columbia and Maine). This resulting inaction at both levels of government harms consumers who continue to pay unreasonable amounts for necessary drugs. These consumers currently have no recourse against these outrageous actions by the pharmaceutical companies.

### C. A CONSIDERATION OF THE UNIQUENESS OF PHARMACEUTICAL PATENTS

This Note cannot stress the following plea enough: the United States needs to stop pretending pharmaceutical patents are similar to any other patented item. Drugs are not televisions, cellular devices, or high-end glass.<sup>117</sup> Pharmaceuticals are necessary—without them, people die. The same cannot be said for almost any other patented device. When political pundits and economists say the market acts as a constraint on the monopolistic power pharmaceutical patents provide their holders, this falsely represents reality. The truth is that pharmaceutical patents, under current U.S. law, allow patent holders to unjustifiably raise their prices 5000%; and nothing can stop that from happening. If a consumer dislikes an Apple iPhone, she can buy a Samsung Galaxy. If a consumer does not want to pay thousands of dollars for an expensive television, she chooses something else—or goes without one entirely. When the patient who

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115. *Id.*

116. Even though numerous bills have been proposed in 2017 alone. See Lanton, *supra* note 58.

117. See Robert Pearl, *Why Patent Protection in the Drug Industry Is Out of Control*, FORBES (Jan. 19, 2017), <https://www.forbes.com/sites/robertpearl/2017/01/19/why-patent-protection-in-the-drug-industry-is-out-of-control> (“Patent protection was never intended for use in a situation when human life would be endangered through its use. In other areas of society, broad legal prohibitions exist to protect human life and the well-being of citizens. For example, individuals are prohibited from yelling ‘Fire!’ in a theater, and utility monopolies that control all of the electricity for a city are prohibited from price gouging. Patents make sense in a retail or manufacturing context. If you don’t want to purchase Venetian glass, you can decide it’s too expensive. In contrast, if your child is born with a genetic defect, you have no choice but to obtain the medication available for treatment regardless of price.”).

cannot afford Daraprim or an EpiPen “takes a chance” (or makes the “decision”) to go without it, there is a distinct possibility that “choice” could prove fatal.<sup>118</sup> Pharmaceutical patents are unique and should be treated as such. This is a unique problem that requires a unique solution. With this backdrop, this Note now turns to suggest a way to combat the increasingly drastic price increases of pharmaceutical products.

### III. A SUGGESTED MODEL STATE STATUTE DESIGNED TO AVOID FEDERAL PREEMPTION AND GIVE STATES MEANINGFUL ABILITY TO CONTROL SOARING DRUG PRICES WHILE STILL RESPECTING PATENT RIGHTS

This Part sets forth a model state statute (Model Act) that state legislatures could enact to effect meaningful change in preventing dramatic price increases in pharmaceutical products. Section A brings together pieces of state consumer protection statutes and antigouging laws to create a framework for the Model Act. Section B lays out the Model Act and discusses the reasoning behind each specific provision. The Model Act builds on what previous legislative enactments did well, while improving on areas where they fell short.<sup>119</sup> It is designed to avoid federal preemption while effectively controlling prices.<sup>120</sup>

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118. See Anna Edney, *EpiPen Failures Cited in Seven Deaths This Year, FDA Files Show*, WASH. POST (Nov. 4, 2017), [https://www.washingtonpost.com/national/health-science/suspected-epipen-failures-have-been-linked-to-deaths-and-hospitalizations/2017/11/03/446d847a-bff6-11e7-97d9-bdab5a0ab381\\_story.html](https://www.washingtonpost.com/national/health-science/suspected-epipen-failures-have-been-linked-to-deaths-and-hospitalizations/2017/11/03/446d847a-bff6-11e7-97d9-bdab5a0ab381_story.html) (noting that even those that have EpiPens have died due to injector malfunctioning).

119. See *supra* Part.II.B.2.

120. This Note also seeks to build on two prior Notes that advocated for revisions to the District of Columbia’s Prescription Drug Excessive Pricing Act to ensure a court would not find it preempted. See Serena Lipski, Note, *Excessive Pricing and Pharmaceuticals: Why the Federal Patent Act Does Not Preempt State Regulation of Pharmaceutical Prices*, 39 U. TOL. L. REV. 913, 940 (2008) (“If D.C. enlarges its statute to affect pricing of all pharmaceutical products, patented or not, the new statute should be free from preemption problems.”); Christopher Lea Lockwood, Note, *Biotechnology Industry Organization v. District of Columbia: A Preemptive Strike Against State Price Restrictions on Prescription Pharmaceuticals*, 19 ALB. L.J. SCI. & TECH. 143, 179 (2009) (“If the Excessive Pricing Act was revised to apply generally to all pharmaceuticals rather than targeting only those protected by patents, the Act would probably not be subject to preemption.”).



A. SUPPORT FOR PHARMACEUTICAL PRICING LEGISLATION  
DRAWN FROM EXISTING LEGAL PRINCIPLES

This Section provides an overview of principles from various consumer protection statutes that provide a base and justification for state-level regulation of pharmaceutical pricing. Using consumer protection statutes as a framework for the Model Act ensures consumers remain at the forefront of who the Model Act is designed to protect.

1. State Consumer Protection: Unfair and Deceptive Acts and Practices Statutes

State consumer protection statutes establish a helpful starting point for why state-level regulation of pharmaceutical pricing can and should succeed. Unfair and Deceptive Acts and Practices (UDAP) statutes exist in all fifty states and the District of Columbia.<sup>121</sup> These statutes provide the main protection for consumers against predatory and unscrupulous business practices.<sup>122</sup>

One of two main takeaways from general UDAP statutes to apply to state-level regulation is the comprehensive prohibition on unfair business practices. By broadly prohibiting unfair business practices of manufacturers, distributors, and other actors in the pharmaceutical industry, “rather than confining the prohibition to a closed list of [unfair] practices,” states could regulate and prohibit new methods of unfair practices as they emerge.<sup>123</sup> By broadly prohibiting unfair business practices, states could give themselves the leeway to keep up with current and future pharmaceutical pricing practices.<sup>124</sup>

The second main takeaway from UDAP statutes to apply to state-level regulation is the delegation of rulemaking authority. According to the National Consumer Law Center:

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121. See generally CAROLYN L. CARTER, NAT’L CONSUMER LAW CTR. INC., CONSUMER PROTECTION IN THE STATES: A 50-STATE REPORT ON UNFAIR AND DECEPTIVE ACTS AND PRACTICES STATUTES (2009), [http://www.nclc.org/images/pdf/udap/report\\_50\\_states.pdf](http://www.nclc.org/images/pdf/udap/report_50_states.pdf) (discussing UDAP statutes in the United States).

122. *Id.* at 5 (“Although UDAP statutes vary widely from state to state, their basic premise is that unfair and deceptive tactics in the marketplace are inappropriate. UDAP statutes are the basic legal underpinning for fair treatment of consumers in the marketplace.”).

123. *Id.* at 11.

124. This argument is specifically addressed in the context of patent preemption in Part.IV.A, *infra*.

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The strongest UDAP statutes . . . allow a state agency to issue detailed regulations prohibiting specific unfair . . . practices. The authority to issue regulations means that the state can target emerging or persistent unfair . . . acts and practices and develop state-based solutions. It means that states can add bright-line rules to their general prohibitions, so that there is no question that a certain practice is unfair. . . . Specific rules also act as helpful guidelines for businesses that want to use fair practices.

Similarly, states could delegate authority and rulemaking power to state agencies to monitor and regulate unfair pharmaceutical business practices, including regulating unfair pricing. By delegating authority, states would give agencies broad leeway to continuously monitor and update their rules according to ever-evolving unfair practices. This would also ensure faster responses—and faster decision making—to dramatic price increases as the specified agency would be able to monitor such practices more effectively than the state legislature. Delegating to state agencies also prevents vexatious litigation, a concern often voiced when discussing consumer protection laws.

## 2. Antigouging Laws After Emergencies

Many states, including California<sup>125</sup> and New Jersey,<sup>126</sup> have antigouging laws to curb businesses from raising their prices for a specified period after a declared emergency. Virginia, Florida, and Georgia have similar anti-price-gouging laws as well.<sup>127</sup> Three primary models of state anti-price-gouging laws include: (1) a “percentage increase cap model,” which limits “post-disaster price increases . . . to a specific percentage over

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125. California’s law limits the maximum price retailers can raise their prices after an emergency to ten percent. See Rafi Mohammed, *The Problem With Price Gouging Laws*, HARV. BUS. REV. (July 23, 2013), <https://hbr.org/2013/07/the-problem-with-price-gouging-laws>.

126. N.J. STAT. ANN. § 56:8-109 (West 2017) (“It shall be an unlawful practice for any person to sell or offer to sell within 30 days after the declaration of a state of emergency, or for such other period of time as the Governor may specify in the declaration of a state of emergency, in the area for which the state of emergency has been declared, any merchandise which is consumed or used as a direct result of an emergency or which is consumed or used to preserve, protect, or sustain the life, health, safety or comfort of persons or their property for a price that constitutes an excessive price increase. The Governor may by executive order extend the period during which this prohibition remains in force.”). New Jersey’s anti-price-gouging law also limits the maximum amount a business can increase its prices after an emergency to ten percent. *Id.* § 56:8-108 (defining “excessive price increase”).

127. See Geoffrey C. Rapp, *Gouging: Terrorist Attacks, Hurricanes, and the Legal and Economic Aspects of Post-Disaster Price Regulation*, 94 KY. L.J. 535, 542–43 (2005).

pre-disaster prices”; (2) a bar on “unconscionable” price increases, which bars increases deemed unconscionable “with varying definitions of unconscionability” depending on the state; and (3) a total ban on any price increases at all.<sup>128</sup> Exceptions may be granted to merchants—at least as they relate to the percentage-increase cap model—who can show specific increases in their own costs, such as increased production and distribution costs.<sup>129</sup>

Comparing the rising costs in pharmaceutical drugs to declared emergencies initially sounds inapplicable, as many would not consider pharmaceutical price increases a natural disaster. Rather, the ability to price without limitation reflects a patent holder’s ability to freely conduct its business as condoned by federal patent law. However, states can draw inspiration from anti-price-gouging laws and apply it to anti-pharmaceutical laws in several ways. First, the notion that a state can enact a law that bars unconscionable price increases after an emergency is compelling. Many states already have anti-price-gouging laws that bar the sale of goods at “unconscionably high prices” or “grossly excessive prices” after emergencies.<sup>130</sup> States could also implement a broad prohibition against unconscionable price increases when attempting to regulate pharmaceutical companies from dramatically increasing their prices.<sup>131</sup>

Second, comparing the United States’ current healthcare situation—specifically the cost of healthcare and medication—to an emergency is not an unfounded assertion.<sup>132</sup> States could

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128. *Id.* at 543.

129. *Id.*

130. Rapp, *supra* note 127, at 544 (stating “Massachusetts, Virginia, Florida, Indiana, and South Carolina, attack gouging by barring the sale of goods” if the price is deemed excessive or unconscionable).

131. Maryland has done just that by prohibiting unconscionable price increases of generic drugs within a certain period. *See* H.B. 631, 2017 Reg. Sess. (Md. 2017), [http://mgaleg.maryland.gov/2017RS/Chapters\\_noln/CH\\_818\\_hb0631e.pdf](http://mgaleg.maryland.gov/2017RS/Chapters_noln/CH_818_hb0631e.pdf).

132. For instance, the United States has recently declared a health emergency over the opioid-addiction epidemic. *See* Julie Hirschfeld Davis, *Trump Declares Opioid Crisis a “Health Emergency” but Requests No Funds*, N.Y. TIMES (Oct. 26, 2017), <https://www.nytimes.com/2017/10/26/us/politics/trump-opioid-crisis.html>; German Lopez, *What Declaring a National Emergency Over the Opioid Epidemic Could Actually Do*, VOX (Oct. 23, 2017), <https://www.vox.com/policy-and-politics/2017/8/9/16118526/opioid-epidemic-national-emergency>. Additionally, several states, including Maryland, Virginia, and Florida, have declared a public-health emergency to expand access to overdose reversal medication. *See* Erin Mershon & Andrew Joseph, *How U.S. States Have Used Emergency Declarations to Fight the Opioid Epidemic*, STAT (Aug.

draw inspiration from anti-price-gouging statutes and declare the current state of pharmaceutical price increases an emergency that necessitates state intervention and regulation.<sup>133</sup>

Lastly, state regulation of pharmaceutical pricing can utilize the exceptions that numerous states include in their anti-price-gouging statutes. For example, Arkansas's does not outlaw a business from increasing its pricing so long as it can demonstrate that costs imposed on it by its supplier, or increased costs of labor or materials, directly attributed to the increased price of its product.<sup>134</sup> New Jersey has a similar provision in its anti-price-gouging statute.<sup>135</sup> Similarly, state pharmaceutical pricing laws could offer exceptions that allow for price increases based on increased costs of labor, supplies, or other increases in business expenses.

### 3. Enacted State Legislation that Regulates Pharmaceuticals

In addition to the above-mentioned principles of consumer protection law, the District of Columbia's and Maine's efforts to enact meaningful legislation provide important insight. Although courts found them preempted by federal law, the Prescription Drug Excessive Pricing Act and the MPA contain useful provisions that can further establish the basis for state regulation of pharmaceutical pricing.

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9, 2017), <https://www.statnews.com/2017/08/09/opioids-state-of-emergency-states>.

133. See the discussion of patent preemption and other arguments against such state regulation in Part IV, *infra*.

134. ARK. CODE ANN. § 4-88-303 (West 2017) ("However, a greater price increase shall not be unlawful if that person can prove that the increase in price was directly attributable to additional costs imposed on it by the supplier of the goods or directly attributable to additional costs for labor or materials used to provide the services, provided that in those situations where the increase in price is attributable to additional costs imposed by the seller's supplier or additional costs of providing the good or service during the state of emergency, the price represents no more than ten percent (10%) above the total of the cost to the seller plus the markup customarily applied by the seller for that good or service in the usual course of business immediately prior to the onset of the state of emergency.").

135. See N.J. STAT. ANN. § 56:8-108 (West 2017) (stating that price increases of more than ten percent from the price offered immediately before the state of emergency are unlawful "unless the price charged by the seller is attributable to additional costs imposed by the seller's supplier or other costs of providing the good or service during the state of emergency," and even then, the merchant is prohibited from marking up the price more than ten percent of their own cost).

a. *Prescription Drug Excessive Pricing Act of 2005*

The main provision of the District of Columbia's Excessive Pricing Act read as follows: "It shall be unlawful for any drug manufacturer or licensee thereof, excluding a point of sale retail seller, to sell or supply for sale or impose minimum resale requirements for a patented prescription drug that results in the prescription drug being sold in the District for an excessive price."<sup>136</sup> When finding the Excessive Pricing Act preempted by federal law, the Federal Circuit acknowledged that states have general police powers over all property within their borders.<sup>137</sup> However, the court concluded that "any state law, however clearly within a State's acknowledged power, which interferes with or is contrary to federal law, must yield."<sup>138</sup> The court determined that the Act was "in no way general, affecting only patented products" and "applie[d] only to patented drugs," which had the effect of the District attempting to "change federal patent policy within its borders" contrary to "the goals established by Congress in the patent laws."<sup>139</sup> State regulation of pharmaceutical products generally, and not just "patented prescription drugs" and their pricing as provided for in the Excessive Pricing Act, should not violate federal patent law and may therefore avoid federal preemption.<sup>140</sup>

b. *Maine Pharmacy Act*

Although attempting to legalize the importation of drugs from Canada—a different objective than direct state regulation of pricing—the MPA contained useful language regarding the State's ability to bring action against violators of the Act. The MPA allowed for "[t]he State [to] bring an action to enjoin any licensee or person from violating this chapter, regardless of whether proceedings have been or may be instituted in the District Court or whether criminal proceedings have been or may be instituted."<sup>141</sup> As discussed further below,<sup>142</sup> states may wish to consider delegating monitoring and enforcement authority to a state agency to monitor and regulate pharmaceutical pricing. In

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136. D.C. CODE ANN. § 28-4553 (West 2005).

137. *Biotechnology Indus. Org. v. District of Columbia*, 496 F.3d 1362, 1373 (Fed. Cir. 2007) (quoting *Felder v. Casey*, 487 U.S. 131, 138 (1988)).

138. *Id.*

139. *Id.* at 1373–74.

140. See Part.IV.A, *infra*.

141. ME. REV. STAT. ANN. tit. 32, § 13731 (2013).

142. See Part.III.B.2, *infra*.

addition, states may also choose to bring an action to enjoin a pharmaceutical company from violating its regulations regardless of whether the delegated agency has brought one. Delegating responsibility to an agency will help states maintain control and authority to enforce their own regulations while leaving most of the day-to-day responsibilities under the direction of the agency.

#### B. THE MODEL STATE STATUTE FOR REGULATING DRAMATIC PRICING INCREASES OF PHARMACEUTICALS

This Section sets forth a model statute designed for states to draw upon when implementing their own pharmaceutical pricing laws. This proposed Model Act seeks to protect consumers from high pharmaceutical costs by creating a meaningful option for states to prevent and prohibit unconscionable price increases.

##### 1. Core Statutory Language

The District of Columbia's Prescription Drug Excessive Pricing Act<sup>143</sup> provides the foundation for this Model Act, with additional input from the legal principles discussed in Section III.A, *supra*. Although the District of Columbia legislation was ultimately preempted, it serves as a useful starting point for two reasons. First, the Act was the first and only act to directly attempt to reign in soaring drug prices. Second, the opinion in *Biotech* provides guidance as to why the original Act violated constitutional principles. The Prescription Drug Excessive Pricing Act serves as a guide for the Model Act to avoid a similar fate.

##### a. *The Model Act's Language*

The suggested Model Act's main statutory provision is as follows:

*It shall be unlawful for any pharmaceutical or biological manufacturer, producer, licensee, patent holder, or any other pharmaceutical or medical-related organization or distributor, excluding a point of sale retail seller, to sell, supply for sale, or impose minimum resale requirements for a pharmaceutical, biological, or other medical product or service, whether drug, device, or otherwise, that results in the product being sold in this state for an unconscionably excessive price, or otherwise engage in unfair business practices, unless otherwise exempted by this Act.*<sup>144</sup>

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143. D.C. CODE ANN. § 28-4553 (West 2005).

144. The Prescription Drug Excessive Pricing Act, the foundation for this proposal, read as follows: "It shall be unlawful for any drug manufacturer or licensee thereof, excluding a point of sale retail seller, to sell or supply for sale

*b. Explanation of the Model Act's Language*

i. Pharmaceutical or biological

The Model Act includes these broad categories of business practices in order to capture the full array of organizations a state would wish to regulate. By including pharmaceuticals or biologicals, a state can ensure that any organization relating to pharmaceutical products,<sup>145</sup> or any other organization creating drugs or other products derived from biological sources,<sup>146</sup> must abide by this regulation. The Model Act is designed to apply broadly in order to prevent any unintentional exceptions to the statute's authority other than those expressly provided by the statute.

ii. Patent holder

The addition of the phrase "patent holder" serves the primary purpose of preventing investment companies from purchasing patent rights, and profiting from those rights while not serving any other manufacturing or distribution roles. By including patent holders in the Act to regulate unconscionable prices or unfair business practices, organizations who hold patents for various drugs or devices could not separate that business from the manufacturing or distribution process to avoid the reach of the Model Act. The language will also prevent companies who did not initially invent the product or hold the patent, but subsequently purchased the patent rights from the company who did, from claiming the purchase price justifies an increased markup of their product.<sup>147</sup>

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or impose minimum resale requirements for a patented prescription drug that results in the prescription drug being sold in the District for an excessive price." D.C. CODE ANN. § 28-4553.

145. See *Pharmaceutical*, OXFORD DICTIONARIES, <https://en.oxforddictionaries.com/definition/pharmaceutical> (last visited June 18, 2018) (defining "Pharmaceutical" as "[R]elating to medicinal drugs, or their preparation, use, or sale").

146. See *Biological*, OXFORD DICTIONARIES, <https://en.oxforddictionaries.com/definition/biological> (last visited June 18, 2018).

147. See what this justification looks like in the context of a company not being exempt from the Act's reach in Part.III.B.1. Turing Pharmaceuticals acquisition of the Daraprim patent comes to mind. See Almendrala, *supra* note 2.

iii. Other pharmaceutical or medical-related products;  
other medical product or service

This broad language solely intends to ensure the Act captures every possible situation of unconscionable pricing or unfair business practices, whether in relation to drugs, medical devices, or some other product or service.<sup>148</sup> The Act seeks to broadly prevent and prohibit unconscionable price increases and unfair activities in the pharmaceutical industry.

iv. Unconscionably excessive price

The unconscionable language comes from various states' anti-price-gouging laws after emergencies. Several states, including Massachusetts, Virginia, and Florida, have these laws that bar the sale of goods at "unconscionably high prices" or "grossly excessive prices" after emergencies.<sup>149</sup> Unconscionability is a broad legal principle that can be applied to the regulation of pharmaceutical conduct, especially to the extent that raising a drug price by 5000% is unconscionable.<sup>150</sup> A state may choose to use "grossly excessive prices" instead of "unconscionable," but this Note proceeds using the latter.<sup>151</sup>

Although a broad term, using unconscionable rather than a more unambiguous measurement such as a specific percentage<sup>152</sup> or dollar amount (for prices, specifically) protects the pharmaceutical industry. Pharmaceutical organizations, like most businesses, exist to make a profit. Some drugs and devices are more profitable than others; indeed, some drugs might even

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148. It is worth pointing out that EpiPen is patented not for Epinephren (the substance itself that reduces the impact of an allergic response), but rather for the design of its auto-injector. Therefore, the broad language consisting of "medical device or some other product or service" is designed to cover patented pharmaceutical items like an injector.

149. Rapp, *supra* note 127, at 544.

150. See Almendrala, *supra* note 2.

151. For example, Maryland prohibits "price gouging," defined as "an unconscionable increase in the price of a prescription drug." See H.B. 631, 2-801(c), 2017 Reg. Sess. (Md. 2017), [http://mgaleg.maryland.gov/2017RS/Chapters\\_noln/CH\\_818\\_hb0631e.pdf](http://mgaleg.maryland.gov/2017RS/Chapters_noln/CH_818_hb0631e.pdf).

152. The District of Columbia's Excessive Pricing statute, for example, used the following percentage standard: "A prima facie case of excessive pricing shall be established where the wholesale price of a patented prescription drug in the District is over 30% higher than the comparable price in any high income country in which the product is protected by patents or other exclusive marketing rights." D.C. CODE ANN. § 28-4554 (West 2005).



lose money.<sup>153</sup> Research-and-development costs exceeding profits, or a competitor inventing a newer or better drug or device, increases the chance of unprofitability. If the Model Act capped the price of a device or product at a specific dollar amount, percentage of profits or costs, or some other numeric measurement, that would unfairly harm pharmaceutical companies who rely on pricing certain drugs to a higher-than-desired level—from the prospective of the consumer, at least—to cover for losses and other operating expenditures. Using unconscionability as the applicable measurement allows courts to determine on a case-by-case basis whether the pharmaceutical company set the price of its product unreasonably high. The pharmaceutical companies could easily refute the charge of unconscionably high pricing by demonstrating that recovering their expenses and making a reasonable profit justifies the price they set.

v. Otherwise engage in unfair business practices

This language seeks to keep the scope, reach, and enforcement ability of the Model Act as broad as possible. Because pharmaceutical companies can harm consumers in ways other than directly increasing prices, such as by reducing supply or refusing to sell their products in the state,<sup>154</sup> this provision would restrict a broad range of unfair practices.<sup>155</sup>

vi. Otherwise exempted by this Act

This language stems from the exemptions found in various anti-price-gouging laws. Those exemptions allowed businesses to increase their prices for valid business reasons. For example, Arkansas's anti-price-gouging statute provides that it is not unlaw-

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153. See, e.g., Max Nisen, *The 10 Best Selling Prescription Drugs in the United States*, BUS. INSIDER (June 28, 2012), <http://www.businessinsider.com/10-best-selling-blockbuster-drugs-2012-6> (“Only a fraction of drugs succeed, but a look at how much a blockbuster [drug] is worth makes it clear why companies continue to chase them.”).

154. See discussion *infra* Part IV.

155. For example, section 5 of the FTC Act defines an unfair practice as: “An act or practice is unfair where it: causes or is likely to cause substantial injury to consumers; cannot be reasonably avoided by consumers; and is not outweighed by countervailing benefits to consumers or to competition.” FEDERAL TRADE COMM’N ACT SECTION 5: UNFAIR OR DECEPTIVE ACTS OR PRACTICES, CONSUMER COMPLIANCE HANDBOOK 1 (2016), <https://www.federalreserve.gov/boarddocs/supmanual/cch/ftca.pdf>. Such a broad understanding of unfair business practices for purposes of this Model Act will ensure that a broad range of unfair pharmaceutical behavior is implicated by the Act.

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ful for a business to increase its pricing if it can prove that increased costs imposed on it by its supplier or increased costs of labor or materials caused the increase in their own pricing.<sup>156</sup>

The Model Act does not propose to prevent pharmaceutical organizations from making a profit or engaging in business practices as they see fit. Rather, the Act attempts to prevent those companies from unjustifiably increasing their prices or engaging in other unfair behavior. The Arkansas statute capped price increases after emergencies to ten percent more than the price of the product before the emergency, and allowed for adjustment of the allowable percentage if it resulted from increased costs.<sup>157</sup> This Note does not propose for a state statute to use hard percentages. A pharmaceutical company has a variety of costs, risks, and uncertainties that make a hard cap unreasonable. For instance, a pharmaceutical distributor may be justified in increasing the price of one of its drugs to cover the costs of research and development for a new medication. It may be justified for a company to increase the price of its medication or device by 100%. What may not be justified, however, is an organization increasing the price of its drug by 5000%.<sup>158</sup> For the same reason the Model Act proposes using unconscionability as the measure of prohibited behavior, the exemption to allow organizations to increase their prices should be broad and require a fact-intensive inquiry—by the enforcing agency first, and a court in the event of a lawsuit—regarding the reasonableness of the action at issue. Exemption language could allow for price increases based on a proven surge in research and development costs, increased price of resources, or other unexpected expenditures.

Ultimately, organizations in the pharmaceutical and biologicals industry are businesses designed to turn a profit, and this Act does not limit that ability. That said, this Note suggests states should include specific language in the exemption section excluding the purchase of a patent as a justification for raising the cost of the pharmaceutical product or engaging in other unfair behavior. Thus, companies such as Turing Pharmaceuticals, who merely purchase the rights to a patent but do not engage in any research or development of a pharmaceutical, could not

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156. ARK. CODE ANN. § 4-88-303 (West 2017).

157. *Id.*

158. See Almendrala, *supra* note 2 (discussing Turing Pharmaceuticals increasing the price of Daraprim, a medication for patients with HIV, by 5000%, from \$13.50 to \$750 per tablet).

claim that the expense of purchasing the patent alone justifies increasing the price of the drug.

## 2. Delegate Authority to State Agency to Monitor and Enforce

The strongest state UDAP statutes allow for a state agency to issue detailed regulations prohibiting specific unfair practices.<sup>159</sup> Similarly, individual states could mandate regulatory and enforcement responsibilities to state agencies. These agencies may be better situated to monitor and regulate unconscionable and unfair business practices. The authority granted could include establishing exemptions allowing for price increases based on proper or reasonable business purposes. A state agency may have more time, expertise, and resources to monitor price increases and recognize when a price increase is justified (i.e. reasonable) and when it is not. Furthermore, an agency could be better positioned to negotiate with the companies to lower the price of their products or refrain from certain behavior—acting as their own form of alternative dispute resolution. In fact, states could limit the amount or type of remedies and include a requirement to exhaust any administrative proceedings; the possibilities of an agency managing the monitoring and enforcement of the law are quite broad. Further, because the purpose of the Model Act is to allow states to protect their citizens from dramatic price increases, having a state agency with some expertise in pricing practices enforce the Act would ensure the most extreme cases of unconscionable pricing are being addressed rather than going after less egregious examples.

## 3. Additional Considerations

This Note posits two additional considerations. First, the importance of transparency. California's Pharmaceutical Cost Transparency Act of 2016,<sup>160</sup> discussed in Part II.A.1, *infra*, requires each manufacturer of a prescription drug with a wholesale acquisition cost of \$10,000 or more to annually file a report containing the costs for each qualifying drug with the Office of Statewide Health Planning and Development.<sup>161</sup> While the effects of the Act have yet to be seen, it is unclear if transparency by itself would provide a sufficient mechanism for states to lower

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159. CARTER, *supra* note 121, at 11.

160. AB-463 Pharmaceutical Cost Transparency Act of 2016, 2015–2016 Reg. Sess. (Cal. 2016), [https://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill\\_id=201520160AB463](https://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=201520160AB463).

161. *Id.*

drug prices. However, transparency—knowing how much it cost a specific company to develop a specific drug—will help the states that enact this Note’s Model Act determine what level of pricing crosses the line of high to unconscionable. It also ensures that the public, and not just the state government or agency, can monitor pharmaceutical pricing.

A second important point to consider is the negotiated prices different entities and agencies are paying for drugs. The state of Ohio had a ballot initiative planned for November 2017 to vote on the Ohio Drug Price Relief Act.<sup>162</sup> The Act was designed to “require state agencies to pay no more for prescription drugs that [sic] the U.S. Department of Veterans Affairs.”<sup>163</sup> Even though the measure was ultimately rejected by the voters, it offered a way for states to monitor whether a price for a drug was too high by comparing the price to that paid by the U.S. Department of Veterans Affairs (VA). Although difficult to achieve in practice because the “prices paid by the VA are not public,”<sup>164</sup> using similar benchmarks and comparisons—such as how much the drug is sold for in another state or country, or how much a state’s Medicaid program pays for the drug—provides one way for states who enact this Note’s proposal to determine when the price of a drug becomes unconscionable. While this should not be the sole indicator of the reasonableness of a pharmaceutical’s price, it is one option for states to consider when enforcing the Act.

#### IV. CONCERNS AND CRITICISMS OF STATE REGULATION OF PHARMACEUTICAL PRICING

This Part discusses dangers and critiques of the Model Act’s effectiveness. Potential pitfalls include: patent preemption, discussed in Section A; antitrust preemption, discussed in Section B; and Dormant Commerce Clause concerns, discussed in Section C. Section D discusses the normative economic concern that

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162. See Julie Carr Smyth & Dan Sewell, Associated Press, *Ohio Voters Reject Drug-Price Measure, Back Victims’ Rights*, US NEWS (Nov. 8, 2017), <https://www.usnews.com/news/best-states/ohio/articles/2017-11-07/ohio-voters-to-decide-ballot-issues-mayoral-races> (“[The measure] sought to curb prescription drug prices paid by the state for prisoners, injured workers and poor people.”).

163. Monica Robins, *What Is the Ohio Drug Price Relief Act?*, WKYC (May 31, 2017), <http://www.wkyc.com/news/health/what-is-the-ohio-drug-price-relief-act/444606883>.

164. Rachel Sachs, *State Drug Price Cap Laws: How Do They Work?*, HARV. PETRIE-FLOM CTR. (Apr. 27, 2016), <http://blogs.harvard.edu/billofhealth/2016/04/27/state-drug-price-cap-laws-how-do-they-work>.

an organization whose products are being regulated by the Act may decide to discontinue selling its products in that state, thus negatively impacting the consumers who the statute is trying to protect.

#### A. PATENT PREEMPTION

For the sake of protecting inventors' interests while also serving the public good, the Patent Act strikes a balance between these competing interests by providing for a limited property right and a twenty-year (effective) monopoly on the invented technology.<sup>165</sup> Patent holders have a right to do as they wish with their invention and are therefore free of certain competitive constraints;<sup>166</sup> they also enjoy certain protections.<sup>167</sup> The benefits enjoyed by patent holders raises the question of whether the Model Act conflicts with this regulatory scheme and purpose of federal patent law. The baseline assumption when answering this question is "that the historic police powers of the States [are] not to be superseded by the . . . Federal Act unless that [is] the clear and manifest purpose of Congress."<sup>168</sup>

Patent preemption can consist of explicit, field, and conflict preemption.<sup>169</sup> Explicit preemption is likely not a concern here, as "federal patent law does not provide explicit preemption."<sup>170</sup> Further, field preemption, while arguably a closer call, is also likely not a concern for the Model Act's enforcement. Field preemption occurs when the scheme of federal regulation—in this case, the Patent Act—is "so pervasive as to make reasonable

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165. See Joan E. Schaffner, *Patent Preemption Unlocked*, 1995 WIS. L. REV. 1081, 1082 ("Congress enacted the federal patent statute which provides limited property protection to discoveries which meet the basic patentability requirements of eligibility, utility, novelty, nonobviousness, and disclosure. The congressional scheme carefully balances the need for property-right incentives with the need to maintain free access to prior invention." (footnotes omitted)).

166. See Lipski, *supra* note 120, at 922 ("In other words, the patentee enjoys the exclusive right to manufacture, sell, market, or use the invention for a period of twenty years.").

167. See Schaffner, *supra* note 165, at 1081–83 (explaining that the federal law, as well as additional state laws, prevent actions by competitors which are deemed to be "commercially unethical"—for example, copying the trade design of a competitor, engaging in industrial espionage, or breaching confidentiality agreements).

168. *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947).

169. *Ultra-Precision Mfg., Ltd. v. Ford Motor Co.*, 411 F.3d 1369, 1377 (Fed. Cir. 2005).

170. *Id.*; see also Patent Act of 1970, 35 U.S.C. §§ 1–376 (2012).

the inference that Congress left no room for the States to supplement it.”<sup>171</sup> The Patent Act does not regulate unfair or unconscionable behavior by pharmaceutical companies, nor does it regulate pricing; it does not grant a right to sell anything.<sup>172</sup> Patent law grants certain protections and prohibits others from infringing the rights of the patent holder. This Act, on the other hand, would prevent pharmaceutical companies from engaging in unconscionable behavior, whether through their pricing strategies or otherwise. Thus there is a strong argument against the notion that field preemption could apply in this case.<sup>173</sup> The court’s analysis in *Biotech* supports this conclusion as well.<sup>174</sup>

As a result, conflict preemption presents the largest obstacle to the Act’s validity.<sup>175</sup> Conflict preemption exists where state regulation actually conflicts with federal law, or where state regulation “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.”<sup>176</sup>

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171. *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 167 (1989).

172. *See Leatherman Tool Grp., Inc. v. Cooper Indus., Inc.*, 131 F.3d 1011, 1015 (Fed. Cir. 1997) (“In fact, the federal patent laws do not create any affirmative right to make, use, or sell anything.”); *Herman v. Youngstown Car Mfg. Co.*, 191 F. 579, 584 (6th Cir. 1911) (“A patent is not the grant of a right to make or use or sell. It does not, directly or indirectly, imply any such right. It grants only the right to exclude others.”).

173. *See generally CardioVention, Inc. v. Medtronic, Inc.*, 430 F.Supp. 933, 939 (2006) (finding it “evident that federal patent law and state unfair competition claims occupy different fields”). If Congress had truly meant to occupy the entire field of patent rights, including pricing, to the exclusion of states, it would have, or should have, stated so in the Patent Act and subsequent legislative additions.

174. The court decided the case using a conflict preemption analysis, and found that the “Act’s operation stands largely—indeed, exclusively—within the scope of the patent laws, and its effect is to shift the benefits of a patented invention from inventors to consumers.” *Biotechnology Indus. Org. v. District of Columbia*, 496 F.3d 1362, 1373–74 (2007).

175. It should be noted that impossibility preemption—“the principle that state law cannot require a drug manufacturer to take an act that the drug’s federal approval precludes”—does not apply here, as the Model Act does not require the manufacturer to engage in any behavior whatsoever and does not contravene any FDA regulations or grants. *See Mut. Pharm. Co., Inc. v. Bartlett*, 133 S. Ct. 2466 (2013) (holding that a New Hampshire law requiring drug manufacturers to make changes to warning labels was preempted by federal law); Adam E. Lyons, *Federal Preemption Precludes Challenge to FDA-Approved Drug*, LITIG. NEWS (Apr. 27, 2016), <https://apps.americanbar.org/litigation/litigationnews/mobile/article-preemption-fda.html>.

176. *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941).

On its face, the Act does not conflict with federal law.<sup>177</sup> As stated, patent law protects certain property rights and prevents infringement of those rights. The Model Act, on the other hand, does not restrict property rights or infringe on the patent holder. But does the Model Act stand as an obstacle to the execution of patent law? The court in *Biotech* said the District of Columbia's Excessive Pricing Act, which inspires the Model Act, did. The court determined that the District of Columbia legislation was "in no way general, affecting only patented products" and "applie[d] only to patented drugs," which the court interpreted as the District of Columbia attempting to "change federal patent policy within its borders" contrary to "the goals established by Congress in the patent laws."<sup>178</sup>

There are several key distinctions between the Model Act and the District of Columbia's Excessive Pricing Statute that support the conclusion that the Model Act is not preempted by patent law. First, the Model Act regulates pharmaceutical companies' behavior in general; it does not restrict enforcement of the Act to only drug prices. Second, the Act does not limit enforcement to actions that relate only to drugs or medications, but any actions and products. Third, the Act does not limit enforcement to only patented products. Fourth, the Excessive Pricing Act attempted to compare the prices of patented drugs in other countries with the price of the drug in the United States in order to determine the appropriate price of the drug.<sup>179</sup> As a result, under the *Biotech* reasoning, this Model Act does not conflict

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177. See *Sabri v. United States*, 541 U.S. 600, 609 (2004) (finding that facial challenges, in the strictest sense, are challenges that allege no application of the statute is constitutional) (citation omitted); Alex Kreit, *Making Sense of Facial and As-Applied Challenges*, 18 WM. & MARY BILL OF RTS. J. 657, 657 (2010) ("A facial attack is typically described as one where no application of the statute would be constitutional.").

178. *Biotechnology*, 496 F.3d at 1373–74.

179. *Biotechnology Indus. Org. v. District of Columbia*, 505 F.3d 1343, 1347 (Fed. Cir. 2007) (Gajarsa, J., concurring).

with federal patent law.<sup>180</sup> The Model Act further does not conflict with the line of reasoning under *Bonito Boats*,<sup>181</sup> *University of Colorado*,<sup>182</sup> or *Aronson*.<sup>183</sup>

A hurdle for the Model Act is an as-applied challenge to the Act's constitutionality.<sup>184</sup> A pharmaceutical company whose patented drug is implicated by the Act may argue that the Act limits their rights and abilities granted by federal patent law and is therefore unconstitutional *as applied* to them. The court in *Aronson* found that

[T]he purposes of the federal patent system [are] to foster and reward invention; [] to promote disclosure of inventions, stimulate further innovation, and permit the public to practice the invention once the patent expires; and [] to assure that ideas in the public domain remain there for the free use of the public.<sup>185</sup>

The argument against the Act based on these principles is that prohibiting unconscionable conduct, which could include dramatic price increases under the Model Act, conflicts with the patent system's purpose of fostering and rewarding inventions

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180. In sum, because the Model Act applies broadly to all pharmaceutical companies and manufacturers, and is not limited to just patented drugs, there are many applications of the statute that would be constitutional. For example, if after a state emergency the manufacturer of a product that is not patent protected dramatically and unjustifiably increases the prices of its products, the State could bring an action against the manufacturer for unfair business practices and unconscionably setting its prices. The legality of such an act is without question, as exemplified by various state anti-price-gouging statutes. *See supra* Part III.A.2. Thus it is likely a facial challenge would fail.

181. *See Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 142 (1989) ("By offering patent-like protection for ideas deemed unprotected under the federal patent scheme, the Florida statute conflicts with the 'strong federal policy favoring free competition in ideas which do not merit patent protection.'" (citing *Lear, Inc. v. Adkins*, 395 U.S. 693, 656 (1969))).

182. *See Univ. of Colo. Found., Inc. v. Am. Cynamid Co.*, 342 F.3d 1298, 1307 (Fed. Cir. 2003) ("[T]he Doctors' claim of unjust enrichment does not undermine the purposes of the federal patent scheme: the Doctors can collect the fruits of their research, which fosters both specific and general incentives to innovate, while their reformulations stimulate further innovation; at the same time, no information in the public domain is denied free circulation. The unjust enrichment claim does not prevent the public from using these ideas.").

183. *See Aronson v. Quick Point Pencil Co.*, 440 U.S. 257, 262 (1979) ("Enforcement of Quick Point's agreement with Mrs. Aronson is not inconsistent with any [patent law] aims. Permitting inventors to make enforceable agreements licensing the use of their inventions in return for royalties provides an additional incentive to invention.").

184. *See Kreit, supra* note 177 ("Courts define an as-applied challenge as one 'under which the plaintiff argues that a statute, even though generally constitutional, operates unconstitutionally as to him or her because of the plaintiff's particular circumstances.'" (footnote omitted)).

185. *Aronson*, 440 U.S. at 257.



by limiting the amount of economic return a company can make from its development of a new drug or device. Congress allowed patent holders to exclude competitors from the market for a limited time and therefore effectively allowed the patent holders to price their products however they deemed fit. Restricting drug prices contradicts that right given by Congress and serves as a disincentive to engage in the risks and costs of developing a new drug.<sup>186</sup> However, the Model Act does not directly regulate patented pharmaceutical prices, nor does it conflict with a company's ability to set and increase the price it sells its product for. Instead, the Act regulates unconscionable behavior by pharmaceutical companies in general. Once behavior becomes unconscionable, it is up to the company to correct it back to less-than-unconscionable levels. What that means in any given situation will depend on the facts and what behavior is deemed unconscionable or unfair; and because this is a flexible standard designed to adjust to changing circumstances, there is little risk of arbitrary application in the same way that might happen with a more rigid standard. The Act does not stand as an obstacle to the accomplishment and execution of federal patent law to exclude competitors for a period of twenty years, nor does it deprive the patent holder of any other rights granted by their patent.<sup>187</sup> The Act entirely permits companies to make a profit and to otherwise engage in business unimpeded—subject to otherwise applicable law.

Further, the Model Act does not conflict with the *Aronson* principle that state regulations of patented products should not stifle new drug innovation. The Model Act does not conflict with a pharmaceutical company's development efforts or profit realization through the right to exclude others from the marketplace.

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186. See, e.g., *King Instruments Corp. v. Perego*, 65 F.3d 941, 950 (Fed. Cir. 1995) (“[T]he Patent Act creates an incentive for innovation. The economic rewards during the period of exclusivity are the carrot. The patent owner expends resources in expectation of receiving this reward. Upon grant of the patent, the only limitation on the size of the carrot should be the dictates of the marketplace.”). The issue with this characterization of patent rights, however, is that it completely ignores the reality of how pharmaceutical patents operate. The Cambridge Dictionary defines marketplace as “the system of buying and selling in competitive conditions.” *Marketplace*, CAMBRIDGE DICTIONARY, <http://dictionary.cambridge.org/us/dictionary/english/marketplace> (last visited June 18, 2018). There are no dictates of the marketplace for pharmaceutical patents—all competitors are excluded for a period of time. The carrot doesn't engage in a system of buying and selling in competitive conditions; it is impossible for that to occur.

187. *King Instruments Corp.*, 65 F.3d at 950.

*Aronson* also determined that one of the purposes of the Patent Act is “foster[ing] and reward[ing] invention[s].”<sup>188</sup> The Model Act does not impede the fostering and rewarding of inventions, as only companies that set their prices at unconscionably high levels without justification will be under the purview of the Act. Analogously, the Act’s limitation on pricing does not conflict with the rewards of developing a new drug in the same way that rent control, regulations on the quality of food items, and caps on the price of electricity do not impede the rewards of conducting business in those fields; profits are still earned.<sup>189</sup> Further, because the Act does not propose setting a specified cap on the price of a product, but rather encourages an analysis of the justification of the price on a case-by-case basis, a pharmaceutical organization is always “fostered and rewarded” for its new invention until the point in time when its actions become unconscionable. Nothing in federal patent law promotes or immunizes a company from behaving unconscionably.<sup>190</sup> The Model Act does not prohibit profiting, but rather prohibits unfair behavior or setting unconscionable prices. The Model Act does not conflict with federal patent law.<sup>191</sup>

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188. *Aronson*, 440 U.S. at 262.

189. An argument against price controls is that they can actually lead to higher prices because the ceilings can promote collusion among suppliers who would be competitors. But that is not a concern in the context of pharmaceuticals, as the industry generally lacks competition as a result of patent protection, and therefore competitors generally cannot collude with one another; but there is one exception to this general principle. Even if generic drugs can compete with brand name drugs, brand-name companies often engage in the practice of reverse payments in order to maintain their effective monopoly for longer than twenty years, something prohibited by the Hatch-Waxman Act. See the discussion of reverse payments in Part I.C. For more information on reverse payments and its impact on generic drugs entering the market, see Audra J. Passinault, *A Prescription for the Future: Reverse-Payment Settlements in the Wake of FTC v. Actavis Pharmaceuticals*, 29 NOTRE DAME J.L. ETHICS & PUB. POL’Y 549 (2015). Thus controlling unconscionable prices in the pharmaceutical field will not lead to collusion, as its either not possible—there is no competition—or it is already prohibited by Hatch-Waxman.

190. See *Herman v. Youngstown Car Mfg. Co.*, 191 F. 579, 584 (6th Cir. 1911) (“A patent is not the grant of a right to make or use or sell. It does not, directly or indirectly, imply any such right. It grants only the right to exclude others.”).

191. After finding the District of Columbia’s Excessive Price Act was preempted by patent law and denying an en banc rehearing, a judge agreeing with the legal conclusions reached by the majority acknowledged:

This does not mean that any state regulation that affects a patentee’s profits so undermines the goals of the patent system as to be preempted. It is well established that states can generally regulate patented products as part of their general exercise of police powers without preemption, even if this regulation incidentally affects the profits

## B. ANTITRUST PREEMPTION

Congress passed the Sherman Act in 1890 as a “comprehensive charter of economic liberty aimed at preserving free and unfettered competition as the rule of trade.”<sup>192</sup> In addition, the FTC Act and the Clayton Act constitute the antitrust laws. The Sherman Act outlaws every conspiracy in restraint of trade and any attempted monopolization, while the FTC Act bans unfair methods of competition.<sup>193</sup> The Clayton Act further bans conduct that lessens competition.<sup>194</sup>

In interpreting the Model Act to discern preemption by antitrust law, a court would first decide if the Model Act “mandates or authorizes conduct that necessarily constitutes a violation of those laws in all cases, or if it places irresistible pressure on a private party to violate the antitrust laws in order to comply with the statute.”<sup>195</sup> The Model Act does not violate any of these principles, and therefore avoids antitrust preemption. First, the Model Act does not mandate or authorize conduct that violates antitrust law. The Model Act does not promote a monopoly, nor does it incentivize monopolistic behavior. Rather, the Model Act forbids unconscionable behavior by pharmaceutical companies. Second, the Model Act does not place pressure on pharmaceutical companies to violate antitrust law. The Model Act, rather, pressures pharmaceutical companies to engage in more reason-

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a patentee gains from its patent . . . . But that states have broad leeway to regulate patented products does not mean that they have unlimited ability to do so in situations in which the regulation significantly and directly impedes Congress’s purpose in providing the federal patent right.

*Biotechnology Indus. Org. v. District of Columbia*, 505 F.3d 1343, 1346 n.1 (Fed. Cir. 2007) (Gajarsa, J., concurring). The judge further went on to state that “[i]n my view, a price discrimination provision presents no conflict with the purpose of the federal patent law.” *Id.* at 1349.

192. *The Antitrust Laws*, Subsection in *Guide to Antitrust Laws*, FTC, <https://www.ftc.gov/tips-advice/competition-guidance/guide-antitrust-laws/antitrust-laws> (last visited June 18, 2018).

193. *Id.*

194. *Id.*

195. *Rice v. Norman Williams Co.*, 458 U.S. 654, 661 (1982) (“Such condemnation will follow under § 1 of the Sherman Act when the conduct contemplated by the statute is in all cases a *per se* violation. If the activity addressed by the statute does not fall into that category, and therefore must be analyzed under the rule of reason, the statute cannot be condemned in the abstract . . . . Analysis under the rule of reason requires an examination of the circumstances underlying a particular economic practice, and therefore does not lend itself to a conclusion that a statute is facially inconsistent with federal antitrust laws.”).

able behavior—engage in behavior that does not lead to unconscionable prices or other unfair behavior. This Act serves as a complement to antitrust law, not as an impediment.

### C. DORMANT COMMERCE CLAUSE CONCERNS

The power to regulate interstate commerce is exclusively vested in Congress<sup>196</sup> through the Commerce Clause.<sup>197</sup> According to the seminal *Limbach* case, the “Commerce Clause not only grants Congress the authority to regulate commerce among the States, but also directly limits the power of the States to discriminate against interstate commerce.”<sup>198</sup> This “reversed” facet of the Commerce Clause, better known as Dormant Commerce Clause, “prohibits economic protectionism—that is, regulatory measures designed to benefit in-state economic interests by burdening out-of-state competitors.”<sup>199</sup> As a result, “state statutes that clearly discriminate against interstate commerce are routinely struck down, unless the discrimination is demonstrably justified by a valid factor unrelated to economic protectionism.”<sup>200</sup>

#### 1. Why the Dormant Commerce Clause Does Not Prohibit the Model Act

In *Limbach*, the Supreme Court found that the state statute at issue deprived “certain products of generally available beneficial tax treatment because they [were] made in certain other States, and thus on its face [appeared] to violate the cardinal requirement of nondiscrimination.”<sup>201</sup> In rejecting the appellant’s “reciprocity”<sup>202</sup> argument—essentially “encouraging”

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196. *Gibbons v. Ogden*, 22 U.S. 1, 180 (1824).

197. See U.S. CONST. art. I, § 8, cl. 3 (stating that Congress shall have power “[t]o regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes”).

198. *New Energy Co. of Ind. v. Limbach*, 486 U.S. 269, 273 (1988) (citations omitted).

199. *Id.* (citations omitted).

200. *Id.* at 274.

201. *Id.*

202. The appellants argued that

[T]he availability of the tax credit to some out-of-state manufacturers (those in States that give tax advantages to Ohio-produced ethanol) shows that the Ohio provision, far from discriminating against interstate commerce, is likely to promote it, by encouraging other States to enact similar tax advantages that will spur the interstate sale of ethanol. *Id.*

other states to enact a similar piece of legislation—the Court determined that states “may not use the threat of economic isolation as a weapon to force sister States to enter into even a desirable reciprocity agreement.”<sup>203</sup> In contrast, the Model Act does not include such a reciprocity facet or anything resembling an encouragement for other states to enact similar legislation. The Model Act does not discriminate between products from pharmaceutical companies based on their location, whether inside or outside of the state. Instead, the Model Act applies to all pharmaceutical companies that engage in unfair practices or unconscionable pricing within the state. Further, the Model Act does not create minimum pricing limitations,<sup>204</sup> reward certain pharmaceutical companies while discriminating against others, or create an economic isolation that forces other states to enact similar policies to stay competitive through pricing. Instead, the Model Act has the exact opposite result: for pharmaceutical companies, it may make other states that do not enact the Model Act, and therefore have no restrictions on unconscionable prices or other unfair behavior, appear more favorable for business operations and sales. There is no disparity of treatment that implicates the reciprocity principle under the Dormant Commerce Clause line of cases.<sup>205</sup>

Furthermore, the concern of economic protectionism is also not implicated by the Model Act.<sup>206</sup> The Model Act does not discriminate between different companies within the pharmaceutical industry; it treats them all the same, and only limits certain conduct. It is not illegal to require certain industries to engage

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203. *Id.* (citations omitted).

204. *See* *Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511, 528 (1935) (“It is a very different thing to establish a wage scale or a scale of prices for use in other states, and to bar the sale of the products, whether in the original packages or in others, unless the scale has been observed.”).

205. *See* *Sporhase v. Nebraska ex rel. Douglas*, 458 U.S. 941, 957 (1982) (holding that “the reciprocity provision operates as an explicit barrier to commerce between the two States”); *Hunt v. Wash. Apple Advert. Comm’n*, 432 U.S. 333, 349–51 (1977) (invalidating a North Carolina statute that did not exclude apples from other states but imposed additional costs upon Washington sellers and deprived them of their commercial advantage); *Great Atl. & Pac. Tea Co. v. Cottrell*, 424 U.S. 366, 379 (1976) (holding that “Mississippi may not use the threat of economic isolation as a weapon to force sister States to enter into even a desirable reciprocity agreement”); *Baldwin*, 294 U.S. at 527 (finding that the New York law was “an economic barrier against competition” that was “equivalent to a rampart of customs duties”).

206. *See* *Limbach*, 486 U.S. at 273 (“[E]conomic protectionism—that is, regulatory measures designed to benefit in-state economic interests by burdening out-of-state competitors.” (citations omitted)).

in, or prohibit from doing, certain practices that other industries are not prohibited from engaging in.<sup>207</sup> The fact that pharmaceutical companies may be held to a different standard—in the form of a prohibition on unfair practices and unconscionable prices—than companies within other, distinct industries, does not benefit in-state economic interests by burdening out-of-state competitors. The competitors in the pharmaceutical industry are the pharmaceutical companies themselves—and patent holders—who would all be regulated by the Model Act. In-state pharmaceutical companies are not treated differently than out-of-state companies for purposes of the Model Act.

## 2. The Model Act Advances Local Purposes in the Absence of Reasonable Alternatives

Even if a court would find that the Model Act is discriminatory by being economically protectionist, the Model Act still does not violate the Dormant Commerce Clause. Although a heavy burden,<sup>208</sup> the case law “leave[s] open the possibility that a State may validate a statute that discriminates against interstate commerce by showing that it advances a legitimate local purpose that cannot be adequately served by reasonable nondiscriminatory alternatives.”<sup>209</sup> The proponent of the state law must also show “whether the challenged statute regulates evenhandedly with only ‘incidental’ effects on interstate commerce, or discriminates against interstate commerce either on its face or in practical effect.”<sup>210</sup> The Court in *Limbach* did not agree with appellant’s characterization of the act in question as being health-related. Rather, the Court found that “[i]t could not be clearer that health is not the purpose of the provision, but is merely an occasional and accidental effect of achieving what is its purpose, favorable tax treatment for *Ohio*-produced ethanol.”<sup>211</sup> In contrast, the Model Act does not hide its intent or purpose; it is to regulate unfair practices and unconscionable prices. It is designed to protect the wellbeing of consumers within the state by

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207. For example, telemarketers can be prohibited from calling consumers through use of the FTC’s do-not-call list, while nonprofit and political organizations do not have such a restriction. See *Mainstream Market. Servs., Inc. v. Fed. Trade Comm’n*, 358 F.3d 1228 (10th Cir. 2004).

208. See *Philadelphia v. New Jersey*, 437 U.S. 617, 624 (1978) (“[W]here simple economic protectionism is effected by state legislation, a virtually *per se* rule of invalidity has been erected.”).

209. *Limbach*, 486 U.S. at 278 (citations omitted).

210. *Hughes v. Oklahoma*, 441 U.S. 322, 336 (1979).

211. *Limbach*, 486 U.S. at 279.

offering protections against highly-priced pharmaceutical products and other unfair behavior. The Act certainly advances a local purpose, as it would apply to and protect residents of the state itself.

Further, the interests the Act is designed to protect cannot be adequately served by reasonable nondiscriminatory alternatives. As discussed above,<sup>212</sup> federal patent law provides strong exclusionary protections to patent holders that effectively allows them to price their products at exorbitant levels. To date, the federal government has refused to provide any sort of relief for the decades-long practice of dramatic pharmaceutical price increases. States that have tried to enact meaningful policy have met staunch resistance in the courts. Consumers who rely on pharmaceuticals that have increased 5000% in price need some protection.<sup>213</sup> To date, this Model Act is the only thing that can provide that protection, as it serves a local purpose that no other adequate measure could achieve.

Finally, at worst, this Act burdens interstate transactions only incidentally. The Act does not prohibit engaging in any commerce, business, or trade.<sup>214</sup> The Act does not prevent certain actions that do not meet a set list of criteria. Further, the Model Act does not impose a burden on trade excessive in relation to the local benefits.<sup>215</sup> Under the Model Act, pharmaceutical companies can price their products, or engage in any other behavior, so long as it is not unconscionable or unfair—subject to other U.S. laws. Consumers, on the other hand, are protected from unconscionable price increases or other unfair behavior. Protecting the economic wellbeing of consumers as well as providing a fairer opportunity for them to access life-saving medications certainly outweighs the burdens imposed on pharmaceutical companies.

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212. See *supra* Part I.B.1.

213. See Almendrala, *supra* note 2 (discussing Turing Pharmaceuticals increasing the price of Daraprim, a medication for patients with HIV, by 5000%, from \$13.50 to \$750 per tablet).

214. See, e.g., *Hughes*, 441 U.S. 336–37 (“[The Act] forbids the transportation of natural minnows out of the State for purposes of sale, and thus ‘overtly blocks the flow of interstate commerce at [the] State’s borders.’” (citing *Philadelphia v. New Jersey*, 437 U.S. 617, 624 (1978))).

215. See *Maine v. Taylor*, 477 U.S. 131, 138 (1986) (determining statutes that burden interstate transactions incidentally “violate the Commerce Clause only if the burdens they impose on interstate trade are ‘clearly excessive in relation to the putative local benefits.’” (quoting *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970))).

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D. ECONOMIC REALITIES OF PROHIBITING UNCONSCIONABLE PHARMACEUTICAL PRACTICES

A major concern with the Model Act's regulation of pharmaceutical behavior, including restricting unconscionable prices, centers around the possibility that a pharmaceutical company could decide to discontinue selling its regulated product in that state, thus penalizing the consumers more than they had been without the Act's protections. While the prospect of pharmaceutical companies pulling their products off the shelves in a state that enacts the Model Act is concerning, there are two responses to this problem.

First, it is important to recognize that pharmaceutical companies' actions or prices will only be impacted if a court finds their practices to be unfair or their prices unconscionable. A court would only find those situations to occur—and specifically, that the price is unconscionable—if the pharmaceutical company cannot provide any rationally-justified reasons why the price of the medication or device that prompted the application of the Model Act needs to be at the level the company set it at. For discontinuation to become an actual threat, a court would need to determine that the company's actions were unconscionable—an admittedly difficult standard to prove—despite the pharmaceutical company's ability to prove its justifiableness as it relates to its internal operations and needs; it does not have to compare its pricing to what is a “normal” price for a similar medication, nor is the pricing limited to a certain, arguably arbitrary percentage.<sup>216</sup>

Second, it is also important to remember that the Model Act does not seek to punish pharmaceutical companies for attempting to make a profit. Rather, the Model Act attempts to reign in unjustifiable, soaring pharmaceutical prices and regulate other unfair behavior. Again, the Model Act proposes a loose standard for high prices; the Act does not limit pricing by industry standards or a set percentage. Drug development and implementation is an expensive and risky endeavor, and pharmaceutical companies may rely on certain “profit making” medications to replenish their profits from other failed or less profitable ventures.<sup>217</sup> As a result, it makes sense that some products may cost more

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216. Arbitrary in this case would look like imposing a percentage cap (whether a percentage of the costs to develop that particular drug or something similarly related) that is used in anti-price-gouging statutes after emergencies.

217. See *supra* Part I.A.



because companies rely on them for profits. That said, this reliance itself does not justify selling the product at any price. It does not justify increasing the cost of medication 5000% when the company itself did not incur the costs of researching and developing the product, but rather bought patent rights from the organization that did.<sup>218</sup> A pharmaceutical company or patent holder can make a profit, and the Act does not intend to hinder that ability. However, the Act does not condone an organization pricing its products at unconscionable levels. Ultimately, if the pharmaceutical organization can justify its pricing decisions, then it can continue its practices.

However, a pharmaceutical company may still decide to pull its products from a state after being found to have engaged in unfair practices or unconscionably pricing its products. There are several responses to that event. First, the public would likely respond swiftly and with force. Public sentiment and collective action can influence business decisions and create social movements. If the public collectively decides to boycott a pharmaceutical company that puts peoples' lives in danger by refusing to sell a product at a less than unconscionable price, that could force the company to continue selling in the state. Profits matter, and hurting the bottom line draws attention. Second, even if the company refuses to continue selling its products, public outcry may finally persuade Congress to enact some sort of meaningful federal legislation to protect consumers from unfair acts and unconscionable pricing. If consumers put enough pressure on politicians, some change may come.

### CONCLUSION

Dramatic price increases in pharmaceutical products is not a new phenomenon. For decades, pharmaceutical companies have gouged consumers' pocketbooks by raising the prices of pharmaceuticals with no justifiable explanation. The federal government has been unable or unwilling to enact any meaningful legislation, and states that have tried to prohibit this behavior have found their efforts preempted by federal patent law.

This Note proposes that states can regulate pharmaceutical conduct, including pricing, by enacting a statute similar to the Model Act provided herein. States need to be sure to keep their statutes general enough to avoid preemption, and must conduct

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218. This is the case of Turing Pharmaceuticals and Daraprim, as well as Mylan and EpiPen. See Almendrala, *supra* note 2.

reasonable investigations of pharmaceutical companies' reasons for price increases, to effectively and fairly regulate unconscionable pricing and other unjust behavior. As expressed throughout this Note, this Model Act does not attempt to impinge on fair profit-making activities of pharmaceutical companies. Rather, this Note proposes that the law should no longer promote and tolerate unnecessary and unconscionable price increases of pharmaceutical products.