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## State Regulation of Generic Drug Price Gouging

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# STATE REGULATION OF GENERIC DRUG PRICE GOUGING

PHILIP FITZGERALD

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## INTRODUCTION

“I know he’s the most hated man in America,” said one of the prospective jurors in the securities fraud trial of Martin Skhreli – the notorious “Pharma Bro” who raised the price of a generic, life-saving drug from \$13.50 to \$750 per pill.<sup>1</sup> According to Zoe Thomas and Tim Swift at BBC News, “He’s been called a ‘morally bankrupt sociopath’, a ‘scumbag’ a ‘garbage monster’ and everything that is wrong with capitalism.”<sup>2</sup> To the public, Skhreli was the personification of rampant greed gone wrong; however, he was not alone in raising prices to unconscionable levels for life-saving drugs and other necessary medications. Around the same time that Skhreli’s company, Turing Pharmaceuticals LLC (“Turing”), was increasing prices, other companies, such as Valeant Pharmaceuticals International, Inc. (“Valeant”), Retrophin Inc. (“Retrophin”), and Rodelis Therapeutics (“Rodelis”) also increased prices on generic

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<sup>1</sup> Renae Merle, *Pharma Bro Trial Hits Speed Bump, Finding Jurors Who Don’t Already Dislike Him*, WASH. POST (June 28, 2017), [https://www.washingtonpost.com/news/business/wp/2017/06/27/pharma-bro-martin-skhreli-goes-on-trial-where-he-finds-another-kind-of-limelight/?utm\\_term=.ab4ad3364076](https://www.washingtonpost.com/news/business/wp/2017/06/27/pharma-bro-martin-skhreli-goes-on-trial-where-he-finds-another-kind-of-limelight/?utm_term=.ab4ad3364076).

<sup>2</sup> Zoe Thomas & Tim Swift, *Who is Martin Skhreli- “The Most Hated Man in America,”* BBC NEWS (Aug. 4, 2017), <http://www.bbc.com/news/world-us-canada-34331761>.

drugs to exorbitant levels.<sup>3</sup> While Skhreli drew the bulk of media attention through his ostentatious behavior,<sup>4</sup> the Government Accountability Office conducted a study that found that out of a basket of 1,441 established generic drugs, more than 300 had at least one extraordinary price increase of 100 percent or more from the beginning of 2010 to the beginning of 2015.<sup>5</sup>

These recent forays of pharmaceutical companies into charging whatever-the-market-will-bear for previously inexpensive treatments have made “price gouging” a key term in discussions on rising health care costs. Pursuant to such discussions, state legislators are working to pass laws that prevent pharmaceutical companies from charging excessive prices for their drugs.<sup>6</sup> In addition to the state of Maryland passing a generic drug price-gouging law in 2017, the states of Massachusetts, New York, Rhode Island, and Tennessee are also considering price gouging legislation to reign in pharmaceutical costs.<sup>7</sup> These laws attempt to remedy the situation by putting a cap on drug price increases and/or requiring greater pricing transparency in the pharmaceutical market.

This note acknowledges that the high cost of drugs, both generic and patented, is an important issue for patients and policy makers alike. This note focuses solely on generic drugs, as the rights of drug patent holders are protected by the Copyright Clause of the United States Constitution,<sup>8</sup> which this note does not seek to address. Additionally, although the cost of drugs can be heavily impacted by Congress and federal regulatory agencies such as the Department of Health and Human Services and the Food and Drug Administration, this note will only look at the measures being taken by legislatures at the state level.

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<sup>3</sup> Andrew Pollack, *Drug Goes from \$13.50 a tablet to \$750, Overnight*, N.Y. TIMES (Sept. 20, 2015),

<https://www.nytimes.com/2015/09/21/business/a-huge-overnight-increase-in-a-drugs-price-raises-protests.html?mcubz=0>.

<sup>4</sup> Emily Jane Fox, *Pharma Bro Martin Shkreli Is Even More Terrible Than You Thought*, VANITY FAIR (Feb. 19, 2016),

<https://www.vanityfair.com/news/2016/02/pharma-bro-martin-shkreli-threat>.

<sup>5</sup> U.S. Gov’t Accountability Off., GAO-16-706, *Generic Drugs Under Medicare: Part D Generic Drug Prices Declined Overall, but Some Had Extraordinary Price Increases* (Aug. 2016),

<https://www.gao.gov/assets/680/679022.pdf> [hereinafter GAO Report].

<sup>6</sup> *To Dent Soaring Drug Costs, States Turn to ‘Price-Gouging’ Laws*, MANAGED CARE MAG. (Sept. 6, 2017),

<https://www.managedcaremag.com/archives/2017/9/dent-soaring-drug-costs-states-turn-price-gouging-laws>.

<sup>7</sup> *Id.*

<sup>8</sup> U.S. Const. art. I, § 8, cl. 8.

Part I of this note will explain how generic drugs are brought to market, how manufacturers were able to charge so much for these generic or off-patent drugs without challenges from competitors, as well as what the consequences of price spikes are for patients, hospitals and insurers. Part I will also delve into the history of price gouging laws and examine the results from past economic regulations. Part II of this note will analyze the benefits and drawbacks of the relevant state laws and legislation regulating generic drug price increases. Part III of this note argues that state laws that cap prices on generic drugs should not be enacted, as they may result in shortages of necessary drugs; however, laws requiring greater transparency for drug price increases should be enacted to allow patients and providers the opportunity to find alternatives and to signal competitors that there may be an opportunity to enter the market.

## I. BACKGROUND ON GENERIC DRUGS AND THE HISTORY OF PRICE GOUGING LAWS

### A. Price Spikes in the Generic Market

Analyzing new laws regarding the generic drug market requires an understanding of the Hatch-Waxman Act (“Act”), which created the modern generic drug industry.<sup>9</sup> The Act was intended “to balance two conflicting policy objectives: to induce name-brand pharmaceutical firms to make the investments necessary to research and develop new drug products, while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market.”<sup>10</sup> Prior to the Act, when a manufacturer wished to produce a drug for which patent protection had expired, the manufacturer was required to conduct expensive and lengthy premarket clinical trials of the drug to prove its safety and efficacy.<sup>11</sup> This costly process reduced the incentive for manufacturers to enter the generic drug market, which resulted in less competition and higher prices for prescription drugs.<sup>12</sup>

To ensure a competitive market that would lower prices, the Act established an expedited system for generic drug approval.<sup>13</sup>

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<sup>9</sup> See 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 (2015).

<sup>10</sup> *Abbot Labs. v. Young*, 920 F.2d 984, 991 (D.C. Cir. 1990)(Edwards, J., dissenting).

<sup>11</sup> Kesselheim, *supra* note 9, at 297.

<sup>12</sup> *Id.*

<sup>13</sup> *Id.* at 301.

Rather than conduct clinical trials, the generic drug manufacturer only had to show that the active ingredients in the new generic drug were the same as the original listed drug, that the “route of administration, the dosage form, and the strength of the new drug [were] the same as those of the listed drug, and that the generic drug [was] absorbed by the body at the same rate as the listed drug (bioequivalent).”<sup>14</sup> Because it was easier for manufacturers to enter the market, robust competition in the generic pharmaceutical industry ensued. The new process under the Act resulted in decades of relief from rising prescription drug costs.<sup>15</sup> On average, generic drugs cost 80 percent less than brand-name drugs.<sup>16</sup> How then was Skhrelis and his ilk able to raise their prices on generic and off-patent<sup>17</sup> drugs as if they had a monopoly?

Following a spate of high profile drug price spikes, the bipartisan Senate Special Committee on Aging began an investigation into abrupt and dramatic price increases in prescription drugs whose patents had expired.<sup>18</sup> Turing, Valeant, Retrophin, and Rodelis were the focus of the investigation and the committee uncovered a business model used by these companies to exploit market failures. The business model consists of five key elements: (1) acquire a sole-source drug, with only one manufacturer and no immediate competition; (2) ensure the drug was the gold standard—the best drug for the condition it treats; (3) select a drug serving a

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<sup>14</sup> *Id.* at 301-02 (quoting 21 U.S.C. § 355 (j)(2)(A)(ii)-(iii)).

<sup>15</sup> *Understanding Recent Trends in Generic Drug Prices*, U.S. Dep’t of Health and Human Servs., (Jan. 27, 2016), available at <https://aspe.hhs.gov/pdf-report/understanding-recent-trends-generic-drug-prices>.

<sup>16</sup> Senate Special Committee on Aging, *Sudden Price Spikes in Off-Patent Prescription Drugs: The Monopoly Business Model that Harms Patients, Taxpayers, and the U.S. Healthcare System* (2016) [hereinafter “Sudden Price Spikes”], available at <https://www.congress.gov/114/crpt/srpt429/CRPT-114srpt429.pdf>.

<sup>17</sup> For purposes of this note “off-patent” refers to a drug that is not under patent protection and “generic” refers to one that is the biological equivalent of another drug. *See generally* Generic Drug Development, FDA, <https://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/abbreviatednewdrugapplicationsandgenerics/ucm142112.htm> (last updated July 19, 2018).

<sup>18</sup> *See, e.g.*, Press Release, *Collins, McCaskill Open Senate Investigation into Rx Drug Pricing, Announce Intention to Hold Hearings*, Senate Special Committee on Aging, (Nov. 4, 2015), <https://www.aging.senate.gov/press-releases/collins-mccaskill-open-senate-investigation-into-rx-drug-pricing-announce-intention-to-hold-hearings>.

small market which would be unattractive to competitors and which was too small to mount an organized opposition; (4) control access to the drug through a closed distribution system where a drug could not be obtained through normal channels, thus depriving competitors access to samples of the drug for bioequivalency tests; and (5) price gouge by charging as much as possible.<sup>19</sup>

The drug that Turing acquired, Daraprim, is used to treat a rare tropical parasite, toxoplasmosis, that typically is only dangerous in HIV/AIDS and cancer patients due to their weakened immune system.<sup>20</sup> Daraprim is an off-patent drug for which patent protection had expired decades ago; however, at the time, there were no other manufacturers producing it.<sup>21</sup> This made Daraprim a sole-source drug.

Turing believed that Daraprim was considered by physicians to be the gold standard of drugs for treating toxoplasmosis, and that doctors would go out of their way to make sure patients had access to the drug because it was the best available treatment.<sup>22</sup> There was a substandard alternative to Daraprim used by a small subset of physicians, but it did not diminish Daraprim's value as the gold standard.<sup>23</sup>

Daraprim was also a small market drug; it only sold 9,708 units (bottles) in 2014 with net sales under \$5 million.<sup>24</sup> Turing had analyzed the market and found that just 10.8 percent of off-patent drugs with under \$10 million in annual sales faced generic competition within three years.<sup>25</sup> Turing found that a significant amount of effort and resources was required to serve small patient populations, and that manufacturers were not likely to compete in those markets.<sup>26</sup> Additionally, Turing also believed that the number of Daraprim patients was "too small to stimulate a significant lobbying effort were the cost of therapy to become an issue."<sup>27</sup> If the price were to rise drastically, Turing counted on the relatively insignificant population to be ignored.

Turing not only purchased a sole-source drug, but also attempted to protect its *de facto* monopoly status by restricting its

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<sup>19</sup> Sudden Price Spikes, *supra* note 16, at 4.

<sup>20</sup> Naren P. Tallapragada, *Off-Patent Drugs at Brand-Name Prices: A Puzzle for Policymakers*, J. LAW BIOSCI. 3 (1): 238-47 (2016).

<sup>21</sup> *Id.*

<sup>22</sup> Sudden Price Spikes, *supra* note 16, at 34.

<sup>23</sup> *Id.*

<sup>24</sup> *Id.* at 36.

<sup>25</sup> *Id.*

<sup>26</sup> *Id.*

<sup>27</sup> *Id.* (Turing's internal documents).

distribution.<sup>28</sup> Under “closed distribution,” the drug cannot be obtained through normal pharmacy channels, but instead had to be obtained from “specialty” pharmacies.<sup>29</sup> This means that Turing could control the distribution of its product to prevent other generic drug manufacturers from getting their hands on Daraprim.<sup>30</sup> For a drug manufacturer to get a generic alternative approved by the FDA, the manufacturer must perform bioequivalency tests, and the manufacturer is required to have a supply of the original drug.<sup>31</sup> By closing distribution, Turing was able to keep Daraprim out of the hands of any generic manufacturers who would try to manufacture a lower priced alternative. Lastly, the goal of this business plan is to charge monopoly prices, and Turing completed the final phase of its business plan by raising the price of Daraprim 5,000 percent overnight.<sup>32</sup>

Drug price spikes have a terrible effect on patients gaining access to the treatment they need. These price increases also interfere with physicians and hospitals providing care to their communities. Furthermore, price increases also elevate the costs of private insurance and government programs, which have a broader impact on all consumers.

Sudden price hikes can create a financial crisis that compounds a patient’s health issues. The Senate Committee on Aging found that following price spikes, some patients were forced to go without vital medicine, skip doses, or hoard pills out of fear that their next refill would not be affordable.<sup>33</sup> Patients who were able to maintain coverage for their medication through insurance worried that they could lose access without warning if the drugs were dropped from their insurance plan’s formulary, and patients getting their medication through Patient Assistance Programs<sup>34</sup> worried that their application for assistance could be denied at any point.<sup>35</sup>

Following Turing’s price increase of Daraprim, from \$1,350 to \$75,000 for a bottle of 100 pills, patients experienced treatment interruptions or went without treatment entirely, and some insurance

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<sup>28</sup> *Id.*

<sup>29</sup> *Id.*

<sup>30</sup> *Id.* at 37.

<sup>31</sup> *Id.* at 31

<sup>32</sup> Pollack, *supra* note 3.

<sup>33</sup> Sudden Price Spikes *supra* note 16 at 98.

<sup>34</sup> Patient Assistance Programs help patients who cannot afford the drugs they need. *See, e.g., Merck’s Patient Assistance Program, Merck Helps* (last visited on May 23, 2018), <https://www.merckhelps.com>.

<sup>35</sup> Sudden Price Spikes, *supra* note 16, at 98.

companies made it more difficult for their beneficiaries to get Daraprim.<sup>36</sup>

When Valeant raised prices on two of its drugs used to treat Wilson disease,<sup>37</sup> patients who had been successfully managing their disease with those drugs for most of their lives were suddenly at risk of losing treatment.<sup>38</sup> While some patients managed to get assistance in order to obtain the medication they needed, many had to go without medication for some time, thus increasing the risk to their health, while others switched to medications that posed additional risks, side effects and lifestyle restrictions.<sup>39</sup>

Price spikes can also affect patients by placing undue burdens on physicians, hospitals and insurers. Valeant had increased the prices of two drugs that were primarily used by hospitals for emergency care: one by 720 percent and the other by 310 percent.<sup>40</sup> The Committee found that the extra costs put a strain on hospital budgets, and in attempting to lower costs, physicians lost time with patients, which contributed to hospital inefficiency because they had to expend effort searching for substitute drugs and developing new treatment protocols.<sup>41</sup> Additionally, hospitals began rationing these drugs and did not stock them on every crash cart in the hospital, which increased the time it took for a patient to receive the drugs in an emergency.<sup>42</sup> The Committee also heard testimony that the increased drug prices would cause hospitals to cut back on services to the broader community.<sup>43</sup>

Rising drug prices also affect private insurance companies by increasing costs, which are then passed on to the consumer in the

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<sup>36</sup> *Id.* at 102.

<sup>37</sup> Wilson's disease can be fatal if left untreated, serious complications include scarring of the liver, liver failure, persistent neurological problems, kidney problems, psychological problems, and blood problems. *Wilson's Disease*, Mayo Clinic (March 7, 2018), <https://www.mayoclinic.org/diseases-conditions/wilsons-disease/symptoms-causes/syc-20353251>.

<sup>38</sup> Sudden Price Spikes *supra* note 16 at 99.

<sup>39</sup> *Id.* citing Qato, Dima M, et al., *Changes in Prescription and Over-the-Counter Medication and Dietary Supplement Use Among Older Adults in the United States, 2005 vs 2011*, 176 J. AM. MED. ASSOC. 473, 473 (Apr. 2016).

<sup>40</sup> Sudden Price Spikes *supra* note 16 at 64.

<sup>41</sup> *Id.* at 105.

<sup>42</sup> *Id.*

<sup>43</sup> Sudden Price Spikes *supra* note 16 at 105 (explaining that initiatives to connect low-income and vulnerable communities with health care services, food, transportation and housing, as well as initiatives to stem the opioid crises would be at risk of being cut because of price hikes).

form of higher premiums and/or a lower percentage of coverage.<sup>44</sup> A patient with insurance coverage may not notice the immediate effect of a price spike (unless they have a high deductible to meet and are billed for the prescription); however, the patient will still feel the effect in the form of across-the-board increases in premium costs, deductibles and consumer cost share.<sup>45</sup>

Federal government programs such as Medicare, Medicaid, Veterans Affairs and the Children's Health Insurance Program spend around \$126 billion on prescription drugs.<sup>46</sup> Drug price spikes contribute to higher government expenditures, which are ultimately borne by American taxpayers.

In 2016, Medicare asked the Government Accountability Office ("GAO") to study trends in generic drug pricing.<sup>47</sup> The GAO interviewed manufacturers, pharmacy associations, plan sponsors and their Pharmacy Benefit Managers ("PBM") – almost all of which indicated that competition, influenced by various factors, impacts the price of generic drugs.<sup>48</sup> The manufacturers explained that the generic drug market operates like a commodities market – the manufacturers submit their offer to their customers (pharmacies or wholesalers), and if another manufacturer offers a lower price to a customer, then the competing offeror is asked to match the price or risk losing market to the other manufacturer.<sup>49</sup> When a manufacturer brings a generic drug into an established market, it typically offers a lower price than that of the current market in order to build its customer base.<sup>50</sup> The price falls as each new

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<sup>44</sup> Skinner, Ginger, *Why Drug Costs Keep Rising—and What You Can Do About It*. CONSUMER REPORTS (May 16, 2017), available at <https://www.consumerreports.org/drug-prices/why-drug-costs-keep-rising-what-you-can-do-about-it/> (explaining that insurance companies may also reduce coverage for certain drugs during the year or drop them entirely from their formulary).

<sup>45</sup> *Is There a Cure for High Drug Prices?*, CONSUMER REPORTS, <https://www.consumerreports.org/drugs/cure-for-high-drug-prices/> (last updated July 29, 2016),

<sup>46</sup> Sudden Price Spikes *supra* note 16 (citing CMS, *Prescription Drug Expenditures*, National Health Expenditures by Type of Service and Source of Funds, CY 1960-2015, at lines 287,289,292,294,295,299,302, and 308, which totals to \$126.246 billion, <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.html>).

<sup>47</sup> GAO Report *supra* note 5.

<sup>48</sup> *Id.* at 23.

<sup>49</sup> *Id.*

<sup>50</sup> *Id.*

manufacturer enters the market, with one manufacturer noting that each entrant typically results in a twenty-percent decline in price.<sup>51</sup> The price stays low until manufacturers begin exiting the market.<sup>52</sup> As such, it follows that prices should fall if manufacturers decide later on to re-enter the market.

While generic drugs contribute to lower overall drug prices, the GAO found that the rate at which generic drugs contribute to lower prices is declining.<sup>53</sup> The GAO also found that the decline in generic drug prices has been significantly slowed by price hikes.<sup>54</sup> Out of a basket of 1,441 generic drugs, the GAO found that 315 drugs experienced an extraordinary price increase (categorized as one-hundred percent or more) from 2010 to 2015.<sup>55</sup> These drugs increased the average price of the GAO's established drug basket by twenty-five percentage points. Specifically, the average price of the 1,441 drugs fell by fourteen percent – when calculated without those 315 drugs, the average price fell by thirty-nine percent.<sup>56</sup> Furthermore, the GAO also found that the price increases lasted for longer than a year and most did not go down in price after the increase.<sup>57</sup> Price spikes are an emerging trend in the generic drug market and have considerably slowed the downward movement in generic drug prices. While Martin Skhreli managed to exploit a sole-sourced drug for monopoly level price hikes, extraordinary price increases have been occurring with greater frequency throughout the generic drug market. These price hikes place patients' overall health and well-being at risk while simultaneously increasing insurance costs and costs of government programs.

## B. Price Gouging Laws

Governments have a long history of using price controls to assuage popular enmity against rising prices.<sup>58</sup> Price controls have been an issue dating as far back as the Second Century A.D., when the Roman Empire was challenged by rapid price increases in

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<sup>51</sup> *Id.*

<sup>52</sup> *Id.*

<sup>53</sup> *See Id.* at 16.

<sup>54</sup> *Id.*

<sup>55</sup> *Id.*

<sup>56</sup> *Id.*

<sup>57</sup> *Id.* at 17.

<sup>58</sup> *See generally* Hugh Rockoff, *Drastic Measures: A History of Wage and Price Controls in the United States*, (Cambridge University Press 1984); *see also* *Income Policies In the United States: Historical Review and Some Issues*, Congressional Budget Office (1977), available at <https://www.cbo.gov/publication/20636?index=10150>.

commodities.<sup>59</sup> At the time, emperor Diocletian had recently split the empire into four ruling parts, which had the effect of raising taxes across the land. Additionally, emperor Diocletian had also debased the currency, which resulted in a rapid upwards movement in pricing.<sup>60</sup> Diocletian blamed the price increases on greed, and he intended to rectify the problem through government intervention, stating:

But since it is the sole desire of untamed fury to feel no love for the ties of our common humanity . . . it suits us, who are the watchful parents of the whole human race, that justice step in as an arbiter in the case, in order that the long-hoped-for result, which humanity could not achieve by itself, may, by the remedies which our fore-thought suggests, be contributed toward the general alleviation of all.<sup>61</sup>

To combat high prices, Diocletian issued his Edict fixing maximum prices for thousands of consumer items.<sup>62</sup> Stiff penalties were imposed on any merchant selling wares for more than the mandated maximum price.<sup>63</sup> This resulted in a drastic shortage of goods as merchants hoarded their wares, awaiting a better time to sell.<sup>64</sup> Prices went even higher, and any trading that happened occurred on the black market.<sup>65</sup> Despite the good intentions behind the Edict, Diocletian's price fixing solution had resulted in even higher prices, and four years after the Edict, Diocletian abdicated his power and the law was rescinded.<sup>66</sup>

A more recent example of a price control legislation is Hawaii's gas cap law. In 2002, Hawaii became the first state to pass

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<sup>59</sup> *Id.* at 35.

<sup>60</sup> *Id.* at 37-38; see also Hans Kirchberger, *An Ancient Experience With Price Control*, J. OF FARM ECON., Vol. 24, No. 3 621-636 (Aug. 1942) (explaining that farmers let land go untilled because high taxes made it unprofitable to work the land, and subsequently because food was in shorter supply, prices went up. As a means of getting more money into circulation to help with the price increases, rather than cutting taxes on farmers, Diocletian replaced silver coins for copper, essentially debasing the currency, which resulted in rapid price hikes which were met with price controls.)

<sup>61</sup> Roland G. Kent, *The Edict of Diocletian Fixing Maximum Prices*, 69 U. PA. L. REV. 35, 41-42 (1921)

<sup>62</sup> *Id.* at 39.

<sup>63</sup> *Id.* at 40.

<sup>64</sup> *Id.*

<sup>65</sup> *Id.*

<sup>66</sup> *Id.*

legislation with the main objective of establishing a maximum wholesale gasoline price cap.<sup>67</sup> At the time, Hawaii's gasoline market had not only posted the highest prices in the country for the past five years, but also maintained an "upwardly sticky" trend which did not fluctuate downward with the rest of the country.<sup>68</sup> The legislature perceived that there was a lack of competition at the wholesale level, and responded by enacting a law to cap prices for gasoline sold from the refinery.<sup>69</sup> The price was capped at the average regular unleaded gasoline price of three interstate markets.<sup>70</sup> After the wholesale cap went into effect, prices at the pump promptly went up, with some experts opining that prices would have gone higher without the price cap, and detractors saying that it increased prices because it allowed gas companies to charge up to the maximum allowed.<sup>71</sup> The law was suspended by the state's governor eight months after it went into effect.<sup>72</sup>

A few years after the suspension, studies indicated that the price for fuel was trading at more than what the capped price would have pegged it at.<sup>73</sup> An argument in favor of the price caps was that oil costs were on an upward trajectory when the caps were implemented, so even though it did not appear that the caps were working to the Hawaiians, prices were still held in check relative to where they would have risen.<sup>74</sup>

Many price gouging laws were enacted by state legislatures because of complaints from the public about price hikes for essential goods following a disaster.<sup>75</sup> Following the terrorist attacks of

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<sup>67</sup> See Brandon H. Ito, *Price Controls in Paradise: Foreshadowing the Legal and Economic Consequences of Hawai'i's Gasoline Price Cap Law*, 27 U. HAW. L. REV. 549 (2005).

<sup>68</sup> *Id.* at 550 (explaining that prices would go up when the mainland price goes up, but prices would not go down when the mainland price went down, taking into account transportation costs of the oil to Hawaii and its surrounding islands).

<sup>69</sup> *Id.* at 551.

<sup>70</sup> *Id.*

<sup>71</sup> Mark Niese, *Hawaii Gas Cap Running on Fumes*, WASH. POST (May 6, 2006), <http://www.washingtonpost.com/wp-dyn/content/article/2006/05/05/AR2006050501294.html>.

<sup>72</sup> *Id.*

<sup>73</sup> Greg Wiles, *Hawaii Gas Above 'Cap' Level of Suspended Law*, HONOLULU ADVERTISER, Jan. 27 2010, <http://the.honoluluadvertiser.com/article/2010/Jan/27/ln/hawaii1270349.html>.

<sup>74</sup> *Id.*

<sup>75</sup> Geoffrey C. Rapp, *Gouging: Terrorist Attacks, Hurricanes, and the Legal and Economic Aspects of Post-Disaster Price Regulation*, 94 KY. L.J. 535, 542 (2006).

September 11, 2001, some businesses in Tennessee engaged in price gouging, which spurred the legislature to enact a law to protect consumers when a “declared state of emergency results in abnormal disruptions of the market.”<sup>76</sup> Tennessee’s law also states that “protecting the public from price gouging is a vital function of state government in providing for the health, safety, and welfare of consumers.”<sup>77</sup> California also has a price gouging statute, which was enacted to protect consumers following a natural or man-made disaster.<sup>78</sup> More than half of all states in the U.S. have some form of price gouging law on the books.<sup>79</sup> These laws typically follow one of three models in instituting price caps:

- 1) Percentage Price Caps that bar price hikes from exceeding a percentage increase from the pre-emergency level.
- 2) Unconscionability laws that focus on gross disparities between the offered price and the price prior to the emergency.
- 3) No Increase laws that bar any price increases beyond costs associated with the disaster.<sup>80</sup>

Although prohibitions on excessive price increases following a disaster are supported by most people, economists claim that they “discourage extraordinary supply efforts that would help bring goods in high demand into the affected area.”<sup>81</sup> A prevailing argument against price controls is that price caps reduce the supply of the product being regulated.<sup>82</sup> In a market, prices are set by two

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<sup>76</sup> Tenn. Code. Ann. § 47-18-5101 (2002).

<sup>77</sup> *Id.*

<sup>78</sup> Ca. Penal Code § 396.

<sup>79</sup> Emily Bae, *Are Anti-Price Gouging Legislations Effective Against Sellers During Disasters*, 4 ENTREPRENEURIAL BUS. L.J. 79, 83 (2009).

<sup>80</sup> *Id.*

<sup>81</sup> Andrew Sorkin, *Hurricane Price Gouging is Despicable, Right? Not to Some Economists*, N.Y. TIMES (Sept. 11, 2017) (quoting Michael Giberson, instructor with the Ctr. for Energy Commerce in the Rawls College of Bus. at Texas Tech Univ.), <https://www.nytimes.com/2017/09/11/business/hurricane-price-gouging.html>.

<sup>82</sup> See John Maynard Keynes, *The Economic Consequences of the Peace* (1920) (“The presumption of a spurious value for the currency, by the force of law expressed in the regulation of prices, contains in itself, however, the seeds of final economic decay, and soon dries up the sources of ultimate supply”), available at <https://www.gutenberg.org/files/15776/15776-h/15776-h.htm>; see also Bruce Bartlett, *The Futility of Price Controls*, FORBES (Jan. 15, 2010),

factors: (1) the buyer's demand and (2) the seller's supply. The more the buyer demands the product, the more the seller can charge.<sup>83</sup> Economists argue that in a free market, high prices are inevitable until demand subsides or supply expands.<sup>84</sup> High prices are an important element in getting necessary resources where they are most needed, but an artificial cap on prices will result in a shortage of supply, thus leaving people without the commodities they need.<sup>85</sup> Price hikes following a disaster signal scarcity, which puts consumers on notice to be more judicious in their use of resources, and those prices signal to potential producers that there is room to enter the market.<sup>86</sup> If prices are kept artificially low then consumers will not conserve scarce resources and producers will not increase supplies, which would result in shortages of necessary goods.<sup>87</sup> Although public sentiment may demand a political solution to the problem of price hikes, oftentimes price controls result in shortages.

## II. STATE LAWS REGULATING DRUG PRICES

In the last year, many states have introduced legislation with the purpose of countering prescription drug price hikes.<sup>88</sup> Such legislation typically attempts to regulate prices by either placing a cap on drug price increases, or by requiring detailed reporting and advance notice of large price increases to relevant state agencies.<sup>89</sup>

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<https://forbes.com/2010/01/14/venezuela-inflation-price-controls-opinions-columnists-bruce-bartlett.html#e0472c658272>.

<sup>83</sup> Emily Bae, *Are Anti-Price Gouging Legislations Effective Against Sellers During Disasters*, 4 ENTREPRENEURIAL BUS. L.J. 79, 81 (2009) (citing Eugene Silberberg, *Principles of Microeconomics* (Pearson Custom Publishing 5<sup>th</sup> 2007)).

<sup>84</sup> See Gregory N. Mankiw, *I Paid \$2,500 for a 'Hamilton' Ticket. I'm Happy About It*, N.Y. TIMES (Oct. 21, 2016), <https://www.nytimes.com/2016/10/23/upshot/i-paid-2500-for-a-hamilton-ticket-im-happy-about-it.html?smprod=nytcore-iphone&smid=nytcore-iphone-share&mtrref=t.co>.

<sup>85</sup> Donald J. Boudreaux, *Price Gouging' after a Disaster is Good for the Public*, WALL ST. J. (Oct. 3 2017), <https://www.wsj.com/articles/price-gouging-after-a-disaster-is-good-for-the-public-1507071457>.

<sup>86</sup> Sorkin, *supra* note 81.

<sup>87</sup> Matt Zwolinski, *The Ethics of Price Gouging*, BUS. ETHICS Q., 18(3), 347, 362-63 (2008), [http://facpub.stjohns.edu/~flanagap/3305/readings/Zwolinski\\_Price\\_Gouging.pdf](http://facpub.stjohns.edu/~flanagap/3305/readings/Zwolinski_Price_Gouging.pdf)

<sup>88</sup> Boudreaux, *supra* note 85.

<sup>89</sup> Kimberly Leonard, *California to Pass Drug Price Transparency Bill*, WASH. EXAMINER (Dec. 8, 2017),

On October 1, 2017, Maryland became the first state in the country to enact a generic drug price gouging law.<sup>90</sup> The first-of-its-kind law has both a price gouging prohibition and a notice requirement. First, it prohibits manufacturers of essential off-patent or generic drugs from engaging in price gouging.<sup>91</sup> Second, it allows the Maryland Medical Assistance Program (“MMA”) to notify the Attorney General of any increase in the price of any essential off-patent or generic drug.<sup>93</sup>

Under the first provision, an off-patent or generic drug means any prescription drug for which exclusive marketing rights have expired.<sup>94</sup> A drug that is “essential” is defined as one that has either appeared on the Model List of Essential Medicines adopted by the World Health Organization,<sup>95</sup> or that has been designated as essential by the Secretary because of its effectiveness in treating life-threatening or debilitating chronic health conditions.<sup>96</sup> Maryland’s law defines price gouging as “an unconscionable increase in the price of a prescription drug.”<sup>97</sup> An “unconscionable increase” is an “excessive” increase which is not justified by the cost of producing or marketing the drug, and the consumer has no meaningful choice about purchasing the drug, either because they need it for their health or because there is not enough competition in the market.<sup>98</sup>

Under the notice provision, MMA may notify the Attorney General if the price increases 50% or more in the wholesale acquisition or in the price paid by MMA for the drug within the preceding one year period.<sup>99</sup> The Attorney General may request from the drug manufacturer a statement that itemizes the components of the cost of producing the drug and identifies the circumstances and timing of any expenditures made by the

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<http://www.washingtonexaminer.com/california-to-pass-drug-price-transparency-bill/article/2636919>.

<sup>90</sup> Md. Code Ann., Health–Gen. § 2-802 (2017)

<sup>91</sup> *Id.*

<sup>92</sup> Maryland’s name for its Medicaid program. See Public Assistance, Maryland.gov, [dhr.maryland.gov/weathering-tough-ties/medical-assistance/#medi](http://dhr.maryland.gov/weathering-tough-ties/medical-assistance/#medi) (last visited Sept. 4, 2018).

<sup>93</sup> § 2-803.

<sup>94</sup> § 2-801(b)(1)(i).

<sup>95</sup> *Model List of Essential Medicines*, World Health Organization (2017), available at

[http://www.who.int/medicines/publications/essentialmedicines/20th\\_EM\\_L2017\\_FINAL\\_amendedAug2017.pdf?ua=1](http://www.who.int/medicines/publications/essentialmedicines/20th_EM_L2017_FINAL_amendedAug2017.pdf?ua=1).

<sup>96</sup> § 2-801(b)(2)(ii).

<sup>97</sup> § 2-801(c).

<sup>98</sup> § 2-801(f).

<sup>99</sup> § 2-803(a)(1).

manufacturer to market the drug.<sup>100</sup> A manufacturer may be required to produce any relevant records or other documents.<sup>101</sup>

After Maryland's generic drug price gouging bill was passed into law, the Association for Accessible Medicine ("AAM") brought an action challenging the constitutionality of the new law.<sup>102</sup> AAM is a non-profit, voluntary association representing a number of manufacturers and distributors of generic and biosimilar medicines.<sup>103</sup> AAM alleged that Maryland's law violates the dormant Commerce Clause because it "regulates conduct occurring wholly outside the state, because its members are manufacturers and wholesalers of generic drugs who almost all reside outside of Maryland, operate under national contracts, and do not sell directly to actors in Maryland."<sup>104</sup> AAM also alleged that Maryland's law is impermissibly vague under the Due Process Clause of the 14th amendment because "the definition of 'unconscionable' increase' is keyed on 'expansive adjectives,' including 'excessive,' 'justified,' 'appropriate,' and 'meaningful.'"<sup>105</sup> On the Defendants' Motion to Dismiss, the district court dismissed the first cause of action under the dormant Commerce Clause,<sup>106</sup> but did not dismiss AAM's claim under the Fourteenth Amendment Due Process Clause.<sup>107</sup> AAM then appealed, and the Fourth Circuit held that Maryland's statute was unconstitutional because it violated the dormant commerce clause.<sup>108</sup> The Court emphasized that it was not prohibiting Maryland from regulating price gouging, only that Maryland could not do so "in the manner utilized by the Act."<sup>109</sup> Maryland may

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<sup>100</sup> § 2-803(b).

<sup>101</sup> § 2-803(c).

<sup>102</sup> Ass'n for Accessible Meds. v. Frosh, No. MJG-17-1860, 2017 U.S. Dist. LEXIS 161168 (D. Md. Sep. 29, 2017).

<sup>103</sup> *Id.* at \*2.

<sup>104</sup> *Id.* at \*14.

<sup>105</sup> *Id.* at \*2,\*26.

<sup>106</sup> *Id.* at \*15,\*21-22 (finding that Maryland's law would only be applicable to prices charged on drugs to be sold within Maryland, and that the State's legitimate interest in protecting its citizens was not shown by AAM to be outweighed by the burden on interstate commerce).

<sup>107</sup> *Id.* at \*26-28 (finding that the term "unconscionable" has been defined by judges only in the contracts context, and even though the term is defined within the statute with broader language, the comparative term "excessive" requires a benchmark to measure from, which is not clearly stated in the law).

<sup>108</sup> Ass'n for Accessible Meds. v. Frosh, 887 F.3d 664, 674 (4<sup>th</sup> Cir. 2018) (sympathizing with affected consumers but constrained to apply the dormant commerce clause).

<sup>109</sup> *Id.* (finding that the Act regulated transactions that took place outside of Maryland).

petition the Supreme Court for a writ of certiorari, or it may simply redraft the law to only regulate in-state transactions, as the Court seems to be suggesting.<sup>110</sup> Regardless of how Maryland goes forward, one of the main criticisms is that price gouging laws will have the unintended consequence of affecting the availability of essential generic drugs in Maryland.<sup>111</sup> If Maryland enacts a law which becomes too burdensome on pharmaceutical companies, they may simply exit the market, which would force residents to acquire their drugs from outside the state.

On October 9, 2017, California passed a law requiring drug companies to provide advance notice of drug price increases.<sup>112</sup> The law requires manufacturers to notify purchasers in writing and at least sixty days prior to an increase of over sixteen percent of a prescription drug's price.<sup>113</sup> Manufacturers must also report information about drug price increases quarterly to the Office of Statewide Health Planning and Development.<sup>114</sup> The report requires virtually all financial information related to the cost of the drug, the history of the drug's acquisition, and whether any changes have been made to the drug.<sup>115</sup> This information will be published within sixty days of receipt from a manufacturer on a per drug basis to ensure identification.<sup>116</sup> This law creates much greater transparency for drug price increases and puts all interested parties, including competitors, on notice that prices are rising.

Shortly after being enacted, California's law was challenged by the Pharmaceutical Research and Manufacturers of America ("PhRMA") as being unconstitutional as a violation of: (1) the Commerce Clause, because it directly restricts the drug list price used nationwide; (2) the First Amendment, because the mandatory reporting requirement constitutes compelled speech; and (3) the Fourteenth Amendment's Due Process Clause, because the language of the statute does not address notice requirements for price

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<sup>110</sup> *Id.* (explaining that "Maryland must address this concern via a statute that complies with the dormant commerce clause of the U.S. Constitution").

<sup>111</sup> Thomas Hemphill, *Maryland's Drug Pricing Law: The Potential Consequences*, REALCLEAR HEALTH (June 9, 2017), [http://www.realclearhealth.com/articles/2017/06/09/marylands\\_drug\\_price\\_gouging\\_law\\_the\\_potential\\_consequences\\_110628.html](http://www.realclearhealth.com/articles/2017/06/09/marylands_drug_price_gouging_law_the_potential_consequences_110628.html).

<sup>112</sup> S.B. 17, Cal. 2017-2018, reg. sess. (Cal. 2017)(enacted).

<sup>113</sup> *Id.* at 127677.

<sup>114</sup> *Id.* at 127679.

<sup>115</sup> *Id.*

<sup>116</sup> *Id.*

increases that occur within sixty days of the enactment of the law.<sup>117</sup> In addition to the constitutional arguments, criticisms of California's law are that the advance notice requirement diminishes competition by creating informal price arrangements between manufacturers,<sup>118</sup> and that the law would create shortages by encouraging wholesalers and distributors to stockpile drugs in the sixty days prior to the increase so that they may benefit from buying the drug at the lower price and selling it when it goes up.<sup>119</sup> However, since informal price fixing schemes can easily occur over dinner meetings and phone calls,<sup>120</sup> the risk that a reporting requirement intended to protect consumers will facilitate price fixing is significantly outweighed by its benefits. Additionally, stockpiling is not a real issue since most manufacturers already negotiate distribution service agreements with wholesalers that recapture the value of price appreciation, which prevents the wholesaler from benefiting on inventory bought at a lower price.<sup>121</sup> California's transparency law may work to discourage price hikes because its advance notice requirement would signal to consumers to seek alternatives, and it would also signal to competitors that there may be room to enter the market.

Tennessee has also recently proposed legislation in response to drug price increases. Tennessee's proposed legislation is known as the "Prescription Drug Fair Pricing Act" ("PDFPA").<sup>122</sup> Under the proposed legislation, the commissioner of health in consultation with TennCare<sup>123</sup> will examine changes in prices for essential generic drugs in prescription drug programs operated by the state

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<sup>117</sup> Complaint for Declaratory and Injunctive Relief ¶¶ 1-12, *Pharmaceutical Research and Manufacturers of America v. Brown*, No. 2:17-cv-02573 (E.D. Cal. Dec. 8, 2017).

<sup>118</sup> *Id.* at ¶ 6.

<sup>119</sup> Ian Spatz, *California Takes on Drug Pricing: Real Progress or Illusion?*, HEALTH AFFAIRS (Oct. 2, 2017), <https://www.healthaffairs.org/doi/10.1377/hblog20171002.062240/full/>.

<sup>120</sup> See Jeremy Olson, *Minnesota Expands Generic Medicine Price-Fixing Lawsuit*, STAR TRIBUNE (Oct. 31, 2017) (reporting that a Minnesota sales person arranged meetings where company reps could agree to inflate prices), <http://www.startribune.com/price-fixing-lawsuit-targeting-minnesota-reps-is-expanded/454325993/>.

<sup>121</sup> *How Wholesalers Profit from Brand Name Price Inflation*, DRUG CHANNELS (Oct. 5, 2015), <http://www.drugchannels.net/2015/10/how-wholesalers-profit-from-brand-name.html>.

<sup>122</sup> H.B. 1328, 110th Gen. Assemb., first reg. sess. (Tenn. 2017).

<sup>123</sup> TennCare is the state of Tennessee's Medicaid program. See TennCare, [tn.gov https://www.tn.gov/tenncare/members-applicants/eligibility/tenncare-medicaid.html](http://www.tn.gov/tenncare/members-applicants/eligibility/tenncare-medicaid.html) (last visited on Jan. 5, 2018).

over the past five years.<sup>124</sup> The commissioner shall report the finding of the study and any recommendations for appropriate action to prevent price gouging for essential generic drugs. Additionally, the PDFPA would require the Commissioner of Commerce and Insurance to examine issues relating to price transparency for prescription drug pricing, and to make any recommendations for appropriate action to implement price transparency.<sup>125</sup> This bill takes a “wait and see” approach to fair drug pricing. Its key provisions being that drug price changes and price transparency issues will be looked at.

While the California and Maryland laws have been passed, several states have pending legislation addressing the same issue. New York has a million-dollar solution to price gouging in the drug market.<sup>126</sup> If a drug manufacturer or wholesaler sells pharmaceuticals at an unconscionably extreme price, then it is subject to a one-million-dollar fine and payment of restitution to aggrieved consumers.<sup>127</sup> Under New York’s proposed legislation, a determination of price gouging is based on a combination of the unconscionably extreme price and the unfair leverage or unconscionable means to get that price.<sup>128</sup> Evidence must be shown that there is a gross disparity between the price of the drug when it led to legal action and the price of the drug over the six months prior, or that the amount charged grossly exceeded the price at which the pharmaceuticals were available by other consumers.<sup>129</sup> The defendant may rebut a prima facie case of price gouging by providing evidence that costs outside the defendant’s control are responsible for the price increase.<sup>130</sup> Unlike the Maryland law, New York’s law sets a less ambiguous benchmark with which to measure what an “unconscionable” price is. The law also makes a provision for price increases that are related to production costs. However, New York’s proposed legislation makes no distinction between brand name or generic drugs, which may cause it to run afoul of the Copyright Clause.<sup>131</sup> Additionally, the penalty is so large that it may discourage producers from entering the market place or,

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<sup>124</sup> Tenn. H.B. 1328.

<sup>125</sup> *Id.*

<sup>126</sup> S.B. 2402, 2017-2018 Leg., Reg. Sess. (N.Y. 2017).

<sup>127</sup> *Id.*

<sup>128</sup> *Id.*

<sup>129</sup> *Id.*

<sup>130</sup> *Id.*

<sup>131</sup> U.S. Const. art. I, § 8, cl. 8 (“to 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”).

alternatively, encourage producers to leave, which would reduce competition and potentially create shortages.

Rhode Island takes price gouging prohibitions to a new level. Rhode Island's proposed legislation makes it a felony to charge unreasonably excessive prices for vital drugs or pharmaceuticals in times of market emergency or market shortages.<sup>132</sup> Under Rhode Island's bill, "unreasonably excessive drug pricing" means there is a gross disparity between the amount charged and the average price at which the drug was available for sale within the local area in the course of the thirty days preceding the declaration of a market emergency.<sup>133</sup> In calculating the disparity, the bill accounts for costs attributable to retailers, suppliers, and replacement costs imposed by the vendor's source, while also excluding discounted prices offered as a bona fide manufacturer's or supplier's limited discounts or rebates.<sup>134</sup> The bill's provisions would only be applicable during a market emergency, which is any declaration of a state of emergency by the state governor or the President, or a market shortage where the total supply of all clinically interchangeable versions of an FDA-regulated drug is inadequate to meet the current or projected demand at the user level.<sup>135</sup> Because of its criminal penalties, this bill may go even further than the New York bill in reducing the number of market participants, thus creating an even greater risk of a shortage. Producers whose costs go up during a market emergency would be open to criminal liability should they pass those costs on to consumers. While the bill does take their costs into account, criminal penalties may dissuade producers from participating in the market.

Massachusetts has proposed a price transparency bill that would require drug companies that increase prices to provide to the Attorney General a justification for the increase in the wholesale acquisition cost of the drug.<sup>136</sup> The bill limits the reporting requirement to the fifteen prescription drugs that the State spends significant health care dollars on and for which the acquisition cost has increased by fifty percent or more over the past five years or by fifteen percent in the past twelve months.<sup>137</sup> Manufacturers that fail to provide the required information are subject to a \$10,000 fine per violation.<sup>138</sup> This bill is similar to California's transparency law, but the reporting requirement is limited to only the drugs that cost the state the most money. While this may help to protect state expenditures, medically necessary drugs used by a small population

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<sup>132</sup> H.B. 5032, 2017 Leg., Reg. Sess. (R.I. 2017).

<sup>133</sup> *Id.*

<sup>134</sup> *Id.*

<sup>135</sup> *Id.*

<sup>136</sup> S.B. 627, 190th Gen. Ct., reg. sess. (Mass. 2017).

<sup>137</sup> *Id.*

<sup>138</sup> *Id.*

would not be required to report if their total costs were below the fifteen most expensive drugs overall. This bill would not address the most recent spate of drug price hikes because the most egregious price spikes occurred in small market drugs.

The states mentioned above are not the only ones pursuing legislation, many other states have introduced legislation in an attempt to regulate price spikes either through price caps, reporting requirements, or a combination of the two.<sup>139</sup>

### III. WHAT LAWS SHOULD STATES ENACT TO PROTECT THEIR CITIZENS?

This note argues that to combat price gouging in the generic drug market, states should not enact price controls, but should instead pursue legislation that increases drug price transparency. Although the drug market does not work like other markets, price controls will most likely result in shortages of needed drugs. However, transparency laws with advance notice requirements for price increases will act as signals to consumers to begin searching for alternative sources of medication, and competitors will be put on notice that there is an opportunity to enter the market.

There is a strong argument for controlling prices in the drug market, in particular, because consumers do not have a choice to switch to another drug, and there is no time to wait for the market to correct itself through competition, as discontinuing a necessary drug can result in serious injury or death. Unlike markets for fuel or other commodities, the healthcare market has variables that cause it to act unlike other markets, a primary distinction being that when it comes to essential healthcare, there are no viable alternate markets.<sup>140</sup> If gas goes up in price, consumers can reduce their consumption by carpooling, walking, bicycling or taking public transportation.<sup>141</sup> For most goods on the market, a consumer can switch to an alternative, or exit the market altogether. Essential medicines are

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<sup>139</sup> *Curbing Unfair Drug Prices: A Primer for States*, Global Health Justice Partnership (Aug. 2017), [https://law.yale.edu/system/files/area/center/ghjp/documents/curbing\\_unfair\\_drug\\_prices-policy\\_paper-080717.pdf](https://law.yale.edu/system/files/area/center/ghjp/documents/curbing_unfair_drug_prices-policy_paper-080717.pdf).

<sup>140</sup> See Kenneth Joseph Arrow, *Uncertainty and the Welfare Economics of Medical Care* (*American Economic Review*, 1963), *J. OF HEALTH POL., POL'Y AND L.*, Vol. 26, Number 5, 141-143 (Oct. 2001), *reprinted at* <http://www.who.int/bulletin/volumes/82/2/PHCBP.pdf>.

<sup>141</sup> *As Fuel Prices Surge, Bike Business Rolls Along*, NBC NEWS (May 11, 2008), [http://www.nbcnews.com/id/24566705/ns/business-us\\_business/t/fuel-prices-surge-bike-business-rolls-along/#.WznOWaZNsM](http://www.nbcnews.com/id/24566705/ns/business-us_business/t/fuel-prices-surge-bike-business-rolls-along/#.WznOWaZNsM).

different because in many cases the alternative to treatment is suffering and death. When prices go up, patients risk serious damage to their health if they cut down on their treatment or decide forego treatment altogether. There is no real choice for the consumer. Additionally, medical conditions are not going to wait for competitors to enter the market after a price spike. In the time it takes for a generic manufacturer to see the price signal and decide to compete in that market, as well as get approval from the FDA to manufacture a generic equivalent and bring it to market, patients who are cutting down on medication or foregoing treatment entirely will most likely suffer adverse effects. A popular quote among economists is that “the market can stay irrational longer than you can stay solvent.”<sup>142</sup> In the case of a newborn infant with toxoplasmosis, the market can stay irrational longer than the baby can stay asymptomatic.<sup>143</sup>

While the specter of a sick infant creates a sense of urgency to remedy the issue through sheer political will, it does not benefit the patient if law-makers forget that price controls have a tendency to limit the number of market participants by removing incentives to bring more supply to meet the demand. Merchants in ancient Rome removed their wares from the marketplace when confronted with Diocletian’s Edict,<sup>144</sup> and shortages of goods following a hurricane are exacerbated when price gouging laws disincentivize people from bringing supplies to the affected area.<sup>145</sup> While the drug market may act differently than other markets, fewer incentives to participate in the market will result in less supply. Should shortages occur, a patient would have no alternative other than to forego medication. In a realm where prices simply went up, a patient who could not afford medication would be able to seek financial relief through several avenues.<sup>146</sup> In a world where medication is in short supply, a patient would be left with no cure. On balance, the patient is better off seeking financial assistance to secure expensive medication than being without medication because it is not being produced or sold. A state whose price-control laws discourage drug providers to the point that they no longer participate in the market ultimately drives its citizens to seek relief outside of its borders. It is a distinct possibility that the citizens of Maryland would be forced

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<sup>142</sup> Paul Krugman, *How Did Economists Get It So Wrong*, N.Y. TIMES MAG. (Sept. 2, 2009), <http://www.nytimes.com/2009/09/06/magazine/06Economic-t.html>.

<sup>143</sup> See Sudden Price Spikes *supra* note 16 at 103.

<sup>144</sup> Kent *supra* note 61 at 39-40.

<sup>145</sup> Zwolinski *supra* note 87, at 362-63.

<sup>146</sup> See Partnership for Prescription Assistance, [https://www.pparx.org/prescription\\_assistance\\_programs/list\\_of\\_participating\\_programs](https://www.pparx.org/prescription_assistance_programs/list_of_participating_programs) (last visited Jan. 7, 2018).

to seek their medications elsewhere because drug producers did not wish to be subjected to the fees, penalties and other regulatory burdens imposed by the recent legislation.

Capping generic drug price increases may also increase the average price of drugs. Just as the gas price cap in Hawaii may have caused the price to go up to the maximum allowed, by enacting a set percentage increase, drug producers would then be able to raise prices to the maximum allowed without incurring a penalty. The incentive for doing so, besides increasing profits, would be to offset losses from not being able to increase prices as needed in the future without incurring regulatory scrutiny. While the GAO found that the average cost of generic drugs was declining despite the price spikes, a set price increase cap may cause the prices of those drugs to rise. While small market patients would have some price protections, an overall increase in prices would have a detrimental effect on insurers and government programs.

Laws that increase drug price transparency and require advance notice of price hikes are a good way to keep generic drug prices down. Unlike most markets where the price of a commodity is readily available to buyers and sellers, the true cost of pharmaceuticals is obscured by a web of rebates and discounts between pharmacy benefit managers, manufacturers, and insurance companies.<sup>147</sup> Because of a lack of information, buyers do not always know how much they are truly paying, and other producers do not know when prices are appropriate to manufacture a competing generic drug. By requiring drug companies to give the state sufficient prior notice of a price hike, as well as the detailed reasons therefor, the state can publish that information to signal competitors. This could lower prices by either accelerating the entrance of market participants, or by discouraging drug manufacturers from raising prices exorbitantly to avoid drawing in more competition. Advance notice of a price hike could also signal to patients, physicians, and hospitals that the drug is entering a period of scarcity, and that they should conserve its use, find alternative treatments, or find alternative sources for the drug (i.e. compounding pharmacies).<sup>148</sup>

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<sup>147</sup> Grace-Marie Turner, *Price Transparency is Critical to Drug Price Solutions*, FORBES (July 11, 2017), <https://www.forbes.com/sites/gracemarieturner/2017/07/11/price-transparency-is-critical-to-drug-pricing-solutions/#5055cc56204a>.

<sup>148</sup> “Drug compounding is often regarded as the process of combining, mixing, or altering ingredients to create a medication tailored to the needs of an individual patient.” *Compounding and the FDA: Questions and Answers*, FDA,

California's drug price transparency law sets out detailed reporting requirements,<sup>149</sup> as does Massachusetts's transparency bill.<sup>150</sup> A new law regulating drug price transparency should have an advance notice requirement for price hikes in excess of a specific benchmark measure. Although California's law is being challenged because its benchmark is ambiguous, Massachusetts sets its benchmark as the "average manufacturer price,"<sup>151</sup> which is "[t]he average price paid to the manufacturer for the drug in the United States by—(i) wholesalers for drugs distributed to retail community pharmacies; and (ii) retail community pharmacies that purchase drugs directly from the manufacturer."<sup>152</sup> Having a specific benchmark price would help to alleviate challenges that the law is unconstitutionally vague. Additionally, a transparency law should take into account production and marketing costs so that a manufacturer is not unduly penalized for increasing prices because of increased costs. Unlike the Massachusetts law, which limits the reporting to the fifteen prescription drugs that the state spends the most money on,<sup>153</sup> a state reporting law should apply to each drug that has experienced a large price increase. One of the key elements of the Turing business plan was to target drugs with a small patient population,<sup>154</sup> and under the Massachusetts law, Turing might not have had to report its increases because its total costs may have been less than the fifteen costliest drugs, by total state expenditure. A transparency law should also require an explanation for the price increase, as well as an itemized listing of the cost of the drug's ingredients, much like California's law.<sup>155</sup> Lastly, the state should publish the relevant cost information in a timely fashion in order to alert consumers, third-party payers, and competitors that a price hike is on the way.

### CONCLUSION

"Pharma Bro" Martin Shkreli infuriated the public, and that anger has manifested as price gouging laws that seek to implement price controls on pharmaceuticals. State legislatures are bound by the will of their constituents to do something about these egregious offenders. But while price controls are an emotionally satisfying

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<https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339764.htm> (last updated June 22, 2018).

<sup>149</sup> Cal. S.B. 17.

<sup>150</sup> Mass. S.B. 627.

<sup>151</sup> *Id.*

<sup>152</sup> Payment for Covered Outpatient Drugs, 42 U.S.C. § 1396r-8(k)(1)(A).

<sup>153</sup> Mass. S.B. 627.

<sup>154</sup> Sudden Price Spikes *supra* note 16.

<sup>155</sup> Cal. S.B. 17.

way to solve the problem of high prices, they typically result in shortages of the items at issue. The unintended consequences of price controls have a long history. A better approach is to implement transparency laws that require advance notice of a price hike so that consumers can make adjustments and competitors can lay plans to participate in the market. While patients in financial need may have to seek assistance while awaiting a correction in price, in the long run they would be better served if states focus on ways to increase competition in the drug market.