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## **The Cost of Living: The Impact of the Increasing Cost of Pharmaceutical Drugs on Public Health**

### **I. Introduction**

The rise in pharmaceutical prices has become a growing public health concern, particularly in a society where approximately 50% of all Americans take at least one prescription drug.<sup>1</sup> From 2008 through 2015, the price of brand name drugs increased by 164%.<sup>2</sup> The twenty most commonly prescribed brand name drugs offered under Medicare’s Part D program has increased approximately 12% every year.<sup>3</sup> The Center for Medicare and Medicaid Services (“CMS”) predicts an average increase of 6.3% per year for prescription drugs.<sup>4</sup>

The rising pharmaceutical costs impacts many different constituents. Most directly, individual purchasers bear the greatest burden and many must choose between the cost of medicine and foregoing treatment.<sup>5</sup> Insurance companies also face increased costs of insuring individuals. Government budgets, at the federal and state levels, swell to sustain funding for Medicare and Medicaid coverage. Conversely, pharmaceutical companies stress a need to generate suitable profit margins and funds for additional research and development. Without proper remediation, pharmaceutical costs may have a detrimental effect on the nation’s economy and public health.

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<sup>1</sup> CENTER FOR DISEASE CONTROL AND PREVENTION, PRESCRIPTION DRUG USE IN THE PAST 30 DAYS BY SEX, RACE, AND HISPANIC ORIGIN, AND AGE: UNITED STATES, SELECTED YEARS 1988-1994 THROUGH 2011-2014 (2017), <https://www.cdc.gov/nchs/data/abus/2017/079.pdf>.

<sup>2</sup> GLEN STETTIN AND ROCHELLE HENDERSON, EXPRESS SCRIPTS 2015 DRUG TREND REPORT 8 (2016).

<sup>3</sup> UNITED STATES SENATE HOMELAND SECURITY & GOVERNMENTAL AFFAIRS COMMITTEE, MINORITY OFFICE, 115TH CONG., MANUFACTURED CRISIS: HOW DEVASTATING DRUG PRICE INCREASES ARE HARMING AMERICA’S SENIORS 3 (2018).

<sup>4</sup> CENTER FOR MEDICARE AND MEDICAID SERVICES, NATIONAL HEALTH EXPENDITURE PROJECTIONS 2016-2025 (2017).

<sup>5</sup> Timothy Kelley, *When the Cost of Medications Keeps Patients from Taking Them*, MANAGED CARE (June 3, 2018), <https://www.managedcaremag.com/archives/2018/6/when-cost-medications-keeps-patients-taking-them>.

This paper will discuss (i) the causes of these increasing costs, (ii) the impacted parties, (iii) measures taken and proposed by federal and state governments, (iv) the challenges with the taken and proposed measures, and (v) lastly, propose four strategies to combat rising pharmaceutical costs.

## **II. Background**

### **A. What are Pharmaceutical Drugs?**

The purchase of prescription and over-the-counter drugs determines the success of the pharmaceutical industry. Prescription drugs can be separated into two primary categories: (1) brand-name drugs; and (2) generic drugs. Each play an integral role in the pharmaceutical industry and contribute to price fluctuations within the market.

The Food and Drug Administration (FDA) defines brand-name drugs as “a drug marketed under a proprietary, trademark-protected name.”<sup>6</sup> Brand-name drugs are researched, developed and tested by pharmaceutical companies, large and small. At some point during the development phase, companies then file for patent protection.<sup>7</sup> An approved patent protects the drug formula from being copied or marketed, affording a company with years of protection against competition. In addition to patent protection, the FDA can grant brand-name drugs “exclusivity;” thereby, allowing for an additional period of time when a brand-name drug is protected from generic drug competition.<sup>8</sup> As such, brand-name drugs typically charge a higher price.

A generic drug is “the same as a brand-name drug in dosage, safety, strength, how it is taken, quality, performance and intended use.”<sup>9</sup> The primary difference is that the generics do not

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<sup>6</sup> Food and Drug Administration, *Glossary of Terms*, FOOD AND DRUG ADMINISTRATION (Nov. 14, 2017), <https://www.fda.gov/drugs/informationondrugs/ucm079436.htm#B>.

<sup>7</sup> DEPRESSION AND BIPOLAR SUPPORT ALL., *GENERIC AND BRAND NAME DRUGS: UNDERSTANDING THE BASICS* 3 (2007).

<sup>8</sup> FOOD AND DRUG ADMINISTRATION, *EXCLUSIVITY AND GENERIC DRUGS: WHAT DOES IT MEAN?* (2018).

<sup>9</sup> Food and Drug Administration, *supra* note 6.

have a patent and, oftentimes, do not operate under a brand name. As such, generic drugs can be expected to have equal effect and no difference when substituted for the brand-name product.<sup>10</sup> Moreover, Generic drugs are typically cheaper than their brand-name counterparts.

## **B. Pharmaceutical Pricing Trends**

Pharmaceutical pricing has remained a growing public health concern since the early 1990s as U.S. drug spending grew between 11 and 17% per year. As more complex and expensive drugs were developed, insurance plans utilized formularies and co-payments to keep drug costs low.<sup>11</sup> Additionally, drug manufacturers began offering rebates and discounts in order to decrease the number of drugs excluded from coverage.<sup>12</sup> As prices rose, private insurers took other means to quell the increases in net drug prices by closing formularies to manage drug spending and negotiating higher rebates and discounts from drug manufacturers.<sup>13</sup> However, the narrative remains the same approximately thirty years later; pharmaceutical prices continue to rise. As previously stated, from 2008 through 2015, the price of brand-name drugs increased by 164%<sup>14</sup>; with brand price inflation nearly doubling between 2011 and 2015.<sup>15</sup> In the U.S., cancer drugs routinely cost \$10,000 per month.<sup>16</sup> Twenty of the most commonly prescribed brand-name drugs offered under Medicare's Part D program increased approximately 12% annually from 2012 through 2017.<sup>17</sup>

As pharmaceutical prices increased, so did prescription drug spending. Between 2006 and

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<sup>10</sup> *Id.*

<sup>11</sup> THE UNITED STATES DEPARTMENT OF HEALTH & HUMAN SERVICES, AMERICAN PATIENTS FIRST: THE TRUMP ADMINISTRATION BLUEPRINT TO LOWER DRUG PRICES AND REDUCE OUT-OF-POCKET COSTS 13 (2018).

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

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

<sup>14</sup> GLEN STETTIN, ROCHELLE HENDERSON, *supra* note 2 at 8.

<sup>15</sup> *Id.*

<sup>16</sup> Robert Langreth, *Drug Prices*, BLOOMBERG, May 11, 2018, <https://www.bloomberg.com/quicktake/drug-prices>.

<sup>17</sup> UNITED STATES SENATE HOMELAND SECURITY & GOVERNMENTAL AFFAIRS COMMITTEE, MINORITY OFFICE, 115TH CONG., MANUFACTURED CRISIS: HOW DEVASTATING DRUG PRICE INCREASES ARE HARMING AMERICA'S SENIORS 2 (2018).

2015, retail prescription drug spending increased by an average of approximately 4.8% annually.<sup>18</sup> For much of this time, the use of generic drugs limited price increases.<sup>19</sup> However, drug spending in 2014 and 2015 grew by an astounding 12.4% and 9% respectively.<sup>20</sup> These figures are even more overwhelming when compared to the average rate of inflation, between 2006 and 2016, of 1.8%.<sup>21</sup>

Americans spend more on drugs than the rest of the world. On average, Americans spend \$1,200 per year on pharmaceuticals.<sup>22</sup> Switzerland, the second highest, spends \$1,080.<sup>23</sup> Canada spends \$860; Germany spends \$777; France spends \$663; and the United Kingdom spends \$476.<sup>24</sup> Increased spending is not a distinguishable difference. U.S. prices for the world's top-twenty medicines are, on average, three times higher than in Britain.<sup>25</sup> For example, Roche Holding AG's Herceptin breast cancer drug, after rebates of roughly 15%, still cost approximately 85% more in the U.S. than in other high-income countries.<sup>26</sup> After an estimated discount of 60%, AstraZeneca charges twice as much in the U.S. for Crestor compared to Germany. A 2013 study that found that 20% of adults in the U.S. failed to complete a prescribed course of medicine because of cost.<sup>27</sup> Comparatively, Germany, Canada, and Australia had a rate of 10%.<sup>28</sup>

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<sup>18</sup> UNITED STATES SENATE HOMELAND SECURITY & GOVERNMENTAL AFFAIRS COMMITTEE, MINORITY OFFICE, *Supra* note 3, at 3.

<sup>19</sup> Robert Langreth, *Drug Prices*, BLOOMBERG, May 11, 2018, <https://www.bloomberg.com/quicktake/drug-prices>.

<sup>20</sup> UNITED STATES SENATE HOMELAND SECURITY & GOVERNMENTAL AFFAIRS COMMITTEE, MINORITY OFFICE, *Supra* note 3, at 3.

<sup>21</sup> Kimberly Amadeo, *U.S. Inflation Rate from 1929 to 2020*, THE BALANCE (July 6, 2018), <https://www.thebalance.com/u-s-inflation-rate-history-by-year-and-forecast-3306093>

<sup>22</sup> Organisation of Economic Co-Operation and Development, *Pharmaceutical Spending*, OECD (Nov. 8, 2018), <https://data.oecd.org/healthres/pharmaceutical-spending.htm>.

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

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

<sup>25</sup> Ben Hirschler, *Transatlantic Divide: How U.S. pays three times more for drugs*, REUTERS (Oct. 12, 2015), <https://www.reuters.com/article/us-pharmaceuticals-usa-comparison/exclusive-transatlantic-divide-how-u-s-pays-three-times-more-for-drugs-idUSKCN0S61KU20151012>.

<sup>26</sup> Robert Langreth, Blacki Migliozi, Ketaki Gokhale, *The U.S. Pays a Lot More for Top Drugs Than Other Countries*, BLOOMBERG (Dec. 18, 2015), <https://www.bloomberg.com/graphics/2015-drug-prices/>.

<sup>27</sup> Robert Langreth, *Drug Prices*, BLOOMBERG (May 11, 2018), <https://www.bloomberg.com/quicktake/drug-prices>.

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

Under the current law and policy initiatives, the Centers for Medicare and Medicaid Services (“CMS”) projects national health spending to grow at an average rate of 5.5% per year from 2017 through 2026<sup>29</sup>; totaling \$5.7 trillion by 2026.<sup>30</sup> Within health spending, CMS anticipates that prescription drug costs will see the fastest annual growth among health care expenditures over the next decade.<sup>31</sup> Its February 2018 report, CMS projected a 2.3% acceleration in prescription drug prices: from 2.1% in 2017 to 4.4% in 2018.<sup>32</sup> This acceleration “reflects the expectation that brand-name drug prices will more strongly influence growth in that year because the dollar value of drugs losing patents in 2018 is smaller than in prior years.”<sup>33</sup> Though drug price growth is lower than previous years, CMS predicts that through 2025 pharmaceutical prices will rise an average of 6.3% per year due to a greater use of specialty drugs such as those used for genetic disorders and cancer.<sup>34</sup>

### **III. Causes of the Increasing Costs**

The cost of pharmaceutical drugs can be attributable to various factors including regulatory advantages (patent and exclusivity durations), commercially creative approaches deployed by manufacturers (discounts and rebates, “gag” clauses) and limitations on government’s ability to intervene (absence of direct price regulation, and inability for Medicare to negotiate directly with manufacturers).

Patent and “Exclusivity” periods give a manufacturer a non-competitive marketplace to sell their drugs. A U.S. patent precludes another party, including generic drug makers, give a

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<sup>29</sup> CENTER FOR MEDICARE AND MEDICAID SERVICES, NATIONAL HEALTH EXPENDITURE PROJECTIONS 2016-2025 (2017).

<sup>30</sup> Id.

<sup>31</sup> CENTER FOR MEDICARE AND MEDICAID SERVICES, NATIONAL HEALTH EXPENDITURE PROJECTIONS 2017-2026 (2018).

<sup>32</sup> Id.

<sup>33</sup> Id.

<sup>34</sup> CENTER FOR MEDICARE AND MEDICAID SERVICES, NATIONAL HEALTH EXPENDITURE PROJECTIONS 2016-2025 (2017).

patent holder the exclusive right to exclude others from making, using, importing, and selling the patented innovation for a limited period of time, typically twenty years.<sup>35</sup> Manufacturers argue that the protections and the related costs are necessary to recover years of research and development costs. In certain cases, the FDA may grant a drug “exclusivity” for a period of time to protect it from generic drug competition<sup>36</sup> and promote a balance between innovation and generic drug competition.<sup>37</sup> Drugs may be granted exclusivity for a variety of reasons. Drugs that feature a new chemical entity are given five-year exclusivity.<sup>38</sup> Orphan drugs, defined as drugs for a disease or condition affecting fewer than 200,000 people, are granted seven-year exclusivity.<sup>39</sup> A brand-name drug may receive three-year exclusivity if the drug’s active ingredient can be delivered in a new way or be used to treat a different disease or condition.<sup>40</sup> Exclusivity and patent protections provide brand-name drugs a monopoly allowing them to charge higher rates. Upon the expiration of patent and exclusivity protection, the cost of the brand-name drug decreases; though typically not to the level of its generic counterparts due to recognition.

While “generics” cannot be granted patent protection, “the first generic drug applicant to submit a substantially complete generic application” that challenges a brand-name drug’s patents and satisfies regulatory and legal requirements may be eligible for a 180-day exclusivity period.<sup>41</sup> The 180-day period begins from the first occurrence of either the date the sponsor begins commercial marketing of the generic drug product or the date of a court decision holding “the patent is invalid, unenforceable, or not infringed.”<sup>42</sup> Prior to reaching the market, the generic drug

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<sup>35</sup> 35 U.S.C. §1 et. Seq. (1999).

<sup>36</sup> FOOD AND DRUG ADMINISTRATION, EXCLUSIVITY AND GENERIC DRUGS: WHAT DOES IT MEAN? (2018).

<sup>37</sup> Id.

<sup>38</sup> Id.

<sup>39</sup> Id.

<sup>40</sup> Id.

<sup>41</sup> FOOD AND DRUG ADMINISTRATION, EXCLUSIVITY AND GENERIC DRUGS: WHAT DOES IT MEAN? (2018).

<sup>42</sup> FOOD AND DRUG ADMINISTRATION, PATENTS AND EXCLUSIVITY 3 (FDA/CDER SBIA Chronicles, 2015).

must be approved by the FDA. As such, the generic drug undergoes rigorous testing to ensure its “substitutability” to its brand name counterpart.<sup>43</sup> Testing must reveal that the generic drug contains identical amounts of the same ingredient(s) as the brand-name product.<sup>44</sup> Since the chemical makeup is identical, generic drugs can be expected to have equal effect and no difference when substituted for the brand-name product.<sup>45</sup> Generic drugs are typically cheaper than their brand-name counterparts costing on average between 80 to 85% less than brand name drugs.<sup>46</sup> In 2010, the use of generic drugs saved consumers \$158 billion.<sup>47</sup>

Discounts and rebates are used by pharmaceutical manufacturers as a means to provide the purchaser a price reduction without impacting the manufacturer’s profit margin. In both scenarios the manufacturer increases the list-price of the drug, with the understanding that price reductions will be provided to entice purchasers and pharmacists. A discount is a reduction in the amount that a seller charges a buyer<sup>48</sup>, typically a pharmacy, with the intent that the pharmacy will promote that manufacturer’s product rather than a competitor’s.<sup>49</sup> Discounts are provided in order to increase the use of higher priced drugs.

Rebates also operate as a reduction in price with the intent of increasing sales. Unlike discounts which are paid upon purchase, a buyer receives the benefit in the future. Such is necessary because rebates are based upon product sales.<sup>50</sup> While rebates for generic drugs are paid to a pharmacy or wholesaler, rebates for patented, brand-name products are paid to the pharmacy benefit managers (PBMs). PBMs operate as a healthcare intermediary and include

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<sup>43</sup> Food and Drug Administration, *supra* note 6.

<sup>44</sup> *Id.*

<sup>45</sup> *Id.*

<sup>46</sup> FOOD AND DRUG ADMINISTRATION, FACTS ABOUT GENERIC DRUGS 2 (2009).

<sup>47</sup> *Id.*

<sup>48</sup> Norman V. Carroll, *Discounts, Rebates, and Kickbacks*, PHARMACY BUSINESS AND ECONOMICS BLOG (June 17, 2015), <https://wp.vcu.edu/nvcarroll/2015/06/17/discounts-rebates-and-kickbacks/>.

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

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

companies such as CVS Health, Express Scripts, US Scripts, and Humana. PBMs represent health insurers, union health plans, and government purchasers in the selection, purchase and distribution of pharmaceuticals.<sup>51</sup> Since PBMs influence which drug products are the most frequently used, rebates are paid so a PBM will grant the drug exclusive or preferred status. Exclusive status guarantees that the drug is the only one available on the formulary.<sup>52</sup> Preferred status provides that that drug's copay is less than the copay for similar products.<sup>53</sup> Rebates remain extremely costly for pharmaceutical manufacturers. In 2017, rebates paid by the thirteen largest manufacturers totaled \$150 billion, double those paid in 2011.<sup>54</sup> Because health plans, PBMs and wholesalers receive higher rebates and fees when list prices increase, there is little incentive to control list prices.<sup>55</sup>

“Gag clauses” are commercial contracts between a pharmacy and a PBM that remain largely invisible to consumers purchasers.<sup>56</sup> These arrangements restrict pharmacists from informing consumers about “available alternative pricing, including paying out-of-pocket, generics or brand-name products that may be less costly, or those which may be comparatively more suitable for a patient” than the prescribed drug.<sup>57</sup>

Government's inability to impact drug pricing also significantly contributes to the problem. Unlike Europe, the U.S. does not directly regulate pharmaceutical prices. As such, pharmaceutical companies are able to set prices according to what they or the market dictates leading to U.S.

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<sup>51</sup> Cole Werble, *Pharmacy Benefit Managers*, HEALTHAFFAIRS (Sept. 14, 2017), <https://www.healthaffairs.org/doi/10.1377/hpb20171409.000178/full/>.

<sup>52</sup> Carroll, *supra* note 48.

<sup>53</sup> *Id.*

<sup>54</sup> David Belk, Paul Belk, *The Pharmaceutical Industry*, True Cost of Healthcare Blog (2018), [http://truecostofhealthcare.org/the\\_pharmaceutical\\_industry/](http://truecostofhealthcare.org/the_pharmaceutical_industry/).

<sup>55</sup> THE UNITED STATES DEPARTMENT OF HEALTH & HUMAN SERVICES, AMERICAN PATIENTS FIRST: THE TRUMP ADMINISTRATION BLUEPRINT TO LOWER DRUG PRICES AND REDUCE OUT-OF-POCKET COSTS 17 (2018).

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

<sup>57</sup> Richard Cauchi, *Recent Approaches and Innovations in State Prescription Drug Laws*, NATIONAL CONFERENCE OF STATE LEGISLATURES (Oct. 1, 2018), [http://www.ncsl.org/research/health/rx-costs.aspx#Rx\\_transparency](http://www.ncsl.org/research/health/rx-costs.aspx#Rx_transparency).

pharmaceutical prices being are among the highest in the world. From 2011 through 2017, the thirteen largest pharmaceutical companies received 45% of its global revenue from the U.S.<sup>58</sup> The remaining 55% came from all other countries combined.<sup>59</sup>

Comparatively, European governments directly regulate prices using different formulations. The most widely accepted formulation is “External Price Referencing” (“EPR”), where is used in twenty-nine countries in the European Union as well as Iceland, Norway, Switzerland, and Turkey.<sup>60</sup> EPR is defined by the European Commission, the governing body of the European Union, “as the practice of using the price(s) of a medicine in one or several countries in order to derive a benchmark or reference price for the purposes of setting or negotiating the price of a medicine in a given country.”<sup>61</sup> The United Kingdom ‘s National Health Service employs a “sufficient value for money” formula and has refused to pay for certain cancer drugs, widely used in the U.S.<sup>62</sup> As a result, pharmaceutical manufacturers are constricted when setting prices in European markets; leading manufacturers to charge higher fees in the U.S. market.

More limiting is Medicare’s inability to negotiate drug prices with pharmaceutical companies. Under the Social Security Act, Medicare “may not interfere with the negotiations between drug manufacturers, pharmacies and PDP sponsors, and may not require a particular formulary or institute a price structure for the reimbursement of covered Part D drugs.”<sup>63</sup> By not giving Medicare, one of the largest global purchasers of pharmaceuticals, the right to negotiate prices, the average per capita costs within the Part D prescription drug program have risen and are

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<sup>58</sup> David Belk and Paul Belk, *supra* note 54.

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

<sup>60</sup> Zachary Brennan, *European Drug Prices: New Commission Report on What Policies Work and What Could Work*, REGULATORY AFFAIRS PROFESSIONALS SOCIETY (Feb. 25, 2016), <https://www.raps.org/regulatory-focus%E2%84%A2/news-articles/2016/2/european-drug-prices-new-commission-report-on-what-policies-work-and-what-could-work>.

<sup>61</sup> *Id.*

<sup>62</sup> Robert Langreth, *Drug Prices*, BLOOMBERG, May 11, 2018, <https://www.bloomberg.com/quicktake/drug-prices>.

<sup>63</sup> 42 U.S.C. 1395w-111(i)(1) (2017).

projected to rise 4.7% annually over the next decade.<sup>64</sup>

The length of patent and exclusivity protections, the various commercial approaches taken by the drug companies and the government's own imposed restraints to limit drug prices have, collectively and individually, added to the size and scope of this national crisis. A crisis that impacts individuals, companies and government budgets.

#### **IV. Parties to the Price Increases**

Drug prices impact a variety of parties. Individuals, employers, and the government are harmed from the increasing prices in their own ways. Meanwhile, pharmaceutical and insurance companies derive an economic benefit from the increasing costs.

Individuals are the greatest impacted from increased pharmaceutical costs. A 2009 study conducted by Elizabeth Warren found that 62.1% of all bankruptcies were due to medical bills.<sup>65</sup> Moreover, the high cost of prescriptions are causing more and more patients to not fill or not complete their course of treatment according to the Center for Disease Control and Prevention ("CDC").<sup>66</sup> Skipping medications is known to worsen an individual's health and quality of life, resulting in higher medical costs. A study from the *Annals of Internal Medicine* found that a lack of adherence to self-administered medications causes approximately 125,000 deaths in the United

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<sup>64</sup> Juliette Cubanski, Tricia Neuman, *Searching for Savings in Medicare Drug Price Negotiations*, KAISER FAMILY FOUNDATION (Apr. 26, 2018), <https://www.kff.org/medicare/issue-brief/searching-for-savings-in-medicare-drug-price-negotiations/> (From 2007 through 2013, the average per capita costs increased 2.4%, and increased 4.4% between 2013 and 2016).

<sup>65</sup> Kimberly Amadeo, *Medical Bankruptcy and the Economy*, THE BALANCE (May 16, 2018), <https://www.thebalance.com/medical-bankruptcy-statistics-4154729>.

<sup>66</sup> CENTERS FOR DISEASE CONTROL AND PREVENTION, STRATEGIES USED BY ADULTS TO REDUCE THEIR PRESCRIPTION DRUG COSTS (2015) (The study states that 8% of adults in general do not take their medication to save money. Additionally, the study notes that adults between 18 and 65 were twice as likely as those over 65 to not take their medication. Moreover, 14% of uninsured adults, 10% of Medicaid patients and 6% of privately insured patients do not take their medication to save money.)

States<sup>67</sup> and costs the U.S. health care system between \$100 billion and \$289 billion annually.<sup>68</sup>

Increased pharmaceutical costs also directly impacts employers. Under the Affordable Care Act (“ACA”), employers are required to provide health insurance to full-time employees. The increase in spending for pharmaceuticals has been a primary reason for annual increases of employer health care costs.<sup>69</sup> Retail drugs consist of approximately 21% of employer insurance benefits.<sup>70</sup> A 2017 survey by Mercer, a consultancy firm, found that 46% of employers would take steps to cut costs through new strategies such as high-deductible health plans, which shift the burden of initial medical costs to patients, but have lower monthly premiums.<sup>71</sup>

Pharmaceutical costs negatively impact the government as well. In 2017, the National Health Expenditure, the official measurement of total healthcare spending, accounted for 17.9% of the U.S.’s GDP.<sup>72</sup> Medicare spending was 15% of the total federal budget in 2017 and is projected to rise to 18 percent by 2028.<sup>73</sup> Medicare benefit payments totaled \$705.9 billion.<sup>74</sup> Medicaid, ACA, and Children’s Health Insurance Program spending was 11% of the federal budget in 2017. Combined, Medicare and Medicaid spend \$174 billion on prescription medications in 2016.<sup>75</sup>

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<sup>67</sup> Viswanathan M, Golin CE, Jones CD, Ashok M, Blalock SJ, Wines RC, et al., *Interventions to Improve Adherence to Self-administered Medications for Chronic Diseases in the United States: A Systematic Review*, 157 *Annals of Internal Med.*785–95 (2012).

<sup>68</sup> *Id.*

<sup>69</sup> Robert Galvin, Troyen Brennan, *Can Employers Take a Bigger Role in Controlling Drug Costs*, HEALTHAFFAIRS, (Feb. 17, 2017), <https://www.healthaffairs.org/doi/10.1377/hblog20170217.058822/full/>.

<sup>70</sup> Rabah Kamal, Cynthia Cox, *What are the recent and forecasted trends in prescription drug spending?*, PETERSON-KAISER HEALTH SYSTEM TRACKER (December 20, 2017), [https://www.healthsystemtracker.org/chart-collection/recent-forecasted-trends-prescription-drug-spending/?\\_sf\\_s=recent+trends#item-start](https://www.healthsystemtracker.org/chart-collection/recent-forecasted-trends-prescription-drug-spending/?_sf_s=recent+trends#item-start).

<sup>71</sup> Divya Grover, *Costly drugs to weigh on U.S. employers’ expenses in 2018: survey*, REUTERS (Sept. 18, 2017), <https://www.reuters.com/article/us-usa-healthcare-survey/costly-drugs-to-weigh-on-u-s-employers-expenses-in-2018-survey-idUSKCN1BT1FR>.

<sup>72</sup> CENTER FOR MEDICARE AND MEDICAID SERVICES, NATIONAL HEALTH EXPENDITURES 2017 HIGHLIGHTS 1 (2018).

<sup>73</sup> Juliette Cubanski, Tricia Neuman, *The Facts on Medicare Spending and Financing*, KAISER FAMILY FOUNDATION (June 22, 2018), <https://www.kff.org/medicare/issue-brief/the-facts-on-medicare-spending-and-financing/>.

<sup>74</sup> CENTER FOR MEDICARE AND MEDICAID SERVICES, NATIONAL HEALTH EXPENDITURES 2017 HIGHLIGHTS 2 (2018).

<sup>75</sup> Tami Luhby, *Check out how much Medicare spends on drugs*, CNN BUSINESS (May 15, 2018), <https://money.cnn.com/2018/05/15/news/economy/medicare-drug-spending/index.html>.

Insurance companies are also directly impacted and must manage drug prices. Increased drug prices lead to increased costs of insurance. However, rather than bearing the costs themselves, insurance companies transfer the costs onto purchasers in the form of increased plan prices or higher co-pays.<sup>76</sup>

With the demand for more cost control, pharmaceutical companies argue that drug prices are high in order to bankroll development of future medical advances, that pharmaceutical advances justify price, and restricting prices would harm innovation. Studies show the average cost of developing a prescription drug which gains market approval is \$2.6 billion.<sup>77</sup> Much of their defense is undermined by their own success. Estimated pharmaceutical and biotechnology sales revenue increased from \$534 billion to \$775 billion from 2006 through 2015 with approximately 67% of all drug companies increasing profit margins during the same time.<sup>78</sup> Interestingly, the twenty-five largest pharmaceutical companies, had an average profit margin between 15 and 20% compared an average profit margin for nondrug companies for the largest 500 globally of 4 to 9%.<sup>79</sup>

Additional facts further weaken that drug companies' arguments. First, more than 50% of important discoveries and 85% of basic discoveries are made in independent academic centers.<sup>80</sup> Second, a study from the Journal of Clinical Oncology found that drug effectiveness does not necessarily translate to cost effectiveness for cancer drug pricing.<sup>81</sup> Third, the median deal of

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<sup>76</sup> ELSEVIER CLINICAL SOL., THE IMPACT OF RISING GENERIC DRUG PRICES ON THE U.S. DRUG SUPPLY CHAIN 1 (2015).

<sup>77</sup> Rick Mullin, *Tufts Study Finds Big Rise in Cost of Drug Development*, C&EN (Nov. 20, 2014), <https://cen.acs.org/articles/92/web/2014/11/Tufts-Study-Finds-Big-Rise.html>.

<sup>78</sup> UNITED STATES GOVERNMENT ACCOUNTABILITY OFFICE, DRUG INDUSTRY: PROFITS, RESEARCH AND DEVELOPMENT SPENDING, AND MERGER AND ACQUISITION DEALS 1 (2017).

<sup>79</sup> *Id.*

<sup>80</sup> Hagop Kantarjian and Vivian Ho, Opinion, *The Harm of High Drug Prices*, U.S. NEWS (Dec. 12, 2016), <https://www.usnews.com/opinion/policy-dose/articles/2016-12-12/the-harm-of-high-drug-prices-to-americans-a-continuing-saga>.

<sup>81</sup> Bruce E. Hillner, Thomas J. Smith, *Efficacy Does Not Necessarily Translate to Cost Effectiveness: A Case Study in the Challenges Associated With 21st-Century Cancer Drug Pricing*, 27 J. of Clinical Oncology 2111-13 (2009). <http://ascopubs.org/doi/pdf/10.1200/JCO.2008.21.0534>

mergers and acquisitions increased while the volume remained steady, suggesting that manufacturers are buying drug discoveries and not developing them in-house.<sup>82</sup> Fourth, research and development equaled 17% of their revenue for the thirteen largest drug companies from 2011 through 2017.<sup>83</sup> While the pharmaceutical companies' arguments must be taken into account, they must also be scrutinized carefully.

Any remedial action must take into consideration all parties so that advances in medications can continue while allowing individuals to benefit from those innovations without damaging the economic health of individual, employers and governments.

#### V. Steps being taken—State Governments

Since 2015, states have enacted a wide variety of policy initiatives related to prescription drug regulation, with more than 200 signed bills from forty-five states to affect pricing, payment, and costs of prescription drugs.<sup>84</sup> In 2018 alone, forty-one states enacted 121 bills regulating the pharmaceutical industry.<sup>85</sup> Legislation has been adopted by both Republican and Democrat leaning states to signal bipartisan concern over this growing public health concern. State measures include: (1) Drug cost transparency; (2) allowing for importation of prescription drugs from Canada; (3) drug anti-price gouging; (4) drug co-payment limitations; and (5) determining Medicaid prescription coverage based upon negotiation and cost effectiveness.<sup>86</sup> Some measures have been rejected by the courts as being unconstitutional.

First, more than 60 drug cost transparency bills have been proposed in thirty states across

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<sup>82</sup> *Id.*

<sup>83</sup> David Belk, Paul Belk, *supra* note 54.

<sup>84</sup> Richard Cauchi, *Supra* note 57.

<sup>85</sup> National Conference of State Legislature, *Statewide Prescription Drug Database: 2015-Present*, NATIONAL CONFERENCE OF STATE LEGISLATURES (November 11, 2018), <http://www.ncsl.org/research/health/prescription-drug-statenet-database.aspx>.

<sup>86</sup> Richard Cauchi, *Supra* note 57.

the country.<sup>87</sup> Among these 60 bills, twenty-seven have been implemented in seventeen states, and many more are still pending.<sup>88</sup> Most notably, California and Vermont are considered “pioneers” of drug transparency having been the first states to implement such plans. These bills, which apply to both brand-name and generic drugs, are designed to identify the costs that contribute to drug manufacturer expenses, list prices, and unveil the business practices of PBMs.<sup>89</sup> PBMs are heavily scrutinized due to the secrecy of their business practices.

Generally, transparency bills require drug manufacturers to report the reasons behind drug price increases that exceed 10% or more over a twelve-month period.<sup>90</sup> The price increase rationale must be in an understandable and appropriate format and are publicized. The transparency “give[s] hospitals access to pricing information that they could use when communicating with manufacturers to establish rates.”<sup>91</sup> Some believe drug price transparency would hold manufacturers accountable for the cost of medications.<sup>92</sup> Depending upon the specific state’s requirements, failure to comply with the reporting requirements may result in fines up to \$10,000 per day.<sup>93</sup> States with drug cost transparency laws often stipulate differing reporting requirements. California, for example, places requirements on both pharmaceutical manufacturers and health insurers.<sup>94</sup> Manufacturers must provide purchasers with 60-day advance notification of price increases “that exceeds a specified threshold” for prescription drugs currently on the

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<sup>87</sup> Center for State Prescription Drug Pricing, *Lowering Drug Costs: Transparency Legislation Sets Off Flurry of New State Approaches*, NATIONAL ACADEMY FOR STATE HEALTH POLICY (Aug. 22, 2017), <https://nashp.org/lowering-drug-costs-transparency-legislation-sets-off-flurry-of-new-state-approaches/>.

<sup>88</sup> National Academy for State Health Policy, *State Legislative Action to Lower Pharmaceutical Costs*, NATIONAL ACADEMY FOR STATE HEALTH POLICY (Oct. 4, 2018) <https://nashp.org/state-legislative-action-on-pharmaceutical-prices/>.

<sup>89</sup> Center for State Prescription Drug Pricing, *supra* note 87.

<sup>90</sup> National Academy for State Health Policy, *supra* note 88.

<sup>91</sup> Kaitlyn Dana, et. al., *Drug Pricing Transparency*, 156 *Hospital Pharmacy* 155, 156 (2017).

<sup>92</sup> Allan Coukell, Chuck Shih, *What’s driving increased pharmaceutical spending?*, THE PEW CHARITABLE TRUSTS (May 26, 2016), <https://www.pewtrusts.org/en/research-and-analysis/articles/2016/05/26/whats-driving-increased-pharmaceutical-spending>.

<sup>93</sup> H.R. 4005, 79th Gen. Assemb., Reg. Sess. (Or. 2018).

<sup>94</sup> S.B. 17, Chapter 603, Reg. Sess. (Ca. 2017).

market, including reasons and justifications for such increases.<sup>95</sup> Manufacturers must also provide justification of launch prices for new drugs.<sup>96</sup> Health insurers filing rate information must report specific cost information regarding prescription drugs covered under their plan, including generic, brand-name, and specialty drugs and the percentage of their insurance premium that are attributable to prescription drugs.<sup>97</sup> Nevada, in addition to price increase reporting justifications, requires the (i) reporting of free goods or compensation by sales representatives to licensed health providers and (ii) the dollar value of manufacturer drug rebates they collect.<sup>98</sup>

Second, states have taken steps to increase competition through the importation of drugs. In May 2018, Vermont enacted legislation that enabled the wholesale importation of prescription drugs into Vermont from Canada.<sup>99</sup> Since then, Colorado, Louisiana, Montana, New York, Oklahoma, West Virginia, and Wyoming have introduced similar bills.<sup>100</sup> These bills apply a market-based approach to decreasing pharmaceutical prices by “providing more affordable medicines from Canada, where prescription drugs cost on average 30 percent less than in the United States.”<sup>101</sup> The approach would create a state-administered system of wholesale importation and distribution, limited solely to pharmaceuticals from Canada and by contracting with a fully licensed, regulated Canadian supplier that is compliant with Canadian law.<sup>102</sup> The

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<sup>95</sup> *Id.*

<sup>96</sup> *Id.*

<sup>97</sup> *Id.*

<sup>98</sup> S.B. 539, 79 Sess., Reg. Sess. (Nv. 2017).

<sup>99</sup> S.B. 175, 2018 Leg., Reg. Sess. (Vt. 2018).

<sup>100</sup> National Academy for State Health Policy, *supra* note 88 (Colorado, Louisiana, Montana, New York, Oklahoma, Utah, Vermont, West Virginia, and Wyoming).

<sup>101</sup> Center for State Prescription Drug Pricing, *Four More States Submit Bills to Import Prescription Drugs from Canada*, NATIONAL ACADEMY FOR STATE HEALTH POLICY (Feb. 6, 2018), <https://nashp.org/four-more-states-submit-bills-to-import-prescription-drugs-from-canada/>.

<sup>102</sup> Center for State Prescription Drug Pricing, *Managing High Drug Prices through Importation: We Can Get to “YES”*, NATIONAL ACADEMY FOR STATE HEALTH POLICY (May 30, 2017), [https://nashp.org/managing-high-drug-prices-through-importation-we-can-get-to-yes/#\\_ftn1](https://nashp.org/managing-high-drug-prices-through-importation-we-can-get-to-yes/#_ftn1).; National Academy for State Health Policy, *State Wholesale Importation Program Explained*, NATIONAL ACADEMY FOR STATE HEALTH POLICY (May 30, 2017), <https://nashp.org/wp-content/uploads/2017/05/Wholesale-Importation1.pdf>.

Canadian supplier would manage distribution to state-licensed pharmacies. Participating states would decide the extent of coverage for public and private health plans and programs.

However, the state importation legislation requires federal approval, thereby delaying the legislation's implementation. Section 804 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("Section 804") provides that the Health and Human Services Secretary ("HHS Secretary") may allow the importation of prescription drugs from Canada if it can be proven that it will (1) pose no additional risk to the public's health and safety and (2) result in a significant reduction in the cost of covered products to the American consumer.<sup>103</sup> Proponents argue that importation would be safe and produce savings for American consumers. Specifically, Section 804 would be satisfied because: (i) a state must select a Canadian supplier that is licensed and regulated under Canadian law and could be licensed under state pharmacy or wholesaler law as well; (ii) a state would select drugs that are approved for the Canadian market; (iii) participants would agree to purchase and reimburse drugs at the import price and patient cost sharing would be based upon the import price as well; (iv) states must monitor and audit the system for compliance, safety, and savings; and (v) the legislation (a) allows for greater transparency for consumers and (b) requires the imported products be distributed in-state only.

HHS does not seem t convinced of the legislation's merits.<sup>104</sup> However, there has yet to be a HHS Secretary that has deemed Section 804's standard to be satisfied. Alex Azar, the current HHS Secretary, stated in May 2018 that programs designed to reduce pharmaceutical prices through importation are "just a gimmick."<sup>105</sup> In dissent of importation programs, Azar referenced

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<sup>103</sup> H.R. 1, 108th Cong. (2003).

<sup>104</sup> CONGRESSIONAL BUDGET OFFICE, PRELIMINARY ESTIMATE - S. 469, THE AFFORDABLE AND SAFE PRESCRIPTION DRUG IMPORTATION ACT (2017), <https://www.cbo.gov/system/files?file=115th-congress-2017-2018/costestimate/s469preliminary.pdf>.

<sup>105</sup> Steven Porter, *Drug Importation "Just a Gimmick" Says HHS Secretary*, HEALTHLEADERS (May 14, 2018), <https://www.healthleadersmedia.com/strategy/drug-importation-just-gimmick-says-hhs-secretary>.

a 2004 analysis by the Congressional Budget Office (“CBO”) that determined that importation would not have a meaningful impact on U.S. prescription drug prices.<sup>106</sup> Azar, relying upon findings from four prior FDA commissioners, also stated that allowing drugs to come into the U.S. from Canada raises safety concerns.<sup>107</sup> Regardless of the potential benefits, importation from Canada will not occur until approval by the HHS Secretary.

Another unique approach to tackle the rise in drug prices is the implementation of anti-price gouging laws. In October of 2017, Maryland became the first state to implement such a law, which prohibited a manufacturer or wholesale distributor from engaging in “price gouging” in the sale of an essential off-patent or generic drug.<sup>108</sup> The act defined price gouging as “an unconscionable increase in the price of a prescription drug.”<sup>109</sup> An “unconscionable increase” was further defined as an increase that “is excessive and not justified by the cost of producing the drug or the cost of appropriate expansion of access to promote public health.”<sup>110</sup> A manufacturer or wholesale distributor determined to be in violation of the act faced numerous legal consequences, including a civil penalty of \$10,000 per violation or an action enjoining the sale of the medication at the increased price.<sup>111</sup> Ultimately, the act was challenged and struck down by the Fourth Circuit Court of Appeals in April of 2018.<sup>112</sup> The Court held that the act violated the Dormant Commerce Clause because it directly regulated the price of transactions that occurred outside the state of

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<sup>106</sup> *Id.*

<sup>107</sup> Letter from Margaret Hamburg, Foreign Secretary, National Academy of Medicine, et. al., to Congress (Mar. 16, 2017) (on file at [https://healthpolicy.duke.edu/sites/default/files/atoms/files/2017\\_03\\_16\\_commissioners\\_letter\\_final\\_signed.pdf](https://healthpolicy.duke.edu/sites/default/files/atoms/files/2017_03_16_commissioners_letter_final_signed.pdf)) (Four former commissioners, Robert Califf, Margaret Hamburg, Mark McClellan, and Andrew von Eschenback contested that it could lead to a “host of unintended consequences and undesirable effects, including serious harm stemming from the use adulterated, substandard, or counterfeit drugs.”).

<sup>108</sup> Md. Code Ann., Health–Gen. § 2-802 (2018).

<sup>109</sup> *Ass'n for Accessible Meds. v. Frosh*, 887 F.3d 664, 666 (4th Cir. 2018).

<sup>110</sup> *Id.*

<sup>111</sup> Md. Code Ann., Health–Gen. § 2-803(d).

<sup>112</sup> *Ass'n for Accessible Meds. v. Frosh*, 887 F.3d 664, 666 (4th Cir. 2018).

Maryland.<sup>113</sup> As such, the act imposed a significant burden on interstate commerce involving prescription drugs.<sup>114</sup> Since being struck down, similar bills in 16 other states have stalled, with bills in 11 states no longer active.<sup>115</sup>

Fourth, legislation addressing cost-sharing and deductibles has been adopted in 20 states across the country.<sup>116</sup> This legislation implements caps on pharmaceutical pricing without directly regulating the prices themselves, focusing primarily on specialty drugs that are typically more expensive for consumers. In California, “cap the copay” legislation was enacted.<sup>117</sup> This law prohibits an individual health insurance policy or group health care service plan that provides coverage for anticancer medications from requiring an enrollee to pay more than \$250 in copayments and coinsurance for a 30-day supply of an individual prescription.<sup>118</sup> Alongside California, 19 other states have adopted similar cost-sharing legislation.<sup>119</sup> In January of 2018, the Biotechnology Innovation Organization commissioned a report seeking to understand the economic impact of prescription drug cost-sharing cap legislation. The report found that, compared to states without cost-sharing cap legislation, California could expect approximately a one percent decrease in spending for individual plans and a three percent decrease for group plans.<sup>120</sup> However, the net paid costs would remain unchanged as insurers compensated for the copayment and coinsurance cap by increasing premiums accordingly. Thus, any benefit may be

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

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

<sup>115</sup> Richard Cauchi, *State Actions to Halt Price Gouging for Generic Drugs*, NATIONAL CONFERENCE FOR STATE LEGISLATURES (July 20, 2018), [http://www.ncsl.org/Portals/1/Documents/Health/Generic\\_drug\\_antiprice\\_gouging\\_Maryland\\_31894.pdf](http://www.ncsl.org/Portals/1/Documents/Health/Generic_drug_antiprice_gouging_Maryland_31894.pdf).

<sup>116</sup> Richard Cauchi, *supra* note 57.

<sup>117</sup> Assemb. B. 1806, 2018 Leg., Reg. Sess. (2018).

<sup>118</sup> *Id.*

<sup>119</sup> Richard Cauchi, et. al., *Recently Enacted State Laws Affecting Pharmaceutical Costs, Pricing and Payment: 2015-2017*, National Conference of State Legislatures (May 30, 2018), [http://www.ncsl.org/Portals/1/Documents/Health/Cost\\_Enacted\\_RX\\_052518\\_32352.pdf#page=3](http://www.ncsl.org/Portals/1/Documents/Health/Cost_Enacted_RX_052518_32352.pdf#page=3).

<sup>120</sup> Gabriela Dieguez, et. al., *The Impact of California’s Prescription drug-cost-sharing cap 3* (Milliman Report 2018).

substantially limited.

Fifth, a majority of states have implemented legislation, subject to CMS approval, that determines Medicaid prescription drug coverage based upon negotiation and cost-effectiveness.<sup>121</sup> Under this legislation, states have adopted four payment models for determining cost-effectiveness: (1) establishing a Medicaid drug cap; (2) utilizing value-based contracting; (3) a subscription-based payment model; and (4) a closed formulary approach. In 2017, New York established a Medicaid drug cap to balance the growth of drug expenditures with the growth of total Medicaid expenditures.<sup>122</sup> Under New York's law, New York's Drug Utilization Review Board follows a recommended target for the value of a Medicaid rebate to be paid by the manufacturer to the State.<sup>123</sup> If a satisfactory rebate agreement is not agreed upon, any non-cooperating manufacturers are required to file a detailed financial report including, but not limited to, the actual cost of developing, manufacturing, producing and distributing the drug; research and development costs; administrative and marketing costs; the price of the drug when sold outside the United States; the average rebates and discounts provided per payer type in the state; and the average profit margin of each drug.<sup>124</sup>

In 2018, CMS approved Oklahoma legislation that utilized a value-based model. The value-based model authorizes the state to negotiate supplemental rebate agreements for pharmaceuticals involving value-based purchasing agreements with manufacturers that could produce additional rebates for states if specific outcomes were not achieved.<sup>125</sup> Thus, if certain

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<sup>121</sup> Center for Consumer Information and Insurance Oversight, *Compliance and Enforcement*, CENTER FOR MEDICARE AND MEDICAID SERVICES (Apr. 3, 2015), <https://www.cms.gov/ccio/programs-and-initiatives/health-insurance-market-reforms/compliance.html>.

<sup>122</sup> New York Public Health Law § 280 (2017).

<sup>123</sup> *Id.*

<sup>124</sup> *Id.*

<sup>125</sup> Letter from John Coster, Director, Department of Health & Human Services, to Becky Pasternik-Ikard, Chief Executive Officer, Oklahoma Health Care Authority (July 27, 2018) (on file with author).

clinical or cost benchmarks were not achieved, the drug manufacturer is required to provide additional rebates to the state.<sup>126</sup> Louisiana adopted a subscription-based payment model for Hepatitis C drugs.<sup>127</sup> Under this model, the state pays drug manufacturers for unlimited access to the treatment for individuals enrolled in Louisiana's Medicaid or correctional system.<sup>128</sup> The cost would be equal to or less than the state's current expenditures for providing the medication to these groups.<sup>129</sup> Lastly, Massachusetts adopted a closed formulary approach. Under this approach, the state would be not be required to cover every drug made by a manufacturer that participates in the federal Medicaid rebate program.<sup>130</sup> Instead, the law would have allowed the state to choose which prescription drugs to cover according to cost effectiveness and their beneficiaries' needs.<sup>131</sup> However, CMS denied the Massachusetts law because the proposal would have also preserved statutory rebates.<sup>132</sup> CMS stated that they would consider a closed-formulary approach in Medicaid if the state agreed to forgo the available mandatory rebates through the Medicaid rebate program.<sup>133</sup>

State legislative efforts have had mixed success. Some of the legislation has been effective in curtailing increases in pharmaceutical costs, while the benefits of other legislation have been blocked by the courts or a reluctant federal government.

## **VI. Steps being taken—Federal Government**

Alongside state legislation, the federal government has taken unilateral steps to curtail the

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<sup>126</sup> Richard Cauchi, *supra* note 57.

<sup>127</sup> LOUISIANA DEPT. OF HEALTH, REQUEST FOR INFORMATION ON SUBSCRIPTION PAYMENT MODELS 1 (2018).

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

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

<sup>130</sup> Tiernen Meyer, Laura DiAngelo, *CMS Rejects Massachusetts' Medicaid Closed Formulary Proposal*, AVALERE (July 3, 2018), <https://avalere.com/insights/cms-rejects-massachusetts-medicaid-closed-formulary-proposal>.

<sup>131</sup> Martha Bebinger, *Trump Administration Rejects Mass. Plan to Curb Medicaid Drug Prices*, WBUR (June 27, 2018), <http://www.wbur.org/commonhealth/2018/06/27/trump-administration-rejects-massachusetts-plan-to-curb-medicaid-drug-prices>.

<sup>132</sup> Tiernen Meyer, *supra* note 130.

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

rising costs of pharmaceuticals. In May of 2018, President Donald Trump’s administration released the American Patients First blueprint to explain initiatives designed to lower drug prices and reduce out-of-pocket costs for consumers.<sup>134</sup> The blueprint’s initiatives are premised upon increasing competition, improving negotiation, creating incentives to lower list prices, and reducing patient out-of-pocket spending costs.<sup>135</sup>

Pursuant to its Drug Competition Action Plan, the FDA implemented two new policies in 2017 to increase competition in the pharmaceutical industry. First, the agency published a list of off-patent, off-exclusivity, branded drugs without approved generics in order to improve transparency and encourage the development and submission of new generic drug applications for drugs with limited competition.<sup>136</sup> Second, the agency implemented a new policy to expedite the review of generic drug applications in situations where competition is limited.<sup>137</sup> FDA Commissioner Scott Gottlieb stated, “[g]etting safe and effective generic products to market in an efficient way, being risk-based in our own work and making sure our rules aren’t used to create new obstacles to new competition can all help make sure that patients have access to more lower-cost options.”<sup>138</sup> In 2017 alone, over 1,000 generic drugs were approved and saved American consumers and taxpayers approximately nine billion dollars.<sup>139</sup>

In May, Congress passed, nearly unanimously, both the Know the Lowest Price Act and the Patient Right to Know Drug Prices Act.<sup>140</sup> These laws ban the inclusion of pharmacy “gag

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<sup>134</sup> THE UNITED STATES DEPARTMENT OF HEALTH & HUMAN SERVICES, AMERICAN PATIENTS FIRST: THE TRUMP ADMINISTRATION BLUEPRINT TO LOWER DRUG PRICES AND REDUCE OUT-OF-POCKET COSTS 9 (2018).

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

<sup>136</sup> FOOD AND DRUG ADMINISTRATION, LIST OF OFF-PATENT, OFF-EXCLUSIVITY DRUGS WITHOUT AN APPROVED GENERIC (2018).

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

<sup>138</sup> Press Release, Food and Drug Administration, FDA Tackles Drug Competition to Improve Patient Access (June 27, 2018) (on file at <https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm564725.htm>).

<sup>139</sup> THE UNITED STATES DEPARTMENT OF HEALTH & HUMAN SERVICES, AMERICAN PATIENTS FIRST: THE TRUMP ADMINISTRATION BLUEPRINT TO LOWER DRUG PRICES AND REDUCE OUT-OF-POCKET COSTS 18 (2018).

<sup>140</sup> S. 2553, 115th Cong. § 2 (2018); S.2554, 115th Cong. § 2 (2018).

clauses.”<sup>141</sup> This federal action follows after twenty-nine states enacted laws to protect pharmacies and pharmacists from penalties by a PBM for disclosing such information.<sup>142</sup> The CBO estimates the law will reduce the deficit by \$40 million over the next decade.<sup>143</sup>

The Trump administration plans to further increase competition in 2019 by limiting companies from using its 180-day exclusivity period to indefinitely delay real competition and savings for consumers.<sup>144</sup> The concern stems from first filers that receive tentative generic drug approval, but then intentionally delay seeking final approval as a means to block competitions.<sup>145</sup> Thus, first filers “park their exclusivity, and consumers are denied access to generic products and must keep paying brand price.”<sup>146</sup> In its 2019 budget proposal, HHS proposed legislation that proposal “makes the tentative approval of a subsequent generic drug applicant that is blocked solely by a first applicant’s 180-day exclusivity, where the first applicant has not yet received final approval, a trigger of the first applicant’s 180-day exclusivity.”<sup>147</sup> HHS believes that this proposal will enhance competition and expedite timely access to generic drugs without compromising the safety of the drug approval process. The proposal is estimated to create \$1.8 billion in Medicare savings over the next decade.<sup>148</sup>

The federal government is also implementing measures to improve negotiation, especially

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<sup>141</sup> S.2554, 115th Cong. § 2 (2018).

<sup>142</sup> Richard Cauchi, *States Regulating Pharmaceutical Benefit Managers*, NATIONAL CONFERENCE OF STATE LEGISLATURE (Oct. 11, 2018), <http://www.ncsl.org/research/health/pbm-state-legislation.aspx>.

<sup>143</sup> CONGRESSIONAL BUDGET OFFICE, DIRECT SPENDING AND REVENUE EFFECTS FOR THE PATIENT RIGHT TO KNOW DRUG PRICES ACT (2018).

<sup>144</sup> THE UNITED STATES DEPARTMENT OF HEALTH & HUMAN SERVICES, AMERICAN PATIENTS FIRST: THE TRUMP ADMINISTRATION BLUEPRINT TO LOWER DRUG PRICES AND REDUCE OUT-OF-POCKET COSTS 19 (2018).

<sup>145</sup> UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, PUTTING AMERICA’S HEALTH FIRST: FY 2019 PRESIDENT’S BUDGET FOR HHS 15 (2018).

<sup>146</sup> *Id.*

<sup>147</sup> *Id.*

<sup>148</sup> *Id.*

in regard to Medicare. While the blueprint does not go so far as currently allowing Medicare to directly negotiate prices with manufacturers, it does propose to alter regulations under Part C and Part D of the Medicare Prescription Drug Program to allow for faster mid-year substitutes.<sup>149</sup> Mid-year substitutions permit Part D sponsors to immediately substitute generics for brand-name drugs on the same or lower cost-sharing tier.<sup>150</sup> Currently, Medicare participants face difficulties when trying to substitute prescription drugs. Removing limitations on mid-year substitutes promotes the use of generic drugs while decreasing the cost imposed on Medicare participants.

Outside of Medicare negotiations, the federal government plans to work alongside the Department of Commerce, the U.S. Trade Representative, and the U.S. Intellectual Property Enforcement Coordinator to address the disparity between drug prices in the U.S. compared to other developed countries.<sup>151</sup> However, no specific plans have been created or implemented.

The federal government also seeks to establish a maximum for out-of-pocket spending to benefit those that spend the most on drugs.<sup>152</sup> The plan suggests an “inflation penalty” in the form of increased rebates from drug companies whose price increases are greater than the rate of inflation.<sup>153</sup> These changes would create strong incentives for manufacturers to negotiate lower prices on over-priced drugs. The government also plans to combat the high list prices through increased transparency; specifically, the FDA has sought to include list prices in direct-to-consumer (“DTC”) advertising.<sup>154</sup> CMS has sought to hold manufacturers “accountable for high

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<sup>149</sup> THE UNITED STATES DEPARTMENT OF HEALTH & HUMAN SERVICES, AMERICAN PATIENTS FIRST: THE TRUMP ADMINISTRATION BLUEPRINT TO LOWER DRUG PRICES AND REDUCE OUT-OF-POCKET COSTS 19 (2018).

<sup>150</sup> Press Release, Center for Medicare and Medicaid Services, CMS Finalizes Policy Changes and Updates for Medicare Advantage and the Prescription Drug Benefit Program for Contract Year 2019 (Apr. 2, 2018).

<sup>151</sup> THE UNITED STATES DEPARTMENT OF HEALTH & HUMAN SERVICES, AMERICAN PATIENTS FIRST: THE TRUMP ADMINISTRATION BLUEPRINT TO LOWER DRUG PRICES AND REDUCE OUT-OF-POCKET COSTS 19 (2018).

<sup>152</sup> *Id.* at 34.

<sup>153</sup> DAN BEST, REPORT ON 100 DAYS OF ACTION ON THE AMERICAN PATIENTS FIRST BLUEPRINT 4 (Dept. of Health and Human Services 2018).

<sup>154</sup> THE UNITED STATES DEPARTMENT OF HEALTH & HUMAN SERVICES, AMERICAN PATIENTS FIRST: THE TRUMP ADMINISTRATION BLUEPRINT TO LOWER DRUG PRICES AND REDUCE OUT-OF-POCKET COSTS 25 (2018).

price increases, highlight drugs that have not taken price increases, and recognize when competition is working with an updated drug pricing dashboard.”<sup>155</sup> Critics contend that there is no evidence that inclusion of list prices in DTC advertising will reduce pharmaceutical prices. Instead, they argue that focus on price disclosure “is a distraction from additional action that would benefit people—lowering prices.”<sup>156</sup> Industry supporters believe that the measure will confuse, mislead, and potentially harm patients. Jon Bigelo, an executive director of the Coalition for Healthcare Communications wrote that it may, “discourag[e] them from initiating important conversations with health providers and seeking medical care they need.”<sup>157</sup>

The federal government is also seeking to reduce out-of-pocket costs by implementing a policy in which biosimilar drugs receive similar billing and payment codes under Medicare Part B.<sup>158</sup> Biosimilar drugs are FDA-approved, which are determined to have a biological or chemical structure that is interchangeable with an FDA-approved biological product.<sup>159</sup> The FDA implemented the biosimilar process “as a way to provide more treatment options, increase access to lifesaving medications, and potentially lower health care costs through competition.”<sup>160</sup> It is anticipated that this program will incentivize the development of additional lower-cost biosimilars at a cheaper production cost while maintaining innovation among the pharmaceutical manufacturers.<sup>161</sup>

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<sup>155</sup> *Id.*

<sup>156</sup> Memorandum from Ben Wakana, Executive Director, Patients for Affordable Drugs, to Interested Parties (Oct. 15, 2018), <https://www.patientsforaffordabledrugs.org/2018/10/15/disclosure-of-drug-prices/>.

<sup>157</sup> Laura Entis, *Trump Orders drug companies to disclose prices. Will it actually happen?*, MM&M (Oct. 17, 2018), <https://www.mmm-online.com/home/channel/regulatory/trump-orders-drug-companies-to-disclose-list-prices-in-dtc-ads-will-it-actually-happen/>.

<sup>158</sup> THE UNITED STATES DEPARTMENT OF HEALTH & HUMAN SERVICES, AMERICAN PATIENTS FIRST: THE TRUMP ADMINISTRATION BLUEPRINT TO LOWER DRUG PRICES AND REDUCE OUT-OF-POCKET COSTS 19 (2018).

<sup>159</sup> UNITED STATES FOOD & DRUG ADMINISTRATION, BIOSIMILARS ACTION PLAN: BALANCING INNOVATION AND COMPETITION 3 (2018).

<sup>160</sup> *Id.*

<sup>161</sup> THE UNITED STATES DEPARTMENT OF HEALTH & HUMAN SERVICES, AMERICAN PATIENTS FIRST: THE TRUMP ADMINISTRATION BLUEPRINT TO LOWER DRUG PRICES AND REDUCE OUT-OF-POCKET COSTS 19 (2018).

Lastly, the government has sought to reform the 340B Drug Discount Program. The 340B program allows for qualified medical providers to purchase outpatient drugs at deep discounts.<sup>162</sup> Because the program does not require these discounts to be passed onto patients or payers, the program promotes financial stability by allowing participating providers to generate revenue from the sale of these drugs.<sup>163</sup> Effectively, the program allows these entities to “stretch scarce financial resources as far as possible.”<sup>164</sup> However, there are concerns that a lack of program oversight has harmed the program.<sup>165</sup> A 2016 review by the Office of Pharmacy Affairs in the Health Resources and Services Administration (HRSA) found that HRSA audited less than two percent of all participating providers.<sup>166</sup> There are also concerns as to whether new participants are using the 340B benefits to improve healthcare access for low income patients or whether the 340B revenue is used to increase revenue for hospital systems.<sup>167</sup> Under the current statute, DSHs do not have to demonstrate that the 340B revenues are utilized to enhance safety-net engagement.<sup>168</sup> Rather, they must only demonstrate that they provide a “sufficient amount” of inpatient services to Medicaid and low-income Medicare beneficiaries.<sup>169</sup> The Office of the Inspector General in 2014 found that most DSH hospitals did not offer discounted prices to uninsured patients.<sup>170</sup>

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<sup>162</sup> Rena Conti, et. al., *Proposed Reforms to the 340B drug Discount Program*, HEALTHAFFAIRS (Mar. 7, 2018), <https://www.healthaffairs.org/doi/10.1377/hblog20180306.70004/full/>.

<sup>163</sup> *Id.*

<sup>164</sup> *Id.*

<sup>165</sup> Gretchen Moore, *The Time for Strengthening the 340B Program is Now*, ALLIANCE FOR INTEGRITY AND REFORM OF 340B (Mar. 9, 2017), [http://340breform.org/userfiles/FINAL%20-%20AIR340B%20Sign%20On%20Letter%20Release%20030917%20\(1\).pdf](http://340breform.org/userfiles/FINAL%20-%20AIR340B%20Sign%20On%20Letter%20Release%20030917%20(1).pdf).

<sup>166</sup> Rena Conti, *supra* note 178.

<sup>167</sup> *Id.*

<sup>168</sup> *Id.*

<sup>169</sup> *Id.*

<sup>170</sup> Letter from Stuart Wright, Deputy Inspector General for Evaluation and Inspections, Dept. of Health and Human Services, to Mary Wakefield, Administrator, Health Resources and Services Administration (Feb. 4, 2014), <https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf>.

As a result, the 340B PAUSE Act and the 340B HELP Act have been proposed.<sup>171</sup> The two acts, taking slightly different approaches, propose a two year freeze on the approval of new disproportionate share hospitals (DSHs), their clinics, and contract pharmacies.<sup>172</sup> The two Acts also propose increasing reporting requirements and enforcing eligibility criteria for DSHs and their affiliates and imposing additional requirements for pharmacies.<sup>173</sup> The enactment of this legislation aims to increase accountability for those participating under the 340B program and increase care for underprivileged patients by assuring that they receive the discounted prices as provided under the current 340B program. Critics of the PAUSE Act and HELP Act contend that there are issues regarding the scope and implementation. Critics also argue that freezing the approval of additional DSHs would limit the accessibility for those that the 340B program seeks to protect.

Since the Trump administration released its blueprint to reduce prescription drug prices and out-of-pocket costs earlier this year, notable changes to the pharmaceutical sector have occurred. Within the first 100 days, fifteen drug companies reduced their priced and either rolled back planned price increases or committed to price freezes for the rest of 2018.<sup>174</sup> During this period, there was 60% fewer brand-drug price increases than during the same period in 2017.<sup>175</sup> Price decreases occurred in 54% of generic and brand-name drugs than during the same period in 2017.<sup>176</sup> Dan Best, Senior Advisor to the Secretary for Drug Pricing Reform, referred to the rollbacks as “unprecedented recognition of fundamental changes going on in drug markets.”<sup>177</sup> Additionally, the FDA in July of 2018 approved more generic drugs than in any other month in its

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<sup>171</sup> S.2312, 155th Cong. (introduced Jan. 16, 2018); H.R. 4710, 155th Cong. (introduced Dec. 2, 2017).

<sup>172</sup> S.2312, 155th Cong. (introduced Jan. 16, 2018); H.R. 4710, 155th Cong. (introduced Dec. 2, 2017).

<sup>173</sup> S.2312, 155th Cong. (introduced Jan. 16, 2018); H.R. 4710, 155th Cong. (introduced Dec. 2, 2017).

<sup>174</sup> Dan Best, *supra* note 169 at 1.

<sup>175</sup> *Id.* at 2

<sup>176</sup> *Id.* at 2.

<sup>177</sup> *Id.* at 1.

history. These approvals included a generic version of the EpiPen and a biosimilar competitor for a costly drug which fights infections in cancer patients.<sup>178</sup>

While these facts are an encouraging sign that the drug companies are reacting positively to the increased scrutiny, many critics contest that the pharmaceutical industry improvements are not correlated to the Trump administration's blueprint. Health policy expert Rachel Sachs, an associate professor of law at Washington University in St. Louis, opined that, "[t]he administration seems to be feeling a need to deliver results quickly on the drug pricing front, and so they are pointing to metrics like fewer price increases...rather than metrics that will be meaningful to patients."<sup>179</sup> Additionally, HHS's analysis was limited in its access to information and relied instead upon a subscription database, AnalySource, which was unable to link directly to sales volume.<sup>180</sup> HHS acknowledged flaws in its analysis stating that its calculation was limited to "simple counts and descriptives" of price increases.<sup>181</sup> Because HHS lacked supporting information and could not identify the magnitude of the price changes, HHS could not determine the blueprint's effectiveness on overall drug spending.<sup>182</sup>

Overall, the federal government has implemented a vast number of policies with the goal of reducing the rising costs of pharmaceuticals. While some policies have seen immediate results, others have not. Regardless of the determination of success, a reduction in pharmaceutical prices is more likely to occur through increased federal legislation.

## **VII. Proposed Strategies for Combatting the Increasing Costs**

Various market, legislative, and societal approaches have been taken, with mixed results

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<sup>178</sup> Id. at 2.

<sup>179</sup> Donna Young, *HHS offers scant evidence Trump's drug blueprint putting brakes on price hikes*, S&P GLOBAL (Aug. 22, 2018), <https://platform.mi.spglobal.com/web/client?auth=inherit#news/article?id=46078235&cdid=A-46078235-12332>.

<sup>180</sup> Id.

<sup>181</sup> Id.

<sup>182</sup> Id.

to impact the cost of pharmaceutical drugs. In evaluating the various approaches to combating the rise in pharmaceutical prices, three measures provide the greatest upside: (1) allowing international importation of approved drugs from Canada; (2) allowing direct negotiation for Medicare; and (3) expediting approval of generic drugs.

#### **A. Allowing importation of drugs from Canada**

Allowing the importation of drugs from Canada will have the greatest impact on reducing the cost of pharmaceuticals. Despite the apprehensions over the importation of pharmaceuticals from Canada, importation legislation (1) does not pose any additional risk to the public's health and safety; and (2) would result in a significant reduction in the costs of covered products to the American consumer.

Steep regulatory requirements embedded in the legislation would ensure that imported drugs will not pose an additional risk to the public's health and safety. Under the various legislation, the importer must be licensed in accordance with Canada's laws and state specific pharmacy and wholesaler regulations. Imported drugs must be approved by the Canadian regulatory board, Health Canada; an agency that the FDA previously recognized and with whom the parties agreed to cooperate on regulatory requirement and standards.<sup>183</sup> Finally, the imported drugs would only be distributed in-state, preventing interstate transportation and limiting possible contamination.

Enacting this program will also result in a significant savings given the material difference in drug prices between Canada and the U.S. According to Vermont Senator Bernie Sanders, drug

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<sup>183</sup> UNITED STATES-CANADA REGULATORY COOPERATION COUNCIL, JOINT FORWARD PLAN (2014) (The FDA has also regulated standards of foreign drugs for distribution in the U.S., acknowledging that “[s]ome drugs approved in the United States are either fully manufactured overseas or made in the United States but contain some foreign ingredients.” The FDA also acknowledged that it routinely inspects domestic and foreign drug manufacturing plants to assure compliance with FDA standards. Press Release, Food and Drug Administration, FDA takes unprecedented step toward more efficient global pharmaceutical manufacturing inspections (Oct. 31, 2017), <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm583057.htm>).

importation could save tax payers 6.8 billion dollars over ten years.<sup>184</sup> While HHS disagrees with Senator Sanders' economic analysis, arguing that drug importation from Canada alone was projected to produce only a negligible reduction in drug spending it is hard to argue that any competition would not result in savings for American patients.<sup>185</sup> Furthermore, HHS continues to rely on a 2004 Congressional Budget Office ("CBO") study that would seemingly be outdated given the significant developments in drug manufacturing, legislation and markets. As such, any delay in implementing drug importation should be based on a new study to better understand the economic benefits of such legislation.

### **B. Allowing Medicare to directly negotiate with pharmaceutical companies**

Amending the Social Security Act, so that Medicare may negotiate with drug manufacturers, pharmacies and PDP sponsors, and allow particular formulary or institute a price structure for the reimbursement of covered Part D drugs would be a seismic step in combating unbridled increases drug prices. The Center for Economic and Policy Research estimated federal savings between \$230 billion to \$541 billion over ten years if Medicare negotiated the same prices for drugs as countries where prices are set automatically.<sup>186</sup> The analysis also estimated annual savings of approximately fifteen billion dollars per years if Medicare paid the same prices as Medicaid and the Veterans Association.<sup>187</sup> Such an amendment has broad bipartisan support. Furthermore, implementation would be widely supported by the American people. According to the Henry J. Kaiser Family Foundation, among the public, Medicare negotiation is supported by

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<sup>184</sup> CONGRESSIONAL BUDGET OFFICE, PRELIMINARY ESTIMATE: THE AFFORDABLE AND SAFE PRESCRIPTION DRUG IMPORTATION ACT (2017).

<sup>185</sup> CONGRESSIONAL BUDGET OFFICE, ECONOMIC AND BUDGET ISSUE BRIEF: WOULD PRESCRIPTION DRUG IMPORTATION REDUCE U.S. DRUG SPENDING? 5 (2004) (citing CONGRESSIONAL BUDGET OFFICE, THE PHARMACEUTICAL MARKET ACCESS ACT OF 2003, CBO COST ESTIMATE (2003)).

<sup>186</sup> *Id.*

<sup>187</sup> *Id.*

96 percent of Democrats, 92 percent of Republicans and 92 percent of Independents.<sup>188</sup>

The impediment to such legislation appears to be the CBO 2004 study, and its analysis that giving the HHS Secretary such authority would produce a “negligible effect on cost management efforts.”<sup>189</sup> Its conclusion relied on the expectation that the HHS Secretary would be limited in his ability to negotiate substantial discounts. Instead, the Congressional Budget Office proposed that savings could be achieved by authorizing the HHS Secretary to set drug prices administratively rather than negotiating on prices.<sup>190</sup> The Congressional Budget Office’s conclusion on savings does not incorporate its propositions into its calculation.

Given the size and scope of the Medicaid budget and the minimal leverage that such a consumer would have at any negotiating table, it is difficult to understand CBO’s conclusion that HHS could not seek significant reductions in drug pricing. Even more compelling would be the leverage that Medicare and the Veteran’s Association would add to any such negotiations. Government, as a major purchaser of pharmaceuticals, should not be hampered in price negotiations as any decreases, even negligible, in drug pricing would undoubtedly have significant impacts on federal and state budgets.

### **C. Expediting approval of generic drugs**

Expediting approval of generic drugs will aid in reducing pharmaceutical costs by increasing competition in the open market. Manufacturers enjoy a lengthy period of non-competition from with a patent, during which time they can charge a suitable, albeit not necessarily reasonable, price to reward their innovation. But this monopoly period should not be enhanced by a slow approval process for generic drugs. The availability of generic drugs, after patent

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<sup>188</sup> Id.

<sup>189</sup> CONGRESSIONAL BUDGET OFFICE, A CBO PAPER: A DETAILED DESCRIPTION OF CBO’S COST ESTIMATE FOR THE MEDICARE PRESCRIPTION DRUG BENEFIT (2004) at 14.

<sup>190</sup> Id.

expiration, demonstrably shows significant price decreases.

Enacting HHS's 180 day acceleration rule proposed in their 2019 budget, the first filers would be encouraged to move their applications without delay; thereby getting generic drugs to market faster. Furthermore, abbreviating the applications but not testing would further accelerate the influx of generic drugs into the market. According to the FDA's policy manual, applications for generic products may receive expedited review if there are no blocking patents or exclusivities and if the reference drug has less than three approved generics.<sup>191</sup> Helping generic drugs into the market quickly and safely will have the tremendous effect of decreasing drug prices.

### **VIII. Conclusion**

Increased pharmaceutical costs have posed an ever-growing public health problem for the nearly thirty years. These increases, well above the rate of inflation, have compromised some individual's health as they elect to forego treatment due to cost; causing long-term health implications; and imposing costs upon the public health system. Understandably, pharmaceutical companies need to be able to recoup investments in drug research and deliver returns for their shareholders in order to continue to deliver innovative drugs. However, without effective mechanisms to limit increases in drug costs drug prices are causing a public health care crisis.

Drug prices are causing economic and physical harm to the Americans. As drug prices rise without restraint, individuals, employers and federal and state governments must find ways to cover these costs from strained resources. Moreover, studies show that patients skip taking some, if not all, their prescribed medication because of drug prices, which in turn leads to additional health problems, loss productivity and, in some cases, death. These costs add further burden on society and can be measured in the billions.

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<sup>191</sup> FOOD AND DRUG ADMINISTRATION, CENTER FOR DRUG EVALUATION AND RESEARCH, MANUAL OF POLICY AND PROCEDURES (2017).

Federal and state governments have taken different approaches to limit drug increases and their effect, from transparency regulations, use of generic drugs, payment restrictions and even public humiliation. Some of these measures have worked, others moderately so, and still others are obstructed by a lack of interest or belief that a particular legislation would be more than negligibly helpful.

But given the change and, if fully embraced, by the purchasing factions, some measures can significantly combat the rise in drug prices. Allowing greater competition by importing medications from abroad, specifically Canada, would reduce drug prices. Further expediting the approval and release of generic drugs into the market would force brand-name drugs to reduce prices or risk significant loss in a drug's market power. But the most significant change would be to unleash the power of the federal government, not to impose regulations, but to use market power to demand cost adjustments and limit price increases on drugs. Each of these measures on its own would have significant, if not material, benefit to patients and providers. But taken together, these three approaches would provide patients safe and affordable medications and the drug market to operate in a more natural commercial market without the unnecessary restraints imposed on providers and payers.