

# What Is Increasing the Cost of Generic Drugs?

## (Part II: Regulatory and Legal Reasons)<sup>1</sup>

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by Devon M. Herrick

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*Compared to the funds spent on doctors and hospitals, prescription drug therapy is a bargain. Generic drugs are especially inexpensive, accounting for 88 percent of drug prescriptions filled but only 28 percent of expenditures on drug therapies.*



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### Executive Summary

The average price of a brand drug falls by about 80 percent or more within a year after it faces competition from generics. Whereas the average cost of a name-brand prescription was \$268 in 2011, it was only about \$33 for a generic drug.

Intense competition usually holds generic drug prices in check. Oddly, during the past few years many generic drugs that have been on the market for decades have suddenly become expensive. In 2014, the price of more than one-fourth of generic drugs rose 10 percent to 100 percent or more. In other cases, old generic drugs have become scarce and hard to procure. The following are some of the regulatory and legal reasons drug prices are rising.

**Slow FDA Approvals Reduce Generic Competition.** Over the past five years, the U.S. Food and Drug Administration (FDA) has approved an average of 400 to 500 generic drugs annually. But this is only a fraction of the applications received. The FDA still has a backlog of about 4,000 applications, with an average time to approval of more than two years.

**Quality Compliance on Aging Production Lines.** Old drugs are often made on aging production lines. These are sometimes shut down for maintenance or are stopped after the manufacturer is warned by the FDA that the facility is out of compliance with current good manufacturing practices. According to the FDA, much of the problem of sterile generic injectable drugs that are in short supply is the result of poor quality compliance.

**The FDA's Unapproved Drugs Initiative.** Thousands of drugs predate the approval required under the 1938 Food, Drug & Cosmetics Act — many were grandfathered but never officially approved. The FDA wants these cheap drugs off the market and replaced with more costly “approved” versions from drug makers willing to conduct clinical studies to determine the safety and effectiveness of the drugs — the standard for approval under the 1938 act.

**Pay-for-Delay.** So called *pay-for-delay* is a negotiated agreement whereby the patent holder compensates the ‘first-filer’ to delay a patent

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challenge for an agreed upon length of time. The Federal Trade Commission believes pay-for-delay costs consumers \$3.5 billion annually due to higher drug costs.

**Generic Substitution Laws.** Pharmacists and pharmacies are governed by state laws and state regulations. The degree to which states allow pharmacists to substitute cheaper generic drugs for brand drugs varies from one state to the next.

**How Not to Deal with Rising Drug Prices.** Barriers to competition in all forms ultimately hurt consumers, employers, insurers, drug plans and taxpayers. If prices rise, consumers pay through higher premiums, higher taxes or lower wages. Today, most health plans include some drug benefits. Insurers and employers often hire Pharmacy Benefit Managers (PBMs) to administer drug plans. PBMs use a variety of techniques to control costs for their clients and enrollees. PBMs encourage enrollees to use cost-effective alternatives, such as generic drugs. They also negotiate with pharmacies and assemble preferred pharmacy networks to mitigate the problem of rising prices. When price volatility impacts local pharmacies, politicians often attempt to insulate drugstores and local business from the pain this causes. In the process, state lawmakers often make the situation worse. The following are some harmful regulations that should not be used to deal with rising drug prices.

*Banning Efficient Pharmacy Networks.* Increasingly, health plans and PBMs reduce premiums by negotiating and contracting with qualified pharmacies offering competitive prices. Some state legislatures have passed *any willing pharmacy* regulations that restrict the right of health plans to contract with exclusive narrow networks.

*Restricting Mail-Order Pharmacies.* PBMs often use discounts and lower cost-sharing to encourage beneficiaries to use convenient, low-cost mail-order pharmacies. Many state legislatures have tried to ban the use of financial incentives to reward consumers for using mail-order.

*Restricting Maximum Allowable Cost (MAC).* The wholesale cost of generic drugs can vary tremendously from one manufacturer to the next. So-called MAC price lists are a tool health plans, drug plans and insurers use to place an upper payment limit on what the plan is willing to reimburse for a given drug. Without a limit, pharmacies would have little reason to hold down costs since they could pass the higher cost onto drug plan members. More than a dozen states have laws restricting some aspect of maximum allowable cost (MAC) lists.

**How to Lower America's Drug Bills.** Generic drugs are inexpensive when there is competition, but less so when markets consolidate and the FDA lacks the resources to quickly process competitors' applications to produce generic drugs. The FDA needs to clear the backlog of applications and allow competition to flourish. This, in turn, would alleviate some of the price hikes caused by market consolidation in both drug manufacturing and distribution. Finally, states need to resist pleas from local constituents to pass perverse regulations designed to protect local business (and pharmacies) at the expense of competition.

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## Introduction

Americans consume nearly \$3 trillion of medical care annually, about half of which is spent on physician care and hospital care.<sup>2</sup> Compared to spending on doctors and hospitals, prescription drug therapy is a bargain. Americans spend twice as much for physician care and three times as much on hospital care as they do for drugs. [See Figure I.]

Drugs are also convenient. Most patients prefer medication over surgery to treat significant health problems. Indeed, one of the main reasons many Americans see their doctors is to access prescriptions or to monitor drug therapies. About three-fourths of physician visits result in prescription drug therapy.<sup>3</sup>

While drugs represent the greatest value in the U.S. health care system, generic drugs are a bargain compared to alternative forms of care. Generic drugs are often 85 percent to 90 percent less expensive than their name brand counterparts were just prior to patent expiration. However, the prices of many generic drugs have increased significantly recently — often for no apparent reason. This report explains the multiple reasons Americans increasingly experience sticker shock at the drugstore and what can be done about it.

**Background on Drug Therapies.** Drug therapy is the most efficient method to treat most ailments, and most drugs are prescribed to treat chronic conditions.

- More than 60 percent of Americans take a prescription drug in any given year, including 90 percent of all seniors.<sup>4</sup>
- An estimated 4.3 billion retail prescriptions were filled in 2014 — about a dozen per person in the United States, on average.<sup>5</sup>

Broader use of prescription drugs for chronic conditions could improve health status and reduce medical costs by avoiding expensive emergency room visits, costly complications and

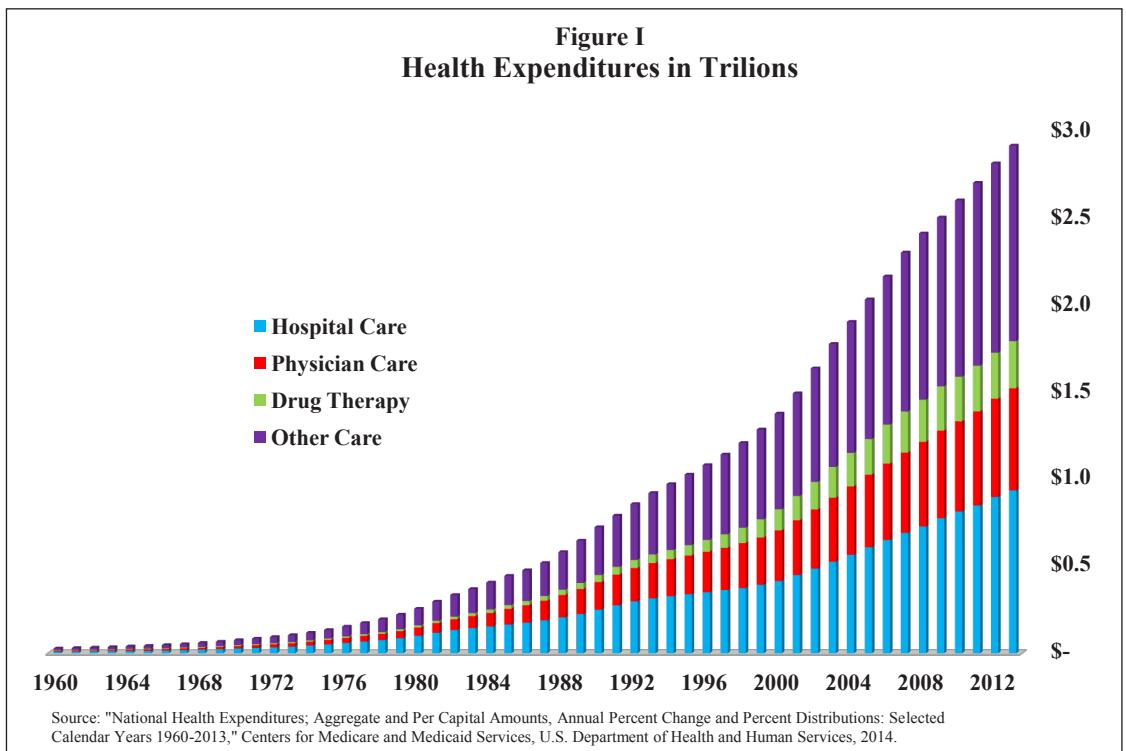
hospitalizations. Spending on prescription drugs has grown at a tremendous rate for the past two decades, jumping almost 13 percent in 2014 alone.

- U.S. residents spent about \$329 billion on prescription therapies in 2013, rising to \$374 billion in 2014.<sup>6</sup>
- This is a significant increase from the \$40 billion spent on prescriptions just over two decades ago.<sup>7</sup>

America’s drug bill is expected to continue rising into the foreseeable future. Specialty drugs now account for one-third of drug spending, even though they only represent 1 percent of drugs prescribed. Name-brand drugs cost (11 percent of drugs filled) account for 39 percent of drug spending.<sup>8</sup> Generic drugs account for 88 percent of prescriptions but only 28 percent of expenditure on drug therapies. [See Figure II.]

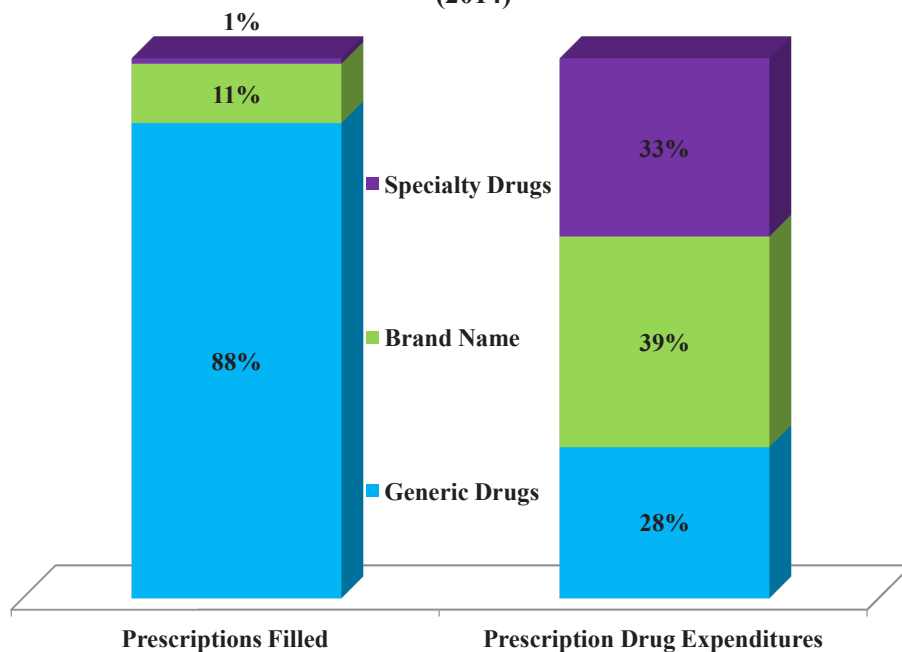
**America’s Health Care Bargain: Generic Drugs.** Often ignored in discussions of so-called “miracle drugs,” specialty drugs and new drug innovation is a type of drug therapy that costs consumers comparatively little and produces benefits far exceeding costs: generic drugs. Generic drugs include expensive blockbuster drugs approved years ago that have lost patent protection.

*The Drug Price Competition and Patent Term Restoration Act of 1984* (the Hatch-Waxman Act) created a pathway for multiple firms to produce generic versions



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**Figure II**  
**Prescription Drug Utilization**  
**(2014)**



Source: Murray Aitken, Michael Kleinrock, Jennifer Lyle, Deanna Nass and Lauren Caskey, "Medicine Use and Spending Shifts: A Review of the Use of Medicines in the U.S. in 2014," IMS Institute for Healthcare Informatics, April 2015.

of name-brand drugs. When a patent for a branded medication expires, competing firms can submit an abbreviated new drug application to the FDA to produce chemically similar versions. Prior to Hatch-Waxman, generic drug makers had to perform clinical trials for their generic drugs similar to the innovator drug maker.<sup>9</sup> Generic drugs are not required to be *identical* to the branded drug with which they compete; rather, they have to be very *similar* in key ways.<sup>10</sup>

**Recent Generic Drug Prices.** Americans spend an estimated \$106 billion annually on generic prescription medications.<sup>11</sup> These drugs are generally inexpensive; the average price of a generic drug falls by about 80 percent or more within a year after a name brand drug loses patent protection and faces competition. Precise estimates are difficult to make, however:

- The estimated average cost of a name-brand prescription was \$268 in 2011.
- By contrast, the cost of a generic prescription was much lower — only about \$33.
- Whereas the average cost of a branded prescription increased by nearly 18 percent that year, the average cost of a generic prescription fell by 7 percent in 2011.<sup>12</sup>

But that is only part of the story. Some generic drug prices increased dramatically from July 2013 to July 2014:

- Nearly half of generic drugs declined in price, whereas the other half increased in price.
- More than one-quarter of generic drugs increased in price by 10 percent or more.<sup>13</sup> [See Figure III.]
- Only 3 percent of generic drugs fell in price by 25 percent or more, whereas 18 percent rose in price by 25 percent or more.

By comparison, consumer prices for all other goods rose only about 2 percent from 2013 to 2014.

In a competitive market with numerous firms competing to sell drugs that are not protected by patents, prices that rise this quickly should entice other firms to enter the market. Unfortunately, competition is unable to hold prices in check.

### **Regulatory and Legal Reasons Why Generic Drug Prices Rise**

Following are some of the factors that raise the cost of generic drugs before they reach the pharmacy shelves.

**Slow Approvals Holding Back Generic Competition.** Prior to 1984, before a drug company could bring a generic drug to market, it had to jump through the same hoops as the manufacturer of the original innovator drug — including expensive clinical trials. The Hatch-Waxman Act of 1984 changed this, allowing new entrants to go through an abbreviated process to prove their chemically-similar versions were absorbed in the body in a way similar to the original.<sup>14</sup> Today, there are nearly 3,000 molecules for which generic versions compete with branded medications — generating savings of approximately \$1.2 trillion over a 10-year period.<sup>15</sup> Although products offered in generic form generate savings for decades, more recently approved generic copies of newer drugs generate most

of the savings. [See Figure IV.] This suggests speeding up the approval process for firms seeking to enter the marketplace would benefit consumers.

The FDA assesses fees on the generic drug industry to boost its resources to review and approve drugs in a timely manner. But the agency is inundated with new drug applications and is slipping behind.

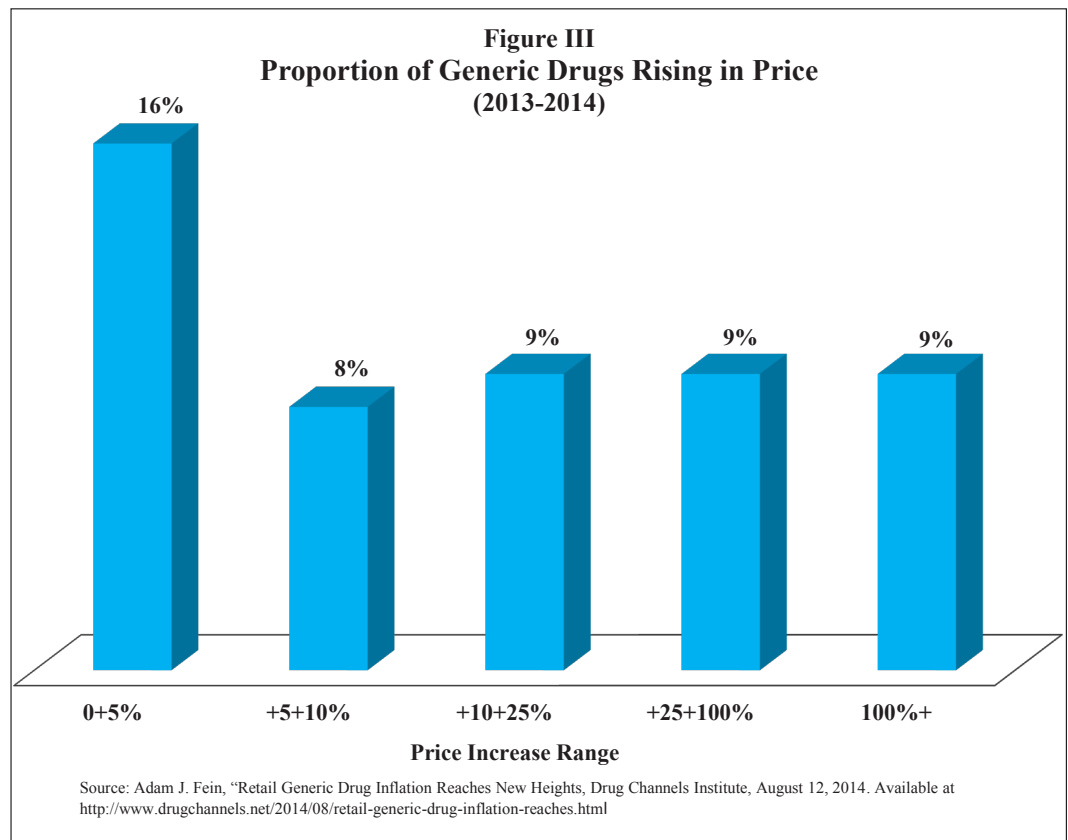
- In the past five years, the agency has approved an average of 400 to 500 generic drugs annually.<sup>16</sup> But this number was only a fraction of the abbreviated new drug applications (ANDA) received by the FDA.
- There were an estimated 800 to 1,000 applications annually from 2010 to 2013.
- About 1,473 applications were received in the fiscal year ending September 30, 2014.<sup>17</sup>
- The FDA currently has a backlog of about 4,000 applications for generic drug manufacturing to clear — up about 40 percent from two years earlier.<sup>18</sup>

In 2005, it took the FDA about 16 months to approve a generic drug application. By 2010, however, the median approval time for new generic drugs had increased to 27 months, including time lapsed after the FDA requested additional information from applicants. While the FDA has taken steps to speed up the process, the number of applications has increased even faster.

One concern with slow approvals is that it makes pricing strategies possible that sharply increase the price of old generic drugs used to treat rare conditions, for which there may be only one or two manufacturers. The FDA's backlog provides a window in which a firm can jack up the price exorbitantly, knowing it will get two years or more of monopoly profits before it faces competition. For example:

- Albendazole is an antiparasitic medication approved for sale in the United States in 1996 cost \$6 per daily dose a few years ago, but now runs about \$275.<sup>19</sup>

**Figure III**  
**Proportion of Generic Drugs Rising in Price (2013-2014)**



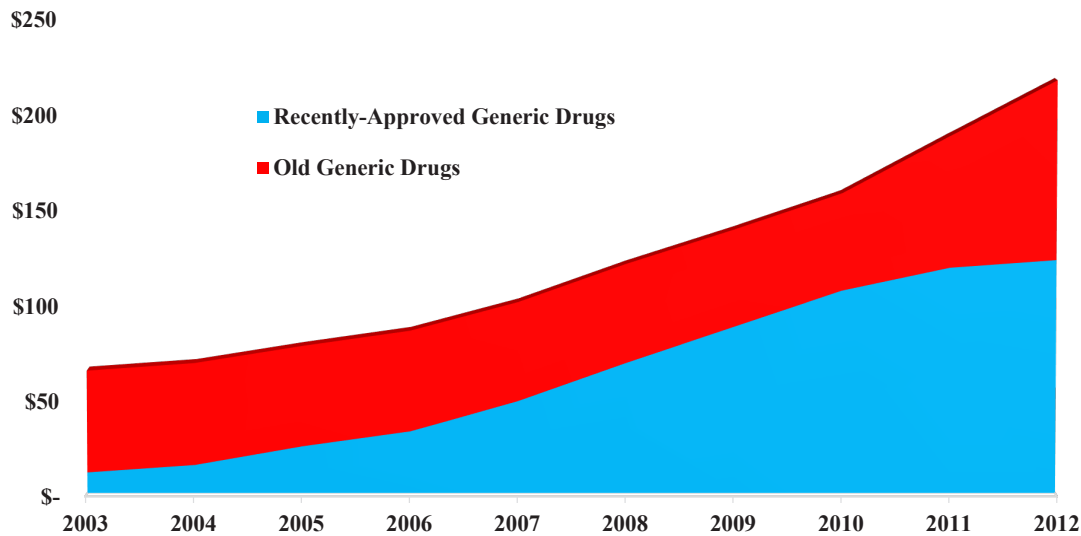
- Turing Pharmaceuticals, run by a former hedge fund manager, bought the rights to Pyrimethamine, a 60-year old remedy also used to treat parasitic infections as well as malaria, and announced a price increase only a month later. A tablet that cost \$1 a few years ago, and \$13.50 before the price hike, increased to \$750 per tablet in September 2015.<sup>20</sup>
- The price of the 60-year old tuberculosis drug, Cycloserine, recently acquired from a nonprofit, was increased from \$500 for 30 tablets to \$10,800 — before the new owner rescinded the price rise under pressure.<sup>21</sup>

New specialty drugs and biological agents to treat rare conditions have become increasingly common in recent years. To encourage drug makers to research and develop new drugs for rare conditions with small markets, the FDA provides lucrative financial incentives in the form of market exclusivity that ensures high prices for a limited time period. As a result, specialty drugs under patent protection are very expensive; although only 1 percent of prescriptions are for specialty drugs they account for one-third of all drug spending.<sup>22</sup> [See Figure II.]

Pharmaceutical manufacturers are free to establish price levels they believe the market will bear. This is

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Figure IV  
Annual Savings from Generic Drugs  
(billions of dollars)



Source: IMS Health, *Generic Drug Savings in the U.S.* 5th ed. Washington, DC: Generic Pharmaceutical Association, 2013.

especially true of branded medications protected by patents. But old drugs don't have patent protection. In the case of Pyrimethamine, Turing Pharmaceuticals figured out this old, little-used drug had a niche that could be exploited. The makers of the old generic drugs mentioned above apparently reasoned they too should be allowed to profit handsomely from drugs for rare conditions — even though they didn't perform the research and development. This strategy is only possible if new competitors are barred from entering the market in a timely manner.

Actions that slow or delay approvals can have huge ramifications for the prices Americans pay. Research shows a significant inverse relationship between the number of generic competitors and the price of a generic drug compared to its brand counterpart. The greater the number of competing generic products on the market, the lower the price.<sup>23</sup> [See Figure V.]

### Quality, Compliance and Aging Production Lines.

The prices of older generic drugs sometimes skyrocket due to shortages caused by aging equipment. According to the FDA, shortages of generic sterile injectable drugs are often the result of poor compliance with FDA quality standards.<sup>24</sup> Sterile injectable drugs are more difficult to manufacture than pills, tablets or capsules. Because they are administered intravenously, sterility and the absence of foreign matter are of greater concern for

injectable drugs than for pills or tablets. Old drugs are often made on aging production lines, which are sometimes shut down for maintenance or are stopped after the manufacturer is warned by the FDA that the facility is out of compliance with current manufacturing standards (referred to as GMPs). The FDA estimates that just over half of supply disruptions for sterile injectable drugs are due to quality problems in the manufacturing process.<sup>25</sup> The rising list of drugs in short supply due to regulatory enforcement is not the result of new regulations; the FDA is seeking to better enforce existing quality

requirements.<sup>26</sup>

A report by the U.S. Government Accountability Office found that quality concerns are often a primary or secondary cause of shortages.<sup>27</sup> When there are only a handful of suppliers for an old generic product with a small market share, stocks of the drug can dwindle — causing the price to skyrocket when one of the few remaining suppliers ceases production for repairs or retools to make newer, more profitable drugs. After one manufacturer leaves the market, remaining manufacturers cannot always boost production to make up for the loss.

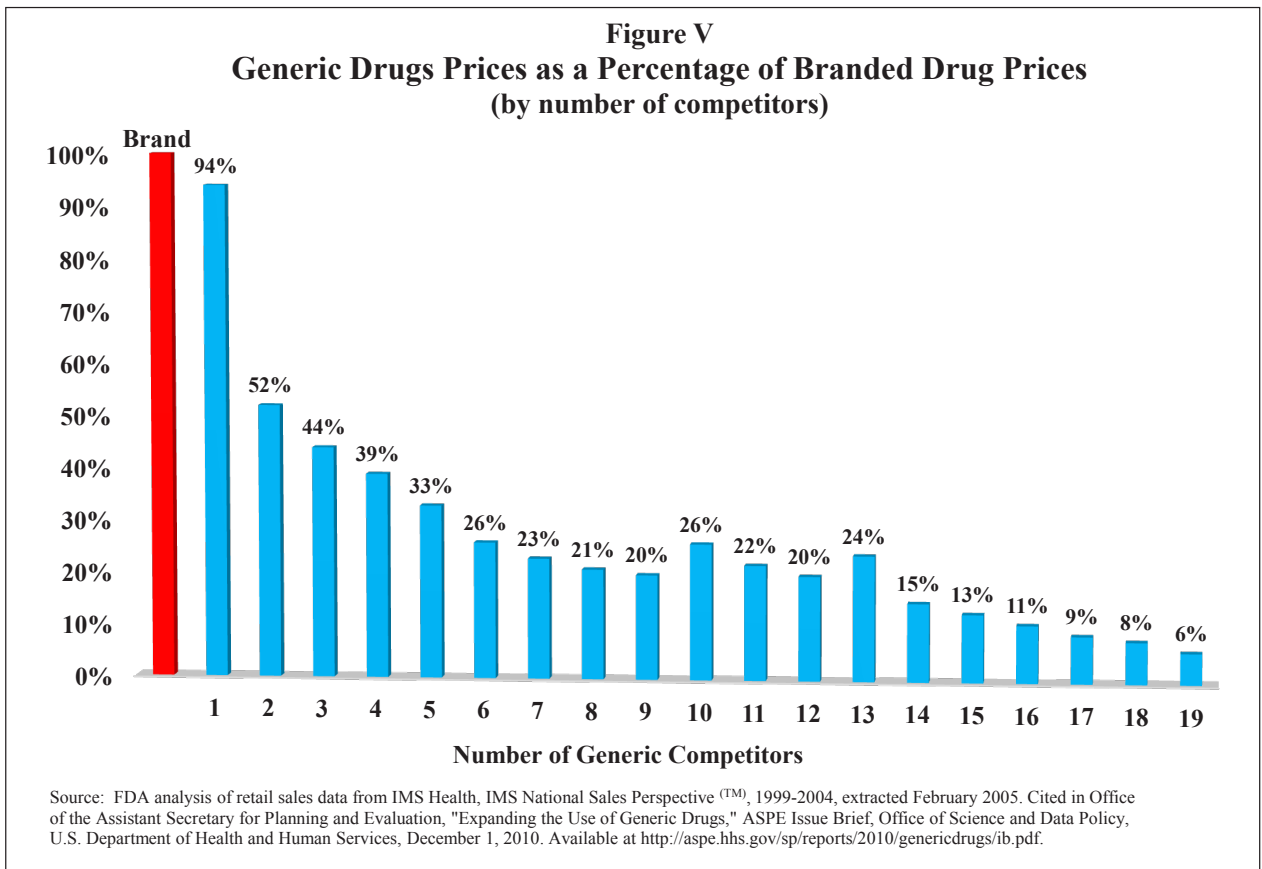
In addition, the FDA is also discouraging a few Indian generic drug makers from entering the market with regulatory hurdles — including banning drugs made by Ranbaxy Laboratories Ltd. from the U.S. market.<sup>28</sup>

In 2015, shortages of the bladder cancer drug BCG, a generic oncology drug derived from live bacteria, were due to production problems.<sup>29</sup> An aging Toronto factory owned by French drug maker Sanofi SA was one of only two manufacturing the drug for the U.S. market. A fire sprinkler malfunction flooded the plant in 2011, causing the recall of some batches. The FDA and Health Canada both found contamination in supposedly sterile injectable drugs at the plant in 2012. A mold infestation at the factory stopped production for two years after failing

tests designed to ensure the sterility of products leaving the plant. After Sanofi halted production and began renovating the plant, its efforts were slowed by a heavy rainstorm that flooded the plant in 2013. In July 2014, the only other manufacturer of BCG for the U.S. market temporarily stopped production when air quality tests identified it also had mold contamination.<sup>30</sup>

Most of the generic drugs in short supply are difficult to manufacture and have low profit margins, making firms reluctant to correct problems and causing manufacturers to leave the market for more lucrative products.<sup>31</sup> Once a shortage occurs, it can take months for the FDA to approve applications from new firms.

**The FDA's Unapproved Drugs Initiative.**<sup>32</sup> In 2006, the FDA adopted the goal of getting some potentially harmful generic drugs off the market.<sup>33</sup> Thousands of drugs predate the FDA's approval process required under the 1938 Food, Drug & Cosmetics Act — many were grandfathered but never officially approved. Under the previous policy, drugs already on the market could be sold if the formulation, dosage, instructions and labeling for its intended use all remained identical to the way it was prior to the 1938 Act. The FDA now argues that few — if any — old drugs whose manufacturers claim grandfathered status actually comply with this precise legal requirement.<sup>34</sup> Although these remedies have been used for decades, the FDA wants them off the market and replaced with “approved” versions from any drug maker willing to conduct clinical studies for them.<sup>35</sup> Shortly after the FDA's 2006 initiative began, Deborah Autor, director



of the Office of Compliance, FDA Center for Drug Evaluation and Research (CDER), told *FDA Consumer* magazine that, “Even if the drug has been marketed for many years with no known safety problems, companies will still need to comply. The absence of evidence of a safety problem does not mean a product is truly safe.”<sup>36</sup>

The process of forcing old generic drugs off the market invariably results in higher prices for the newly approved versions compared to their generic versions — something the FDA acknowledges.<sup>37</sup> Joseph Biskupiak, a research professor in the Department of Pharmacotherapy at the University of Utah, explained that it is hard to fault companies for trying to recoup the cost of expensive clinical trials. Furthermore, federal regulations restrict the ability of the FDA to approve drugs without clinical trials. In an interview, Biskupiak stated, “Congress could come up with an alternative pathway of approval for these grandfathered drugs that does not require a costly clinical trial.”<sup>38</sup>

One example of an old grandfathered drug that was recently approved is colchicine, formerly an inexpensive drug used to treat gout and other inflammatory conditions. A pharmaceutical company agreed to conduct clinical studies on the 3,000 year-old remedy and sought FDA

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approval as a new drug. After FDA approval, the generic, grandfathered versions of the drug were pulled from pharmacy shelves. As a result, the therapy's price rose from pennies per pill to \$5 per tablet.<sup>39</sup>

Another example is neostigmine, which is routinely used at the end of surgery to reverse the effects of anesthesia. It had been used for decades and predated the FDA's approval process. After a drug maker began clinically testing the product, the generic versions of the old drug became scarce — as other manufacturers knew the older, generic versions would be forced off the market.<sup>40</sup> Once the newer version, Bloxiverz, was approved in June 2013, the exclusive manufacturer was able to raise the price to recoup its clinical trial costs and reap a profit. Between October 2103 and April 2014, the price shot up 522 percent, according to a congressional investigation.<sup>41</sup>

Occasionally, the FDA grants an exclusive right to market for performing clinical studies on an old drug for an off-label therapy that hardly differs from the original use [see the sidebar, “Case Study: Delalutin”].

**Pay-for-Delay.** Patent expiration in the drug industry is contentious. There are usually multiple patents protecting a drug, some of which are filed well after the initial patent. The exact date a drug's patent protection expires is often hotly contested in a court of law. The

first generic manufacturer to file for an abbreviated new drug application and successfully challenge a brand drug maker's patent is granted a 180-day period of market exclusivity. This means the *first-filer*, the company aggressive enough to successfully challenge a patent, can command prices that are about 94 percent of the brand drug's price for a six month period. [See Figure V.] In many cases, the challenger needs this windfall. The legal process of challenging a patent can be very costly, often costing more than \$10 million in legal fees.<sup>49</sup>

So called *pay-for-delay* is a negotiated agreement whereby the patent holder agrees to compensate a generic challenger in return for delaying the patent challenge for an agreed upon length of time. Rather than both firms spending exorbitant amounts of money on legal fees, the patent holder essentially shares a portion of the revenue received during the period when competition is delayed — often for months and possibly longer.

The Pharmaceutical Research and Manufacturers of America, the trade association for innovator drug makers, supports negotiated patent settlements as a reasonable compromise that avoids the cost of extensive litigation.<sup>50</sup> The Generic Pharmaceutical Association, the trade association for generic drug makers, also supports the right of its members to negotiate patent settlements, including delaying patent challenges in

### Case Study: Delalutin

One of the most egregious examples of price hikes resulting from testing an old drug is Delalutin (generic name 17-Hydroxyprogesterone caproate), a progesterone injection originally approved in 1956 to prevent miscarriages.<sup>42</sup> Squibb, Delalutin's manufacturer, informed the FDA in 1999 that it had withdrawn Delalutin from the market.<sup>43</sup> However, generic versions of Delalutin could still be obtained from compounding pharmacies for about \$10 to \$15 per injection.<sup>44</sup> Compounding pharmacies are allowed to manufacturer small batches of approved drugs that have no generic manufacturer. As evidence emerged that the drug was more effective at preventing preterm births than initially thought, K-V Pharmaceutical Company applied for the right to manufacture the drug. In return for performing some small clinical trials for its use in preventing preterm births, the drug maker was granted an exclusive seven-year permit to market it as an “orphan drug” under the brand name Makena.<sup>45</sup> Once the FDA approved Makena, compounding pharmacies were no longer allowed to make cheap copies of the drug.<sup>46</sup> Armed with an exclusive right to market the drug, drug maker K-V Pharmaceutical raised the price from \$15 per injection (typical at compounding pharmacies) to \$1,500 for the name brand injections.<sup>47</sup>

By approving a new version of an old drug, the FDA needlessly exposed consumers to higher prices to test a drug that had been safely used for decades. The 100-fold price increase so infuriated FDA officials (and the public) that the FDA later refused to enforce the exclusivity K-V Pharmaceutical needed to keep its price high. The firm lowered its price to \$690 per injection. It also sued the FDA in an attempt to force the agency to prevent compounding pharmacies from making less expensive, generic versions.<sup>48</sup>



return for compensation.<sup>51</sup> By contrast, the Federal Trade Commission (FTC) and several prominent members of Congress strongly believe consumers pay higher prices for longer periods of time due to these agreements.<sup>52</sup> The FTC calculates pay-for-delay settlements boost drug costs by more than \$3.5 billion annually.<sup>53</sup>

Over the past decade, the FTC has filed numerous lawsuits to block pay-for-delay settlement agreements, and continues to do so.<sup>54</sup> In 2013, the U.S. Supreme Court heard arguments brought by the FTC and agreed the more egregious of these agreements could potentially face antitrust scrutiny.<sup>55</sup> Recently, an appeals court in California ruled a pay-for-delay settlement violated state law.<sup>56</sup> It is thought this case could have significant implications beyond California.

Whether pay-for-delay settlements cost consumers or merely avoid unproductive lawsuits is difficult to say with any certainty. Indeed, the effect on consumers likely varies from one patent challenge to the next. Yet it is an issue that many consumer advocates point to as further evidence consumers would benefit from laws speeding the process of resolving patent challenges.

One reason opponents of pay-for-delay argue patent settlements are detrimental to consumers is the fact that first-filers gain limited market exclusivity (180 days), a period in which other generic drug makers cannot file applications while theirs is in process — even if the first filer has been paid to delay entry into the field.<sup>57</sup> Some legal scholars have proposed limiting the 180-day period of exclusivity to first-filers who either invalidate a patent, or prevail in court by proving they did not infringe upon a patent.<sup>58</sup>

**30-Month Rule.** Under a process created by the Hatch-Waxman Act of 1984, the FDA is required to wait 30 months before approving a generic version of a drug whose patent is being challenged through the federal courts. The 30-month period was intended to set aside a period when generic challengers and innovator drug makers could settle patent disputes. But drugs are often protected by multiple patents — each of which can potentially delay competition during the 30-month period when challenges are litigated.

In recent years so-called Patent Trolls, also known as nonoperating companies, have acquired or licensed numerous overlapping patents and used their patent library as the basis to sue technology companies for patent infringement. The grounds for these challenges are often without merit. But even if the defendant is

likely to prevail, the firm being sued often settles just to avoid a costly, prolonged legal battle. Beginning in 2012, an administrative process called Inter Partes Review, or IPR, allows firms accused of patent infringement to quickly have their case reviewed by administrative judges employed by the U.S. Patent and Trademark Office, avoiding the federal court system.<sup>59</sup> An Inter Partes Review takes only about 15 to 18 months, potentially reducing the time bring a generic drug to market compared to a federal court challenge. Shortening patent dispute could lower drug prices by getting generic versions to market sooner.

There are discussions in Congress about whether to prevent drug patent challengers from using the IPR process. The Congressional Budget Office (CBO) estimates the cost of preventing drug patent challenges through the IPR process would boost costs to federal health programs by \$1.3 billion over a 10-year period.<sup>60</sup> The CBO did not estimate the costs to consumers not covered by a federal health program, but it would likely cost consumers as well.

**Generic Substitution Laws.** Pharmacists and pharmacies are governed by state laws and state regulations. The degree to which states allow pharmacists to substitute generic drugs for brand drugs varies from one state to the next. For instance:

- All states require pharmacists to dispense a brand drug if specified by a physician.
- Thirty-nine states allow pharmacists to substitute a generic drug when “brand only” is not specified.
- But 14 states *require* generic substitution if “brand only” is not written on the prescription, and all but three states allows patients to request a brand name drug.<sup>61</sup>

States where patients must consent before a generic drug can be substituted tend to have higher drug costs than those that don’t require explicit patient consent. Some states also regulate generic substitution for drugs that have a narrow therapeutic index — drugs that are more dose-sensitive. Sometimes a small change in dose or a change in the way the drug is absorbed into the body can cause unanticipated problems. These drugs — including some epilepsy medications — require careful monitoring.<sup>62</sup>

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### Consumers and Payers Lose When Generic Drug Prices Rise

Barriers to competition in all forms ultimately cost consumers, employers, insurers and taxpayers. If prices for employers, insurers and taxpayers rise, ultimately consumers pay through higher premiums, higher taxes or lower wages. While generic drug prices may fall after a price spike, the volatility still harms not only cash-paying customers, but other payers too. Drug plans often bear the cost of price escalation. PBMs administer drug benefits for approximately 170 million people. Once contracts are signed, there is often no opportunity to renegotiate until the next contract negotiation period. Finally, consumers who purchase their drugs have to bear the cost of drug price hikes.

When inexpensive drugs rise in price, it doesn't take long before consumers feel the pain. Generic drugs that rise sharply in price may be moved from a formulary tier with no cost-sharing to one with significant cost-sharing. Patients taking a drug that becomes scarce and expensive may have to ask their doctor for a different drug that may not work as well. Seniors may experience higher cost-sharing in their Medicare Part D plans if some of the

generic drugs they take become more costly. Health plan members often have high-deductible plans that require meeting hefty deductibles before drug coverage begins to pay benefits. Finally, those who lack a drug benefits plan may find drugs that once were pennies now cost dollars.

**Insurers and Health Plans.** Today, most health plans include some drug benefits. Consumers (and workers) pay indirectly for drug benefits through higher premiums or lower wages.

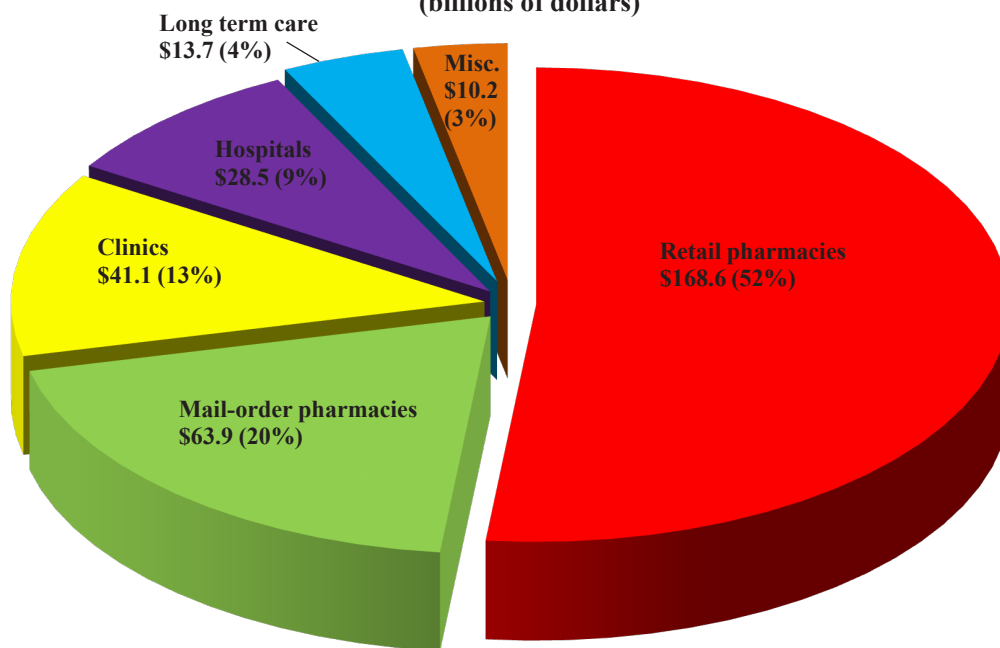
When consumers walk into their local drugstore, drug plans reimburse much of that cost. An estimated 70 percent of Americans belong to a drug plan, and relatively few patients are unable to afford their medications. According to industry data:<sup>63</sup>

- Nearly one-fourth (23 percent) of retail prescriptions are fully covered by insurers and require no copayment by the patient.
- An additional one-third (34 percent) cost the patient \$5 or less.
- And three-fourths (78.6 percent) cost the patient \$10 or less. [See Figure VI.]

The proportion of drug expenses Americans pay out of pocket has fallen sharply over the past 30 years. Patients typically pay only about 17 percent out of pocket for their drugs, on average.<sup>64</sup> The remainder is paid for by a drug plan, insurer or government program.

For the most part, drugs are very affordable for most American consumers — including seniors with multiple prescriptions. The primary reason drugs are affordable is drug coverage and competition from generic drugs. Nearly nine-in-10 drug prescriptions are generics. But this could all change if low-cost generics become expensive. To keep drugs affordable, health plans often employ the services of pharmacy benefit managers (PBMs), large firms that specialize in designing and managing drug benefits.

**Figure VI**  
**Prescription Drug Spending by Source**  
(billions of dollars)



Source: Glen T. Schumock et al., "National trends in prescription drug expenditures and projections for 2014," *American Journal of Health-System Pharmacy*, Vol. 71, March 15, 2014, pages e6-e23.

**Pharmacy Benefit Managers.** PBMs use a variety of techniques to control costs for their clients and enrollees. With multiple clients, large national PBMs can negotiate lower prices from manufacturers, and therefore possess far more bargaining power than individual firms. They also negotiate with pharmacies and build preferred pharmacy networks.

PBMs consult with health plan sponsors to determine which drug therapies to include in their formularies, and to encourage enrollees to use cost-effective alternatives. Within the same therapeutic class, multiple drugs with vastly different costs may be available. This is where generic drugs come in; they are the preferred drug therapy on most formularies. PBMs also check for drug interactions and inappropriate or duplicate prescriptions. Finally, PBMs assemble pharmacy networks, contract with mail-order pharmacies and process payments.

### **Bad Ideas: How Not to Deal with Rising Drug Prices**

With the problem of some generic drugs rising in price unexpectedly, drugstores and chain-store pharmacies are turning to their lobbyists in an attempt to insulate their industry from the effects. Although generic drug inflation is a problem that ultimately affects drug purchasers, state lawmakers are pressured by constituents who own and operate small neighborhood pharmacies struggling to compete. The following are some common regulations state lawmakers pass to accommodate local drugstores in their state avoid competition and pass on price hike to customers and consumers further down the supply chain.

**Banning Efficient Pharmacy Networks.** Increasingly, health plans and PBMs have experimented with exclusive or “preferred” pharmacy networks as leverage to negotiate lower drug prices from pharmacies competing to become exclusive network drug providers.<sup>65</sup> Opponents of this practice argue “open” pharmacy networks offer enrollees more choices and more convenience, and promote competition. However, PBMs counter that the “preferred pharmacies” in exclusive networks have agreed to deeper discounts in return for the business.<sup>66</sup>

When PBMs create pharmacy networks, they negotiate the lowest possible prices. Negotiated prices are the result of bargaining power — the ability of the drug plan to deny business to a firm if their bid isn’t favorable. However, so-called “any-willing-provider” and “retail-choice” laws are designed to reduce pharmacy benefit managers’ bargaining power and protect less-efficient pharmacies from competition.<sup>67</sup> The Federal Trade

Commission has argued time and time again — in numerous reports and opinions issued on specific state proposals — that these laws lead to higher drug prices and higher premiums.<sup>68</sup> In a recent letter to the Centers for Medicare and Medicaid Services, the FTC wrote:<sup>69</sup>

“The proposed any willing pharmacy provisions threaten the effectiveness of selective contracting with pharmacies as a tool for lowering costs. Requiring prescription drug plans to contract with any willing pharmacy would reduce the ability of plans to obtain price discounts based on the prospect of increased patient volume and thus impair the ability of prescription drug plans to negotiate the best prices with pharmacies. Evidence suggests that prescription drug prices are likely to rise if Prescription Drug Plans (PDPs) are less able to assemble selective pharmacy networks. The proposed provisions may also hinder the ability of plans to steer beneficiaries to lower-cost, preferred pharmacies and preferred mail order vendors through financial incentives or other terms.”

**Restricting Mail-Order Pharmacies.** Health plans reduce premiums by negotiating and contracting with qualified pharmacies offering competitive prices. Pharmacies and other suppliers excluded from the network (due to price or quality considerations) lobby sympathetic politicians to force employee health plans, PBMs and insurers to do business with them — boosting costs to consumers. Recent legislative proposals — some that were passed and some that were not — would weaken or prohibit the agreements PBMs negotiate with pharmacy networks.<sup>70</sup> One way this occurs is through regulation aimed at restricting or prohibiting PBMs from offering drug plan members a financial incentive (a discount) for using a health plan’s preferred pharmacy or its mail-order option.

Many states have passed laws designed to benefit local community pharmacies by prohibiting PBMs from rewarding members who use the mail-order option. In 2011, New York State passed Assembly Bill 5502, making it illegal to charge less for mail-order drugs. The law required to reimburse for prescriptions purchased at either local or mail-order pharmacies without consumers incurring additional PBMs cost-sharing or fees.

**Restricting Maximum Allowable Cost.** More than a dozen states have laws regulating some aspect of maximum allowable cost (MAC) lists. In early March 2015, legislation was introduced in Arkansas (Senate Bill 688) that increased the administrative tasks and

## What Is Increasing the Cost of Generic Drugs? (Part II: Regulatory and Legal Reasons)

burdens of drug plans and PBMs when pharmacies serve health plan members.<sup>71</sup> The stated reason for the bill was because a few generic drugs were rising in price faster than the MAC list could be updated. Among other things, the new law requires weekly updates to MAC lists and specifies which drugs can be included. It also allows a pharmacy that has contracted with a drug plan to reject prescriptions for unprofitable drugs while filling prescriptions that are profitable, regardless of the contract terms. The proposal went from a senate bill to law in about one month.

At first glance these requirements may not seem problematic, but they could have dire consequences. Pharmacy owners could purposely refuse to fill selected prescriptions. For example, rather than decide to participate or not participate, drugstores could fill customers' prescriptions for some drugs, but purposefully send them away for others — using drug plan members as pawns in a game to force higher reimbursements.

In July 2015, Assembly Bill 627 was passed by the California legislature. The bill requires drug plans to update the MAC list at least one a week. It also regulates the drugs that can be on a MAC list and requires disclosure of how the list is created.<sup>72</sup> Legislative Document 1150, a regulation debated in Maine, would allow drugs to be on MAC price lists “only if that prescription drug is nationally available and has 3 or more nationally available therapeutically equivalent drug substitutes with a significant cost difference.” That puts the bureaucratic onus of verifying the existence of competitive wholesalers on drug plans rather than expecting drugstores shop for the most competitive prices. In competitive industries, each purchaser in the supply chain is rewarded for negotiating the best deal possible. This would negate this incentive if drugstores could merely pass on higher prices.

The wholesale cost of generic drugs can vary tremendously from one manufacturer to the next. MAC price lists are a tool health plans, drug plans, and insurers use to place an upper payment limit on what the plan is willing to reimburse for a given drug. Without a limit, pharmacies would have little reason to hold costs down. If a drug plan was forced to pay whatever cost a drugstore paid for a generic drug, the drugstore would have little reason to look for competitive vendors of generic drugs. In other words, attempts to limit the use of MAC lists inhibits a tool drug plans used to promote competition among pharmacies. Some state laws attempt to force drug plans to disclose the MAC update the list more frequently

and sooner. These types of regulations can actually reduce the incentive for drugstores to continually search for the best deals on multisource drugs.<sup>73</sup> The drug inflation that would result would be passed on to drug plans, employer plans and ultimately workers and consumers.

More than one-third of states have debated or passed regulations governing MAC pricing in the past several years.<sup>74</sup> These laws are advanced by pharmacy trade associations to protect the profits of local pharmacies at the expense of employers, insurers, drug plans and consumers.

**How to Lower America's Drug Bills.** The trade association for generic drug makers sent a letter to the editor the *Wall Street Journal* Pharamlot blog that read, “if Congress wants to explore ways to keep costs down it could increase competition from generics by examining ways to address the growing backlog of generic applications and supporting a biosimilar policy that promotes competition.”<sup>75</sup> Generic drugs are inexpensive when there is competition, but less so when markets consolidate and the FDA lacks the resources to quickly process competing manufacturers' applications to produce a generic drug.

### Conclusion

The problem of generic drugs in short supply, and the accompanying price increases, have a range of distinct causes. Some of these are unavoidable as supply chains for raw materials are disrupted by war, famine or natural disasters. Other shortages that cause prices to rise are due to production problems. Many generic drug price spikes are unavoidable as firms update facilities or decide to exit the market.

However, some of the price increases have little to do with shortages. Some of these price spikes are avoidable; the FDA needs to clear the abbreviated drug application backlog and allow competition to flourish. This, in turn, will alleviate some of the price hikes caused by market consolidation in both drug manufacturing and distribution. Finally, states need to resist the call to pass perverse regulations designed to protect local business (and pharmacies) at the expense of competition that benefits consumers, employers, insurers and drug plans.

## Notes

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