

## **Regulatory and Legal Reasons for Generic Drug Price Hikes**

Statement for the Record

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“Developments in the Prescription Drug Market”

Committee on Oversight and Government Reform  
United States House of Representatives

February 4, 2016

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## Regulatory and Legal Reasons for Generic Drug Price Hikes<sup>1</sup>

Chairman Chaffetz, Ranking Member Cummings, and members of the committee, thank you for the opportunity to submit written comments about recent prescription drug market developments in general, and recent price increases in particular. I am Devon M. Herrick, a health economist and senior fellow at the National Center for Policy Analysis. We are a nonprofit, nonpartisan public policy research organization dedicated to developing and promoting private alternatives to government regulation and control, solving problems by relying on the strength of the competitive, entrepreneurial private sector.

Americans consume nearly \$3 trillion of medical care annually, about 10 percent of which is spent on prescription drug therapy. Americans spend twice as much on doctors and three times as much on hospital care as on drugs.<sup>2</sup> More than 60 percent of Americans take a prescription drug in any given year, including 90 percent of all seniors.<sup>3</sup> An estimated 4.3 billion retail prescriptions were filled in 2014 — about a dozen per person in the United States, on average.<sup>4</sup> About three-quarters of physician visits result a prescription.<sup>5</sup> Prescription drugs are a great value; drugs are arguably the most cost-efficient way to treat most health problems. Drugs often eliminate, lessen or delay the need for more expensive treatments such as surgery or inpatient care.

So-called “miracle drugs,” specialty drugs and new drug innovation are often credited with improving Americans health. Often ignored are the immense benefits derived from generic drugs, which costs consumers comparatively little and produces benefits far exceeding costs. Generic drugs account for 88 percent of prescriptions but only 28 percent of drug therapy expenditures.<sup>6</sup> Within a year after a brand drug faces competition from generics, the average price falls 80 percent or more. Intense competition usually holds generic drug prices in check. However, during the past few years, many generic drugs that have been on the market for decades have suddenly become more expensive. For instance, the period from 2013 to 2014 was one characterized by very low consumer inflation (about 2 percent).<sup>7</sup> Yet, 27 percent of generic

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<sup>1</sup> This testimony was adapted from Devon M. Herrick, “What Is Increasing the Cost of Generic Drugs? (Part I: The Supply Chain),” National Center for Policy Analysis, NCPA Policy Report N. 371, September 2015; and Devon M. Herrick, “What Is Increasing the Cost of Generic Drugs? (Part II: Regulatory and Legal Reasons),” National Center for Policy Analysis, NCPA Policy Report No 373, October 2015.

<sup>2</sup> “National Health Expenditures; Aggregate and Per Capital Amounts, Annual Percent Change and Percent Distributions: Selected Calendar Years 1960-2013,” Centers for Medicare and Medicaid Services, U.S. Department of Health and Human Services, 2014.

<sup>3</sup> Agency for Healthcare Research and Quality, “Prescription Medicines—Mean and Median Expenses per Person with Expense and Distribution of Expenses by Source of Payment: United States, 2010,” Medical Expenditure Panel Survey Household Component Data

<sup>4</sup> 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.

<sup>5</sup> “National Ambulatory Medical Care Survey: 2010 Summary Tables,” National Center for Health Statistics.

<sup>6</sup> Ibid.

<sup>7</sup> The CPI-U in July 2013 was 233.596 and 238.250 in July 2014;  $[(238.250/233.596)-1]=1.99$  percent.

drugs rose in price by 10 percent or more. About one-in-five generic drugs rose in price more than 25 percent, while 9 percent of generic drugs increased in price more than 100 percent.<sup>8</sup>

In theory, generics face unlimited competition since any qualified drug maker can apply to the U.S. Food and Drug Administration (FDA) to produce a generic version when the original drug patent expires. The reality, however, is often far different. Many factors can restrict competition and delay potential competitors from entering the field and producing generic drugs. Drug makers profit when the price of a drug they produce rises. They also gain when competing drugs' prices rise. The reasons for generic drug price increases are many, some of which fall within the supply chain — the path a drug follows from raw ingredients to the consumer. However, FDA regulations, internal policies and workflow exacerbates the problem of rising drug prices due to large backlog of abbreviated new drug applications (ANDAs).

**Industry consolidation.** Mergers and consolidation within the industry, coupled with an FDA that is slow to approve new entrants into the field, are among the reasons for the sharp rise in the price of some generic drugs. When there are generic drugs for which there are only two or three competing manufacturers, price hikes become more likely.<sup>9</sup> For instance, research shows the price of a generic drug drops sharply as the number of makers of a given drug rises.<sup>10</sup>

**Informal collusion and price-fixing.** When only a handful of producers make a given drug, there exists opportunities for informal collusion and informal (or formal) price-fixing. Although it is illegal for competing firms to coordinate pricing, no law is broken when one firm unilaterally raises its price and other firms decide to follow suit.

For example, the drug Digoxin had been around for many years. Most generic drug makers had stopped producing it, although there was no shortage. By January 2014, only three firms were producing the drug. Around the beginning of 2014, one of the firms producing Digoxin raised its price and the other two soon followed. By mid-2014, the price of the drug had doubled from a year earlier, although some patients were faced with prices for the drug that were much higher.<sup>11</sup>

**Hedge fund drug investing.** A generic drug with only a single producer creates the opportunity to jack up the price and derive monopoly profits for two years or more — the time it would likely take the FDA to approve a competitor's ANDA. Using a strategy that is sometimes referred to as the "hedge fund model," old, single-source generic drugs with small market shares are purchased inexpensively as an investment.<sup>12</sup> A few pharmaceutical firms use this strategy is to game the system, knowing the FDA backlog of ANDAs will protect price hikes from competition for years.

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<sup>8</sup> Adam J. Fein, "Retail Generic Drug Inflation Reaches New Heights, Drug Channels Institute, August 12, 2014. Available at <http://www.drugchannels.net/2014/08/retail-generic-drug-inflation-reaches.html>.

<sup>9</sup> Trefis, "Why Are Generic Drug Prices Shooting Up?" Forbes (blog), February 27, 2015. Available at <http://www.forbes.com/sites/greatspeculations/2015/02/27/why-are-generic-drug-prices-shooting-up/>

<sup>10</sup> Office of the Assistant Secretary for Planning and Evaluation, "Expanding the Use of Generic Drugs," ASPE Issue Brief, Office of Science and Data Policy, U.S. Department of Health and Human Services, December 1, 2010. Available at <http://aspe.hhs.gov/sp/reports/2010/genericdrugs/ib.pdf>.

<sup>11</sup> Elisabeth Rosenthal, "Rapid Price Increases for Some Generic Drugs Catch Users by Surprise," *New York Times*, July 8, 2014.

<sup>12</sup> Soeren Mattke, "Will the Pharmaceutical Industry Learn from Past Mistakes?" RAND, January 22, 2016.

Thus, Turing Pharmaceuticals, run by a former hedge fund manager, bought the rights to Pyrimethamine, a 60-year old remedy 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>13</sup> The huge increase was far from a coincidence; the drug was undoubtedly purchased due to its small niche and lone U.S. supplier.

***Drug wholesalers.*** The wholesale drug industry has undergone tremendous market consolidation in the past few decades. Today, three large firms control nearly 90 percent of the distribution of wholesale drugs — resulting in less price competition.<sup>14</sup> Drug wholesalers have also been accused of manipulating industry price lists to boost profit margins for themselves and pharmacies.

***Aging drugs and niche therapies.*** Many of the drugs rising sharply in price are older therapies approved decades ago. Many manufacturers have dropped them either due to low profitability or in favor of newer generics that are in higher demand. In addition, when one firm stops production to produce another drug, shortages and higher prices often result.

***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.<sup>15</sup> A report by the U.S. Government Accountability Office found that quality concerns are often a primary or secondary cause of shortages.<sup>16</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.

***Delayed FDA approvals reduce 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 that by 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>17</sup> Over the past five years, the FDA has approved an average of 400 to 500 generic drugs annually.<sup>18</sup> But

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<sup>13</sup> Andrew Pollack, “Drug Goes From \$13.50 a Tablet to \$750, Overnight,” *New York Times*, September 20, 2015.

<sup>14</sup> “2014 Market Leaders: Top Pharmaceuticals Distributors,” *Modern Distribution Management*, 2015. Available at [http://www.mdm.com/2014\\_pharmaceuticals\\_mdm-market-leaders](http://www.mdm.com/2014_pharmaceuticals_mdm-market-leaders).

<sup>15</sup> “Frequently Asked Questions about the Drug Shortages Program,” Food and Drug Administration, U.S. Department of Health and Human Services, page last updated April 24, 2015. Available at <http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050796.htm>.

<sup>16</sup> GAO, “Drug Shortages: Public Health Threat Continues, Despite Efforts to Help Ensure Product Availability: Report to Congressional Attendees,” U.S. Government Accountability Office, GAO Publication No. GAO-14-194, February 2014. Available at <http://www.gao.gov/assets/670/660785.pdf>.

<sup>17</sup> Trefis Team, “Why Are Generic Drug Prices Shooting Up?” *Forbes*, February 27, 2015. Available at <http://www.forbes.com/sites/greatspeculations/2015/02/27/why-are-generic-drug-prices-shooting-up/>.

<sup>18</sup> In 2010, 426; 2011, 458; 2012, 517; 2013 440; and 2014, 409. See Ed Silverman, “Is FDA ‘Buried’ Under a Backlog of Generic Drug Applications?” *Wall Street Journal* blogs, Pharnalot, July 29, 2014. Available at <http://blogs.wsj.com/pharnalot/2014/07/29/is-fda-buried-under-a-backlog-of-generic-drug-applications/>.

this is only a fraction of the applications received. The FDA has a backlog of about 4,000 applications, with an average time to approval of more than two years.<sup>19</sup> 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 speed the process of reviewing and approving drugs in a timely manner. But the agency is inundated with new drug applications and is slipping behind.

***FDA's Unapproved Drug Initiative.*** Thousands of drugs predate the approval process required under the 1938 Food, Drug & Cosmetics Act; many were grandfathered but never officially approved.<sup>20</sup> The FDA's Unapproved Drugs Initiative aims to get these drugs off the market.<sup>21</sup> Ideally, they would be 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. 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>22</sup>

- One example of an old grandfathered drug that has recently been subjected to the approval process 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 approval as a new drug. After FDA approval, the cheap 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>23</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 predates 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 versions would be forced off the market.<sup>24</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>25</sup>

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<sup>19</sup> Data from the U.S. Food and Drug Administration, cited in Adam Fein, "Retail Generic Drug Inflation Eases, but the FDA Keeps Prices High," *Drug Channels*, April 15, 2015. Available at <http://www.drugchannels.net/2015/04/retail-generic-drug-inflation-eases-but.html>.

<sup>20</sup> Janelle Derbis, Brenda Evelyn and Judy McMeekin, "FDA Aims to Remove Unapproved Drugs from Market: Risk- Based Enforcement Program Focuses on Removing Potentially Harmful Products," *Pharmacy Today*, August 2008.

<sup>21</sup> Val Jensen and Cynthia Schnedar, "Reducing the Number of Unapproved Drugs while Working to Prevent Drug Shortages: a Job that Calls for Strong Collaboration in FDA," *FDA Voices*, April 10, 2015. Available at <http://blogs.fda.gov/fdavoices/index.php/2015/04/reducing-the-number-of-unapproved-drugs-while-working-to-prevent-drug-shortages-a-job-that-calls-for-strong-collaboration-in-fda/>.

<sup>22</sup> *Ibid.*

<sup>23</sup> M. Alexander Otto, "Unbranded Colchicine Getting Hard to Find," *Internal Medicine News*, June 15, 2010.

<sup>24</sup> Ashley N. Lewis and Sandra Hanna, "Neostigmine Methylsulfate Injection (Bloxiverz)" *Pharmacy Times*, (Published Online), November 15, 2013.

<sup>25</sup> "Ranking Member Cummings and Chairman Sanders Investigate Staggering Price Increases for Generic Drugs," Senator Bernard Sanders (D-Vt.), October 2014.

- Even the over-the-counter expectorant, Guaifenesin (the generic name for Mucinex), was the target of FDA’s unapproved drug initiative.<sup>26</sup> The remedy was originally derived from the guaiac tree and used by Native Americans 500 years ago.

**Raw materials shortages.** Though it is frequently the case that there are multiple manufacturers of a drug, there may be only one or two suppliers of the raw materials used by all producers.<sup>27</sup> About 40 percent of finished drugs come from abroad, but about 80 percent of raw pharmaceutical materials are derived from foreign sources.<sup>28</sup> Estimates vary, but about 10 percent of drug shortages are thought to be related to raw material shortages.<sup>29</sup>

In 2008, heparin sourced from raw materials processed in China were found to be contaminated — probably adulterated intentionally — with a hazardous chemical (oversulfated chondroitin sulfate) that mimics the properties of heparin just enough to pass tests for purity.<sup>30</sup> A dozen or more drug makers had bought the tainted supplies, resulting in numerous deaths.<sup>31</sup>

**Conclusion.** Although there are numerous causes, much of the increase in generic drug prices can be attributed indirectly to FDA policies and regulatory challenges that exacerbate the aforementioned problems. 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, the FDA needs to resist the urge to stamp out old therapies that have been used safely for many decades merely because they haven’t been subjected to current approval process. The best proof of safety is decades of safe use — not an FDA stamp of approval.

Thank you for the opportunity to submit these written comments.

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<sup>26</sup> “FDA Takes Action to Stop Marketing of Unapproved Timed-Release Guaifenesin Drug Products,” U.S. Food and Drug Administration, FDA News Release P07-92, May 25, 2007. Available at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2007/ucm108921.htm>

<sup>27</sup> C. Lee Ventola, “The Drug Shortage Crisis in the United States: Causes, Impact, and Management Strategies,” *Pharmacy & Therapeutics*, Vol. 36, No. 11, November 2011, pages 740-742 and 749-757.

<sup>28</sup> Mari Serebrov, “Solutions Needed to Protect The U.S. Drug Supply Chain,” *BioWorld Today*, Sept. 15, 2011.

<sup>29</sup> GAO, “Drug Shortages: Public Health Threat Continues, Despite Efforts to Help Ensure Product Availability: Report to Congressional Attendees,” U.S. Government Accountability Office, GAO Publication No. GAO-14-194, February 2014

<sup>30</sup> Walt Bogdanich, “Heparin Find May Point to Chinese Counterfeiting,” *New York Times*, March 20, 2008

<sup>31</sup> Charles Calvert et al., “Rx-360 Upstream Supply Chain Security,” White Paper, April 14, 2014.