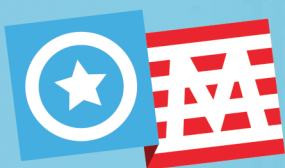


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The Role of Monopoly in America's Prescription Drug Crisis

MICHAEL BLUHM



OPEN MARKETS

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Executive Summary

The Trump administration, members of Congress from both parties, and many states have introduced proposals to combat high drug prices. Too often missing from these reform efforts, however, is a clear understanding of a root cause of the crisis: the suppression of fair market competition through various forms of monopoly.

This white paper examines and proposes solutions for the two main ways that monopoly drives up the costs and lowers the quality of prescription drugs: increasing corporate concentration in the pharmaceutical industry, and the monopoly markets for individual drugs created by a deeply flawed and increasingly abused patent and regulatory system.

Both brand drug manufacturers and generic drugmakers use mergers and acquisitions to gain market share and stifle competition. This corporate consolidation is a significant factor in driving up prices, driving down innovation, and causing shortages and disruptions of the supply of many key drugs. Consolidation also drives the movement of drug production overseas, which has substantially raised the risk of unsafe drugs being sold to U.S. consumers.

Consolidation among generic drugmakers is particularly problematic. Almost all 50 states have joined in a lawsuit charging that industry leaders have for years practiced widespread collusion. The Department of Justice is investigating this vast criminal conspiracy to divvy up markets into monopoly fiefdoms and bilk consumers out of massive sums of money through artificially high prices.

Abuses of the patent system and FDA regulations are the other major cause of exorbitant drug prices. Though intended to spur innovation, laws and regulations that grant a single corporation patent monopolies or exclusive marketing rights have created cornered markets in which drug manufacturers charge monopoly prices and spend significant resources protecting their privileged positions, rather than investing in research and development.

Drugmakers game the regulatory system by registering thickets of similar patents around a single brand drug for minor tweaks devoid of innovation. These patent thickets lock in monopoly profits well the 20-year statute of

patent protection. Drug manufacturers also manipulate the FDA's system of market exclusivities and other regulations to add extra, undeserved years of monopoly protection for their drugs.

For example, brand and generic drugmakers often settle patent lawsuits through pay-for-delay deals, which lock in monopoly markets and exorbitant prices for one or both firms. These deals, many of which are clear antitrust violations, deprive consumers of competitive markets and cost consumers significant, unnecessary spending.

Brand drug manufacturers also stifle competition and gain monopoly profits by filing sham citizen petitions with the FDA to raise spurious safety concerns with potential generic rivals. Some brand drugmakers offer substantial rebates or discounts to large-scale buyers—but only if the purchasers refuse to buy a competing generic drug that might erode the brand drug's market dominance.

These monopoly markets create perverse incentives for drugmakers to focus on rent-seeking ahead of improving public health through groundbreaking medicine. The vast majority of new FDA drug approvals are merely minor modifications of existing drugs, known as me-too drugs. Multiple studies have found that only about 10 percent of drugs approved in recent years are clinically superior to existing drugs.

Fortunately, many of these problems can be solved or ameliorated through better competition policy. Sometimes, this involves the application of traditional antitrust laws. In other instances, competitive markets can be restored by rethinking the means and ends of intellectual property rights. In some extreme cases, competition can be constructively channeled through the forced licensing of patents or by government incentives for production in the interests of public health. In each instance, we are looking for public policies that will reset the terms of competition and the balances of power in drug markets so that they serve the public good.

MAJOR POLICY RECOMMENDATIONS FOR RESTRUCTURING DRUG MARKETS

- The Department of Justice (DOJ) and the Federal Trade Commission (FTC) should adopt guidelines (similar to those in place before the 1970s) that would prevent mergers and acquisitions resulting in any single drugmaker controlling 10 percent or more of U.S. markets. Vertical mergers between wholesalers and retailers in the drug distribution system should also be closely scrutinized.
- The U.S. should institute the patent regulation known as “one-and-done,” which limits every new drug to a one-time grant of one type of monopoly protection, whether patent or market exclusivity, to be chosen by the drugmaker.
- In cases where federal funding contributed to the research behind a patent, and the patent holder has not reasonably satisfied public health or safety needs, the federal government should use a legal doctrine known as “march-in rights” to require licensing to third parties.
- In the case of certain high-priced drugs, the federal government should use its authority under Section 1498 of Title 28 of the U.S. Code to appropriate patents in exchange for reasonable compensation and then either manufacture its own generic versions or license production to generic drugmakers.
- The Food and Drug Administration (FDA) should accelerate the approval process of generic drugs, giving priority to approving generic drugs that would be the first and second competitors of a brand-name drug.
- The administration should use its rule-making authority and prosecutorial discretion to crack down on drugmakers’ use of exclusive dealing and bundled discounts to protect monopoly markets. The administration should instruct the FTC to investigate and to sue drugmakers who conclude or offer these kinds of deals.
- The FDA should permit importing drugs that are in shortage.
- To encourage innovation, Congress should fund a system of cash prizes for drug innovations.
- In cases where open and fair market competition cannot be restored, the administration should institute a system of price regulation, whether cost-based pricing, value-based pricing, or international-reference pricing.
- To increase the safety of imported drugs, the FDA should improve its inspection process overseas.

I. Introduction

HIGH PRICES, INCREASING SHORTAGES, LACK OF INNOVATION

The majority of Americans say they want government action to bring down the cost of prescription drugs. A February 2019 Kaiser Health Tracking Poll found that nearly 80 percent of respondents agreed that prescription drug prices were unreasonable. Whether they identified as Democrats, Republicans, or independents, majorities of respondents supported a wide array of reform measures.¹

The reforms ranged from allowing Americans to buy their drugs in Canada, to capping annual out-of-pocket spending by Medicare beneficiaries, and to pegging the prices of Medicare drugs to the prices paid abroad.² Bipartisan majorities also backed reforms of drug advertising, such as requiring drugmakers to list drug prices in ads and ending drug manufacturers' tax breaks for advertising.³ Perhaps most surprisingly, majorities of Republicans, Democrats, and independents supported more regulation to limit drug prices.⁴

This strong, bipartisan demand for government action is fueled by widespread individual experience of hardship. Almost 30 percent of survey respondents said they had not taken a prescribed medication because of high costs, with 19 percent saying they had not filled a prescription, and 12 percent saying they had skipped doses or cut pills in half.⁵

Demand for reform is also driven by increasing price-gouging involving common but vitally important drugs. The price of insulin, for example, has risen by 600 percent over the past 15 years.⁶ A vial of generic insulin—yes, generic insulin, not a brand-name drug still protected by patents—costs anywhere from \$270 to \$290 per vial.⁷ The same vial costs \$55 in Germany.⁸

It gets worse. Not only do Americans pay far more for prescription drugs than consumers do in other advanced countries, but the United States still suffers from shortages of urgently needed drugs, such as morphine, anesthetics, and certain antibiotics. The FDA website lists more than 130 drugs as currently in shortage.⁹

Drug safety suffers because of high drug prices. Exorbitant prices have driven at least 19 million Americans—or 8 percent of the population—to buy drugs from Canadian retailers and other retailers based abroad.¹⁰ This, according to the FDA, often leads to patients using medications that are mislabeled, expired, or even counterfeit.¹¹

Meanwhile, the pace of innovation is declining by many measures, even though the drug industry argues that Americans must pay high prices for drugs in order to cover the cost of research and development. Multiple studies have found that, at best, about 10 percent of newly approved drugs are clinically superior to existing medications.¹²

Responding to public outrage, members of Congress from both parties have put forward more than a dozen bills aimed at reducing prices through various approaches. States have also introduced a passel of bills that would combat various aspects of high drug prices.¹³ Many of these bills include important, worthy ideas. But what is too often missing from these reform efforts is a clear understanding of a root cause of America's prescription drug crisis: the suppression of market competition through various forms of monopoly.

This paper examines the two main ways that monopoly drives up the costs and lowers the quality of prescription drugs. The first is through increasing corporate concentration. As drug manufacturers merge with one another, they are increasingly able to collude in fixing prices and engage in other abusive business practices, while also having fewer incentives to invest in research and development. Corporate concentration also plays an increasing role in enabling self-dealing down the supply chain, as intermediaries between wholesale suppliers and buyers increasingly merge with one another and, most recently, with large retail pharmacy chains, as well.

A second type of monopoly plays an even larger role in suppressing competition in prescription drug markets: the monopolies created by a deeply flawed and increasingly abused patent and regulatory system. Though intended to spur innovation, laws and regulations that grant a single corporation the exclusive right to market a drug have become deeply distorted in practice. Their primary effect now is to create cornered markets where drug manufacturers charge monopoly prices for brand drugs and spend significant resources protecting their privileged positions.

Other forms of monopoly also play a role, including the increasing concentration occurring farther down the supply chain. These include the growing signs of cartelization and self-dealing among Pharmacy Benefit Managers (PBMs) and increasing vertical integration among insurance companies, PBMs, and dominant retailers such as CVS. In this paper, however, we concentrate on the first two forms of monopolization, because we believe they play a much larger yet less discussed role in driving up prices and suppressing innovation.

Fortunately, fixing the problems of patent monopoly and concentration among drugmakers does not require radical, new policy ideas. In many instances, competitive markets can be restored simply by restoring the historical boundaries surrounding intellectual property rights. In other situations, competition can be constructively channeled through well-precedented measures such as the forced licensing of patents or government incentives for production in the interest of public health. In still other instances, more rigorous enforcement of existing antitrust laws is needed. In each instance, we are looking for public policies that will reform the terms of competition and the balances of power in drug

II. Corporate Consolidation

Drug manufacturers worldwide have been intensively consolidating for three decades now. The annual value of mergers and acquisitions typically ranges from \$200 billion to \$400 billion, though the values of many deals remain private.¹⁴ Each year brings another roughly 800 deals, a huge leap from the annual average of about 100 in the late 1980s. The total annual value of mergers and acquisitions is usually more than twice the annual value a decade ago.¹⁵

One industry newsletter called 2018 an “extraordinary period for consolidation in the pharmaceutical industry.”¹⁶ In 2019, Bristol-Myers Squibb launched what would be the fourth-largest pharmaceutical merger ever, with a proposed \$74-billion takeover of Celgene.¹⁷ AbbVie, maker of the world’s best-selling drug, the rheumatoid arthritis drug Humira, has agreed to purchase Allergan, in a proposed \$63-billion deal announced in June 2019.¹⁸

The industry’s largest firms were all created through wave after wave of mergers and acquisitions. The world’s 12 largest pharmaceutical firms

were formed through more than 1,200 mergers and acquisitions from 1990 to 2014. In other words, each giant pharmaceutical firm made an average of about 40 deals in each of those 24 years. Those 12 firms raked in more than 60 percent of global pharmaceutical sales from 2005 to 2013.¹⁹

Consolidation is also a dominant trend among generic drugmakers, who account for about 90 percent of all drug prescriptions today.²⁰ There were 22 mergers and acquisitions in 2014, 34 in 2015, and 42 in 2016.²¹ In 2016, the annual value of these deals was about \$44 billion.²²

Price competition among generic drugmakers remains fierce for many generic drugs, so these mergers and acquisitions are the industry's strategy to suppress competition and keep profits robust. The industry trade press reports that nearly all generic drug companies are actively seeking to consolidate as a way of avoiding price competition.²³

Another worrisome trend is that many brand drug manufacturers, having lost lucrative income when patent protections expired, are now actively seeking out mergers and acquisitions with generic drugmakers.²⁴ After this kind of consolidation, economic logic would dictate that the company cease or delay the production of generic drugs, to eliminate competition for highly profitable brand drugs.

For generic drugs, less competition means higher prices. One study compared what happened to generic drug prices between 2008 and 2009 under different degrees of market concentration. It found that in markets where four companies competed, the price of a pill costing \$1.07 in 2008 typically fell to just 73 cents by 2013. By contrast, in markets monopolized by just one company, the price of a pill costing \$1.07 in 2008 typically rose to \$1.57 by 2013.²⁵ Another study found that the most reliable predictor of a price spike was the existence of a monopoly market.²⁶ These data provide a compelling argument for policies to increase competition, reject further consolidation, and bring more generic drugs to market.

For drug manufacturers, less competition means higher profits. Many generic drugmakers now pursue business plans based on the domination of markets for older drugs through mergers and acquisitions, because drugmakers can raise prices substantially in these markets after buying up competing manufacturers.²⁷

Other studies have found that mergers and acquisitions among drugmakers are often correlated with significant price increases, shortages

of drugs, disruption of supplies, and reduced competition.²⁸ Even officials in pharmaceutical firms have expressed worries about the anticompetitive potential of industry consolidation, because the resulting corporate behemoth can dominate a particular type or class of drug and deter other potential market entrants.²⁹

EFFECTS OF CONSOLIDATION ON INNOVATION

Data clearly show that drug manufacturers engaging in mergers and acquisitions innovate less than manufacturers not engaged in consolidation. Pharmaceutical firms involved in mergers and acquisitions from 1988 to 2004 showed decreases in R&D spending, as well as in the numbers of patents and important patents registered, in the year of the merger and in the subsequent three years, when compared to firms not involved in any such deals.³⁰

Consolidation is also associated with reduced research productivity, as measured by the ratio of new patents to R&D expenditures.³¹ Worse yet, consolidation also seemed to deter competitors from undertaking research in the areas where the merging firms were active players.³² In simple terms, drugmakers that relied heavily on M&A tended to lag in innovation behind the firms that had not engaged in consolidation.³³

After mergers, R&D spending declines, new drug compounds in the development pipeline seem to progress more slowly,³⁴ and drugmakers look to cut spending by eliminating entire research sites.³⁵ For example, after Pfizer underwent rounds of mergers, it closed the sites where the enormously profitable drugs Viagra and Lipitor had been created.³⁶

These negative effects compound with multiple rounds of consolidation—the former president of Pfizer Global Research and Development said that repeated mergers were “crippling” for the momentum of research programs.³⁷

The consolidation frenzy continues because it benefits shareholders, even though the post-merger slump in research productivity is not in the interest of public health or of consumers. Drug manufacturers with similar product portfolios have larger increases in market value after they merge.³⁸

The leaders in pharmaceutical innovation today are smaller, nimbler

firms. Smaller pharmaceutical and biotechnology companies invent a commanding majority of the new drugs entering the market today, which makes the argument against consolidation even stronger. Smaller firms create almost 70 percent of the drugs approved by the FDA, and these companies account for almost 70 percent of the drugs under development worldwide.³⁹

But big pharmaceutical firms still wind up cashing in on these innovations. Even though smaller, nimbler firms tend to invent new drug compounds, large pharmaceutical firms often end up conducting the final, most expensive clinical trials, as well as handling the marketing and distribution of the new drugs.⁴⁰ Big drugmakers typically acquire the rights to these innovative drugs through mergers, buyouts, licensing deals, or some other form of alliance.⁴¹

Half of the revenues of big pharmaceutical companies now derive from drugs that other companies developed.⁴² Big drug manufacturers now depend on smaller firms for 74 percent of the new drugs that the bigger firms wind up producing.⁴³ In other words, consolidation has hollowed out the internal R&D at big pharmaceutical companies, so their best strategy is to buy out smaller, more innovative firms. Giant drugmakers argue that they're helping smaller firms bring new drugs to market,⁴⁴ but their gobbling up of the most innovative drugmakers is leaving U.S. public health with fewer and fewer innovative firms.

EFFECTS ON DRUG SHORTAGES

The FDA says that the United States suffers from shortages of “critical” drugs.⁴⁵ The majority of drug shortages involve generic drugs, especially sterile, injectable drugs such as morphine and anesthetics, as well as antibiotics, electrolytes, and cancer drugs.⁴⁶ A primary cause of these shortages is industry consolidation, along with manufacturing and quality problems.

Small, generic drugmakers have combined into larger entities, and other generic drugmakers have been acquired by brand manufacturers, and these new behemoths focus production on their most profitable drugs, instead of these typically older, generic drugs that return relatively lower profit margins.⁴⁷ In other words, industry consolidation means fewer and fewer production lines of certain drugs, so any quality or equipment problem in a production facility can cause a drug shortage if hospitals and other buyers don't have another source for the drug.⁴⁸ Worse yet,

some vendors take advantage of shortages to engage in price-gouging, wringing additional hundreds of millions of dollars from consumers every year.⁴⁹

The FDA's system of exclusivities is also causing shortages by creating monopolies on drugs that used to be widely available. The FDA's Unapproved Drugs Initiative was designed to ensure the safety of drugs that were in use before FDA approval procedures were in place, but the FDA offered drugmakers temporary market exclusivities—monopolies—for going through the approval process.⁵⁰

For example, Par Pharmaceuticals obtained FDA approval in 2012 for vasopressin, a drug that had been in use for nearly a century, and the average wholesale price soared from \$4.27 to \$138.40 in November 2016, leading some hospitals to limit their stock of the drug.⁵¹ These windfall market exclusivities led to an increase in the number of drug shortages by 25 percent, and the median length of shortage increased dramatically from 31 days to 217 days.⁵²

A broader kind of generic drug shortage also inflates prices and profits. Roughly 43 percent of the 1,600 generic drugs approved by the FDA since January 2017 were not for sale in the United States in January 2019.⁵³ Nearly one-third of those unavailable drugs would have been the first to compete against a branded drug.⁵⁴ The first generic competitor usually sells for about half the price of a brand drug, so consumers have been forced to keep spending untold millions of dollars on expensive brand medications.

The reasons vary for the drugs' unavailability. Generic drug manufacturers have not been able to arrange manufacturing facilities for some of these approved drugs. Other approved generic drugs are tied up in patent litigation, but generic drugmakers are intentionally keeping some of these drugs off the market as part of patent-litigation settlements (for more on this problem, see Part IV, Pay for Delay). It is also difficult not to assume that generic drug manufacturers are keeping some of these approved drugs off the market as part of the criminal conspiracy detailed in Part IV.⁵⁵

EFFECTS ON DRUG SAFETY

Consolidation in the generic industry imperils drug safety by facilitating offshoring. As the generic industry consolidates, manufacturers are closing production facilities and moving the vast majority of production offshore

to slash labor and production costs in order to keep quarterly dividends and share prices high.⁵⁶

About 40 percent of all generic drugs now come from India, and more than 80 percent of the raw materials in U.S. drugs come from China and India, where production facilities are far more difficult for the FDA to inspect and thus can quickly cause major safety problems.⁵⁷ Since 2005, the FDA has had more drug plants to inspect overseas than it does within the United States.⁵⁸

From 2012 to 2017, one FDA investigator inspected 86 plants in India and China, and 67 of these facilities provided him with fraudulent or deceptive data.⁵⁹ The Indian drugmaker Ranbaxy fabricated data on more than 200 drugs for regulators in more than 40 countries.⁶⁰

These deceptive practices have grave safety implications. In 2007, almost 240 patients died in the U.S. after taking heparin, a blood thinner used for kidney patients.⁶¹ The heparin had been produced in a Chinese plant for the U.S. drugmaker Baxter, and someone in the plant had apparently added a chemical intended to stretch the drug's yield and profitability.⁶² The FDA had never inspected the plant,⁶³ and the FDA did not have any inspectors in China who even spoke Mandarin.⁶⁴

In 2018, dozens of generic versions of the blood pressure medicines valsartan and losartan were recalled because the ingredients—manufactured in China—contained a carcinogen that had gone undetected for years.⁶⁵

III. Legal and Regulatory Barriers to Entry

PATENT MONOPOLIES

The patent system was intended to provide drugmakers with a temporary monopoly, to spur innovation motivated partly by potential monopoly rents.⁶⁶ But pharmaceutical giants are gaming the system. Drugmakers manipulate patent law and regulation as a business strategy to preempt competition and to reap unmerited profits at the expense of health care purchasers, including patients, private insurers, and governments at all levels. Drug manufacturers build thickets of patents around their brand drugs. They claim new patents for trivial tweaks to dosage schedules or

for changing from pills to chewable tablets. Drugmakers carefully file these supplemental patents just before a drug's original patents expires, so the drug can then undeservedly enjoy extra years of high monopoly rents.

This gaming of the patent system is a root cause of high drug prices. Continually extended patents cost consumers money that could otherwise be saved by cheaper generic drugs. Drugmakers, however, usually raise the prices of patent-protected drugs each year.⁶⁷

Rampant abuse of the patent system also harms innovation. Once a class of drugs has produced lucrative monopoly profits, drugmakers devote resources to developing copycat drugs. In other words, pharmaceutical firms are not primarily allocating their finite research budgets toward innovation and breakthrough medications, but rather they are spending years developing me-too drugs that have marginal public-health value but a robust chance at cashing in on a lucrative market. This business strategy helps explain why only about 10 percent of newly patented drugs demonstrate clinical superiority over existing medications.⁶⁸

The consolidation described in Part II worsens patent abuse. As pharma firms become larger and more powerful, they can more easily overwhelm underfunded regulators with bundles of spurious patent applications. Patent abuse is the foundation for the anticompetitive business practices to be discussed in Part IV.

This part examines the damage done by patent manipulation, with sections on the techniques of prolonging patents, the form of monopoly known as market exclusivities, the relationship between patent monopolies and high prices, and the relationship between patent gaming and innovation.

It's important to keep in mind that this increase in gaming the regulatory environment has mirrored the strengthening of patent protections.⁶⁹ Since the Hatch-Waxman Act went into effect in 1984, patent protections are stronger—and drug-patent monopolies longer—than at any point in the last century, exacerbating the costs of this regulatory game-playing.⁷⁰

THICKETS OF EVERGREEN PATENTS

Drug manufacturers retain the exclusive rights to produce and sell

Drugmakers game the regulatory system by registering thickets of similar patents around a single brand drug for minor tweaks devoid of innovation. This practice locks in monopoly rents well beyond the 20-year statute of patent protection.

a patented drug during the 20-year length of a patent. To be fair to pharmaceutical firms, they generally patent new drug formulations during clinical trials, so drugs coming to market usually wind up with an average of 8 to 12 years of patent protection remaining.⁷¹

But drugmakers today rarely apply for only a single patent for their new drugs. Instead, they game the regulatory system by registering thickets of similar patents around a single brand drug for minor tweaks devoid of innovation. These patent thickets lock in monopoly rents well beyond the 20 years of patent protection.

Drugmakers deploy multiple, overlapping strategies to abuse the patent system this way. Pharmaceutical firms commonly file additional patents for individual features of a product, such as isomers, polymorphs, metabolites, or intermediates.⁷² Drugmakers also claim patents for minimal variations in methods of use, dosage schedules, or the method of manufacture.⁷³

The bases for these patents might sound dubious, but any potential market competitor would have to go through expensive, lengthy litigation to challenge a single patent.⁷⁴ To ward off competition, drugmakers cobble together a complex scaffolding of patents around each brand drug.

The scope of the abuse of the patent system is breathtaking. Almost 80 percent of drugs receiving U.S. patents from 2005 to 2015 were not new drugs, but drugs that already enjoyed patent protection.⁷⁵ The total number of additional patents for existing drugs soared from 349 additional patents in 2005 to 723 additional patents in 2015.⁷⁶ More recent data show a stark increase in drugs with multiple patents and exclusivities.⁷⁷

As of 2018, almost 40 percent of all drugs on the market had walled off competition through multiple patents or exclusivities.⁷⁸ Almost half of all available drugs were shielded by at least four additional patents, and some drugs were cocooned by more than 20 additional patents.⁷⁹

Drugmakers build patent thickets to extend monopoly rents, and this motivation is obvious in the size of the thickets protecting best-selling drugs. A blockbuster drug usually brings in billions of dollars each year in revenue, so extending monopoly protection by even a few months will produce hundreds of millions of dollars in extra revenue.⁸⁰

Each of the 12 best-selling drugs of 2018 was shielded by an average of 71 patents and 125 patent applications, with three of the 12 drugs having more than 200 patent applications.⁸¹ Thanks to these dozens of patents, each best-selling drug had, on average, an effective patent protection period of 38 years, nearly double the 20-year monopoly granted by a patent.⁸² Because all 12 drugs remain under patent protection, these total numbers of patents and years of monopoly could still grow.

Industry insiders also refer to this practice as evergreening, when drugmakers claim fresh patents for drugs whose original patents are about to expire. Similarly, drug manufacturers also engage in product-hopping, when they marginally change a product shortly before its patent expires, and then they pressure doctors to prescribe the newer version, to keep patients from using a generic alternative to the original brand formulation.⁸³

CASE STUDY: HUMIRA

The world's best-selling drug, AbbVie's Humira, is used to treat rheumatoid arthritis, psoriasis, and other inflammatory ailments. The story of its patents illustrates how failures in competition policies contribute to overpriced drugs.

The inventors of Humira applied for initial patents on the drug in 1994, and the FDA approved the drug in 2002. Since arriving on the market, Humira has brought in more than \$130 billion in worldwide revenues. In 2018, Humira brought in more than \$18 billion, more than the global revenues of Monsanto, General Mills, or Visa.

And the price of Humira keeps rising. AbbVie has raised the price of Humira by 144 percent since 2012. The price shot up by 9.7 percent in 2018 alone. Humira's list price per patient now averages \$50,000.

And yet, the primary patent on Humira expired in 2016. How can AbbVie keep raising Humira's price every year? Because Humira still doesn't have any competition in the United States, thanks to the 136 other patents AbbVie holds related to the formulation of the drug.

This patent thicket has kept would-be competitors off the market and has prolonged by decades its market monopoly. In all, AbbVie submitted 247 patent applications in the U.S. for processes, formulas, and other elements that it claims are proprietary, and the last patent won't expire until 2034.

AbbVie filed almost 90 percent of Humira's patent applications after the drug was already on the market. Stunningly, nearly 50 percent of these patent applications were filed 20 years after the initial Humira patent application was submitted. Generic drugmakers have made deals with Humira to allow competition in the U.S. market in 2023—even though the main patent on Humira expired in 2016.

Humira's position overseas shows how AbbVie has gamed the U.S. patent system. AbbVie has only 76 patent applications for Humira on file at the European Patent office, and 63 patent applications in Japan. Many of AbbVie's patent applications in Europe were rejected, withdrawn, or revoked after legal challenges. In European markets, Humira already has competition.

A lawsuit filed in March 2019 in a U.S. district court could provide the first legal test of whether patent thickets constitute an antitrust violation. A class action suit (UFCW Local 1500 Welfare Fund v. AbbVie et al., <https://www.labaton.com/hubfs/Filed%20Humira%20Complaint.pdf>) is claiming violation of the Sherman Antitrust Act, and it seeks to recover unnecessary spending on Humira since the expiration of Humira's primary patent.

MARKET EXCLUSIVITIES

The FDA operates a system of market exclusivities, which are intended to promote drug innovation by granting newly approved drugs a period of time free from competition.⁸⁴ The time periods of these exclusivities run independently of the 20-year terms of patents, which are issued by the Patent and Trademark Office.⁸⁵

During a period of market exclusivity, the FDA will not approve any applications from potential competitors. The FDA offers more than 10 different types of market exclusivities, which last for varying periods of time and can cover brand or generic drugs.

Congress established most of these exclusivities as incentives for drugmakers to develop certain types of drugs, such as antibiotics or entirely new chemical molecules, or drugs for certain patient populations, such as children or small groups with a particular condition.⁸⁶ So, drug manufacturers can apply for market exclusivities for performing pediatric studies, developing new antibiotics, or developing drugs for a disease or condition that affects fewer than 200,000 people in the United States (known as orphan drug exclusivity).⁸⁷

But drugmakers game market exclusivities in much the same way that they abuse the patent system. Instead of upholding the principles of exclusivity categories, drugmakers repurpose or simply reframe existing drugs and claim that the medication meets the requirements to obtain freedom from competition.

The orphan drug exclusivity is the most commonly abused category—not coincidentally, the orphan drug exclusivity lasts seven years, longer than any other period of FDA market exclusivity.⁸⁸ Drugmakers can apply for multiple orphan drug exclusivities for a single drug, as long as they claim different populations of fewer than 200,000 individuals for each exclusivity.

The number of orphan drug exclusivities skyrocketed by nearly 400 percent from 2010 to 2015. Orphan drugs now account for 40 percent of the new drugs approved by the FDA.⁸⁹

The orphan drug exclusivity is ripe for abuse, because drugmakers can apply for the exclusivity for drugs that have long been on the market. By securing an exclusivity, drugmakers can gain an additional seven years of monopoly, once a patent nears its end. One investigation found that

The FDA's market exclusivity for orphan drugs lasts seven years, longer than any other type of market exclusivity. Drugmakers can apply for multiple orphan drug exclusivities for a single drug. Today, about 40 percent of the new drugs approved by the FDA obtain an orphan drug exclusivity.

one-third of orphan drugs approved since the program began in 1983 were either repurposed mass-market drugs or drugs that received multiple orphan approvals.⁹⁰

Drugmakers' main technique for gaming orphan drug exclusivity is so pervasive that it has a name: salami slicing.⁹¹ Drug manufacturers will slice up the total number of users of a particular drug into populations of fewer than 200,000 individuals—based on how patients acquired a condition or their current stage of the disease, for example—and then the drugmakers will secure exclusivities for each slice.

Thanks to the absence of competition, orphan drugs are exceptionally expensive. Of course, drugmakers would need to charge relatively higher prices to recoup their investments in developing drugs for small patient populations. But many, if not most, of the orphan drugs today are sold to far more than 200,000 patients.

The median annual price of an orphan drug for a single patient is nearly \$100,000, compared to the median cost of roughly \$5,000 per patient per year for non-orphan drugs.⁹² For one class of orphan drugs, the median annual price per patient is \$140,000.⁹³

In a practice known as spillover pricing, drugmakers then collect the same high prices of orphan drugs from much broader populations through off-label use. Off-label use means having doctors prescribe the orphan drug for uses other than the basis for the exclusivity, so that far more than 200,000 consumers can be prescribed the drug.⁹⁴ Off-label uses now comprise up to 40 percent of all uses of many drugs.⁹⁵

MORE PATENTS, HIGHER PRICES

The costs of these regulatory abuses are staggering.

Generic competition yields significant price reductions and savings for the public. The introduction of two generic competitors usually cuts the price of a drug by about 50 percent.⁹⁶ FDA data show that six generic competitors lead to prices 94 percent lower than the price of the original brand drug, on average.⁹⁷ Given these facts, brand manufacturers have a powerful incentive to prolong their monopolies and pricing power for as long as possible.

With those steep price cuts in mind, brand drugmakers relentlessly drive prices higher. Drug manufacturers raised the prices of the country's 12 best-selling drugs by an average of 68 percent from 2012 to 2018.⁹⁸ In 2017 alone, these 12 drugs cost \$96 billion to health insurers, government payers, and consumers.⁹⁹ Economists estimate that the average markup for any patented drug is nearly 400 percent.¹⁰⁰

It is difficult to calculate an exact dollar amount that consumers overpay because of spurious patents and market exclusivities, but exorbitant brand drug prices have grave consequences for American citizens. About 20 percent of U.S. households report that the high cost of drugs has prevented them from filling a prescription in a recent year.¹⁰¹

MORE PATENTS, LESS INNOVATION

The original intent of the patent system was to grant a monopoly as an incentive for innovation. Prescription drugs are protected today by more patents and market exclusivities than ever before, but innovation is stagnant, if not declining. Few new drugs are clinically superior to existing drugs, and many new pharmaceutical products are merely copycat drugs of lucrative medications.

Multiple studies have found that only about 10 percent of drugs approved in recent years are clinically superior to existing drugs.

Stronger regulatory monopolies for drugs do not correlate with greater innovation. On the contrary, they create perverse incentives for drugmakers to place rent-seeking ahead of improving public health through groundbreaking medicine.

The vast majority of new FDA drug approvals are merely minor modifications of existing drugs, known as me-too drugs. Vanishingly few of these drugs have demonstrated superiority to existing drugs in clinical trials, which is not a standard the FDA applies in approving new drugs.¹⁰² Three studies, each covering a minimum of five years of recently approved drugs, found only 6 to 11 percent of these new medications to be clinically superior to available drugs.¹⁰³

Certainly, a handful of new drugs have made life-changing improvements in the lives of many individuals, but much industry R&D spending is just investment in me-too drugs.¹⁰⁴ Me-too drugs are frequently medications for cancer or rare diseases, because the FDA approval process for these classes of drugs is faster, cheaper, and less risky, and prices for these drugs remain lucratively high.¹⁰⁵ The FDA still does not require comparative trials for me-too drugs entering drug classes with

multiple effective drugs.¹⁰⁶

The regulatory environment, including patents and exclusivities ripe for abuse, is creating perverse incentives for pharmaceutical firms against real innovation. Once a drug provides high monopoly profits, rival drugmakers have an incentive to spend relatively less to produce a me-too version of this known entity, instead of developing from scratch a new drug that will face a longer and more expensive approval process—and might not pan out at all. Drugmakers produce me-too drugs for the same purposes as the profitable original drug, but the active ingredients in copycat versions—though structurally quite similar—differ enough so that manufacturers can claim patent protection for these drugs, too.

Patent thickets provide a similarly perverse incentive against innovation. Drugmakers can extract decades of monopoly profits by creating patent thickets, so their incentive is to allocate R&D spending to fiddle with the formulations and dosage methods of profitable existing products, rather than pursuing new, uncertain treatment options.¹⁰⁷

This anti-innovation strategy also keeps prices high and thwarts competition. When drugmakers choose to produce me-too drugs in drug classes with premium pricing, they choose to reinforce the premium prices with their me-too offerings. They might be able to win a greater market share by selling their me-too drug for less, but instead drug manufacturers are choosing a more reliable financial return for shareholders and other investors.

The pharmaceutical industry presents a different narrative, however. The industry says that high drug prices are justified by uniquely intensive spending on R&D. The pharmaceutical industry has long burnished an image of spending a higher percentage of revenue on R&D than does any other industry.¹⁰⁸

The industry estimates the cost of bringing one new drug to market at \$2.6 billion,¹⁰⁹ but this figure appears wildly overinflated. An independent calculation puts the cost at 10 percent of the industry's estimate.¹¹⁰

The Drugs for Neglected Diseases Initiative, an international nonprofit, estimates that it spends between \$110 million and \$170

Pharmaceutical firms spend almost twice as much on marketing as they do on research and development.

million to develop one new drug, including the cost of other failed projects.¹¹¹ One study found that drugmakers had been spending only 1.3 percent of revenues on basic research to discover new molecules, once taxpayer subsidies were subtracted from R&D costs.¹¹²

The role of taxpayer funding for research undercuts the industry narrative that intensive R&D spending requires high prices. Public funding accounts for about 80 percent of the spending on basic biomedical research that leads to the development of new drugs and vaccines.¹¹³

Drug manufacturers do shell out enormous sums of money to influence the decision-making of health care professionals and to target consumers with direct advertising.¹¹⁴ The regulatory environment has helped to create perverse spending incentives for drugmakers. Once drugmakers erect patent thickets and salami-slice patient populations to claim orphan drug exclusivities, their incentive is to invest in marketing to push clinicians to prescribe their drugs for off-label uses.¹¹⁵

Me-too drugs also demand intensive marketing, to generate demand for copycat versions in lucrative markets.

Pharma companies' balance sheets show that they spend almost twice as much money on marketing as they do on R&D. A 2008 study found that the industry spent 24.4 percent of the previous year's sales revenue on promotion and spent 13.4 percent on R&D.¹¹⁶ Annual marketing spending for the industry reached nearly \$30 billion by 2016.¹¹⁷

Pharmaceutical innovation may be weak, but industry profits are strong. Global revenues for the industry reached \$1.2 trillion in 2018, which represented a substantial increase of \$100 billion (or 9 percent) from 2017.¹¹⁸ Drug manufacturers' profit margins are similarly impressive. Drug manufacturers take 23 percent of revenues for the entire health care sector in the United States, but they make 63 percent of the profits. In 2013, Pfizer boasted a profit margin of 42 percent.¹¹⁹

To sum up, then:

- Pharmaceutical firms spend far less than they claim on R&D.
- Most new drugs coming to market replicate existing drugs, without providing added clinical value.
- Demand for new drugs is largely driven by advertising.

MORE PATENTS, LESS DRUG SAFETY

The perverse incentives to game FDA patent regulation for excessive profits also carry grave risks to the health of American patients. The potential of multi-decade patent monopolies has encouraged drugmakers to conceal evidence that their drugs are harmful.

For example, experts allege that Merck concealed longstanding evidence that its arthritis drug Vioxx—which raked in sales of \$2 billion annually—increased the risk of heart attack and stroke among patients with heart conditions.¹²⁰ Any drug manufacturer might discover that a potential new medicine has dangerous side effects, but the point here is that Merck officials chose to cover up the drug's potential harms. Disclosing these side effects would have put billions in profits at risk.

IV. Anticompetitive Practices

In addition to gaming the patent system, brand and generic drug manufacturers keep drug prices high through anticompetitive business practices. Brand drugmakers abuse the regulatory environment to suppress competition, through game-playing with safety regulations and citizen petitions. Brand drugmakers also conspire with generic drugmakers in patent-litigation settlements to guarantee monopoly markets for brand drugs and eventual generic competitors. Generic drugmakers have apparently been engaging for years in a massive illegal conspiracy to split up markets and avoid competition, which defrauded U.S. consumers out of potentially billions of dollars through artificially inflated prices.

CONSOLIDATION, COLLUSION, AND CRIMINAL CONSPIRACY

As described in Part II, the generic drug industry has consolidated around a group of behemoths, after an initial burst of competition in the wake of the 1984 Hatch-Waxman Act. Once the industry sufficiently consolidated more than a decade ago, that enabled the leading manufacturers to collude to establish protected fiefdoms and to fix grossly inflated prices on hundreds of drugs, including some of the nation's best-selling medications.

With noncompetitive markets assured by illegal behavior, generic manufacturing has become a race to the bottom, with drugmakers free to cut increasingly more corners to squeeze out every possible penny of profit. These comfortably noncompetitive markets have led to shortages of critical basic drugs, such as morphine and antibiotics, as well as an intentional disregard for safety that has killed U.S. patients with toxic drugs.¹²¹

In May 2019, a coalition of 44 states filed a criminal and civil lawsuit against 20 pharmaceutical companies and 15 of their executives for years of collusion and price-fixing.¹²² The machinations detailed in the lawsuit explain why generic drug prices have soared in recent years.

Led by Teva Pharmaceuticals, the world's largest generic drugmaker, these firms spent years conspiring to inflate generic drug prices by up to 8,000 percent in some cases, the lawsuit says.¹²³ Pfizer, Sandoz, and Mylan also participated in some of the 33 episodes of conspiracy laid out in the lawsuit.

These ostensible competitors continually cooked up illegal agreements to divvy up markets and to raise prices on as many drugs as possible, bilking U.S. consumers out of tens of billions of dollars. These antitrust violations have raised prices for hundreds of drugs, including common generic drugs for asthma, diabetes, high cholesterol, high blood pressure, HIV, cancer, and epilepsy, as well as antibiotics, contraceptives, and antidepressants.

These ostensible competitors continually cooked up illegal agreements to divvy up markets and to raise prices on as many drugs as possible, bilking U.S. consumers out of tens of billions of dollars.

Teva, the ringleader of criminal conspiracy, raised the prices on about 400 formulations of 112 generic drugs from 2013 to 2015.¹²⁴ During this time period, the prices of 1,215 generics rose by an average of more than 400 percent.¹²⁵ For example, between 2013 and 2014, the price of one bottle of the antibiotic doxycycline skyrocketed by 8,281 percent, from \$20 to more than \$1,829.¹²⁶ The price of a bottle of the asthma medication albuterol sulfate ballooned more than 4,000 percent, from \$11 to \$434.¹²⁷

These jaw-dropping crimes put in context the data showing that generic drug prices have declined slightly during the past three years in some respects. The massive price jumps in 2012, 2013, and 2014 mean that the recent mild decreases have done almost nothing to counteract the long-term spike in generic drug prices.¹²⁸

To be sure, the U.S. justice system presumes the innocence of the drugmakers, but one major drugmaker in the lawsuit has already pleaded

guilty to a felony antitrust charge,¹²⁹ and six cooperating witnesses have corroborated the accusations in the lawsuit.¹³⁰ Moreover, the 524-page lawsuit lays out emails, text messages, and phone transcripts that demonstrate the drugmakers' collusion to avoid competition.

In addition to the lawsuit filed by the 44 states, the Department of Justice is pursuing an ongoing criminal investigation of generic price-fixing, and it has already filed some antitrust charges.¹³¹ In the wake of the states' lawsuit, dozens of class-action lawsuits have been filed by pharmacies, school employees, unions, and other groups seeking damages.¹³²

The absence of competitive markets was a necessary condition for generic drugmakers to weave this criminal conspiracy. Connecticut Attorney General William Tong said, "The generic drug industry is the largest private sector corporate cartel in history."¹³³

Industry consolidation and concentration facilitate these kinds of antitrust violations. A conspiracy of this scope can only emerge when dominant market actors have the ability to divvy up dozens of similarly noncompetitive markets for specific drugs. The illegal price-gouging at the core of the generic drug industry is rooted in the noncompetitive markets nurtured by market exclusivities and corporate consolidation.

Not only do these anticompetitive markets cost U.S. consumers billions of dollars year after year, but these deformed markets cause drug shortages and intentional violations of drug safety, which cost the lives of patients, as discussed in Part II, Effects on Drug Safety.

THE REMS PROBLEM

Beyond the gaming of the patent system, manufacturers of brand-name drugs manipulate FDA safety regulations to eliminate competition and entrench monopolies, by preventing potential generic competitors from entering the market. Brand drugmakers are manipulating an FDA safety program to stop generic manufacturers from obtaining the samples of the brand drugs necessary to create generic versions and to pass FDA testing. Brand manufacturers follow this anticompetitive strategy for drugs that are still protected by patents or exclusivities, as well as for drugs that are no longer protected by patents and should be facing competition. As long as drug prices remain exorbitant, pharmaceutical firms will have a powerful financial incentive to keep competitors out of the marketplace for as long as possible, by whatever means they can get away with.

In order to ensure that the benefits of a drug outweigh its risks, the FDA can require any drugmaker to develop a Risk Evaluation and Mitigation Strategy (REMS), a system created by the Food and Drug Administration Amendments Act of 2007.¹³⁴ If the FDA assesses a drug as a safety risk, then the manufacturer constructs a REMS program for its product, and then the FDA reviews and approves the program.¹³⁵ Drugmakers game the REMS system in a relatively simple fashion to stop potential generic competitors from getting the samples that they must have to produce a cheaper alternative.

Brand manufacturers are increasingly restricting potential competitors' access to brand drugs by using the REMS measure known as elements to assure safe use, or ETASU.¹³⁶ As an ostensible ETASU precaution, drugmakers circumvent traditional wholesalers and limit distribution to a single specialty distributor or to select pharmacies,¹³⁷ and drugmakers forbid any distributor from selling the drug to persons or organizations not approved in the REMS program.¹³⁸ This tactic prevents generic manufacturers from obtaining samples of the brand drug, which they must have before they can develop a generic alternative and can conduct the bioequivalence tests necessary for FDA approval.¹³⁹ Of the 60 drugs in the FDA's REMS program in June 2019, 53 used ETASU measures.¹⁴⁰

If generic manufacturers cannot obtain samples from wholesalers or other distributors, the generic drugmakers can also ask brand manufacturers to sell samples of the drug directly to potential generic competitors. But brand manufacturers simply reject the requests and cite REMS restrictions as justification for refusing to sell samples.¹⁴¹ Until generic manufacturers can obtain the required samples, they cannot produce their own drugs or perform the bioequivalence tests necessary to secure FDA approval, so brand drugmakers can prolong monopolies on their drug and continue charging monopoly prices, even for drugs that are no longer protected by patents.

This game-playing by brand manufacturers violates the letter of the 2007 law passed by Congress, but the FDA is powerless to extract drug samples from brand manufacturers or to punish the pharmaceutical firms for their law-breaking. Congress knew that drugmakers might try to twist REMS provisions to thwart generic competitors from getting access, so the 2007 act explicitly stated that no brand manufacturer "shall use any element to assure safe use required by the Secretary [of HHS] under this subsection to block or delay approval of an application" for a generic

drug.¹⁴² When brand drugmakers prevent generic drugmakers from getting samples of brand drugs, generic drugmakers can notify the FDA, but the FDA can do nothing more than send the brand manufacturer a letter affirming that providing brand samples to the generic manufacturer would not violate the REMS program.¹⁴³

More drugmakers are also designing REMS programs that require ETASU provisions. In 2009, shortly after the REMS system was created in 2007, about 75 percent of REMS programs required only a medication guide as a measure to ensure the drug's safe use.¹⁴⁴ Today, more than 50 percent of REMS programs require ETASU.¹⁴⁵

Drugmakers' abuse of the REMS system is only increasing, as roughly 40 percent of new drugs approved by the FDA are subject to REMS.¹⁴⁶ From the point of view of pharmaceutical firms, the REMS system presents a ripe opportunity to thwart competition and undermine generic competition. If a brand drugmaker produces a particularly profitable drug, a REMS program can serve as an effective business strategy to protect monopoly rents.

For example, the brand manufacturer Celgene produces the blockbuster cancer drug Revlimid, which accounted for 63 percent of Celgene's revenue in the first quarter of 2018 and is subject to REMS.¹⁴⁷ The generic drugmaker Mylan offered Celgene market price for samples of Revlimid, so that Mylan could try to create a generic version, but Celgene refused to sell, citing the safety concerns in the REMS program.¹⁴⁸ Without any generic competitors, Celgene inflated the price of Revlimid by 40 percent from 2012 to 2016.¹⁴⁹ In 2016, the drug cost \$75,200 per beneficiary for the year, and Medicare Part D spent \$2.7 billion on Revlimid in 2016, the second-highest spending on any single drug.¹⁵⁰

As of 2019, the FDA has received 13 inquiries from generic drugmakers that had tried and failed to obtain samples of Revlimid.¹⁵¹ Mylan sued Celgene in 2014 because of Celgene's refusal to sell samples to Mylan of Revlimid and Celgene's related cancer drug Thalomid.¹⁵² The companies had been negotiating an agreement since 2009 to sell Revlimid samples, but Celgene continually refused to close the deal, and now, 10 years later, Mylan has still not been able to buy samples of Revlimid or Thalomid.¹⁵³

The FDA has long known that brand manufacturers manipulate the REMS program to stave off competition from generic drugmakers. In 2018, the FDA published a webpage explaining how brand manufacturers are

Brand drug manufacturers have long abused an FDA safety initiative to deny samples of brand drugs to generic drugmakers, so these generic firms cannot pass the tests required for FDA approval.

“gaming” REMS and otherwise denying samples to potential competitors. The page contains a list of drugs about which the FDA has received inquiries from generic manufacturers stating that they want to produce competing drugs but have been prevented from acquiring samples.¹⁵⁴ In mid-2019, the list contained 60 drugs and 164 inquiries from generic drugmakers related to those drugs.¹⁵⁵

This game-playing provides mammoth profits to brand drugmakers, but it also squeezes unmerited billions of dollars from patients and the public. An analysis by Kaiser Health News found that 47 of the 60 drugs on the FDA’s list cost Medicare and Medicaid about \$12 billion in 2016, and nearly all these 47 drugs had hiked their prices significantly during the preceding five years.¹⁵⁶

The exorbitant prices of brand drugs drive these fraudulent tactics. High prices mean that every month can represent tens of millions of dollars of revenue for brand manufacturers, so any delay in generic competition is vital to brand manufacturers’ business interests. This explains not just the continual extension of patents and exclusivities to preserve monopolies, but also the efforts to manipulate safety regulations to prevent generic drugmakers from even getting samples of brand drugs, regardless of whether the drugs are nearing the end of their patents or are unprotected by patent or exclusivities.

The strategy has been so successful that brand manufacturers have even begun imposing distribution restrictions on drugs that aren’t in the REMS program, just to thwart potential competitors from acquiring samples of the drugs.¹⁵⁷ In one particularly egregious case, Turing Pharmaceuticals raised the price of its anti-parasitic drug Daraprim by 5,000 percent overnight, from \$13.50 per pill to \$750 per pill, because the firm had a monopoly on that type of anti-parasitic medication.¹⁵⁸ Daraprim was not subject to a REMS program, but Turing still decided to channel distribution of the drug solely through one specialty pharmacy distributor, so that Turing could prevent any generic manufacturer from buying samples of the drug.¹⁵⁹ In testimony to the Senate, the former general counsel of Turing, which was owned by Martin Shkreli, said that an “integral part” of the company’s business strategy was to block any generic entrant to the market for at least three years.¹⁶⁰

There is a perverse irony that pharmaceutical firms have twisted the intent of an FDA safety initiative into a business strategy to block competition and extort undeserved monopoly rents. Brand drugmakers have the

overwhelming market and financial power to use the REMS program to dictate limits on drug distribution, to tie up legal challenges for years, and to ignore any attempt by the FDA to make drugmakers uphold the law. The FDA, unfortunately, does not today have the enforcement power or legal leverage to challenge the drug monopolies enabled by REMS or to create competitive markets.

PAY-FOR-DELAY

Pharmaceutical firms perpetuate high monopoly prices also by closing deals to prevent cheaper generic drugs from competing in the market. The potential entry of a cheaper, generic competitor represents a serious threat to the monopoly rents collected by brand manufacturers, so brand manufacturers thwart competition—and entrench exorbitant drug prices—by paying generic manufacturers to postpone selling their generic alternatives, often for as long as a thicket of patents covers the brand drug.¹⁶¹

These collusive deals between brand and generic drugmakers are known as pay-for-delay settlements or reverse-payment settlements. Brand manufacturers often sue generic drugmakers after the generic drugmakers apply for FDA approval to market the first generic version of a brand-name drug, and then drugmakers use pay-for-delay deals to settle patent-infringement lawsuits. Brand manufacturers want to prolong brand-drug monopolies as long as possible, while generic drugmakers enter these agreements because they typically get a cut of the brand drug's monopoly revenues, without having to spend any money producing, marketing, and distributing their own generic version of the drug.

Pay-for-delay deals, however, cost patients and insurers billions of dollars per year in the form of monopoly profits, when consumers could otherwise be paying a small fraction of a brand drug's monopoly price for a generic alternative. Moreover, the premise of a pay-for-delay agreement appears to be a clear antitrust violation, because drugmakers are explicitly colluding to keep prices inflated.¹⁶² In other words, pharmaceutical firms use pay-for-delay deals as a business strategy to artificially extend the length of time that their drugs can enjoy monopoly markets and monopoly profits.

Much like REMS abuses, pay-for-delay shows how drugmakers work to undermine competition-promoting regulation in order to boost their bottom lines. Drug manufacturers concocted pay-for-delay deals in the

Brand and generic drugmakers often settle patent lawsuits through pay-for-delay deals, which lock in monopoly markets and exorbitant prices for one of both firms—depriving consumers of competitive markets and costing consumers significant, unnecessary spending.

wake of the Hatch-Waxman Act of 1984, a primary goal of which was to lower prescription drug prices by bringing generic drugs to market more quickly.¹⁶³ Ostensibly to foster competition, the Hatch-Waxman Act created incentives for generic drugmakers to challenge the patents of brand drugs, but this patent litigation sometimes serves instead to entrench patent monopolies and monopoly prices.¹⁶⁴

To its credit, the Federal Trade Commission has for 20 years been fighting pay-for-delay deals as antitrust violations.¹⁶⁵ Since 1999, all FTC commissioners—Democrats, Republicans, and an independent—have called for an end to pay-for-delay settlements, deals that former FTC Chairman Jon Leibowitz labeled “unconscionable.”¹⁶⁶ The FTC has long asked Congress to pass legislation that would forbid pay-for-delay agreements, but to no avail.¹⁶⁷

Plaintiff attorneys such as Daniel Berger were successful in convincing some lower courts that such practices were either per se or presumptively illegal.¹⁶⁸ But in 2005, another appellate court, in a case brought by the FTC, upheld a pay-for-delay agreement as legal.¹⁶⁹ The FTC, plaintiff attorneys, and pharmaceutical companies continued to litigate the antitrust question in court for years, until the Supreme Court decided in the 2013 case *FTC v Actavis* that pay-for-delay deals were not presumptively illegal but subject to antitrust scrutiny and could constitute potentially illegal, anticompetitive actions.¹⁷⁰ During the oral arguments in the case, Justice Elena Kagan succinctly expressed the essence of pay-for-delay deals: “It’s clear what’s going on here is that they’re splitting monopoly profits, and the person who’s going to be injured are all the consumers out there.”¹⁷¹

Since *Actavis*, the FTC has recorded a steep drop in the number of drug-patent settlements that include direct financial payments to a generic drugmaker in exchange for delaying the entry of a generic drug to the market.¹⁷² Instead, pharmaceutical firms have devised new types of agreements that have the same end result: delayed generic competition—or none at all—and the preservation of monopoly drug markets and monopoly prices.¹⁷³

These newer deals typically give generic drugmakers some non-monetary form of compensation in exchange for not competing against brand drugs by postponing the market entry of generic drugs. In one type of deal, a generic manufacturer agrees to delay competition in exchange for a brand manufacturer agreeing not to compete against the eventual generic

product with the brand manufacturer's own authorized generic. The Hatch-Waxman Act gives a monopoly of 180 days to the generic drug that first files an FDA application, a period during which no other generic drugs are allowed to compete—but brand manufacturers can release their own authorized generic, or AG, during this 180-day monopoly.

This type of agreement, known as a no-AG deal, ensures both a monopoly for the brand manufacturer, who remains free from generic competition, as well as for the generic drugmaker, who ensures a 180-day monopoly as sole manufacturer of the generic alternative. These deals made up about 25 percent of all patent-litigation agreements from 2004 to 2008.¹⁷⁴ The number of no-AG deals spiked in 2010, accounting for nearly half of the deals that the FTC classified as potentially constituting pay-for-delay settlements, but drugmakers conclude few such deals today.¹⁷⁵

In another category of monopoly-reinforcing settlements, brand and generic manufacturers collude to delay the entry of cheaper generic drugs in exchange for side deals. For example, a generic drugmaker can agree not to compete with a brand drug, in exchange for a contract to manufacture one of the brand manufacturer's other drugs.¹⁷⁶ Or, a generic manufacturer can agree not to compete with a brand drug, in exchange for the rights to distribute a different form of the brand drug (e.g., chewable versus non-chewable) that will be manufactured by the brand drugmaker.¹⁷⁷

It's important to understand what these convoluted settlements mean. In exchange for a portion of the branded drug's monopoly profits (in cash or non-cash form), generic drugmakers agree with brand manufacturers not to compete with brand drugs, typically for the entire length of the patents claimed by the brand, however spurious those patents might be (see Part III for details on how drugmakers game the patent system).

Pharmaceutical firms can even agree to delay competition beyond the length of the patents, because the generic drugmaker, if it is the first to file a generic-drug application with the FDA, controls the 180-day window during which no other generic drugs can compete. A deal can lock in exorbitant brand-drug monopoly rents for the length of all brand-drug patents, plus an additional 180 days.

The costs to patients and insurers of these pay-for-delay deals amount to billions of dollars every year, though these agreements affect a relatively small share of overall spending on prescription drugs. In a 2010 study,

the FTC calculated that pay-for-delay deals cost U.S. consumers \$3.5 billion per year and postponed competition from cheaper generic drugs by an average of 17 months.¹⁷⁸ Including all forms of patent-litigation settlements involving some form of compensation, the FTC estimated their cost to consumers at \$20 billion per year.¹⁷⁹

The FTC estimates, however, might drastically understate the damage. Moreover, the FTC has not updated its estimates since 2010, but the number of patent-litigation settlements per year more than doubled from 2010 to 2016.¹⁸⁰ A 2013 study by an independent research group examined the 20 best-selling drugs that had been subject to patent-litigation settlements.¹⁸¹ The study found that these deals led to an average delay of five years in the entry of generic competition.¹⁸² Because of these delays, these 20 drugs alone raked in roughly \$98 billion in revenue from U.S. consumers, and they cost an average of 10 times more than their eventual generic competitors.¹⁸³

The FTC is continuing to fight against all forms of patent-litigation settlements that compensate generic drugmakers for delaying the entry of their generic drugs. In February 2019, the FTC settled three of its lawsuits against Teva Pharmaceuticals, the world's largest generic manufacturer; one of these settlements concluded the Actavis case that the Supreme Court had ruled on in 2013.¹⁸⁴ In the FTC settlement, Teva agreed that it would never again enter into a patent-litigation settlement that included either a no-AG deal or a side deal including another business transaction that enriches Teva.¹⁸⁵ In a March 2019 decision, the FTC found generic drugmaker Impax liable for entering into a pay-for-delay agreement with branded drug company Endo over an extended-release opioid. The decision is being reviewed by a court of appeals.

The Teva settlement and Impax case marks a clear victory for patients and insurers, but the broader scope of patent-litigation settlements today is murky at best. Each year marks another increase in the number of settlements that delay the entry of generic competitors to brand-name drugs, and the FTC seems to be having difficulty categorizing the nature of more and more of these transactions.¹⁸⁶

One obstacle is that the FTC's capabilities are limited—it takes the agency two years to produce a report on the settlements it receives in a given year.¹⁸⁷ The number of patent-litigation settlements has skyrocketed during the past 15 years, soaring from four settlements in 2004 to 113 settlements in 2010, and finally to 232 in 2016, the last year for which the FTC has released data.¹⁸⁸

Even though explicitly pay-for-delay and no-AG deals are disappearing, the FTC reports now include a category of “possible compensation,” because the FTC can’t tell whether the terms of some settlements provide generic manufacturers with enrichment.¹⁸⁹ By far the largest category of settlements in recent FTC reports—about 65 percent of all patent-litigation settlements in 2016—is a type of deal under which the generic drugmaker agrees to delay entry of a generic drug in exchange for no compensation.¹⁹⁰ It does not seem to require a conspiracy theory to suggest that perhaps pharmaceutical firms are sometimes able to thoroughly obfuscate the compensation to the generic drugmaker. For example, the FTC has described deal structures in which the brand drugmaker agrees not to license the right to sell an authorized generic to any third party, or in which the brand drugmaker agrees to declining royalties from the generic drugmaker if the brand manufacturer were to release an authorized generic.¹⁹¹ Though somewhat convoluted, these deals could essentially amount to no-AG deals.

But even if these generic manufacturers are freely surrendering their rights to produce and distribute a presumably profit-making generic drug for some period of time without any compensation whatsoever, such deals still guarantee brand-name drugs monopoly rents and delay the entry of generic competition.

Much more significantly, the FTC had not until 2019 seen any settlements concerning biologic and biosimilar drugs, a burgeoning and exceptionally costly segment of the prescription-drug market.¹⁹² Biosimilars are the equivalent for biologic drugs of generic small-molecule drugs. In 2017, biologic drugs comprised only 2 percent of prescriptions in the U.S. but accounted for 37 percent of net drug spending.¹⁹³ From 2014 to 2017, spending on biologic drugs made up 93 percent of the growth in net drug spending.¹⁹⁴ In other words, we have no idea yet whether pay-for-delay or similar deals are perpetuating monopolies in a drug market worth more than \$100 billion per year.

The market for prescription drugs is littered with deals among brand and generic manufacturers that restrict the entry of generic drugs. These deals entrench many extra years of brand monopolies on drugs, regardless of the validity of the underlying patents. Many of these deals also establish a monopoly on the market for a subsequent generic drug, which will be free of competition from an authorized generic. All these deals cost patients and insurance providers billions of dollars per year, just to preserve the unwarranted monopolies of pharmaceutical firms.

SHAM CITIZEN PETITIONS

To delay the entry of generic competition, brand drug manufacturers manipulate the filing of citizen petitions with the FDA. In these sham petitions, brand drugmakers pretend to raise safety issues regarding a potential generic competitor. But brand manufacturers typically file these petitions shortly before the generic competitor is about to arrive in the market, in order to exploit the requirement that the FDA properly investigate the concerns presented in the petitions. Brand manufacturers are hoping that the FDA investigation will extend into the time that the generic drug would otherwise have entered the market, so that the brand drug can enjoy and exploit every last moment of monopoly.

Much like the gaming of the REMS program and pay-for-delay deals, these practices are another type of exclusionary conduct that limits generic competition. Sham citizen petitions are not a central or root cause of high drug prices, but they represent an offshoot of that root: the tireless asphyxiating of competition by powerful pharmaceutical corporations.

Brand drug manufacturers file sham citizen petitions with the FDA to raise spurious safety concerns with potential generic rivals.

The right to petition the government is enshrined in the First Amendment, and in the 1970s, the FDA established a process to allow citizens the opportunity to express in petitions their concerns about food and drug safety.¹⁹⁵ The Food and Drug Administration Amendments Act (FDAAA) of 2007 further elaborated the petition process, and the FDA refers to citizen petitions as 505(q) petitions, according to the subsection in the 2007 legislation.¹⁹⁶

Brand drugmakers abuse the petition process by filing petitions against potential generic drug rivals shortly before a brand drug's patent is set to expire, when the generic drug is about to enter the market. The FDA has 150 days to investigate and resolve the issues raised in a petition, so brand drugmakers can hope that the months necessary for the FDA to address a petition's claims will delay, even if only for a relatively short time, the arrival of a generic competitor. After all, if a brand drug is bringing in billions of dollars in annual monopoly rents, every day of monopoly is worth millions of dollars.

In its annual reports to Congress, the FDA has confirmed that these sham petitions have needlessly delayed the arrival of new generic drugs to the market.¹⁹⁷ Delays in competition are not the only result of these petitions—FDA officials must dedicate time and resources to investigate the petitions, and this is time that could have been spent bringing other

competing drugs more quickly to market or pursuing serious drug-safety concerns. In 2018, then-FDA Commissioner Dr. Scott Gottlieb said that these petitions' "increased burden on the FDA can take resources away from the daily work of application review."¹⁹⁸

These petitions are shams also because brand manufacturers could have raised safety concerns years earlier than they do. Generic versions of brand drugs generally take years to develop, and brand drugmakers have access to FDA data about the testing of their potential generic competitors. The FDA has confirmed that many petitions "contained data that had been available to the petitioner well before the date of the petition."¹⁹⁹

The data show that almost all petitions filed by brand drugmakers are shams to preserve monopoly rents. A study of all 505(q) petitions from 2011 through 2015 found that 92 percent of petitions were submitted by brand drugmakers, and the FDA rejected 91 percent of the brands' petitions.²⁰⁰ Moreover, almost 40 percent of the brand drugmakers' petitions were filed within six months of the date when the brand drugs would lose their monopolies.²⁰¹ It's worth noting that many of the remaining 8 percent of petitions filed during this time were filed by generic drugmakers seeking to delay the market entry of new generic competitors.

To take two of the more egregious examples of frivolous petitions, Mylan submitted a petition in 2015 alleging safety problems with a prospective generic competitor to the lucrative EpiPen. Mylan told the FDA that a study had shown that the generic rival had a failure rate of 93 percent, but this study had been commissioned by Mylan, and expert review dismissed the study as fatally flawed.²⁰²

In the second example, Mutual Pharmaceuticals submitted a petition to the FDA in 2007 to delay approval for a generic version of Mutual's blood-pressure medicine Plendil. Mutual literally requested that the FDA investigate which type of orange juice had been given to patients in clinical trials of the generic version. The drugmaker presented the ludicrous hypothesis that perhaps patients had been given orange juice made from Seville oranges, which are a more bitter type of orange, and this could have affected the absorption of the generic drug into their blood.²⁰³

In October 2018, the FDA announced new guidelines to combat these

frivolous petitions,²⁰⁴ but such attempts in the past have not deterred brand manufacturers from filing sham petitions—on the contrary, the trend during the past 20 years has been a steady increase in the average number and complexity of the petitions submitted by brand drugmakers.²⁰⁵ Legislation enacted in 2007 was partly intended to halt abuse of the petition system, but the number of sham petitions has steadily risen since then.²⁰⁶

The 2007 law allowed the FDA to summarily dismiss a petition that had been filed primarily to delay a generic drug's market entry, but the FDA has never used this provision.²⁰⁷ In 2016, the FDA enacted more rules designed to prevent any delays to the market entry of generic drugs, but the FDA decided to issue new draft guidance in October 2018 because the manipulation of citizen petitions is clearly continuing. In announcing the 2018 guidelines, the FDA commissioner says that sham citizen petitions are an attempt to "game" the system and "exploit loopholes," as one of many "anticompetitive techniques" pursued by brand manufacturers to stifle generic competition.²⁰⁸

But the new guidance seems to add little to existing FDA authorities. The 2018 draft rules slightly modify the factors allowing for the summary dismissal of frivolous petitions. The FDA could also now publicly name the brand drugmakers who submit sham petitions, reflecting the hope that naming and shaming pharmaceutical corporations will change their approach to protecting their monopolies. The new guidance also moves to align the deadline for review of petitions with pre-existing deadlines for review of generic drug applications, in an attempt to ensure that sham petitions do not push back the date of approval for generic drugs.

Perhaps the most potentially meaningful provision is the authority for the FDA to refer sham petitions to the FTC for investigation as an anticompetitive business practice. The FTC has already taken one drugmaker to court for sham petitions.²⁰⁹ In 2017, the FTC lodged a complaint against Shire ViroPharma, which had filed an astounding 43 petitions—all without merit—to block and delay the entry of a generic competitor to the antibiotic Vancocin. Shire also filed three lawsuits against the FDA.²¹⁰ However, the court dismissed the FTC suit because the drugmaker's illegal conduct had ceased before the FTC filed suit, and this decision was upheld on appeal.²¹¹

It's appalling and disheartening that drug manufacturers can get away with blatantly illegal conduct as long as they stop their anticompetitive practices before the FTC files suit—but the 2018 FDA guidance offers a

new chance to combat the sham petitions. The draft expressly allows the FTC to begin legal action before the FDA rules on a sham petition. After the FDA announced the draft guidance in 2018, the FTC publicly stated that it stood ready to work with the FDA to fight the abuse of citizen petitions and other anticompetitive practices.²¹²

DISTRIBUTION DEALS TO BLOCK COMPETITION

Three recent lawsuits revealed that brand manufacturers are using a new anticompetitive technique to create barriers to market entry for potential rivals. Brand drugmakers are offering substantial rebates or discounts to large-scale buyers—such as insurance companies, PBMs, Medicaid, or Medicare Part D—but only if the purchasers refuse to buy a new, competing generic drug. In other words, pharmaceutical firms' strategy is to kill off competition before it can even reach the marketplace of drug consumers.

These deals take two forms. In one version, the brand drugmaker offers buyers exceptionally large rebates for each purchase of a brand drug, but on one condition: The buyer cannot make any purchases of a generic competitor. This contract structure is called exclusive dealing, because it compels the buyer to purchase one drug exclusively. The second form is bundled discounts, through which a brand drugmaker offers buyers a package of discounts on multiple drug products in exchange for the buyer not purchasing a generic rival.

Insidiously, brand manufacturers can then raise the list price of their drugs after concluding either type of deal, because the rebates or discounts will still make the purchases attractive for the buyers. But buyers without these anticompetitive deals wind up paying inflated prices, while cheaper versions struggle to enter the marketplace.

In April 2017, Sanofi-Aventis sued Mylan over the EpiPen, Mylan's epinephrine autoinjector. The lawsuit said that Mylan closed exclusive dealing arrangements with insurance companies, PBMs, and Medicaid, in exchange for these buyers not purchasing a new competing autoinjector developed by Sanofi-Aventis. From 2013 to 2016, Mylan raised the wholesale price of the EpiPen from \$219 to \$609. Rebates would have erased much of this difference for distributors with exclusive contracts, but patients would have had to make up the difference, if they didn't have the random luck to be covered by one of these anticompetitive deals.²¹³

Brand drugmakers offer substantial rebates or discounts to large-scale buyers—but only if the purchasers refuse to buy a new, competing generic drug.

In September 2017, Pfizer sued Johnson & Johnson and Janssen Biotech because of deals to protect the latter two's blockbuster drug Remicade, which has sales of about \$5 billion per year. Pfizer introduced a biosimilar in 2016, but Johnson & Johnson offered rebates, discounts, and other forms of exclusive deals to insurers in order to eliminate competition and prevent purchases of Pfizer's would-be biosimilar rival. Johnson & Johnson increased the list price of Remicade by 9 percent, after closing these deals.²¹⁴

In October 2017, Shire ViroPharma sued Allergan regarding products for dry-eye disease. Allergan gave Medicare Part D bundled discounts for four Allergan products, so that Medicare Part D could reduce spending on four drugs, as long as it did not buy Shire's product. Allergan wound up with about 90 percent of the Medicare Part D market, even though Shire's new product won a market share of 35 percent in the commercial insurance market for drugs to treat dry-eye disease.²¹⁵

Sanofi's lawsuit against Mylan is ongoing, but the other two suits have provided conflicting signals. In March 2019, a district court dismissed Shire's lawsuit against Allergan over bundled discounts, though the judge's somewhat odd rationale for dismissal was that Shire had not shown that Allergan also controlled a monopoly share of the markets of the other drugs that it bundled with the dry-eye medication.²¹⁶ Shire has filed a new lawsuit.²¹⁷

On the other hand, a judge denied in August 2018 Johnson & Johnson's motion to dismiss Pfizer's lawsuit, and the judge's harsh description of Johnson & Johnson's conduct hints that the court might favorably view Pfizer's lawsuit. The judge wrote that "market participants on many levels are injured from J&J's ability to sell Remicade without having to compete with [Pfizer's product] and other biosimilars" and that "J&J's efforts ... have led to increased prices for prices and limited competitive options for end payers, providers, and patients."²¹⁸ In 2019, the FTC issued a civil investigative demand—a kind of subpoena—as part of an investigation into whether Johnson & Johnson's exclusionary deals for Remicade had violated antitrust law.²¹⁹

As the FTC move indicates, these business practices raise several problems. In the simplest terms, exclusive dealing and bundled discounts seem to be a clear antitrust violation. To be sure, sellers generally are entirely within their rights to contract with buyers in a way that gives the seller a competitive advantage over its rivals. Exclusive dealing is not, a priori, illegal or an antitrust violation.

But these cases are not a random seller trying to compete in a free market, creating deal structures that confer competitive advantage. These are dominant—and sometimes monopoly—market actors devising deals to keep potential competitors out of the market. These deals are identical to decades of precedents of antitrust violation, such as creating barriers to market entry and harm to consumers.

These deals deny U.S. patients potentially more effective or cheaper products, solely because of anticompetitive business practices. Allowing these generic drugs to compete should lower prices and give consumers more choices, as well as full access to products best suited to treat the unique traits of their conditions.

These three cases, all quite recent, raise the question whether this business practice might be emerging as a major strategy to stifle competition. Now that other anticompetitive practices, such as REMS manipulation and pay-for-delay deals, have come under close regulatory and legal scrutiny, these three cases could reveal a new, large-scale trend in anticompetitive strategy. If courts allow these anticompetitive deals to stand, those decisions could unleash a flood of new deals to entrench monopolies, kill off competition, and keep prices high.

Worse yet, we have no idea how common these deals are. Abuses of the REMS program or the patent system are easier to uncover, because these anticompetitive practices leave a record of public information through the FDA. But exclusive dealing and bundled discounts are business agreements among market actors and not part of the public record.

The private nature of these deals also underlines the thoroughly opaque process of setting drug prices. This utter lack of transparency means that many more similar deals might exist, which could explain the persistence of monopolies for many drugs whose patents have expired.

It is profoundly disturbing that the government, through Medicaid and Medicare Part D, is participating in anticompetitive contracts. Of course, the government should strive to secure the lowest possible prices for the goods and services that it purchases—but prescription drugs are a different type of good.

Medicare Part D patients might be using a worse product for their condition because of the deal with Allergan. Medicare Part D shut out Shire's dry-eye disease generic drug, even though Shire has test results

showing that its drug might be more efficacious for some patients than Allergan's medication. In addition, Medicaid and Medicare Part D might well have prevented the prices of these drugs from dropping to even lower levels than they paid, had the government agencies not helped to choke off competition through these deals. Simply put, the government should not chase lower prices for itself by perpetuating monopoly markets.

Finally, these deals provide yet more evidence that pharmaceutical firms pursue anticompetitive practices as a primary business strategy, instead of pursuing innovation, free-market competition, and greater public health.

V. Solutions

Exorbitant drug prices are the result of multiple causes: industry consolidation, patent thickets, gaming of the regulatory system, and an array of anticompetitive business practices. To reduce drug prices and reinvigorate competition, we need a coherent, comprehensive set of reforms that addresses all these problems.

The reforms in this part are a cohesive, inseparable whole. If we adopt only a few measures, then drugmakers will simply continue exploiting the remaining loopholes, and prices are unlikely to come down significantly.

The overarching goal is to create as much competition as possible in drug markets, because competition brings lower prices and more innovation. A patent inescapably confers a monopoly, so we must also cut off opportunities for abusing monopolies. We want to encourage innovation in public health and deter over-investment in me-too drugs. We want to end drug shortages and ensure that all drugs are safe. We want to establish new mechanisms for setting drug prices, so that the primary financial incentive for pharmaceutical firms will be to create innovative and needed drugs that substantially improve public health.

ATTACK CORPORATE CONSOLIDATION

ANTITRUST

The Department of Justice and the FTC should closely scrutinize mergers and acquisitions in the pharmaceutical industry, because consolidation

harms drug innovation.²²⁰ Consolidation also frequently leads to higher drug prices, especially consolidation among generic drugmakers.²²¹ In many instances, the FTC does not need any new statutory authority to embark on much more aggressive prosecutions of antitrust cases.²²²

REDUCE BARRIERS TO ENTRY

PATENT REFORMS

Reforming the patent system is a crucial step toward reducing drug prices. As long as the patent system is vulnerable to abuse, drugmakers will enjoy unchallenged monopolies on crucial medicines, and they can exploit their market power to stifle competition and inflate prices.

Simply put, a patent creates a monopoly—an exclusive right, for a fixed period of time, to benefit from an invention or innovation. Certainly, the business of researching and developing drugs is risky, so the patent system grants substantial financial rewards as an incentive to improve public health.

But the scope of these incentives should always be weighed against their potential to stymie competition and harm consumers—and, in the case of drug patents, to negatively affect public health. Today, the regulatory environment offers easily exploited opportunities to twist patents into entrenched monopolies, exorbitant prices, and unmet health needs.

Substantial patent reform requires a substantial overhaul of trade policies. The United States—and all other World Trade Organization member nations—are bound by international agreements to protect patents. Thus, renegotiating or abrogating these agreements, which may produce other benefits, would be a necessary and challenging requirement for any proposal to eliminate patents or substantially trim their length.

LIMIT APPLICATIONS FOR PATENTS

AND EXCLUSIVITIES

A smart reform of the patent system is called “one-and-done.” To implement this reform, the administration would enact an FDA rule limiting every new drug to a one-time grant of one type of monopoly protection, whether patent or market exclusivity. When the FDA approves a drug, the manufacturer would choose a patent or one type of exclusivity,

whichever form of property rights the company views as its best chance to recoup its investment in the drug. The drug cannot receive any other patent or exclusivity.

This reform would eliminate the problem of evergreening, when drugmakers marginally tweak the dosage schedule or use code for a drug, in order to claim new patent protection as the original patent nears expiration. This reform would also end the practice of salami-slicing, through which drugmakers find small patient populations that could be treated by a drug under patent and then apply for an extended market exclusivity—or multiple exclusivities—based on the orphan drug exclusivity.²²³

Congress should pass legislation enshrining this system into law.

MARCH-IN-RIGHTS AND SECTION 1498

Even under a one-and-done patent system, monopolies would remain, but the government has two under-utilized and under-publicized tools to lower drug prices and combat the abuse of patent monopolies.

The first of these tools are march-in rights.²²⁴ Under march-in rights, the government has the authority to require a drugmaker to license its patented intellectual property to third parties, if the patent research involved federal funding and if the patent holder has not “reasonably satisfied” health or safety needs.²²⁵

The 2017-18 Congress asked the NIH to use march-in rights to lower the price of an expensive prostate-cancer drug, but the NIH refused to intervene or hold hearings on the use of march-in rights.²²⁶ A group of 50 members of the House of Representatives asked the Trump administration to direct the NIH to use its march-in rights, but the administration has not done so.

The administration should direct the NIH to use its march-in rights for a brand drug under patent that charges extremely high prices, to prompt the inevitable legal test of whether a drugmaker charging extortionate monopoly rents has “reasonably satisfied” health needs.

If the government wins in court, drug prices would likely fall significantly, because drugmakers would face government-sanctioned competition for

any patented drug whose high price tag put it out reach for many needy patients. If the administration merely considered using march-in rights, this would likely push drugmakers to negotiate more urgently on ways to rein in drug prices, because a loss in court would likely mean the definitive end of excessive drugs prices.

Quite similarly to march-in rights, Section 1498 of Title 28 of the U.S. Code entitles the government to use patents without the permission of the patent holder, as long as the government provides reasonable compensation. Congress amended this law in 1942 with the expressed goal of fighting high prices.²²⁷ Importantly, patent holders cannot seek injunctions to stop the process—they can only sue for damages, if they feel the government did not provide reasonable compensation.

Using Section 1498, the administration could either manufacture its own generic versions of high-priced drugs, or, more likely, it could license production to generic drugmakers. The government routinely used Section 1498 in the 1950s and 1960s to save tens of millions of dollars on vital medications.²²⁸

The Louisiana state secretary of health and the Baltimore health commissioner have asked the government to consider using Section 1498.²²⁹ This administration or a future one should use march-in rights and Section 1498, to set a legal precedent of forceful government action to bring down drug prices and to fight for the rights of American patients.

SPEED UP APPROVALS OF GENERICS

Once patents expire, the introduction of two competing generic drugs causes the prices of brand drugs to fall by at least 50 percent, on average. So it is clearly in the best interest of consumers to bring multiple generic drugs to market as quickly as possible. Even if legislators and regulators take all measures described here to stop drugmakers' game-playing with the system of patents and exclusivities, generic competitors will still need FDA approval.

The FDA has long suffered from a significant backlog of generic drug applications. There were some 3,000 applications awaiting review in October 2012.²³⁰ To its credit, Congress reacted to this backlog by passing the Generic Drug User Fee Amendments (GDUFA) in 2012 and by passing GDUFA II in 2017. The GDUFA mandated the FDA by 2017 to review 90 percent of the pre-GDUFA backlog and to review 90 percent of new applications within 10 months.

The FDA met these targets, but the fundamental problem largely persists. The FDA reviews 90 percent of initial applications within 10 months, but drugmakers must go through multiple rounds of applications and reviews before FDA approval. In 2017, the median length of time from application to approval was a little more than 37 months, which is markedly worse than the 2010 median time of slightly less than 29 months and the 2012 median of less than 32 months.²³¹

The FDA needs to shorten the time from application to approval.

There are three areas that the FDA needs to reform. First, the FDA needs to shorten the time from application to approval, not just the review of the initial application. The next GDUFA should reframe its goal from accelerating review time to decreasing the time between application and approval. Today, the FDA can conduct multiple review of a generic drug application without approving the drug—in fact, the FDA conducts a median of 3.8 reviews of a generic drug application before final approval.

²³²

The FDA needs to focus on approving generic drugs that would be the first and second generic competitors for brand-name drugs.

Second, the FDA needs to focus on approving generic drugs that would be the first and second generic competitors for brand-name drugs. A Pew analysis found that more than 90 percent of the increase in FDA approvals from 2012 to 2017 were approvals of generic drugs for which at least three competing generic drugs already existed.²³³ In other words, the FDA was simply approving generic drugs that were likely nearly identical to at least three other generic drugs that the agency had previously approved.

The problem here is not the speed of the approval process—the problem is that adding a fourth, fifth, or sixth generic competitor does not bring about a large reduction in drug pricing, on average. Drug prices decline most substantially when the first and second generic competitors enter the market, so the FDA should accelerate the approval process for these applications ahead of all others.

The FDA needs to dedicate more staff to the approval process.

Third, the FDA needs to dedicate more staff to the approval process and to monitoring the industry, because the number of applications soared far beyond what the FDA anticipated in the GDUFA. The FDA expected 750 applications per year, but generic drugmakers submitted more than 2,500 applications in 2013 and in 2014.²³⁴

GDUFA II partly addresses each of these shortcomings, but the FDA needs to provide more data more quickly on the new measures, and the FDA (with the help of Congress) should not wait five years to adjust its practices in subsequent GDUFA amendments. Congress should increase the FDA

budget to accelerate the approval process, and the FDA must also be large and capable enough to find and resolve the problems that delay the review process. The administration should include these spending increases in its proposed budget.

The situation with biosimilars is analogous to the dynamic with generic drugs. Biosimilars are generic versions of biologic drugs, which tend to be among the most expensive drugs on the market. Congress intended to spur competition by passing the Biologics Price Competition and Innovation Act (BPCIA) in 2009, but the law largely forced drugmakers into years of patent litigation so intricate that it is commonly known as the “patent dance.”²³⁵ Regardless of drugmakers’ legal entanglements, the FDA should also follow the reforms above to simplify and expedite the approval process for biosimilars.

CRACK DOWN ON ME-TOO DRUGS

To lower prices and to create incentives for competition, the administration should instruct the FDA to deter the production of me-too drugs and to promote drugs for markets lacking competition. In drug classes with multiple effective medications, the FDA should only approve drugs that demonstrate substantial improvements over existing treatments.

This would discourage drugmakers from investing in saturated markets, which are usually filled primarily because of their profitability. This would also encourage drug manufacturers to focus on developing clinically superior drugs. Congress should pass legislation to the same effect.

Today, regulators do not require comparative trials for me-too drugs applying to enter drug classes in which multiple effective products already exist.²³⁶ The FDA should require comparative trials before the approval of me-too drugs.

Similarly, the FDA should establish a measure of competitiveness within a given drug class or market. Once a market passes this threshold, then any new applicant would have to show clinical superiority to existing drugs in a comparative trial.²³⁷ Otherwise, the FDA would reject the application.²³⁸

To foster competition, the FDA should offer expedited approval for drugs that have shown clinical superiority in preliminary trials. This would offer an incentive to manufacturers to focus on therapeutic areas where treatment

The administration should instruct the FDA to deter the production of me-too drugs and to promote drugs for markets lacking competition.

options are limited or have serious side effects.²³⁹ The FDA should also offer expedited approval for potential competitors to generic drugs or off-patent brand drugs that have had substantial price increases.²⁴⁰

ALLOW DRUG IMPORTS IN SPECIFIC CASES

Congress is considering two bills that would allow more drug imports in order to reduce prices, increase competition, and prevent drug shortages. The Short on Competition Act, introduced in the Senate by a bipartisan group of four senators, would allow organizations to import drugs approved in certain foreign countries, if there were a shortage of the drug or if there were a “marginally competitive” market for a drug in the United States.²⁴¹ The bill defines a marginally competitive market as one where five or fewer drugs are commercially available.

Drugs usually sell for lower prices outside the United States, so this act could potentially help lower drug prices, even in markets in which generic drugmakers nominally compete. Congress should approve this act, and the administration should sign it into law.

The Safe and Affordable Drugs from Canada Act of 2019 would allow individuals to purchase drugs from a list of FDA-approved Canadian pharmacies.²⁴² The types of drugs that individuals could purchase, however, would not include biologics, injectables, or even drugs that require refrigeration at any point during manufacturing or processing.

Still, for the drugs that individuals could import, the bill would likely lower prices for consumers and introduce greater competition into many markets.

Even if the Short on Competition Act is not approved, the FDA has the authority today to import drugs in case of a shortage.²⁴³ To mitigate drug shortages, the administration should instruct the FDA to import drugs subject to shortage. Manufacturers have long been required to notify the FDA about potential upcoming shortages,²⁴⁴ so the FDA should improve its capability to acquire drugs from abroad, in order to preempt the possible shortage of critical drugs.

Congress should also increase the FDA budget for inspections of overseas production facilities, to more accurately reflect the predominance of overseas production facilities in the making of drugs consumed in the United States, as well as to take seriously the increased likelihood of safety

shortcomings at these manufacturing facilities. Congress should also mandate critical changes in the FDA inspection process, as described in the final section of this chapter.

PRIZES

Exorbitant prescription drug prices create incentives for drug manufacturers to pursue drugs that produce the highest profit margins and shareholder returns, instead of addressing the most acute and important public health needs. To encourage innovation in the interest of the public health, Congress should establish and provide funding for a system of cash prizes for drug innovations. Senate legislation from 2011 already proposed these prize systems, so Congress should use the language of these bills.²⁴⁵ The administration should include these prizes in its budget proposals to Congress.

To encourage innovation in the interest of the public health, Congress should establish and provide funding for a system of cash prizes for drug innovations.

The WHO,²⁴⁶ the European Commission,²⁴⁷ and Nobel laureate Joseph Stiglitz²⁴⁸ have all advocated for a prize system to combat the perverse incentives of the prescription drug market and the patent system. There are many suitable ways to structure a prize system, which is essentially another form of public funding for drug research.

For example, a buyout system would offer pharmaceutical companies a prize for developing a badly needed drug. The prize would require the drugmaker to produce enough of the drug for all patients who need it, at the marginal cost of production. Importantly, the prize money would also purchase the drug's patent, and the government would place the intellectual property in the public domain. The government should also hold a public tender, to encourage other drugmakers to bid the lowest possible price to produce the drug.

To lower buyout prices, a buyout system should proactively offer buyouts for drugs that have shown clear clinical superiority in early trials or for drugs that would bring competition to monopoly markets or markets deemed overpriced. An early buyout would offer a lower price, because the government would pay for the final stage of clinical trials, which are an expensive part of drug development.

A second prize system could be based on public health professionals' estimates of the value of a cure or treatment for specific diseases and conditions. Pharmaceutical firms—and other inventors—could win the prize either by creating a cure for the disease, by reducing the number of patients with the disease, or by improving quality of life for the affected

population. This prize system would shift incentives from profits to measurable improvements in public health.²⁴⁹

Of course, it would not be simple to calculate the amounts of the prizes, whether in estimating the potential profits of a drug or the value of lives saved or improved. Another potential negative impact is that the second system might slow the development of drugs for diseases or conditions affecting relatively smaller patient populations.

If Congress is able to pass a prize system, it should also allocate more public health funding for potential public-private consortia to conduct basic research on pressing public health needs. Patents would be public for any drug innovations produced by the consortia, which could lead to breakthrough drugs at the lowest possible prices.

MITIGATE MONOPOLY THROUGH PRICE REGULATION

While reforming patent monopolies is a key policy lever for solving the drug crisis, it is not a panacea. Some of the largest price increases in recent years have been for drugs with expired patents, such as Daraprim.²⁵⁰ Similarly, the use of antitrust action to break up the concentration of ownership among drugmakers will not always be sufficient to ensure well-functioning competitive markets for every drug, particularly those that target rare diseases for which aggregate demand is limited and only a single drugmaker enters the market. Moreover, there can never be a generic version of many biologic drugs, such as those involving gene therapy. In the end, as long as the patent system exists, monopoly markets appear to be inescapable for some length of time. This raises the question of whether and how price controls may be used in instances in which open, competitive markets are not possible and a high degree of monopolization is inevitable.

Other developed economies use various forms of price controls for prescription drugs, and these controls have achieved significant cost savings without an apparent loss to public health.²⁵¹ Some countries follow a single model of price regulation, and other countries employ multiple approaches to regulate prices.

Australia and the United Kingdom use forms of cost-based pricing, also known as cost-plus pricing, in which regulators add up production costs and tack on a profit margin. Another system, value-based pricing,

sets drug prices based on the value that regulators assign to the drugs, typically through quantifying health improvements. A third, internal reference pricing, sets prices based on comparable medicines in the same country, while external reference pricing (or international reference pricing) sets prices according to a benchmark of prices in other countries.

Twenty-nine European countries use forms of international reference pricing, and the Trump administration has proposed using international reference pricing for some Medicare drug purchases.²⁵² This approach is not flawless, but it has clearly led to reduced drug prices in other countries.

Value-based pricing involves balancing cost and effectiveness, with effectiveness usually measured in terms of the number of extra years of healthy life, or Quality Adjusted Life Years, that a particular drug may deliver. Currently, limited public research examines how some drugs compare with each other in clinical effectiveness, but neither the FDA nor any other part of the federal government makes any attempt to measure the cost-effectiveness of different drugs. Developing such information would not only be helpful in establishing administered prices for certain drugs, but it could also make open markets more efficient by improving the quality of information available to buyers and sellers.²⁵³

A bipartisan bill in the Senate takes still another approach by holding drug-price increases to inflation.²⁵⁴ Without a comprehensive system of price regulations, however, drugmakers would be likely to simply introduce drugs at extremely high initial prices, in order to game the effects of moderate annual increases.²⁵⁵

NEGOTIATED PRICES FOR MEDICARE

Another policy option is for the Department of Health and Human Services to negotiate drug prices with manufacturers on behalf of Medicare Part D beneficiaries. This measure has also been proposed in the Medicare Prescription Drug Price Negotiation Act of 2019, a bill in the House.²⁵⁶

To get Congress to pass the Affordable Care Act, the Obama administration agreed that Medicare would not negotiate the price of drugs,²⁵⁷ unlike Medicaid and the Veterans Health Administration. By 2015, Medicare Part D was paying an average of 73 percent more for brand name drugs than Medicaid paid and 80 percent more than the VA paid.²⁵⁸

The 2019 bill instructs HHS to prioritize negotiations for drugs with the highest prices and the least competition.²⁵⁹ HHS would renegotiate drug prices every three years, and the bill also includes other instruments designed to promote competition. If the department can't come to an agreement with drug manufacturers on price, then prices would be set based on a calculation of what other government agencies pay and what five other countries (Canada, the United Kingdom, Germany, France, and Japan) pay. The administration's instructions to HHS should follow the provisions of the bill.

The approach has merit, but if enacted in isolation it would leave prescription drug consumers exposed to monopoly prices if the consumers were not covered by Medicare. Moreover, HHS's ability to negotiate lower prices for specific drugs is limited, if it is dealing with drug companies that have monopoly power over the production of those specific drugs. In the absence of smart competition policy, HHS's bargaining position would be largely equivalent to that of the Pentagon in negotiations with sole-source contractors for weapons systems.

DIRECT MANUFACTURING

Consolidation has helped create monopoly markets for many generic drugs, which have seen extreme price increases in recent years. Consolidation has also indirectly led to shortages of older yet important generic drugs, because generic drugmakers can choose to focus production on more lucrative markets.²⁶⁰

Direct manufacturing of generic drugs by governments, nonprofit organizations, or public-private consortia is a potential policy response to this problem. During World War II, the U.S. government actively coordinated and directed the mass production of penicillin.²⁶¹ Today, a group of hospital systems has joined together to produce their own generic drugs. Known as Civica Rx, the coalition includes seven organizations—Catholic Health Initiatives, HCA Healthcare, Intermountain Healthcare, Mayo Clinic, Providence St. Joseph Health, SSM Health, and Trinity Health—that represent about 500 U.S. hospitals, and three philanthropic organizations.²⁶²

Vertical integration of drug manufacturing with monopolistic hospital chains and health care provider platforms could have anticompetitive effects in the absence of smart regulation and antitrust enforcement. But when properly managed, direct manufacturing of generic drugs by state

or local governments, or by public-private partnerships, could introduce new competition into markets that would otherwise remain monopolies.

TRANSPARENCY

The administration should mandate that the FDA increase the transparency of information about patents, and Congress should increase the FDA budget to hire staff for these record-keeping purposes.

The administration should mandate that the FDA increase the transparency of information about patents, and Congress should increase the FDA budget to hire staff for these record-keeping purposes. The FDA annually publishes the Orange Book,²⁶³ which includes a complete list of all FDA-approved drugs, as well as the attendant patents and exclusivities, but there is no readily available archive of past editions.

Today, when drugmakers claim new patents that extend an existing patent monopoly, the Orange Book only includes the new patent claim, but it does not indicate which component of a previous listing qualifies as new and merits monopoly protection. This makes it nearly impossible to contest potentially spurious patent claims.

In addition, there is no resource today to locate the filing date for an abbreviated new drug application (ANDA), the application for generic drug approval.

The FDA publishes the Purple Book for biologics and biosimilars, but this book does not include a section on patents and exclusivities.²⁶⁴ The absence of all the above data makes it easier for drugmakers to game the patent system, while also making it vastly more difficult for regulators and the public to police manipulation of the system.

In the simplest terms, the FDA should maximize the amount of information provided in these publications on the bases, dates, and lengths of patents; it should update these publications monthly; and it should make all this information available online to the public, including an archive of previous annual versions. Creating a one-and-done patent system would make most of these changes obsolete, but the administration should enact these simple transparency measures immediately. That would at least enable some meaningful progress against abuse of the patent system, until the entire patent system is overhauled.

CRACK DOWN ON ANTICOMPETITIVE PRACTICES

REMS REFORMS

The REMS program has a solid rationale: The FDA should have a stringent program to ensure the safe usage of prescription drugs. The problem is that pharmaceutical corporations are gaming safety regulations to avoid competition, by denying brand-drug samples to potential generic competitors. The solution to the problem, then, is not to change the safety measures of the REMS system, but instead to enable generic drugmakers to get samples quickly so they can produce competing generics rapidly and create competitive markets.

There are two bills in Congress intended to accomplish these goals, the CREATES Act of 2019²⁶⁵ and the FAST Generics Act of 2019.²⁶⁶ The CREATES Act has deeper bipartisan support,²⁶⁷ and it has already been reported out of committee in the House and is ready for a full House vote.²⁶⁸ The CREATES Act mandates that brand manufacturers provide generic drugmakers with samples upon request, whether the brand drug is in the REMS system or not.²⁶⁹ If the brand drug is in the REMS system, then the generic drugmaker can quickly obtain a letter from the FDA stating that acquiring samples of the drug does not contravene the drug's REMS program.²⁷⁰

A key to the bill is its enforcement mechanism: Generic drugmakers can immediately turn to the courts for monetary compensation from brand manufacturers, if the brand manufacturers do not provide drug samples within 30 days of receiving either the generic drugmaker's request or the FDA's letter.²⁷¹ The courts can order brand manufacturers to provide the necessary samples and can award generic drugmakers damages from brand manufacturers up to the revenue that the brand manufacturer earned on the drug in question during the time that the brand manufacturer did not provide the samples.²⁷²

By helping bring generic drugs more quickly to the market, the enforcement provision should spur competition and bring down prices. The Congressional Budget Office estimated that these lower prices would cut federal spending by \$3.3 billion from 2019 to 2028 and would increase government revenues by \$600 million during the same period.²⁷³

Big Pharma's primary lobby, Pharmaceutical Research and Manufacturers

The administration could also direct the FTC to begin antitrust proceedings against any brand manufacturer that does not provide the samples according to the rules.

of America (PhRMA), opposes the CREATES Act and offers a raft of spurious arguments about unintended consequences of the bill.²⁷⁴ PhRMA worries about a possible flood of frivolous lawsuits or about scary drug shortages, but these prognostications are baseless. If brand manufacturers are willing to provide sufficient samples to generic drugmakers and to produce as many drugs as the market demands, the CREATES Act won't lead to lawsuits or shortages. The act does not guarantee lower drug prices, nor does it even guarantee that generic drugmakers will produce or sell generic alternatives, but it should stamp out this illegal business strategy to stymie competition.

If Congress does not approve the bill, the administration can take the same steps. The administration can make rules for the REMS program based on the text of the CREATES Act. The administration could also direct the FTC to begin antitrust proceedings against any brand manufacturer that does not provide the samples according to the rules.

PAY-FOR-DELAY REFORMS

Pay-for-delay deals should be eliminated. These anticompetitive agreements involve only a relatively small percentage of U.S. spending on prescription drugs, but they perpetuate exorbitant monopoly prices and cost consumers billions of dollars in unnecessary spending each year.

Pay-for-delay deals entrench patent monopolies, no matter how specious the patent claims might be. These deals delay the market entry of cheaper generic drugs, which could save patients and insurers billions of dollars. These deals also violate antitrust law, as brand and generic drug manufacturers collude to foster an anticompetitive market to guarantee drugmakers monopoly rents extracted from U.S. consumers.

One remedy may be the Preserve Access to Affordable Generics and Biosimilars Act, introduced by Democratic Senator Amy Klobuchar and co-sponsored by Republican Senator Chuck Grassley.²⁷⁵ The act would prohibit any patent-infringement settlement that provides anything of value to a generic drugmaker in exchange for delaying the entry of the generic drug market.²⁷⁶ Importantly, the act also covers biologic drugs and biosimilars.

The act allows settlements only if the drug manufacturers can demonstrate that the procompetitive benefits of the deal outweigh its anticompetitive effects, or if the compensation is for other goods or services that the

One remedy may be the Preserve Access to Affordable Generics and Biosimilars Act

generic drugmaker has agreed to provide.²⁷⁷ We should support any contract among drug manufacturers that promotes competition, but these loopholes will likely lead to an abundance of FTC lawsuits against various pharmaceutical corporations claiming procompetitive effects for their settlements.

Still, Congress should pass the act, and the administration should sign it into law. Congress should also raise the FTC budget specifically to increase the commission's capacity to examine and challenge anticompetitive behavior by drug manufacturers.

A largely identical bill was signed into law in October in California.²⁷⁸ The bill had been approved in April 2019 with bipartisan support in the legislature's Judiciary Committee.²⁷⁹ State-level bills represent a potentially effective measure to stamp out pay-for-delay deals, for at least two reasons.

First, Congress might very well not pass its bill. Second, if several states were to pass these bills, this could lessen the burden on the FTC of examining and pursuing legal action on the more than 200 patent-infringement settlements filed each year, a number that does not include deals involving biologic drugs and biosimilars.

The leadership of the Association for Accessible Medicines, a major lobby for the generics industry, opposes these bills.²⁸⁰ They say that some of these settlements bring generic drugs to market earlier than if generic drugmakers were simply to wait for the expiration of all relevant patents. But this argument doesn't make sense, because these bills clearly welcome any procompetitive settlement.

To take a broader view, the foundation of all pay-for-delay deals and patent-litigation settlements is a legal conflict over the validity of brand-drug patents. A simple solution would be to amend patent law, as previously discussed, so that there is no legal question about when generic drugs can enter the market to compete with brand-name drugs. There should not be any confusion about when the FDA can approve generic competitors to a brand drug, nor when the drug can enter the market.

Most patent-litigation settlements involve contortions with the 180-day period of exclusivity for the generic drug that is first to file for FDA approval. We question the basic premise of the exclusivity. The Hatch-Waxman Act created this limited monopoly for generic drugs in order to

spur generic drugmakers to compete with brand manufacturers.²⁸¹ But generic drugs dominate prescriptions in the United States today, so the premise of the monopoly is no longer valid.

Generic drugmakers are ready to compete for lucrative markets without government assistance. Today, this 180-day period of exclusivity is just another form of monopoly that prevents competition, encourages game-playing, and keeps prices unreasonably high. It is worth considering whether to eliminate or shorten the 180-day period, since this would substantially reduce the number of patent-litigation settlements.

In the area of pay-for-delay settlements, the patent-reform measures elucidated above would carry an additional benefit. By drawing bright lines for when competition may commence in drug markets, these reforms should also largely eliminate the publicly funded burden of FTC legal challenges to patent-infringement settlements. Each FTC lawsuit costs millions of dollars and exhausts the resources of the courts, as well.

Any attempt to combat pay-for-delay and other types of patent-infringement settlements should be based on a clear delineation of when and under what conditions brand drugs are subject to competition, in order to reduce as much as possible the potential for lawsuits—and game-playing—among pharmaceutical firms.

PETITION REFORMS

The FDA should increase the transparency of 505(q) petitions. In its annual report to Congress, the FDA should provide more information about every 505(q) petition filed that year, specifically any information relevant to any possible delays in competition. The FDA should publish the timing of the petition in relation to the expiration of the patents of the brand drug that would face competition, as well as any delay in generic approval caused by the petition.²⁸²

The administration should instruct the FTC to investigate these practices and levy fines, in order to punish and dissuade brand drug manufacturers from filing sham petitions.

Filing sham petitions and gaming the filing date of petitions are anticompetitive behavior, and the FTC should investigate and sue drugmakers who file sham petitions. The administration should use its rule-making authority to make clear that sham petitions constitute illegal anticompetitive behavior. The administration should instruct the FTC to investigate these practices and to levy fines, in order to punish and dissuade brand drug manufacturers from filing sham petitions.

One simple, bright-line reform would be for the FDA to require that all

petitions regarding a generic drug be submitted within one year after the generic manufacturer submits its application for approval. This application contains all necessary safety information that any entity—whether brand manufacturer, watchdog group, or concerned citizen—would need to alert the FDA to possible safety hazards.²⁸³ Of course, the FDA must always be open to learning of important drug-safety concerns, but the handling of such information after this deadline should not be tied to the timing of application approval, in order to ensure the earliest possible entry of competition to the marketplace.

DISTRIBUTION REFORMS

The administration should write an administrative rule to give the FTC clear guidance on when the terms of a purchase agreement constitute an antitrust violation. The rule should state that it is an antitrust violation when a market actor with monopoly or near-monopoly power for a product concludes distribution agreements that create barriers to entry for a potential competitor in exchange for a favorable selling price for the monopoly product, whether through rebates on the monopoly product or a bundle of discounts that include a discount on the monopoly product.

The administration should enact a rule that any government-run health care provider, such as Medicaid, Medicare Part D, or the Veterans Administration, is prohibited from entering into a distribution agreement as described above.

The FTC should aggressively investigate every instance of exclusive dealing or bundled discounts that shield a monopoly market from competition. The administration should use its rule-making authority to make clear that drugmakers are engaging in illegal anticompetitive behavior if they use exclusive dealing and bundled discounts to protect monopoly markets. The administration should instruct the FTC to investigate and to sue drugmakers who conclude or offer these kinds of deals, to recoup the damages or potential damages done to competitors and consumers.

SAFETY REGULATION

To increase the safety of imported drugs, the FDA should improve its inspection process overseas. It would be best if the FDA markedly increased the number of inspections in drug production facilities abroad, but budget increases are not the only way to solve the problem.

The FTC should aggressively investigate every instance of exclusive dealing or bundled discounts that shield a monopoly market from competition.

To increase the safety of imported drugs, the FDA should improve its inspection process overseas.

FDA inspectors should not give advance notice for their inspections.²⁸⁴ Unfortunately, the FDA has long given the management of overseas production facilities the ability to control the visits of FDA investigators. The FDA sometimes gives as much as two months' advance notice before an inspection.²⁸⁵

The FDA should conduct only unannounced inspections, and it should seize the metadata in the facilities' computer systems, to investigate all records of drug testing—even deleted records—in the facilities. Overseas production facilities regularly hide failed tests by deleting the records of these tests.²⁸⁶

Author Bio

Michael Bluhm, Ph.D., is managing editor of Open Markets Institute. He is a journalist, editor, and academic. He covered business for The Daily Star in Beirut, where he also worked as political analyst and editorial writer. Since the 1990s, he has been teaching university students about the perils of industry concentration and monopoly. His doctoral research focused on the use of communication technologies in social movements.

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