

Lowering Drug Prices

A Blueprint for Reform

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Executive Summary

The steep price of many lifesaving prescription drugs in America poses a financial and health risk to average Americans, yet U.S. policy is rigged to work for pharmaceutical companies rather than the public. Federal law confers monopoly status to drug manufacturers, who have insulated themselves from competition and inflated their prices, reaping huge profits. There are many proposals in Congress to address high drug prices, but partisanship and policymakers' deep ties to the pharmaceutical industry stand as barriers to congressional action. There are several things a presidential administration could do to help ensure affordable prescription drugs and encourage innovation in drug research without waiting for Congress. This paper offers options for executive actions to bring down the cost of drugs while promoting innovation. Its recommendations include:

- Leveraging federal investments in research to incentivize reasonable pricing.
- Using the government's patent approval authority more responsibly, including implementing the government's longstanding patent use authorities and march-in rights to procure drugs at a fair price.
- Using the Federal Trade Commission's full range of powers and remedies to ensure competition.
- Ending the pharmaceutical lobby's stranglehold on prescription drug policy by instating new ethics rules.

Introduction

A majority of American families list the price of prescription drugs as a top concern in their daily lives, and it's easy to understand why. American spending on retail drugs alone hit \$328 billion in 2016.ⁱ Sky-high drug prices threaten both our finances and our health: One in five Americans who have health insurance report not filling a prescription because of cost.ⁱⁱ And Americans aren't just skipping out on treating minor ailments: A 2013 study showed that one quarter of cancer patients chose not to fill a prescription because of cost.ⁱⁱⁱ

Pricing average Americans out of life-saving treatments is unconscionable no matter what the cause, but it is particularly cruel given that hikes in prescription drug prices are often a result of greed and monopoly power, not supply scarcity or the cost of research and development. Companies are selling the very same drugs in other countries at much lower prices. On average, customers in Canada, France, and Germany pay 10-15 percent less for drugs than customers in the United States.^{iv} On top-selling drugs like Humira or Advair, customers in the U.S. pay upwards of 50 percent more than customers in those countries.^v

Here are some recent examples of how this plays out:

- Mylan, the maker of the emergency allergy treatment EpiPen, raised the cost of a two-pack of EpiPens from \$100 to \$600 over a decade—an increase of 500 percent.^{vi}
- Sovaldi, a drug used to treat hepatitis C, debuted on the market at \$1,000 per pill; a standard course of treatment costs a total of \$84,000. Sovaldi's developer had expected to sell the drug for less than half that price, but when Gilead Sciences acquired the product, it inflated the price.^{vii}
- Gilead also makes Truvada, a drug patented by the United States government as a treatment to prevent H.I.V. infection. Though a one-month supply costs about \$6 in other countries, Gilead charges \$1,600 in the United States.^{viii}

Generic drugs are often cited as a solution to high prices, but even generics are susceptible to price manipulation. In a now-infamous case, Martin Shkreli's Turing Pharmaceuticals hiked the price of the generic antiparasitic treatment Daraprim by

¹ "Retail" drugs are those available by prescription. "Non-retail" drugs include those administered by a hospital, doctor's office, nursing home, or other inpatient or outpatient health care provider.

more than 5,000 percent, from \$13.50 to \$750 per pill.^{ix} The price of 500 tablets of the antibiotic doxycycline, often used to treat Lyme disease, rose from \$20 to \$1,849 between 2013 and 2014.^x

Drug companies often argue that high prices are necessary to fuel investments in innovation. But the Daraprim example illustrates the flaws in this argument: Drug companies have raised prices on treatments that were developed long ago. Price hikes are driven by drug companies' power in the market, not their investments in innovation. And their ability to exert this kind of power is directly related to the web of public policy that shapes their behavior.

The rules that shape our economy incentivize corporations, including drug companies, to prioritize shareholder value and the enrichment of corporate officers.^{xi} Furthermore, pharmaceutical companies have shaped U.S. research, patent, and drug approval policies to their advantage. U.S. policies allow companies to rely on federal government investment to fund basic research and secure extended market exclusivity rights to ward off competitors, while limiting the government's ability to use its power to ensure wide availability of life-saving drugs.

The result is an industry that produces huge profits for stakeholders while endangering average Americans' health. In 2015, the 10 highest-paid chief executives in the pharmaceutical industry collectively made \$327 million.^{xii} The biggest pharmaceutical companies spend more on marketing than they do on research. Pharmaceutical giants like Gilead spend more on stock buybacks than on R&D.^{xiii} And while patients are forced to go without much-needed antibiotics and other treatments, companies focus on incremental tweaks to existing drugs rather than investing in new life-saving products.^{xiv}

Despite the government's role in creating and sustaining our country's drug pricing woes, the federal government has done little thus far to address this crisis. Drastic drug price increases often become high-profile scandals that result in public outcry, a flurry of congressional hearings and impassioned speeches, and vows to change the industry. But once the grandstanding and hand-wringing subsides, pharmaceutical companies continue with business as usual. Daraprim still costs \$750 per pill, and Mylan still charges \$600 for EpiPens. There have been some promising proposals in Congress, but the pharmaceutical lobby's widespread influence in Washington makes it difficult for such plans to gain traction.^{xv}

Though congressional action would be ideal, there are several things the executive branch could do to fix the broken incentives governing drug development and pricing. This paper identifies potential administrative actions that federal agencies can take to ensure affordable access to prescription drugs, including:

- Leveraging federal investments in research to incentivize reasonable pricing.
- Using the government's patent approval authority more responsibly, including implementing the government's longstanding patent use authorities and march-in rights to procure drugs at a fair price.
- Using the FTC's full range of powers and remedies to ensure competition.
- Ending the pharmaceutical lobby's stranglehold on prescription drug policy by instating new ethics rules.

Background: The Government Works for Pharma, Not the Public

Prescription drug policy should revolve around what will meet the health and safety needs of all Americans. But there are two factors that have steered American pharmaceutical policy astray. First, the political influence exerted by the prescription drug industry tilts policymaking at both the congressional and agency level in favor of companies' interests. Second, in part due to industry influence, the United States' approach to prescription drug availability has been narrowed to incentivizing industry investment by funding research and offering time-limited monopolies through patents and market exclusivities. As such, the government's other tools for ensuring fair drug pricing, including negotiating prices on behalf of participants in federal health insurance programs, prohibiting unfair competition, and public manufacturing of essential drugs, lay dormant. This section provides a brief background on the extent to which public policy has been skewed to protect the interests of the prescription drug industry at the expense of the American public.

STACKING THE DECK

The pharmaceutical lobby is among the strongest interest groups in Washington, D.C. In 2017, members of Congress were outnumbered by pharmaceutical lobbyists by nearly three to one. In that same year, the industry spent more than \$280 million on lobbying.^{xvi} Pharmaceutical companies use this political power to block unfavorable legislation and to secure advantages at the legislative and executive level.

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Government agencies, including the Food and Drug Administration (FDA) and the Department of Health and Human Services (HHS), have broad authorities that help shape the prescription drug market—from patent enforcement to drug approvals and federal health insurance drug coverage. But too many of the officials who make these decisions have deep ties to the pharmaceutical industry. For example, HHS Secretary

Alex Azar was previously an executive at Eli Lilly and Company, one of the largest pharmaceutical companies in the world. Though President Donald Trump stated that Azar would be a “star” on lower drug prices, Azar’s proposals so far mirror drug manufacturers’ wish lists, targeting middlemen instead of focusing on the drug makers who have primary control over price.

The revolving door between government and the drug industry goes much deeper than Secretary Azar. A recent study showed that more than half of the officials charged with regulating one particular class of drugs at the FDA over a nine-year period took jobs in the pharmaceutical industry upon leaving government service.^{xvii} Potential future employment gives FDA employees a strong incentive to retain good relationships with the drug companies they are supposed to regulate, and this creates a conflict with addressing the public’s needs.

Agency employees are not the only ones entangled with the drug industry. In addition to taking campaign contributions from the pharmaceutical industry, members of Congress can have a direct financial interest in the growth of particular drug companies. For example, Rep. Chris Collins (R-NY) was one of the largest shareholders of Innate Immunotherapeutics and had served on the company’s board. For years, he used his position as a member of Congress to push for the company’s interests, advocating for legislation that would have improved Innate’s position in the market. In 2018, he was indicted for insider trading related to nonpublic information he allegedly shared about the company’s drug trial results.

RIGGING THE RULES

Pharmaceutical companies have leveraged these conflicts of interest and lobbying efforts to rig government program rules in their favor, narrowing the government’s role in drug pricing to protecting market exclusivities.

No-Strings Government Protection.

Medicare payments might seem like the government’s biggest contribution to pharmaceutical profits, but drug companies actually profit far more from government intellectual-property protections than from taxpayer subsidies. Through its patent and exclusivity laws, the federal government allows drug companies to build time-limited monopolies, prohibiting competition from other manufacturers.

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In theory, exclusive rights to sell products spur innovation, giving drug developers an incentive to discover new medicines and technologies and giving investors a reason to fund these discoveries. In reality, patent law and the exclusivities offered by the FDA often act to inhibit innovation and confound public health goals. As discussed further below, drug companies often focus on patenting small tweaks to existing treatments in order to extend their market advantage rather than investing in new treatments. Further, patent protections inhibit the market's ability to respond to conditions like excessive price increases, drug shortages, or immediate needs for expanded production (like an outbreak of a particular disease). Finally, drug makers have pushed for protections beyond patent law in the name of innovation, resulting in FDA-conferred market exclusivities that can extend a company's monopoly power far beyond the standard patent term.

Fortunately, patent laws include a safety valve: The federal government can manufacture any patented product, or assign a license to another company to produce it, as long as the government offers reasonable compensation to the patent holder.^{xviii} This long-standing "government use" right is routinely invoked by various government agencies on patents including electronic passports, genetically mutated mice, fraud-detection software, and hazardous-waste cleanup methods.^{xix}² In the 1960s and 1970s, it was invoked for the purchase of pharmaceutical products by both the Department of Defense and the Department of Veterans Affairs at a lower price than the patent holder offered.^{xx} Yet, despite drastic price increases, alarming drug shortages, and clear administrative guidance that the government can use its patent infringement power to address excessive prices, the government has not risked the wrath of drug manufacturers by using this authority in almost 20 years.

² 28 U.S.C. § 1498 was codified in 1948, but it built on decades of legislative and case history defining the recourse available to patent holders in the case of patent infringement by the government or its assignees.

Legally Sanctioned Patent Bullying and Delay Tactics.

When patent law and FDA exclusivity rights expire, competition in the market should drive lower drug prices. But pharmaceutical companies have developed a playbook of anticompetitive tactics that undermine Congress's intent by ensuring that no one will infringe on companies' ability to gouge consumers and reap huge profits.

Patent evergreening. Companies that wish to exclude others from manufacturing their drug can manipulate the patent system to prevent competition. Through patent "evergreening," also referred to as "product hopping," pharmaceutical companies patent slight variations on their drugs just before the patent on the original drug expires. Often, these modifications have no therapeutic value; for example, variations may involve a change to a drug's formula that makes it slightly easier for the body to absorb a medicine. Though competitors are free to manufacture a generic version of the original drug, pharmaceutical companies vigorously market the health benefits of the newly tweaked drug, making it harder for the generic version to gain traction.

Patent thicketing. Another abuse of the patent systems is "patent thicketing." Although some drugs are relatively straightforward to make, others—particularly biologic medicines (those made from living organisms and complex combinations of molecules)—require a number of specific processes to manufacture. To keep others out of the market, companies patent all of the individual processes related to the manufacture of a drug, creating a "thicket" of patents that keep competitors out. A prime example is the world's number-one selling drug, Humira, with \$18 billion in global sales in 2017. It is used to treat many inflammatory conditions, such as arthritis, psoriasis, and Crohn's disease. It is also one of the worst patent offenders, with 247 patent applications for the drug that, in effect, will delay competition for 39 years.^{xxi}

Limiting access to samples. If a company wishes to manufacture a generic version of a drug, it must first obtain a large quantity of samples of the patented product in order to conduct the tests required to prove a generic's equivalence. Companies that are trying to fend off competition consequently have an enormous advantage: To crush competitors, they can simply restrict access to the drug. Some companies use agreements with distributors to restrict access; others manipulate government protections to avoid giving samples. The FDA's Risk Evaluation and Management Strategies (REMS) program requires makers of certain drugs with risks of severe health effects to develop safety plans for their distribution. While the REMS program may seem like an additional

regulatory burden, pharmaceutical companies use it as a federally sanctioned way to restrict competitors' access to its products.

Citizen petitions. If a drug company cannot keep competitors from developing generic versions of its products, it may employ tactics designed to delay or stop FDA approval of their competition. Citizen petitions are a key tool in this strategy. The citizen petition process is designed to allow more citizen participation in FDA processes. Anyone can petition the FDA to issue, amend, or revoke a regulation, or to otherwise take or revoke an administrative action, and the FDA must respond within 180 days. Pharmaceutical companies use this process to block competitors' drug approvals by filing frivolous petitions. In fact, 92 percent of all citizen petitions are filed by manufacturers of branded drugs, and recent research shows that 92 percent of those petitions were rejected by the FDA.^{xxii}

Pay for delay. When all else fails to keep manufacturers from bringing a generic product to market, drug companies have one final, powerful trick. Companies can bring costly patent-infringement lawsuits against their competitors—not because they want to win, but because they want to settle. Drug companies offer “pay-for-delay” settlements, in which they pay competitors not to make generic versions of their branded products. These deals are a win-win for the industry, but a loss for consumers: The branded-drug company gets to keep its monopoly, the generic-drug manufacturer gets paid, and corporations continue to charge Americans inflated prices for their medicine.

Taxpayer-Supported Seed Funding.

The Bayh-Dole Act adds another layer to the government support that drug companies enjoy. Prior to Bayh-Dole, the government required that discoveries made with government support—by universities, nonprofits, or government contractors—be made freely available. To incentivize private-sector research and development, Congress changed the rules to allow companies to patent technologies developed with federal financial assistance and to allow the government to license government-owned inventions to the private sector for commercialization. That move opened up the potential for the pharmaceutical industry to use taxpayer funding to support research, and then turn around and sell the fruits of that research to those same taxpayers at exorbitant rates.

Again, in an effort to balance innovation against public interest, Congress included specific language in the legislation allowing the government to manufacture a patented product or grant a license to another company to do so. And again, the first half of Congress's

intent was fulfilled: A majority of drugs approved by the FDA rely on government-funded research. A recent study published by the National Academy of Sciences showed that federal funding contributed to every single one of the 210 new drugs approved by the FDA from 2010 to 2016.³ The second half of Congress’s intent, however, was not met, as no federal agency has ever invoked Bayh-Dole’s so-called “march-in” rights.

Limiting Market Forces.

Given that government health insurance programs are huge players in the prescription drug marketplace, the government could play an important role in drug pricing just by negotiating prices on behalf of participants in government health plans. Some government health plans, like the Veterans Affairs health system, already do negotiate lower prices, but Medicare is specifically prohibited from doing so.^{xxiii} In 2003, Congress sought to expand Medicare to cover outpatient prescription drugs. This change would greatly expanded Americans’ access to prescription drug coverage, but it would have also greatly expanded the federal government’s buying power in the prescription drug market: As a major purchaser of pharmaceuticals, the government would have gained increased negotiating power to determine the terms of the availability—and price—of prescription drugs for Medicare recipients. To avoid this undesirable outcome, pharmaceutical companies lobbied hard to ensure that the bill included a key provision: a prohibition on the negotiation of drug prices.^{xxiv}

Drug companies have rigged the rules so that government interventions work for them rather than the American public.

When policymakers propose changes that would fix the drug-pricing crisis, critics label the efforts as government overreach, arguing that the federal government should not interfere in the market. But the reality is that the government is already heavily involved in the pharmaceutical market—it’s just that drug companies have rigged the rules so that government interventions work for them rather than the American public by narrowing the government’s role to promoting pharmaceutical companies’ market power.

³ There are many different ways to measure the impact of federal research funding on drug development, so there are a range of estimates for the impact of government funding on FDA-approved drugs. Studies evaluating the impact of “basic research” (research to understand diseases and potential interventions) find substantial reliance, whereas those that examine the prevalence of government-funded “applied research” (research to develop specific drugs) suggest that about one-tenth of FDA approved drugs benefit from government funding.

A Plan for Lowering Drug Prices

Simple but essential tweaks would shift the government's role in the pharmaceutical market from protecting drug company profits to promoting market competition and better health outcomes for all Americans. Though congressional action is necessary in some areas, the executive branch could take significant steps toward lowering drug prices without legislative change.

1 STOP COMPANIES FROM EXPLOITING TAXPAYER-OWNED INVENTIONS

Americans are paying twice over for many prescription drugs: As taxpayers, they fund the research that leads to drug development, and as consumers, they pay to purchase those treatments. Drug companies that rely on taxpayer-funded research should not be allowed to gouge those same taxpayers when it comes to purchasing treatments. The government has some levers to impact pricing of innovations that were funded by government but owned by private companies (discussed below), and it has significant leverage when it comes to innovations that are actually owned by the government itself. The federal government frequently develops technology, products or processes that can be patented; according to the Washington Post, the Department of Health and Human Services alone has patented more than 2,500 inventions since 1976.^{xxv} The Bayh-Dole Act requires the government to offer these government-owned inventions on exclusive, partially exclusive, or non-exclusive licenses to businesses that can commercialize the invention.

There are a few problems that arise under current practice. The first is that the government does not always enforce its patent rights against private companies. For example, the government holds a patent for the use of Truvada as an HIV preventative (commonly known as "Truvada for PrEP"). The drug company Gilead persists in producing Truvada for PrEP and selling it to the public at outrageous prices, yet it took immense public pressure to get the federal government to step in to enforce its patent rights. Experts argue that patent enforcement against private companies does not align with government agencies' perceived mission to bring its technological advances to the public.^{xxvi}

The second problem is that the government has been far too lenient in licensing its inventions. The National Institutes of Health and other agencies that invent pharmaceuticals or their component parts, like the Department of Defense, could

require that companies that license government-owned inventions—or that engage in research partnerships with federal agencies—agree to reasonable pricing for any products that result from the agreement. In the late 1980’s and early 1990’s, National Institutes of Health (NIH) policy dictated the use of reasonable pricing clauses; however, the NIH repealed this policy, arguing that it discouraged industry from participating in partnerships with NIH.^{xxvii} One reason why the NIH may have changed course on reasonable pricing is that it does not have a formal responsibility to address the affordability of prescription drugs, but its mission does drive it to ensure that its research has practical application. As such, it is more interested in industry use of NIH discoveries than in the ultimate prices consumer pay to access them. Further, there is no standard practice among federal agencies for determining whether to offer an exclusive or a non-exclusive license; often, the pharmaceutical industry’s interest in having exclusive rights ends up being the deciding factor.^{xxviii}

To ensure that taxpayers are able to benefit from the innovations they paid to develop, the president should:

- Issue an executive order requiring agencies that fund research related to drug development to prioritize the development of affordable, widely-available treatments.
- Direct the Department of Commerce to engage in rulemaking to create a single, standard process for contracting related to the use of government-owned inventions.
- Require agencies to present any proposed exclusive licensing arrangement to an expert panel; employ exclusive licensing only when the panel determines it would be impossible to commercialize the invention without an exclusive license.
- Ensure the inclusion of reasonable pricing clauses in exclusive license agreements for government-owned products and processes related to drug production, as well as any agreements related to research partnerships with pharmaceutical companies.

2 CHANGE INCENTIVES BY REBALANCING POWER IN THE PATENT SYSTEM

One of the biggest problems in the prescription drug market is that drug companies hold too much power. They understand that patients need their drugs to survive and thrive and will pay almost anything to get them. And when drug companies have the exclusive right to produce a particular treatment, they can raise prices without consequence. The exclusive right to manufacture and market a particular product can sometimes

encourage innovation, but it can also give companies a strong incentive to focus their energies on manipulating the system to bully competitors or making tiny tweaks to existing products to prolong their market dominance. But Congress already gave federal agencies important tools to rebalance power: the authority to deny, revoke, or infringe on patents under certain circumstances.

Patent Application Review and Revocation

The U.S. Patent and Trademark Office has the authority to examine and approve patent applications. In the last few decades, the USPTO has emphasized alleviating application backlogs and ensuring efficient patent application processes. But this emphasis on quick turnaround has also led to concerns that patent examiners do not have the time or resources necessary to conduct thorough reviews, corresponding to a spike in patent infringement actions. A 2016 report from the U.S. Government Accountability Office cited challenges with searching for and identifying prior art that would negate the patent applicant's claim of novelty, as well issues relating to the technical expertise necessary to evaluate a patent request.^{xxix} Improving the quality and depth of patent reviews is an important step in avoiding the patent thickening and evergreening that plague the drug industry.

Further, USPTO has other tools when it comes to avoiding issuing undeserved patents: Post-grant review and inter partes review. These processes allow interested parties to challenge the validity of patents that were already issued while avoiding costly litigation. However, USPTO has the authority to set the fees that challengers must pay to engage in these processes, and they are prohibitively high – about \$20,000 – particularly for consumer-focused organizations aiming to prevent patent abuses.^{xxx} USPTO could limit these fees across the board or eliminate the fees for non-commercial entities or non-profit organizations.

Compulsory Licensing

These powers go by different names, including “march-in rights” and “compulsory licensing,” but essentially, under certain circumstances, the federal government has the ability to override companies’ monopolies and produce patented drugs or components itself or license other producers to produce patented drugs or drug components. The government has three main mechanisms for compulsory licensing, each with slightly different criteria for use.

Section 1498: Government Patent Use. The government may exercise its right to produce or license a patented product or process under U.S. patent law. Patent law confers broad rights to the government to step in to manufacture a product or assign a license to another company to do so as long as the government provides reasonable compensation to the patent holder.⁴ Many experts agree that, in the case of pharmaceutical products with drastic price increases, it would be both reasonable and prudent for the government to use this power more frequently.^{xxxii} As explained above, the government routinely invokes the “government use” provision of patent law in other areas, but it has not done so in the case of pharmaceuticals for several decades. There are two potential explanations for this.

First, there is no clear decision-maker when it comes to invoking the government’s patent use authority for pharmaceuticals. In the case of straightforward government procurements, as when the Department of Defense seeks to purchase a certain technology, it is easy to identify the circumstances under which the government patent use should be exercised and the proper decision-maker for invoking its use. In that case, the Department of Defense’s interest in invoking its patent use authority—whether to secure a lower price or for the sake of efficiency—would be clear, and the responsibility for invoking patent use authority would clearly sit within that agency. In the case of high drug prices, there is no clear responsibility or authority resting within a particular agency.

In 2001, the government hinted at using its authority to license the production of Cipro (ciprofloxacin) during the anthrax scare. In that case, HHS was seeking to procure the drug directly, so it had a clear interest in reaching a fair price. The effort worked: By simply indicating its openness to licensing generic production of ciprofloxacin, the government secured a 50 percent discount from the drug’s manufacturer, Bayer.^{xxxiii}

When it comes to lowering drug prices for a broader group of Americans, it is far less clear which agency would be responsible. The law states that patent infringement (with reasonable compensation) is allowed when the subject invention is “used or manufactured by or for the United States.”^{xxxiii} Though the provision is typically invoked when the government is procuring a product for its own use, the plain language of the law—manufacture “by or for the government”—would allow the government to procure

⁴ Past payments for government use of patented pharmaceuticals suggest that “reasonable payments” would be far below the patent holder’s lost profits: In one case, the government paid a royalty of 2 percent of the patented price. Additionally, in cases not involving pharmaceuticals, courts have held that lost profits do not control in the determination of reasonable compensation; rather, courts look to “residual profits” (the amount the patent infringer netted that exceeds its average profits on other products) as well as other relevant factors.

or manufacture pharmaceuticals in order to provide lower-priced drugs through federal health programs, such as Medicare and Medicaid. It would even allow the government to procure or manufacture pharmaceuticals for resale in the private market. But there is currently no federal agency specifically tasked with accomplishing this.

The second barrier to employing the government use provision to drive down drug prices is that there is no mechanism to remove regulatory roadblocks. In addition to patents, pharmaceuticals often have a web of FDA-granted exclusivities—protections against competing products—that are layered on top of patents to further insulate manufacturers of brand-name drugs from competition. Even if the government were to license generic drug production to a particular company, these exclusivities might prevent the FDA from approving the generic version in a timely manner.

Bayh-Dole Act: March-In Rights for Federally-Supported Inventions. The government also has specific authority to license inventions under the Bayh-Dole Act. Bayh-Dole states that the government should “march in” in a variety of circumstances, particularly where the benefits of an invention developed using federal funding are not “available to the public on reasonable terms.”^{xxxiv} The law also identifies the agency responsible for making decisions about marching in: In the case of prescription drugs, the National Institutes of Health.⁵ Yet the NIH has denied each request to march in on pharmaceutical products, arguing that high prices alone do not justify exercise of Bayh-Dole march-in authority. This is clearly wrong, given that the plain meaning of “reasonable terms” includes reasonable prices, and the legislative history of Bayh-Dole’s march-in provision evinces an intent to ensure competition in the market and prevent unfair profiteering.^{xxxv} Further, the law allows march-in where it is necessary to “alleviate health or safety needs which are not reasonably satisfied;” unreasonably high prices could trigger this provision as well.

Compulsory Licensing as an Antitrust Remedy. Finally, compulsory licensing of patented products or processes is a remedy available to the Federal Trade Commission or the Department of Justice in enforcing antitrust laws. In several notable cases, the courts have used compulsory licensing as a remedy to address patent abuses in antitrust actions, though courts and scholars have cautioned against using compulsory licensing too broadly.^{xxxvi} As will be discussed further below, pharmaceutical companies often engage in abusive practices that may well violate antitrust law. Federal agencies

⁵ The Department of Defense also funds research that may lead to the development of vaccines or other medicines, so it also bears some responsibility for marching in.

could not only stop these practices; they could also remedy the effects the practices have on competition, innovation, and affordability by requiring companies to license the processes, formulations, and other information covered by their patents. This holds particular promise in the case of biologic drugs, which are derived from living organisms. Biologics tend to be particularly expensive. They also entail a number of different patents related to formulation, manufacturing, methods of use, and other considerations, and this makes them particularly ripe for patent abuses designed to inhibit competition.

If the government chose to use its patent denial, rescission, and infringement authorities more robustly, it would have a significant impact on the pharmaceutical market. It would give the government a way to drastically reduce the price of specific pharmaceutical products. But more than that, it would change the incentive structure for pharmaceutical companies, tilting them toward useful, innovative developments and reasonable pricing. A president who is serious about reducing prescription drug prices could take significant steps toward lowering drug prices using march-in and other patent authorities by:

- Charging the Secretary of Commerce with reforming patent prosecution and review processes to cut down on patent abuses;
- Designating a single agency to be responsible for identifying pharmaceutical products with unfairly high prices and determining whether these products would be good candidates for licensing under patent law;
- Tasking this agency with developing rules and processes for the use of the government's manufacture and licensing authority under patent law, as well as the guidelines for determining reasonable compensation for the patent holder;
- Directing the NIH to develop rules for the exercise of Bayh-Dole march-in rights in the case of excessively high prices for drugs developed using federal funding;
- Creating an interagency task force comprising officials from the FDA, NIH, HHS, Centers for Disease Control and Prevention, VA, and any other relevant agencies with a mandate to clear regulatory hurdles in order to ensure effective implementation of government patent use and march-in rights, as well as efficiency in bringing generics developed under these authorities to market;
- Appointing FTC Commissioners and leadership at the Department of Justice who recognize compulsory licensing as a potential remedy in antitrust cases related to patent abuse.

3 CRACK DOWN ON ANTICOMPETITIVE TACTICS

Instead of using the government's patent programs to promote innovation and pave the way for more effective treatments, pharmaceutical companies have twisted the law to thwart competition and ensure long-lasting monopolies on decades-old technologies. Policymakers tend to look for healthcare-based solutions to high drug prices, like negotiating drug prices through Medicare Part D. But competition-based solutions are equally important because they inhibit drug companies' ability to maintain high drug prices by squeezing out competitors. Cracking down on anticompetitive practices in the pharmaceutical industry is important not only for consumers, but for the American economy overall, as it encourages productive investment.

Instead of using the government's patent programs to promote innovation and pave the way for more effective treatments, pharmaceutical companies have twisted the law to thwart competition and ensure long-lasting monopolies on decades-old technologies.

Though some policymakers have introduced legislation to enhance the Federal Trade Commission's authority, the FTC already has ample ability to address unfair and abusive practices under current law. Section Five of the FTC Act allows the agency to go after unfair methods of competition, a broad charge that encompasses both violations of the Sherman and Clayton Acts as well as actions that "contravene the spirit of the antitrust laws."^{xxxvii} It also prohibits "unfair or deceptive acts or practices," including conduct that "causes or is likely to cause substantial injury to consumers which is not reasonably avoidable by consumers themselves and not outweighed by countervailing benefits to consumers or competition."^{xxxviii} Each of these authorities can be used to inhibit excessive drug prices. As FTC Commissioners Rohit Chopra and Rebecca Kelly Slaughter point out, the FTC can bring enforcement actions "when excessive drug price increases are accompanied by exclusionary conduct or the result of a merger."^{xxxix} Further, significant price increases on a drug—particularly an off-patent one, the acquisition of which did not require any research or development funding—could be considered an unfair practice. Under both authorities, the FTC has the ability to define violations through rulemaking. The FTC could define certain types of price increases as violations in and of themselves, but it could also identify practices, like pay-for-delay,

as presumptive unfair methods of competition. It could also outlaw patent thicketing and evergreening when companies are engaging in these practices for the purpose of maintaining or increasing prices.

The penalty for these transgressions, and for other anticompetitive behaviors, should be a meaningful deterrent. Steep fines are important, but they may not be enough to keep companies from engaging in exclusionary practices or remedy the effects of anti-competitive practices—particularly when compared to the prospect of increased or prolonged profits. As described above, where appropriate, the FTC can use compulsory licensing as a remedy as well.

4 END THE CONFLICTS OF INTEREST THAT PUT LOBBYISTS IN THE DRIVER'S SEAT ON DRUG POLICY

Policymakers and agency officials cannot act in the best interests of the country if they are distracted by their own financial stakes in the industries they regulate. These conflicts of interest are rife in pharmaceutical policy, from the relationships between legislators and pharmaceutical lobbyists all the way to the relationships between NIH researchers and the companies that license their inventions. Current laws are insufficient to curb conflicts of interest in both the legislature and federal agencies. Without meaningful changes, our drug pricing laws will continue to be written by the drug companies themselves. To remedy this, a president could institute the following changes described in Roosevelt Institute's *Unstacking the Deck* report by executive order:

- **Ban lobbyists from taking jobs in federal agencies.** Lobbyists for pharmaceutical companies should not be able to continue pushing their former employers' point of view from inside the government. The president should ban lobbyists of for-profit entities from employment in federal agencies without clear consent.
- **Expand required recusals from agency decision-making.** Government officials should not be able to participate in decisions that affect their former employer's interests. The president should expand required recusals to include any agency action that would benefit or hurt former employers and clients, as well as their competitors.
- **Tighten post-employment restrictions for public servants.** Reduce the temptation for government officials to make decisions based on their future job prospects by banning highly regulated entities and government contractors from directly or indirectly hiring senior government officials.

- **Ban stock trading by senior executive branch officials.** We must eliminate the temptation for officials to enrich themselves by trading on insider information or using government programs to help companies in which they are invested. Senior officials should be able to invest in diversified mutual funds and federal nonretirement assets, but the president should prohibit securities trading.

Conclusion

Excessively high drug prices put Americans in the impossible position of choosing between health and financial security. Powerful pharmaceutical companies use lobbying and soft corruption to twist federal law in their favor: Instead of promoting innovation and public health, our patent and drug laws now promote monopoly power and profits. It does not have to be this way. Congress has already given the president the tools to take significant steps toward lowering pharmaceutical prices. These steps would help rebalance the tilted power dynamics in the pharmaceutical market,

Congress has already given the president the tools to take significant steps toward lowering pharmaceutical prices.

giving drug companies an incentive to lower their prices. But it bears noting that the actions proposed in this report would only be enhanced by congressional action that carves out a stronger role for government to address failures in the prescription drug market, including expanded federal investments in research and capacity for public manufacturing of pharmaceuticals. If policymakers are willing to stand up to the drug industry, America's pharmaceutical market can deliver the quality, affordable drugs America desperately needs.

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