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Policy Prescriptions to Lower Drug Prices

The unfettered monopoly power and greed of the pharmaceutical industry has brought about an affordable medicines crisis in the United States. Nearly three-in-ten people in the United States report not taking a medicine as prescribed because of the cost, including by not filling a prescription, taking an inappropriate alternative treatment, cutting pills in half or skipping doses.[i]

Ever-increasing launch prices of new drugs and routine price hikes on existing medicines are the key drivers of pharma's price gouging. Drug companies have increased the launch prices of new anticancer medications by more than 10 percent annually,[ii] with the average price of new cancer medicines now at a staggering $149,000.[iii] Hiking prices on existing drugs has become a standard feature of pharmaceutical corporations' business model.[iv] For the 45 top-selling drugs, more than half of all sales growth in the past three years was due to price increases.[v] Industry analysists project that by 2024 Americans will spend $38.3 billion on just five drugs alone.[vi]

U.S. policymakers so far have not enacted any reforms to meaningfully lower prices. As the elections approach, it will be key for anyone that wishes to be President in 2020 to put forth a bold set of legislative and executive policy solutions to provide the relief that people around the country need. Taken together, the policies must increase government negotiating power, stop price hikes, and curb monopoly abuses.[vii] This document provides a template for comprehensive legislative reform as well as actions the President can take at any time under existing law.

Legislative Solutions

1) Stop Pharmaceutical Companies from Setting Prices as High as They Want

Prescription drug prices are higher in the United States than other wealthy countries because, unlike nearly every other country, the U.S allows drug companies to set prices.[viii] Conversely, other countries regulate prices through negotiations or decide what companies may charge through other means, such as international reference pricing. Key features of a U.S. drug pricing system include making government negotiations or pricing determinations available for all branded drugs, and for such prices to be enforced through a strong backstop authority when pharma refuses to offer a fair price. A well-designed backstop will ensure patient access, strongly deter noncompliance, and will be impervious to pharma tricks.

- Require the Department of Health and Human Services (HHS) to negotiate directly with pharmaceutical companies to obtain fair prices or administratively determine fair prices.
- Assess whether a fair price has been obtained based on—

    - therapeutic benefit, including whether the product provides a significant improvement in health outcomes over existing therapies;
    - prices paid in other large, wealthy countries;
    - research and development costs associated with bringing the drug to market;
    - public support of research and development, including grants and tax credits;
    - the impacts of the price on health program spending and budgets;
    - the impacts of the price on patients' access and finances; and
    - the extent to which the manufacturer has obtained or is expected to obtain a reasonable return on its investment through global sales of the drug.
- If a company refuses to sell the drug at a fair price, issue open licenses on patent and clinical data to allow competition.
- Claw back revenues derived from excessive pricing prior to the establishment of the fair price.
- (option) In addition to the fair pricing assessment above, consider the price of a drug in excess of the price paid by other large, wealthy countries to be *de facto* unfair.
- (option) Begin with Medicare Part D, under which the government is currently forbidden from engaging in direct price negotiations or administrative pricing determinations, before expanding the system to the entire U.S. prescription drug market.

2) Penalize Prescription Drug Price Spikes

Drug companies routinely spike prices on old medicines without providing any meaningful therapeutic improvement, simply because they can. Unless strict limitations are placed on price increases that prevent drug companies from profiting off this behavior, they will continue to price gouge consumers.

- Impose a 100 percent excise tax equivalent to the amount by which the price of a prescription drug is increased beyond the rate of general inflation multiplied by all U.S. sales of the drug.
- Assess the tax based on price increases over annual and multi-year periods so companies cannot benefit in future years from price spikes in prior years.
- (option) The tax could begin at 50% for smaller price spikes and increase to 100% for price spikes above a higher threshold.

3) Curb Monopoly Power and Gaming

Pharmaceutical companies' ability to price gouge consumers is derived from government-granted patent and other monopoly privileges, which they often abuse to charge U.S. consumers higher prices than those in other high-income countries that better regulate price. Facilitating competition by putting in place safeguards to limit the exploitation of government-granted monopolies, better structuring rules so companies cannot inappropriately extend monopoly privileges and curbing their abuse are core components of reform.

- Require a fair return on public investment by establishing statutory requirements for government agencies to license generic competition through exercising march-in rights when drug companies charge U.S. consumers more than those in other large, wealthy countries.
- Reduce the biologic marketing exclusivity term to five years to help spur earlier biosimilar competition.

- Raise the bar on granting patents so only truly new biopharmaceutical inventions qualify and drug companies can no longer "evergreen" their patent exclusivity terms, extending monopoly terms without providing corresponding improvements in therapeutic value.
- Define the creation of patent thickets through filing excessive and redundant patent applications to prevent competition as anticompetitive and provide the Federal Trade Commission (FTC) sufficient resources for aggressive enforcement.
- Define product hopping, wherein a company introduces a follow-on product with no significant therapeutic benefit over its predecessor in order to stymie competition, as anticompetitive and provide the FTC sufficient resources for aggressive enforcement.
- Establish a private right of action for generic and biosimilar firms to sue branded drug companies when they refuse to provide samples necessary for bioequivalency and biosimilarity studies necessary for a potential competitor to receive marketing approval.
- Make pay-for-delay patent settlement deals that delay generic and biosimilar competition presumptively anticompetitive and provide the FTC sufficient resources for aggressive enforcement.

Executive Authority

1) Ensure a Fair, Public Return on Public Investment in Pharmaceutical Research

The U.S. federal government is the world's largest funder of biomedical research.[ix] Yet when public dollars lead to the invention of a new drug, too often that medicine is priced out of reach for U.S. consumers. But the government has existing rights to allow for generic competition precisely when a product developed with taxpayer dollars isn't being made available to the public on reasonable terms.[x]

- When prescription drug corporations are charging U.S. consumers and health programs more than other large, wealthy countries for medicines developed with taxpayer dollars, exercise march-in rights (35 U.S. Code § 203) to license patents on inventions that relied on federal support and authorize generic competition.
- Develop and adopt licensing guidelines at the National Institutes of Health and other agencies that sponsor government-funded research, which require march-in rights to be exercised when the U.S. list price of a medicine including a qualifying patent is higher than the median price paid in a set of large, wealthy countries.
- In conjunction with march-in rights, exercise royalty-free rights (35 U.S Code § 209(d)(1)), which do not require licensee payment of royalties for uses of the invention that are by and for the United States.

2) Authorize Generic Competition on Monopoly Products through 'Government Use'

Since patent laws were created, governments around the world, including the United States, have preserved and exercised the right to use the patented technologies they protect.[xi] Just as the U.S. government does not allow a private land owner from block the government from making use of the land to advance the public interest through eminent domain, the government may use patented

inventions without the permission of the patent holder to advance the public interest, as long as it provides reasonable compensation.[xii]

- When prices set by prescription drug corporations are imposing an undue burden on federal health programs, including by limiting the impact of U.S. government humanitarian assistance programs, such as PEPFAR, exercise government use patent licensing authority (28 U.S. Code § 1498(a)) to facilitate use of low-cost generics.
- Where appropriate, exercise royalty-free rights (35 U.S. Code § 202(c)(4) & 35 U.S. Code § 209(d)(1)) in conjunction with government use to reduce the level of compensation necessary for the government to pay to the patent holder.

3) Block Mergers that Impede Competition

Generic competition can reduce prices to a fraction of their pre-generic levels, but this is only possible with many companies competing to deliver lower prices. Competition between branded pharmaceuticals can also deliver lower prices, to the extent that products are interchangeable for treating a given condition. Pharmaceutical mergers can impede this competition, and ultimately lead to higher prices for consumers.

- Challenge horizontal mergers between brand-name pharmaceutical firms with products in the same therapeutic class or products in the research and development pipeline that may result in future competition between the companies.
- Challenge horizontal mergers between generic pharmaceutical firms that reduce potential for robust competition in the generic marketplace, which is necessary to deliver lower prices, avoid de-facto monopolies that allow price spikes and avert supply disruptions that lead to shortages.
- Challenge vertical mergers between companies across the drug supply chain, including insurers, pharmacy benefit managers and pharmacies, which may lead to anticompetitive abuse.

4) Treat Abusive Pricing as an Antitrust Violation

Inappropriately narrow interpretations by the Department of Justice of antitrust authority with regard to pricing have prevented the U.S. government from exercising from using important tools to protect consumers.

- Revise current Department of Justice guidelines regarding antitrust, pricing, and intellectual property issues to consider abusive pricing of patented and off-patent medicines an antitrust violation.

5) Crack Down on Pharma Fraud

Many prescription drug corporations routinely break our laws, overcharge states, bribe healthcare providers, manipulate safety data and illegally market their drugs.[xiii] The federal government must crack down corporate crime and demand that drug corporations are as accountable as the rest of us.

- Strengthen so-called Corporate Integrity Agreements (CIAs), into which companies enter with the Office of the Inspector General (OIG) of HHS as parts of civil settlements, to allow more rigorous federal monitoring of pharmaceutical companies in order to identify, and ultimately prevent, systematic fraud that has long been the norm.
- Make public annual compliance reports submitted to the OIG pursuant to CIAs and impose significant punishments on companies for violations of CIAs.

6) Stop Pharma Giveaways in Trade Agreements

For more than 20 years, the pharmaceutical industry has used U.S. trade policy as a vehicle to export broader, longer and stronger monopoly protections around the world. These rules lead to preventable suffering and death in lower- and middle-income countries, and help entrench harmful rules that contribute to high medicine prices in the United States.

- Exclude intellectual property rules from trade agreements that impede access to medicines in other countries, especially lower- and middle-income countries, and which entrench harmful monopoly rules in the United States.
- Exclude from trade agreements so-called "transparency and procedural fairness" rules which may be used to restrain government decision-making authority and enshrine greater pharmaceutical company influence in coverage and reimbursement decisions.

7) Adopt a Humanitarian Licensing Policy

Patenting and exclusive licensing of medical technologies developed with NIH funding can lead to very high prices for pharmaceuticals throughout the world. This makes it difficult for humanitarian organizations to keep pace with global need, and reduces access to these technologies. Many lives could be saved if license for publicly-funded inventions were made available in lower- and middle-income countries.

- Adopt a standard clause to be used in federal grants to make licenses to intellectual property rights presumptively available to international organizations, lower- and middle-income country governments and non-governmental organizations providing services in lower- and middle-income countries, for all forthcoming inventions to which government rights attach under existing law (35 U.S. Code § 202(c)(4) & 35 U.S. Code § 209(d)(1)), subject to a decision by HHS to declare that a particular intellectual property right is not subject to the terms of the general agreement.
- Alternatively, adopt a humanitarian licensing policy to be applied based on the demand for U.S. government-funded technologies in lower- and middle-income countries and the health benefits of such technologies.

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