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Fellowship Capstone | Policy Brief

America's War on Healthcare: Juggling Corporate and Patient Interests

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I. Executive summary

Inaccessibility to prescription drugs is a problem that the majority of Americans face. The greed of large pharmaceutical corporations and an abuse-prone patent system drive this crisis, forcing many Americans into a negative socioeconomic corner. This brief will evaluate and analyze the economic and social implications of unaffordable prescription drugs, past efforts to solve the issue, and possible routes for reform.

II. Overview

Currently, more than one-third of American adults report difficulties in affording their medications. [1]

Despite efforts to reform the healthcare system, millions of Americans still struggle to obtain lifesaving medication. This is largely due to corporate greed, but also skyhigh research and development costs coupled with weakened supply chains and patent thickets filed by big pharma to maintain monopolies. Past policies have attempted to aid Americans through price negotiations, but they fail to consider both corporate and patient interests and don't apply to the majority of struggling individuals. Without policy that can adequately address both parties, legislators risk long-term stability for short-term gains that may not be feasible. As a result, the United States has yet to find a long-term solution to rising prescription drug costs.

A. Relevance

Because of high drug prices, nearly 30% of Americans haven't taken their medication as prescribed, and more than 1.1 million Medicare patients alone are estimated to die in the next decade because they cannot afford prescribed medications. [2] Even worse, patent thickets are obstacles to biosimilars and generics entering the market, at best delaying affordable options for years and at worst deterring any competition at all, keeping prices high.[3] Reforming the healthcare and patent systems are crucial to ensuring life-saving medication is available to all.

III. History

A. Current Stances

From 1980 to 2018, nationwide spending on prescription drugs increased by $305 billion. [4] This was largely due to the introduction of new drugs, decreasing the need for medical services provided by hospitals and physicians as consumers

turned to new drugs with a wide variety of benefits. Spending grew most during 1995 and the mid-2000s with the introduction of "blockbuster drugs," which are drugs used to treat common illnesses and conditions such as high cholesterol, high blood pressure, acid reflux, and depression. [4]

Prescription drug prices began falling mid-2000s as drug patents expired and generic alternatives flooded the markets, increasing accessibility and affordability. Furthermore, the creation of Medicare Part D allowed enrollees to receive federal assistance in purchasing drugs. [4] In 2022, then President Joe Biden passed the Inflation Reduction Act, which requires Medicare to negotiate prices for high-cost drugs and companies to pay Medicare rebates if drug prices rise faster than inflation. [5]

It is clear that there are safeguards in place to ensure Americans can afford medication, but, nonetheless, big pharma maintains its monopoly on prescription drugs by exploiting and abusing the U.S. patent system through patent thickets. Patent thickets are created when a drug company files tens upon hundreds of patents on a single drug so that no competitors can enter the market, keeping prices high. Currently, pharmaceutical companies receive 12 years of guaranteed market exclusivity for biologics and 20 years for each patent. [6] However, the top 12 brand drugs are protected by a total of 848 patents, allowing for an average of 38 years without generic competition. [7]

IV. Policy Problem

A. Stakeholders

The primary stakeholders are Americans on or in need of prescription drugs, especially those who are low-income and in marginalized communities, because they need medication to survive. Current barriers in prescription drug accessibility prevent them from receiving life-saving treatment, limiting their options in healthcare and threatening their livelihoods socioeconomically. That said, meaningful healthcare reform would open the doors to quality care and save countless lives. These individuals should have a stake in the policy that increases the accessibility of prescription drugs, ensuring that the mechanisms in use are effective and fair.

Pharmaceutical, biosimilar, and generic corporations are stakeholders as they stand to benefit financially from the development and introduction of prescription drugs. However, greed and abuses against the patent system stemming from these entities cause and exacerbate inaccessibility to prescription drugs. Therefore, it's crucial to regulate the timeframe in which these organizations can control drug prices.

The U.S. Patent and Trademark Office (USPTO), Food and Drug Administration (FDA), and Congress are stakeholders as they have the authority and financial means to enact legal change to combat patent thickets and regulate a drug's market exclusivity.

B. Risks of Indifference

The risk of indifference to high prescription drug prices lies in its devastating implications for low-income Americans, marginalized communities, and individuals with poor or no insurance coverage. For Americans with diabetes, 1.3 million have already turned to rationing insulin because pharmaceutical companies increased prices, which could have live-threatening consequences.[8] Financially, more Americans would slip into poverty as expensive drugs are a major reason for medical debt.[9] When faced with medical debt, people cut spending on basic necessities like food, tap into

their savings, and take on additional debts to pay off their existing medical debt.[10]

C. Nonpartisan Reasoning

Access to healthcare is a basic right, and corporate greed should not outweigh American lives, therefore it's imperative that action is taken to address high prices and abuse of the patent system.

Intervention would reduce strain on Medicaid, Medicare, and emergency assistance programs because patients wouldn't have to ration or refuse to take medication, decreasing the likelihood of worsened health outcomes and need for hospitalization or emergency care.[11]

V. Tried Policy

In 1984, the Hatch-Waxman Act (Drug Price Competition & Patent Term Restoration Act) established the modern generic drug approval system and provided brand-name drugs market exclusivity with patent term extension to compensate for time spent in the lengthy FDA approval process. This policy has been abused by pharmaceutical corporations who file patent thickets to further extend their patent terms, preventing biosimilar and generic competition from driving down prices.

More recently, the Inflation Reduction Act of 2022 introduced price negotiation for high-cost drugs in Medicare and required companies to pay Medicare rebates if drug prices rise faster than inflation. [5] Negotiated prices of the first ten drugs are set to be implemented in January 2026. The problem with this policy, however, is that it simply shifts the initial burden away from patients onto insurers through the policy's plan liability, which is triggered after patients reach the $2,000 annual out-of-pocket cap. To offset financial risks, insurers may retaliate with increased premiums, co-insurance requirements, and restrictive formularies, further impacting patient affordability and access.[12]

VI. Policy Options

Promote competition by limiting claims of patent violation

Patent thickets are designed to deter competition from biosimilars by patenting minor variations of drugs; this keeps prescription drug prices high.

To overcome this, I recommend limiting the number of patents drug makers can claim were violated by biosimilar manufacturers, which is outlined in the Affordable Prescriptions for Patients Act of 2023, which passed in the Senate, but not the House. Not only would this policy streamline the process for biosimilars to enter the market and decrease select drug prices by up to 20%, but the patent system reform could decrease litigation spending by $1.5 billion over the next decade.[13] This new policy can be overseen by the Federal Trade Commission (FTC) and enforced by the Department of Justice (DOJ) Antitrust Division and USPTO.

Increase scrutiny in the USPTO

The USPTO is notorious for being understaffed, and, as of October 2024, patent backlog has risen to 804,658 applications.[14] Many of these patents include biosimilars or generics that could significantly lower costs for patients, so it is imperative that we increase efficiency in the patent approval process to allow for alternative drugs to enter the market.

I suggest allocating $5 billion in federal funding for the USPTO, which currently operates on fees paid by users of the patent and trademark system. Increasing the organization's budget would allow it to hire more employees to review more patents and ultimately approve more generic and biosimilar drugs.

Improve current accelerated approval pathway
Currently, the FDA's accelerated approval pathway allows for faster approval of drugs for serious or life-threatening conditions that address an unmet medical need, but some drugs will stay on the market even if they are proven ineffective and even harmful.

To begin, regulations should be enforced to reject drugs with negative trial results on clinical outcomes. That way, ineffective drugs are kept off the market, keeping the standard for prescription drugs and treatments high for patients. The FDA should codify this policy and oversee and enforce it as well. To aid in the process, Congress should allocate more funding to the FDA to strengthen oversight and regulation.

VII. Conclusions

In this paper, I have explored a plethora of topics underlying unaffordable prescription drugs in the U.S., going into an in-depth analysis of the patent system and consequent policy options for the same. Of the possible solutions, the one that seems most implementable is the promotion of competition by limiting claims of patent violation. Doing so will elicit competition, which is key to making prescription drugs affordable for the Americans.

There is no one size fits all solution for America's drug pricing problem, but when developing policy, we must consider corporate and patient interests to obtain the best outcomes. The American healthcare system is heavily flawed, but with careful consideration, open mindedness, and a shift away from heavily polarized policymaking, change can be made, one reform at a time.

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