Title

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Publication Date

2024-12-09

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INTRODUCTION

Private pharmaceutical companies set their drug prices based on a "value-based pricing" strategy. These companies describe that they have a perceived value of the drug to patients, taking into account its efficacy, benefits, and the cost of research and development in addition to production costs. These factors and pricing strategies allow private pharmaceutical companies to charge high prices for medications. However, market forces, healthcare providers, and insurance companies ultimately determine the final price that is paid for these medications by patients, increasing prices yet again.

Pharmaceuticals are costly, especially those distributed by private companies, due to high cost of research and development (R&D), the patent system (monopolies on newer drugs), the profit motive of pharmaceutical companies, and lack of price negotiation within the United States healthcare system. In 2019 alone, the pharmaceutical industry spent over $83 billion on R&D, covering the discovery and testing of new drugs, development of incremental innovations, clinical testing for safety-monitoring, and testing for marketing purposes. Pharmaceutical companies overall spend one-quarter of their revenues on R&D expenses, which is two times more than what they spent in the past decade [1]. The largest pharmaceutical drug curators in the United States only spend twenty-two cents out of every dollar they make on R&D, and in

another study from the Journal of the American Medical Association, there was no relationship found between the price that brand name drug makers set and the amount those companies invest in R&D [2].

Patents grant exclusive rights to those who manufacture and sell a new drug for a limited period of time, which allows companies to set high and unfair prices without any competition for that period. Monopolies become temporary as patents expire, but unfortunately for cancers or life threatening diseases, when the drug runs out of patent life, it is considered obsolete (planned obsolescence), and no longer is the standard of care [3]. This ties directly into how pharmaceutical companies charge higher prices for drugs that treat serious or chronic conditions, situations in which patients have limited or no alternatives, as the need for this medication outweighs the cost concern. [3] Utilizing the previous example with cancer patients, although there are multiple drugs needed to treat a specific malignancy, there is no actual competition based on price because most cancers are incurable [3]. Each drug must be used in sequence, so *each* drug *must* be used, and it becomes a matter of *when* the drug is used, not *if* [3].

With all factors considered, drug product pricing from private pharmaceutical companies in the United States remains extremely high, limiting necessary access to medications, increasing out-of-pocket costs for patients, and decreasing transparency in terms of patient understanding of pricing.

ABSTRACT

This literature review examines the progressive issue of proliferating pharmaceutical prices, focusing on the challenges posed by off-patent, life-saving medications. We address the impact of monopolistic pricing strategies, specifically prices of medications distributed by private pharmaceutical companies, the ethical responsibility of ensuring access to necessary

medicines, and the role of government regulations in the pricings of pharmaceutical products. Our paper highlights the need for effective and equitable policies to regulate pricing, including the involvement of pharmaceutical benefit managers, and the potential for reform through governmental intervention to ensure equal access to affordable medications.

DISCUSSION

The regulation of pharmaceutical pricing, particularly for off-patent life-saving medication, has become a critical issue as private companies have increasingly engaged in monopolistic practices to maximize profits. Companies like Turing, Retrophin, Rodelis, and Valeant have acquired sole-sourced decades-old drugs and dramatically raised their prices, often employing closed distribution systems to block competition from generics. This business model, which prioritizes investor returns over patient access, has led to devastating consequences for patients, families, and healthcare systems [1]. While federal policies have traditionally balanced innovation incentives with generic competition, the recent price spikes highlight the need for new regulatory measures to prevent price gouging and ensure that affordable, essential medications remain accessible to all.

Private companies' pricing of pharmaceutical products has become a pressing issue in the U.S., particularly as it relates to the affordability of off-patent, life-saving medications. According to the Senate Special Committee on Aging's report in 2016, “Sudden Price Spikes in Off-Patent Drugs: The Monopoly Business Model that Harms Patients, Taxpayers, and the U.S. Health System,” nearly 60 percent of Americans rely on prescription drugs to treat various conditions, from cancer to high blood pressure [4]. However, the skyrocketing prices of certain medications threaten both individual well-being and the financial security of American

households. In 2015, the Senate launched an investigation into price-gouging tactics of pharmaceutical companies which exploit market failures by acquiring sole-sourced , off-patent drugs and significantly increasing prices, resulting. in de facto monopolies. The investigation by the Senate revealed a complex pharmaceutical pricing system, underscored by confidential agreements between drug manufacturers, wholesalers, and pharmacy benefit managers (PBMs), which raised the cost burden on patients and federal programs like Medicare and Medicaid. As the nation grapples with these price hikes, the report calls for policy solutions that balance pharmaceutical innovation with making vital medications accessible and affordable to all.

Unreasonable and skyrocketing prices of pharmaceutical products continue to exacerbate health inequities especially within marginalized communities, and it is crucial to consider this perspective within criticisms of pharmaceutical corporations. However, when considering government action that can and has been taken on a policy level to address this issue, it is crucial more now than ever to deeply understand the errors made in their approaches that cause the continued oppression of these populations in terms of healthcare access. Major reformation of current policies and dismantling of current infrastructures is required in order to eliminate this disparity. A prominent example is the 340B Drug Pricing Program, created in the late 1990s specifically targeted towards underserved populations, that continues to affect populations today. This program allows Federally Qualified Health Centers, otherwise referred to as “covered entities,” to receive discounted prices from manufacturers, and these savings are able to provide medications at lower costs to marginalized communities [5]. Whether that’s providing financial relief to rural communities or the broad range of medications that these discounts can apply to, this program seemingly laid a solid foundation to achieving equitable health outcomes. However, while this initiative saw an increasing number of hospitals participating in this program and a

possible increase in access and services, much criticism has been directed at the program for not regulating how hospitals distribute the savings equitably; in other words, the savings made from this program were not going back to the patients, and there seemed to be no evidence that hospitals were implementing the changes that were supposed to be enabled by these savings such as enhancing care or investing in safety-net providers [15]. Most relevantly, this has been an issue that was recently voted on in California by means of Prop 34, in which a “YES” vote would work towards undermining the maldistribution of surplus funds garnered by 340B by requiring health care providers to spend 98% of revenues received from this program on direct patient care. The case of 340B proves that while the government can take action to establish intervention to counteract unfair prices from manufacturers and thus pharmaceutical companies themselves, limits and loopholes that hospitals and related institutions take advantage of in order to become as lucrative as possible requires our governments to take an even more active role in shaping policies and programs that strictly ensure pharmaceutical prices remain low, and that those savings have no way to be extracted except by the patients themselves.

Additionally, there is a pressing need to address the ethical responsibility of pharmaceutical companies to prioritize patient welfare over profit, especially when it comes to life-saving medications."The current social contract...struggles to sufficiently address the global provision of pharmaceutical products during an international health crisis" [6]. States should work together to protect their population by ensuring equitable access to essential medicines and health technology. By striving towards this common goal, states can “ensure global health security and sustainable development” [6]. Monopolistic pricing strategies highlight a critical gap in public health responsibilities. Companies profiting from healthcare systems should have a social contract to make essential medications accessible and affordable. Policies encouraging

companies to meet ethical standards could reinforce price regulations, ensuring that public health remains a priority alongside innovation.

In the article "The Price of Prescription Drugs: A Bipartisan Problem" by R.S. Hubbard, the author presents strong evidence supporting the government regulation of pharmaceutical prices to ensure access to essential medications [7]. Hubbard argues that while the U.S. represents only 15% of the global insulin market, it generates 50% of global insulin revenue, highlighting the disproportionate cost burden on American patients. The author also notes that 25% of Americans struggle to afford necessary prescription drugs, emphasizing the financial strain caused by rising pharmaceutical prices. Additionally, Hubbard provides data showing that the U.S. spent $6.8 billion more on price increases for existing cancer drugs from 2012 to 2017 compared to the rest of the world, illustrating the need for price controls. The author argues that these measures, such as H.R. 3 and S.2543, would prevent excessive price hikes while still allowing pharmaceutical companies to maintain research investments by reallocating marketing and lobbying funds [7]. However, both bills were passed by the House in late 2019 but were not taken up by the Senate. Thus, the movement for governing pharmaceutical prices is still in the present tense and should be brought to the public's attention. Overseeing the price of medications would not only reduce financial barriers for patients but also encourage companies to innovate their products, enforcing the advancement in health care and expanding the responsibility of the public’s health.

The Inflation Reduction Act provisions would allow the government to negotiate the prices of select prescription drugs covered by Medicare Part B and Part D. Currently, Medicare Part D covers retail prescription drugs through private plan sponsors working with pharmacies. However, the Noninterference Clause under Part D prevents the HHS Secretary from intervening

in these negotiations. This limits the government's ability to reduce pharmaceutical prices which are set by private companies and sold at high costs. Medicare Part B drug prices are also outside the HHS Secretary's control and are determined by provider reimbursements, meaning costs can vary widely. The article "Explaining the Prescription Drug Provisions in the Inflation Reduction Act" discusses how this act would amend the noninterference clause by granting the HHS Secretary authority to negotiate directly with drug companies, establishing a maximum fair price as an upper limit for negotiations [8]. Non-compliant drug companies would face tax penalties but could avoid these fees by withdrawing all their Medicare-covered products. The impact on patients will largely depend on which pharmaceutical drugs qualify for negotiation, as there are specific criteria determining eligibility. Additionally, the extent of price reductions achieved will shape the overall effect on patient out-of-pocket costs.

The role of state-authorized prescription drug-pricing boards in the U.S. is to negotiate with drug manufacturers to address rising drug costs. The study "Pursuing Value-Based Prices for Drugs: A Comprehensive Comparison of State Prescription Drug–Pricing Board" reviews six boards in New York, the Drug Accountability Board (DAB) and the Medicaid Drug Utilization Review Board (DURB), Massachusetts, Maine, Maryland, and New Hampshire, highlighting their varying structures, scopes of authority, and effectiveness in negotiating with drug manufacturers [9]. Each board utilizes a different combination of leverages ranging from binding upper payment limits to public reporting in an effort to lower drug prices and achieve value-based pricing. All state boards besides Maryland and Maine can also Compel Manufacturers to Report Confidential Information while New York and Massachusetts have the additional power to impose penalties if manufacturers fail to provide the required information [9]. Despite the various methodologies and circumstances of each of these boards, only New

York's Medicaid DURB has completed pricing reviews which have successfully reduced the prices of two prescription drugs [10]. While this study sheds light on a valuable resource in making prescription drugs affordable, it also questions the efficacy of drug-pricing boards with a limited scope of authority and legal frameworks under which they can operate. New York DURB's success demonstrates that drug-pricing boards equipped with the right leverage, authority, and alignment with their state's political landscape can make significant impacts on the prescription drug market. The current challenge of replicating this success is largely due to the lack of transparency as negotiations between state boards and manufacturers are private and a lack of synergy among factors that support effective drug-pricing boards [6].

In the article "California Moves to Cap Health Care Costs at 3%" by Ana B. Ibarra describes an ambitious plan that was introduced by California's Office of Health Care Affordability to control rising health care costs. The proposed plan describes goals to limit annual health care cost increases to a staggering 3%, aiming to slow the steady rise of medical expenses that have long outpaced wages in the state [11]. While this cap could make healthcare costs more affordable over time, its immediate effects are subtle, and do not bring enough change to create a lasting impact. Overall, there is ambivalence in regards to the plan: consumer advocates view it as a positive step toward controlling costs, while healthcare providers argue that it's unrealistic. Providers warn that the cap will lead to reduced access to care if they are forced to cut services when meeting financial targets [12]. Despite the concerns, experts believe that slowing cost growth would eventually alleviate the financial burden on Californians. While the cap is an operational idea in theory on curbing rising expenses, its long-term success and efficacy depends on its implementation and whether it addresses the concerns of both consumers and providers.

The California legislature is nearing the end of the process of enacting the bipartisan bill, SB966, which creates a regulatory body for pharmacy benefit managers in efforts to reduce the ballooning cost of prescription drugs in the state. In the past 5 years costs have risen 39% to $12.1 Billion. Democrat Scott Wiener, one of the authors of the bill, states that, “They’re way overdue for regulation.” [15] CVS Caremark, Express Scripts and OptumRx represent more than 80% of the market and according to Stanford professor of medicine Kevin Schulman, “research shows they have only ever driven drug prices up—not down.” The pharmacy benefit manager interest group has argued that pharmaceutical companies are the cause of skyrocketing drug prices and that the bill would not allow employers to leverage the cost containment solutions used in the last 10 to 20 years and raise health insurance premiums. However, this fails to mention that pharmacy benefit managers exclude cheaper biosimilars and generic drugs from the formulary so that they may reap higher benefits. While pharmacy benefit managers were intended to save consumers money, their consolidation and perverse incentive to profit have left both consumers and governments with higher costs. SB966 is a necessary tool to begin the cost to reign in the industry giants through policy [16]

CONCLUSION

Private pharmaceutical companies are one of the most important stakeholders when considering shaping the cost and accessibility of essential medications and treatments. Their profit-driven pricing strategies clash with the nation’s need for affordable healthcare. By exploiting monopolistic practices, patents, and market dynamics, these companies prioritize investor returns over equitable access to prescription drugs. This has led to widespread financial strain on patients, healthcare systems, and healthcare workers, especially those in marginalized communities.

Addressing this issue *requires* government intervention to regulate pricing practices and increase transparency. Policies like the Inflation Reduction Act and state-level prescription drug-pricing boards bring promising steps to the table of holding pharmaceutical companies accountable. Additionally, enforcements of code of conduct and implementations of measures to prevent price gouging, such as stricter supervision of pharmacy benefit managers and patent reforms, can help to counteract these corrupt practices.

Ultimately, private pharmaceutical companies must reinforce their profit motives with their responsibility to ensure public health at the forefront of it. Through collaboration between policymakers, healthcare providers, the public, and the industry, a more equitable approach can be achieved—one that fosters innovation whilst ensuring equal access to affordable prescription medications for all.

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