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REGULATING BIG PHARMA

By Alexa Shumway

INTRODUCTION

Big Pharma *– large international companies that dominate the pharmaceutical industry*

The influence of **Big Pharma,** the common name for the types of pharmaceutical companies that control the majority of production, is everywhere. Johnson & Johnson, for example, manufactures products needed by a vast array of consumers across the globe like Tylenol, a COVID-19 vaccine, and Band-Aids (Johnson and Johnson, 2023). Pharmaceutical giants like Johnson & Johnson have become deeply integrated into several parts of the healthcare industry, from pain management to skincare. Pharmaceutical giants gain and maintain their influence by targeting both patients and providers as their consumers. Given the incredible reach of the healthcare industry, having so few companies control so much of it puts both the quality of care and democratic systems at risk.

To mitigate the consequences of this oligopoly, policymakers have moved to implement more regulations on pharmaceutical companies. A current area of concern is the affordability of prescription drugs. The issue is more complex than simply making pharmaceutical companies sell their products cheaper. Low prices come at the expense of less capital available to invest in innovation in the form of research and development (Blumenthal et al., 2021). When drugs are less profitable for pharmaceutical companies, these companies are less likely to invest in drugs that have fewer consumers.

Therefore, while the US is a global leader in pharmaceutical innovation, American consumers pay significantly more than those from other countries for prescriptions (Ginsburg and Lieberman, 2021). In an effort to improve affordability, some lawmakers have proposed various regulations that seek to make drugs cheaper without compromising innovation. Nevertheless, prescription drugs in the US remain more expensive than in any other country.

EXPLANATION OF THE ISSUE

Historical Development

One of the first attempts to regulate drugs in the United States was the Harrison Narcotics Act of 1914. This law regulated the use of narcotics found in medicines including heroin, opium, morphine, and cocaine (McGrath, 2023). This regulation was an important step by the United States to better protect its citizens from addictive pharmaceuticals. The pharmaceutical industry continued to grow throughout the 20th century and, by the middle of the century, had grown to become the most profitable industry in the United States (Singer, 2020).

In 2018, the United States spent over $535 billion on prescription drugs, which is 150% more than in 2010 (Ahmed and Meller, 2019).

In 1951, pharmaceutical companies greatly expanded their use of marketing. Pfizer, a pharmaceutical company, set aside $7.5 million to market a new antibiotic, Terramycin. Prior to 1951, no company had invested this much into their marketing budget. To spearhead their unprecedented marketing campaign, Pfizer hired advertising executive and psychiatrist Arthur Sackler. Using his experience working with Terramycin, Sackler later developed an opioid called OxyContin and used similar marketing techniques to sell the drug. The introduction of OxyContin is thought to be the cause of the opioid crisis (Singer, 2020). According to the Centers for Disease Control and Prevention (CDC), in 2020, 75% of drug overdoses were from opioids ("Data Overview," 2023). Additionally, opioid deaths hit a record high in 2021 with 80,411 opioid-related deaths ("Drug Overdose Death Rates," 2023).

Scope of the Problem

Most pharmaceutical regulation focuses on addressing two issues: affordability and accountability. In polls conducted by Kirzinger, et al., 79% of United States residents believe that the cost of prescription drugs is unreasonably high. In 2019, 29% of adults reported taking less medication due to cost . In the case of insulin, this cost-related rationing has even resulted in death. Additionally, 70% of Americans think that lowering the cost of prescription drugs should be Congress's top priority regarding health policy (Kirzinger et al., 2019). The desire to lower costs is mostly directed towards large pharmaceutical companies which, 78% of Americans "are making too much money" (Kirzinger et al., 2019).

Per capita *– per person*

It is difficult, however, to reconcile these immense costs with the perception of immense gain in drug development. Despite a wide-scale lack of accessibility to affordable drugs, 59% of Americans believe that prescription drug developments over the past 20 years have improved health outcomes (Kirzinger et al., 2019). Americans

clearly value the quality, range, and effectiveness of treatments being developed, primarily by Big Pharma.

According to a study run by Gallup, a management consulting firm, in 2019, 58% of Americans viewed the pharmaceutical industry negatively, which is the lowest rating since Gallup started its industry polls (McCarthy, 2019). With so many Americans wanting a change to the healthcare system and less power to rest in the hands of large pharmaceutical companies, the problem of making drugs more affordable without compromising quality and availability is questioned.

This image above shows the tradeoff between affordability and innovation.

[erhui1979, Getty Images]

Ineffective Spending

The United States spends more **per capita** on healthcare than any other country in the **Organization for Economic Co-operation and Development (OECD)**. To be precise, the United States spent $12,318 per capita on healthcare in 2021 ("How does the US Healthcare System Compare...," 2022). Of these $12,138, $1,000 accounts for administrative costs, a sum that is over five times the OECD average. With this ineffective spending by the US government, American patients are paying more for healthcare with fewer benefits. Additionally, Pharma spends millions of dollars on government relations: from 2016 to 2020, pharmaceutical companies spent over $800 million on political contributions and lobbying (Blumenthal et al., 2021). To regulate Big Pharma ineffective government and pharmaceutical company spending needs to be examined.

Fear of Declining Innovation

Intellectual property *– idea or product spawned from one's own creativity*

Many industry leaders fear that a decrease in revenue would stifle innovation. According to the Congressional Budget Office, a reduction in the revenues of Big Pharma would lead to two fewer drugs developed in the next 10 years, 23 fewer drugs in the next 20 years, and 34 fewer drugs in the next 30 years (Blumenthal et al., 2021). Although losing the innovation of two new drugs in the next 10 years to many is a small price to pay for affordability, a loss of 34 drugs in the next 30 years could be more concerning. Despite the reduction in revenue for large pharmaceutical companies, the 2/3 of new drug patents in 2018 were filed by small pharmaceutical companies outside of Big Pharma. Due to the potential loss of innovation, policy makers must consider how to best regulate Big Pharma in a way that preserves both the innovation of the American pharmaceutical industry and equitable access of these drugs to the American public.

Consumer Affordability in the US

Pharmaceutical prices have been on the rise in recent years in the US. In 2021, American drug prices were 256% of the average price

of drugs in 32 countries with comparable economies (Mulcahy et al., 2021). The US government is not responsible for paying the majority of healthcare costs, unlike other European countries, and thus has less power to push down the price of drugs (Smith, 2022). Additionally, the US also has strongly protected **intellectual property** and **patents** for the last 20 years. ("Frequently Asked Questions," 2020). This combination of lack of efficient negotiation and regulation on pharmaceutical companies and long patents has led to an unaffordable consumer landscape.

Patent *– a government license confirming sole ownership of a piece of intellectual property for a specified period of time*

Congressional Action

Despite agreement between politicians and the American public that pharmaceutical drugs need to become more affordable, enacting substantive regulations on Big Pharma has proven challenging. In the search for effective policy today, it is helpful to turn to the past in search of lessons on reining in the prices of drugs. For example, the 2021 Elijah Cummings Lower Drugs Costs Now Act (H R 3) was passed by the House of Representatives in 2021 (Ginsburg and Lieberman, 2021). This bill would have allowed for the Secretary of **Health and Human Services (HHS)** to determine drug prices through formulas, negotiations, and impose penalties on pharmaceutical companies that do not sell drugs at the set price. However, the bill failed to pass the Senate (Ginsburg and Lieberman, 2021). While this legislation failed to be enacted the passage of the Inflation Reduction Act

Department of Health and Human Services (HHS) *– a department in the executive branch that protects the health of American consumers*

Other Policy Action

Instead of setting price caps, the Trump administration took a different approach to lowering costs. In July 2020, former President Donald Trump issued an executive order opening imports of drugs from Canada ("Congress Must Take Action," 2020). Although this executive order went into effect, no state that has filed a petition with the US **Food and Drug Administration (FDA)** has been successful in its efforts to import drugs from Canada. States such as Florida, Colorado, New Hampshire, and New Mexico have all filed with the FDA, but have yet to be approved (Galewitz, 2022).

Food and Drug Administration (FDA) *– federal agency that protects public health and regulates drugs*

In other countries, different approaches have been taken to ensure affordable and quality healthcare. In Sweden, the **Dental and Pharmaceutical Benefits Agency (DPBA)** sets the prices of drugs, typically with negotiation of companies. Nevertheless, the DPBA has the final say on pricing (Appelgren et al., 2021). The DPBA considers factors such as cost-effectiveness, marginal utility, and what group the drug is targeting (Appelgren, et al., 2021). With these factors in mind, the DPBA can produce a holistic assessment of the pricing of the drug.

IDEOLOGICAL VIEWPOINTS

Conservative View

Dental and Pharmaceutical Benefits Agency *(DPBA)* – *Swedish regulatory body that determines drug pricing and monitors drug profitability*

Both conservatives and liberals believe that drug costs need to be lowered but have different policy approaches. In general, conservatives are highly supportive of requiring drug companies to include prices in ads and increasing the number of generic drugs available. Ninety percent of Republicans support greater price transparency and 85% support expanding generic drug access (Kirzinger et al., 2019). A key difference from the liberal view is that many Republicans do not believe that taxes should be levied on pharmaceutical companies, with only 48% of Republicans supporting higher taxes on pharmaceuticals (Kirzinger et al., 2019). Conservatives are generally wary of government intervention such as price ceilings in free markets.

Liberal View

The Trump Administration and some states have begun to explore the idea of importing drugs from Canada. *[AlexLMX, Getty Images]*

Liberals, like conservatives, believe that drug companies should list drug prices in their ads and generic varieties should be easier to move to the market phase, with 90% support for the former policy and 89% for the latter policy among Democrats (Kirzinger et al., 2019). Additionally, liberals support government negotiations with pharmaceutical companies, with 90% of Democrats supporting negotiation compared to 80% of Republicans (Kirzinger et al., 2019). Lastly, the majority of liberals want to provide tax incentives for pharmaceutical companies with high prices to lower them, including raising taxes on companies selling overpriced drugs. Seven out of ten Democrats would agree with such a proposal (Kirzinger et al., 2019). Liberals generally tend to value affordability and public sector intervention as opposed more lax market-based approaches.

AREAS OF DEBATE

Imported Drugs

One option to challenge the dominance of Big Pharma is to allow the importation of foreign drugs. Former President Donald Trump initiated a framework for doing so through trade with Canada (Neuman et al., 2021). A study conducted by Mulcahy et al. found that Canadian drug prices were only 46% of drug prices in the United States (Mulcahy et al., 2021). Florida Governor Ron DeSantis claims that his state's plan for drug importation from Canada could reduce healthcare costs for the state by $80-150 million in one year (Neuman et al., 2021).

Proponents of this plan argue that importing drugs is a way to create more affordable drugs without sacrificing innovation. If drugs are already on the market as generic in other countries, the drugs will be cheaper, but this still leaves room for pharmaceutical innovation in the United States. Importing generic drugs still allows pharmaceutical companies to capitalize on specialty drugs that they reserve the right to produce.

Partnership for Safe Medicines and the Council for Affordable Health Coverage argued that drug safety would decline with the introduction of imported foreign drugs and sued the United States government as well as petitioned against Florida and New Mexico's filings with the FDA (Neuman et al., 2021).

Opponents of this plan argue that the importation of drugs could lead to an increase in counterfeit drugs and could put the health of American consumers at risk (Neuman et al., 2021). Additionally, some opponents also argue that Canadian leaders do not support exporting drugs to the United States. The Government of Canada has stated that if the United States imports significant quantities of Canadian drugs, Canadian residents may find it more difficult to obtain the medication they need (Neuman et al., 2021).

Political Perspectives on this Solution

Conservative policymakers have tended to support this policy more than liberal policymakers. Among voters, however, 76% of Republicans and 78% of Democrats support drug importation from Canada (Kirzinger et al., 2019). The biggest challenge in passing pharmaceutical trade legislation is not convincing voters, but convincing several other stakeholders. The biggest opponents of foreign drug importation are US-based pharmaceutical companies and foreign governments. Delegates should consider the international impacts of importing drugs into the US and the amount of bipartisan support on this solution when considering implementation.

Peg Medicare Prices

Peg *– set equal to a fixed amount*

Another opportunity to regulate Big Pharma is to **peg Medicare** drug prices to the prices of drugs abroad (Nathan-Kazis, 2020). The idea behind this proposal is to peg the prices in Part B of Medicare, the section that covers prescription drugs, to the prices in other OECD countries (Nathan-Kazis, 2020). Pegging Medicare prices could benefit older Americans in particular, who are the main beneficiaries of the federal health insurance program.

Medicare *– federal health insurance program for United States citizens 65 years old or older*

Proponents of this policy think that it will help the elderly population and that innovation will not be substantially stifled.

Opponents think that the policy is not as simple as it is proposed above and that foreign list prices are not a good indicator of true value (Gardner, 2018). For example, 11 of 13 advanced economies have confidential **rebates** with pharmaceutical companies. Additionally, opponents also think that the policy ignores negotiations between Medicare and pharmaceuticals as an important price reduction tool (Gardner, 2018).

Rebates *– partial refund, in this case discounts on drug prices*

Political Perspectives on this Solution

In general, conservatives support this approach and think that it will lower drug prices without a significant decrease in innovation since the move only affects those on Medicare and not the entire population. Liberals tend to oppose this solution because it does not accurately account for rebates in socialized medical systems. Pharmaceutical companies also tend to oppose this policy as it does decrease their profits on drugs sold to Medicare consumers. Delegates should consider whether the international drug market is stable and the ease at which it would be to peg Medicare prices.

Authorize the HHS to Set Prices

Another potential solution to address rising drug costs is to have the Department of Health and Human Services (HHS) set prices for drugs ready for the market (Ginsburg and Lieberman, 2021). Establishing a price ceiling in markets for which a monopoly exists can theoretically lower prices without inducing a shortage. However, price ceilings can easily lead to supply issues.

Limitations could also be implemented to secure support for this policy by limiting jurisdiction to specific drugs with high profit margins or only allowing HHS to decrease the price by a certain percentage in negotiations.

Pictured above is collaboration and discussion, similar to that which would occur in HHS discussing with pharmaceutical companies.

[andreser, Getty Images]

Proponents of this policy argue that allowing the HHS to set drug prices would streamline the process and ensure that affordability is a top priority. With the HHS at the top of the chain of command, the federal government would be able to efficiently select prices that are fair to both the pharmaceutical companies and American consumers.

Opponents of this policy argue that it would limit innovation and push out smaller pharmaceutical companies that cannot afford reduced revenues out of the industry. Additionally, opponents argue that abuse of power could occur if HHS had too much authority over setting prices.

Political Perspectives on this Solution

Conservatives tend to disagree with this policy and argue that it stifles pharmaceutical innovation. Conservatives may also argue that this concentration of power in the HHS places too much control in the hands of the government and not enough control in the people and companies. Liberals tend to agree with price controls, but many liberals do not necessarily support unilateral price-setting power by the HHS (Leonard and Reader, 2022). Senator Marco Rubio (R-FL .) argued that companies will not invest in new treatments without a large profit margin and that drug prices should not be lowered in a way that undermines the development of new drugs (Ollstein, 2022). Delegates should consider how their district views the role of the

government in healthcare and how to create bipartisan support for a solution within existing infrastructure.

Arbitrator *– an independent group or individual that settles a conflict*

Independent Arbitrator Sets Prices

Instead of using the HHS to influence prices, another option to regulate Big Pharma is to use an **arbitrator** (Ginsburg and Lieberman, 2021). This would allow an independent group to regulate drug prices. The HHS and the pharmaceutical company would pick a price they would like the drug to be, and an arbitrator could either pick a price in between the two values or choose one of the two prices (Ginsburg and Lieberman, 2021). This could involve a new independent board or the existing **Provider Reimbursement Review Board (PRRB)** (Ginsburg and Lieberman, 2021).

Provider Reimbursement Review Board (PRRB) *– board used to settle Medicare disputes*

Proponents of this policy argue that the use of an arbitrator makes the process fairer and doing so leads to a price that does not favor the government or pharmaceutical companies. It allows for both more affordable prices and innovation to occur.

Opponents of this policy come from both sides of the political s spectrum. Some opponents of this policy argue that it gives too much power to the pharmaceutical companies and will not achieve enough affordability. Other opponents of this policy argue that a federal board such as the PRRB might have a bias towards the HHS and tend to rule in favor of their needs.

Drugs are becoming too expensive for American consumers.
[Tero Vesalainen]

Political Perspectives on this Solution

Conservatives tend to be skeptical of arbitration, although they may favor it over a policy that vests power in HHS. In general, conservatives value innovation at the cost of affordability. Liberals, on the other hand, tend to support independent arbitration but have not shown a clear preference for using the HHS as a negotiator directly. Pharmaceutical companies also tend to prefer this policy over the HHS setting prices as they have better negotiating power when working with an independent arbitrator. Delegates should consider the feasibility of establishing an independent arbitrator and whether it would gain bipartisan support depending on the methodology of arbitration.

Evaluating Patents

One way to regulate Big Pharma is to reduce patent life and increase regulations. Currently, patents are 20 years in length in the US and new brand biologics are guaranteed 12 years of exclusivity on the market (Komendant, 2023). Pharmaceutical companies also often file new patents to allow for longer time to sell their drugs. On average, 2/3 of pharmaceutical patents are filed after FDA approval (Lovelace, 2022). By reducing patent life to and creating stricter

regulations surrounding additional patents on approved drugs, drug affordability could increase.

Proponents of the policy think that it will lead to more affordable prices as there will be more generics on the market and more opportunities for smaller pharmaceutical companies to grow. With shorter patents and increased regulation over post-approval patents, the drug market should be more accessible to Americans.

Opponents of this policy believe that it will limit innovation as pharmaceutical companies will have less financial motivation to produce drugs, especially ones that have less lucrative markets. This may put potential customers for these less profitable drugs at risk of not receiving the treatment they need.

Political Perspectives on this Solution

Conservatives tend to disagree with this policy because they believe it would limit innovation and decrease incentiveS to produce high-quality and quantity drugs. Liberals especially support the provision to limit unnecessary patents, although have mixed opinions on decreasing patent life. Delegates should consider what the optimal patent length is for both affordability and innovation, and how to best reduce misuse of patent law and regulations.

BUDGETARY CONSIDERATIONS

The HHS receives $2.8 trillion in Fiscal Year 2023 ('Department of Health…', 2023). Of this sum, the HHS has already committed $1.5 trillion to existing obligations for the current fiscal year ('Department of Health', 2023).

CONCLUSION

Reining in Big Pharma is a difficult goal, one that Congress has struggled to accomplish for decades. At the crux of the problem is the tradeoff between innovation and affordability. From importing foreign drugs to pegging Medicare, there are many ways to approach regulation and reconcile both affordability and innovation.

As drug prices continue to rise, immediate action is necessary to ensure that all Americans have access to a reliable supply of high-quality drugs. It is now up to the House Committee on Energy and Commerce to fix these issues and help Americans obtain the drugs they need.

There are many ways to solve this issue. Accordingly, the policies listed above are not an exhaustive list of all of the ways to approach this topic. A solution can include one of the policies, a combination

of the policies, or none of them at all. The House Committee on Energy and Commerce is looking forward to hearing solutions to regulating Big Pharma at HMC Boston 2024.

GUIDE TO FURTHER RESEARCH

Delegates should review databases and libraries in order to find reputable sources. I used my school library database, as well as Google Scholar. It is important to look at the credibility of each source you use.

In particular, I would recommend conducting additional research at sources such as USASpending, the CDC, the National Institute on Drug Abuse (NIDA), Health Affairs, Center for American Progress, RAND Corporation, Brookings Institution, and the Commonwealth Fund.

For general information about the House Committee on Energy and Commerce, I would recommend going to energycommerce.house.gov. For more information on regulating Big Pharma, I would recommend using your local library and online databases for reliable information.

GLOSSARY

Arbitrator – an independent group or individual that settles a conflict

Big Pharma – a group of large international pharmaceutical companies that dominate the industry

Dental and Pharmaceutical Benefits Agency (DPBA) – Swedish regulatory body that determines drug pricing and monitors drug profitability

Food and Drug Administration (FDA) – federal agency that protects public health and regulates drugs

Department of Health and Human Services (HHS) – a department in the executive branch that protects the health of American consumers

Intellectual property – idea or product spawned from one's own creativity

Medicare – federal health insurance program for United States citizens 65 years old or older

Organization for Economic Co-operation and Development (OECD) – an intergovernmental organization that consists of democracies with market economies

Patent – a government license confirming sole ownership of intellectual property for a specified period of time

Per capita – per person

Peg – set equal to a fixed amount

Provider Reimbursement Review Board (PRRB) – board used for Medicare disputes with three-year term limits

Rebates – partial refunds, in this case discounts on drug prices

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