“The Cost of America’s Identity Crisis: Rising Pharmaceutical Prices Among a Fragmented Regulatory System”

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I. Introduction

In July of 2002, the list price of a vial of insulin, one of the most broadly needed medications in the United States, was under fifty dollars. For 1.25 million people in the U.S. with Type I Diabetes, this meant that their self-sustainment, a grueling task requiring daily insulin injections, was largely affordable. As of July 2016, however, the price of insulin skyrocketed by approximately three hundred percent, and rose to almost three hundred dollars per vial (Ramsey). Diabetes patients in today's world thus face an inescapable reality that plagues our country, affecting almost *everyone* in our population: the astronomical cost of healthcare in the United States. In 2017, nationwide healthcare costs skyrocketed to 3.5 trillion dollars, meaning that the average U.S. resident spent $10,739 that year (National Health Expenditures 2017 Highlights). This fact, coupled with a median household earning of about $62,000 a year in the United States, means that Americans are spending over a sixth of their annual earnings just towards their healthcare costs (Guzman). Gazing beyond the statistics, many middle-class American citizens have relatives, friends, and colleagues that are personally suffering from chronic, progressive

medical conditions requiring intensive treatment that they cannot afford to pay for. It is evident that this dilemma has stemmed into a self-perpetuating epidemic, and one that is only worsening.

The large proportion of both these national and individual healthcare costs that this paper will focus upon is dominated by the American pharmaceutical industry, which supplies patients with prescription drugs and treatments for thousands of illnesses. Retail prescription drug spending constitutes approximately 10% of the American health care market, a staggering 333 billion dollars in 2017 (National Health Expenditures 2017 Highlights). Without context, however, these numbers and statistics are meaningless. The true lapse in our system emerges when American costs and spending are compared with that of other countries. For example, in referencing "nine other high-income countries," such as Switzerland, Germany, and France, Dana O. Sarnak states, "by 2015, U.S. spending on pharmaceuticals… was 30 percent to 190 percent higher than in the other nine countries." Shockingly, Sarnak also exposes that in a 2017 international survey, 14 percent of U.S. citizens reported declining or skipping their medication due to costs, compared to just 10 percent of citizens in the next highest-rated country (Sarnak, Squires, and Bishop). All the while, this exuberant spending is not leading to better clinical outcomes in the United States. In fact, according to the Peter G. Peterson Foundation, "The U.S. actually performs worse [than other developed countries] in some common health metrics like life expectancy, infant mortality, and unmanaged diabetes" ("How does the U.S. Healthcare System Compare to Other Countries"). These statistics beg the evident question at hand: why are pharmaceutical costs so high in the United States compared to other developed countries?

The answer to this question is highly debated among healthcare workers, politicians, and economists alike, and there is no one obvious explanation. The true reasoning is broad and

systemic, rooted primarily in the widespread view of the United States' economy as a *pseudo*-free market with minimal regulation. This paper will closely examine the elements of a *true* free-market economy and discuss its infeasibility in the United States, instead arguing that the United States' economy, in reality, must synthesize socialist and capitalist ideology for a successful market. Next, this paper will dissect how American lawmakers' collective uncertainty in pharmaceutical regulation results in "selective socialisation" and "selective privatisation," finally analyzing specific policies and actions such as private negotiation, market exclusivity, and lobbying. Essentially, this paper argues that American lawmakers' inability to effectively synthesize free-market and socialist beliefs and their perception of our economy as a pseudo-free market leads to a combination of policies that unnecessarily raise prescription drug prices for consumers, making the self-management of health much more difficult for all of us.

II. America's Unique Economy: A *Pseudo*-Free Market

The United States' economy is undeniably complex and multifaceted. However, an overarching theme and differentiating factor that has long defined American economics in the larger global sphere is the presence of a capitalist free market largely unbound by government regulation. Many economists perceive the United States as a laissez-faire economy since, according to Yale graduate Alex Berenson, it has spent the past decade "[driving] growth by deregulating markets, lowering tax rates, and promoting trade" (Berenson), all characteristics of a free market. Theoretically, then, considering the definition of a free market economy itself, its presence implies that all U.S. costs are dictated purely by the laws of supply and demand and driven down by competing corporations. However, it is fairly common knowledge that this is not

at all the case, and that government regulation absolutely exists in America. This is largely because in the absence of a regulatory agency "checking" the moves made by corporate powerhouses, these free market systems are subject to easy manipulation by for-profit corporations with no real interest in the well-being of the general public. Thus, contrary to laissez-faire principles, it is the government's responsibility in maintaining a successful, thriving nation to recognize when its citizens are being mistreated by the private sector and passing regulation for the benefit of citizens.

The basic concept of a government's existing to facilitate the growth and well-being of its citizens gives rise to the dichotomy between government involvement in a true free market and in the American economy. When Congress enacts policy that protects citizens from corporate greed, it is essentially limiting the abilities of private businesses in doing so, thus completely violating the core principles of a laissez-faire economy. In the United States, lawmaking bodies use processes which can be called "selective socialisation" and "selective privatisation" to establish a balance between allowing private businesses to function independently within the laws of supply and demand and ensuring that citizens are not manipulated through this process. While the default policy choice in America's economy is privatizing, or giving free rein to industry, there are certain instances when the government transition service from a private commodity to a public utility. In this process, the buying and selling of the product is shifted from being regulated by the trends of supply, demand, and competition to often being *collectively paid for* by tax-payers or government funds and operating under state or federal law. This concept of "collectivity" or "one for all" essentially encapsulates a socialist market, while a free market is instead defined by an "each for their own" mentality. Through historical evidence

and repeated failures, American policymakers have realized that neither of these philosophies can operate completely independently, and are now operating in a mixture of the two systems in our pseudo-free market.

While an economy that synthesizes unique aspects of different systems to achieve a desired goal is not necessarily flawed, the United States' combination of directly opposing philosophies has led to an identity crisis on the part of both policymakers and citizens alike, a factor that we will later see has directly impacted the success of our domestic economy. According to a survey conducted by the Pew Research Center, "a large majority of Republicans and Republican-leaning independents (68 percent) had both a positive impression of capitalism and a negative view of socialism." Even among Democrats, only 38 percent viewed *both* socialism and capitalism in a positive light (Meyerson). Although the larger Democratic view was not included in the study, we can infer that a substantial portion of this party may have viewed socialism positively and capitalism negatively. This polarization of various parties leaning heavily towards one end of the free-market/regulation spectrum has led to heavy debate for years regarding the level of regulation needed in our economy, and more importantly, a lack of acceptance of the fact that both laissez-faire and regulatory principles are needed to coexist and build off each other for a successful economy. For example, in a 2017 policy statement by the Committee for Economic Development of the Conference Board, it was stated that "there is an elegant efficiency in the market price system… but there is still a role for government where markets fail to price goods and services to reflect social values" (Regulation & The Economy). Although this perspective may seem limited in its implications, it is largely the thought process that drives the U.S. economy. This concept of using government regulation on a discretionary,

case-by-case basis to duct-tape together the cracks of a free-market economy seems largely unsustainable, and an inadequate reason to bring together these opposing philosophies. From this perspective itself, we can realize that the United States is not seamlessly synthesizing these different economic systems to create a thriving economy, but instead using regulation as almost a sloppy cover-up for the weaknesses of a free-market. Thus, American lawmakers are struggling to grapple with our identity as a mixed economy, instead polarizing our lawmaking bodies and insisting on the existence of an economy that more closely resembles a *pseudo*-free market.

III. Selective Privatization in Pharmaceuticals

Now that this paper has thoroughly dissected our country's unique economic structure and its associated flaws, we can more easily understand the driving forces behind specific pharmaceutical policies which contribute heavily to high prescription drug costs. One of the greatest disparities between pharmaceutical power distribution in the United States and other high-income, developed countries is governmental negotiation power in drug pricing. Many European countries' pharmaceutical systems operate under single-payer insurance plans, meaning that a singular governmental insurance agency must buy medicine in bulk from pharmaceutical companies to provide coverage to the country's citizens. Thus, this agency has the power to negotiate down drug prices, as pharmaceutical companies *must* sell to this agency in order to have their drugs reach the public market. In the United States, however, "there are thousands of health insurance plans all across the country. Each has to negotiate its own prices with drugmakers separately. Because Americans are fragmented across all these different health insurers, plans have much less bargaining power to demand lower prices" (Kliff). Private

insurance plans, as described by Sarah Kliff, are a unique facet of the United States healthcare system and another product of the free-market ideology of privatisation. Among this system, in which each insurance plan independently negotiates prices, one may argue that there is no real need for governmental negotiation. However, there is one governmental insurance plan in the United States that has retained a relatively high potential negotiatory power: Medicare. According to Jordan Huffman, "more than 39 million Americans receive pharmaceutical drug benefits under Medicare Part D, which accounts for approximately 23% of pharmaceutical drug purchases within the United States" (Huffman 232). Therefore, we can conclude that analogously to large insurance plans in other countries, Medicare buys drugs in bulk stock and should theoretically be able to negotiate down costs with pharmaceutical companies to ensure that it purchases medicine at the optimal price for its clinical benefit to patients. However, due to the free market ideologies, or "selective privatisation," of the U.S. economy, this is far from the reality.

In November of 2003, Congress passed the Medicare Modernization Act (Megellas), the language of which "specifically prohibits the government from being involved in the negotiations for the prices of drugs included in the [prescription drug plan's] formularies" (Huffman 232). Currently, instead of having the government negotiate down drug prices, we rely on pharmacy benefit managers, private companies that exist to manage prescription drug plans on behalf of insurers, to carry out this task. This is counter-intuitive because pharmacy benefit managers are for-profit companies, meaning that they generate revenue from both pharmaceutical companies and from the insurance sponsor (Medicare Part D, in this case) for their services (Morse). Thus, they have a conflict of interest to generate revenue to meet the sales

goals characteristic of a for-profit company, rather than worrying about the well-being of patients. Furthermore, since multiple pharmacy benefit managers negotiate on behalf of a single pharmacy drug plan sponsor, this practice fragments the system further, giving these companies much less negotiating power than a single governmental agency negotiating on behalf of Medicare Part D. An example of Medicare's low negotiatory power can be seen when contrasting prescription drug prices for Medicare and those for the Veteran's Health Administration, another insurer that negotiates its drug prices *independently*. According to Jordan A. Huffman, "the ability of the VA to both control its formulary and negotiate prices had both a dramatic and negative impact on the prices it paid for its drugs, with this same study reporting that the VA paid on average only 60% of the prices paid by Medicare Part-D PDPs for the same drugs" (Huffman 233). With this evidence that American citizens covered by Medicare could easily pay much less for their prescription drugs if Medicare was allowed negotiatory power, the question at hand seems evident: Why doesn't Congress allow Medicare Part D to negotiate the price of prescription drugs?

Much of the reasoning given for the United States' disinclination to involve the government in pharmaceutical transactions traces back to the widespread belief in a *pseudo*-free market rather than a fully mixed economy. As stated by Jordan A. Huffman, one of the most prominent justifications for restricting Medicare's negotiatory power is that "the restriction allegedly protects the quality of the formularies available to Medicare Part-D enrollees" (233). On the surface level, this is *partially* true. In other countries in which governmental agencies participate in negotiatory efforts with pharmaceutical companies, there are certain drugs that do not make it to market, while these same drugs are made available to the general public of the

United States. According to Sarah Kliff , “Countries like Australia will often refuse to cover drugs that they don’t think are worth the price. In order for regulatory agencies to have leverage in negotiating with drugmakers, they have to be able to say no to the drugs they don’t think are up to snuff” (Kliff). In other words, for the United States government to help regulate the price of drugs covered by Medicare Part D, they would have to use their judgement to decide *on behalf of the American public* which drugs are “worth it” for their price. The rejection of this largely socialist principle by many American citizens, as well as the majority of lawmakers, reflects the widespread American belief in government’s role as merely a last resort in economy. In fact, the Medicare Modernization act discussed earlier also mandates that Medicare Part D’s formulary, or list of drugs covered for those enrolled, contain a widespread array of drug in *each* of the 41 therapeutic categories defined by the law (Megellas). This is an additional, largely unnecessary precaution taken to make sure that negotiatory agencies do not interfere with Americans’ receiving the treatments they need, and yet another factor that limits the power of these bodies against high prescription drug prices. The true folly of both this policy and the belief that government negotiation will restrict drug choices is revealed when looking at clinical outcomes for countries in which the government plays an active role in negotiation, which, as seen before, often fare better than the United States itself in many common metrics (“How does the U.S. Healthcare System Compare to Other Countries”). By observing the systems of other countries and even insurers in the United States, we can infer that American lawmakers must have been aware of both the better clinical outcomes *and* potentially lower drug prices when Thus, we see that it is not logic and reasoning, but rather an irreversible rejection of active government

participation in the economy, that has removed Medicare's negotiatory power in the United States.

IV. Selective Socialisation in Pharmaceuticals

While the privatisation of drug costs in the United States forces citizens to pay much more for prescription drugs than is necessary, this alone has not caused a crisis of the magnitude that we are witnessing today. Theoretically, if our pharmaceutical industry truly followed the rules of a free-market economy, competition from generic brands would drive down drug costs in the absence of governmental regulation. However, as with most completely free-market sectors in the United States economy, government regulation is used to fill the cracks of privatisation. In the case of pharmaceutical companies, the most prominent problem with a fully privatised economy is, in fact, unrestricted competition with generic brand corporations. According to Aaron S. Kesselheim et al., "industry often makes expensive investments in drug development and commercialization, particularly through late-stage clinical trials, which can be costly" (Kesselheim, Avorn, and Sarpatwari). Although this shows that large corporations spend significant time and money into the research needed to produce a new drug, the compound still becomes easily replicable by other companies upon publication. In a free market, these companies can then avoid the rigorous trial-and-error process that pre necessitates a new product and can afford to undercut the original compound prices, thus causing the original drug-maker to lose resources and therefore be de-incentivized to further invest into product development.

To prevent the waste of industrial resources and to further incentivize pharmaceutical companies to invest in research, the American government has intervened and posed one of the

only regulations on the pharmaceutical industry other than testing and safety laws: market exclusivity. “Protected by monopoly rights awarded upon Food and Drug Administration Approval and by patents” (Kesselheim, Avorn, and Sarpatwari), market exclusivity is essentially a policy that prevents other manufacturers from replicating a compound for a certain period of time after it is put onto the market. On the surface level, this law makes sense to foster innovation, and it is working. According to Jasenko Karamehic et al., “in the last 35 years, and at a rate that especially accelerated in the 1990s, the United States of America became the worldwide leader for pharmaceutical research, clinical testing, marketing, and sales” (Karamehic et al.). With the combination of free rein in terms of negotiatory power and reduced competition from generic brands, pharmaceutical companies are more incentivized to invest money into research in America than any other country, but at what cost?

While market exclusivity, if enacted correctly, would be an excellent use of governmental regulatory power, there are several facts which prove that in reality, this policy contributes to a broken system that pointlessly raises prescription drug costs. First of all, pharmaceutical companies continuously abuse this system with no action being taken by the government to tighten restrictions on how market exclusivity can be attained. For example, product hopping, a practice commonly used by several large pharmaceutical companies, “involves a brand-name company switching the market for a drug, prior to its patent expiration date, to a reformulated version that has a later-expiring patent, but which offers little or no therapeutic advantages” (Jones et al.). This practice and manipulations similar to it should logically be protected against by tightened market exclusivity policies, as they cause consumers to pay the highest price for the drug for an unnecessarily extended period of time. However, these types of practices are

constantly taking place with no push-back from the government. Furthermore, and perhaps even more shockingly, the whole premise on which market exclusivity is based is also somewhat compromised. This regulation has been enacted with the justification of incentivizing pharmaceutical companies to invest in research by rewarding their expenditures with monopolistic control of industry. However, according to Alfred B. Engelberg, "taxpayers are spending $30 billion a year on basic biomedical research the benefit from which flows to the pharmaceutical industry free of charge" (Engelberg). Essentially, this means that much of the money that finances pharmaceutical research expenditure costs comes from American citizens. However, it is still us that have to pay higher prices for the same prescription drugs under market exclusivity. This notion, combined with the fact that pharmaceuticals are one of the most profitable industries in the world (Karamehic et al.), can easily serve as reason to believe that market exclusivity is not particularly *necessary* to pharmaceutical innovation, but rather just another contributor to drug manufacturers' excessive profitability. Once again, this short-sighted use of government regulation to merely fill in the cracks of a privatised economy rather than work in tandem with free-market ideologies seem rash, and certainly has costly implications

V. Lobbying – Divide and Conquer

In our thorough exploration of two major policies that define the pharmaceutical industry from a financial and regulatory standpoint, we come to a striking realization: both the free-market ideology used to argue against Medicare's negotiatory power *and* the government regulation implemented to foster research investments somehow work in the interest of large drug manufacturers. While fragmented, privatized negotiation agencies give industry

powerhouses more leverage in setting prices, market exclusivity strikes away all generic competition that may drive down costs and reduce profitability. This seems bizarre, as the purpose of government involvement itself is largely to protect its citizens. However, lobbying, a practice where corporations, non-profits, or even individual people donate money and resources to government committees and officials to influence them on a particular issue, plays an enormous role in this eventual outcome.

Once again, the causes for lobbying's effectiveness in the pharmaceutical industry branch back to the fragmentation and polarization of America's government. According to Melanie Senior, lobbyists often find themselves "turning to Capitol Hill, congressional committees, and/or individual members of congress, and persuading them, in turn, to put pressure on the FDA" (Senior 2). This strategy of targeting individual members and committees is particularly effective because, as discussed before, there is already much debate regarding regulation of industries in the U.S. government, and this is easily capitalized upon by the pharmaceutical industries. For example, lobbyists can further push a known free-market supporter to believe in privatised negotiation, while they can also speak to socialist-leaning democrats about maintaining market exclusivity and regulation. Pharmaceutical lobbying expenditure is thus put to good use because unlike the government, each major corporation in the industry is united in their goals to maintain high profitability, and they can therefore "divide and conquer" an already fragmented government, a game-changing factor in prescription drug costs.

VI. Conclusion

The rise in prescription drug prices across the United States is the clear product of a skewed perception of government's role in a mixed economy as well as political polarization that runs through lawmaking agencies and ordinary citizens alike. Upon both this paper's examination of specific policies in the pharmaceutical industry and its broad, structural overview of the American economy, it is easy to see America's economic identity crisis in the disjunction between the selective privatization and selective socialization in the pharmaceutical industry. Alfred B. Engelberg artfully summarizes this paper's findings regarding policy within the pharmaceutical agency, stating, "federal law essentially socializes the cost of drug discovery while privatizing the profits" (Engelberg). Essentially, while allowing taxpayers to face much of the costs of pharmaceutical research, policy also gives these same corporations the power to decide their own prices with minimal regulation. Therefore, while both free-market and regulatory ideologies are present in the industry, they absolutely do not seem to be working together. In fact, while they have been combined to incentivize pharmaceutical companies to innovate drugs, they fail to achieve adequate reasonable drug prices for American citizens. This itself makes it apparent that the combination of ideologies in American economy is more *reactive* to problems than proactive to counter the issues that could possibly arise. This *reactivity* can be traced back to the perception of government intervention "where markets fail to price goods and services to reflect social values" (Regulation & The Economy). This broad description of regulation itself is poised as almost a last resort rather than a useful tool, something that is reflected in how regulation is only enacted to tackle a specific problem in a certain part of the pharmaceutical sector, rather than holistically sprinkled *throughout* the industry to balance power between citizens, government, and corporations.

Not only has America's identity crisis caused haphazardly strung-together policies to dominate the pharmaceutical industry, it is also quite likely hindering progress in passing policies that fix our broken system. Since different parties are heavily polarized regarding how regulation should be employed in industry, there is likely much disagreement in Congress about *how* prescription drug prices should be lowered between preventing competition and increasing regulation. While these lawmakers and government officials grapple with the country's identity has a mixed economy, however, pharmaceutical corporations continue reaping the profits, and diabetics, stroke victims, and cancer patients throughout the country continue to pay the price.

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