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Competition in Healthcare Markets

12/7/20

A Comparative Analysis of Pharmaceutical Price Regulations in the United States

Within the United States, discussions regarding the pricing of pharmaceutical drugs have remained a hot-button issue for the better part of a decade. Public outcry, coupled with major health crises such as the Covid-19 pandemic and the subsequent economic instability of many of American households, have brought these debates to the kitchen table for the first time in many American's lives. The American public is often paying extraordinarily large prices for much needed prescriptions. Many are paying anywhere from 5% - 198% more than consumers in comparable national markets for the exact same brand name pharmaceutical products[1]. This apparent inequality has only become more pronounced with time, as the cost of many important products continues to balloon. With little to no external financial support, many consumers are suffering from the rapidly decreasing affordability. The causes for these increases are multivariate, however, many would heavily scrutinize the lax pricing regulations within the United States pharmaceutical market as a major influence. Currently, the United States is the only country that allows the pharmaceutical market to operate with virtually no regulation on drug prices [2] Every other global market has and continues to implement some form of direct or indirect pricing regulations to prevent the price-creep of brand name drugs and increase widespread affordability [3]. Some of the most commonly implemented pharmaceutical pricing regulations currently implemented across the globe are Direct Price Controls, Profit Controls, and Reference Pricing. The question remains: to address public outcry and what appears to be an economic crisis for many American residents, should the US implement pricing regulations on the pharmaceutical market? If so, which of the currently existing global models of regulations might bring about the most desirable economic result?

The Current United States Pharmaceutical Market

Before applying potential solutions, it is critical to provide an accurate assessment of the current state of the pharmaceutical market and industry within the United States. In its current form, the market prices of most pharmaceuticals are almost completely unregulated [4]. One of the few limits on the industry comes in the form of patent exclusivity due to the Hatch-Waxman Act. The Hatch-Waxman Act became public law in 1984, affording name-brand drug producers the ability to produce at a profit-maximizing level for several years after bringing their product to market by extending their patent life[5]. This profit-maximization approach can continue

[1] Panos Kavanos, Uwe Reinhardt "Reference Pricing for Drugs: Is it Compatible with U.S. Health Care?". *Health Affairs*, vol. 22, no.3 (healthaffairs.org, 2003), 3.

[2] Thomas Abbot, John Vernon. "The Cost of US Pharmaceutical Price Regulation: A Financial Simulation Model of R&D Decisions". *Managerial and Decision Economics*, vol. 28, (interscience.wiliey.com, 2007), 293.

[3] Ibid., 294.

[4] Ibid., 295.

[5] United States, Congress, Public Law 98-417. *An act to amend the Federal Food, Drug, and Cosmetic Act to revise the procedures for new new drug applications, to amend title 35, United States Code, to authorize the extension of the patents for certain regulated products, and for other purposes.* (S. Rept 98-547, 1984).

unfettered until their patent expires, at which point generic substitutes are permitted to enter the market and the prices decrease to a competitive level due to an increase in supply [6]. This period of protected profit maximization is what is most concerning, as there is a legal workaround that can almost indefinitely extend the profit maximizing behavior of a pharmaceutical producer. By innovating on their current drug design and releasing a new form of the current product before the patent-life expires, pharmaceutical producers can pull the supply of the previous drug to force the consumers to be prescribed the new variation of the drug with the extended patent-life. While generic producers can still enter the market based on the old design, the competition that they provide is substantially reduced, as many doctors and consumers are hesitant to switch to generic alternatives as there is little incentive to take the steps to do so. This cycle of "hard-switches" can be repeated for as long as a pharmaceutical company continues to innovate their products in a meaningful enough way that they are approved for a new patent before their previous one expires.

This cycle of profit maximization lies at the heart of the discourse regarding the US pharmaceutical market and pricing structure. While the prices can certainly remain high for the consumer due to the unregulated profit-maximization of producers and constricted market competition, the incentive for profit leads to the constant innovation of existing pharmaceutical products. In one study conducted using data from 1992-2004, the United States was responsible for 43.7% of all drugs containing new molecular entities (NME) [7]. The measure of NMEs is a valuable flag for the level of innovation produced by a pharmaceutical industry. The United States was also responsible for 40% of total Gross Domestic Product among the total number of countries whose innovations contributed to the development of NMEs [8]. However, the US was also responsible for 42% of total spending on prescription drug development in the global pharmaceutical market [9]. All this to say, the US contributes a vast number of innovative pharmaceutical products to the global marketplace that provide needed advancements that improve the well-being of many. By looking solely at the domestic results of innovation, it is apparent that there has been a measurable positive effect due to advances in drug efficacy and availability and the advancement of other medical technologies. From 1991 to 2004, US life-expectancy improved by 2.33 years on average [10]. While this change might not have been solely attributable to innovations produced by the pharmaceutical industry as there were several contemporary public health initiatives focused on combating health crises such as obesity and smoking, it was likely the largest contributor to observed decrease during the measured period [11].

Comparative Analysis of US and OECD Countries Health Outcomes

How does the United States life expectancy compare against other competitors in the global pharmaceutical markets who also ranked highly in NME contributions? As stated, the United States was responsible for 43.7% of patented drugs containing NMEs developed between

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[6] Ibid.

[7] Keyhanis Salomeh, et al. "US Pharmaceutical Innovation in an International Context*". Am J Public Health*, vol. 100(6) pp. 1075 – 1080. (Am J Public Health, 2010), 1076.

[8] Ibid.

[9] Ibid., 1077.

[10] Sundeep Mishra. "Does Modern Medicine Increase Life-Expectancy: Quest for the Moon Rabbit?". *Indian Heart J*, vol. 68, pp. 19-27, (Indian Heart J, 2016), 21.

[11] Ibid., 23.

1992 and 2004 [12]. However, this measure includes drugs developed in partnership with other countries. The number of NMEs developed solely in the US is closer to 36% [13]. The country responsible for the next highest number of NME development was the United Kingdom at 10% followed by Japan and Germany at 8% and 7% respectively [14]. In available data from the Organisation for Economic Co-Operation and Development that measures life expectancy in these countries from 2000- 2004, we can see an accurate comparison of the health outcomes of each country. The United States saw a 0.9 year increase in average life expectancy, the United Kingdom saw a 1.1 year increase in average life expectancy, Japan, a 0.9 year increase in average life expectancy, and Germany, a 1.0 year increase in average life expectancy (OECD). From this, we can see that the level of innovation of a specific market does not drastically improve the health outcomes in that country compared to other pharmaceutical markets with comparable levels of innovation. It also becomes clear that pharmaceutical innovation is not necessarily bounded by or as related to pricing concerns as many in the US might claim due to the international nature of most pharmaceutical developments [15]. While the United States certainly provides a significant portion of innovation to the global market, it is also the only country of those who contributed to NME development which does not implement any pharmaceutical pricing regulations in its domestic market. Furthermore, US spending on the pharmaceutical industry is far above competing countries, and when adjusted for relative spending per-capita, does not show a significant level of increase in innovation tied to countries with comparable spending [16]. Ultimately, this seems to indicate that for the most part, the lack of pricing regulations with the United States' pharmaceutical market does not necessarily have a significant correlation with its continued innovation as development capability appears to have a greater link with a country's level of wealth than it does with pharmaceutical pricing [17].

Among the three other countries mentioned in comparison to the US's level of NME production−the United Kingdom, Germany, and Japan−all have implemented some form of pharmaceutical price regulation. The United Kingdom implements a form of Profit Control to keep drug prices reasonably low [18]. Germany instead opts for a Reference Pricing model [19]. Japan, on the other hand, implements a form of Direct Price Controls [20]. Thus, of the top four domestic producers of innovative pharmaceutical products by the measure of patented NMEs, three of the four each implement different methods of pricing regulations with the US remaining as the sole hold-out for any meaningful pricing regulations whatsoever. With the goal in mind of finding a reasonable form of existing pricing regulation that can be abstracted and mapped onto the current US pharmaceutical market, a meaningful comparative analysis of potential regulation implementations can be conducted using the forementioned Profit Controls, Reference Pricing, and Price Control models.

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[12] Keyhanis Salomeh, et al. "US Pharmaceutical Innovation in an International Context*". Am J Public Health*, vol. 100(6) pp. 1075 – 1080. (Am J Public Health, 2010), 1076.
[13] Ibid., 1077.
[14] Ibid.
[15] Ibid., 1078.
[16] Ibid., 1079.
[17] Ibid.
[18] Margaret Kyle. "Pharmaceutical Price Controls and Entry Strategies". *The Review of Economics and Statistics*, vol. 89, No.1, (Massachusetts Institute of Technology, Cambridge, MA., 2007), 25.

[19] Ibid.
[20] Ibid.

The Profit Control Model

Profit Controls are a form of pricing regulation that, as the name implies, attempts to limit the profit or profit growth rates which a pharmaceutical company receives from the sales of their product. This limit is often a profit cap that is applied to the company annually [21]. The intended effect of the model is to indirectly regulate the price of pharmaceuticals sold by setting a limit to the amount of profit that the company can collect [22]. Profit Controls does not have many adopters, however, countries who implemented the regulations have continued to abide by it since. The study that will be referenced measured the effect of profit controls on a country's pharmaceutical market following its implementation between the years of 1995 and 2004. The countries measured include the United Kingdom, Spain, and Turkey [23]. It should be noted that Turkey later switched a reference pricing model in 2004, however, their results were still usable from the study conducted by Sood and others. The team used two models to measure the percent change in the pharmaceutical companies' revenue over the period measure. The first model was a broad aggregate of the price regulation levels, making little distinction on implementation or nuance of application. The second model broke each pricing model down into sub-models based on what part of the pharmaceutical industry was being targeted [24]. This allowed for a more accurate comparison of the effects that each implementation had on total revenue. Sood's team found that according to the first model, Profit Controls led to a -6.3% decrease in revenue, and according to the second, a -4.3% decrease in revenue [25]. This study, however, is not able to account for changes in medication, quantity sold, or other variations in the localized market over time as consumer needs fluctuate. However, it is still a very reasonable indicator of the general effect that Profit Controls would induce in the market.

Knowing the measured, general effect on revenue, how would profit controls fare if applied to the United States pharmaceutical market? Is it a policy worth implementing? To best answer this, one can look to the UK's implementation of Profit Controls within its healthcare industry. The UK's Department of Health implemented the current iteration of the system in 1999, termed as "The Pharmaceutical Price Regulation Scheme" [26]. In theory, the Scheme would work to both "secure medicine for the National Health Service at reasonable prices" while simultaneously "encouraging a strong and profitable pharmaceutical industry capable of competitive and sustained development of new, innovative medicines" [27]. If these goals were truly accomplished, this model would be an ideal candidate for implementation in the United States−however, proposed models often fail to meet their initial goals. The issue with the UK's implementation lies primarily in its vague approach to defining what "reasonable prices" means, as it seems to be a very arbitrary goal set by those who might display a vested interest in securing

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[21] Neeraj Sood, et al. "The Effect of Regulation on Pharmaceutical Revenues: Experience in Nineteen Countries". *Health Affairs*, vol. 27, no. Supplement 1: Web Exclusives, (healthaffairs.org, 2008), 127.

[22] Monique Mrazek. "Comparative Approaches to Pharmaceutical Price Regulation in the European Union". *Croatian Medical Journal*, vol. 43, pp. 453-461, (Croatian Medical Journal, 2002), 456.

[23] Neeraj Sood, et al. "The Effect of Regulation on Pharmaceutical Revenues: Experience in Nineteen Countries". *Health Affairs*, vol. 27, no. Supplement 1: Web Exclusives, (healthaffairs.org, 2008), 127.

[24] Ibid., 132.

[25] Ibid.

[26] Monique Mrazek. "Comparative Approaches to Pharmaceutical Price Regulation in the European Union". *Croatian Medical Journal*, vol. 43, pp. 453-461, (Croatian Medical Journal, 2002), 456.

[27] Ibid.

profit. Upon implementation, companies were given a profit cap of 21%, measured by a return in sales [28]. After the study was completed, it was inconclusive whether drug prices were affected almost at all as there was no significant general correlation found between an increase in the profit cap and a change in the price of pharmaceuticals. The inconclusive results are mainly due to the lack of transparency within the pricing scheme. Furthermore, there remained very easy ways to finagle the system by overinvesting capital throughout the year to increase the company's allowed price cap [29]. Ultimately, by the end of the study, the UK's comparative pharmaceutical prices with the rest of the EU had increased from middle-of-the-range to topping the charts−seemingly the opposite desired effect. The UK's experience with Profit Control pricing regulations would seem to indicate that implementations within the US would be ineffectual at best, and at worst, aggravate the pricing issues and lack of transparency present within the current market. While a study conducted by Monique Mrazek in 2002 did not find any significant changes in the price of medicine, Sood's simultaneous study measured a marked decrease in revenue to the pharmaceutical company. While this may be a desirable effect, it's worth noting that there could be significant tradeoffs in the amount of R&D the US market could continue to facilitate with very little benefit by means of price reduction in cost of pharmaceuticals for the average consumer. The resulting loss would mean less productive innovation due to the decreased incentive for competition within the market, and, as a result, an increase in the measure of social welfare loss. Thus, it is difficult to justify implementing the model within the US at present. Ultimately, the success of the implementation would depend primarily on whether the pricing goals were transparent, thus allowing adjustments to be made as needed. Otherwise, the model seems like more difficulty than its implementation is worth.

The Reference Pricing Model

Another price regulation model that has become increasingly popular is Reference Pricing. Reference Pricing operates by dividing interchangeable medicines into groups. The prices of these groups of drugs are then compared to the prices for the same drugs in international markets, and then priced accordingly to minimize discrepancy [30]. For the most part, these price ceilings are rather informal, but are still maintained by each country's governing body. If a pharmaceutical company continues to price their product above the reference price set, the consumer is usually expected to cover the cost of the difference on their own. Occasionally, for pharmaceuticals with a much greater difference in price, select insurance providers will help cover the cost [31]. In an article published by Marie Salter in 2015, she points out that for the most part, reference pricing is implemented in countries who have adopted a form of socialized healthcare, as it would be incongruous to do otherwise with the Reference Pricing model [32]. There does exist a weakness in the model when it comes to the disparity of pricing between countries of different economic standing. If a weaker country is using reference pricing with several countries which are economically prosperous, it could lead to comparatively high pharmaceutical prices for the per-capita wealth of the poorer nation. Ultimately, this pricing

[28] Ibid., 457.
[29] Ibid.
[30] Marie Salter. "Reference Pricing: An Effective Model for the U.S. Pharmaceutical Industry?". *Northwestern Journal of International Law & Business*, vol. 35, Issue 2, (Northwestern Pritzker School of Law, 2015), 5.

[31] Ibid., 6.
[32] Ibid.

model relies primarily on the discretion and guidance of each country's government when it comes to who should act as the price reference to minimize costs to the consumer.

Before applying this model to the US, it is important to observe the effects of Reference Pricing in comparable markets. Due to the number of potential variations in each market structure due to the differences in economies, Reference Pricing can lead to undesirable results for both consumers and producers if misapplied. In a study conducted by Panos Kavanos, his team concluded that according to their model, Reference Pricing results in an ambiguous net effect, with the implementations of certain countries bringing about desirable economic results, with others leading to rising long run costs [33]. While it appears that there is a short run benefit in the price reduction of many pharmaceuticals, it is apparent that innovation is disincentivized due to a lack of potential profit. This is not a particularly surprising result. What Kavanos did find is that the model indicates that the short run benefits to consumers may not be large enough to outweigh the long run cost of reducing the development of new, cost-effective drugs [34]. This, however, is a speculative result that brings into question the balance of short run versus long run social costs in healthcare policy. This balance of long run and short run cost is one that each country must find and prioritize for themselves as it requires thorough, multivariate analysis of the country's economy and healthcare system. Kavanos also examined Germany's experience with the implementation of Reference Pricing, which provides a worthwhile point of comparison for the US when it comes to pharmaceutical innovation. Under Reference Pricing, Germany's price index for products affected by the model decreased by 30% over the period of 1989-2001 [35]. However, when measured against the general increase of the non-Reference Priced index, it is difficult to measure what real impact the model had on cost to consumer. This highlights one of the primary issues with Reference Pricing models−it is nearly impossible to build a helpful model to extract and predict information accurately without also performing an analysis for every aspect of a country's healthcare system simultaneously. Reference Pricing by its very nature is uniquely interlocked with numerous tangential factors that all play a role in the success of its outcomes. This makes drawing any significant conclusions a very difficult process, as a very large majority is guesswork or extrapolation without much supporting context [36]. Kavanos makes note of these factors, observing that that there are three primary tradeoffs that result from the implementation of a Reference Pricing model. First: the quality of medical treatments, second: the overall cost of prescription drugs, and third: the probably long run progress of innovation in drug therapy [37]. These tradeoffs are significant factors to consider, as a policy slanted to much one way or the other could have potentially harmful result years later. Reference Pricing has received its fair share of criticism on this front with many economists disparaging the policy as simple or misguided. Economist Mark Roberts describes Reference Pricing as "an imperfect half measure that is inferior to alternative approaches" [38]. In the study from Sood, their results indicated that in model 1, Reference Pricing lead to a revenue increase of 1.6% within OECD countries. When these results are further broken down in model 2, Reference Pricing for

[33] Panos Kavanos, Uwe Reinhardt "Reference Pricing for Drugs: Is it Compatible with U.S. Health Care?". *Health Affairs*, vol. 22, no.3, (healthaffairs.org, 2003), 28.

[34] Ibid.
[35] Ibid., 26.
[36] Ibid., 27.
[37] Ibid., 24.
[38] Ibid., 28.

generics and Reference Pricing for both generics and on-patent drugs lead to increases in Pharmaceutical revenue of 3.4% and 9.7% respectively [39]. From these observed results, the benefits of Reference Pricing are ambiguous to say the least.

While the policy certainly captures the intention behind any good pricing regulations for pharmaceuticals, it seems to fail at being anything more than a performative method of price regulation in many instances. Furthermore, it remains nearly immune to a true numerical and critical analysis of its impact on the pharmaceutical market in countries in which it is applied. There are too many variations and impacting factors to paint a true picture of Reference Pricing's viability. From what data is available, it appears that Reference Pricing is not quite the policy that many hoped it would be. While it may lower the pharmaceutical prices for many, the unseen damage in the long run is too much to ignore. To even begin to apply such a model of regulation in the US, it would require immediate and over-arching changes to several aspects of the healthcare system. Kavanos points out that due to the unknown nature of many aspects of Reference Pricing, the reliance on centralized forms of control for pricing, and the importance of innovation for the health of the US, it would most likely be an uphill battle to shift any policy towards an effective version of the Reference Pricing model [40]. However, the Reference Pricing model is consistent with current US efforts to reduce pharmaceutical prices, so if implemented well, it would certainly appear to be a viable model for policy to follow [41]. Ultimately, even with the model's potential, it seems reasonable to conclude that despite promising intentions, the damning ambiguity of effects and questionable long run cost of the model could quite possibly lead to a step backwards when it comes to improving the pharmaceutical market within the US.

The Price Control Model

The final, and most popular of the regulation models are Direct Price Controls. Direct Price Controls were adopted and implemented by a total of 16 different countries in 2004 [42]. Price Controls are either a price-cap on the amount that a national health service can pay for a product or a cap on the price of the ex-manufacturer [43]. This price cap is determined by a combination of several factors: the therapeutic value of the drug, the cost of production, the manufacturer's impact on the economy and the cost of similarly used drugs or treatments [44]. While the terms of analysis may be uniform among countries, the weighted importance of each factor varies from implementation to implementation. In theory, this model should allow countries to keep prices reasonable for the consumer and continue to incentivize innovation in order to develop cost-effective drugs and remain competitive within the market while under the drug's price cap [45]. However, this intention can often fall short due to ambiguity and bias within

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[39] Neeraj Sood, et al. "The Effect of Regulation on Pharmaceutical Revenues: Experience in Nineteen Countries". *Health Affairs*, vol. 27, no. Supplement 1: Web Exclusives, (healthaffairs.org, 2008), 132.
[40] Panos Kavanos, Uwe Reinhardt "Reference Pricing for Drugs: Is it Compatible with U.S. Health Care?". *Health Affairs*, vol. 22, no.3, (healthaffairs.org, 2003), 28.
[41] Ibid., 25.
[42] Neeraj Sood, et al. "The Effect of Regulation on Pharmaceutical Revenues: Experience in Nineteen Countries". *Health Affairs*, vol. 27, no. Supplement 1: Web Exclusives, (healthaffairs.org, 2008), 130.
[43] Margaret Kyle. "Pharmaceutical Price Controls and Entry Strategies". *The Review of Economics and Statistics*, vol. 89, No.1, (Massachusetts Institute of Technology, Cambridge, MA., 2007), 4.

[44] Ibid.
[45] Monique Mrazek. "Comparative Approaches to Pharmaceutical Price Regulation in the European Union". *Croatian Medical Journal*, vol. 43, pp. 453-461, (Croatian Medical Journal, 2002), 457.

each country's final implementation. For instance, one country might prioritize the market power of a pharmaceutical company above all other factors in the price cap leading them to overregulate in areas that a country which prioritizes therapeutic value above all else might not.

However, no model is free from the cost of its regulation. Price Controls appear to have a statistically significant effect on the production and distribution of many drugs in the global market. Drugs produced by firms in countries with strict price control regulations eventually reach fewer total markets and suffer longer delays than their alternative counterparts which are produced in countries without price controls [46]. Furthermore, firms which enter countries with strict price controls are much less likely to introduce products from additional markets following their entry [47]. These effects are enough to substantially cripple many firm's competitive capability as there is no incentive to enter some foreign markets as a competitor. This effect can be observed in Sood's 2004 study which measured the impact of regulations on the revenue of pharmaceutical companies. Companies subject to Direct Price Controls experienced a 16.8% decrease in revenue following implementation−by far the most drastic decrease in revenue of any of the pricing models [48]. This should not necessarily be a shock, however, it is important to remember that as the study from Keyhani affirmed, innovation is relatively tied with a country's wealth and for the most part, will remain relatively unbothered by less stringent pricing regulations [49]. However, this is also a debated assertion when it comes to price controls. In an article published by the National Bureau of Economic Research, the writer claims that

> cutting prices by 40 to 50 percent in the United States will lead to between 30 and 60 percent fewer R and D projects being undertaken in the early stage of developing a new drug. Relatively modest price changes, such as 5 or 10 percent, are estimated to have relatively little impact on the incentives for product development -perhaps a negative 5 percent [50].

Thus, it stands to reason that there will certainly be a measurable effect on a country's pharmaceutical development if the Price Controls are within reason. Drastic shocks to the system will lead to damaging effects in the long run. With this in mind, analyzing the other important impacts that such a policy would have on a country's economy and wellbeing becomes a necessity to judge how, or if Price Controls should be implemented in the first place.

In another study conducted by Sood, the research team modeled the impact of Price Controls within the current US pharmaceutical market. The team decided to use a simulated reduction in price of 20%, along with a 20% copay reduction which would result in an increase in taxes[51]. From this model of simulated Price Controls, the team was able to predict the long

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[46] Margaret Kyle. "Pharmaceutical Price Controls and Entry Strategies". *The Review of Economics and Statistics*, vol. 89, No.1, (Massachusetts Institute of Technology, Cambridge, MA., 2007), 2.
[47] Ibid.
[48] Neeraj Sood, et al. "The Effect of Regulation on Pharmaceutical Revenues: Experience in Nineteen Countries". *Health Affairs*, vol. 27, no. Supplement 1: Web Exclusives, (healthaffairs.org, 2008), 132.
[49] Keyhanis Salomeh, et al. "US Pharmaceutical Innovation in an International Context*". Am J Public Health*, vol. 100(6) pp. 1075 – 1080. (Am J Public Health, 2010), 1079.
[50] David Francis. "The Effect of Price Controls on Pharmaceutical Research". *National Bureau of Economic Research*, no. 5, (National Bureau of Economic Research, Cambridge, MA., 2005), 1.

[51] Neeraj Sood, et al. "U.S. Pharmaceutical Policy in A Global Marketplace". *Health Affairs*, vol. 27, no. Supplement 1: Web Exclusives, (healthaffairs.org, 2008), 139.

global decrease in lifespan as a result of the US's implementation of Price Controls. The results indicate that by 2030, there would be a decrease in average life expectancy by 0.5 years for the US population and 0.19 years for the European population [52]. By 2060, the life expectancies would drop by -0.7 years and -0.65 years for the US and European populations, respectively [53]. However, the benefits of such a policy implementation would also lead to a drastic decrease in lifetime health spending with a reduction in up to 15% for US citizens by 2060, and 2.75% for European Citizens [54]. However, the same model also demonstrates that despite the short run benefits of price reductions, a benefit of less than $1000, by 2060 the 55-59 year old population will be losing $51,000 of value per year due to the price controls [55]. None of these results should be taken as gospel however, as there is significant evidence to suggest that the impact of Price Controls fluctuates vastly over time due to an incredibly complex combination of multiple factors [56]. It is also important to consider that the results of both of the Sood team's studies make a point to highlight the difference between introducing Price Controls to a previously unregulated market versus a pharmaceutical market structure with pre-existing regulations. The system-shock of introducing Price Controls as the first step in regulation can lead to a much more volatile response from the market, whereas slowly building a base of regulations, and then implementing Price Controls will lead to a more stable and predictable response [57]. Ultimately, as with any pricing model, it relies completely on a country's implementation and commitment to working with the decided regulation model to bring about the healthiest result possible. It remains to be seen if the modest short run payoffs are able to be preserved upon implementation while minimizing the large, long run costs that represent the sacrifices in future innovation.

The Copayment Reduction Model

It is worth noting that Sood's team proposes an alternative method of price regulation in the US in the form of Copayment Reductions. A 20% copay reduction in cost to the consumer would preserve the prices that the pharmaceutical manufacturers want to charge, while alleviating the burdensome cost that often befalls the consumer [58]. This model also brings about positive results regarding the preservation of innovation, as the manufacturers still maintain their incentive to compete−resulting in a continuous increase in cost-saving pharmaceuticals in the long run. In a comparison of the responsiveness of innovation to revenue between the models of Copayment Reductions and Price Controls, Copayment Reduction demonstrated a positive increase of value of the policy, whereas Price Controls demonstrated a substantially larger negative decrease in value of policy to the US [59]. While it is hard to say for certain whether this policy leads to more desirable results than Price Controls might induce, Sood's team believes that Copayment Reductions "represents the more broadly beneficial choice for US policymakers" [60].

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[52] Ibid., 144.
[53] Ibid.
[54] Ibid.
[55] Ibid.
[56] Neeraj Sood, et al. "The Effect of Regulation on Pharmaceutical Revenues: Experience in Nineteen Countries". *Health Affairs*, vol. 27, no. Supplement 1: Web Exclusives, (healthaffairs.org, 2008), 133.
[57] Ibid.
[58] Neeraj Sood, et al. "U.S. Pharmaceutical Policy in A Global Marketplace". *Health Affairs*, vol. 27, no. Supplement 1: Web Exclusives, (healthaffairs.org, 2008), 139.
[59] Ibid., 147.
[60] Ibid., 148.

Future Pharmaceutical Price Regulation Policy in the US

What is the future of price regulation policy in the US? During the past several months, the Trump administration has been taking steps to lower prescription drug prices for American patients [61]. On July 24, 2020, President Donald Trump signed four executive orders to

> End a shadowy system of kickbacks by middlemen that lurks behind the high out-of-pocket costs many Americans face . . . Under this action, American seniors will directly receive these kickbacks as discounts in Medicare Part D. [62]
>
> Require federally qualified health centers who purchase insulins and epinephrine in the 340B program to pass the savings from discounted drug prices directly on to medically underserved patients . . . [63]
>
> Authorize the re-importation of insulin products made in the US if the secretary finds re-importation is required for emergency medical care. . . [64]
>
> Create a pathway for safe personal importation through the use of individual waivers to purchase drugs at lower cost from pre-authorized U.S. pharmacies. [65]
>
> Take action to ensure that the Medicare program and seniors pay no more for the most costly Medicare Part B drugs than any economically comparable OECD country . . . [66]

In effect, this policy is a combination of the Reference Pricing model and the Copayment Reduction model that Sood's team hypothesized. While this could certainly be a step in the right direction, the executive orders by themselves accomplish very little as the actual regulation policy that follows will be the crucial element to determining how the market reacts. However, the response to the President's executive orders has been mixed, as many have questioned their efficacy, and whether the timing was appropriate [67]. Citizens Against Government Waste President, Thomas Schatz criticized the plan as " . . . absolutely the wrong approach . . . And it could not have come at a worse time" [68]. In an article published by HeinOnline, former economist for the Senate Republican Policy Committee, Eric Schlecht, criticized the trump administration for ". . . (the belief that) PBMs are unnecessary and costly middlemen between pharmaceutical companies and consumers. . . . by narrowly focusing on PBMs, the administration ignores the large structural problems that are driving up drug prices" [69]. At this point, almost all discussion regarding the topic is purely speculative. However, given the previously established weaknesses of implementing a Reference Pricing scheme without the proper underlying healthcare structure, policymakers should be cautious in jumping to an attractive short run benefit. While the discussion regarding the role of Pharmacy Benefit

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[61] "Trump Administration Announces Historic Action to Lower Drug Prices for Americans". *US Department of Health & Human Services*. (HHS, July 24, 2020), 1.
[62] Ibid.
[63] Ibid., 2.
[64] Ibid.
[65] Ibid.
[66] Ibid.
[67] "President's Eos Will Not Reduce Drug Prices". *Associated Press*. (apnews.com, 24 July 2020), 1.

[68] Ibid., 2.
[69] Schlecht, Eric. "Eliminating Rebates in Medicare Part D Will Not Reduce Drug Prices" *HeinOnline*, 43 Regulation 8. (heinonline.org, 2020).

Managers, PBMs for short, in the pricing of drug regulations is outside the scope of this paper's central topic, Schlecht's criticism is worth regarding. The role of PBMs, in part, fosters competition among insurance companies, leading to a reduction in out-of-pocket costs for policyholders. While there are fears regarding the monopsony power that large PBMs could wield, this would lead to a reduced quantity of purchases and lower prices that would pose significant antitrust concerns under the Sherman Act[70]. In a case where monopsony power is severely unbalanced, this would lead to significantly decreased competition in the domesting pharmaceutical market, and thus, decreased innovation. Whether or not the kickback discounts are enough to outweigh the competitive benefits of PBMs remains to be seen. However, this should be a source of concern.

Concluding Remarks

The United States is in a unique position in that it is the singular pharmaceutical market without any pricing regulations. However, the ambiguity that surrounds every policy decision regarding this market is unenviable, as it is un-treaded territory. For the US to implement any effective Price Regulation policy, it is important to look first to the comparable countries who have implemented similar models in the past. Despite the comparative analysis of the three primary policies across the global market conducted throughout this paper, it remains near impossible to declare which pricing model is "most desirable" or "least desirable" because of the multi-faceted ambiguity baked into the difference of execution of each country's policy. A feasible system of classification might be a measure of difficulty that a transition from the current Pharmaceutical Market regulation model to the comparable models would pose. On this, I believe that Sood's Copayment Reduction plan, while not necessarily a pricing regulation and more of a price alleviation, would be most feasible to attempt to implement. Copayment Reduction would also continue to facilitate many of the desirable pro-competitive incentives that exist in the current market structure. Without delivering a system-shock to the market that creates irreparable damage. Once implemented, Copayment Reduction alongside another pricing models such as a soft form of Price Controls could be an effective solution to the observed price-creep in the market. Following from this, Reference Pricing would perhaps be the most difficult to effectively implement. As many have pointed out, the US is an aberration from the typical pharmaceutical market and healthcare structure, and thus would require a vast number of policy and institutional changes to effectively implement consumer savings while minimizing the long run cost of a chosen model's tradeoff. Unfortunately, the analysis of economic policy often begs more questions than it answers, as predictive models and historical data are only so helpful when approaching subjects that are as unique in their structure as the United States' pharmaceutical market. Hopefully, with time and incremental steps taken to establish workable policy, the United States is able to implement a form of pricing regulations that encourages pro-competitive behavior among producers while alleviating welfare-damaging increases in cost from innovation or lack thereof.

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