# A HEALTH IMPACT FUND IN THE U.S.: HOW A THEORETICAL IMPLEMENTATION OF THE HIF CAN INFORM FUTURE DRUG PRICING POLICY IN AMERICA

BY

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# ABSTRACT

Over the last two decades, pharmaceutical prices in the U.S. have risen at an unprecedented rate. As a result of the incentive structure through which the U.S. currently drives pharmaceutical development, pharmaceutical companies have made decisions that increasingly limit the ability of individuals and populations to obtain drugs necessary for their health. In light of this growing strain, the need for reform to the current U.S. incentive structure is becoming ever more clear. A multitude of solutions have been proposed, each offering their own unique strengths and limitations – and each hoping to navigate the enormously complex path to successful implementation.

This thesis begins with an overview of the current dysfunction of pharmaceutical pricing in the U.S., and outlines the incentivization structure behind this dysfunction and how it has contributed to the current state of affairs. The thesis then examines one potential reform strategy – the Health Impact Fund – and how a hypothetical implementation of the strategy might perform in the U.S. Finally, this project assesses that hypothetical implementation of pharmaceutical incentive reform through the lens of Rawlsian Justice as Fairness. In doing so, it distills general insights that will help guide the implementation of any potential U.S. reform in the future – toward being both practically successful and morally just.

# INTRODUCTION

## Background

The cost of pharmaceutical products in the U.S. is at an unprecedented high, and continues to rise. In 2016, the total money spent on pharmaceuticals amounted to $480 billion - 3% of the nation's entire GDP.[i,ii] This figure is compounded by a 2017 study's finding that prescription drug prices are increasing at 2.5 times the rate of inflation.[iii] This reality leaves many who are in need of increasingly expensive drugs forced to make difficult choices in order to attain treatment, or unable to afford necessary drugs altogether.

These high drug prices are largely a symptom of the current drug development and pricing framework in the U.S.[iv,v] In light of this reality, a number of potential strategies have been put forward for reforming the present system. These proposed strategies aim to either overhaul the current regulatory structure, or to incentivize pharmaceutical companies to behave differently when pricing their products. One notable strategy is that proposed by Thomas Pogge. Pogge's model is an incentivization structure that aims to encourage pharmaceutical companies to develop and distribute their drugs so as to maximize the effects of the drugs on their population. He refers to this model as the Health Impact Fund (HIF). Pogge's proposal is for this model to be implemented and operate on the global scale – encouraging changes in international drug pricing and delivery and assessing the success of drug manufacturers based on

their global distribution.[vi] The practicality of applying the HIF as a global pricing tool has been broadly discussed. From a more localized perspective, the HIF model can also be evaluated as a tool to reform pricing within the U.S. Such an evaluation demonstrates the strengths and weaknesses of the model, which in turn provide valuable, generalizable insight into how the U.S. should move forward as it looks to institute potential pricing reform.

With this end in mind, this thesis evaluates a hypothetical adoption of Pogge's Health Impact Fund in the U.S. and discusses the insights this model yields into how drug pricing reform in the U.S. may be implemented in a just, practical manner.

## Chapter 1

In the first chapter, I outline the current U.S environment that has led to high pharmaceutical prices. With this outline in place, I subsequently establish the importance of evaluating this environment – and all steps taken to reform it – through the lens of justice.

One of the primary considerations at play in the determination of drug prices is the initial cost of drug production. This cost is the result of several contributing factors within the development process – costs of pre-clinical research, costs of clinical research, and costs of working within the FDA's stringent approval framework.[vii] I

evaluate each of these factors in turn and detail their contribution to the overall cost of production. I also consider the costs associated with drug marketing and distribution, and how they can play a role in the determination of drug pricing as well.

With the costs faced by pharmaceutical companies established, I outline the current structure that the U.S. has put in place to motivate these companies to continue navigating this process. At its most fundamental, the incentive structure in U.S. offsets the considerable investments of time and money that drug manufacturers take on with the potential for high payouts when drugs are successfully developed. The driving forces of the current structure are the U.S. patent framework and the practice of market exclusivity.[viii,ix] I present how these forces combine to give pharmaceutical companies the pricing power that they currently exercise. There are also secondary forces at play that influence the outcomes of this structure. The most notable of these are political pressures and the shareholder interests that are present for publicly traded manufacturers.[x]

This incentivization structure leads to high payouts for pharmaceutical companies, which ultimately fall on the backs of consumers, who pay high prices for developed drugs.[xi] High consumer prices not only place a burden on those consumers who rely on these products, they also limit access to these products altogether for some consumers who can't afford to pay the prices.[xii]

As this current incentive structure for pharmaceutical development results in such a burden on often vulnerable consumers, a number of strategies – including the

HIF – have been proposed for reforming this structure. All of the proposed reform strategies attempt to answer the same fundamental question – what can we do to mitigate this outsized burden that is currently being placed on consumers?

The many proposed answers to this question can be (and have been) contrasted through a number of different lenses. One such lens is that of justice, which is the one through which I opt to look at this question. I first establish the importance of conducting an analysis based on justice, before then outlining Rawlsian Justice as Fairness - the specific conception of justice to which I appeal in this paper. It is important when presenting this idea of justice in general to also identify how it can be applied to healthcare. To this end, I describe not only the original proposal of Justice as Fairness put forward by John Rawls, but also the subsequent justification of healthcare as a human right championed by Norman Daniels.

Having established this foundation, the stage is set to dig more deeply into one specific pricing reform strategy.

## Chapter 2

In the second chapter, I introduce the drug pricing reform strategy on which this thesis focuses - the Health Impact Fund (HIF). I describe the details of the proposal as outlined by its designer - Thomas Pogge. Fundamentally, the HIF asks pharmaceutical

companies to opt into an agreement. From their side, pharmaceutical companies will distribute their drugs at or below the cost of production. In return, these companies will receive payouts from the pool of money held in the Health Impact Fund. The payouts are to be based on the qualitative health improvements that the participating drugs make on the global scale – and are split between all drugs opted into the fund proportional to their respective health impacts.[xiii] The money that the HIF has available to deliver these incentives can be provided by countries sponsoring the fund – which Pogge outlines as a reasonable expectation and relatively insignificant economic burden.

Through this setup, the HIF aims to maximize the benefit that drugs provide and foster valuable competition among drug developers, while simultaneously minimizing the negative impact that such competition has on consumers. As with all proposed reform strategies, a general implementation of the HIF has both strengths and limitations. This section presents each in turn so as to paint a complete picture of the HIF model.

One key aspect of the HIF is that it does not attempt to fundamentally alter the current drug development process or approval structure. This means that the model does not risk compromising the process that ensures drugs are safe and effective, which is currently a strength of the FDA approval framework. In a similar vein, the HIF also preserves the current competition between pharmaceutical companies, which can be a critical driver for innovation.

Another valuable feature of the HIF that bears further discussion in this chapter is that this model incentivizes the effective delivery of drugs to as many consumers as feasible. It also incentivizes improved delivery of healthcare and public health in general.[xiii]

There are several caveats associated with HIF that are important to lay out as well. Notably, implementation of the HIF requires a means by which to measure health impact reliably. It also requires the establishment of guidelines to control competitive behaviors and other practices that may be detrimental to drug consumers. On top of these frameworks that must be set up, the HIF requires a scope of operation, and buy in from drug developers who enter their products into the initiative, and from sponsors who commit real money into the fund so that the entire project can get off the ground.[xiii]

## Chapter 3

In the third chapter, I walk through a theoretical application of the HIF in the U.S., explore how it might look, and evaluate this application through the lens of Rawlsian Justice. Analysis of this hypothetical establishment of the HIF assesses each notable aspect of the model both generally and based on its potential implications in the U.S.

Much of the HIF model has clear implications in terms of justice. By design, the HIF has the potential to provide improved drug accessibility to all U.S. consumers, improved healthcare infrastructure, and an increased focus on public health and social determinants of health. Each of these potential changes increases the access to drugs for those to whom drugs are currently least accessible – those who most justly deserve them.

Application of the HIF also raises concerns in terms of this conception of justice. Rawlsian justice applied to healthcare has been critiqued as too idealistic, leading to the expenditure of impossibly large amounts of money in order to deliver the ideal minimum of healthcare.[xiv] This situation can manifest itself in communities that currently lack the health infrastructure to readily achieve the improved outcomes that the HIF will rely on when judging drug success. In addition to this concern, the changes to pricing and distribution of drugs encouraged by the HIF have the potential to dampen the incentives for pharmaceutical innovation and drug development in general. This is potentially problematic, as it entails that pushing too hard for improved drug accessibility to all through the wrong methods today could lead to worse future outcomes than simply sticking with the status quo. This exploration of the implications of the hypothetical application of the HIF yield insights that can be applied more generally toward reforming the current U.S. model.

Chapter 4

In the fourth chapter, I discuss the insights highlighted by the theoretical application of the HIF presented in the previous chapter. I evaluate the guidance that these insights provide for approaching pricing reform in the U.S. in general and why it is important to place emphasis on each.

The first notable insight gleaned from this thought experiment is that the approach to drug pricing reform should fundamentally change what is being incentivized, and not merely look at drug production itself as an end. This delinking of pharmaceutical prices from the costs of development and production is important, as the overall costs of drug production are unlikely to decrease considerably.

A second key for approaching pricing reform is that special value should be placed on drug accessibility and efficacy when shifting away from incentivization of drug production. Encouraging valuation of drugs based on their health impact has the potential to not only directly improve drug accessibility and efficiency, but also to indirectly improve healthcare infrastructure and public health measures. These are important factors in drug efficacy that may otherwise be overlooked.

A third insight that can be applied generally is that price reform should lower prices in the present, but simultaneously not preclude lower prices in the future. This point is worth emphasizing as some strategies may fall victim to focusing too narrowly on short term implications of reform and neglect to consider long-term outcomes.

Guidance derived from potential limitations of the HIF is as important to explore here as guidance derived from its potential strengths. One such point is that reform in drug pricing should be context-specific. Policy should be grounded in an informed understanding of the existing variations in drug need, access, and efficacy across the U.S. Reform that overlooks this and focuses in on certain factors or goals without taking the broader context into account risks overlooking important information or inappropriately prioritizing the measures on which to focus. In a similar vein, guidelines and regulations must be well laid out. These will need to prevent competitive acts between pharmaceutical companies that may be detrimental for consumers. As is pertinent, guidelines will also need to establish exactly how drug performance will be quantified and how incentive payments will be delivered.

After exploring all of these points in additional detail, this chapter assembles them into a strong, structured set of ideas that tie back to the big picture question – what can the U.S. do to mitigate the burden currently placed on consumers by high drug prices?

## Conclusion

In this final section, I conclude by laying out the distilled findings of the discussion – that evaluating the potential implementation of the HIF in the U.S. yields a number of insights, and that these insights are important considerations that the

country should take into account as it approaches reformation of current pharmaceutical pricing practices. In presenting these recommendations, I will also outline the limitations that exist alongside them. These insights are not all-encompassing, and are not themselves a roadmap for reform. They do, however, provide valuable guidance that future reform efforts should reference – especially those looking to attain an altogether just outcome.

# CHAPTER 1

## Setting the Stage

In this chapter, I begin by outlining the current U.S environment that has led to the high prices of pharmaceutical products. I also present the implications that these prices have for patients and potential patients in the U.S. With this outline in place, I subsequently establish the informative value of assessing the current environment – and strategies proposed to reform it – through the lens of Justice.

## The High Cost of Pharmaceuticals

As the introduction established, total pharmaceutical spending in the U.S. amounted to a substantial $480 billion in 2016 – representing nearly 15 percent of all national healthcare spending.[i, ii] This number is expected to increase rapidly over the next decade, at over twice the rate of inflation.[iii] While the situation is the result of price increases for pharmaceutical products at all levels, the ever-increasing price tags of the most expensive prescription drugs is representative of this trend. In May 2019, the gene therapy Zolgensma was approved to treat a potentially fatal condition in infants - it

raised the drug price ceiling to new heights with its $2.1 million price tag for a course of treatment.[xi]

Bringing a Drug to Market

As this crisis in pharmaceutical prices escalates, it is important to recognize that it does not exist in a vacuum. It is a natural eventuality of structures that the U.S. employs to foster pharmaceutical innovation and spur production. In order to understand this system and how it works, it is necessary to first outline why such an incentive structure exists at all. Its roots can be traced back to the painstaking and costly process of bringing a drug to market. First, primary research must identify a bioactive compound that can confer a benefit to humans and be delivered effectively. This is a significant undertaking in and of itself. It is also important that the use of this drug in humans be both safe and effective. To this end, the U.S has established a rigorous approval framework that new drugs must pass through before they can be distributed to consumers. This requires that the drug be subjected to substantial clinical investigation in order to gain approval.

This rigorous framework is implemented and overseen by the U.S. Food and Drug Administration (FDA). The FDA is the federal agency responsible for the regulatory oversight of drugs in the U.S.[ix] This regulation stipulates that drugs to be delivered to humans must be safe, effective, and provide sufficient benefit to justify any associated

risks. If the FDA's evaluation of the relevant clinical data suggests that a potential drug falls short of any of these standards, the organization will not approve this drug to be made available to consumers.[xv] As such, the successful navigation of this approval process is critical to a pharmaceutical company's prospects of bringing a product to market – and thereby obtaining a profit from its sale.

The FDA's approval process takes into account several key aspects of a potential pharmaceutical product. First, FDA reviewers look at the condition that the drug treats and assess its severity. In taking this look at the treated condition, reviewers also consider the current treatment landscape for this condition. This may involve assessing whether or not other treatments exists targeting this same condition or how the efficacy of existing alternatives compares to that of the novel drug. It is worth noting here that the FDA does not actually require such comparisons between a potential drug and its peers – only between a potential drug and a placebo. Further comparisons may be taken into account, but they are not necessarily a part of the approval process.

Fundamentally, the purpose of this analysis is to determine what new potential benefits a drug may bring to patients, and whether these potential benefits are sufficient to outweigh any of the drug's associated risks. With this understanding established, the FDA assesses the risks and potential benefits of the drug as demonstrated by the clinical data submitted by the drug's manufacturer. Here, it is important that the drug manufacturer has completed appropriate clinical trials that demonstrate the safety and efficacy of the drug in its target population. Any risks or uncertainties indicated by these studies should be outweighed by the benefits that the

drug can be expected to provide.[xix] Because of the clear stakes associated with the distribution and use of pharmaceutical compounds, the entire FDA approval process is undertaken with care. This is no small task. Successful navigation of this process takes a significant investment in both time and money.

Several studies have been published that aim to quantify the investment that pharmaceutical companies must make. While these studies tend to vary in their methodology and in their findings, taken together they paint a clear picture of the cost of bringing a drug to market. A 2017 study published in JAMA Internal Medicine looked at a number of approved drugs and evaluated the time and cost involved in their paths to approval. Based on the Securities and Exchange Commission filings for ten drugs from ten different companies[1], this study followed each compound through its complete life cycle – from the advent of related research and development all the way through to the FDA's ultimate approval. The investigators found that the median cost of bringing these drugs to market was $648 million, and the median time for a drug to progress from initial research to eventual approval was 7.3 years.

The findings of this study highlight the substantial amount of time that pharmaceutical companies devote to the development of a given drug. Notably, while this study also reveals a median cost of $648 million, this is a relatively low estimate in contrast to the numbers that other studies have shown. This is largely the result of one

[1] While the drugs included in this study were from different companies, it is worth noting that they were all drugs designed to treat cancer and were therefore more similar than a sample of ten unrelated treatments may have been.

of the choices that the investigators made in their methodology by only looking at drugs that had obtained FDA approval. This estimate does not look at drugs that failed to obtain FDA approval, and so reflects only the cost of bringing a compound *that will be successful* to market, not the true cost of bringing a drug to market from any given initial compound.[xvi] This is not an insignificant caveat. Most prospective drugs never reach market – and the cost to pharmaceutical companies of these failures can be substantial.

A 2016 study of success rates for drugs in clinical development looked at 7,455 drug development programs from the preceding decade and found that the overall likelihood for a drug to progress from Phase one clinical testing all the way to approval was just 9.6% (this would require passing through Phase I-III of clinical trials and submission of a New Drug Application (NDA) or Biologic License Application (BLA)).[xvii] An investigation published the same year, from the Tufts Center for the Study of Drug Development, does take the costs associated with ill-fated compounds into account. It estimates development costs in a risk-adjusted figure that factors in not only the cost of creating successful compounds, but also the cost of compound failures and the monetized cost of the delay between initial investments and eventual returns. Using this methodology, the study looked at the costs of research and development that were incurred for 106 different drugs from 10 different pharmaceutical companies.

The researchers found that the average out-of-pocket investment per approved new drug, accounting for peer compounds that had failed, was $1.4 billion. The inclusion of the monetized cost of the delay between investment and return brings the total cost per approved new drug up to an estimated $2.56 billion. This number can be

further inflated by accounting for the anticipated costs of post-approval research and development. Based on previous observations of these costs, the total estimated cost per approved drug was $2.87 billion.[xviii] Taken together, these two studies demonstrate not just that the path to drug approval is expensive and time-consuming at face value, but also that its costs can balloon even further when the losses from failed prospective compounds and foregone investments are acknowledged.

In addition to the costs of drug production in time and resources, there are several additional factors that also play a part in the overall investment pharmaceutical companies make in order to deliver a drug to consumers. These include the cost of drug synthesis itself, the cost of drug distribution, and the cost of marketing the product to increase its utilization. With all of these costs incurred, drug manufacturers rely on additional protection to ensure that development of their products is worth the trouble. If pharmaceutical companies that invested so heavily in a drug's development had to then compete immediately with other sellers distributing generic versions of their product, they would have difficulty recouping the cost of bringing their drug to market. With minimal prior investment to offset, generic manufacturers could sell the same drug at close to the cost of manufacturing the drug – a fraction of the price that the drug developer would need to charge in order to offset the expenses associated with the drug's development.

Incentivizing Drug Development

In order to prevent this undercutting situation and help encourage pharmaceutical manufacturers to continue researching new drugs and carrying them through the FDA approval process, the U.S. has put in place an incentive structure. This structure aims to offset the considerable investments of time and money needed to bring a drug to market in order to motivate pharmaceutical companies to continue navigating the process. The driving forces of the current U.S. incentive structure are the patent system and the availability of market exclusivity.

The patent system grants intellectual property rights to the developers of new inventions. Awarded by the U.S. Patent and Trademark Office, patents are a means of promoting innovation by affording the patent holder exclusive rights to the manufacture, use, and sale of their invention.[ix] Patents awarded to pharmaceutical companies for novel drugs grant them a 20-year period of federal protection for their product. Companies that have obtained their patent and submitted the corresponding NDA for their compound are afforded protected exclusivity from the FDA for the remainder of the patent term. As the House committee on Energy and Commerce outlines, these exclusive rights confer the opportunity for significant profit.[ix]

Patent holders are able to charge higher prices and control the market for their product in ways that would not be possible with the presence on competition from other companies. The ample returns that pharmaceutical companies are able to achieve

as a result of these exclusive rights are well documented. Researchers in 2016 analyzed the profits that pharmaceutical companies were able to achieve once their drugs gained FDA approval. They found that after a median of only four years, the studied drugs generated a total revenue of $67 billion for their developers. These returns more than offset the total cost of research and development that the drug developers put into these drugs, which was only $7.2 billion.[xx] These findings are a strong example of the power of patents to provide significant returns – and thereby meaningful incentives – to those who hold them. The potential for such an upside helps convince pharmaceutical companies to take on the otherwise unappealing drug development process. If this patent system did not exist, other companies could bring competition to the market by developing and selling their own generic versions of patented drugs - dropping drug prices overall and driving down the associated profits.[viii]

Patents alone are not the only incentive structure available to drug developers. FDA market exclusivity periods also grant manufacturers exclusive rights to produce and sell their drug. These exclusivity periods are awarded either concurrent with the length of patent exclusivity or in addition to its term. The primary purpose of FDA market exclusivity is to ensure that pharmaceutical companies do not lose out on the opportunity to control their market and return on investment because of delays caused by the FDA approval process. In order to protect their products, developers are incentivized to patent their products at the advent of the drug approval process. This process however can be lengthy, so many years of the 20-year patent term can elapse before drug companies are ever able to bring their product to consumers. For example,

the median approval length of 7.3 years found in the previously cited JAMA study would mean that over a third of the exclusivity afforded by the patent terms for those drugs was gone before the drugs reached market.[xx]

Supplemental market exclusivity periods were developed by the FDA in order to address this issue and assuage concerns from drug manufacturers that exclusivity associated with patents afforded them insufficient incentive. Pharmaceutical companies have the opportunity to receive five years of market exclusivity with the approval of their NDA, and can have further exclusivity periods addended onto this term as well. These additional exclusivity periods can result from positive features of the compound, tacking on valuable years to the length of market exclusivity. Even a one-year extension can be an opportunity for significant profit. This incentivizes manufacturers to further innovate in search of beneficial aspects of their compound even in the face of high costs of doing so. A powerful example of this incentivization is the 12 additional years of market exclusivity that can be awarded for the development of biologic drugs – a process that can be especially difficult and expensive.[ix]

It is worth noting that while the incentivization structures of patents and market exclusivity exist largely to offset the costs of drug development, the profits that pharmaceutical companies are able to make with this exclusivity are not necessarily proportional to the costs. This is because market exclusivity places all pricing power in the hands of the pharmaceutical companies. They are assured that no competitors are able to drive prices down by creating generic alternative drugs, which allows them to set the floor at the same time that they set the ceiling – wherever they choose.

With pharmaceutical companies effectively self-regulating the price of their products, the exclusive market does nothing to cap drug prices at a particular level, or to ensure that drug pricing has any relationship to the actual costs of drug production or the health and social impacts of drug delivery. Because pharmaceutical companies have this control, other factors beyond simply the cost of research go into drug pricing. Some have asserted that drugs are instead priced primarily based on the anticipated income that they can create.[xix] How the pricing of these drugs shakes out is a relevant concern, as it has a very tangible impact. In allowing pharmaceutical companies an exclusive market for their drugs so that they can recoup investments and obtain profits to make their undertaking worthwhile, both patents and market exclusivity enable manufacturers to increase the cost of drugs that falls to consumers.

## The Implications of High Pharmaceutical Prices

These high drug costs have direct, often detrimental implications for consumers. Because pharmaceutical companies are able to leverage their exclusive markets, patients and consumers have to pay the prices that these companies determine to be appropriate – without significant control from oversight or limitation. The high payouts that drug manufacturers secure ultimately come from consumers, which makes it more difficult, or even impossible, for many consumers to afford these drugs. Individuals who would otherwise be interested in using a given drug may simply have no option to do so

if they are unable to afford the price tag. This becomes especially problematic when consumers are not merely interested in a pharmaceutical product, but are reliant upon it to gain or maintain health or quality of life. The inability to access medications of such importance can have serious consequences.

One of the striking examples of these consequences can be seen as a result of the heights to which the cost of insulin has climbed. Insulin is an essential drug for individuals living with Type 1 Diabetes. It allows them to manage their body's blood sugar when the pancreatic cells that typically handle this task are unable to do so. In an alarmingly common reality, patients with Type 1 Diabetes are unable to access insulin due to its rapidly rising cost and their own limited economic means. The cost of insulin over the last 20 years has increased at an unprecedented rate. In the decade between 2002 and 2013, insulin prices tripled. Within just a few more years – in 2016 – prices had doubled again. By 2016, the average individual living with Type 1 Diabetes spent $5,705 per year on insulin to treat their condition.[xx, xxi] This is not an insignificant amount of money, and even those with reliable sources of income can struggle to meet their all of their needs when this much must be set aside in order to survive. A 2018 survey found that over a quarter of Type 1 Diabetics rationed their insulin – treating themselves with less than the medically recommended dosage – in order to make the medicine last longer so that they could save some money and more easily afford the next dosage.[xii]

Having to intentionally ration a drug in this way, or simply being unable to afford access to it at all, renders the drug less effective at treating the conditions for which it was designed. Beyond the clear negative impact that situations such as this have on the

potential of drugs to benefit society, these situations can also lead to more tragic consequences. Articles in recent years have documented the difficult scenarios in which individuals can find themselves, some of which have led to death in the absence of affordable medication.[xxii]

Although high drug prices that must be paid by consumers place a burden on them directly, there are additional avenues through which this burden can make its way back to them as well. Most notably, high drug prices must also be paid by the healthcare industry, which has contributed to the inflation of healthcare prices in general. There is some debate over the extent to which rising drug prices are to blame for rising healthcare costs, but they undoubtedly play a role. A 2016 study found that hospital spending on drugs, per admission, increased by 38.7% from 2013-2015. A subsequent study done in 2019 found that this spending continued to rise further by 18.5% from 2015-2017. These increasing costs fall back on consumers, as hospital costs in 2017 accounted for a third of all healthcare spending in the U.S., with individual hospital procedures increasingly attached to price tags of thousands or tens of thousands of dollars.

As these increasing concerns surrounding the pricing and availability of pharmaceutical products can be traced back to the limitations of the current patent-based and market exclusivity-based incentivization strategy, alternative approaches to this incentivization have been proposed. These potential drug development and pricing strategies are all attempts to answer the same fundamental question – how can we best

mitigate the burden of pharmaceutical costs while preserving the drive for drug discovery and innovation?

## Pharmaceutical Reform through the Lens of Justice

In answering this question well, the many varied ideas for pharmaceutical pricing reform must be contrasted. Naturally, these strategies stack up against each other differently, and each has its pros and cons. A difficulty of measuring these policies against each other all on the same playing field is that there are a number of different metrics by which they can be contrasted. The practicality of a reform, for example, is something that can (and should) be taken into account. Cost is another such factor that should come into play, as is Justice. It is challenging to prioritize these metrics, and likely also problematic to attempt to do so. Valuable insights can be gleaned through application of each of these lenses, and all of these insights should be brought together to form a complete picture of a given reform strategy.

In this project, I focus my investigation through one such lens – Justice. The conception of Justice that I appeal to in particular is that of Justice as Fairness, as put forward by John Rawls. Rawls presents an ideal of justice which he motivates with a detailed thought experiment. This thought experiment, which he coins the "original position", intends to make clear the perspective from which reasonable principles of justice can be agreed upon. The first restriction which Rawls suggests is that the

determination of principles should be agnostic of personal circumstances and inclinations.[xxiii] Here, he is controlling for the variation created by the "natural lottery"[2] – the phenomenon by which individuals acquire unique traits and situations through birth.

The natural lottery is so named because its results are outside of the individual's control – people do not play an agentic role in choosing the attributes and social situations that they will inherit. Rawls holds that the influence of advantages or disadvantages conferred by this natural lottery should be absent from our perspective when we conceive of principles of justice.[xxiv] He refers to this perspective with confounding influences removed as one from behind a "veil of ignorance".[xxix] Without adopting such a veil of ignorance, individuals could easily be influenced to reach differing ideals of justice based on the realities that would best suit their situations.

Behind the veil of ignorance, Rawls also stipulates that all individuals – as equal moral persons – should have equal standing in discussing the principles of justice. These individuals will then be able to establish core principles "as those which rational persons concerned to advance their interests would consent to as equals when none are known to be advantaged or disadvantaged by social and natural contingencies."[xxix] One additional feature of this scenario that Rawls specifies is what he refers to as "reflective

[2] Because the results of the natural lottery are outside of the control of an individual, they are often seen as morally arbitrary. Rawls holds that this is unfair. Others however have taken differing stances. Notably, Robert Nozick maintains that individuals are entitled to the advantages that the natural lottery confers, while H. Tristram Engelhardt argues that the resulting inequalities are unfortunate, but not unfair. [xxiv] The principles of Justice as Fairness assume Rawls' assertion that this inequality is unfair and should be addressed.

equilibrium", a process in which principles derived from this theoretical perspective are contrasted with intuitive certitudes (such as the injustice of religious discrimination). By working back and forth between these certitudes and the theoretical premise, he proposes that we will end up with a precise initial situation "that both expresses reasonable conditions and yields principles which match our considered judgements."[xxix] The principles of justice yielded from this initial situation – the original position – constitute Justice as Fairness.

Rawls posits that Justice as Fairness is comprised of two key principles. The first principle asserts that each person has an equal right to the most complete set of basic liberties that they can possibly have, while also ensuring that all persons are able to access this same set of liberties. This is referred to as the "maximin principle" as its goal is to maximize the minimum liberties available to all. The second principle holds that social and economic inequality can be justified, but only when they are tied to positions that all members of society have a comparable chance of attaining. Further, the inequality of these positions may only exist so long as it provides compensating benefits to all - and the greatest benefit to the those who need it most. This principle is referred to as "fair equality of opportunity" because of its focus on enabling all individuals a fair chance at gaining these positions.

Together, the maximin principle and fair equality of opportunity aim to create a justice that mitigates the effects of the natural lottery, and moves from these inherited, undeserved advantages and disadvantages toward a level playing field. More directly, the combination of the maximin and fair equality of opportunity principles entails that a

just society must provide sufficient access to basic liberties such that all have a fair, comparable[3] ability to access to its available opportunities.[xxix]

Based on this Rawlsian account of justice, Norman Daniels has argued that healthcare is a different kind of thing from commercial goods. Specifically, Daniels proposes that healthcare is not a good, but an institution that should be included among those we hold responsible for helping all people achieve fair equality of opportunity. As with institutions like education, healthcare should work to ensure that opportunity is distributed evenly in society – correcting for the inequality of opportunity created by the "natural lottery". This argument for healthcare's inclusion as an essential institution rests on the assertion that it is necessary to provide healthcare to some individuals in order for them to attain access to positions of opportunity comparable to that of their peers. Based on the principles of Justice as Fairness, it follows therefore that each person has a right to the level of healthcare that affords them a fair chance at opportunity.[xxv] This "decent minimum" of healthcare may be considered a low bar, and is notably not the right to "the enjoyment of the highest attainable standard of health" that the World Health Organization outlines in its constitution.[xxvi]

It is also important to note that Daniels' interpretation of Justice as Fairness establishes a right to a "decent minimum" of healthcare whose end is comparable or equal access to positions of opportunity, which is not the same as a right to a "decent minimum" of

[3] This fair, comparable access to opportunity is a step removed from an ideal truly equal access to opportunity. It is a more reserved, practical goal for a society to aspire toward, but its end – nullification of undeserved disparity – is the same. With sufficient means to achieve its ends, Justice as Fairness could become Justice as Equality.

healthcare whose end is comparable or equal health.[xxx] These caveats aside however, the right to healthcare entailed by Justice as Fairness is an informative metric upon which to evaluate both present and future healthcare systems, as it makes clear the advantages and shortcomings that individuals face in a given situation.

# CHAPTER 2

## The Health Impact Fund

In light of the shortcomings of the current incentive structure for pharmaceutical development and distribution, Thomas Pogge has proposed an alternative incentive strategy – the Health Impact Fund (HIF). The HIF model invites participating pharmaceutical developers to sell their products at or below cost of production, and rewards them for doing so based on how these products perform. The products that companies opt into this incentive structure are evaluated based on the overall health impact they show for their patients, and companies are then compensated with a payout proportional to this evaluation and how it stacks up against the other entered products. This proportional compensation comes from a government-funded pool of money into which the competing products are entered.

At its core, the HIF aims to incentivize drug production in a way that aligns maximizing health benefits with company profits, rather than maximizing company profits alone. In this focus and in many other aspects, the HIF is fundamentally different from the current U.S. model for incentivizing the drug development process. This chapter outlines these differences and their importance.

Argument for the HIF

At the root of the HIF is the concept that the current drug pricing system is not the most efficient pricing strategy from an economic perspective. In outlining the economic argument against the current drug development incentive structure, Pogge describes how the present free-market system fails to deliver an optimal outcome. According to his analysis, the free-market approach does not fare well in an environment with such inequality present. Products, in this case pharmaceuticals, will be priced at a relatively high point in order to maximize profits. This reality, however, prices those who cannot afford the high cost of pharmaceuticals out of the ability to access them.

An alternative pricing approach is for society to subsidize the product manufacturer to incentivize the lowering of the sale price of their product. At this lower price point, many who would otherwise be unable to afford the product now have access to it. This increased distribution not only provides added value to the consumers – it also offsets (to some degree) the diminished returns that manufacturers will expect to see as a result of lowering their prices. Increased sale volume, in concert with a sufficient monetary incentive, can allow manufacturers to attain the same revenue as they did under the free-market approach – or even to surpass this mark. The

implication of this scenario is a system in which manufacturers maintain or increase their returns, and consumers have increased access to their product.[4, xxvii]

At its simplest, this is the strategy that the HIF proposes to apply to the pharmaceutical market – using an incentive fund to compensate pharmaceutical manufacturers sufficiently such that they lower drug prices. Because applying such a strategy in practice is of course more fraught with complexity than this, Pogge provides additional detail on how the HIF would operate.

## Structure and Details of the HIF

The simple structure outlined above, with all companies selling their products at reduced costs, would provide weak incentive for competition among pharmaceutical companies who would no longer be able to reap the rewards of market exclusivity to so lucrative an extent. This would be a step backwards from the current system, in which innovators are rewarded for developing new and improved drugs before their peers. In order to preserve this competition and the innovation which it naturally drives, the HIF operates differently.

[4] Some consumers would likely experience a decreased total cost of the product as well, depending on the source of the money used for the monetary incentive and the proportionality with which contributions to this fund are determined.

The HIF preserves the fundamental idea that a pharmaceutical company is entitled to an exclusive market on their unique, novel drug. This allows developers to retain their ability to profit, albeit through an otherwise very different system. When a pharmaceutical company agrees provide their unique drug at a reduced price to consumers (at or near the price of production), the HIF considers this drug as having been opted into a pool of drugs that are all eligible to receive a portion of the fund's annual payout. The HIF would not merely distribute funds equally to all pharmaceutical manufacturers willing to sell their products at a reduced price. Instead, the HIF evaluates the "Health Impact" that each drug has on its target population. This impact, assessed in the quality-adjusted life years[5, xxviii] (QALYs) that the drug provides, is then used as the basis for proportionally distributing payouts to each pharmaceutical company.[xxxiv] The HIF would award drugs that provide more significant health impacts higher payouts, and grant lower payouts to those providing lower QALY increases. As it is currently proposed, the HIF would allow drugs to enroll and receive corresponding payouts for a 10 year term, roughly mirroring the length of time for which a drug can be expected to experience an exclusive market under the current pricing structure.[6, xx]

Such a system incentivizes the creation of drugs that can make significant differences in health outcomes, and the distribution of these drugs as broadly as

[5] At their core, QALYs are a representation of time alive, adjusted for the desirability of the health state during that time. They are an imperfect metric of health, but an established standard nonetheless. For the purpose of this paper, I will set aside the question of whether or not QALYs are the best method for measuring health impact.

[6] Although the patent term is 20 years, much of this time is taken up by the FDA approval process. Considering the previously cited median approval length of 7.3 years, most drugs will only experience 12+ years of exclusive market rather than the full 20 suggested by the patent's term.

possible. It also ensures that these drugs are priced affordably at or near cost of production, in contrast to the more expensive prices reached through the patent-protected markups of the current U.S. pricing structure. Additionally, the HIF fosters competition between drug developers to meet these marks more effectively than their competitors, and to ensure that their products, once distributed, truly make a difference for their target populations. Much like the current incentive system, pharmaceutical companies that fail to innovate as effectively as their peers will reap fewer rewards.

The utility of this strategy can be illustrated contrasting two prototypical prescription drugs. The first – Zolgensma – is a product that resolves spinal muscular atrophy (SMA) in infants (an uncommon but debilitating disease) in a single use. The second is Clarinex, a prescription antihistamine that treats allergy symptoms without resolving the underlying condition. Under the current U.S. incentive structure, Clarinex might garner significant profits due to its large, sustainable market. Conversely, Zolgensma might have more difficulty doing so, as its market is more limited and less reliable. The producer of Zolgensma could raise the drug's price in hopes of generating increased revenue, but this would simultaneously constrict the drug's market further by pricing out potential patients.[7,xxix] As outlined previously, this is exactly what the developers of Zolgensma have done.

[7] It is worth noting that Zolgensma has in fact been profitable for Novartis – largely because insurance companies have so far been willing to foot the $2.1 million bill for the treatment. Nevertheless, this pricing structure does limit the availability of the drug to only those patients who are insured, and risks constricting availability further if insurance companies change their stance on paying for the treatment.

Under the HIF however, Zolgensma could be more viable. It would be in line to receive a larger incentive payout from the fund than a drug like Clarinex due to its more significant health impact. The producers of Clarinex would thereby be incentivized to develop new products with greater focus on health impact in order to better compete with the producers of Zolgensma for a portion of the HIF payout.

Importantly, the incentive structure of the HIF de-links the price of pharmaceuticals from the reward for their production. This is especially significant because, as outlined in the last chapter, the idea that drugs are priced directly in relation to their respective cost of development is misleading. Instead, pricing is often based on the potential income that manufacturers anticipate they will be able to generate. Under the current incentive structure for example, drugs like Zolgensma are likely to be placed at high price points in order to maximize their revenue for each one-off use – regardless of whether their actual cost of development was in fact low. Because the HIF sets the price of a drug at or near what it costs to produce, it de-links drug pricing from the cost of its development or the potential for direct profit. In doing so, it incentivizes the production of drugs that would otherwise not be pursued due to poor prospects of generating income. As a result, pharmaceutical companies are more likely to create and distribute drugs based on their health impact rather than their potential monetary return.

This can have a significant impact on the type of drugs that are produced. For example, imagine that SMA – the condition treated by Zolgensma – happens to be overwhelmingly prevalent in a population with limited ability to pay – through insurance

or out of pocket. When drugs like Zolgensma are assigned a high price in order to account for their one-time usage – and few in the population who would use the drug are able to pay that price tag – the potential for these drugs to generate a profit becomes limited under the current U.S. incentive structure. In these situations where the prospect of profit is limited, distribution of such drugs may not be worthwhile to the manufacturer. This is especially problematic when these limited treatments are ones that would otherwise be lessening the burden of disease on individual populations or demographics. This is a concerning reality for drugs fitting the archetype of Zolgensma under the current pricing structure.

Because the HIF would judge drugs like Zolgensma based on their impact and reward them accordingly, the strategy would create increased incentive for the development of drugs that target afflictions or populations with a greater opportunity for impact. This would notably increase focus on diseases that disproportionately affect underserved populations - where such incentive is absent under the current structure. The potential development of drugs targeting neglected diseases, along with the broad distribution of these drugs, would do more for populations that currently see relatively limited benefits from the pharmaceutical industry. Such benefit is powerful, as the current reality has resulted in the continued absence of treatment for some diseases that are relatively widespread among poorer populations.

The importance that the HIF places on the health impact that drugs can make has further implications that reach beyond just the pharmaceutical industry. Because health impact is measured based on the outcome of drug treatment, rather than merely

drug delivery, the entire treatment process matters. It is therefore in the best interest of pharmaceutical manufacturers to not only ensure that their drug is distributed broadly to its target population, but also that the drug is delivered correctly, and that its delivery is accompanied by adequate medical treatment to ensure that the intended benefit in terms of QALYs is achieved. In the pursuit of ensuring such accompanying care, pharmaceutical companies would likely be incentivized to extend their investments beyond drug distribution and into healthcare infrastructure.[xiii]

When pharmaceutical companies subsidize the strengthening of the healthcare infrastructure that is accessible to their drug's target population, they can increase the potential health impact of their drugs. This higher impact, in turn, entitles manufacturers to receive a higher payout from the HIF. As drug consumers – and in fact all members of the public – are or may become beneficiaries of improvements to health systems, this creates another win-win scenario for all involved parties.

Another key aspect of the HIF is that it is not meant to replace the existing drug pricing structure altogether, but rather to exist alongside it and thereby reform the overall result. Importantly, this means that the HIF does not risk compromising the current drug development process which ensures that drugs are safe and effective – a marked strength of the existing FDA approval framework. An additional implication is that pharmaceutical companies are not obligated to opt their drugs into the HIF pool to compete for a slice of the payout.[xxxvi] They can alternatively choose not to opt into the pool, forego any potential HIF payouts, and instead continue charging any desired price for their products in a patent-protected exclusive market. For some drugs, low health

impacts or small target populations may make participation in the HIF undesirable. This would be the case with Clarinex – the allergy treatment outlined previously.

The drugs for which participation in the HIF can truly be a boon are those that fall into the opposite camp – those that have significant health impact. Drugs like Zolgensma are clear examples of this with their life-altering ability to cure debilitating disease, but less obvious examples can also provide marked improvement to the health of those they treat. This is especially true when drugs have the potential to make an impact for large populations or when they are made accessible at substantially reduced prices – greatly increasing their availability. As outlined previously, drugs that are not widely distributed – or even developed – within the current incentive structure due to their target population can notably benefit her from participating in the HIF.

A natural question that arises with the proposal of the HIF is how the incentive fund will be created and maintained. Sourcing the fund from government contributions is a straightforward way to keep the HIF up and running. It also makes a lot of sense, as the government funds allocated to the HIF are ultimately derived from tax revenue. This means that the citizens of a country where the HIF is operating are all contributing to this fund to a small extent. While this could – and likely would – place an increased tax burden on all, this burden would also be partly or fully offset by the decrease in public costs resulting from an operational HIF.[xxxiii] The presence of drugs sold at a reduced cost would mean decreased government spending directly on pharmaceuticals, as well as indirectly on healthcare and health insurance. This potentially offsetting decrease in public costs is in addition to the aforementioned benefits of the HIF – decreased private

costs of pharmaceutical products and an increased focus by drug developers on diseases with the most widespread health impact.

Limitations of the HIF

As with any strategy for overhauling the current drug pricing structure, the HIF faces a number of practical challenges to its implementation. Each of these limitations, laid out below, is explored in greater depth in the following chapter.

Establishing the HIF in practice requires a functional framework to reliably measure health impact. Without such a framework in place, the evaluation of drugs against each other could risk becoming subjective, or at least readily disputed by drug manufacturers. In a similar vein, establishing the HIF also requires the creation of guidelines to control competitive behaviors and other practices aimed at maximizing HIF incentives that may be detrimental to consumers. Regulations of this type already exist for currently adopted incentive frameworks, but the environment created by the introduction of the HIF would open the door to new, uncontrolled practices.

The HIF would also be reliant upon commitment of support from sponsors and involved drug developers. Monetary investment would be essential to sustain an ample fund, and buy-in from drug developers would be necessary for the model to begin functioning and to take hold. Additionally, this would all function most readily when

implemented within a well-defined, feasible scope of operation. As I explore a hypothetical adoption of the HIF in the U.S. in the next chapter, I expound upon these challenges and how they might be addressed.

# CHAPTER 3

## The HIF in the U.S.

At present, the Health Impact Fund as proposed by Pogge is a purely theoretical approach. The potential application of the HIF on the international scale has been both lauded for its potential and criticized for its impracticality. Much of this criticism stems from the scale of such an implementation and the inherently large number of factors that come into play. The HIF can be more readily outlined within a limited, concretely defined scope. The potential adoption of the HIF at a national level provides an instance of this concrete scope. In order to explore the differing implications of the HIF on the national scale, I outline in this chapter a hypothetical implementation of the HIF in the U.S. I analyze each feature of this implementation in turn through the lens of Rawlsian Justice as Fairness.

## The HIF and Patent Framework

The potential implementation of the HIF that I outline here would have several key features. The first and most important consideration that comes into play is how the HIF fits into the current drug development and incentivization framework in the U.S. As

a reform strategy, the HIF could be established to function in concert with the existing patent and market exclusivity structure, or to replace parts of it. Establishing the HIF alongside the existing incentive structure would be the optimal approach in the U.S., and would be least disruptive to existing development practices and approval processes. With this approach, Pharmaceutical manufacturers would have the same motivation to develop and patent drugs through the current process, but would have an alternative path available as well.

To illustrate this, I again bring in the examples used in chapter two: Zolgensma – the treatment that cures SMA, and Clarinex – the drug that relieves allergy symptoms. Under the continuation of the existing pricing structure, the makers of Clarinex would see sustained success of their drug – priced to earn a profit in its large, reliable market. The company might even bring other drugs like it to market to benefit similarly. Meanwhile, the makers of drugs like Zolgensma would also see success – where it would have been more limited before – through their newfound ability to distribute these drugs so as to maximize their reach and efficacy. These drug developers would no longer need to struggle to generate a profit in a more limited market (which could dry up as patients were cured or insurance coverages changed). Instead, they would be able to reap indirect rewards from the HIF in return for the health impact of their drugs. The HIF's provision of a payout to high-impact drugs like Zolgensma would ensure the economic viability of that drug archetype to pharmaceutical developers in a way that the existing pricing structure does not.

As these examples show, production of some drugs will still provide better economic prospects through the patent and exclusivity incentive structure, prompting pharmaceutical companies to continue taking their drugs to market through that process. In other cases however, drug manufacturers will be encouraged to produce new drugs that the current patent and exclusivity structure gives them little incentive to pursue – drugs that can make significant health impacts when distributed at a discounted price. For drugs under the existing incentive structure, distribution at a discounted price is rarely tenable, as it limits the ability for drug developers to achieve a return on investment. Markets that exist only for discounted drugs (for example affected populations that are only able to pay a discounted price) are therefore rarely available. As a result, drugs that would target these markets are seldom developed.

The upshot of the altered incentive structure created by the HIF would be a shift away from drugs that target the diseases of only those who can pay – toward drugs that target the diseases of those most in need. Retaining the current incentive framework alongside the HIF is important because it ensures that existing incentives for drug production are preserved. Switching abruptly and completely from the current patent model to a health impact model would undermine the incentives driving current drug production; and could risk stifling pharmaceutical innovation now and in the future. Additionally, the combination of both the HIF and the current incentive structure is beneficial in that it creates the potential for a more diverse array of drugs to be available – as the incentives of both frameworks will be in play.

This incentivization of increased diversity in pharmaceutical products would be likely to have effects reaching beyond the pharmaceutical sector as well. Notably, it could alter the state of basic research, bringing increased flexibility and opportunity to the work of early investigators. This would occur through the opening of new avenues for research – into areas that might previously have been overlooked because of their meager prospects to generate economic return (and thereby interest and investment from a pharmaceutical company). Basic research into tropical diseases for example could be an area in line for growth, with pharmaceutical companies newly interested in the returns that treating these diseases could garner through the HIF. Moreover, these new avenues for research would not come at the expense of previous research directions, as the current incentive framework would remain in addition to the HIF – creating new research opportunities without eliminating the old.

A pharmaceutical industry motivated to develop and distribute drugs that target conditions where the most health impact can be made, irrespective or profit, is in line with the values of Justice as Fairness. So too is an academic research community encouraged to pursue research focused on areas of health impact. Such a reality would be a step toward meeting the basic healthcare needs of all - which would allow all a fair chance at opportunity comparable to that of their peers. While this adoption of the HIF in tandem with the existing incentive structure only begins to approach the ideal sought by Justice as Fairness, it strikes an important balance in doing so. In short – it creates a space where drugs that resemble both Zolgensma and Clarinex can flourish. Moreover, the academic community is encouraged to expand the scope of their exploratory

research, the pharmaceutical industry is encouraged to produce a broader range of drugs, and a broader range of patients are able to benefit from them – to a greater extent than they are today. Such a reality makes strides toward neutralizing the inherent healthcare disparity across individuals and populations that the concept of the natural lottery identifies. While drugs priced under the current structure may not be as readily attainable to all as those priced through the HIF, retaining the current drug pricing framework is a necessary concession.

A more hardline implementation of drug pricing reform aligned closely with Rawlsian justice – one prioritizing a decent minimum level of drug development and distribution for all, without making concessions – is tempting. This would create a reality in which both high-impact drugs like Zolgensma and readily-marketable drugs like Clarinex are available and attainable to all. Unfortunately, such reform would also be liable to stifle the current incentives for pharmaceutical innovation and drug development. The developers of Clarinex for example would stand to see losses under this hardline structure – compelled to distribute their drug at its cost of production, with no prospect of a payout from the HIF due to the drug's low health impact in relation to competing drugs. As a result of these dampened incentives for drug development, this approach would trade a more just distribution of drugs in the short term for a long term in which the pharmaceutical industry is less inclined to pursue drug production and development.

This dampening of incentives – and a directly resultant decrease in pharmaceutical research and development – would mean fewer, less available drugs in

the long term, diminishing drug accessibility. Diminished drug accessibility in turn could create a situation ultimately less just than it was prior to the structural reform. This demonstrates the risk of pushing too hard for improved drug accessibility to all without fully taking the implications into account. As Nevin Gewertz and Rivka Amado rightly outline in their critique of the practical application of Rawlsian Justice as Fairness, a more nuanced approach to healthcare policy decisions is crucial so as to avoid hampering pharmaceutical innovation.[xiv] The HIF as an option rather than a mandate presents a means by which justice can be attained in this more nuanced way, to a larger extent than it is attained currently, without committing to or attempting to meet goals that push too forcefully against other aspects of the drug development process.

## Funding the HIF

Another key feature of a Health Impact Fund implemented in the U.S. is the determination of how the model should be funded. In order for the HIF to be effective, it needs to see both financial and ideological buy-in from sponsors and pharmaceutical developers alike. Without sponsors who believe that their investment is leading to a worthwhile end and drug developers who find the reward sufficient and trust in its availability, the HIF won't be able to get off the ground. The international model proposed by Pogge is maintained by contributions from the governments of member nations. The natural corollary of this at the national level in the U.S. would be for the

federal government to allocate money to the fund. The advantage of these strategies is that they ensure that funds for the program are reliably available. This is significant, as Pogge stresses, because pharmaceutical innovation takes time.[xxxiii] Pharmaceutical manufacturers developing new drugs need to be assured not only that an incentive is currently available for the product that they are designing, but also that the incentive still exists years down the line when their product reaches market. The ability for an implementation of the HIF maintained by federal funding to deliver this assurance gives it promise for success.

Sourcing funds for the HIF from the federal government effectively means that the burden for funding the HIF would be on U.S. taxpayers. While this increased burden will likely be small – Pogge estimates that a $6 billion yearly fund could sustain 20 – 30 products – it will nonetheless represent an increase in federal contributions from taxpayers. As outlined in the previous chapter, this increased burden will be offset to at least some extent by decreased public and private costs of pharmaceuticals, and of other services whose costs they currently inflate. Both individuals and the government will spend less on pharmaceutical costs directly, and on healthcare, health insurance, and other costs tied to pharmaceutical prices.

Regardless of whether or not the economic benefits offset the increased tax burden, this method of funding the HIF will lead to a more just distribution of healthcare through increased pharmaceutical availability. The priority of Justice as Fairness is to enable all to have fair access to equal opportunity by providing them with basic liberties. If a burden on all is necessary to further this end, that burden is justified – so long as it

does not deny any other basic liberties by its creation. In this case, the minor increase in tax burden needed to create a $6 billion fund is unlikely to infringe upon any basic liberties with its enactment (and should be adjusted if it does so). It will however improve the minimum level of healthcare available to all by increasing the production of drugs targeted to and affordable by those with limited means.

## Allocating HIF Incentives

How payouts from the HIF should be allocated is also an important feature of a potential implementation of the HIF. With sufficient funding in place, money will be available to incentivize development and distribution of drugs, but it is critical that a framework for measuring the impact of these products against that of their peers is also established. One of the challenges associated with implementing the HIF is the difficulty of evaluating competing drugs against each other in order to determine the proportional payout from the fund. It may be straightforward enough to say that the cure provided by treatment with Zolgensma has a greater health impact than the allergy relief provided by Clarinex, but it is a more difficult, nuanced question to quantify the magnitude of that difference and determine how incentives should be paid out as a result. This of course becomes more challenging still when the distinction must be made between two drugs with more similar health impact. Developing and installing a system to conduct these extensive drug comparisons must be done in order to establish the HIF

effectively. The potential challenges of this step pose a significant obstacle to the concept's practical adoption in the U.S.

A proposed strategy for overcoming this obstacle is for the HIF to embrace an evaluation process similar to that used by some national insurance systems. In this model, analysis of health impact is estimated initially based on pre-approval clinical trial results and then determined subsequently through post-market data collection and analysis. In the case of this proposed HIF in the U.S., this impact could be quantified yearly in terms of QALYs (as in the hypothetical HIF outlined by Pogge).[xiii] Such quantification will be difficult and likely expensive, which would require some portion of the HIF's funding to be directly earmarked for this purpose. Pogge estimates that up to 10% of his international HIF's operating budget would be devoted to this critical evaluation – for the sake of this hypothetical, I assume that this figure will apply similarly in a U.S. implementation.[xiii] While a costly process as merely an assessment tool, the data collection funded by the HIF would also prove valuable toward other ends. It could have utility for further pharmaceutical research and development, and for future clinical treatment or public health improvements. This long-term assessment could even be fed back into the FDA's regulatory process as information with value similar to that of phase four clinical trials – delivering important data on safety and efficacy.[xxx]

Notably, there is also an established precedent in the U.S. for the funding of drug evaluation to be sponsored in part by the health insurance industry. The Affordable Care Act, passed in 2010, included the establishment of the Patient-Centered Outcomes

Research Institute (PCORI) and the similarly-named Trust Fund through which to support it (PCORTF). The PCORI aims to conduct clinical effectiveness research with the goal of improving healthcare decision-making throughout the healthcare sector. Its source of funding, the PCORTF, is sustained in part by federal funds, but also through the PCORTF Fee: a fee assessed on providers of specific health insurance policies, including issuers of private insurance and sponsors of self-insured plans.[xxxi] While the PCORI is not geared specifically toward the quantification of drug efficacy, it establishes a precedent for how the assessment necessary to support the HIF in the U.S. might be funded. A tax similar to the PCORTF Fee might be imposed to help fund this aspect of the HIF in the U.S., or an amount of the existing PCORTF could even be reallocated toward the HIF.

In terms of Justice as Fairness, basing the HIF's incentive allocation framework on the quantification of a product's health impact works well, but has some limitations. The health impact basis directly incentivizes the production of drugs that make the largest difference in terms of QALYs. As a result, the HIF will incentivize the production of drugs that target conditions with high QALY burdens and that are not currently worth the investment under the patent- and exclusivity-based incentive system. The current judgement as to whether or not the development of a drug is a worthwhile investment is based largely on the projected return that drugs will garner from their sale, so drugs deemed worthy of investment are predisposed to be those that affect populations with the means to pay for them. In contrast, conditions that have high QALY burdens and are not deemed worthwhile investments under the current incentive structure are likely to be conditions that afflict populations whose access to healthcare is at risk or lacking. The

focus that the HIF places on quantifying health impact encourages drug developers to target these conditions with high QALY burdens in populations who may have limited means to pay for traditionally priced drugs. Because such conditions are likely to also infringe upon the fair access to opportunity available to these populations, the focus of the HIF on meeting their disproportionate healthcare needs enables progress toward a more just reality. The HIF's basis in quantification of health impact is thereby aligned with the ends of Justice as Fairness.

In addition, this implementation of the HIF would directly incentivize the distribution and administration of drugs so as to maximize their health impact (and thereby the returns that pharmaceutical companies would earn from the fund). This incentivization, in turn, has the potential to strengthen healthcare access and infrastructure, as well as increase the focus by pharmaceutical developers on public health and social determinants of health. These potential improvements will be especially attainable in areas where the need for them is highest. In these areas with a lack of healthcare access and linked resources, fair access to opportunity will likely also be limited. The potential of the HIF to encourage the strengthening of these structures not only provides a benefit to these populations in and of itself, but also brings these populations closer to attaining fair equality of opportunity.

From the perspective of Justice as Fairness, there are also notable limitations that arise as a result of allocating incentives based on health impact. First, pharmaceutical companies can become entangled in the healthcare system in their pursuit of these incentives. This might occur when pharmaceutical companies attempt

to push certain drugs or certain courses of treatment on healthcare providers. For example, a pharmaceutical company marketing a drug to treat respiratory infection might encourage providers to use their drug instead of a competing drug or an alternative course of treatment. This may be contrary to the professional opinion of the healthcare provider, or to the best interests of the patient. In addition to generating conflicts of interest among providers, actions like these by pharmaceutical developers could potentially give them an outsized influence over medical practice. In doing so, drug developers step beyond the bounds of their role in pharmaceutical production and delivery, and infringe on the practice of medicine. This tension between the pharmaceutical and healthcare industries is not unique to the HIF, and will be present under any drug pricing framework so long as the two industries are so closely linked. It is a tension that can be most readily eased if the government takes the lead in implementing any drug reform, and in doing so places appropriate bounds on the relationship between the two industries – balancing the interests of each.

Additionally, allocating incentives based on health impact will not be sufficient to motivate pharmaceutical companies to address all populations in need. The level of investment necessary to achieve health impacts for certain conditions or to improve drug delivery and administration in some areas will prove prohibitive to overcome, or will simply exceed the anticipated payout from the HIF. To demonstrate the issues that can occur when pharmaceutical developers overstep, suppose Drug A is a vaccine against COVID-19 that can be stored only at -80° C – an extremely cold temperature that can only be achieved in certain freezers. In order to facilitate the widespread

distribution of Drug A, the drug's developer must also ensure the widespread availability of -80° C freezers. Suppose also that Drug A can only be administered by a specially trained provider, and must therefore be delivered at a medical center with these specialists available. Meeting these infrastructure requirements in order to deliver Drug A is expensive, but necessary to guarantee the vaccine's optimal performance. The developer of Drug A would therefore be incentivized to make these investments in order to ensure that these requirements are met as broadly as possible.

There is a tipping point here, where these investments will begin to translate to less of an increase in the vaccine's health impact, and thereby less of an increase in the payout from the HIF. As this incentive to invest in improving the health impact diminishes, the investments made by Drug A's developer will also diminish. In order to achieve an ideal outcome in terms of Justice as Fairness however, a hardline policy approach may necessitate that pharmaceutical companies continue to invest in facilitating successful delivery of their product as long as there are those that need it. This may mean investing beyond the point at which this investment is worth the added return, beyond the value of any potential payout, or even beyond the entirety of what the company is able to pay.

In the U.S., this concern of rising investments by pharmaceutical developers outpacing the rewards they generate would most readily manifest itself in communities with lacking healthcare infrastructure. In order to attain the improved outcomes on which the HIF judges drug success, these communities would require assistance from pharmaceutical manufacturers in improving their infrastructure – such as the -80° C

freezers and payrolled, specially trained providers in our vaccine example – which manufacturers may be increasingly reluctant to provide. In some cases, when the cost of infrastructure improvement is too high or the need for it too widespread, investing in such improvement would lead pharmaceutical developers to expend impossibly large amounts of money in order to deliver the ideal minimum of healthcare.

Although infrastructure in the U.S. is generally more developed than it is globally, the challenge of extending and strengthening the healthcare infrastructure available to some populations would still be significant. It could certainly be impossible (or merely undesirable from the perspective of incentivized pharmaceutical developers) to address these scenarios. As such it is at best unrealistic – and more likely not viable – for an implementation of the HIF to achieve the Rawlsian ideal of basic healthcare provision. This concern has also been noted as a challenge for global applications of pricing reform that take too idealistic an approach (in terms of justice).[xxxii]

Despite these concerns that arise from incentivization based on health impact, the limitation on the ability of the HIF to improve drug distribution and healthcare infrastructure in some areas is not to the detriment of an implementation of the HIF, as it would still go further than the current drug pricing structure does. This is however a notable limitation of the model's ability to achieve the Rawlsian ideal of Justice as Fairness.

Pharmaceutical Competition and the HIF

A final area of note for a potential implementation of the HIF in the U.S. centers on the competition between drug developers that the HIF aims to incentivize. In order to ensure that drug developers retain their drive for innovation in the presence of drug pricing reform, the HIF invites competition by allowing drug developers larger slices of the incentive fund based on how well they perform relative to their peers. The competitive practices that this system creates, however, have the potential to be detrimental to the very populations that the HIF aims to benefit.

Jorn Sonderholm provides a specific instance of this in his critique of Pogge's HIF, where he posits that pharmaceutical developers may intentionally deteriorate healthcare infrastructure rather than bolster it. Developers may, for example, find that the best use of their resources is to not only improve the infrastructure that could lead to the greatest health impacts for their product, but also move to degrade the infrastructure that could lead to stronger health impacts for any competing products.[xxxviii] While such extreme manipulation of infrastructure may seem farfetched in the U.S., it could easily take subtler forms. Revisiting the recent example of the COVID-19 vaccine – Drug A – illustrates this. As outlined previously, the developer of Drug A would be incentivized to maximize the impact of its drug by bringing -80° C freezers and specially trained providers to its targeted region or community – improving the infrastructure there. Another company could have a competing COVID-19 vaccine

however – Drug B – that also requires specially trained providers to administer, but is stable at temperatures up to those of a household freezer – -20° C. Knowing that their reward from the HIF can be increased by demonstrating a greater impact than Drug A, the company backing the competing COVID-19 vaccine might invest money in relocating the specialized providers to facilities administering Drug B instead, disrupting care for the community in the process. The company backing Drug B might even go so far as limiting the availability of -80° C freezers in the community – undercutting the viability of their vaccine competition, but also damaging the infrastructure of the community in the process.[8]

Moreover, if Drug A is outcompeted, the vaccine's developer may decide to cut its losses and entirely cease investments in the healthcare infrastructure of an area, leaving the community to move forward on its own. Such push and pull of investment could be problematic for the populations caught in the middle – introducing additional uncertainty into the healthcare infrastructure upon which they rely. Clearly, the incentivization of such competitive behavior without due consideration for the effects it may have on populations at a more granular level could negatively impact these populations. While this risk associated with competition between pharmaceutical developers is a concern for an implementation of the HIF, it is important to note that the risk is not unique to the HIF. A similar risk of competitive practices detrimental to patient populations will be present under any drug pricing structure that incentivizes

[8] While not commonly used residentially, -80° C freezers are important in healthcare delivery and academic research. Limiting their availability in an area could be detrimental to the availability of other treatments and to the advancement of science and medicine.

such competition. The HIF does not present a solution to this potential problem, but it is also not the source of the problem.

From the perspective of Justice as Fairness, this competitive behavior is problematic as it does not increase fair access to opportunity, and may even lead to more limited healthcare access and a subsequent decrease in fair access to opportunity. The behavior risks encouraging pharmaceutical companies to make investments in populations as the means to a self-serving end. In light of the potential for an implementation of the HIF to create such competitive practices, a U.S. implementation of this incentive reform should establish guidelines that govern competition among developers in order to prevent any unacceptable practices from occurring.

## Takeaways from a Hypothetical HIF

This hypothetical implementation of the HIF in the U.S. is not one that is currently in the works or that is likely to take shape in the future. A simple proposal of how the HIF's establishment might manifest is an interesting thought experiment, but does not deliver significant value in and of itself. What this hypothetical scenario does deliver however, is a window into the larger advantages and disadvantages that any strategy implemented to reform the drug pricing structure in the U.S. may face. In the next chapter, I will distill these insights and build upon them in order to propose guidance for future drug pricing reform in the U.S.

# CHAPTER 4

## Lessons to Learn from a Proposed HIF

Implementing a version of the Health Impact Fund in the U.S. would be a complex undertaking. Though the core concepts of the HIF can be readily outlined, fitting them into the existing structures and realities present in the U.S. becomes complicated quickly. This is outlined in the previous chapter, which demonstrates that such an implementation has both potential advantages and sticking points. Each of these aspects of the hypothetical implementation of the HIF provide valuable insight into not only how an attempt at the HIF could best be implemented, but more importantly into how the U.S. should approach any largescale reform of its current drug pricing and incentive structures.

These insights can meaningfully inform the future adoption of any of the myriad possible reforms. Potential reforms span a wide range of proposals. Some models for example embrace a reference-based approach - a strategy commonly used internationally. Reference-based models first establish a group of medications that are functionally similar to the extent that they could be prescribed and used interchangeably. They then establish a standard price for this group of drugs, which reflects what the government is willing to pay to pharmaceutical developers for the drugs. If patients wish to purchase a drug in a given group, they are responsible for

paying only the difference between the actual cost of the drug and the standard price that their government will cover.[xxxiii]

In contrast, other reform models take an outcome-based approach, basing prices for each drug on that drug's efficacy. An example of an outcome-based model is one that weighs a drug's purported effect against the actual outcome it provides, and rewards drug developers accordingly. Similarly, an outcome-based model might require drug developers to provide rebates to patients when their drug fails to deliver its expected outcome.

Beyond these reform alternatives and the HIF strategy outlined previously, many other paths to drug pricing reform exist as well. The insights determined in this project will be valuable to apply in the adoption of any new policy, and will guide the future drug pricing structure of the U.S. toward a more just system. In this chapter, I expound upon these insights, their value, and how they can be more broadly applied in guiding drug policy reform in the U.S.

## Reform should be Implemented Deliberately and Account for the Current Pricing Framework

When considering an implementation of the HIF in the U.S., one of the most important aspects was how the HIF should be introduced into the current drug

incentivization and pricing structure. Introducing the HIF as a replacement for the existing pricing structure would be disruptive to the current drug development process, in addition to potentially undermining future innovation. In contrast, implementing the HIF as a strategy alongside the existing structure preserves the incentives to innovation that are already in place and adds additional incentivization for new drug development. This consideration of how a reform should be implemented in light of the existing system would be similarly important for any newly proposed strategy in the U.S. Putting forward an alternative framework for drug pricing could be a nonstarter without a path for it to integrate smoothly – at least at first - into the existing system.

Implementing reform so that it integrates with the structure already in place has several advantages. Firstly, the adoption of the reform would be likely to occur more readily. Policy proposals that appear to depart too significantly from the norm will experience a higher barrier to enactment. Lawmakers may express more skepticism and be more hesitant to endorse the adoption of reforms that represent such a substantial change. As Jonathan Oberlander has outlined in his comments on the infeasibility of enacting healthcare policy reform, the political system in the U.S. has a tendency to favor the status quo. In his words, "reformers have had to jump over every legislative hurdle, while opponents have only had to trip them up once to win."[xxxiv] This bias against system-wide change means that a potential reform takes a real risk in showing any flaws that can be used as points against it. It is therefore in the best interest of those championing a reform strategy to implement it so as to trip up as little as possible. Drug pricing reform that instead proposes a more measured change and entails a less

extreme overhaul will have a lower potential for unexpected or undesired results. As a result, it will have an easier path to becoming policy. In addition, adopting such a structure incrementally alongside (or in combination with) the established pricing structure rather than doing so abruptly in place of the established structure lessens the possibility that a new policy, once adopted, is rejected in favor of the old.

Implementing drug pricing reform gradually also improves the chances for the reform strategy to become established enough to demonstrate its utility. Policy propositions that appear radical in their departure from the established norm are at risk of failing outright before taking hold. Propositions that fail at such an early stage are thereby denied the opportunity to prove their worth. This is a significant concern, as the effects of any reform made to the drug pricing and incentive structure would take time to be fully realized and quantified. As such, any implementation of a reform that is ultimately short-lived will provide an incomplete picture of its value. It is therefore in the best interest of those implementing a reform strategy that it embraces a tactful model allowing it to exist for long enough to prove its worth.

In a similar vein, this incremental model of policy adoption will also mitigate the opposition that reform to the drug pricing structure is likely to face from pharmaceutical companies. This additional barrier to reform bears highlighting, as the pharmaceutical industry has considerable lobbying power, and any proposed changes to the current pricing structure that present an undesirable potential reality to pharmaceutical companies will be likely to face pushback. Such pushback would mean that the reform

would face a more difficult path to both approval and longevity. Increased resistance to achieving either of these would seriously hamper the prospects of a proposed reform.

Reform should Delink Drug Prices from Development Costs and Expected Returns

Another important consideration that arises when implementing a hypothetical HIF is the value that drug pricing reform can bring if it fundamentally changes the incentivization structure. Rather than aiming to incentivize drug development and discovery as ends in and of themselves, a strong reform strategy should encourage the drug development and distribution process to aim for and be measured by different metrics. Such a fundamental change in the incentive structure is valuable in that it would help delink pharmaceutical prices from the cost of initial production and the expected profits of the final products. Pharmaceutical pricing would move beyond this implicit tie at the heart of the current framework by providing incentives instead for products that improve health outcomes, access to treatment, or similar alternative metrics. Taking this step forward is especially important in the U.S., where pharmaceutical prices have become so elevated. Because a decrease in the cost of pharmaceutical development in the U.S. is unlikely to occur, this delinking is critical in that it creates a path toward achieving lower pharmaceutical prices that is independent of their high cost of production or expected returns.

Simultaneously, this fundamental change to the incentivization structure would increase the impetus for pharmaceutical companies to produce drugs that don't necessarily have the strongest potential for economic return or the lowest production cost – but instead offer promise based on other metrics. Through the lens of Justice as Fairness applied to healthcare, this would be especially beneficial when targeting metrics that could help deliver access to a basic minimum of healthcare. For example, drug developers could instead be incentivized to target the production and distribution of drugs with a high potential for therapeutic impact, or those that treat maladies disproportionally affecting underserved populations. Guiding drug pricing reform away from the current policies and toward a system with these alternative targets would help alleviate disparities in drug access – which are an unfortunate reality in the U.S., especially across demographic backgrounds and socioeconomic standings.[xxxv]

In shifting away from direct incentivization of drug production, the theoretical application of the HIF in the U.S. revealed that there is notable value in targeting two facets in particular: drug accessibility and drug efficacy. Encouraging the valuation of drugs based on their impact to each of these facets has the potential to not only directly increase the overall healthcare impact of new drugs, but also to indirectly improve healthcare infrastructure and public health measures. Pharmaceutical developers would see greater value in taking a more holistic approach to the health of their target demographics and addressing these secondary determinants of health so as to improve overall outcomes. Incentivizing developers to see value in addressing these secondary

determinants as part of providing their pharmaceutical products is important, as these determinants may otherwise be easily overlooked.

Reform should be Forward-Looking

Analyzing the hypothetical adoption of the HIF in the U.S. reveals another important insight in how drug pricing reform in general should be approached. While any proposed drug pricing reform will aim to lower drug prices in the short term, a strong approach to reform will also not preclude lower drug prices in the longer term. While this sounds intuitive, some potential reform strategies may fall victim to focusing too narrowly on the short-term implications of their prescribed changes and neglect to account for the effects that these changes in the present could have on the future pharmaceutical landscape. This can be an especially pertinent concern in attempting to attain drug distribution that meets a theoretical ideal without considering the practical consequences.

In the case of the HIF, an overcommitment to pursuing the Rawlsian ideal of justice applied to pharmaceutical access could push too aggressively for a broad distribution of drugs targeting a decent minimum of health in the short term. This could fail to ensure that drug manufacturers are sufficiently supported to continue the long-term drug development and innovation required to meet the needs of future patients. In designing any reform strategy therefore, this insight should be heeded. Care should

be taken to ensure that reforms are farsighted as well as nearsighted - they should consider how the changed system that they hope to attain will behave in practice, under real-world pressures. If they do not, they risk jeopardizing future drug development and availability in the pursuit of improving the current state of affairs.

The hypothetical implementation of the HIF further demonstrates the importance of being forward-looking with respect to funding the incentive structure. As outlined previously, it is important to pharmaceutical developers that there is continuity within the incentive framework so that they are assured that a deserving product will be appropriately rewarded once it has been created. A successful pricing reform strategy therefore requires a stream of funding that is reliable not only in the present, but also years down the road when a drug that begins the development process today will reach market.

In light of the reality outlined in the 2017 JAMA Internal Medicine study that the median time for a drug to progress through development and reach approval is 7.3 years, the need for long term assurance of available funding is essential in order to give pharmaceutical developers confidence that a new approach to incentivization will be to their benefit.[xx] A reform proposal unable to obtain reliable funding would leave drug companies reluctant to commit to drug development with no assurance that they would continue to receive incentives for their products as promised. Taking on the present expenses of drug development – on the scale of billions of dollars - is daunting on its own, let alone without the guarantee that an incentive will be available in the future once it has been earned.[xxii]

Reform should be Context-Specific

Another overarching guidance for reforming drug pricing in the U.S. is that the adopted strategy should be context-specific. A potential limitation of the HIF in the U.S. was that just distribution of drugs could be hindered in some areas due to lacking healthcare infrastructure. While this issue would not be as severe in the U.S. as it might be in other areas of the world, there are still regions of the U.S. where access to healthcare resources is severely limited, and where lacking infrastructure would result in a more challenging distribution of drugs to patients. This is especially the case in more rural regions of the country where barriers to quality healthcare are prevalent.[xli]

In order to account for these realities, a potential reform to the incentivization of drug development should be tailored to the environment that is undergoing the reform. The policy should be grounded in an informed understanding of the existing variations in drug need, access, and efficacy across the U.S. By grounding itself in this way, a new incentive structure would best situate itself to attain its targeted goals, without taking unnecessary risks.

A drug pricing structure that does not adequately take the full picture into account may push pharmaceutical companies, consumers, or other stakeholders into difficult positions. A policy change might, for example, require pharmaceutical developers to pursue certain drugs or meet certain distribution standards that are unrealistic or ill-conceived – making it difficult for the developers to remain profitable

and viable under the new structure. Similarly, policy reform could create a new reality that proves detrimental to consumers – such as an incentivization that leads drug developers to push healthcare providers toward using some drugs over others, or to focus less on targeting the diseases of certain populations and regions. Situations like these would be liable to occur when the reforms enacted by policymakers neglect to account for the relationships between the pharmaceutical industry, the healthcare industry, and the patient populations within the U.S. that they serve. Such oversight creates the risk of implementing a structure that overlooks important information or inappropriately prioritizes the measures on which to focus – leading to a reformed state that may not be substantially more just than the current state. In order to address this risk, a successful strategy for drug pricing reform should contain nuance that reflects the many variables at play – within patient populations and between industry sectors – and is designed to accommodate them.

Reform should Outline Expectations and Prepare for New Realities

A final takeaway from the theoretical implementation of the HIF comes from taking a step back to look at the bigger picture. Any meaningful reform to the current drug pricing framework will fundamentally alter the pharmaceutical landscape. Whether this change upends the present structure or is merely a minor shift, it will mean a new reality for pharmaceuticals in the U.S. In order to help drug developers successfully

navigate this new reality, expectations should be established and regulations should be put into place to govern which practices are encouraged and which are off the table. Foremost among these outlined expectations are guidelines which will need to establish for drug developers what aspects of a drug they should expect to be quantified, how the drug will be compared to its peers, and how incentive payments will be determined as a result of these considerations. If these details are not clearly set, pharmaceutical companies may be unsure of how to approach drug development and reluctant to invest time and money into the process.

It will also be necessary for guidelines to address competitive practices between drug developers. Such competition is generally beneficial due to its propensity for spurring developers to create more efficient and effective products, and to do so quicker than their peers. Competitive practices may also overstep however, and risk jeopardizing the benefits that a product might have to the public, or taking advantage of the public in order to gain an edge over their peers. For the HIF, this risk manifested in the idea that competing drug developers could sabotage the health outcomes of patients receiving their competitor's treatment in order to improve their own cut of the incentive fund. The concern would present itself similarly under any incentivization structures that facilitate competition in drug distribution. In order to prevent harmful practices like these from occurring, an approach to drug pricing reform should take time to understand what problematic situations and practices are foreseeable. With this understanding of the potential new pharmaceutical landscape in place, limitations should then be set in order to curtail actions that could be detrimental to consumers.

## Applying the Insights

After exploring all of these insights in detail, this chapter assembles them into a structured set of ideas that tie back to our larger question – how should the U.S. work to mitigate the burden that high drug prices currently place on consumers? In my concluding section, I tie these insights back to the Rawlsian right to a decent minimum of healthcare and reinforce the benefits of applying these insights in terms of that right.

# CONCLUSION

This project started out by outlining the costly and inconvenient gauntlet of the FDA approval process, through which prospective drugs must pass. It then looked at the U.S. pharmaceutical pricing structure that exists as a result – in which patents incentivize continued drug development through the creation of market exclusivity. The rising burden of pharmaceutical prices that this structure created has led to the proposal of varying reform strategies – all aiming to answer the same pressing question – how can we mitigate this growing burden – and what is the best path to doing so?

Focusing in on a hypothetical implementation of the Health Impact Fund in the U.S. provided a valuable case study in what challenges a reform can face – and how the reform might address these challenges successfully or succumb to them. The result of this experiment is a list of generalizable insights – pointers for a potential drug pricing reform in the U.S. that could be applied to any such strategy. Because these insights are derived through the lens of Rawlsian Justice as Fairness, a policy reform that is implemented in keeping with them will be tied back to this moral grounding.

Gradual implementation of a pricing reform will promote the adoption of the reform alongside the existing pricing structure. This will allow the U.S. to ease into the reform, and will ensure that drugs remain available throughout the transition to the new structure – in spite of pushback that the structure might face. Ensuring that this reform is implemented with a long-term vision is also important. Such an approach will

create a reliable structure, which will enable pharmaceutical developers and consumers alike to count on continued production of and access to drugs well into the future.

In addition, reform that separates drug pricing from the current and future cost of drug production will allow for the creation and distribution of drugs that target a more diverse array of diseases. This offers a meaningful change from drugs targeting diseases that merely afflict reliable populations with an ability to pay, and will lead to the creation of drugs that are more broadly affordable. When enacting such a reform, controlling its implementation with thoughtfully outlined expectations and standards will ensure that the reform functions well within the new drug pricing landscape, and that it remains focused on its intended aims.

While these guidelines do not present a complete roadmap to successfully reforming drug pricing policy, following them in adopting a reform will help ensure that the reformed policy is aligned with the ideals of Rawlsian justice. It will improve the availability and affordability of pharmaceutical products, and expand the access that consumers have to them. Addressing these critical factors will improve the level of healthcare available to all, and move the U.S. toward a more just reality – where limited access to drugs no longer creates a barrier to opportunity.

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**Technical Solutions Engineer at Epic** (October 2017 – July 2019) Verona, WI

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