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Lowering Drug Prices and Increasing Transparency.”**

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In contrast to most other developed countries, the United States relies more heavily on private markets to finance and provide healthcare services. While this is a source of consternation for some, this use of economic markets is not a policy accident and instead reflects a belief that there are many advantages to market based healthcare. A large and diverse country such as the United States has a wide variety of preferences and meaningful differences in the willingness to pay for quality. In this setting, the central planning inherent to regulated prices is unlikely to maximize welfare, and an economic market is the superior method of allocating goods and services. This is even more true once we consider the variety of economic actors necessary for the development of innovative new healthcare products and services. It is hard to imagine what omniscient actor could more efficiently balance these forces. Therefore, despite many contentions to the contrary, a market-based system remains the best mechanism for providing the appropriate incentives for long term welfare maximization.

However, relying on the market for the provision of such a vital set of goods and services requires both recognizing that healthcare markets, like any other market, can fail and that all markets require vigilant protection of the structures and institutions necessary to promote robust and vigorous competition. In addition, given the unique nature of healthcare there are times where society choose to finance access for a variety of vulnerable groups that otherwise would be unable to afford such goods and services. Ignoring these facts could result in healthcare markets that decrease welfare compared to a more regulated option.

Concerns about the appropriate role for markets in healthcare are perhaps most frequently discussed in the world of pharmaceuticals. At least one reason for this heightened attention is that the pharmaceutical sector requires some amount of government intervention to reach a welfare maximizing outcome. This is because the very heart of the innovative process for new drugs represents a market failure that must be addressed. The failure results from that fact that the scientific advancements generated by firms in the development of innovative pharmaceutical products are essentially a public good, i.e. the knowledge is effectively non-rival and non-excludable.<sup>1</sup> Absent government protection, rational firms realize they will be unlikely to capture the value generated by the large investments necessary to bring a product to market. This results in an economic phenomenon known as “hold up” whereby firms are unwilling to make value creating investments in the first place.

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<sup>1</sup> The degree to which this is fully a public good depends on how much information can be gleaned from the actual product, the regulatory filings, and the published research. For example, small molecule products can be more easily reverse engineered and therefore absent intellectual property protections are relatively easier to copy. Biologic products, however, have a more complex production process and therefore copying the technology is easier than making the product *de novo* but harder than for a small molecule product.

To address this initial market failure, governments offer various forms of intellectual property protection. Through either patents or other forms of market exclusivity, governments arm firms with time limited periods of enhanced market power that allow them to capture the value creating by innovative products. During this time period, the high prices curtail some access to valuable medicines. However, this reduced access today is deliberately traded off for the development of new products in the future. These new products provide access to patients for whom there would otherwise be no treatment.

Effectively, policies governing the development of pharmaceutical products involve trading off the static inefficiency of reduced access to products today in order to create the dynamic efficiency of increased development of new products in the future. To the extent that the value created by the new products exceeds the deadweight losses created by the high prices (and resulting decreased quantity), the periods of market exclusivity are welfare enhancing. This could be true even if the prices are quite high.

This tradeoff is a source of much of the controversy for prescription drugs because the reduced access today involves some number of readily identifiable individuals who are unable to access existing and potentially life-saving medications because of price.<sup>2</sup> Unsurprisingly, this particular form of a lack of access garners large amounts of press and political attention. However, it is important to remember a perhaps far greater access problem for patients suffering from conditions for which no treatment options exist at all.<sup>3</sup> For these individuals, there is no price at which they can purchase a treatment, and patients with these conditions will only gain access in the future by the dynamic efficiency created by intellectual property protection. As we consider the optimality of policies governing the pharmaceutical market, it is critical to balance the oft-discussed need for access to existing products with the less-discussed lack of access from the absence of effective treatments.

In addition, it's important to note that the existing forms of intellectual property protection do not preclude all price competition. While patented products are protected from an exact replica being brought to market, they do face competition from therapeutic substitutes that treat the same condition with a different product. These substitutes do not decrease prices to the same extent as an exact generic replica but they do introduce meaningful competition. In addition, given pharmaceutical products often have fairly heterogeneous treatment effects – these competing products can increase the set of available treatments for patients.

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<sup>2</sup> Garthwaite, Craig, and Benedic Ippolito. 2019. "Drug pricing conversations must take the cost of innovation into consideration." STAT. January 11.

<sup>3</sup> This is particularly true because the impact of high prices on quantity is far more complicated in a world of widely available health insurance. Those who are insured may not suffer as much decreased access as they would in a market without third party payment. However, those for whom drugs do not exist certainly will not access a treatment at any price.

As a result, the innovative firm cannot charge any price it desires but must consider both customer willingness to pay and the potential competition from therapeutic substitutes. In the private market, drug price negotiations between payers (via their pharmacy benefit managers) and pharmaceutical manufacturers are fierce with therapeutic substitutes being pitted against each other to gain access to patients. Products that provide truly unique treatments have fewer potential substitutes and can successfully command higher prices. Those offering limited advances over current products face stiffer competition for customers and must offer lower prices to gain market share.

A key feature of the trade off at the center of innovation policy is that the periods of market exclusivity are meant to be time limited. Society does not intend to grant permanent monopolies to firms that bring even very innovative products to market. Therefore, strict regulatory vigilance is required to ensure that after market exclusivity has expired, products face swift and robust competition from generic or biosimilar competitors. Such post-exclusivity competition both decreases prices and in the case of biosimilars can drive meaningful competition to decrease production costs and increase efficiency in this nascent industry.

While the Lower Drug Costs Now Act that is being discussed in today's hearings has a variety of features, a core of the proposed legislation would supplant this competitive market for drug pricing with a series of government administered prices that are based, in part, on the prices charged in a select group of foreign markets. Despite the fact that the supporters of the legislation describe the bill as promoting drug price "negotiation," there is little about this legislation that represent true negotiation. Instead, the bill intended for the prices of a subset of true to be limited to a small fraction above the prices determined by the leaders of a set of foreign markets. Firms that don't comply would initially face a penalty equal to 65 percent of the drug's gross sales. Each quarter without complying to the price from HHS, the fee would increase by 10 percentage points up to a cap of 95 percent of gross sales. From an economic standpoint, this is a price control not a negotiation.

Perhaps most concerning is the breadth of these so-called negotiated prices. Unlike previous calls for Medicare to take a more active purchasing role, this legislation would extend those prices to the broader private market. This would greatly increase the impact of the proposed negotiated prices. Beyond this greater impact, it also suggests that the purported negotiations function more as an attempt at government administered prices. After all, prices in the private market are already heavily negotiated by experienced private firms. What these firms lack is the threat of an outside option that amounts to effectively taxing away all of the drug's revenue. For this reason, the legislation should be expected to have more of an effect on prices than existing negotiations in the private market.

The existing empirical evidence demonstrates that price concessions of this level would almost certainly decrease investments in innovation.<sup>4</sup> It is important to note that the mere fact that innovation will decrease is not a reason to abandon any reconsideration the parameters of the access and innovation tradeoff described above. It is useful to realize that everything about this tradeoff is fundamentally a policy decision. There is nothing magical or sacrosanct about our current 20 years of patent life, 5 years of market exclusivity, orphan drug policies or other innovation policy parameters that have been established to attempt to promote innovation. One need look no further than the fact that patent lengths are the same across products types (both within the pharmaceutical category but also across the economy) to note that these policies do not seem to be the result of a finely tuned economic model that weighs the economic benefits provided by specific types of products.

While the existing parameters may not reflect a perfectly thought out calculus, they do determine the existing level of investments in innovation in market. Therefore, changing these parameters will decrease investment in innovation and therefore should reflect a willingness to decrease the flow of new products to market in exchange for lower prices. Policies which do not seriously consider the potential negative impacts on innovation from changing these innovation policy parameters are likely to have unintended consequences.

Optimal policy making requires that policymakers decide on the preferred degree of intellectual property protection required to encourage the desired level and type of innovation. After setting these parameters, it is incumbent on regulators to monitor and enforce these systems. This includes providing the necessary structures for strong competition between therapeutic substitutes during periods of exclusivity and the development of robust generic competition beginning immediately at the end of the exclusivity period. Our goal is not to provide unlimited benefits to firms, but instead to provide appropriate market-based incentives that encourage firms to develop innovative products that increase welfare. Ultimately, firms will optimally respond to any incentives government creates – and therefore a well-functioning healthcare market requires policies that embrace economic reality rather than hope for a preferred outcome.

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<sup>4</sup> Acemoglu, Daron, and Joshua Linn. 2004. “Market Size in Innovation: Theory and Evidence from the Pharmaceutical Industry.” *The Quarterly Journal of Economics* 119 (3): 1049-1090.  
Finkelstein, Amy. 2004. “Static and Dynamic Effects of Health Policy: Evidence from the Vaccine Industry.” *The Quarterly Journal of Economics* 119 (2): 527-564.  
Blume-Kohout, Margaret E., and Neeraj Sood. 2013. “Market Size and Innovation: Effects of Medicare Part D on Pharmaceutical Research and Development.” *Journal of Public Economics* 97: 327-336.  
Dranove, David, Craig Garthwaite, and Manuel Hermsilla. 2014. “Pharmaceutical Profits and the Social Value of Innovation.” NBER Working Paper No. 20212. June.  
Dubois, Pierre, Olivier de Mouzon, Fiona Scott-Morton, and Paul Seabright. 2015. “Market Size and Pharmaceutical Innovation.” *The RAND Journal of Economics* 46 (4): 844-871.

This also includes being careful about policies which change the rules of the proverbial “game” mid-stream. The development of pharmaceuticals is a long and risky process where firms make investments that they only expect to payoff over a potentially decades long time horizon. Encouraging firms to make these types of investments requires that they have some certainty that the rules of the game will not be changed midstream. While that doesn’t mean that the U.S. cannot change pricing regimes, it does mean that policies such as retroactive revenue confiscation because of past price increases or the seizing of intellectual property has the potential to break the implicit contracts that underlie firms’ willingness to do business with the U.S. government. This is not a partisan issue. To the same degree that I publicly opposed Republican efforts to defect from making promised risk corridor payments under the ACA, I would strongly caution against any efforts that undermine the faith private firms currently place in the predictability of our innovation policy.<sup>5</sup>

### ***I. The Tradeoff Between Access and Innovation in the Modern Pharmaceutical Market***

It is not surprising that attention about high healthcare prices has focused on the pharmaceutical sector. Patented prescription drugs are sold for many multiples of the marginal cost of production and, as a result, firms *appear* to be profiteering at the expense of patients. Complaints that high prices are simply about corporate greed ignore that they are the result of deliberate government policies intended to provide the necessary incentives for the development of innovative products. By granting intellectual property protection, the government allows innovative firms to earn large profits without the threat of competition resulting from the immediate entry of a firm making an identical product. Economic research suggests this profit incentive matters and consistently documents that pharmaceutical R&D responds to potential market size. Pretending this is not the case ignores reality and will only lead to inefficient value-destroying policies.

While the optimality of trading off some amount of access today in order to gain access tomorrow is clear, the parameters of the length and breadth of this tradeoff are policy decisions for which there is no definitive economic answer. These policy parameters reflect the relative value society places on lost access today and potential welfare gains from innovation in the future.

Understanding the nature of the trade-off and determining the appropriate policy parameters in the contemporary market requires understanding a bit more about the modern pharmaceutical development process. New products come to market through the partnership of a variety of actors in the value chain. This includes basic science done for understanding the nature of disease, early stage pre-clinical research to develop a proof of concept, and then an arduous process of navigating the regulatory process to prove that a product is ultimately safe and efficacious. Each stage of this process represents meaningful risk and firms will

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<sup>5</sup> C. Garthwaite and N. Bagley, “The Republicans’ Uncertainty Strategy,” *New York Times*, June 29, 2017.

only undertake each successive step in the development process if the expected net returns are sufficiently attractive compared to the next best use of the invested funds.

#### *I.A. Basic Science Research and the National Institutes of Health*

Certainly, the development process begins with basic science research – a meaningful portion of which is financed by the National Institutes of Health (NIH) as well as other government entities and non-profit organizations. This means many expensive products on the market rely to some degree on basic science that received government funding. For example, one study found that all of the 210 products approved from 2010-2016 relied to some degree on research funded by an NIH grant.<sup>6</sup> This fact has led many activists and policymakers to contend that the NIH is “responsible” for bringing these products to market and therefore should be required to demand price concessions as part of their patenting activity.<sup>7</sup> Some have gone as far as to say that the NIH should exercise its “march-in rights” and seize the patents of products which are deemed to have prices that are too high.<sup>8</sup> While they might lend themselves to attractive slogans and sound bites, such policies will be far more complicated than is often discussed.

Understanding the limits of proposals to strengthen the role of the NIH in pricing requires thinking more carefully about the government’s role in drug development in the first place. At a broad level, advances in basic science that improve the understanding of how diseases work or the mechanisms of action driving the efficacy of potential products are relatively hard to successfully protect with our existing intellectual property protections. As a result, it is hard for firms to appropriate the value of investments in basic science. In effect, despite various intellectual property protection regimes, investments in basic science retain many of the public good related market failures discussed above. Firms that do not reasonably believe they can profit from investments will not make them, and as a result there is a fear that basic science research will be underprovided. As an economic concept, the NIH is ideally meant to solve this public goods problem by stepping into the market and funding the basic science that otherwise would not occur.

That said, without significant additional investments in drug development, this government funded basic science research does not result in treatments that address unmet needs in the market and increase economic welfare. In current market, these additional investments are provided by private firms that do additional research and development to commercialize the NIH funded basic science. In reality, the goal of the NIH

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<sup>6</sup> E. Galkina Cleary, J. Beierlein, N. Surjit Khanuja, L. McNamee, F. D. Ledley, “Contribution of NIH funding to new drug approvals 2010–2016,” *Proceedures of the National Academy of Sciences*, March 2018, 115(10).

<sup>7</sup> L. Zhou, “The new bipartisan Senate bill aimed at making Big Pharma lower drug prices, explained,” *VOX*, July 31, 2019.

<sup>8</sup> M. Mezher, “Lawmakers Urge HHS to Exercise 'March-in' Rights to Fight Higher Drug Costs,” *RAPS.org*, January 11, 2016.

should be to attract as many firms as possible to leverage its investments in basic science. This would provide the most “bang for the buck” from our government dollars. Currently, this is accomplished by placing relatively few constraints on partnerships between the NIH and private firms.

This was not always the case. Prior to 1995, the NIH included a “fair pricing clause” in its partnerships with the private sector. This clause required firms to provide reasonable evidence demonstrating their pricing decisions were in the public interest goals of the NIH.<sup>9</sup> However, in 1995, this clause was removed. In describing this decision, the Director of the NIH said that the institute agreed “with the consensus of the advisory panels that enforcement of a pricing clause would divert NIH from its primary research mission and conflict with its statutory mission to transfer promising technologies to the private sector for commercialization.”<sup>10</sup> Exhibit 1 shows that number of cooperative research and development agreements (CRADAs) between the NIH and private firms. In the years immediately following this decision, the number of these partnerships increased markedly – likely because of greater certainty about potential returns from these partnerships.<sup>11</sup>

### *I.B. The Decentralization of Early Stage Drug Development*

Proponents of the Lower Drug Costs Now Act point to the fact that the savings from the greater price regulation dictated by the bill can be redirected towards the NIH to offset the expected decline in innovation. However, this belief ignores the current role of the NIH – which is to evaluate and fund basic science and not drug development and commercialization. While there are a small number of examples of the NIH taking part in more advanced stages of drug development, these are certainly the exception rather than the rule – as would be expected given the purpose of the NIH is to solve the public goods problem for basic science research. To move into a primary drug development role, the NIH would need to transform into something that more closely resembles the private market. It is not simply a question of providing more funding for the NIH’s current system, but transforming in many ways the purpose and activities of the current NIH.

While it is possible the NIH could complete this transformation, this would mean it is no longer primarily solving the public goods problem of basic science and instead would attempt to determine which potential

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<sup>9</sup> Specifically, this clause read: “Because of [NIH’s] responsibilities and the public investment in research that contributes to a product licensed under a CRADA, DHHS [Department of Health and Human Services] has a concern that there be a reasonable relationship between the pricing of a licensed product, the public investment in that product, and the health and safety needs of the public. Accordingly, exclusive commercialization licenses granted for the NIH intellectual property rights may require that this relationship be supported by reasonable evidence.” Quoted in “Federal R&D, Drug Discovery, and Pricing: Insights from the NIH-University-Industry Relationship,” *Congressional Research Service*, 2012.

<sup>10</sup> “Federal R&D, Drug Discovery, and Pricing: Insights from the NIH-University-Industry Relationship,” *Congressional Research Service*, 2012.

<sup>11</sup> In interviews prior to the policy change, pharmaceutical manufacturers pointed to uncertainty about pricing as a concern in potential partnerships with the NIH.



opportunities to commercialize this science should come to market. This effectively involves introducing more central planning to the development of new products. Such a shift would run counter to the strategic decisions of the major players in the private market which are *decreasing* the degree to which pharmaceutical firms dictate the path of research through internal R&D programs. Instead, the world of biotech drug development involves large numbers of small startups that are increasingly funded by venture capital firms. The most promising and successful of these firms are generally acquired by the larger market participants that then guide the product through the FDA approval process and handle the post approval sales and marketing strategies.

The fact that so much early stage innovation is done by private firms have led many to claim that regulators are free to decrease prices without harming innovation. After all, since the firms currently selling the product didn't do the early stage R&D, those early innovative activities are not driven by the eventual profits of these more established firms. This couldn't be further from the truth. The ultimate goal of the venture capital investors in these early firms is for a profitable "exit" for their funds in the form of an acquisition. The financial terms of this eventual acquisition are dictated by the potential revenues of the product in the market and thus would be affected by regulated prices that decrease average returns.

In this way, the access and innovation tradeoff is perhaps even greater in the modern world of venture capital backed early stage drug development. This funding is inherently mercenary in nature and in search of the highest returns. If potential returns from biotech investments fall, these funds will simply flow from the pharmaceutical sector to the next best option. In this way, policies which decrease the potential profits will lower investments in early stage investments and the resulting increase in profits. While we might think that the NIH could step into the role of venture capital and provide funding to early stage biotech firms, there is little evidence they would be effective at this role. At a minimum, we must acknowledge that it is a vastly different enterprise than they are currently engaged in and therefore requires more than simply additional funding for their current activities.

Again, we may find it optimal to limit the flow of innovation in exchange for greater access to the smaller number of products. However, this must be a reasoned calculation and not one based on the false belief that the efforts of even a greater funded NIH or the better angels of a scientist's nature will somehow fill the void vacated by the venture capitalists. This reasoned choice must consider the overall value created by innovation over the long term compared to the relatively short period of exclusivity where access is diminished because of high prices but is certainly not reduced to zero.

## *II. Cross Country Pricing Differences and Reference Pricing Systems*

Even a cursory look around the globe reveals that other developed countries that are broadly similar to the United States have chosen different policies with respect to the access to existing pharmaceuticals. Through a combination of direct price controls, active negotiation, and other regimes these countries have successfully negotiated far lower prices than the U.S. market.

This has led many to state that the U.S. could also institute similar policies without suffering decreased access to innovation. After all, the residents of countries such as Denmark and Germany use the same drugs as U.S. citizens at a lower price. At the extreme, such beliefs stand at the center of the various reference pricing schemes that have been proposed by both the Department of Health and Human Services and in the Lower Drug Costs Now Act.

These policies rest on a belief that it is fundamentally unfair that the profits earned from U.S. patients provide the incentives for global innovation efforts that these lower price countries get to enjoy. While I share the belief of a certain level of inequity from the current system, it's unclear reference pricing will correct this situation. Instead, we may be left with the U.S. paying lower prices and everyone having less innovation.

We must first recognize that there is no sense in which the current prices in other developed countries represent the “correct” price simply because it is a lower price. There is absolutely nothing to suggest that the other developed countries most often included in the various reference pricing systems have in anyway determined their prices based on calculation of the innovation tradeoffs. Instead, they have made these decisions with the explicit knowledge that much of the global innovation will be funded by the United States regardless of their actions. In this way these smaller markets free ride of the innovation incentives in other markets.<sup>12</sup>

This leads to the open question of what the ultimate price would be in these other developed economies after the implementation of a U.S. reference pricing system. For some indication of this eventual price, we can look to the literature on most favored nation policies such as the Medicaid “best price” rule. While Medicaid is obviously a different setting, it shares several economic features with the international reference pricing rules.<sup>13</sup> This theoretical and empirical literature suggests that the prices in the countries in the reference price basket will be higher than the current international price but likely lower than what the U.S. is currently paying. There are two reasons for this.

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<sup>12</sup> D. Lakdawalla, “Economics of the Pharmaceutical Industry,” *Journal of Economic Literature*, June 2018, 56(2): 397-449.

<sup>13</sup> M. Duggan and F. Scott Morton, “The Distortionary Effects of Government Procurement: Evidence from Medicaid Prescription Drug Purchasing,” *Quarterly Journal Economics*, Feb 2006, 121(1): 1–30.

First, pharmaceutical manufacturers will now be less likely to give as large of a discount to these countries. Note that this is not because these firms were previously giving a discount to these countries, i.e. these firms are not leaving money on the proverbial table. Manufacturers negotiate as hard as they can with foreign markets to determine how high they can raise their prices before the decreased revenue (from a lower quantity sold) outweighs the higher revenue from the higher margin. After a reference pricing system is in place, this calculation changes. Firms are willing to suffer the decreased sales resulting from demanding higher prices in order to avoid giving such a large discount to the United States.

Second, it is possible in a world where U.S. prices will be suppressed by regulation other countries will increase their prices to account for the lost innovation. Under an ideal setting, this would result in U.S. prices falling and international prices rising to the point that the total returns to innovation remain the same but are more evenly financed across OECD countries. However, it is unclear whether the political systems of those countries would allow for such a shift in the distribution of funding sources. Thus it is possible we will end up in a world where innovation investments are far below what would be optimal for the preferences of U.S. citizens.

Furthermore, it is unclear that even without political constraints, these countries would make the same decisions as the U.S. if our policymakers attempted to actually grapple with the amount of innovation it was willing to sacrifice in order to increase access to existing medications. Effectively, a decision to create reference pricing for U.S. prices is outsourcing our innovation policy decisions to the governments of other developed countries. While this is certainly expedient, there is nothing to suggest that the decisions of these countries would represent the optimal policy outcomes for U.S. citizens.

While it is true the tradeoff is ultimately a policy choice, it would seem that this choice should reflect the preferences of the market participants in our country and not those of foreign markets? There is little evidence to suggest a reference pricing system would reflect the preferences of these U.S. customers.

### ***III. The role of government in U.S. healthcare***

For the reasons discussed above, determining the parameters of the access and innovation tradeoff is difficult. This is made even more complicated by the heavy role of government in the procurement of healthcare for vulnerable populations such as the indigent, elderly, and disabled. Given the fact that healthcare is a unique product for which society places particular value on an individual's ability to access services regardless of their ability to pay, the U.S. has developed a series of social insurance and transfer programs to help vulnerable populations access care. Over time these programs have grown, and public

spending now accounts for just over half of all healthcare spending in the United States – a fact that makes healthcare markets distinct from the rest of the economy.

Given the economically meaningful role of the public sector in the healthcare market, the ability to maintain a competitive market inherently relies, at least in part, on government policies and regulations. Ultimately, healthcare is our nation’s most meaningful public-private partnership. This has become even more apparent as the United States increasingly relies on private markets and firms for the provision of publicly funded social insurance benefits. This includes the Medicare Advantage program, Medicaid Managed Care, and even the much-derided Affordable Care Act – which I’ve previously noted is perhaps the most conservative market based approach to the provision of health insurance for such a large number of low-income individuals.<sup>14</sup> Private firms are being used to provide these services because, at their core, they have the strong incentive to respond to consumer demand in a quest to maximize profits. These incentives allocate resources in ways that increase welfare. It is unlikely that a government entity could achieve a similar result, and therefore optimal healthcare policy harnesses market forces while maintaining no illusions about the motivations of the firms it employs to efficiently provide goods and services.

However, successfully managing these public-private partnerships requires establishing rules that enhance rather than inhibit competition. To this end, the Lower Drug Costs Now Act contains a number of positive modifications to the Medicare Part D program that should be lauded. These are outside of the focus of this hearing, so I will not discuss them in detail. I will note that many of these are in the same spirit as those proposed by Senate proposals – and I hope that this will be an area for bipartisan progress on addressing market based reforms for drug pricing.

#### ***IV. Government Efforts on Drug Pricing Can Be Based in Market Principles***

I want to be clear that belief that increasing access today will decrease innovation does not preclude any role for government in pharmaceutical pricing. First, as noted above the government is already heavily involved in the market because it establishes the rules by which intellectual property is protected and finances large portions of the healthcare market. Second, simply because the U.S. hopes to use regulated markets to establish prices doesn’t mean that the such a market based system is immune to market failures. In such specific cases, regulation maybe create more welfare than a market plagued by failure.

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<sup>14</sup> Garthwaite, Craig. 2017. “Why replacing Obamacare is so hard: It’s fundamentally conservative.” The Washington Post. July 10.

Given these factors, there are clearly potential places for the government to intervene. The question quickly becomes: which types of products do you choose to target? The proposed legislation at the center of this hearing intends to target products which face little competition. On the one hand, the attraction to targeting these products is understandable. After all, these types of products are generally higher priced than those facing either therapeutic or generic competition. On the other hand, these high prices don't clearly reflect some market failure that should be addressed by instead of reflect products the create *unique value*.

Determining which products should be targeted is so important because prices are not simply static policy objects that can be manipulated with little dynamic consequences. Instead, prices send signals to the market about where capital should eventually be allocated. By placing greater pricing pressure on products which address unmet need, we face the danger of shifting resources away from those products and towards those where there may be more competition but also where the U.S. prices will, to a greater degree, be more determined market forces.

Instead of focusing attention on artificially lowering these prices for products with patent protection that generate unique value, optimal policy should focus on two goals: (1) addressing high prices that result not from a deliberate policy tradeoff to reward high value products but instead from a market failure; and (2) fostering competitive pressure among existing products.

Below I document several potential policies that would better address distortions from high prices in the United States.

#### *IV.A. A Lack of Competition for Generic Products Treating Small Patient Populations*

Markets for generic small molecule products are intended to have fierce price competition facilitated by the automatic substitution of prescriptions towards less-expensive generic products. In a well-functioning generic market, firms compete primarily on price and therefore profits are determined by a firm's ability to manufacture products at the lowest marginal cost. This fierce price competition means that successful entrants must be able to produce enough to reach the minimum efficient scale (MES) of their production process. Absent sufficient quantity, entrants realize they will find themselves at a perpetual cost disadvantage to incumbent firms and therefore will rationally decline to enter the market. For sufficiently small markets, there is only enough demand for a single manufacturer to reach MES – and the incumbent firm is a natural monopolist that maintains meaningful pricing power.

In recent years, several firms have recognized the pricing power available to ANDA holders for generic products with sufficiently small potential markets. This was perhaps best personified by the pricing strategies

of Turing Pharmaceuticals, but aspects of this strategy have been implemented by other firms and thoroughly documented in several media outlets.<sup>15</sup> The ability for these firms to charge monopoly prices for generic products is not the result of the above-discussed tradeoff between access today and innovation tomorrow – society has long since paid for the innovation from any of these products. Instead, the high prices represent firms taking advantage of a market failure created by the small patient population. While large pharmaceutical firms were historically either unwilling to exploit this pricing power or unaware of this financial strategy, the practice of firms charging high prices without fear of entry in small generic markets is now widespread throughout the industry (albeit the strategy is typically employed by smaller firms with fewer invested assets in the industry). If Congress hopes that for-profit firms will simply avoid this pricing strategy going forward, they will be sorely mistaken. Instead, solutions to market failures for small-market generics will need to come either from firms being harmed by this practice or through government action.

For some of these products, private firms are stepping forward with market-based solutions. Specifically, a consortium of hospitals led by Intermountain Healthcare has created CivicaRx – a joint venture designed to address the high prices charged for many generics that are administered in a hospital setting.<sup>16</sup> For products administered in the hospital, providers are unable to pass the increased costs along to patients or payers and have therefore decided to vertically integrate and manufacture the products themselves.

While vertical integration in this setting is an efficient response by hospitals in response to a market failure in their supplier market, CivicaRx will likely not find it valuable to undertake the manufacturing of products that are sold directly to patients through retail or specialty pharmacies. Those products do not impact the financial health of the hospitals involved in the joint venture. Therefore, solutions for these other products must come from new government policies that either reduce the number of natural monopoly markets or use economic tools to more directly intervene in the natural monopoly markets that remain.

If high fixed entry costs make it difficult for multiple firms to profitably produce small-market generics, one potential policy solution is to lower these fixed costs. This would decrease the quantity required for a new entrant to reach MES and compete with the incumbent manufacturer. In recent years, the FDA has been focused on programs to accomplish this goal. For example, there have been efforts to streamline and

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<sup>15</sup> Hopkins, Jared S., and Andrew Martin. 2018. “These New Pharma Bros Are Wreaking Havoc on Prescription Drug Prices.” Bloomberg. April 6.

Pollack, Andrew. 2015. “Drug Goes From \$13.50 a Tablet to \$750, Overnight.” The New York Times. September 20.

Rockoff, Jonathan D., and Ed Silverman. 2015. “Pharmaceutical Companies Buy Rivals’ Drugs, Then Jack Up the Prices.” The Wall Street Journal. April 26.

<sup>16</sup> Abelson, Reed, and Katie Thomas. 2018. “Fed Up With Drug Companies, Hospitals Decide to Start Their Own.” The New York Times. January 18.

harmonize the generic application process across developed countries.<sup>17</sup> There have also been attempts to increase the speed and efficiency of the ANDA process, which would decrease barriers to entry and potentially increase the number of markets that could support multiple firms.<sup>18</sup>

I would encourage the FDA to continue to evaluate the approval process to look for additional efficiencies that would decrease entry costs. However, even the most efficient process for entering a generic market will require some expenditures to demonstrate the safety and bioequivalence of the product – and this will always represent a meaningful fixed-cost investment. Therefore, another potential solution to promote entry is to attempt to increase the size of some generic markets. While this can't be accomplished within any geographic boundary (i.e., we are unlikely to uncover more patients with these types of conditions), I would encourage Congress and regulators to consider a broader system of importation across developed countries with similar safety and regulatory systems (i.e., the countries the FDA is currently empowered to turn to in the case of drug shortages). Aggregating demand across these markets would increase total quantity and the number of products that could successfully be produced by multiple manufacturers. Some have argued the FDA could implement this strategy today by considering generic products with large price hikes to be a situation of shortage.<sup>19</sup> However, it is likely that Congressional investigation and debate are needed before we implement such an important change to the sourcing of generic medications.

Even after efforts to decrease costs and increase market sizes, there likely will remain some markets that still cannot support multiple firms. In this case, further regulations are likely necessary to reach an efficient outcome. Senator Elizabeth Warren has previously proposed that the government step in to manufacture generic drugs when products have small market sizes and large drug price increases.<sup>20</sup> I understand and appreciate the motivation for Senator Warren's proposal and think that it is a potentially viable policy option for addressing this particular market failure, i.e., the lack of competition in markets for generic products without sufficient size to support multiple firms.

However, I fear that a government entity will likely fail at being an efficient producer of these products – after all, this is not an enterprise in which they specialize. As a result, the marginal costs of a government producer would likely be higher than for a private firm with experience in drug production. Before the

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<sup>17</sup> Gottlieb, Scott. 2018. "Advancing Toward the Goal of Global Approval for Generic Drugs: FDA Proposes Critical First Steps to Harmonize the Global Scientific and Technical Standards for Generic Drugs." FDA. October 18.

<sup>18</sup> Elvidge, Suzanne. 2018. "FDA sets another record in 2018 for generic drug approvals." BioPharma Dive. October 12.

<sup>19</sup> Greene, Jeremy A., Gerard Anderson, and Joshua M. Sharfstein. 2016. "Role of the FDA in Affordability of Off-Patent Pharmaceuticals." JAMA 315 (5): 461-462. doi:10.1001/jama.2015.18720.

<sup>20</sup> Warren, Elizabeth. 2018. "It's time to let the government manufacture generic drugs." The Washington Post. December 17.

government undertakes such a new and complicated economic activity, I would propose a private-sector solution in which Congress empowers the FDA to provide a new form of market exclusivity for generic products with market sizes that do not support multiple competitors.

The exact specifics of such an exclusivity would need to be worked out, but a first step would be for Congress to ask the FTC to examine how many potential patients are necessary for a market to support multiple generic firms. While most generic prescriptions are likely for molecules that can support multiple competitors, there are potentially a large number of molecules with small patient populations that can't support multiple manufacturers. For example, there has been an increase in the number of exits by ANDA holders in recent years, with many firms citing a lack of profitability. The median generic market currently has only two manufacturers, and approximately 40% have a single manufacturer – which likely is the result of limited market potential for these molecules.<sup>21</sup> That said, the current number of firms participating in the market in equilibrium does not provide sufficient information to understand whether the market could ultimately support multiple firms. After all, it is the threat of entry and not actual entry that disciplines profits. Inferring the number of firms that a particular generic market could support based on the number of current firms could be particularly problematic given the ongoing allegation of collusion in this market.<sup>22</sup> Therefore, it is important for economists at the FTC to determine the exact market size and structure that would indicate that the market for the generic product is a natural monopoly where the incumbent firms possesses significant pricing power. Ideally this investigation would incorporate the potential market-expanding policies of decreasing entry costs and potentially increasing the market size to include some limited foreign markets.

After establishing the market characteristics likely to lead to natural monopolies, I would propose the FDA be required to undertake a request for proposal (RFP) process for those markets. Under this RFP process, any private firm could apply for the rights to be the exclusive manufacturer of a natural monopoly generic medicine at a certain fixed percentage above manufacturing costs. As part of this RFP process, firms would compete on the amount of margin they would require to serve the market. The winning firm would possess the exclusive rights to sell the drug at this regulated price for a time period sufficient to recover the fixed costs of entry. At that time, the FDA would have the option of re-auctioning off the market exclusivity. In order to ensure the efficient operation of this process, it may also be necessary for the FDA to set a maximum percentage that they will accept before they will turn to a non-profit or government supplier for the product. This will limit any ability of firms to collude to divide up the markets they choose to enter.

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<sup>21</sup> Berndt, Ernst R., Rena M. Conti, and Stephen J. Murphy. 2017. "The Landscape of US Generic Prescription Drug Markets, 2004-2016." NBER Working Paper No. 23640.

<sup>22</sup> Silverman, Ed. 2019. "Here's how prosecutors say generic drug makers schemed to fix prices." STAT. February 19.



I would encourage Congress to immediately investigate solutions in the area of small-market generics, as this problem will only grow in importance. Recent scientific advances have allowed for an increasing personalization of medicine. Along with co-authors, I have documented the rising share of clinical trials involving a patient-specific biomarker to determine either efficacy or safety.<sup>23</sup> As can be seen in Exhibit 2, in recent years there has been a marked increase in trials for these types of products. Almost by definition, personalized medicine will involve products with limited patient populations, and for many of these products we should be worried about whether robust generic competition will ever emerge.<sup>24</sup> Therefore, while the problem of small-market generics is not a dominant feature of today's market, it will only grow in importance. It will likely be far easier to address the problem now than it will be when the number of powerful interests manufacturing such products increases.

#### *IV.B. Policies to Promote Robust Competition Between Branded Therapeutic Substitutes*

While innovative firms maintain time-limited exclusivity to manufacture their patented products, competition should still emerge from therapeutic substitutes that can provide meaningful pricing pressure that transfers surplus to consumers and/or increases output. Prescription drug price competition in pharmaceuticals results from intense negotiations between manufacturers and pharmacy benefit managers (PBMs). These negotiations take the following form (which is graphically summarized in Exhibit 3).

First, the actual payer (i.e., a self-funded employer or fully funded insurer) enters into a contract with a PBM. Under the terms of this contract, the PBM manages the payer's pharmacy claims, a process that includes activities such as administering the prescription drug benefits, designing formularies to negotiate price discounts, implementing utilization management, and creating retail pharmacy networks. The compensation received by PBMs in these contracts is complicated and detailed, but at a high level it involves a per-member administrative fee and a portion of negotiated discounts that the PBM can retain.

While PBMs undertake a large number of functions, perhaps the most meaningful economic activity is negotiating discounts or "rebates" from pharmaceutical manufacturers. This negotiation process begins with manufacturers setting a list price, which is the price initially paid by the payer. PBMs and manufacturers then negotiate economically meaningful rebates in order to arrive at a net price. The negotiating power of the manufacturer is determined by the unique value created by its product, and so manufacturers whose products have a large number of potential therapeutic substitutes have less negotiating power. The negotiating power

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<sup>23</sup> Chandra, Amitabh, Craig Garthwaite, and Ariel Dora Stern. 2018. "Characterizing the Drug Development Pipeline for Precision Medicines." NBER Working Paper No. 24026.

<sup>24</sup> The problem of competition for precision medicine will be further complicated in situations where the patented product is a biologic product.

of PBMs results from the number of customers they represent and their willingness and/or ability to move those customers across products after receiving a large discount. The more customers a PBM can credibly shift, the greater the discount they can negotiate. In order to shift share, PBMs use a combination of consumer cost sharing and utilization management techniques such as prior authorization and step therapy.

To the chagrin of many, rebates negotiated between manufacturers and PBMs are closely guarded secrets. However, for many reasons maintaining this confidentiality improves market efficiency by increasing the size of the rebate and expanding output. Perhaps the most important reason is that manufacturers are less likely to give large discounts if they believe other consumers will observe the size of this rebate and use it as a starting point for subsequent negotiations. A rational manufacturer would anticipate such an outcome and ultimately offer smaller rebates to the entire market. For this reason, economic research suggests that widely known negotiated prices will raise prices rather than increase competition.<sup>25,26</sup> In addition, the public posting of prices can facilitate tacit collusion among firms. When negotiated discounts are publicly observable, firms have more certainty that other competitors in the market are not offering lower prices in order to steal share. In a setting with limited potential entry, this knowledge can serve as the basis for tacit collusion. Previous research in other settings has discussed and documented how public knowledge about price discounts therefore can facilitate such tacit collusion – a separate channel through which ending the confidentiality of rebates would lead to higher prices.<sup>27</sup>

The final step of the negotiation process is that PBMs transfer some amount of the rebate back to the payer, which initially purchased the drug at its list price. The amount of the rebate that is transferred is dictated by the contract between the payer and the PBM. Both large and small employers are increasingly likely to have contracts under which they are supposed to receive the entirety of the rebate. However, a meaningful share of both large and small employers are contractually entitled to only a portion of the rebate negotiated by the PBM.

#### *IV.C. Improving Information about Flow of Funds Between Manufacturers and PBMs*

Rebates have gained an undeserved bad reputation, resulting from a lack of understanding of their important role in controlling pharmaceutical prices. This has culminated in a recent Department of Health and Human

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<sup>25</sup> Albæk, Svend, Peter Møllgaard, and Per B. Overgaard. 1997. "Government-Assisted Oligopoly Coordination? A Concrete Case." *The Journal of Industrial Economics*. Vol. 45, No. 4, pp. 429-443. December.

<sup>26</sup> Byrne, David and Nicolas Roos. 2015. "Learning to Coordinate: A Study in Retail Gasoline." *American Economic Review* 109(2): 591-619.

<sup>27</sup> Cutler, David, and Leemore Dafny. 2011. "Designing Transparency Systems for Medical Care Prices." *New England Journal of Medicine* 364 (10): 894-895. doi:10.1056/NEJMp1100540.

Cooper, Thomas E. 1986. "Most-Favored-Customer Pricing and Tacit Collusion." *The RAND Journal of Economics* 17 (3): 377-388.

Services proposal to end the safe harbor protections for rebates under the Medicare program – a regulatory change that would effectively end the use of rebates for publicly insured consumers (and potentially for the entire market).<sup>28</sup>

The proposed rule appears to be motivated by a belief that rebates offered as a discount off of the list price are partially responsible for rising drug prices. However, this belief is misguided. There is nothing about rebates that inherently causes higher pharmaceutical spending. Ultimately, there are two primary concerns about rebates highlighted as rationales for the proposed safe harbor regulation. First, many cost-sharing provisions of prescription drug insurance contracts expose patients to the list rather than the net price of the drug. For example, patients who pay percentage-based coinsurance or who have a deductible that applies to pharmaceutical spending purchase drugs based on the list rather than the net price. The share of the population in such situations has grown markedly and now comprises approximately half the market.

The purpose of consumer cost sharing (copayments, coinsurance, and deductibles) for pharmaceuticals is to address moral hazard, i.e., either the excess consumption of products or consumers purchasing an expensive version of a product when a lower-priced alternative is available. Cost-sharing provisions are based on list prices in an attempt to maintain the confidentiality of negotiated discounts. If patients in the deductible period paid the negotiated price for the medication or if percentage-based coinsurance was based on the negotiated rather than list price, then it would be trivial for rival firms to gather information on the menu of discounts available in the market. As discussed above, maintaining confidentiality of these rebates likely increases price competition and leads to lower net prices – which overall is good for consumers. That said, forcing consumers to pay artificially high cost sharing is likely inefficient, as it unwinds the insurance contract by forcing sicker individuals to pay greater costs and can potentially decrease adherence to prescription protocols.

It is clear we should find policy solutions to pass along more of the negotiated discounts to consumers. However, it is critical that any policy solution saves the proverbial baby while throwing out the bathwater by maintaining the ability of PBMs to effectively negotiate larger rebates with manufacturers. Therefore, I propose that PBMs be required to base cost-sharing payments on a number that more closely approximates the net price of the product. This number could be the average net price across PBMs for that product, the average net price for the therapeutic class, or the minimum price paid in the market, i.e., the Medicaid best price. Assuming that PBMs have sufficient ability to modify their formularies, any of these options should still expose the patient to enough of the cost of the product to address moral hazard concerns while not

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<sup>28</sup> Office of Inspector General and Department of Health and Human Services. 2019. 84 FR 2340. February 6.

exposing consumers to artificially high prices that unwind the generosity and efficiency of the insurance contract.

Note that some have complained that policies that pass along rebates to consumers at the point of sale would lead to higher premiums. While it is true that this would be the case, it is not clear this is necessarily a problem. These higher premiums would reflect, in part, a more complete insurance product. It is not immediately clear consumers are fully aware of the financial exposure they have to expensive medications, and therefore we should not think that increasing the completeness of insurance in this setting is clearly a negative outcome.

A second concern about the current system of confidential rebates and other payments between manufacturers and PBMs is that it creates a potential incentive for a PBM to give preference to a higher-list-price drug that offers greater rebates and other fees. Effectively, the concern is that the PBM will not be a good agent for its principal, i.e., the final payer. I argue that to the extent this is a concern, it is actually not about the structure of the rebate contract and instead reflects a more fundamental question about the amount of competition in the market for PBM services. If that is the case, policies to address this practice should focus on the market structure rather than the contractual form.

In a competitive market, the structure of the PBM contract would not matter. PBMs would compete for a payer's business by offering a set of services of specific cost and quality, and fully informed insurers would pick the preferred combination of these characteristics. If we believe PBMs are using rebates to capture a larger share of surplus in this market, this reflects a lack of competition for these services rather than an inherent problem with this contractual form.

Whether or not the PBM market is competitive is currently unclear. On the one hand, there are reasons why we might be concerned about competition in this market. A series of mergers over the last decade have left three firms with nearly 80 percent market share – a structure that might make one concerned about the degree of competition. Some of these concerns were expressed by FTC Commissioner Brill in a dissenting opinion regarding the merger of Express Scripts and Medco in 2012.<sup>29</sup> However, simple measures of market concentration are not proof of a lack of competition. With three large competitors, it is possible there is sufficient competition, and the actual level of competition in this market is fundamentally an empirical question.

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<sup>29</sup> Brill, Julie. 2012. "Dissenting Statement Of Commissioner Julie Brill Concerning The Proposed Acquisition Of Medco Health Solutions Inc. (Medco) By Express Scripts, Inc. (Esi)." FTC File No. 111-0210. April 2.

The concern about PBMs being attracted to higher-rebate drugs can be best demonstrated by a simple example. Consider a drug that currently has a list price of \$100. The manufacturer proposes to the PBM a 20% list price increase – resulting in a new list price of \$120, which is initially paid by the payer (i.e., employer or fully funded insurer). The manufacturer also proposes to increase the rebate paid to the PBM by \$15, resulting in a net price increase of only 5%. However, the PBM is only required by its contract to transfer 50% of rebates to the payer, meaning it keeps \$7.50 of the rebate and the payer gets \$7.50. Therefore, the payer spends \$12.50 more, with \$5 going to the manufacturer and \$7.50 for the PBM.

Ultimately, the unanswered question is whether the \$7.50 collected by the PBM represents too much surplus or instead is the appropriate payment for its negotiating activities. In a well-functioning competitive market, we would expect that if the \$7.50 the PBM captures from the example above represents too much of the surplus, the PBM would ultimately face competition from another PBM offering a better contract to the payer. Such a contract would propose to decrease the total spending to the payer. However, this requires a market with multiple PBMs actively competing for contracts, a situation that may not exist in the current market. Competition is even less likely to emerge if the firms in the market realize there are large barriers to entry and the incumbent firms would be better off not actively engaging in price wars to gain share.

Strong competition is even less likely to emerge if payers are unaware of the full scope of surplus created by their prescriptions. Many large firms hire sophisticated benefit consultants and increasingly demand fully transparent contracts that provide them full information on all “rebate” dollars. In theory, this provides information about the surplus created by their prescriptions. That said, there are reasons to be concerned that despite these efforts payers may still be unaware of all of the funds flowing between the PBM and the manufacturer. In addition to rebates, PBMs also receive various administrative fees and other payments from manufacturers. Ultimately, the PBM determines which of these payments are rebates (and therefore covered by the price transparency and rebate sharing requirements), and what is instead a fee (that does not need to be disclosed or shared).<sup>30</sup> These fees are not trivial – for some contracts they can account for 25-30% of the money moving between the manufacturer and the PBM.<sup>31</sup> If we consider the simple example above, the situation for the payer could be even worse if, instead of offering a rebate of \$15, the manufacturer offers an administrative fee to the PBM. In that case, the payer would bear the full cost (i.e., \$20) of the list price increase, and the PBM and manufacturer would split the surplus. Ultimately, manufacturers are agnostic

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<sup>30</sup> Eickelberg, Henry C. 2015. “The Prescription Drug Supply Chain ‘Black Box’: How it Works and Why You Should Care.” American Health Policy Institute. December.

<sup>31</sup> Dross, David. 2017. “Will Point-of-Sale Rebates Disrupt the PBM Business?” Mercer. July 31.

between describing payments to the PBM as “fees” or “rebates” – they simply care about the total amount of money they collect and distribute as a result of these negotiations.

To further complicate matters, sophisticated payers hoping to gather more information about the flow of funds between the PBM and manufacturers that results from their prescriptions often face meaningful restrictions on the ability to audit their PBM-payer contracts.<sup>32</sup> These can include the exclusion of particular auditors that are deemed to hold views that are hostile to PBMs, requirements that audits be held at the headquarters of the PBM, unwillingness to provide contracts with manufacturers, restricted access to claims data, and strict limitations on the number of years that can be audited.<sup>33</sup> While many of these restrictions can be cast as attempts to maintain rebate confidentiality, they also increase the amount of asymmetric information between PBMs and payers about the amount of available surplus.

Recently the Department of Health and Human Services proposed to address this problem by eliminating the safe harbor for rebates in the Medicare program. While this policy has been abandoned, other efforts underway have the same goal of ending confidential rebates based on the price of the drug and shift the market to a series of up-front price discounts and flat fees negotiated between PBMs and manufacturers.<sup>34</sup> This would effectively end the confidentiality of negotiated prices while also not decreasing the amount of surplus captured by PBMs – after all, a PBM with market power can calculate a flat fee as easily as the current percentage based-rebate system.

It is perhaps not surprising that policies from both parties are coalescing on attempting to end rebates. Frustrated by rising drug prices, people are looking for a scapegoat and a system of shrouded prices by large firms fits a convenient narrative. That said, it would be extremely unwise to limit the ability of PBMs to negotiate large discounts. Instead of ending the current system of confidential rebates, I’ve proposed (along with Fiona Scott Morton) that we move to a system where all payments currently paid between the manufacturer and the PBM flow first to the payer before being split between the payer and the PBM.<sup>35</sup> PBMs and payers would be free to negotiate any split of the rebates, fees, and other funds that are paid by the manufacturer – but such a negotiation would now occur between two parties with equal information about the amount of money at stake. There are variety of ways to implement the move to such a system. One

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<sup>32</sup> Weinberg, Neil, and Robert Langreth. 2017. “Inside the ‘Scorpion Room’ Where Drug Price Secrets Are Guarded.” Bloomberg. May 4.

<sup>33</sup> Advisory Council on Employee Welfare and Pension Benefit Plans. 2014. “PBM Compensation and Fee Disclosure.” Report to the United States Secretary of Labor.

<sup>34</sup> U.S. Department of Health and Human Services. 2019. “Trump Administration Proposes to Lower Drug Costs by Targeting Backdoor Rebates and Encouraging Direct Discounts to Patients.” January 31.

<sup>35</sup> Garthwaite, Craig, and Fiona Scott Morton. 2017. “Perverse Market Incentives Encourage High Prescription Drug Prices.” ProMarket Blog. November 1.

possible solution would be for regulators to end the safe harbor for payments between manufacturers and PBMs and instead create a separate safe harbor for payments between manufacturers and payers. I'd note that if the current PBM market is competitive, this proposed policy solution should have little effect on the distribution of surplus.

#### *IV.D. Biosimilar Adoption and Rebates*

While rebates serve a vital function in drug price negotiations, there are also situations where the structure of the rebate contract can create a barrier to entry for new competing products. For example, rebate contracts sometimes reference rival products, particularly with respect to a rival's placement on the formulary. Depending on the economic context, such rival-referencing contracts could be either anti-competitive or pro-competitive. For example, a manufacturer may offer larger rebates if its product is the only one in a therapeutic area on the preferred tiers of the formulary. If there are many potential products that are competitors for the entire market, such a contract could be efficient. In fact, these types of contracts are at the heart of the PBM strategy. In describing his strategy, the Chief Medical Officer of Express Scripts said, "So we went to the companies, and we told them, we're going to be pitting you all against each other. Who is going to give use the best price? If you give us the best price, we will move the market share to you. We will move it effectively. We'll exclude the other products."<sup>36</sup> Since 2012, there has been marked growth in the use of these exclusion lists. Likely related to this fact, since 2012 there has also been a large increase in the amount of rebates in the system.

In situations where manufacturers are competing for access to the PBM's entire patient population, these types of contracts can be pro-competitive, leading to large discounts and increased welfare. However, for some types of products, large portions of the market are not truly contestable, i.e., the PBM will not be able to effectively move a fraction of the patients to the low-price product. For example, patients who are currently using a biologic product are unlikely to be willing to switch to a competing biosimilar at almost any price. In addition, PBMs might find that payers would not be happy with strategies that forced their patients to move across biologic products in this manner.

In a situation where a new entrant cannot effectively compete for a large fraction of patients, a rebate contract for the incumbent product that is contingent on the absence of the rival entrant on the formulary can serve as an almost impenetrable barrier to entry. This situation is sometimes referred to as a rebate "wall" or "trap." Effectively, the new entrant finds that it cannot offer the PBM a large enough rebate on its

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<sup>36</sup> Wehrwein, Peter. 2015. "A Conversation with Steve Miller, MD: Come in and Talk With Us, Pharma." *Managed Care*. April 5.

products (which represent a relatively small share of sales) to overcome the lost rebate dollars from the incumbent (which represents a majority of the market). In such a situation, the new entrant would find it quite hard to ever gain meaningful market share. Perhaps more concerning, realizing the existence of these rival-referencing contracts, potential biosimilar firms may never choose to attempt to create products in the first place. Concerns about the use of rebates in this manner have been raised by many individuals, including FDA Chairman Scott Gottlieb and the CEO of Novartis Vas Narasimhan.<sup>37,38</sup> They are also the subject of antitrust litigation between reference products and biosimilar firms, which is winding its way through the court system and should provide additional guidance about the legality of these practices.<sup>39,40</sup>

Given the potential for the rebates contingent on rival products to block potential entrants, regulators should consider more careful oversight and monitoring of rebate contracts that reference rivals. In situations where a large portion of the market is not contestable by the new entrant – for example, in the case of the first biosimilar entering against a reference product – it may be advisable for regulators to create additional restrictions on the ability of rebate contracts to reference the position of rival products on the formulary.

#### **IV. Conclusion**

Pharmaceutical pricing in the U.S. has attracted the attention of a bipartisan set of policymakers. As I discuss above, this is understandable given that the business model involves charging large prices well above the marginal costs of production. Of course, the large fixed costs of drug discovery and development are less obvious to consumers.

These concerns have prompted calls for greater drug price regulation, such as the various features of the proposed Lower Drug Costs Now Act. Price controls of the degree proposed in the legislation would have meaningful consequences on future innovation and therefore must be debated in an intellectually honest manner that grapples with these tradeoffs.

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<sup>37</sup> Liu, Yanchun. 2018. “FDA chief says pharma use rebates to block biosimilar competition.” MarketWatch. July 19.

<sup>38</sup> Narasimhan, Vas. 2018. “Novartis CEO: How To Create Cheaper Alternatives To The Most Expensive Drugs.” Forbes. April 12.

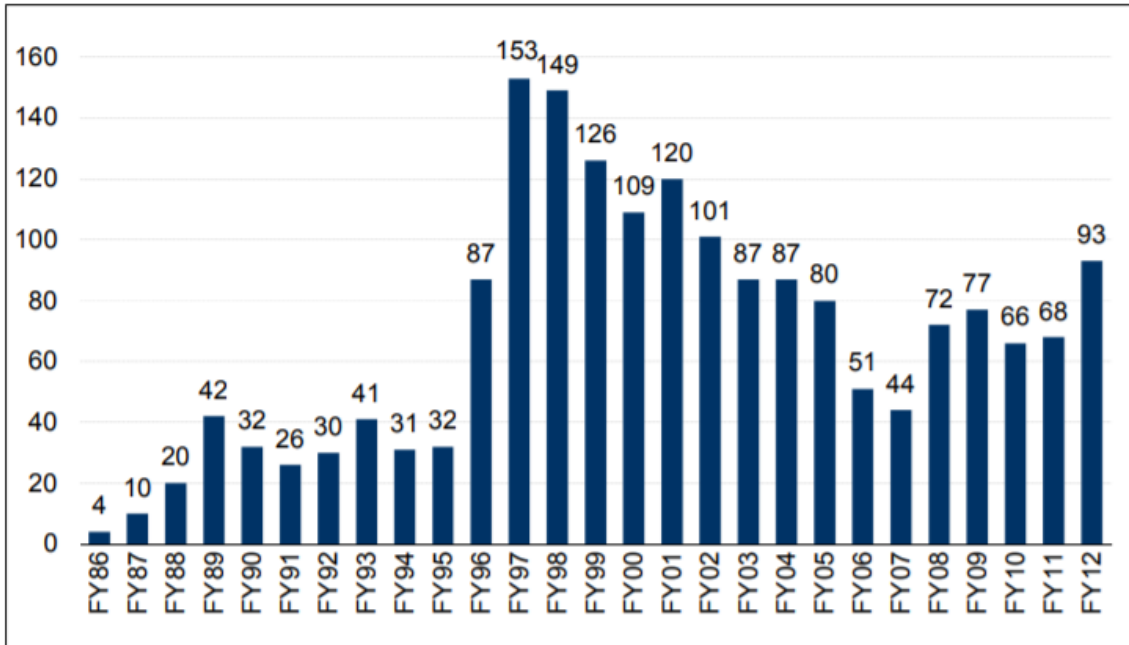
<sup>39</sup> Biosimilars Council. 2018. “Brief Of The Biosimilars Council As Amicus Curiae In Opposition To Defendants’ Motion To Dismiss.” Civil Action No. 2:17-cv-04180-JCJ. United States District Court For The Eastern District Of Pennsylvania, January 26. Accessed March 4, 2019. <https://www.accessiblemeds.org/sites/default/files/2018-01/AAM-Amicus-Brief-Pfizer-vs-J%26J-1-26-18.pdf>.

<sup>40</sup> United States District Court for the Eastern District of Pennsylvania. 2017. “Complaint, Case 2:17-cv-04180-JCJ.” September 20. Accessed March 4, 2019. <https://www.courtlistener.com/recap/gov.uscourts.paed.534730.1.0.pdf>.



Exhibit 1

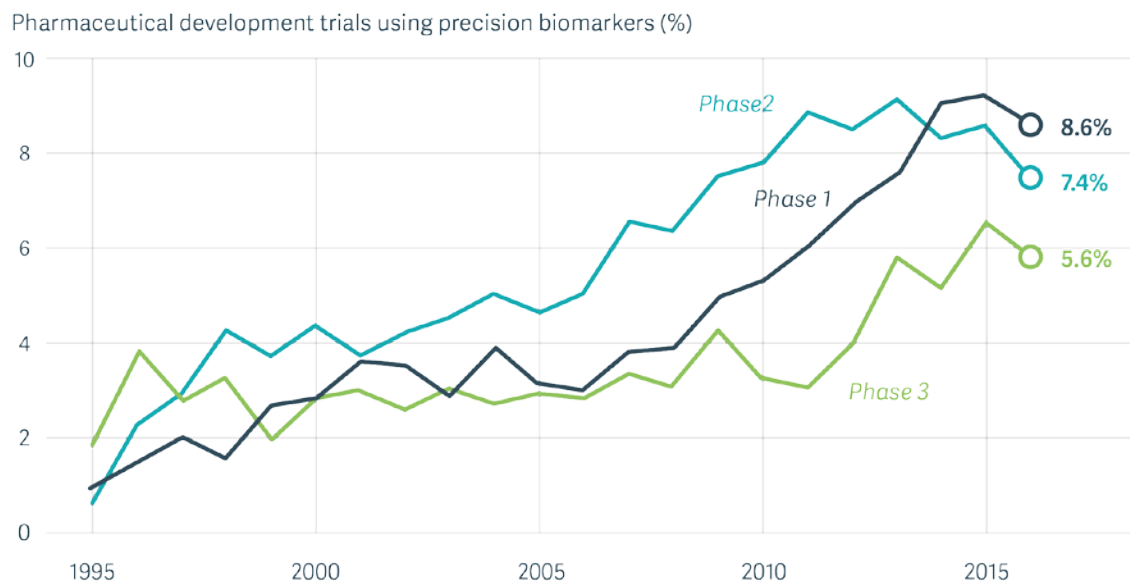
NIH Cooperative Research and Development Agreements (CRADAs), by year



**Source:** National Institutes of Health, Office of Technology Transfer [http://www.ott.nih.gov/about\\_nih/statistics.html](http://www.ott.nih.gov/about_nih/statistics.html).

## Exhibit 2

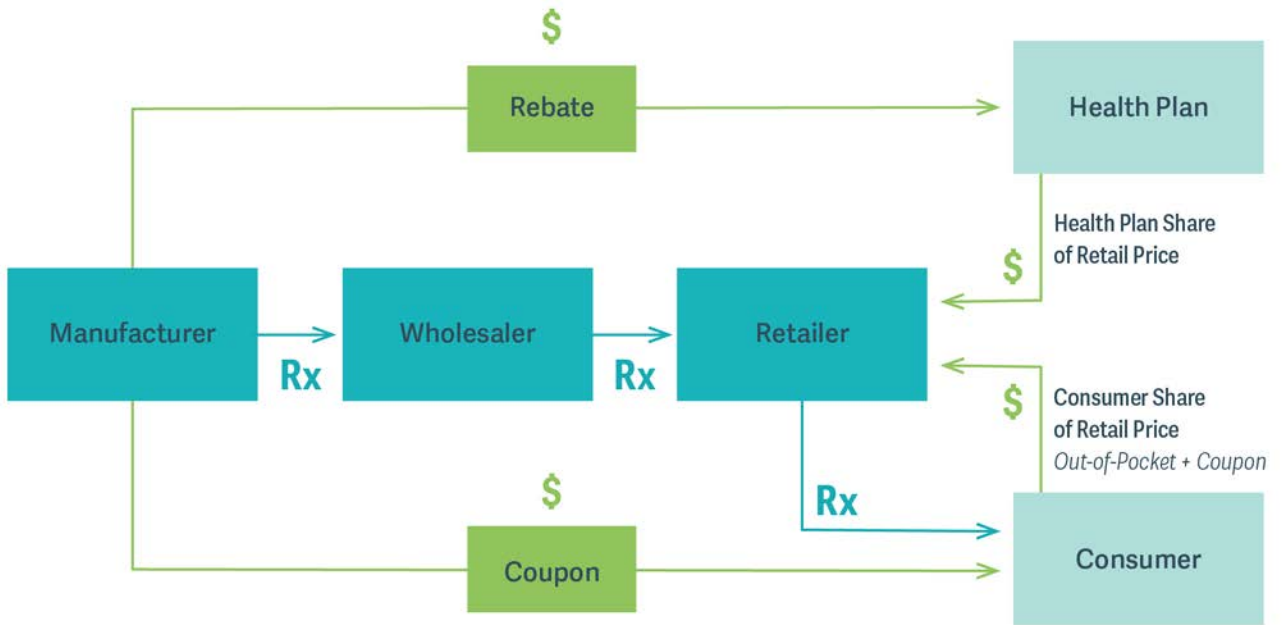
### Precision Medicine Development Trials, 1995-2016



Source: A. Chandra, C. Garthwaite, and A.D. Stern, NBER Working Paper No. 24026 and forthcoming in E. Berndt, D. Goldman, and J. Rowe, eds., *Economic Dimensions of Personalized and Precision Medicine*, University of Chicago Press

**Exhibit 3**

**Simplified Flow of Products (Rx) and Payments (\$) in the Prescription Drug Supply Chain**



Impact of prescription drug rebates on health plans and consumers  
April 2018

Page 3

Source: [https://altarum.org/sites/default/files/Altarum-Prescription-Drug-Rebate-Report\\_April-2018.pdf](https://altarum.org/sites/default/files/Altarum-Prescription-Drug-Rebate-Report_April-2018.pdf)