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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 chooses 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.¹ 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, absent some form of government intervention, are unwilling to make value creating investments in the first place.

¹ 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 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 created by their 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 the increased development of new products in the future. To the extent that the value created by the new products exceeds the welfare 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 today 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.² Unsurprisingly, this particular form of a lack of access garners large amounts of press and political attention. However, it is always critical to remember a perhaps far greater access problem for patients suffering from conditions for which no treatment options exist at all.³ For these individuals, there is no price at which they can purchase a treatment. These patients will gain access in the future only as a result of the dynamic incentives created by intellectual property protection. As we consider the optimality of policies governing the pharmaceutical market, we must balance the oft-discussed need for access to existing products with the less-discussed lack of access from the absence of effective treatments.

There are a variety of factors that influence both sides of this fundamental tradeoff, and there is a clear role for government in managing and regulating this process. My testimony today will focus on two broad areas where government involvement can improve the functioning of these markets. The first is promoting policies which limit welfare losses during periods of market exclusivity by both fostering competition and supporting well-functioning health insurance markets. The second is ensuring that periods of market exclusivity are time limited and followed by robust entry and competition from new firms.

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

³ 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.

In terms of limited welfare losses from access today, the government has an important and meaningful role in promoting and managing robust competition between potential substitute products. Our existing system of intellectual property protection does not preclude all price competition. While patented products are protected from an exact replica being brought to market, they often face stiff 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 meaningfully heterogeneous treatment effects – these competing products can increase the set of available treatments for patients.

As a result, an 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. This results in large rebates for more competitive categories.

In order for this market structure to foster competition, patients and payers must have the ability and incentive to demand price concessions in the face of substitute products. Unfortunately, many features of the Medicare Part D program (our nations' social prescription drug insurance programs for the elderly) diminish the incentives for competition. Similarly, under Medicare Part B, the purchasing rules for prescription drug can serve to promote higher rather than lower prices. Purchasing rules for both of these government programs should be addressed, and I offer policy suggestions below.

While competition is a critical tool for limiting potential welfare losses during periods of market exclusivity, the existence of well-functioning health insurance markets also serves to decrease some of the potential deadweight loss and harm caused by high pharmaceutical prices.⁴ Given the existence of these insurance products, patients do not bear the full cost of these high prices. However, it is important that these markets are truly well-functioning. As I discuss below, onerous cost sharing in many existing insurance contracts can unwind the value of the insurance product – something that could be particularly concerning if patients are not fully aware of the terms of the contract when buying insurance. Some of this onerous cost sharing results from the growing size of rebates in the market while others are a feature of the insurance contract – in particular those in the Medicare Part D program. Policymakers should work to address these issues.

⁴ Lakdawalla, Darius & Sood, Neeraj, 2013. "Health insurance as a two-part pricing contract," *Journal of Public Economics*, vol. 102(C), pages 1-12.

Beyond promoting competition during periods of market exclusivity, a key feature of the trade off at the center of innovation policy is that market exclusivity must be explicitly 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 products. 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.

Increasingly complex pharmaceutical products have led to a far more complicated patenting environment. Given the complexity of production and the increasing ability of products to be used for a variety of indications – successful products are now surrounded by meaningfully large patent estates. There is no question that this makes it harder to a potential competitors to enter. There is, however, an open question as to whether large numbers of patents represent the inherently large amount of intellectual property required to develop new and complex products or a deliberate strategy by firms to deter entry. Of course, there is no single broad answer to this question and any policy solutions must respect the nuance of intellectual property protection and the resulting incentives in this area. That said, I outline several policy solutions below intended to both increase the rigor of patent review (and therefore the strength of the resulting patents) and better regulate the process of generic and biosimilar entry.

In considering this responsibility of government to promote competition and generic entry is important to remember that our optimal policy making in this area simply requires deciding on the preferred degree of intellectual property protection required to encourage the desired level and type of future 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 incentives that encourage firms to develop innovative products that increase welfare. Ultimately, firms will optimally respond to any incentives governments create – and therefore a well-functioning healthcare market requires policies that embrace economic reality rather than hope for a preferred outcome.

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 providing some certainty that the rules of the game will not be changed after the firm makes large, fixed, and sunk investments. 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.⁵ At a minimum, such decisions must be made with a complete understanding of the potential massive ramifications.

At a high level, it is always important to remember that the goal of government policy in this area is to balance the incentives for innovation with the access to value creating products. Others have proposed more drastic exercises of government power in order to simply reduce prices today. When considering the potential access benefits of such proposals we must be comprehensive in our analysis – considering both the degree of improved access today and the ability of the market to continue to provide access in the future to patients who currently lack existing treatments.

The existing empirical evidence demonstrates that price concessions of the level proposed by legislation such as H.R. 3 (i.e. the Lower Drug Costs Now Act) would almost certainly decrease investments in innovation.⁶ It is important to note that the mere fact that innovation will decrease is not a reason to abandon any reconsideration of the parameters of the access and innovation tradeoff described above. After all, as the costs and the benefits of developing new products change, we should reconsider our policies regarding the development process. In discussing these policies, it is always useful to remember 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

⁵ C. Garthwaite and N. Bagley, "The Republicans' Uncertainty Strategy," *New York Times*, June 29, 2017.

⁶ 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 Hermosilla. 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.

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 it is true that the existing parameters are not the result of a perfectly thought out and calibrated calculus, they do determine the existing level of investments in innovation in market. Changing these parameters will decrease investment in innovation and therefore should reflect an explicit 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.

I understand it is tempting to cave to the crass political calculus that purports to increase access in a visible way today and obscures the potential long-term costs of such decisions. After all, once we observe the magnitude of those costs most elected officials making these decisions will have moved on to other careers. But the goal of policy is to carefully weigh those future costs and not believe snake oil promises that strict and large price regulations can cure all of our ills with no side effects.

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

It is not surprising that attention to high healthcare prices has focused so heavily on the pharmaceutical sector.⁷ Patented prescription drugs are sold for many multiples of the marginal cost of production and, as a result, firms *appear* to simply be profiteering at the expense of patients. Complaints that high prices are primarily about corporate greed ignore that they are the result of deliberate government policies intended to provide the necessary incentives for the continued development of innovative products. By granting intellectual property protection, governments allow innovative firms to earn positive economic profits for a period of time without facing the threat of competition that would result 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 expected 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 future innovation. They also reflect the degree to which high prices today may

⁷ In thinking about this attention, we should note that pharmaceuticals make up at most 20 percent of healthcare spending.

not have a correspondingly large reduction in access because of the market expanding features of health insurance.

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 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 government entities such as the National Institutes of Health (NIH) as well a variety of other non-profit organizations. This means many expensive products on the market rely to some degree on knowledge generated as a result of 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.⁸ 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.⁹ 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.¹⁰ While such policies might lend themselves to attractive slogans and sound bites, the reality is far more complicated than is often discussed.

Understanding the pitfalls 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 tools. As a result, firms worry they will be unable to appropriate the value of investments in developing novel advances in basic science. In effect, despite various intellectual property protection regimes, investments in basic science still suffer from many of the public good related market failures that would plague an entirely unrestricted pharmaceutical market. Firms that do not reasonably believe they can profit from investments

⁸ 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).

⁹ L. Zhou, “The new bipartisan Senate bill aimed at making Big Pharma lower drug prices, explained,” *VOX*, July 31, 2019.

¹⁰ M. Mezher, “Lawmakers Urge HHS to Exercise 'March-in' Rights to Fight Higher Drug Costs,” *RAPS.org*, January 11, 2016.

will not make them, and as a result there is a fear that basic science research will be under-provided. Given their lack of profit incentives, the NIH is ideally situated 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 the current market, these additional investments are provided by private firms that do additional research and development to commercialize the NIH funded basic science. The appropriate economic framework for understanding these government investments in basic science is one where this research is a complement to rather than a substitute for research funded by private risk capital. When you consider government funding as a complement to private research, it becomes clear that our should be to attract as many private firms as possible to leverage these NIH 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.¹¹ 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.”¹² 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.^{13,14}

¹¹ 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.

¹² “Federal R&D, Drug Discovery, and Pricing: Insights from the NIH-University-Industry Relationship,” *Congressional Research Service*, 2012.

¹³ In interviews prior to the policy change, pharmaceutical manufacturers pointed to uncertainty about pricing as a concern in potential partnerships with the NIH.

¹⁴ While there are a variety of features that influence the number of CRADAs, including which agreements are counted in the data provided by the NIH, there is clear evidence from both interviews and empirical data that there is a relationship between restrictions on pricing and the willingness of private firms to use publicly funded research. While the direction of the relationship is clear, future research should work to better identify the magnitude of this effect.

I.B. The Decentralization of Early-Stage Drug Development

Proponents of strict price regulation point to the fact that the savings from such efforts could be redirected back to the NIH and offset any expected decline in innovation. This belief, however, ignores the current assets and activities of the NIH – which is to evaluate and fund *basic science* and not undertake drug development and commercialization activities. 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 a private firm. 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 opportunities to commercialize this science should come to market. This effectively involves introducing more central planning to the development of new products where a single firm is undertaking both basic science and drug development activities. In considering the wisdom of such a strategic shift, we should consider that it would run counter to the recent decisions of the major players in the private market. In recent years, large pharmaceutical firms are *decreasing* the degree to which they singularly dictate the path of research through internally funded 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 have the freedom to decrease prices without harming innovation. After all, since the firms currently selling the product didn't actually undertake the costly investments in 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 providers of private risk capital for early stage firms (e.g. venture capital investors) is a profitable "exit" for their funds. This traditionally happens in the form of an acquisition, though increasingly we are also seeing early-stage biotechnology firms going public through an initial public offering. The financial terms of these eventual exist 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 private funding is inherently mercenary in nature and in search of

the highest returns. If potential returns from biotech investments fall, investors will simply redirect their funds from the pharmaceutical sector towards the next best option.¹⁵ 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 firms 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 better 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. The role of government in limiting welfare losses during period of market exclusivity

For the reasons discussed above, determining the parameters of the access and innovation tradeoff is difficult. That said, there is clearly a role for the government in attempting to limit (the extent possible) the loss of welfare that occurs during period of market exclusivity. This can be done both by ensuring the existence of robust competition among therapeutic substitutes and supporting the operation of well-functioning insurance markets. There are three areas where the government could do more in these areas: (1) stronger incentives for actual negotiations in government programs; (2) improved regulations regarding consumer cost sharing; (3) increased transparency on the flow of funds between different players in the supply chain. I discuss policies related to these points below.

II.A. Creating Stronger Incentives for Negotiation in Government Programs

Supporting a competitive market for prescription drugs 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.

¹⁵ While it is true that there are a number of venture capital firms that focus entirely on the biopharmaceutical sector, they are primarily investing other people's funds and those investors are targeting areas that provide the greatest returns.

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 firms for the provision of publicly funded social insurance benefits. This includes the Medicare Advantage program, Medicaid Managed Care, and even the much-decried 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.¹⁶ 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.

II.A.1 Increasing Incentives for Price Negotiation under Medicare Part D

While many policymakers and activities claim that Medicare does not negotiate the prices paid for prescription drugs,¹⁷ they are not correct. Under the structure of Medicare Part D, private firms undertake vigorous negotiations on behalf of the government. Given one of the primary commercial activities of these firms involve negotiating with pharmaceutical manufacturers, they have amassed the skills and expertise to be quite good at this process. Using private firms in this way should be an efficient means of securing large discounts for the public insurer. However, two regulations within the current structure of the Medicare Part D program limit the ability of the market to effectively deliver efficient prices. Congress should act to remove or reform these regulations immediately.

The first regulation subverting competition is Medicare Part D’s reinsurance program, which blunts the incentives of firms to negotiate price discounts for the most expensive drugs. Exhibit 2 shows the distribution of spending responsibilities under Part D. During the deductible period, the beneficiary is responsible for all the spending. Then, during the initial coverage phase, enrollees are responsible for 25% of their drug spending and the plans are responsible for the remaining 75% of spending. If individuals spend

¹⁶ Garthwaite, Craig. 2017. “Why replacing Obamacare is so hard: It’s fundamentally conservative.” The Washington Post. July 10.

¹⁷ Office of United States Congressman Peter Welch. 2019. “Welch, Rooney Introduce Bill Requiring HHS Secretary to Negotiate Medicare Prescription Drug Prices.” January 8.

through the initial coverage period, they find themselves in the coverage gap where they are responsible for 25% of spending, the plan is responsible for 5%, and manufacturers are required to give a discount of 70%. If an individual spends more than the catastrophic coverage threshold (approximately \$8,000 in 2019), then the government is responsible for 80% of all additional costs, plans are responsible for 15%, and beneficiaries are responsible for the final 5%.

Therefore, for products with exceptionally high prices, the private firms empowered to negotiate on behalf of Medicare are largely shielded from the costs of most price increases – limiting the ability of the market to lower these drug prices. Perhaps more concerning, PBMs operating in both the commercial and the Part D markets may face different incentives for rebates across these different markets and could use the confidential nature of rebates to unnecessarily increase government Part D spending. Initially, reinsurance was not a dominant feature of Part D. This has changed. Exhibit 3 shows the average national plan bid across Part D firms by its component parts – the direct subsidy from the government, the base premium from the enrollee, and the expected reinsurance payment. These data show that from 2007 to 2018, the reinsurance component of Part D spending has grown from a relatively minor part of the program (25% of the plan bid) to the dominant source of payments to firms under Part D (60% of the plan bid).

This level of reinsurance shields plans from the costs of the most expensive specialty drugs – a category of products that represents a growing share of the prescription drug market. While such a large amount of reinsurance may have been necessary to attract plans to the newly established Part D market, it is highly unlikely this remains true today. Part D is now an established market where firms have sufficient data to make reasonable projections about potential risk. Therefore, I propose that Congress either remove catastrophic reinsurance entirely from Part D (and force plans to pay 100% of the cost of these expensive products) or at a minimum switch the cost sharing so that the plan is responsible for 80% of the spending above the catastrophic limit and the government is responsible for 20%.¹⁸ This would provide the appropriate incentives for firms to strongly negotiate for larger rebates and lower prices within Part D.

A second feature of Part D that lessens competition and results in higher prices is the institution of protected drug classes. In an effort to ensure full insurance coverage and to limit the ability of firms to use formularies to deter the enrollment of sick individuals, Medicare Part D contains a number of restrictions on formulary construction. For all drug classes, plans must include at least two chemically distinct products. In addition, Medicare Part D identifies six protected classes (immunosuppressants, antidepressants, antipsychotics, anticonvulsants, antiretrovirals, and antineoplastics) for which firms must cover every product on the market.

¹⁸ As I discuss below, very large consumer cost sharing (such as the 5 percent of spending that patients must pay under Part D) can decrease the efficiency of insurance.

Limiting the formulary in this way drastically constrains the ability of private firms to negotiate price discounts – which was a primary rationale for having the Part D program administered by private firms in the first place. Obviously, in developing the optimal formulary adequacy restrictions, we must balance a tradeoff between price and access. The current system of protected classes appears to err too far on the side of access by providing very few tools for private firms to negotiate lower prices for important and expensive drug classes. Therefore, regulators and Congress should consider amending the protected class rule to maintain a minimum level of formulary adequacy while allowing plans to exclude some products that experience large price increases and to implement more utilization management strategies on expensive drugs within these categories.

II.A.2 Implementing Price Negotiation in Medicare Part B

While Medicare Part D involves a large amount of price negotiation, there are still many drugs paid for by Medicare that involve absolutely no price negotiation. These drugs are administered by providers and covered under the Medicare Part B benefit. Rather than use private firms to negotiate prices for these products, Medicare operates under a “buy and bill” system. Physicians purchase these drugs and then are reimbursed a fixed percentage above the average sales price (ASP) of the product – a price measure intended to account for rebates paid by manufacturers to payers. The purpose of this reimbursement system is to provide doctors with simplicity and predictability of reimbursement. These attractive features, however, come at a meaningful cost for the entire system, as the Part B procurement rules increase prices for the public and private markets while also shifting share at the margin to more expensive treatment options.

In order to understand the widespread effects of Part B, consider the motivations of a pharmaceutical manufacturer negotiating with PBMs and payers to determine its optimal price. Given that these firms are attempting to maximize profits, they set prices that are expected to earn the greatest profits. Once those profit maximizing prices are set, higher prices will, by definition, decrease the firm’s total profits. This occurs because the increased margin will not make up for the lost quantity (and related profits) that comes from a greater use of prior authorization, step therapy, increased cost sharing, or other utilization management tools.

By linking public and private prices, the Part B purchasing rule distorts the optimal pricing decision in the private market. Firms are willing to increase private prices, and suffer declining profits in the private market, because they know they can make up those lost profits and more from the public market. In addition, because they know that physicians earn more money from administering a higher-priced drug, they have an additional incentive related to Part B for raising prices.

The combination of these factors means that the Part B procurement rules create the incentives for firms to offer fewer discounts in the private market, resulting in a higher ASP and greater profits from the public market. As a result, the current Part B rules for purchasing physician-administered drugs result in higher prices in both the public and the private markets. These incentives increase with Medicare's market share in each drug – a larger Medicare market means the potentially higher reimbursement from the public payers is more important for determining profits than the lost sales in the private market. Given the age and disease profile of Part B enrollees, there are a large number of high-cost drugs for which Medicare has a meaningfully large market. For example, Exhibit 4 depicts Medicare's market share for the 84 drugs that are either in the top 50 for overall Medicare spending or the top 50 for spending per enrollee (there are not 100 different drugs because of overlap between these two categories). This exhibit shows that Medicare has an economically meaningful role in this market and that, for 22 drugs, Medicare is responsible for a majority of sales.

As we look for policy solutions to address the lack of competition created by the Part B reimbursement rules, we must confront two areas of concern. Part B can cause higher prices both because physicians have an incentive to prescribe higher priced drugs (because at they earn more for administering such products) and because manufacturers have an incentive to raise private prices to influence the public market.

In attempting to address physician incentives, we must be careful not to create perverse incentives to inappropriately prescribe lower-cost drugs. We also must be careful about creating a situation where it is no longer economically viable for physicians to practice in particular areas or in particular organizational forms. For example, attempts to reform the Part B procurement rules that switch to simply paying physicians a flat fee for each administered drug ignore the fact that physicians can face meaningful inventory costs for stocking and maintaining a large volume of high-cost drugs. These costs could be particularly acute for small practices, which may lack sufficient liquidity to maintain sufficient stock of medications and may make prescription choices to limit these costs. At the extreme, this could push further consolidation of the provider market.

Congress should consider policies that adopt a vendor model for the distribution of physician-administered drugs that would transform that market from the existing "buy and bill" system to one where physicians have little financial incentive to prescribe particular medications. The details of such a fundamental shift in the market are important and must be worked out. In doing so, Congress should investigate why previous attempts to establish a similar model under the Competitive Acquisition Program (CAP) did not successfully attract vendors and providers. Certainly, part of this failure results from the fact that many providers are currently dependent on the revenues they earn from the buy-and-bill system. Thus, any successful reform must figure out a way to attract those physicians and other providers into the system. In addition, such a

program would need to be sufficiently attractive to vendors to attract entrants to the market. This would likely require empowering vendors with the ability to walk away from particular drugs in order to secure greater discounts. This may limit the access of Medicare patients to some patients, but we must be honest and adamant that some degree of reduced access is a necessary part of any true price negotiation process.

While there are many details to work out in this area, I would strongly encourage policymakers to follow the policy lead of Part D and find ways to utilize private-sector vendors to negotiate lower prices for Part B, rather than turning this portion of Medicare into a price taker. Failing to do so will continue to perpetuate a policy that increases spending across the system.

II.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 5).

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 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 develop formularies that

employ 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.^{19,20} 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, such as pharmaceutical markets, 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.²¹

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.

Rebates have gained an undeserved bad reputation, resulting from a lack of understanding of their important role in controlling pharmaceutical prices. This appears to stem from 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. There are, however, concerns about how rebates interact with other features of the system. In my testimony below, I identify two primary concerns with the existing rebate system that should be addressed by new policies: (1) excessive cost sharing

¹⁹ 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.

²⁰ Byrne, David and Nicolas Roos. 2015. "Learning to Coordinate: A Study in Retail Gasoline." *American Economic Review* 109(2): 591-619.

²¹ [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.

that increasingly transfers resources from sick to healthy patients; (2) conflicting incentives for PBMs to include particular drugs on the market. I outline potential policy solutions to these concerns below.

II.B.1. Policies to address rebates leading to excessive cost sharing

Given the desire to maintain the confidentiality of rebates, 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. As rebates have grown, this distinction between the price used as the basis of cost sharing has become more important.

A primary 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.²² 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 and/or share 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. Increasingly, research shows that even small amounts of cost sharing can lead to negative health shocks including death.²³

Further complicating matters is the fact that the existence of large rebates is increasingly seen as part of the competitive strategy for firm sponsors. Such rebates can be used to finance lower premiums for all customers. This would help to explain claims by manufacturers that PBMs and plan sponsors are demanding large rebates, even if those rebates are generated by simply increasing the list price (i.e. so that there is no actual change in the negotiated price). At first glance it is unclear why market participants would care about the size of the rebate? It is often argued that this is simply an attempt by PBMs to capture part of the larger rebate as profits. While this is certainly possible (and a feature of the market I discuss below), this explanation

²² It always important to remember that the use of differential cost sharing across products is an important tool for price negotiation in these markets.

²³ A. Chandra, E. Flack, and Z. Obermeyer, “The Health Costs of Cost-Sharing,” *NBER Working Paper #28439*.

is at odds with contract structures where PBMs transfer all of the rebates back to the plan sponsor. Such contracts are a growing part of the market at the same time as rebates have grown in magnitude

Instead of simply reflecting an attempt by one part of the chain to increase the value it captures, it is likely that there is a more subtle transfer going on where rebates are used to allow plans to offer lower premiums to all customers. This makes the plan more attractive to healthy customers that are not purchasing expensive prescription drugs. This would allow firms to better compete for market share and make the plans less attractive for expensive customers.²⁴ In this way, increasingly large rebates serve as a transfer within the risk pool between healthy and sick customers. Evidence of this premium related rationale for higher list prices and rebates can be found in the recent Senate Finance Committee report on insulin prices.²⁵ In this report, an executive from Eli Lilly described PBM objections to a lower list price would come from, among other reasons, that fact that a lower list price would “impair their clients’ ability to lower premiums for patients, thereby impacting their market competitiveness.” In this way, a system of onerous cost sharing based on list prices causes both direct costs (in the form of lower adherence and worse health outcomes) and indirect costs in the form of unwinding the community rating of health insurance markets.

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 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. This is true. However, 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.

²⁴ The degree to which firms find it optimal to avoid potentially expensive patients is dependent, in part, on the effectiveness of risk adjustment in the market. For a more complete discussion of this point see, M. Geruso, T. Layton, and D. Prinz, “Screening in Contract Design: Evidence from the ACA Health Insurance Exchange,” *American Economic Journal: Economic Policy*, 2019; 11(2): 64-107.

²⁵ [https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20\(FINAL%201\).pdf](https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf)

II.B.2. Improving the flow of information between PBMs and plan sponsors

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 2012.²⁶ 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.

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.

²⁶ 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.

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 firm 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 remain 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).²⁷ These fees are not trivial – for some contracts they can account for 25-30% of the money moving between the manufacturer and the PBM.²⁸ Furthermore, these fees are often structured as a function of the list price, which further calls into question the distinction between a “fee” and a “rebate.” Describing this system, the Senate Finance Committee report in insulin pricing said “[a]lthough Part D plans are required to report rebates to CMS, they are not required to report administrative fees collected and retained by PBMs ‘if the fees are for bona fide services and are at fair market value.’ This basic lack of transparency in the Medicare program has been an area of concern to HHS OIG, as has the competing interests that PBMs and manufacturers find themselves in due to the administrative fees being based on the WAC price.”²⁹

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 a \$15 “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 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

²⁷ Eickelberg, Henry C. 2015. “The Prescription Drug Supply Chain ‘Black Box’: How it Works and Why You Should Care.” American Health Policy Institute. December.

²⁸ Dross, David. 2017. “Will Point-of-Sale Rebates Disrupt the PBM Business?” Mercer. July 31.

²⁹ [https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20\(FINAL%201\).pdf](https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf), page 81.

negotiations.³⁰ Given the existing structure of contracts and cost sharing, other members of the value chain are far less agnostic about the labeling of these fund transfers.

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.³¹ 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.³² 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. This can affect the efficiency of bargaining between these two groups.

Two years ago, 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.³³ 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.³⁴ PBMs and payers would be free to negotiate any split of the rebates, fees, and other funds that are paid by the

³⁰ To the extent manufacturers have preferences about this labeling it is likely related to the intersection with cost sharing discussed above. Note that high cost sharing impacts manufacturer revenue by reducing demand for pharmaceutical products.

³¹ Weinberg, Neil, and Robert Langreth. 2017. "Inside the 'Scorpion Room' Where Drug Price Secrets Are Guarded." Bloomberg. May 4.

³² Advisory Council on Employee Welfare and Pension Benefit Plans. 2014. "PBM Compensation and Fee Disclosure." Report to the United States Secretary of Labor.

³³ U.S. Department of Health and Human Services. 2019. "Trump Administration Proposes to Lower Drug Costs by Targeting Backdoor Rebates and Encouraging Direct Discounts." January 31.

³⁴ Garthwaite, Craig, and Fiona Scott Morton. 2017. "Perverse Market Incentives Encourage High Prescription Drug Prices." ProMarket Blog. November 1.

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 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.

III.C. Excessively High Cost Sharing in Prescription Drug Insurance Contracts

In addition to high cost sharing driven by the growing spread between list and net prices, there has been a general movement towards increasing pharmaceutical cost sharing in the market. This is true across both public and private plans. Certainly, a large portion of this activity is the result of robust negotiations between manufacturers and payers over prices. However, some of the movement towards high cost sharing appears to be driven by the same economic incentives detailed in the discussion of rebates above, i.e. differential cost sharing can transfer resources from the sick to healthy and patients in the form of lower premiums and decrease the attractiveness of the plan to potentially expensive patients. In that way, high cost sharing serves as a way to unwind the community rating and guaranteed issue regulations that are extremely popular among consumers and policymakers. It might be particularly concerning that it unwinds these regulations in a way that may not be obvious to customers until they have purchased the insurance product and suffered a negative health shock. At this point, these customers may find that they actually have far less insurance coverage than they anticipated.

In response to this increasing high cost sharing, pharmaceutical companies have implemented a variety of copayment assistance and coupon programs. While these programs increase access to expensive pharmaceuticals, they have also been shown to increase overall drug spending.³⁵ This is particularly true when coupons are available for products that have a bioequivalent generic product on the market. In such a setting, the coupons shift customers away from the less expensive generic alternative.

While it is tempting to view coupon programs as simply an attempt to unwind utilization management by payers, the reality is more complicated. Determining the efficiency of cost sharing requires a careful consideration of reason the tool is being used by payers. Cost sharing can be used to control moral hazard in the form of the overconsumption of drugs that don't provide sufficient value. It can also be used to move patients across products as part of price negotiations. Both of these rationales for cost sharing can increase the efficiency of health insurance markets.

³⁵ L. Dafny, M. Schmitt, and C. Ody. 2017. "When Discounts Raise Costs: The Effect of Copay Coupons on Generic Utilization," *American Economic Journal: Economic Policy*, 9(2): 91-123.

However, high cost sharing on products that do not have therapeutic substitutes or on all products in a class can be a means of unwinding the completeness of the insurance contract. This likely does not improve the efficiency of the insurance contract and is particularly concerning if customers are not fully cognizant of this incompleteness when they make their purchase decision. This is even more apparent in the terms of the formulary in terms of which products are on which tiers changes during the middle of the contract period.

Excessive cost sharing is particularly problematic in Medicare Part D, where patients who use expensive pharmaceuticals face excessively high exposure to the cost of their drugs throughout the catastrophic period. This excessive exposure is entirely in the hands of policymakers and should be addressed as soon as possible – perhaps as part of a broader redesign of cost sharing in Medicare Part D.

Congress should also examine whether it is sensible to jointly address the questions of cost sharing and coupons in the prescription drug market. One possibility would be to create limits on both the amount of cost sharing that can be charged to consumers and copayment assistance in the commercial market. This compromise could address both sides of this issue and is something that deserves far more consideration and study by policymakers. Any policy solution here regarding coupon

III. The role of government in supporting a robust generic and biosimilar market

As discussed above, the access-innovation trade off involves granting firms a time limited period of market exclusivity. At the conclusion of this period, it is in the best interest of society for products to be sold in a robust and competitive market. Our existing system of follow-on competition has largely worked well since the passage of the Hatch-Waxman Act in 1984. However, the complexity of the modern drug market has created a new set of challenges for this previously well-functioning process. Below, I identify three broad issues that should be addressed by new policies: (1) a lack of competition for generic products treating small patient populations; (2) biosimilar adoption and rebates; and (3) patent negotiations between brand and generic/biosimilar entrants.

III.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 appear to 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.³⁶ 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.³⁷ 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.

³⁶ [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.

³⁷ Abelson, Reed, and Katie Thomas. 2018. "Fed Up With Drug Companies, Hospitals Decide to Start Their Own." The New York Times. January 18.

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 harmonize the generic application process across developed countries.³⁸ 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.³⁹

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.⁴⁰ 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.⁴¹ 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.

³⁸ 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.

³⁹ Elvidge, Suzanne. 2018. "FDA sets another record in 2018 for generic drug approvals." BioPharma Dive. October 12.

⁴⁰ 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.

⁴¹ Warren, Elizabeth. 2018. "It's time to let the government manufacture generic drugs." The Washington Post. December 17.

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 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.⁴² 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.⁴³ 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

⁴² 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.

⁴³ Silverman, Ed. 2019. "Here's how prosecutors say generic drug makers schemed to fix prices." STAT. February 19.

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.

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.⁴⁴ As can be seen in Exhibit 6, 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.⁴⁵ 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.

III.B. 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 potentially 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."⁴⁶ 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.

⁴⁴ Chandra, Amitabh, Craig Garthwaite, and Ariel Dora Stern. 2018. "Characterizing the Drug Development Pipeline for Precision Medicines." NBER Working Paper No. 24026.

⁴⁵ The problem of competition for precision medicine will be further complicated in situations where the patented product is a biologic product.

⁴⁶ Wehrwein, Peter. 2015. "A Conversation with Steve Miller, MD: Come in and Talk With Us, Pharma." *Managed Care*. April 5.

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.⁴⁷

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 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.^{48,49} 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.^{50,51}

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. In particular it may be necessary to consider separate rules for contracts and rebates based on whether patients are treatment naïve or medically stable on a particular biologic product.

⁴⁷ Plan sponsors are not simply looking for the lowest cost plan, but instead the plan that best balances costs and benefits for their customers or employees.

⁴⁸ Liu, Yanchun. 2018. "FDA chief says pharmas use rebates to block biosimilar competition." MarketWatch. July 19.

⁴⁹ Narasimhan, Vas. 2018. "Novartis CEO: How To Create Cheaper Alternatives To The Most Expensive Drugs." Forbes. April 12.

⁵⁰ 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>.

⁵¹ 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>.

In considering why government intervention may be necessary to address these contract structures, it is important to note that even if exclusive contracts limit entry and raise market wide prices, each PBM may have an incentive to demand a bid from a manufacturer for exclusive formulary placement. This could maximize the rebate for the PBM and allow for a more competitive product. Any individual PBM would benefit from such a contract and may not be able to influence the individual entry decision for any particular product. This could result in a commons problem that might be best solved by government action.

III.C. Negotiations over patent infringement

Market exclusivity is governed by a variety of governmental institutions. Central to this system are the intellectual property protections provided by patents. Patents offer protection for individuals developing novel products. During the time period of patent protection, firms are safe from competition arising from a new entrant selling an exact copy of their innovative product. After patents expire, the intention is for other firms to swiftly enter the market and sell copies of the patented product, with the resulting competition lowering prices and increasing access.

Obviously, there is a clear role for government involvement in this area. After all, the initial granting of patents and other forms of intellectual property protection is a government action. Governments also regulate the challenges to such patents and the process by which competitors enter the market as exclusivity expires.

Potential entrants observe the rules created by governments and weigh the potential costs and benefits of attempting to enter into competition with a branded product. Increasingly, this includes navigating a myriad of patents related to the underlying pharmaceutical product, the various uses of the product, and its production process. Given the requirement that patents be narrow and specific to a particular invention, modern complex products are often covered by a wide range of patents. Critics claim this large number of patents reflects an attempt by innovative firms to create a “patent thicket” that raises the costs of entry. These critics believe that rather than reflecting intellectual property, the large number of patents is solely intended to create a costly entry barrier that decreases the number of potential entrants and extends the length of market exclusivity. Given this concern, some critics have gone as far as to suggest that each branded product should be limited to a single patent.⁵²

⁵² R. Feldman, “One-and-done’ for new drugs could cut patent thickets and boost generic competition,” *STAT News*, Feb 11, 2019.

While it is surely true that some firms engage in such a “thicketing” strategy to deter entry, the mere existence of even a very large number of patents is not, on its own, evidence of a nefarious strategy. As the complexity of the production process increases, it is reasonable to assume that these processes will also involve the creation of important and necessary intellectual property. All else held equal, this would result in a greater number of patents per product.

Beyond the complexity of production, pharmaceutical products are increasingly used to treat multiple conditions. Discovering potential new uses for these existing drugs requires additional expenditures on scientific discovery and clinical trials. The incentives to invest in those activities stems from the ability to appropriate some of the value created. Given there are great benefits to society from firms developing new uses for existing products, we should encourage firms to investigate whether products which have already been determined to be safe could be used for additional indications. A system that limits the number of patents that can exist for a product would diminish the financial incentives for firms to invest resources to determine these new uses.

That said, it is not debatable that the existence of large numbers of patents creates a more difficult path for generic and biosimilar entry. The heart of this concern, however, should not be about the *number* of patents pertaining to a particular product but instead about the underlying *validity* of those patents. Ultimately, this is a question about the efficacy and rigor of the patent approval process undertaken by the Patent and Trademark Office (PTO). If the PTO is granting a large number of relatively weak patents to firms that are deterring entry, this is something that should be addressed directly. It could be that this is the result of the growth in demand for patents on potential new innovations outstripping the resources available to the PTO. Academic research has shown that resource constraints affect the accuracy of patent examiners, with more time constrained examiners issuing patents that were more likely to be later invalidated.⁵³ Rather than making sweeping rules about the number of patents, policymakers should more directly examine increased resources for a more efficiently run PTO.

One potential model to provide greater resources for the PTO is a process similar to the Prescription Drug User Fee Act (PDUFA) which provides vital additional resources to the FDA. It is possible that pharmaceutical patents could be assessed additional fees that could be used to increase resources in this area.

⁵³ Frakes MD, Wasserman MF. *Investing in Ex Ante Regulation: Evidence from Pharmaceutical Patent Examination*. National Bureau of Economic Research; 2020.

The large number of patents creates a further concern about negotiations between branded firms and potential entrants about the timing and manner of entry. Under our existing system, an economically meaningful fraction of generic entrants come to the market by challenging some of the underlying patents of the branded product. Given the potential cost and complexity of these lawsuits, these firms often settle on a negotiated date of entry. These negotiated dates are invariably before the formal end of every related patent but after the date indicated by the earliest patent affecting the product in question. There are valid concerns that such negotiations are a ruse to extend the exclusivity period for branded firms. Effectively the concern is that the brand and potential entrant are colluding to split the surplus resulting from the lack of competition. Such concerns are correctly heightened when branded firms transfer something of value to the potential entrant. While the oft-discussed *Actavis* decision stops firms from transferring money in exchange for delayed entry, that has not eliminated concerns that settlements detailing entry could be a source of concern.

That said, such settlements are an expected result of a system where we rely on potential entrants to use “Paragraph IV” challenges to effectively police the validity of patents granted by the PTO. Litigation is costly, uncertain, and distracting to the main business activities of firms. For this reason, firms in all markets often attempt to settle lawsuits out of court rather than taking them to trial. Rather than attempt to cast all settlements as attempts to manipulate the market, I would encourage policymakers to revisit the policies that govern such challenges. Over time, Paragraph IV challenges under Hatch-Waxman have become a very common feature of the entry of new products. Even unmeritorious challenges are expensive for the system. It is possible that various features of the market including but not limited to the 180 day exclusivity for the first to file generic firm and the 30 month stay for patent challenges may be an inefficient means of policing and operating an intellectual property protection system.

One potential avenue to consider is the Reforming Evergreening and Manipulation that Extends Drug Years (REMEDY) Act of 2019. This act would eliminate the 30-month delay for generic entry that is automatically triggered when a patent is challenged. Importantly, this act only applies to patents that are not the main product patent. Without the automatic 30 day stay, a generic firm would be free to enter “at risk,” i.e. if they are later found to be infringing on a valid patent they would owe damages to the patent holder. The economic incentives here would result in firms only entering when they believe that the patent is truly weak, i.e. firms would be unlikely to enter at risk against strong patents because they would be afraid of having to pay damages. In that way this would eliminate the protections for weak patents that are currently created by automatic 30 month stay.

VI. Conclusion

The ability of the market to provide an efficient outcome is a function of the degree of competition between market participants. Sustaining competition in healthcare markets requires both addressing features of the market that lead to failure and avoiding the creation of government policies that diminish competitive forces. Given the large role of government actors in the financing and provision of healthcare, it is critical that the policies of the public insurers are routinely evaluated and vetted. After all, public entities are not subject to the competitive forces that would cause private firms to change their policies and protocols.

As policymakers consider policies to address rising costs in the prescription drug market, it is important that they realize that there will not be a single grand solution to addressing this issue. Instead, progress will be made through a series of small, concrete, and addressable policies that target specific areas where competition is thwarted.

As I discuss above, the policymakers focus on drug pricing 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.

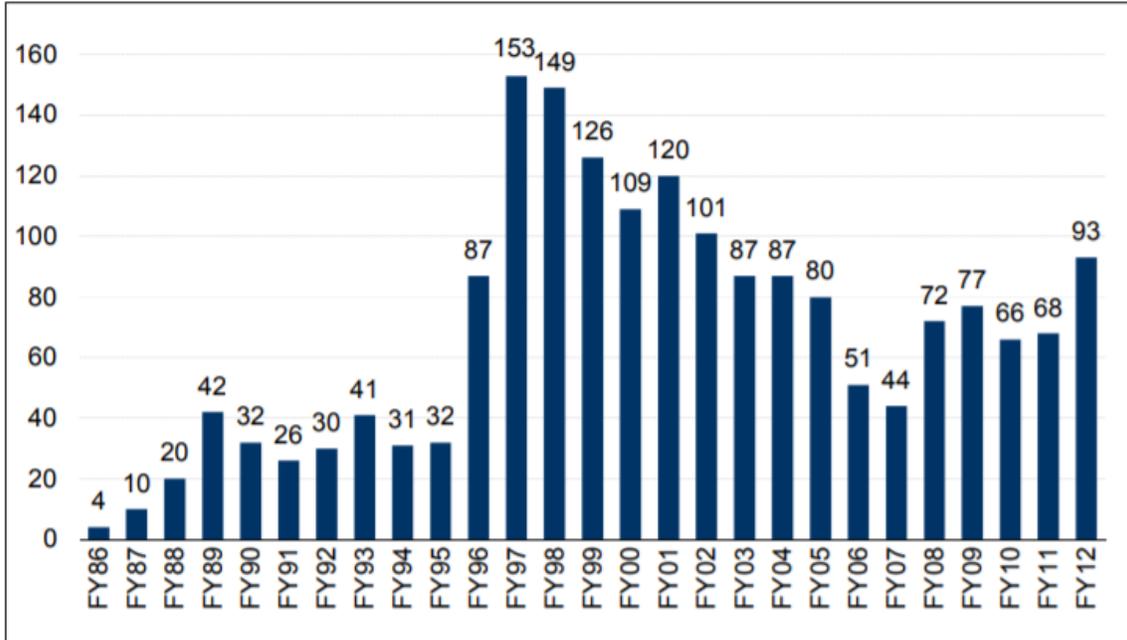
These concerns have prompted calls for greater drug price regulation. Large amounts of price regulation would have meaningful consequences on future innovation and therefore must be debated in an intellectually honest manner that grapples with these tradeoffs.

It is important to recognize that the imposition of large amounts of price regulation, particularly regulation that relied on the decisions of foreign government, would be a massive departure from existing policies. Furthermore, the potential ramifications of such a radical change in policy would not be felt for many years if not decades. At that point, it may be difficult to change course.

Instead, I encourage policymakers to take a more incremental approach to policy reforms. Such an approach would lead to a more competitive market that balances the need for access today with access to new products in the future.

Exhibit 1

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

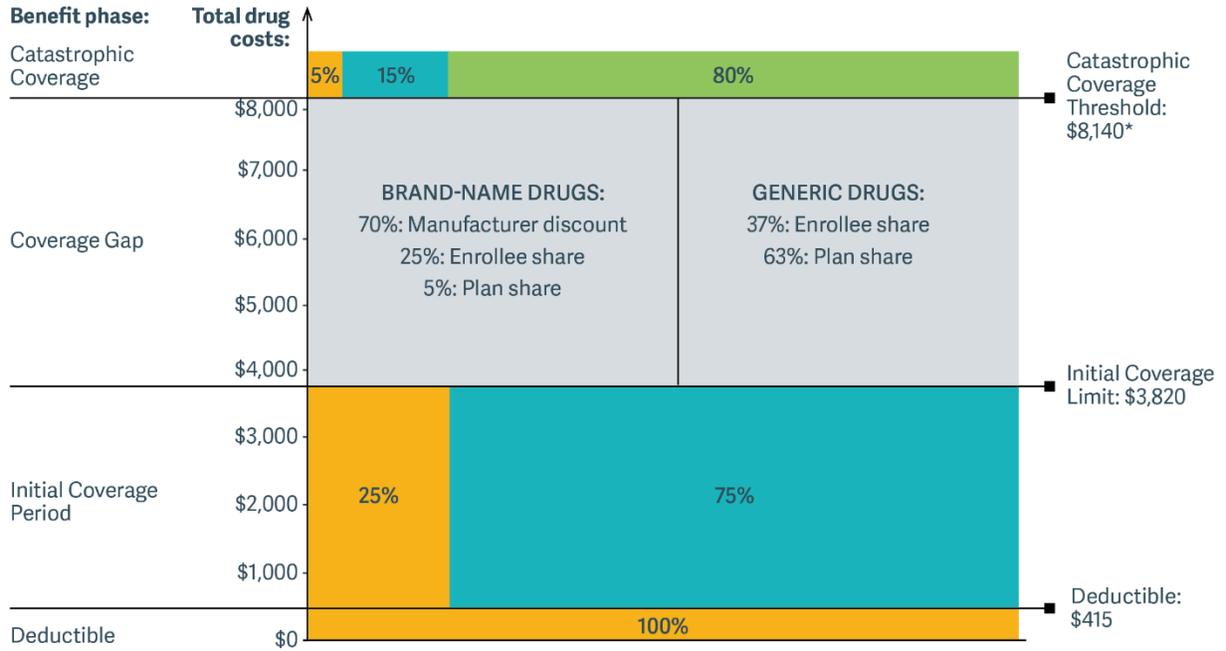


Source: National Institutes of Health, Office of Technology Transfer http://www.ott.nih.gov/about_nih/statistics.html.

Exhibit 2

Medicare Part D Standard Benefit Design in 2019

Share of costs paid by: ■ Enrollees ■ Plans ■ Medicare

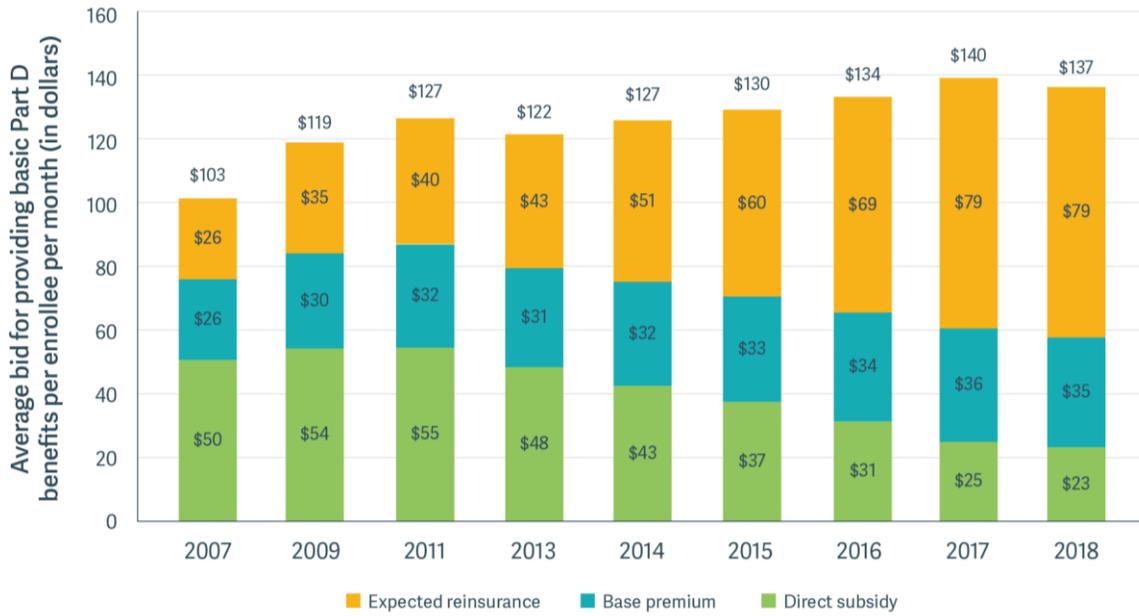


Note: Some amounts rounded to nearest dollar. *The estimate of \$8,140 in total drug costs corresponds to a \$5,110 out-of-pocket threshold for catastrophic coverage in 2019.
Source: KFF, based on 2019 Part D benefit parameters.



Exhibit 3

National Average Plan Bid for Basic Part D Benefits

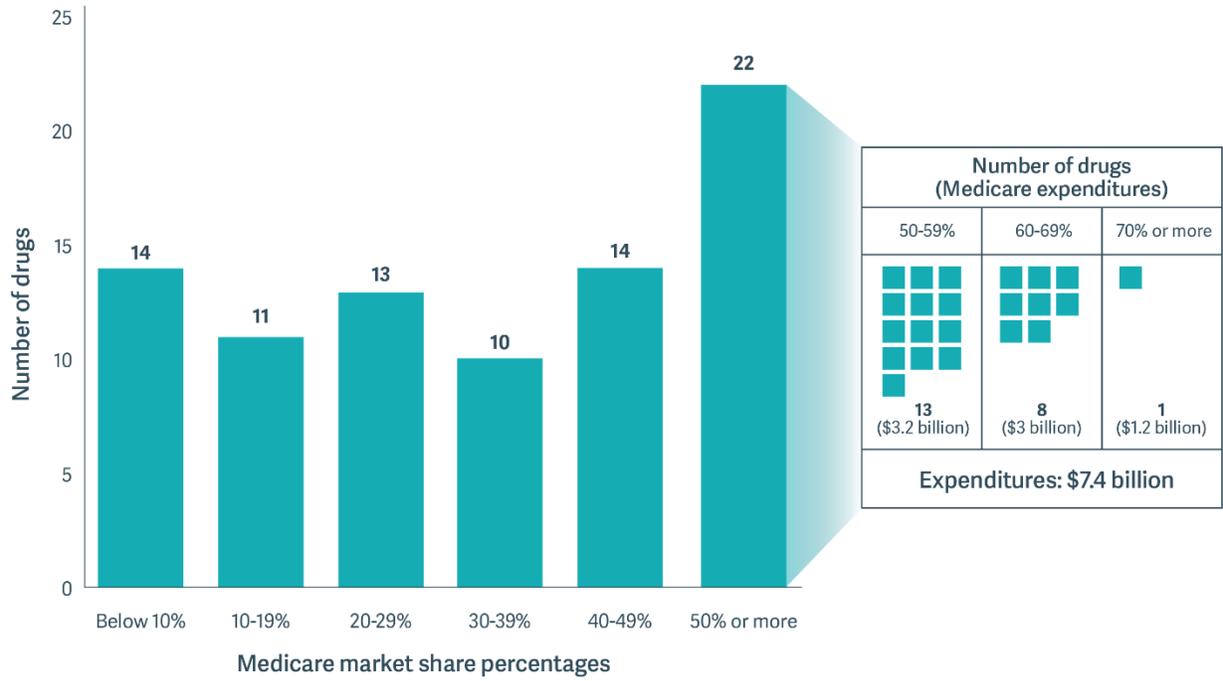


Note: The averages shown are weighted by the previous year's plan enrollment. Amounts do not net out subsequent reconciliation amounts with CMS. Components may not sum to stated totals due to rounding.

Source: MedPAC based on data from CMS.

Exhibit 4

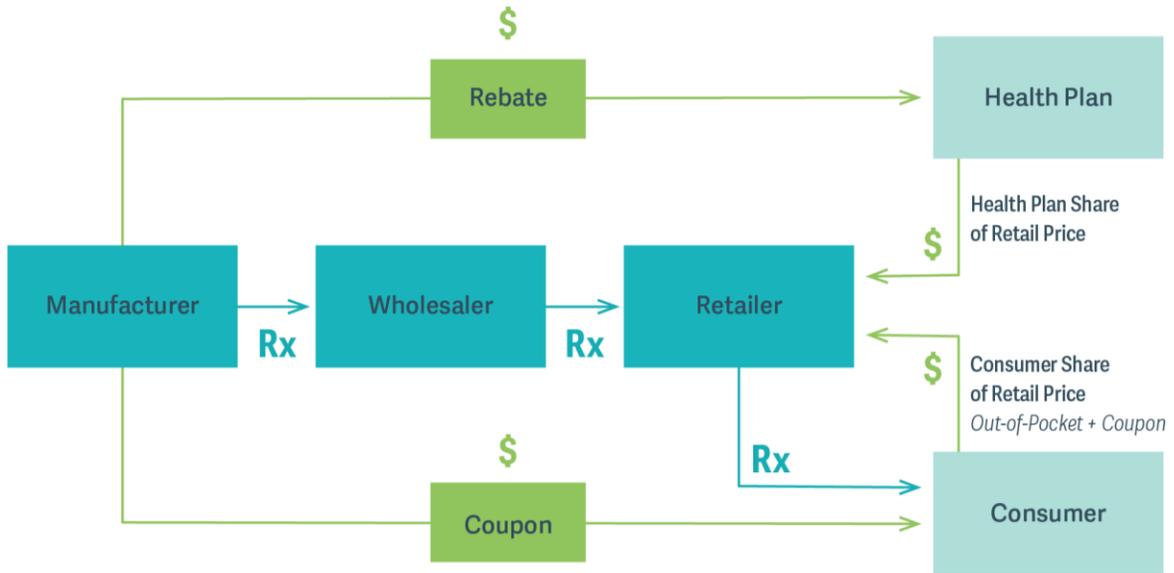
Medicare’s Market Share for the 84 Most Expensive Part B Drugs in 2015



Source: GAO analysis of Centers for Medicare & Medicaid Services data. | GAO-18-83

Exhibit 5

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

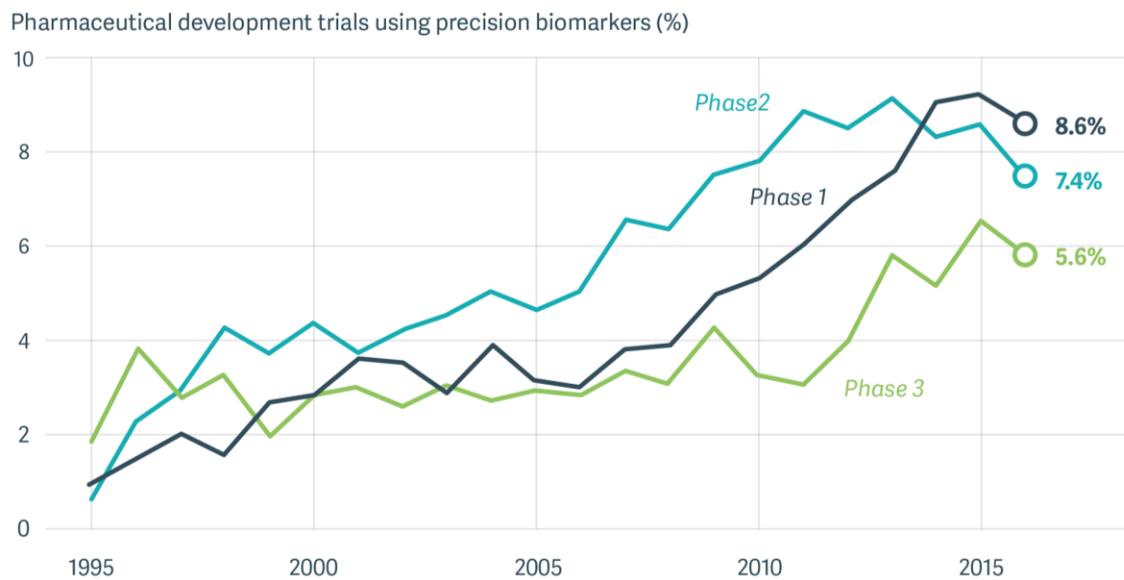


Impact of prescription drug rebates on health plans and consumers
April 2018

Page 3

Exhibit 6

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