

TESTIMONY OF CRAIG L. GARTHWAITE, Ph.D.

**Associate Professor of Strategy
Herman Smith Research Professor in
Hospital and Health Services Management
Director of Program on Healthcare at Kellogg (HCAK)
Kellogg School of Management
Northwestern University**

**Before the
House Judiciary Committee
Subcommittee on Regulatory Reform, Commercial and Antitrust Law**

On

**“Diagnosing the Problem: Exploring the Effects of Consolidation and
Anticompetitive Conduct in Health Care Markets”**

March 7, 2019

In contrast to most other developed countries, the United States relies more heavily on private markets to finance and provide healthcare services for its citizens. While this is a source of consternation for some, there are many advantages to using markets for 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, regulated prices and central planning (by either a government entity or an independent third party) are 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 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. Complicating matters is 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. For this reason, the United States has developed a series of social insurance and transfer programs that allow low-income residents to access healthcare services. Over time these programs have grown, and public spending now accounts for just over half of all healthcare spending in the United States – a fact that makes healthcare markets distinct from the rest of the economy.

Given the economically meaningful role of the public sector in the healthcare market, the ability to maintain a competitive market inherently relies, at least in part, on government policies and regulations. Ultimately, healthcare is our nation's most meaningful public-private partnership. This has become even more apparent as the United States increasingly relies on private markets and firms for the provision of publicly funded social insurance benefits. This includes the Medicare Advantage program, Medicaid Managed Care, and even the much-derided Affordable Care Act – which I've previously noted is perhaps the most conservative market based approach to the provision of health insurance for such a large number of low-income individuals.¹ 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

¹ Garthwaite, Craig. 2017. "Why replacing Obamacare is so hard: It's fundamentally conservative." The Washington Post. July 10.

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.

Currently there are many concerns about the rising cost of healthcare in the United States. These rising costs exist across all healthcare markets – and have caused increased calls for an abandonment of the market and for greater use of government purchasing power, central planning, and regulated prices.²

These calls have perhaps been greatest in the markets for prescription drugs, which have attracted the ire of policymakers and the general public. It is not surprising that such attention has focused on the pharmaceutical sector. Patented prescription drugs are sold for many multiples of the marginal cost of production and, as a result, firms appear to be profiteering at the expense of patients. Complaints that high prices are simply about corporate greed ignore that they are the result of deliberate government policies intended to provide the necessary incentives for the development of innovative products. By granting intellectual property protection, the government allows innovative firms to earn large profits without the threat of competition resulting from the immediate entry of a firm making an identical product. Economic research suggests that this profit incentive matters and consistently documents that pharmaceutical R&D responds to potential market size.³ Pretending this is not the case ignores reality and will only lead to inefficient value-destroying policies.

Intellectual property protections are necessary because the development of new pharmaceutical products involves large investments in research and development, with uncertain prospects for financial success. Once products are patented and approved for sale, generating an exact bioequivalent copy is a relatively simple and inexpensive exercise.⁴ As a result, absent intellectual property protections an innovative firm would rightly suspect it would be unable to earn back its fixed R&D investments before the entry of competitors drove prices towards marginal cost. Realizing they would be unable to recover value from their initial investments,

² Kliff, Sarah, and Dylan Scott. 2018. “We read Democrats’ 8 plans for universal health care. Here’s how they work.” Vox. December 19.

³ 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.

⁴ This ability to generate a bioequivalent generic copy of a medication is limited to the small-molecule market. For biologics, bioequivalent copies are not possible and the process of developing biosimilar products is far more complicated.

rational firms lacking the protection of market exclusivity would never make potentially value-creating investments in the first place.

In order to encourage firms to make these investments, society allows a time-limited period during which innovative firms can exploit the market power that results from no other firm being allowed to manufacture the patented product. As a result, the innovative firm can set an optimal price for its product in competition with others that treat the same therapeutic condition. This does not mean a pharmaceutical manufacturer can charge any price it desires. Ultimately, its pricing decisions are still dictated by market forces (e.g., competition from therapeutic substitutes) and consumer demand. 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.

Effectively, policies governing the development of pharmaceutical products involve trading off the static inefficiency of reduced access to products today in order to create the dynamic efficiency of increased development of new products in the future. This tradeoff is a source of much of the controversy around the prescription drug market, because the reduced access today involves readily identifiable individuals who are unable to access existing medications because of price.⁵ Unsurprisingly, this lack of access garners large amounts of press and political attention. However, it is important to remember a perhaps far greater access problem for patients suffering from conditions for which no treatment options exist at all. For these individuals, there is no price at which they can purchase a treatment, and they will only be assisted in the future by the dynamic efficiency created by intellectual property protection. As we consider the optimality of policies governing the pharmaceutical market, it is critical to balance the oft-discussed need for access to existing products with the less-discussed lack of access from the absence of effective treatments.

While the optimality of trading off some amount of access today in order to gain access tomorrow is clear, the parameters of the length and breadth of this tradeoff are policy decisions for which there is no definitive economic answer. These policy parameters reflect the relative value society places on lost access today and potential welfare gains from innovation in the future. What is clear is that once policymakers have decided on the preferred degree of intellectual property protection required to encourage the desired level and type of innovation, 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.

⁵ Garthwaite, Craig, and Benedic Ippolito. 2019. "Drug pricing conversations must take the cost of innovation into consideration." STAT. January 11.

Our goal is not to provide unlimited benefits to firms, but instead to provide appropriate market-based incentives that encourage firms to develop innovative products that increase welfare. Ultimately, firms will optimally respond to any incentives government creates – and therefore a well-functioning healthcare market requires policies that embrace economic reality rather than hope for a preferred outcome.

I have growing concerns that a lack of competition between various healthcare entities inhibits the ability of the market to operate as efficiently as possible. Some of this lack of competition results from a series of institutional features that inhibit the ability of markets to function. However, the lack of competition is also the result of a series of unhelpful and counterproductive regulations that either limit competition or can be manipulated by incumbent firms to dissuade competition.

Thankfully, there are a series of targeted steps Congress and other regulators could take to harness market forces to moderate the growth of healthcare costs in the United States. These suggestions retain and improve upon the centrality of the market in the provision of healthcare services while recognizing areas where existing regulations and other market structures may inhibit efficiency. While there are many areas in healthcare where I fear that competition is failing, I will focus the majority of my comments on the pharmaceutical market⁶ – which has been the focus of a number of proposed policies and regulations by both Congress and the Trump Administration.

I. Policies to Support a Robust Generic Market

Providing the incentives for the development of new products requires allowing firms a time-limited period of high price-cost margins. However, this is not meant to be an infinite time period, and after intellectual property protections expire, regulators and policymakers should support robust and active competition from generic products. Unfortunately, there are several existing market forces and regulations that currently work against generic competition. This includes firms abusing existing Food and Drug Administration (FDA) regulations to deter the entry of generic competition. It also includes market structures that limit the existence of multiple competitors and allow firms without patent protection to effectively act as monopolists and earn excessively high price-cost margins. I will discuss each of these factors in turn.

I.A. Reducing Barriers to Generic Entry

Firms attempting to enter the market with a generic substitute for an approved FDA product must file an Abbreviated New Drug Application (ANDA). As part of this process, the generic manufacturer must

⁶ As a general note, throughout this testimony when I use the terms “market,” “healthcare market,” or “pharmaceutical market,” this is meant as a general descriptive term and is not intended to describe a market for the purpose of antitrust enforcement.

demonstrate that its product is bioequivalent to the reference product – a scientific process that obviously requires the generic firm to have access to samples of the reference product. Without access to a sufficient quantity of samples, a generic firm faces meaningful difficulty demonstrating bioequivalence and entering the market – extending the time period during which incumbent firms can earn excess economic profits.

Currently, a number of brand-name pharmaceutical manufacturers are allegedly limiting access to these necessary samples. Some of these firms are exploiting the Risk Evaluation and Mitigation Strategies (REMS) system, which is a well-meaning regulation intended to provide a means for firms to monitor the access to and safety of their pharmaceuticals.⁷ While the intention of REMS is to improve safety and monitoring of programs, there are growing concerns that firms are using this system as a means of delaying access by asserting they are unable to certify that distributing such samples would comply with their REMS program. Other firms, such as Turing Pharmaceuticals, allegedly denied access to these products by simply limiting distribution to a closed network of pharmacies.⁸ Regardless of the rationale, denying access to samples deters potential entrants and extends the period of higher price-cost margins.

Recognizing the importance of these samples to a robust generic market, there is existing legislation titled the Creating and Restoring Equal Access to Equivalent Samples Act (CREATES). CREATES does a good job of balancing a number of competing interests in an attempt to promote generic competition. Its primary focus is on creating a cause of action for generic firms to sue brand-name manufacturers that work to deny them access to samples. In addition, CREATES establishes a series of monetary penalties intended to dissuade incumbent firms from engaging in this behavior in the first place. However, the act also recognizes that there are time periods of legitimate drug shortages, and in those time periods the welfare-maximizing course of action is for existing product to be delivered to patients rather than to generic firms. Cognizant of the potential gaming that could occur regarding shortages, the act separates conditions of long-term and short-term shortages – and does not allow firms to fail to provide samples when there is a long-term shortage that they should address. Overall, CREATES is an attractive piece of legislation that should be passed at the earliest opportunity.

While passing CREATES would be a meaningful first step towards reducing barriers to entry for generic competitors, there are additional regulatory barriers to entry for generic firms that Congress and regulators should investigate. For example, as part of the process for approval of generic drugs, individuals are allowed

⁷ Manne, Geoffrey. 2016. “Senator Lee’s prescription for regulatory failure in the generic drug market.” Truth on the Market. June 14.

⁸ Pollack, Andrew. 2015. “New York Attorney General Examining Whether Turing Restricted Drug Access.” The New York Times. October 12.

to file Citizen Petitions about the safety and efficacy of a product. With roots in the First Amendment, Citizen Petitions (like the REMS system) have the potential to serve a vital role in ensuring the safety of the pharmaceutical market. However, like many well-meaning regulations, the existence of the Citizen Petition process creates the opportunity for abuse as some incumbent firms file unnecessary petitions in order to slow down the process of generic products reaching the market. This delay results from the fact that the FDA must carefully evaluate every Citizen Petition – even those primarily intended to create artificial delays. During the time period of this review, the brand name retains greater market power and society continues to pay supracompetitive price-cost margins for the medication.

While Citizen Petitions can serve a valuable role in the approval process, this value must be weighed against the possibility of creating unnecessary and costly delays in the entry of generic products. Therefore, I encourage Congress to ask the Federal Trade Commission (FTC) to investigate the characteristics of Citizen Petitions that appear likely to be attempts by firms to gain an anti-competitive advantage in the marketplace – noting that there are many potentially valid petitions filed by both individual citizens and firms.

I.B. A Lack of Competition for Generic Products Treating Small Patient Populations

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

In recent years, several firms have recognized the pricing power available to ANDA holders for generic products with sufficiently small potential markets. This was perhaps best personified by the pricing strategies of Turing Pharmaceuticals, but aspects of this strategy have been implemented by other firms and thoroughly documented in several media outlets.⁹ 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 –

⁹ 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.

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.¹⁰ For products administered in the hospital, providers are unable to pass the increased costs along to patients or payers and have therefore decided to vertically integrate and manufacture the products themselves.

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

If high fixed entry costs make it difficult for multiple firms to profitably produce small-market generics, one potential policy solution is to lower these fixed costs. This would decrease the quantity required for a new entrant to reach MES and compete with the incumbent manufacturer. In recent years, the FDA has been focused on programs to accomplish this goal. For example, there have been efforts to streamline and harmonize the generic application process across developed countries.¹¹ 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.¹²

¹⁰ Abelson, Reed, and Katie Thomas. 2018. “Fed Up With Drug Companies, Hospitals Decide to Start Their Own.” *The New York Times*. January 18.

¹¹ 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.

¹² Elvidge, Suzanne. 2018. “FDA sets another record in 2018 for generic drug approvals.” *BioPharma Dive*. October 12.

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.¹³ 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. Recently, Senator Elizabeth Warren has proposed that the government step in to manufacture generic drugs when products have small market sizes and large drug price increases.¹⁴ I understand and appreciate the motivation for Senator Warren's proposal and think that it is a potentially viable policy option for addressing this particular market failure, i.e., the lack of competition in markets for generic products without sufficient size to support multiple firms.

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

¹³ 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.

¹⁴ Warren, Elizabeth. 2018. "It's time to let the government manufacture generic drugs." *The Washington Post*. December 17.

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.¹⁵ 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.¹⁶ Therefore, it is important for economists at the FTC to determine the exact market size and structure that would indicate that the market for the generic product is a natural monopoly where the incumbent firms possesses significant pricing power. Ideally this investigation would incorporate the potential market-expanding policies of decreasing entry costs and potentially increasing the market size to include some limited foreign markets.

After establishing the market characteristics likely to lead to natural monopolies, I would propose the FDA be required to undertake a request for proposal (RFP) process for those markets. Under this RFP process, any private firm could apply for the rights to be the exclusive manufacturer of a natural monopoly generic medicine at a certain fixed percentage above manufacturing costs. As part of this RFP process, firms would compete on the amount of margin they would require to serve the market. The winning firm would possess the exclusive rights to sell the drug at this regulated price for a time period sufficient to recover the fixed costs of entry. At that time, the FDA would have the option of re-auctioning off the market exclusivity. In order to ensure the efficient operation of this process, it may also be necessary for the FDA to set a maximum percentage that they will accept before they will turn to a non-profit or government supplier for the product. This will limit any ability of firms to collude to divide up the markets in which 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.¹⁷ As can be seen in Exhibit 1, in

¹⁵ 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.

¹⁶ Silverman, Ed. 2019. "Here's how prosecutors say generic drug makers schemed to fix prices." STAT. February 19.

¹⁷ Chandra, Amitabh, Craig Garthwaite, and Ariel Dora Stern. 2018. "Characterizing the Drug Development Pipeline for Precision Medicines." NBER Working Paper No. 24026.

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.¹⁸ 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.

II. 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 2).

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 use a combination of consumer cost sharing and utilization management techniques such as prior authorization and step therapy.

¹⁸ The problem of competition for precision medicine will be further complicated in situations where the patented product is a biologic product.

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, 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. Exhibit 3 depicts the contract structure regarding the amount of the rebate kept by firms based on employer size in 2014 and 2017. 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.

II.A. Improving Information about Flow of Funds Between Manufacturers and PBMs

Rebates have gained an undeserved bad reputation, resulting from a lack of understanding of their important role in controlling pharmaceutical prices. This has culminated in a recent Department of Health and Human Services proposal to end the safe harbor protections for rebates under the Medicare program – a regulatory change that would effectively end the use of rebates for publicly insured consumers (and potentially for the entire market).²²

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.

²² Office of Inspector General and Department of Health and Human Services. 2019. 84 FR 2340. February 6.

The proposed rule appears to be motivated by a belief that rebates offered as a discount off of the list price are partially responsible for rising drug prices. However, this belief is misguided. There is nothing about rebates that inherently causes higher pharmaceutical spending. Ultimately, there are two primary concerns about rebates highlighted as rationales for the proposed safe harbor regulation. First, many cost-sharing provisions of prescription drug insurance contracts expose patients to the list rather than the net price of the drug. For example, patients who pay percentage-based coinsurance or who have a deductible that applies to pharmaceutical spending purchase drugs based on the list rather than the net price. As Exhibit 4 shows, the share of the population in such situations has grown markedly and now comprises approximately half the market.

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

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

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

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

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

Whether or not the PBM market is competitive is currently unclear. On the one hand, there are reasons why we might be concerned about competition in this market. As shown in Exhibit 5, 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 2012.²³ 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

²³ 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.

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% (i.e., the number that is reported in charts such the one shown in Exhibit 6). However, the PBM is only required by its contract to transfer 50% of rebates to the payer, meaning it keeps \$7.50 of the rebate and the payer gets \$7.50. Therefore, the payer spends \$12.50 more, with \$5 going to the manufacturer and \$7.50 for the PBM.

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

Strong competition is even less likely to emerge if payers are unaware of the full scope of surplus created by their prescriptions. Many large firms hire sophisticated benefit consultants and increasingly demand fully transparent contracts that provide them full information on all “rebate” dollars. In theory, this provides information about the surplus created by their prescriptions. That said, there are reasons to be concerned that despite these efforts payers may still be unaware of all of the funds flowing between the PBM and the manufacturer. In addition to rebates, PBMs also receive various administrative fees and other payments from manufacturers. Ultimately, the PBM determines which of these payments are rebates (and therefore covered by the price transparency and rebate sharing requirements), and what is instead a fee (that does not need to be disclosed or shared).²⁴ These fees are not trivial – for some contracts they can account for 25-30% of the money moving between the manufacturer and the PBM.²⁵ If we consider the simple example above, the situation for the payer could be even worse if, instead of offering a rebate of \$15, the manufacturer offers an administrative fee to the PBM. In that case, the payer would bear the full cost (i.e., \$20) of the list price increase, and the PBM and manufacturer would split the surplus. Ultimately, manufacturers are agnostic between describing payments to the PBM as “fees” or “rebates” – they simply care about the total amount of money they collect and distribute as a result of these negotiations.

²⁴ Eickelberg, Henry C. 2015. “The Prescription Drug Supply Chain ‘Black Box’: How it Works and Why You Should Care.” American Health Policy Institute. December.

²⁵ Dross, David. 2017. “Will Point-of-Sale Rebates Disrupt the PBM Business?” Mercer. July 31.

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.²⁶ 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.²⁷ 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.

The current proposal from the Department of Health and Human Services to address this problem is to eliminate the safe harbor for rebates in the Medicare program. The goal of this policy is to end 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.²⁸ 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.²⁹ PBMs and payers would be free to negotiate any split of the rebates, fees, and other funds that are paid by the manufacturer – but such a negotiation would now occur between two parties with equal information about the amount of money at stake. There are variety of ways to implement the move to such a system. One 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.

²⁶ Weinberg, Neil, and Robert Langreth. 2017. "Inside the 'Scorpion Room' Where Drug Price Secrets Are Guarded." Bloomberg. May 4.

²⁷ Advisory Council on Employee Welfare and Pension Benefit Plans. 2014. "PBM Compensation and Fee Disclosure." Report to the United States Secretary of Labor.

²⁸ U.S. Department of Health and Human Services. 2019. "Trump Administration Proposes to Lower Drug Costs by Targeting Backdoor Rebates and Encouraging Direct Discounts to Patients." January 31.

²⁹ Garthwaite, Craig, and Fiona Scott Morton. 2017. "Perverse Market Incentives Encourage High Prescription Drug Prices." ProMarket Blog. November 1.

II.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 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."³⁰ Exhibit 7 contains the number of excluded products by two large PBMs over time. Since 2012, there has been marked growth in the use of these lists. Likely related to this fact, since 2012 there has also been a large increase in the amount of rebates in the system (as shown in Exhibit 8).

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

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

³⁰ Wehrwein, Peter. 2015. "A Conversation with Steve Miller, MD: Come in and Talk With Us, Pharma." *Managed Care*. April 5.

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.^{31,32} 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.^{33,34}

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.

III. Increasing Incentives for Price Negotiation under Medicare Part D

While many policymakers often claim that Medicare does not negotiate for the prices paid for prescription drugs,³⁵ they are not correct. Under the structure of Medicare Part D, private firms undertake vigorous negotiations on behalf of the government. Given that 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 9 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 75% of spending. If individuals spend through the initial

³¹ Liu, Yanchun. 2018. "FDA chief says pharmas use rebates to block biosimilar competition." MarketWatch. July 19.

³² Narasimhan, Vas. 2018. "Novartis CEO: How To Create Cheaper Alternatives To The Most Expensive Drugs." Forbes. April 12.

³³ 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>.

³⁴ 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>.

³⁵ Office of United States Congressman Peter Welch. 2019. "Welch, Rooney Introduce Bill Requiring HHS Secretary to Negotiate Medicare Prescription Drug Prices." January 8.

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, firms 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 – effectively 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. Exhibit 10 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 expensive specialty drugs – which are 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 not clear 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 95% of the cost of these expensive products) or 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 15%. 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. 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.

IV. 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 those that 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. Higher prices will, by definition, decrease the firm’s total profits because the increased margin will not make up for the lost quantity 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 so suffer declining profits from 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. The effects of these incentives increase with Medicare's market share in each drug – a larger Medicare market share means the potentially higher reimbursement from the public pay 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 11 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 be careful not to create incentives for physicians to inappropriately prescribe lower-cost drugs. 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.

Concerned about the high prices for products covered under the Part B program (and, in particular, the high levels compared to similar products in foreign markets), the Department of Health and Human Services has proposed an International Pricing Index (IPI) model for these types of products.³⁶ Most of the attention for this regulation has focused on the introduction of a reference price for Part B drugs that is based on an average of prices paid in a number of comparable developed countries.

For a variety of reasons, the IPI policy is inadvisable. First, the policy as proposed is quite unclear about what happens if pharmaceutical firms are unwilling to provide the product for the reference price. Given that all drugs must be covered under Part B, it is unclear what providers would do in this case. Second, as discussed above, reducing the prices paid for products of this nature to the levels in other developed countries that use monopsony power to artificially decrease prices would likely have a large impact on innovation. Finally, and perhaps most importantly, the proposal is simply an abrogation of responsibility by our nation's elected officials. If we hope to exploit the market power of Medicare to gain lower drug prices, this will result in decreased investments into new products. The specific nature of that tradeoff is something that we should

³⁶ Centers for Medicare & Medicaid Services. 2018. 83 FR 54546. October 30.

internally debate and decide upon. It is not a decision we should farm out to policymakers in other developed countries who are making decisions intended to maximize the welfare of their citizens and not ours.

While the reference-pricing component of the proposed regulation is inadvisable, the policy also proposes 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, but this portion of the IPI proposal has a number of attractive features. I would 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.

V. Conclusion

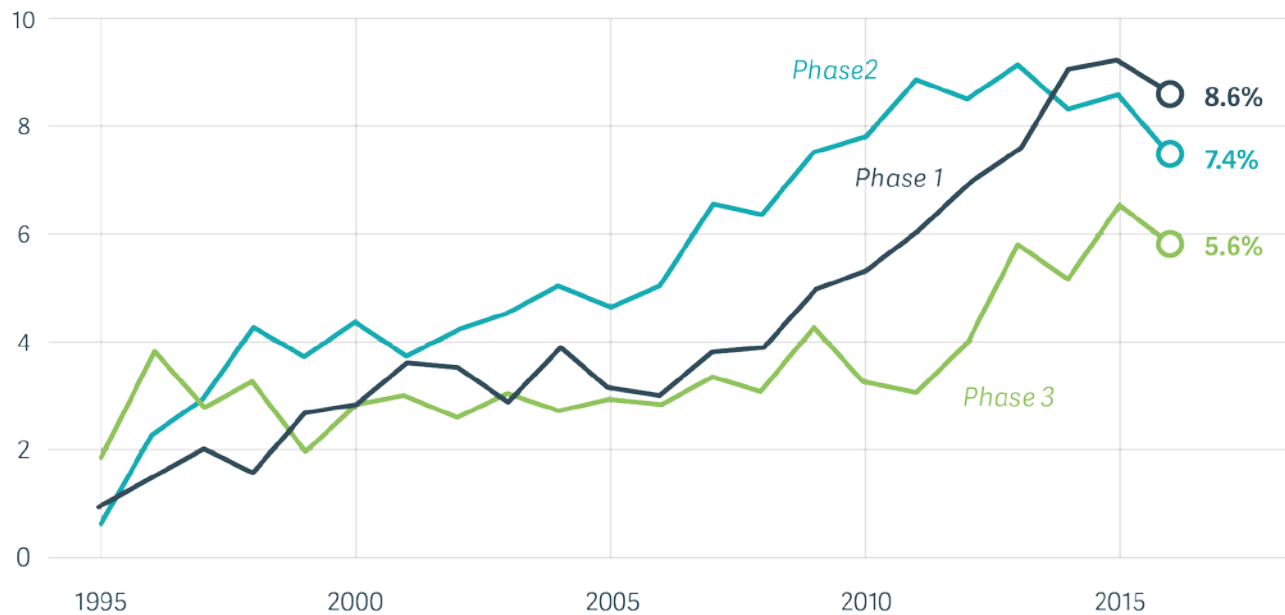
The ability of the market to provide an efficient outcome is a function of the degree of competition between market participants. Sustaining competition in healthcare markets requires both addressing features of the market that lead to failure and avoiding the creation of government policies that diminish 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.

EXHIBIT 1

Precision Medicine Development Trials, 1995-2016

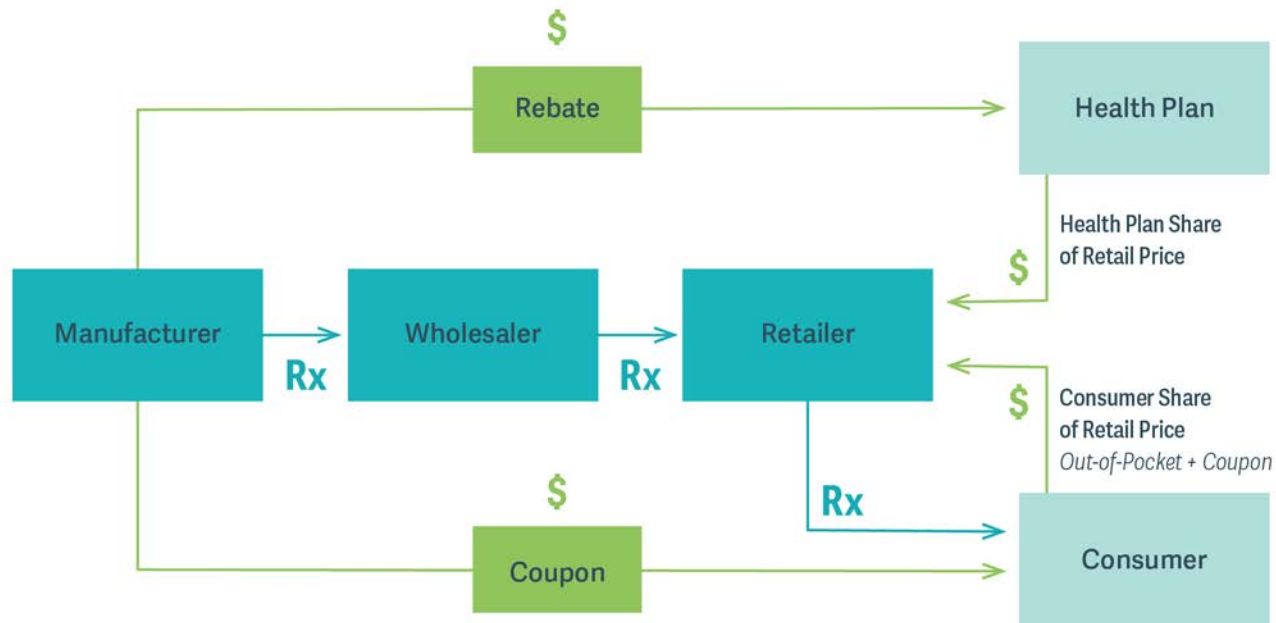
Pharmaceutical development trials using precision biomarkers (%)



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

EXHIBIT 2

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



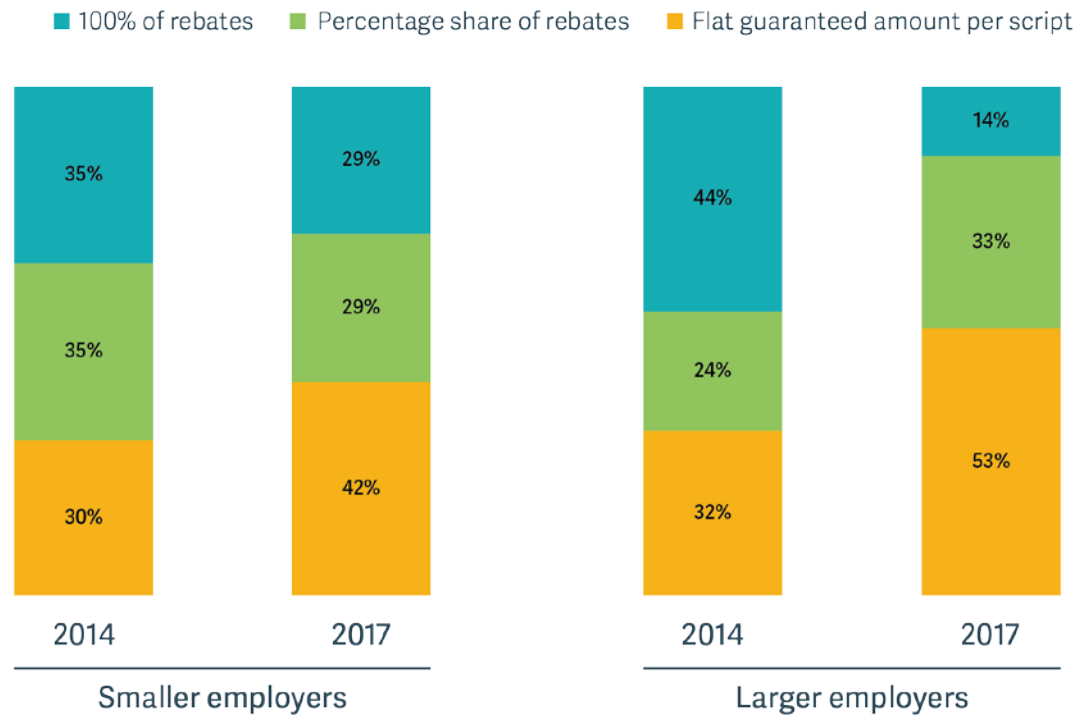
Impact of prescription drug rebates on health plans and consumers
April 2018

Page 3

Source: https://altarum.org/sites/default/files/Altarum-Prescription-Drug-Rebate-Report_April-2018.pdf

EXHIBIT 3

PBM Rebate Arrangements for Traditional Medications in Employer-Sponsored Plans, by Employer Size, 2014 v. 2017

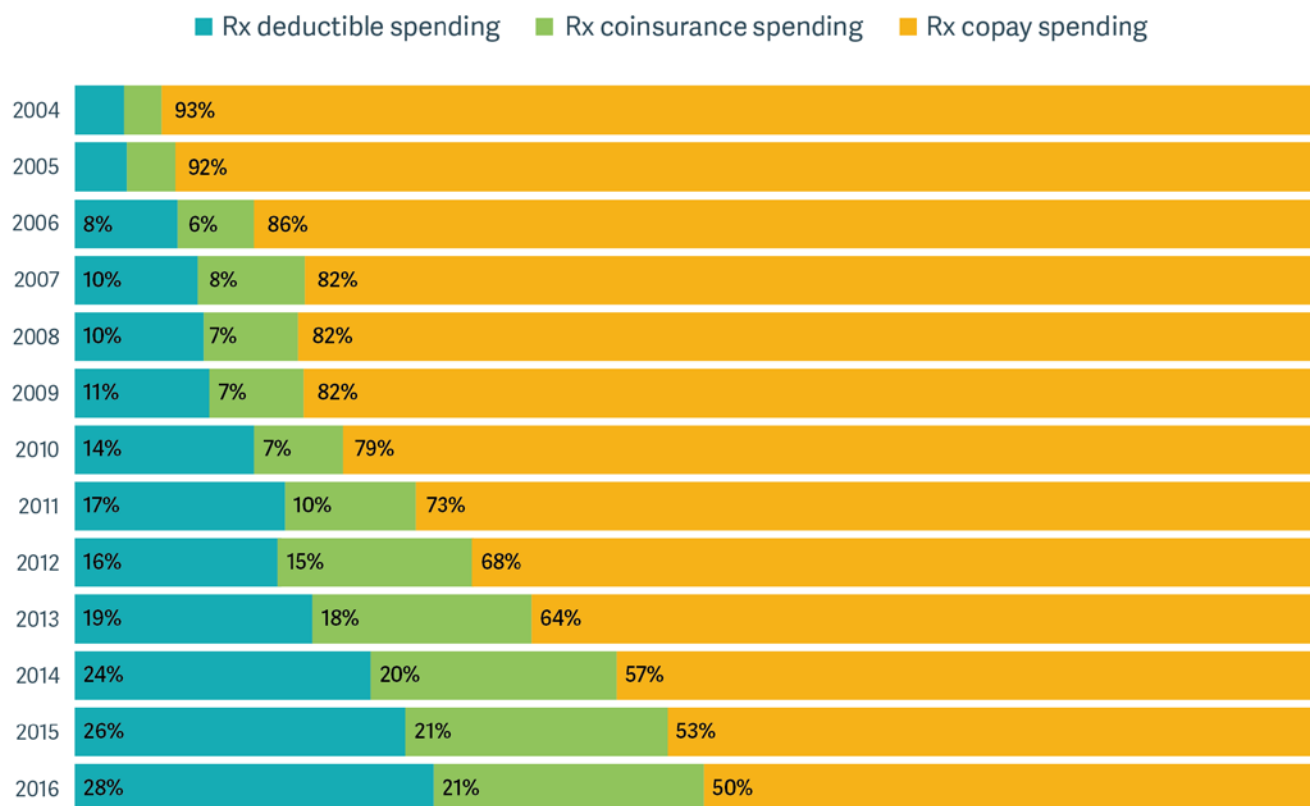


Smaller employers = 5,000 or fewer covered lives; Larger employers = more than 5,000 covered lives. Number of covered lives includes employees and dependents. Source: Drug Channels Institute analysis of *Trends in Drug Benefit Design*, PBMI, various years. Data include only responding firms that receive rebates. 2014 figures recomputed to exclude those who were not sure about their company's rebate arrangements.

Published on Drug Channels (www.DrugChannels.net) on January 17, 2018.

EXHIBIT 4

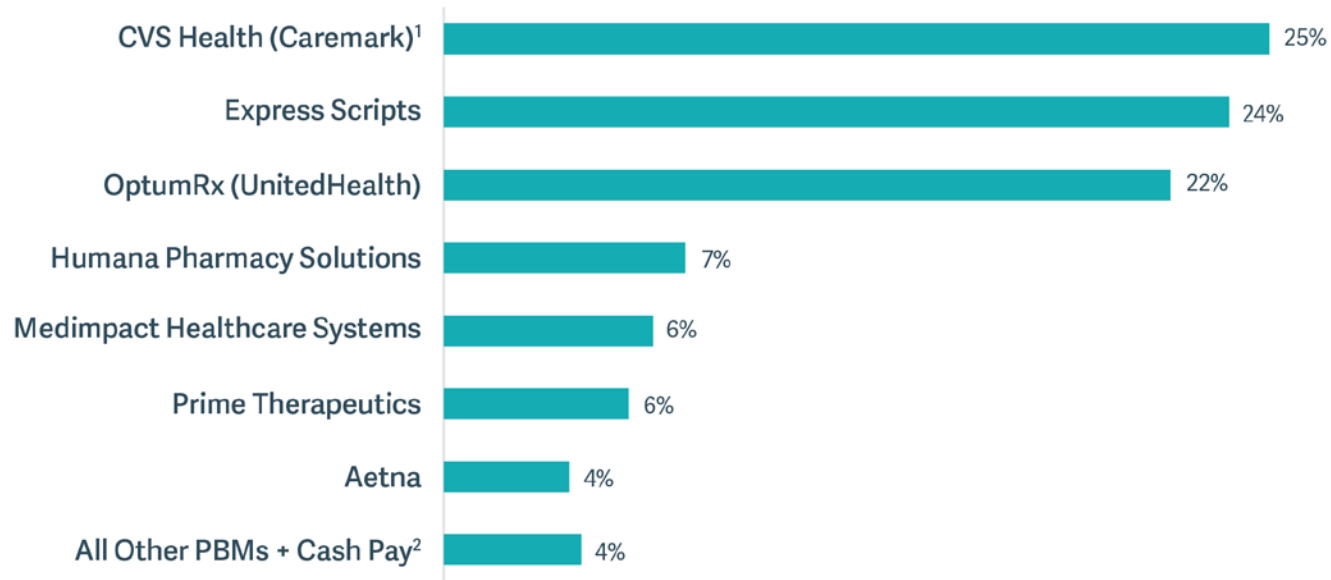
Distribution of Cost-Sharing Payments for Retail Prescription Drugs in Large Employer Plans, by Type of Payment, 2004-2016



Source: Kaiser Family Foundation analysis of Truven Health Analytics MarketScan Commercial Claims and Encounters Database, 2004-2016 - [Get the data - PNG](#)

Peterson-Kaiser
Health System Tracker

EXHIBIT 5
PBM Market Share, by Total Equivalent Prescription Claims Managed, 2017



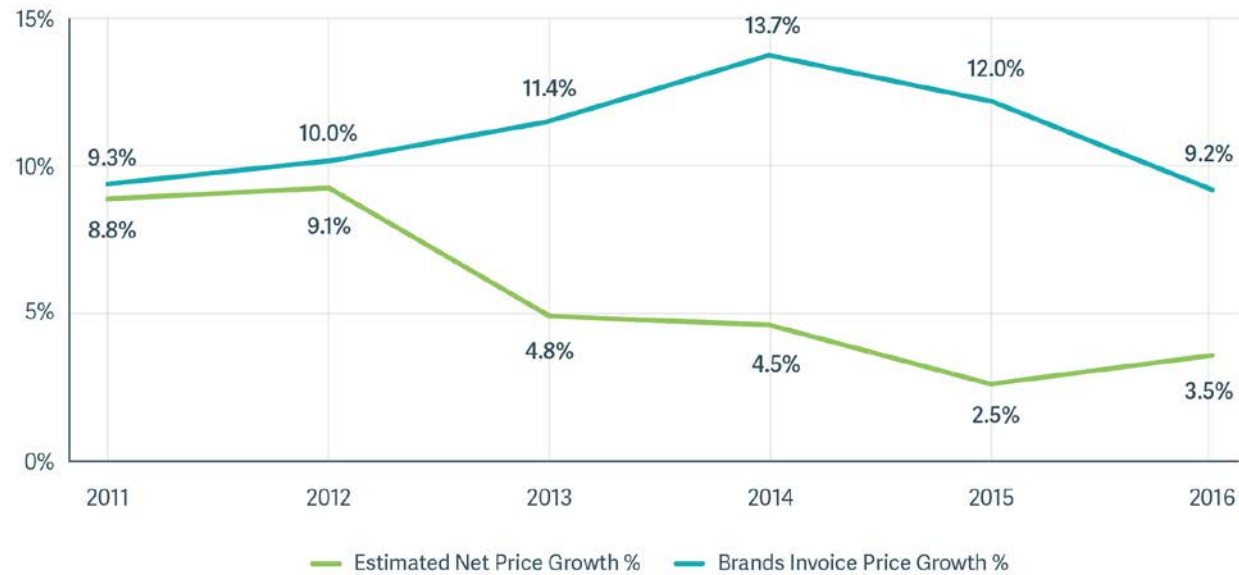
1. Excludes claims processed by Aetna. For 2017, CVS Health changed its publicly reported computation of equivalent prescription claims filled in network pharmacies.

2. Figure excludes cash pay prescriptions that use a discount card processed by one of the 7 PBMs shown on the chart.

Source: Drug Channels Institute research and estimates. Total equivalent prescription claims includes claims at a PBM's network pharmacies plus prescriptions filled by a PBM's mail and specialty pharmacies. Includes discount card claims. Note that figures may not be comparable with those of previous reports due to changes in publicly reported figures of equivalent prescription claims. Total may not sum due to rounding.

This table appears as Exhibit 75 in *The 2018 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers*, Drug Channels Institute. Available at <http://drugch.nl/pharmacy>

EXHIBIT 6 Protected Brand Invoice and Net Price Growth

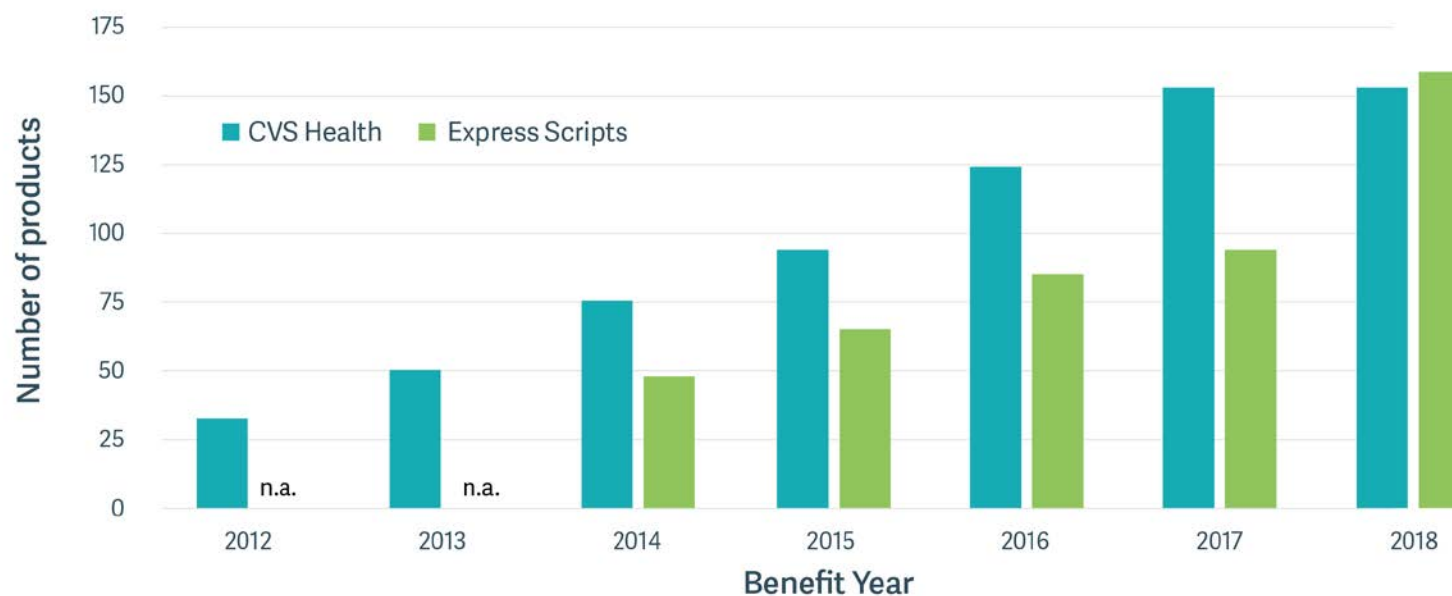


Source: IQVIA, National Sales Perspectives, Dec 2016; IQVIA Institute of Human Data Science

Chart notes:

"Invoice" values are IQVIA Health reported values from wholesaler transactions measured at trade/invoice prices and exclude off-invoice discounts and rebates that reduce net revenue by manufacturers. "Net" value denote company recognized revenue after discounts, rebates and other price concessions. Results are based on a comparative analysis of company reported net sales and IQVIA reported sales and prices at product level for branded products representing 79.93% of brand spending in the period displayed. All growth numbers calculated over same cohort of products in the prior year. See Methodology section for more details.

EXHIBIT 7
Number of Products on PBM Formulary Exclusion Lists, 2012-2018

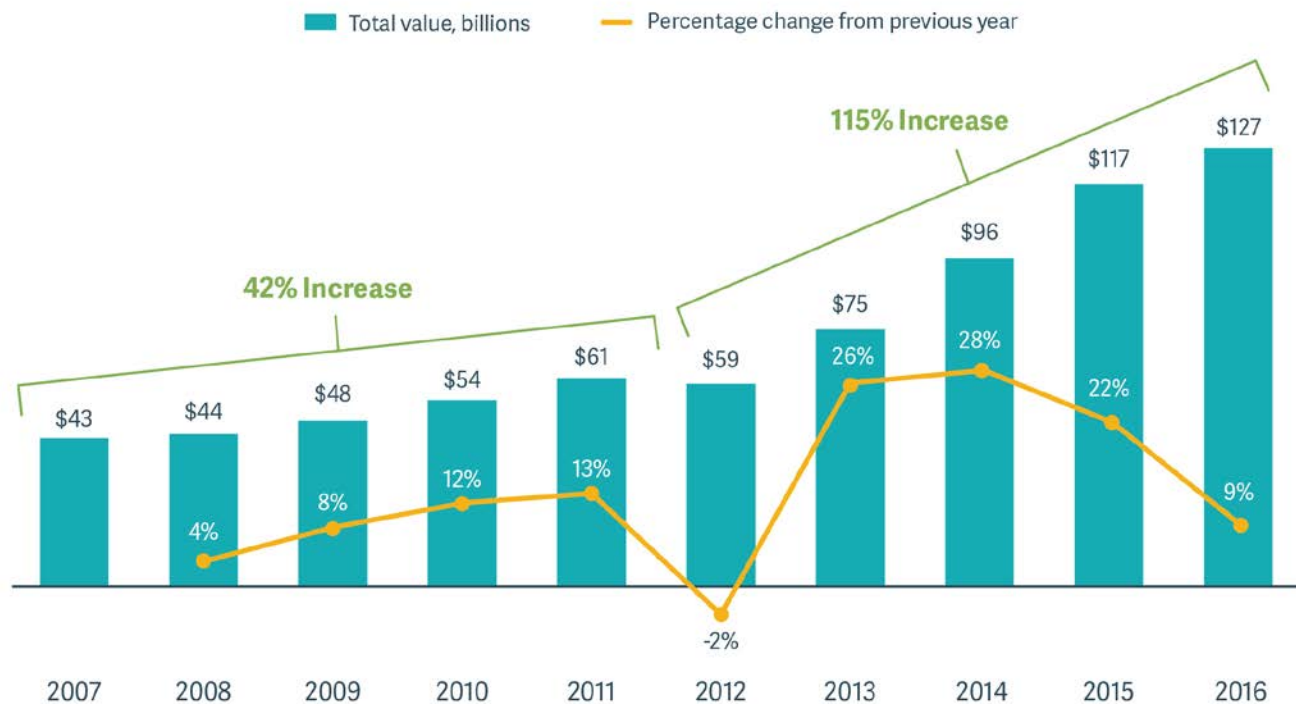


Note: Express Scripts did not publish exclusion lists for 2012 and 2013.

Source: Pembroke Consulting analysis of company reports

Published on Drug Channels (www.DrugChannels.net) on August 3, 2017.

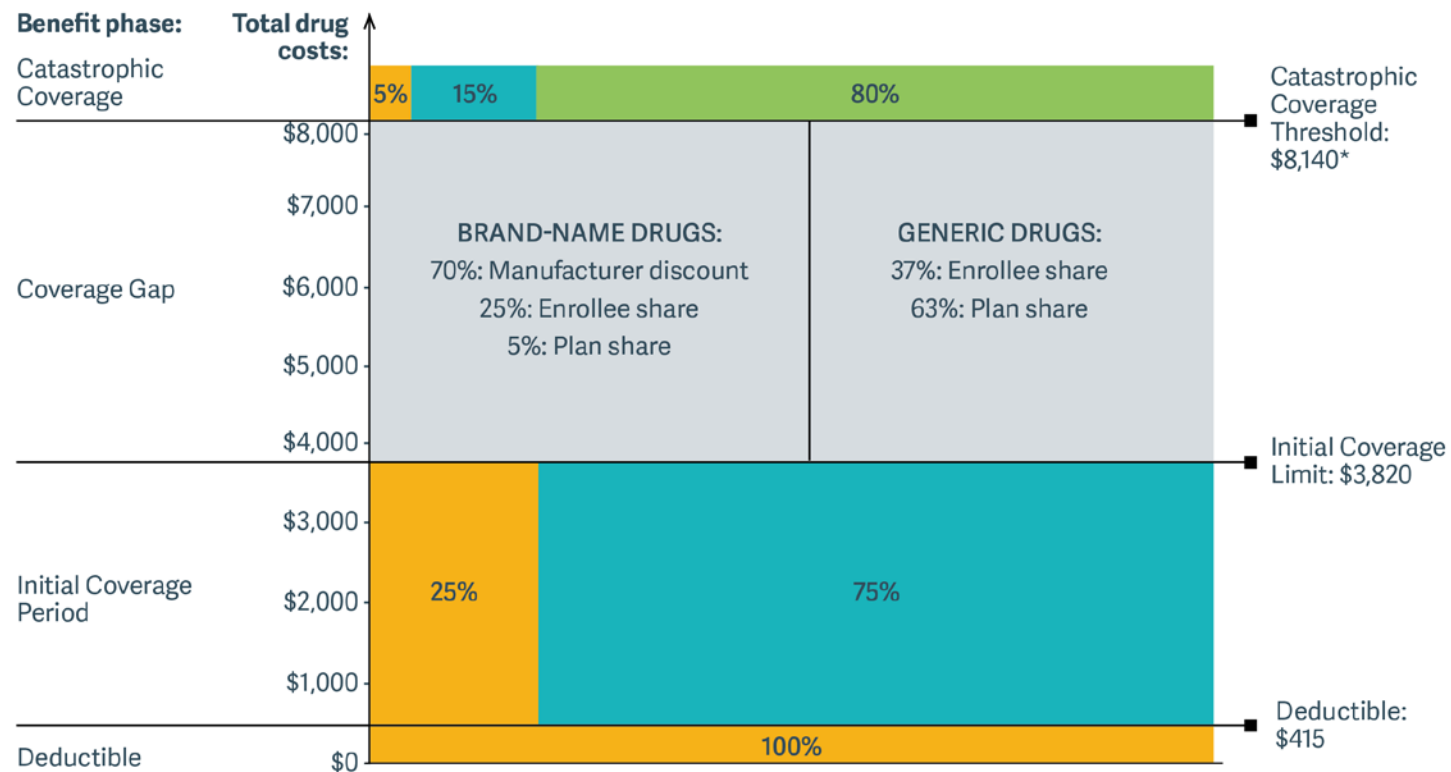
EXHIBIT 8
**Pharmaceutical Manufacturers' Off-Invoice Discounts,
 Rebates, and Price Concessions, 2007-2016**



Source: Pembroke Consulting analysis of *Medicines Use and Spending in the U.S.: A Review of 2016 and Outlook to 2021*, QuintilesIMS, May 2017.
 Published on Drug Channels (www.DrugChannels.net) on June 14, 2017.

EXHIBIT 9 Medicare Part D Standard Benefit Design in 2019

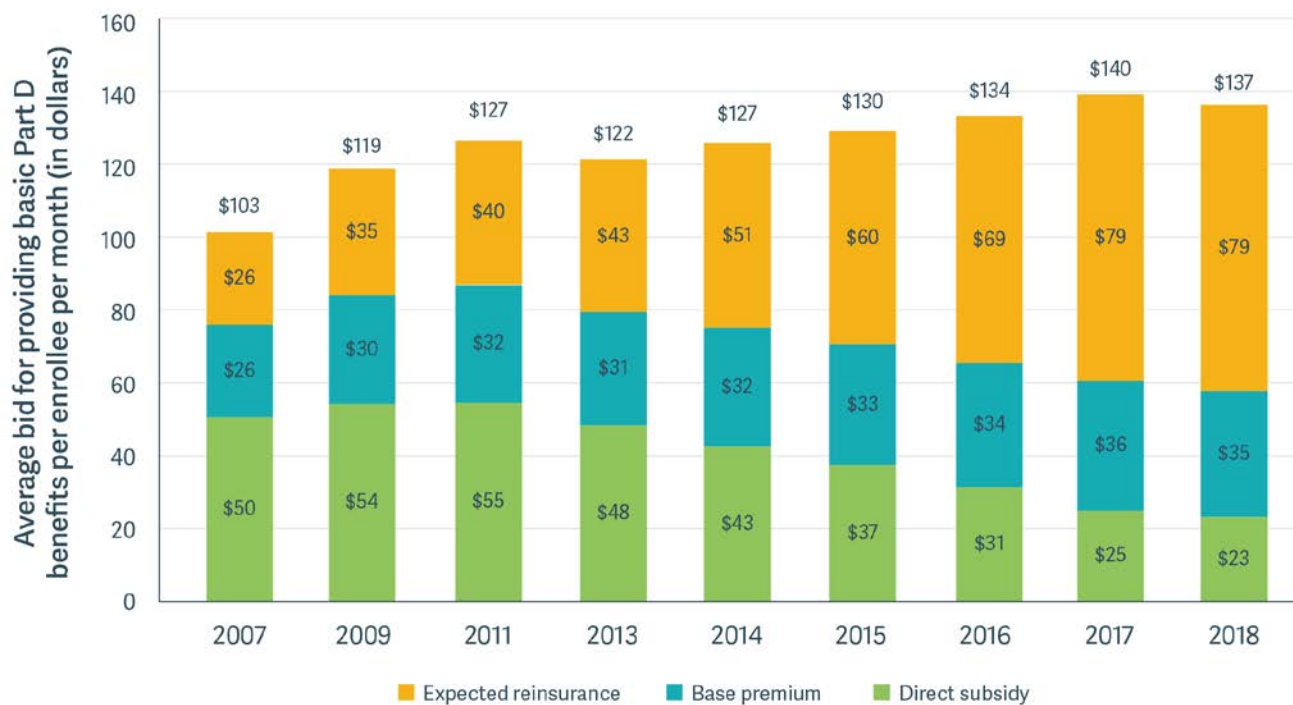
Share of costs paid by: ■ Enrollees ■ Plans ■ Medicare



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 10
National Average Plan Bid for Basic Part D Benefits

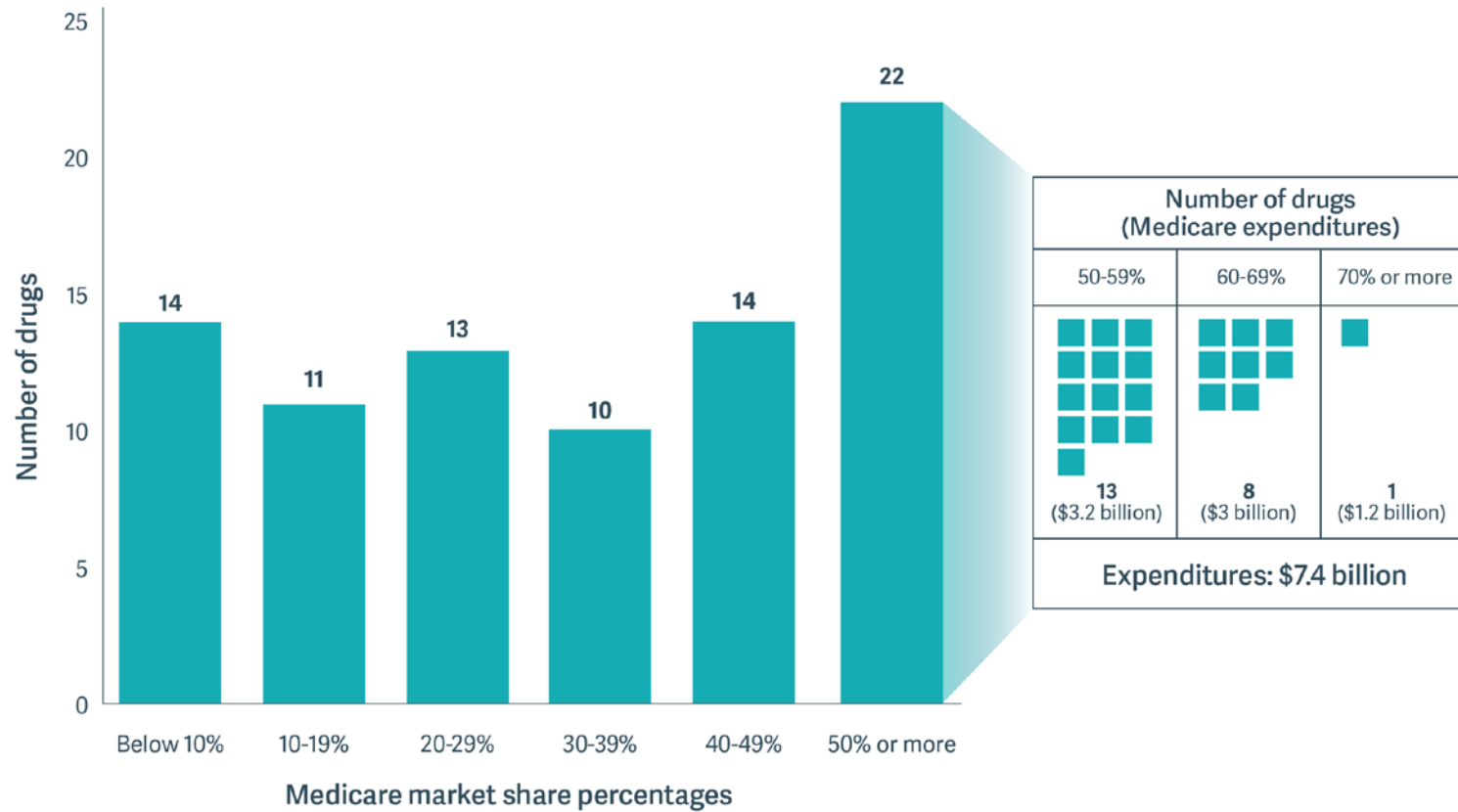


Note: The averages shown are weighted by the previous year's plan enrollment. Amounts do not net out subsequent reconciliation amounts with CMS. Components may not sum to stated totals due to rounding.

Source: MedPAC based on data from CMS.

Source: http://www.medpac.gov/docs/default-source/reports/mar18_medpac_ch14_sec.pdf

EXHIBIT 11
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

Source: <https://www.gao.gov/assets/690/689082.pdf>