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In contrast to other developed countries, the United States relies more heavily on private markets to finance and provide healthcare services. This use of economic markets is not a policy accident and instead reflects an intentional belief that market-based healthcare provides many advantages. 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 balance the forces necessary to promote value creating innovations more efficiently than the market.

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 in the U.S. healthcare market. 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.

Concerns about the appropriate role for markets in healthcare are perhaps most frequently discussed in the world of pharmaceuticals. These discussions are motivated by high and rising pharmaceutical prices. While many claim these high prices provide prima facie evidence of a market failure, in reality they are the result of the complex and delicate balancing of incentives that sits at the center of the U.S. healthcare market.

This delicate balance is necessary because market failures at the center of the innovative process for developing new drugs requires some degree of market intervention in the first place. This failure results from that fact that the scientific advancements generated by firms developing 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 a sufficient amount of the

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

value generated by the large, fixed, and sunk 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.

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 a larger portion of the value created by their innovative products. During this limited time period, higher prices than would otherwise exist curtail some access to valuable medicines. This reduced access is deliberately traded off for the development of new products in the future.² These new products, however, provide access to patients for whom there would otherwise be no available treatments.

In this way, 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. To the extent the value created by the new products exceeds the welfare losses resulting from the high prices (and decreased quantity), the granting of these periods of market exclusivity is welfare enhancing. This could be true even if the prices today are quite high.

This tradeoff is a source of much of the controversy surrounding prescription drug prices because it involves some number of readily identifiable individuals who are unable to access existing and potentially life-saving medications.³ Unsurprisingly, this particular form of a lack of access garners large amounts of press and political attention. However, it is critical to remember a perhaps far greater access problem for patients suffering from conditions for which no treatment options exist at all.⁴ For these individuals, there is no price at which they can purchase a treatment. These patients

production process and therefore copying the technology is easier than making the product *de novo* but harder than for a small molecule product.

² In considering this tradeoff it is important to consider the role of health insurance in mitigating decreased quantity resulting from high prices. To the extent that insurance mitigates some of this quantity decline it is possible that the welfare loss are smaller than would be expected. See D. Lackdawalla and N. Sood, "Health Insurance as a Two-Part Pricing Contract," *Journal of Public* Economics, 2013, 102: 1-12.

³ Garthwaite, Craig, and Benedic Ippolito. 2019. "Drug pricing conversations must take the cost of innovation into consideration." STAT. January 11.

⁴ 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.

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.

A central parameter of this tradeoff of static and dynamic incentives is the relationship between the elevated prices paid for prescription drugs today and the incentives of innovative firms to develop new products in the future. Economic research has clearly documented a relationship between increased market size and investments in research and development.⁵ Therefore, to the extent high prices signal expected economic returns for the providers of the risk-based capital necessary for innovation then the prices could represent a welfare enhancing policy choice. However, if the revenue generated by high drug prices is instead captured by other parts of the value chain there are valid concerns that our current policies are not providing an optimal level of innovation to outweigh the welfare losses from the price related reduced access.

Determining the optimality of this tradeoff in today's market requires a more careful understanding of the pharmaceutical supply chain. In particular, it is important to understand how various firms capture a share of the value created by innovative pharmaceutical products. Figure 1 provides a broad overview of this supply chain and the flow of funds across firms at its various stages. Perhaps most important for today's hearing is the relationship between manufacturers, payers, and pharmacy benefit mangers (PBM), which is depicted in the figure's upper right corner.

While largely unknown to customers, PBMs are the private firms that effectively manage all aspects of insurance coverage for pharmaceuticals. Despite their relative lack of attention, these firms occupy a central role in nearly every facet of the pharmaceutical distribution and insurance market. At a high level, PBMs sign contracts with plan sponsors (e.g. risk bearing health insurers or

⁵ D. Acemoglu and J. Linn. 2004. "Market Size in Innovation: Theory and Evidence from the Pharmaceutical Industry," *The Quarterly Journal of Economics*, 119(3): 1049–1090; A. Finkelstein, "Static and Dynamic Effects of Health Policy: Evidence from the Vaccine Industry," *Quarterly Journal of Economics*, 119(2): 527-564; Dubois et al., 2015"Market size and pharmaceutical innovation," *RAND Journal of Economics*, 46(4): 844-871; and Dranove, Garthwaite and Hermosilla, 2020. "Pharmaceutical Profits and the Scientific Novelty of Innovation," *NBER Working Paper #27093*.

employers) to undertake activities such as negotiating drug prices, establishing pharmacy networks, processing pharmaceutical claims, and developing drug formularies.

In return for these activities, PBMs earn revenue through a variety of means. These include, but are not limited to, direct per member per month (PMPM) fees paid by plan sponsors, the ability to keep a negotiated share of the rebate (i.e. the discount from the manufacturer that the PBM is able to negotiate), spread pricing (i.e. the difference between what a PBM is paid by a plan sponsor for a drug and what they pay to the pharmacy to fill the prescription), and various administrative fees from manufacturers.

The primary role of PBMs is to help manage the static inefficiency resulting from high prices. Historically, these firms emerged to implement some degree of managed care and negotiation to the pharmaceutical benefit offered by plan sponsors. In particular, they allowed relatively small insurers to pool together and negotiate as a group against manufacturers.⁶ By constructing formularies, PBMs negotiate lower prices and can increase access to products and potentially to insurance overall. Of course, such activities limit revenues to pharmaceutical manufacturers and have been shown to blunt incentives to develop new products.⁷ This demonstrates the importance of the role of PBMs in the tradeoff central to drug development.

It is important to note that if the construction of formularies represents the preferences of consumers for access to new products, a reduction in innovative activity is not necessarily a problem. After all, our goal is to maximize welfare not innovation. However, if the reduction of revenues to manufacturers comes instead from PBMs capturing an inappropriately large fraction of spending as profits – there could be concerns about whether the pharmaceutical market is operating in a way that maximizes welfare. In particular, concerns about whether the welfare losses from the lack of access today are sufficiently offset by incentives to develop new products in the future. These concerns are central to today's hearing investigating the PBM market.

⁶ Z. Brot-Goldberg, C. Che, and B. Handel, "Pharmacy Benefit Managers and Vertical Relationships in Drug Supply: State of Current Research," *NBER Working Paper #29959*, April 2022.

⁷ L. Agha, S. Kim, and D. Li, "Insurance Design and Pharmaceutical Innovation," fortheoming American Economic Review: Insights.

Concerns about this possibility stem from features of the existing market. For example, the PBM market is dominated by three large firms – Caremark, Express Scripts and OptumRX. Figure 2 contains the market share of each of these firms in 2021 and shows that these firms comprise approximately 80 percent of all volume in this market. Beyond concentration, there have also been changes in the vertical structure of this industry over time as each of these PBMs is now part of a larger firm that also owns health insurers, specialty pharmacies, and medical providers. The degree of vertical integration can be seen in Figure 3.⁸ These concerns are magnified by the relative opacity of the process by which pharmaceutical prices are determined. While none of these market features (i.e. the high concentration, increased vertical integration, or opaque pricing) provide clear evidence of a potential problem they are areas that should be investigated. This is likely why this market has attracted the attention of a variety of regulators and policymakers.

Given these concerns, I will concentrate my testimony today on the relationships between plan sponsors (i.e. third party payers such as insurers and employers), PBMs, and manufacturers. In particular, I will focus on the degree to which features of these relationships may allow PBMs to capture more value than might be appropriate or whether negative features of the market instead reflect the actions and incentives of firms in other parts of the value chain.

A consistent point to consider throughout my testimony is that any analysis of this market is meaningfully hampered by a lack of information about numerous features of the contractual arrangements between the various types of firms. While it is easy to identify potential areas of concern, without more information about the nature of these arrangements it is difficult to truly understand the validity of such concerns. Therefore, Congressional action in this area should be initially focused on creating more insight for regulators into these areas. That said, I will also highlight several policy options that exist to more directly confront potentially undesirable features of the current pharmaceutical market without generating unintended consequences.

I. Pricing, Rebates, and Cost Sharing in the U.S. Pharmaceutical Market

In the U.S., there are many prices associated with pharmaceutical products. Of particular importance to today's hearing, pharmaceutical products have a publicly available list price that is set by the

⁸ In earlier testimony, I discussed the potential benefits and concerns of this vertical integration. This testimony is available at: https://www.judiciary.senate.gov/download/garthwaite-testimony.

manufacturer. Payers then employ PBMs to, among other things, negotiate rebates (i.e. discounts from list prices) on the pharmaceuticals purchased by their enrollees.

PBMs are able to secure the discounts based on their ability to shift customers across competing therapeutic substitutes. For example, if there are two brand-name statin medications that treat high cholesterol, the PBM can place the product from a manufacturer offering a lower net price on a more preferential tier of its formulary, thus lowering the out-of-pocket payments from an individual enrollee when they purchase the drug. This should result in this product selling higher quantity, albeit at a lower price. In extreme cases, a PBM could entirely exclude a product from its formulary if the manufacturer is unwilling to provide a sufficiently low net price (i.e., they are unwilling to pay the PBM a sufficiently large rebate). The use of exclusion lists has grown in recent years. Figure 4 shows the number of products that are excluded by the largest PBMs. It is this ability to credibly threaten to move volume across products that results in larger discounts from the list price.

The increased use of strict formularies and exclusion lists has contributed to a growing spread between the list and the net (i.e. post rebate) price. Figure 5 depicts these prices from 2014 - 2020 and documents a large spread between the publicly known and often discussed list prices and the actual prices received by manufacturers. This figure demonstrates that any discussion of list prices provides an, at best, incomplete picture of the returns to innovative manufacturers in this market.

The spread between list and net prices has resulted in a large amount of total rebates in the system. Figure 6 shows that in 2016, pharmaceutical manufacturers paid total rebates of approximately \$127 billion – an increase of 108 percent (\$66 billion) since 2011. The recent rise is larger in both absolute and relative terms than the history of this market. From 2007 to 2011, the total magnitude of these rebates increased only 42 percent, for a total increase of \$18 billion.

While the increasing magnitude of rebates in the system is often discussed in a negative light, it is not necessarily a problem. After all, higher rebates could simply reflect more sophisticated or effective bargaining by PBMs. The ultimate question is which parties in the supply chain capture the value of those rebates and what features of the market determines the ability of those firms to capture that amount of value. The split of the rebate between the PBM and the payer is dictated by a contract that is the result of a bilateral negotiation between those firms. The specifics of this contract depends on the relative bargaining power of the two parties. Figure 7 contains estimates of the existing contractual structure in the commercial market with respect to rebates over time based on whether plan sponsors are large or small employers. From 2014-2018, there has been a marked increase in employers with PBM contracts that entitle them to receive 100 percent of the rebates. By that year a majority of both types of employers were using such contracts.

Unsurprisingly, PBMs often point to increasing rebates as evidence of their effectiveness. It is not clear this is accurate. After all, a large rebate can come from a higher list price, a lower net price, or a combination of both. If rebates are only the result of higher list prices then the actual price paid in the market (and the return to manufacturers) has not necessarily changed. It is tempting to think that in that situation the high list prices have little economic effect. However, even in contracts where 100 percent of the rebate flows to the plan sponsor, higher list prices can negatively impact other market participants.

In particular, high list prices can have direct and economically meaningful impacts on consumer outof-pocket payments. This relationship between cost sharing and list prices results from the desire to maintain the confidentiality of negotiated prices. Such confidentiality provides stronger incentives for larger discounts. For this reason, the size of rebates paid to each PBM is kept strictly confidential, up to and including onerous audit restrictions in the contracts that limit the ability of the payer to monitor the financial activities of the PBM.⁹

To maintain this confidentiality, consumers whose cost sharing for pharmaceutical products is tied to prices (either because of a deductible or percentage based coinsurance) make these cost sharing payments as a function of the list rather than the net price.¹⁰ Thus, any inefficiencies that create incentives for higher list prices (even if those are entirely offset by rebates) affect consumer out of pocket spending.¹¹ In the presence of liquidity constraints, this cost sharing could meaningfully reduce access to drugs in ways that magnify the static inefficiency of high drug prices. For this reason, high cost-sharing is not simply a financial inconvenience for consumers. Recent evidence has

⁹ Weinberg, Neil, and Robert Langreth. 2017. "Inside the 'Scorpion Room' Where Drug Price Secrets Are Guarded." Bloomberg. May 4.

¹⁰ This is mainly an issue for consumers enrolled in certain high-deductible health plans, as well as Medicare beneficiaries.

¹¹ While the number of consumers with this type of cost-sharing has grown, it should be noted that customers in the pharmaceutical market are largely shielded from list prices.

shown that increased cost sharing for consumers results in the decreased use of prescription drugs and increased mortality.¹²

The importance of cost sharing for prescription drugs has grown over time. Consider the evidence in Figure 8, which contains the average annual out of pocket payment for Medicare patients purchasing insulin. According to these data, in 2018 nearly 30 percent of Medicare patients purchasing insulin were paying more than \$5,000 per year out of pocket. This is a marked increase from 2010 where less than 5 percent of those customers had that level of cost sharing.

Insulin is not the only place where we see high cost-sharing. Overall, prescription drugs enjoy far less insurance coverage than other parts of healthcare. Figure 9 shows that insured patients are exposed to only 3 percent of their hospital spending. In contrast, patients directly pay 15 percent of their prescription drug spending out of pocket.

Given the negative health and financial effects of high cost-sharing, it is at first puzzling why such high cost-sharing persists in the market. Cost sharing is intended to be a form of utilization management that attempts to overcome the potential moral hazard arising from patients that are fully insured for their pharmaceutical purchases. This moral hazard could occur both through the overconsumption of products where the price exceeds value or more often from purchasing products that have less expensive therapeutic substitutes. Both of these would be negative features of an insurance product that cost sharing was intended to mitigate.

The ability to use cost-sharing to move patients across products is a key tool that PBMs use to negotiate lower net prices from manufacturers. However, we increasingly see high cost-sharing on products that are unlikely to be overconsumed (e.g. insulin and oral oncology products) or in areas where there are no therapeutic substitutes. This suggests this high cost-sharing serves goals other than simply utilization management.

It is not obvious that cost-sharing at the levels we observe is an independent strategic choice PBMs undertake to maximize their profits. After all, if plan sponsors desired less onerous cost-sharing they

¹² A. Chandra, E. Flack, and Z. Obermeyer, "The Health Costs of Cost-Sharing," NBER Working Paper #28439, February 2021.

certainly could instruct their PBMs to construct such a formulary. In fact, in recent testimony before Senate Finance Committee, Cigna's Chief Clinical Officer noted that formularies which pass rebates along to customers at the point of sale have existed for many years but have failed to gain traction with plan sponsors.¹³

Instead of signing contracts that pass rebates to customers, plan sponsors increasingly demand higher rebates from PBMs – even when those rebates are not associated with lower prices.¹⁴ Such rebates come from surging list prices and contribute to higher cost sharing payments by patients. It appears that this is because the combination of large rebate payments and high cost-sharing for expensive products provides a mechanism for plan sponsors to offer lower premiums to healthy patients and higher expected costs to sick patients requiring expensive medications.

Consider the stylized example in Figure 10 where a consumer in the deductible period pays the full list price of the drug. This customer does not benefit from any of the negotiation efforts of the PBM. Both the PBM and plan sponsor, however, can profit from the consumer's purchase of a prescription drug because these firms still collect a rebate when one of their patients buys a pharmaceutical product. This is true even when the product is entirely paid for by the patient. A similar logic exists when a patient makes a very large cost sharing payment because of coinsurance. Sponsors are then able to use those extra rebate dollars to lower premiums or decrease the cost of employer provided healthcare. In this way, high cost sharing combined with large rebates reintroduces medical underwriting and unwinds the community rating of health insurance premiums.

This stylized example is not simply an academic exercise. In a recent Senate Finance Committee report on insulin pricing, the Eli Lilly CFO for Diabetes noted that PBMs reacted negatively to a potential lower list price product because their customers (i.e. plan sponsors) reported that "such adjustment may impair market competitiveness (i.e. rebate levels on lower gross price levels translating to higher plan premiums."¹⁵

¹³https://www.finance.senate.gov/imo/media/doc/Cigna%20ExpressScripts%20Testimony%20of%20Steven%20Miller%20MD.pdf ¹⁴ https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf

¹⁵ https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf

Understanding these dynamics is important in considering the causal role of PBMs with respect to increasing list prices and rebates. It suggests that much of the furor at PBMs over increasing list prices, rebates, and cost sharing may be aimed at the wrong target. If such contractual features are being dictated by PBM clients (i.e. plan sponsors) than regulators should more carefully consider the incentives of those plan sponsors when constructing policy in this area. Furthermore, as I discuss below, if the concern about high list prices is primarily motivated by the effect on cost sharing there are policies that can be considered which more directly address this cost sharing.

II. Lack of Transparency in Financial Relationships in the Value Chain

While a large portion of plan sponsors have signed contracts that allow them to collect all of the rebates associated with prescription drug purchases by their customers, there are still many contracts where the PBM receives a percentage of the rebate as compensation. In addition, PBMs collect other fees that I discuss below which are also a function of the list price. Some have proposed that this provides a perverse incentive for the PBM to prefer higher list priced products where there is a large rebate compared to even lower prices products with a smaller rebate.

The concern about PBMs being attracted to higher-priced 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% (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 in this example 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 concentrated PBM market. Price competition between PBMs also may not emerge if the existing firms realize there are large barriers to entry and that 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. As discussed above, many large firms hire sophisticated benefit consultants and increasingly demand fully transparent contracts that provide them a complete picture of 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 at disclosure, payers remain unaware of all of the funds (particularly those not labeled as rebates) flowing between the PBM and the manufacturer. For example, in addition to rebates, PBMs also receive various administrative fees and other payments from manufacturers – fees that are often a function of the list price of a drug.

The PBM and the manufacturer determine which of these payments are classified as "rebates" (and therefore covered by the price transparency and rebate sharing requirements), and what is instead an "administrative fee" (that does not need to be disclosed or shared).¹⁶ These fees are not trivial – for some contracts they can account for 25-30% of the money moving between the manufacturer and the PBM.¹⁷ Furthermore, since these fees are often structured as a function of the list price there is little economic distinction between an "administrative fee" and a "rebate." Describing this system, the Senate Finance Committee report on 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."¹⁸ Figure 11 documents the increase in such fees over time in this market.

¹⁶ Eickelberg, Henry C. 2015. "The Prescription Drug Supply Chain 'Black Box': How it Works and Why You Should Care." American Health Policy Institute. December.

¹⁷ Dross, David. 2017. "Will Point-of-Sale Rebates Disrupt the PBM Business?" Mercer. July 31.

¹⁸ https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf, page 81.

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 negotiations.¹⁹ 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.²⁰ 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.²¹ 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. Such information asymmetries can affect the efficiency of bargaining between these two groups.

As a result of these concerns, some have proposed policies where PBMs are not allowed to have contracts in which they are compensated based on the size of the rebate or the list price of a product. While this would certainly eliminate any perverse incentives for large rebates, it would also diminish the incentives for PBMs to push for large discounts. If the primary motivation for such policies is an underlying concern about the competitiveness of the PBM market, eliminating the ability for firms to sign incentive compatible contracts could have meaningful unintended consequences

¹⁹ 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.
²⁰ Weinberg, Neil, and Robert Langreth. 2017. "Inside the 'Scorpion Room' Where Drug Price Secrets Are Guarded." Bloomberg. May 4.

²¹ Advisory Council on Employee Welfare and Pension Benefit Plans. 2014. "PBM Compensation and Fee Disclosure." Report to the United States Secretary of Labor.

In a similar vein, the Department of Health and Human Services previously proposed to instead 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.²² 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.²³ PBMs and payers would be free to negotiate any split of the rebates, fees, and other funds that are paid by the manufacturer – including contracts that compensate a PBM as a percentage of the savings that they generate. Importantly, under this policy these contracts would emerge from a negotiation 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 truly competitive, this proposed policy solution should have little effect on the distribution of surplus.

III. Congress Should Address Cost Sharing and Price Negotiations More Directly

While the optimality of the existing PBM market remains unclear, it is becoming apparent that Congress should enact some meaningful reforms in this area. I offer some suggestions for such policies below.

²² 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.

²³ Garthwaite, Craig, and Fiona Scott Morton. 2017. "Perverse Market Incentives Encourage High Prescription Drug Prices." ProMarket Blog. November 1.

As a starting point, there is a clear case for a reform to Medicare Part D's reinsurance program. Currently, this program blunts the incentives of firms to negotiate price discounts for the most expensive drugs and increases consumer cost sharing. Figure 12 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 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%. Given the lack of a lifetime limit on out-of-pocket spending by enrollees, this benefit structure is part of the reason why beneficiaries find themselves on the hook for exceptionally high cost-sharing for prescription drugs.

Furthermore, for high priced products the private firms empowered to negotiate on behalf of Medicare are largely shielded by reinsurance 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. Figure 13 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 overall prescription drug spending. 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%.²⁴ This would provide the appropriate incentives for firms to strongly negotiate for larger rebates and lower prices within Part D.

Beyond changing the incentives to negotiate prices, 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 even if it is not the exact net price associated with that purchase. For example, 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 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.

Some have complained that policies that pass along rebates to consumers at the point of sale would lead to higher premiums. This fact is almost certainly true. However, this is not necessarily a problem. Our current system of using cost sharing by patients requiring expensive products to lower the premiums paid by healthier patients subverts many popular policy goals regarding the treatment of pre-existing conditions in the health insurance market. In addition, 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.

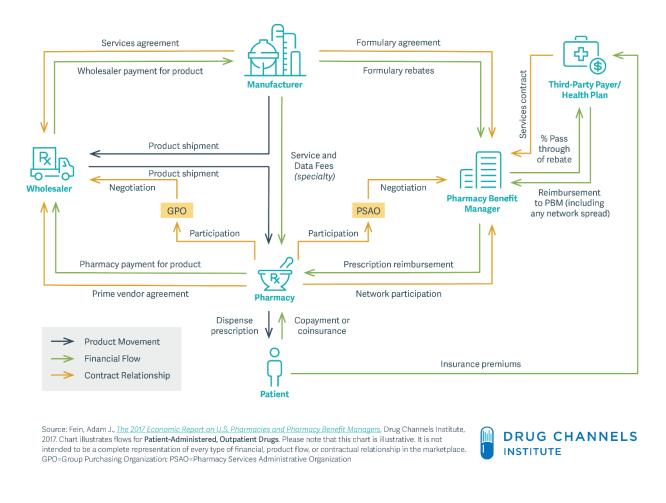
²⁴ As I discuss below, very large consumer cost sharing (such as the 5 percent of spending that patients must pay under Part D) can decrease the efficiency of insurance.

IV. More Information is Needed Before Implementing New Policies Aimed at PBMs

The role of various entities in the supply chain is clearly complicated. Pharmaceuticals move through a relatively lengthy supply chain inhabited by private firms with differing incentives, information, and market power. Given their central role in both negotiating prices and establishing formularies, it is tempting to blame PBMs for every negative feature of the system we observe. And it is possible that such blame may ultimately be valid. However, it is also apparent that we simply lack the information necessary to determine the degree to which these aspects of the market are actually caused by the independent motivations of PBMs to maximize profits versus how much they reflect the incentives of other firms in the value chain. For example, as mentioned above PBMs have offered contracts where rebates are passed along to customers at the point of sale and plans sponsors have largely avoided those plans. This suggests a more complicated story is necessary to explain the current market dynamics.

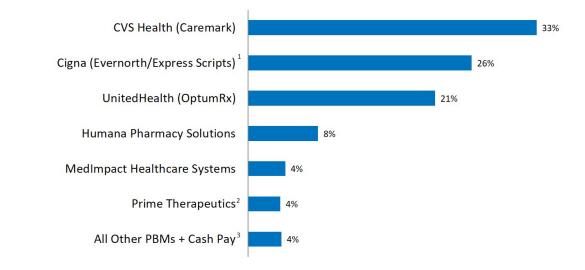
Given the uncertainty in this area, it is incumbent on policymakers and regulators to gather more information before attempting to develop and implement solutions. Certainly, the recent Senate Finance Committee investigation into insulin pricing shed some important light on the relationships between PBMs and manufacturers. In that document we learned more about the role of administrative fees and the views of PBMs about the motivations of their customers, i.e. the plan sponsors. However, that report fell short on investigating the relationship between PBMs and plan sponsors. More information about those contracts and whether the actions of PBMs vary based on the contractual relationship with the plan sponsor would be useful for understanding the degree to which potentially undesirable features of the market are the result of the structure of the PBM market or other features of the supply chain.

Flow of Payments and Contractual Relationships for U.S. Retail Outpatient Drugs



Source: Drugchannels.net, available at: http://www.drugchannels.net/p/about-blog.html

PBM Market Share, By Total Equivalent Prescription Claims Managed, 2021



1. Includes a full year of Cigna claims, which fully transitioned to Express Scripts by the end of 2020, and the portion of Prime Therapeutics network claims volume for which Express Scripts handles pharmacy network contracting.

2. Excludes Drug Channels Institute estimates of 2021 claims for which Express Scripts handles pharmacy network contracting.

3. Figure includes some patient-paid prescriptions that use a discount card processed by one of the 6 PBMs shown on the chart. Source: The 2022 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers, Drug Channels Institute, 2022, Exhibit 87. Total equivalent prescription claims

include claims at a PBM's network pharmacies plus prescriptions filled by a PBM's mail and specialty pharmacies. Includes discount card claims. Includes claims for COVID-19 vaccines administered by retail pharmacies. 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.

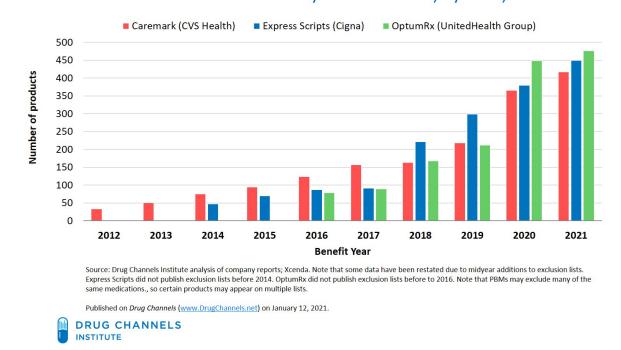
Published on Drug Channels (<u>www.DrugChannels.net</u>) on April 5, 2022.

DRUG CHANNELS

Source: https://www.drugchannels.net/2022/04/the-top-pharmacy-benefit-managers-of.html

Examples of Integrated Healthcare Firms

Insurer	United Healthcare	♥aetna	Humana.	n Cigna.	Anthem. 🚳 🕅	BlueCross BlueShield
PBM		CVS CAREMARK	Humana Pharmacy Solutions.	EXPRESS SCRIPTS*		PRIME THERAPEUTICS"
Pharmacy	📀 briovaex	CVS pharmacy	Humana Pharmacy Solutions.	accredo.		
Provider	OPTUM Care	Health	Kindred Y Hospice			
%€ CenterWell						

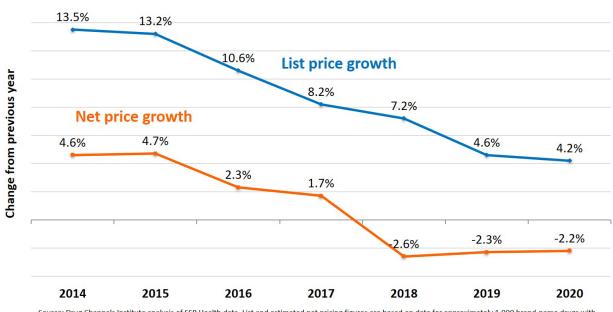


Number of Products on PBM Formulary Exclusion Lists, by PBM, 2012 to 2021

Source: https://www.drugchannels.net/2021/01/the-big-three-pbms-ramp-up-specialty.html



Brand-Name Drugs, List vs. Net Price Growth, 2014 to 2020



Source: Drug Channels Institute analysis of SSR Health data. List and estimated net pricing figures are based on data for approximately 1,000 brand-name drugs with disclosed U.S. product-level sales from approximately 100 currently or previously publicly traded firms. The products and companies account for more than 90% of U.S. branded prescription net sales. Net prices equal list price minus off-invoice rebates and such other reductions as distribution fees, product returns, chargeback discounts to hospitals, price reductions from the 340B Drug Pricing Program, and other purchase discounts. Data for 2020 reflect first three quarters only.

Published on Drug Channels (www.DrugChannels.net) on January 5, 2021.

DRUG CHANNELS

Source: https://www.drugchannels.net/2021/01/surprise-brand-name-drug-prices-fell.html

Pharmaceutical Manufacturers Off-Invoice Discounts, Rebates, and Price Concessions, 2007-2016

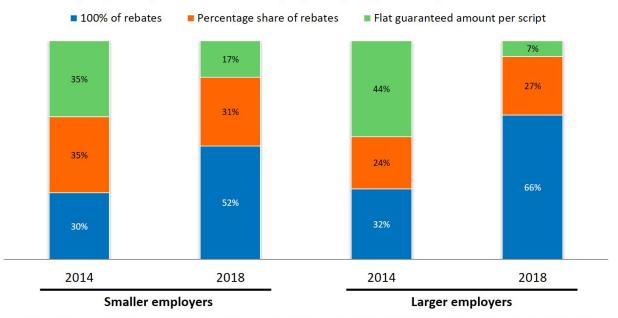


Source: Pembroke Consulting analysis of Medicines Use and Spending in the U.S.: A Review of 2016 and Outlook to 2021, QuintilesIMS, May 2017. Published on Drug Channels (www.DrugChannels.net) on June 14, 2017.



Source: Drugchannels.net, available at: http://www.drugchannels.net/2017/06/new-data-show-gross-to-net-rebate.html

PBM Rebate Arrangements for Traditional Medications in Employer-Sponsored Plans, by Employer Size, 2014 vs. 2018

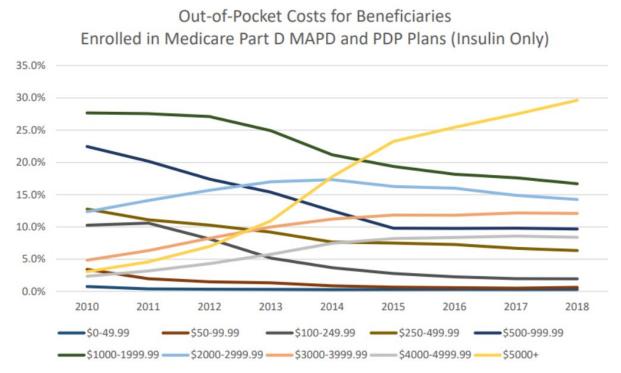


Smaller employers = 5,000 or fewer covered lives; Larger employers = more than 5,000 covered lives. Number of covered lives includes employees and dependents. Source: Drug Channels Institute analysis of *Trends in Drug Benefit Design*, PBMI, various years. Data include only responding firms that receive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

This chart appears as Exhibit 132 in The 2019 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers, Drug Channels Institute. Available at http://drugch.nl/pharmacy

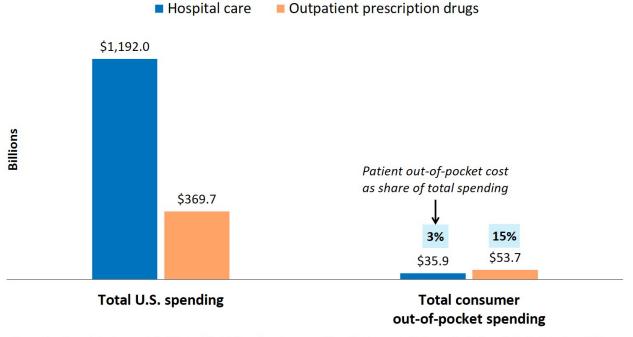
DRUG CHANNELS

Source: https://www.drugchannels.net/2019/03/employers-are-absorbing-even-more.html



Source: <u>https://www.finance.senate.gov/imo/media/doc/Grassley-</u>Wyden%20Insulin%20Report%20(FINAL%201).pdf

Hospital Care vs. Prescription Drugs, Total Spending and Consumer Out-of-Pocket, 2019

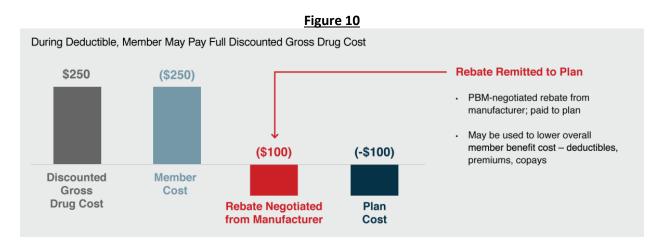


Source: Drug Channels Institute analysis of National Health Expenditure Accounts, Office of the Actuary in the Centers for Medicare & Medicaid Services, 2020. Outpatient prescription drug figures exclude inpatient prescription drug spending within hospitals and nearly all provider-administered outpatient drugs. Figures in billions. Figures may differ from previous reports due to the 2019 comprehensive revision to the national health expenditure accounts.

Published on Drug Channels (www.DrugChannels.net) on January 20, 2021.

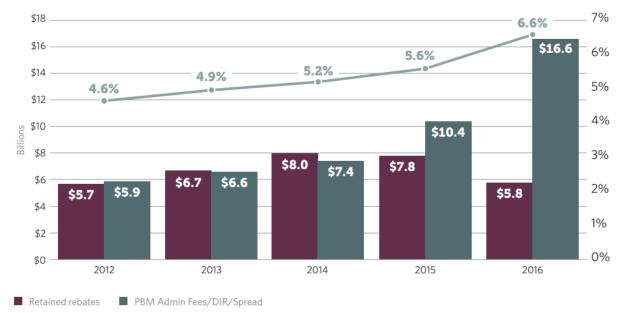
DRUG CHANNELS

Source: https://www.drugchannels.net/2021/01/latest-cms-data-reveal-truth-about-us.html



Source: https://payorsolutions.cvshealth.com/insights/consumer-transparency

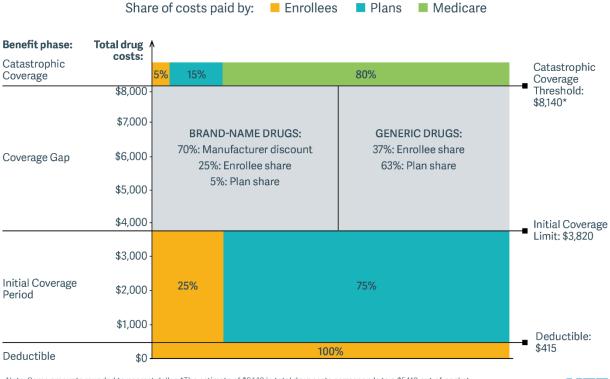
PBM Retained Revenue on Retail Prescription Drugs by Source and Share of Net Spending for Retail Prescription Drug Coverage, 2012-16



PBM retained revenue as share of net spending for retail prescription drug coverage

Source: https://www.pewtrusts.org/-/media/assets/2019/03/the_prescription_drug_landscape-explored.pdf

Medicare Part D Standard Benefit Design in 2019



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.

KFF

160 Average bid for providing basic Part D benefits per enrollee per month (in dollars) \$140 \$137 140 \$134 \$130 \$127 \$127 \$122 \$119 120 \$103 \$40 \$35 \$43 \$51 100 \$60 \$69 \$79 \$79 \$26 80 \$32 \$31 60 \$34 \$36 \$35 40 \$54 \$55 \$50 \$48 \$43 20 \$37 \$31 \$25 \$23 0 2007 2009 2011 2013 2014 2015 2016 2017 2018

National Average Plan Bid for Basic Part D Benefits

Figure 13

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.

Base premium

Direct subsidy

Source: MedPAC based on data from CMS.

Expected reinsurance