

## CHAPTER

# Why Drug Pricing Reform Is Complicated: A Primer and Policy Guide to Pharmaceutical Prices in the US

by Craig Garthwaite and Amanda Starc

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This paper was produced to provide policy-relevant evidence about current challenges confronting the American economy. Authors are invited to share their views about policy issues, which do not necessarily represent those of the Aspen Institute, members of the Aspen Economic Strategy Group, or their affiliated organizations.

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# Why Drug Pricing Reform Is Complicated: A Primer and Policy Guide to Pharmaceutical Prices in the US

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## ABSTRACT

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Pharmaceutical pricing in the United States is a complicated and opaque process. Confusion over price setting and the method by which new drugs are brought to market can lead to ineffective and even harmful policies that decrease society's access to innovative new treatments without providing sufficient decreases in spending to justify the cost. At its core, drug pricing in the United States involves a tradeoff: allowing high prices today provides firms with the incentive to make the large, fixed, and sunk investments necessary to bring future new products to market. In that way, high prices are a central part of the process by which we get new drugs. That being said, firms may—in some areas of the market—take advantage of the complexity of the system to extract profits at a rate that far exceeds any beneficial incentive effects. A wide variety of firms and individuals in the market exhibit such behavior. In this paper we both explain the underlying complexities of how prices are set and suggest areas where policy reforms could improve the market.

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## 1. Introduction

In the United States, prescription drugs are often sold at orders of magnitude over their marginal cost of production. The resulting large margins per unit sold attract attention from policymakers, the media, and customers. As a result, pharmaceutical pricing sparks frequent and heated debate. Of course, the margin on each drug sold provides little insight into the overall costs of developing innovative pharmaceuticals. The total cost of developing and demonstrating the safety and efficacy of potential new drugs involves large research and development investments. All these expenditures are made under considerable risk with the majority resulting in failures. For example, it is estimated that only 10 percent of products that enter into clinical trials in humans make it to the market (Takebe, Imai, and Ono 2018). An even greater number of targets fail long before they ever make it into human trials.<sup>1</sup>

At the same time, the increasing scope of scientific knowledge means that the number of conditions that can be addressed by pharmaceuticals has massively expanded—along with the resulting spending for those treatments. Prices for these treatments have increased, partly as the result of new targeted treatments tailored to better-defined and narrower populations.<sup>2</sup> Combining all these factors together with the broader fiscal burden of increased social welfare spending across the government sets the stage for meaningful controversy over pricing.

This controversy was part of the motivation for the passage of the 2022 Inflation Reduction Act (IRA). This monumental legislation represents the first attempt at government price setting for prescription drugs in the United States. Under the IRA, the Center for Medicare and Medicaid Services (CMS) has the power to “negotiate” prices for the drugs that account for the most spending by Medicare.<sup>3</sup> Firms unwilling to accept the price negotiated by CMS will either be forced to stop selling *all their products* to the Medicare system or pay fines that could amount to over 1,900 percent of a drug’s overall revenue.<sup>4</sup> While these negotiations have not yet begun, and there are existing legal challenges to various features of the law, the IRA likely does not represent the end of policy discussions in this area. For example, President Biden’s 2024 budget proposed both doubling the number of drugs subject to price setting and beginning this process just five years after new drugs come to market

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1 It is, however, important to remember that products that fail earlier require far less investment and in many ways are preferred to those that fail later, after millions of dollars have been invested.

2 As products treat a more defined population, treat more serious conditions, and/or are more effective, society’s willingness to pay for these products should also increase.

3 Under the Inflation Reduction Act (IRA), drugs can only qualify for negotiation if they are among the top 50 products in terms of Medicare spending under either the part D or part B programs.

4 “Inflation Reduction Act Considerations for Pharma Companies,” PWC, August 2022, <https://www.pwc.com/us/en/services/tax/library/inflation-reduction-act-considerations-for-pharma-companies.html>.

(as opposed to the 9–13 years dictated by the IRA) (Newman 2023). Similarly, many Democratic members of Congress have also suggested additional measures to lower prices or shorten periods of market exclusivity. Recently, Senator Bernie Sanders announced he would place a hold on President Biden’s nominees for various health care agencies without a comprehensive plan from the Biden administration for reducing drug prices (Diamond 2023).

The blunt and somewhat clumsy approach of the IRA and many other proposed policies toward drug pricing primarily reflects society’s frustration over high pharmaceutical prices. This frustration stems from the fact that these prices are all too often attributed to unmitigated corporate greed with no other benefit. In many ways, policy reform in this area would be far easier if this simplistic caricature were true.

Nor are high pharmaceutical prices in the United States a mystery, mistake, or accident. Instead, these high prices are a deliberate feature of the complex system by which new products are brought from the scientific bench to the patient’s bedside. Therefore, our goal as a society should not be focused simply on lowering prices but instead on increasing value. In part, reaching this goal depends on achieving the correct balance between access to products today and access to new innovations in the future.

Pharmaceutical innovations result from private firms making large, fixed, and sunk investments in research and development. For successful products, the scientific knowledge created by these investments (i.e., the understanding of the mechanism of action underlying product efficacy and the process for manufacturing and developing the molecule) is largely a public good; that is, it is non-rival and non-excludable.<sup>5</sup> Absent some form of intellectual-property protection, another firm could easily create its own version of these novel innovations at a fraction of the cost invested by the innovator firm.

Firms are unwilling to invest in developing new products without some expectation of a positive return. In our existing system, this expectation is supported by a time-limited period in which the innovative firm can charge high prices for that specific molecule without the threat of direct competition.<sup>6</sup> This broader context of the

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5 These two qualities are the economic characteristics of a public good. Scientific knowledge is non-rival: two firms may both use it at the same time. It is also non-excludable: once it is known, you cannot force others to unlearn it. These economic characteristics mean that the optimal provision of public goods often requires some form of government intervention. Such intervention can also include the direct financing or provision of the public good, as if the case with “basic science” research funding from the National Institutes of Health. Given that basic science research is difficult to fully protect with intellectual-property legislation, the government has become more involved in direct support.

6 During this time period, innovators do face competition from other products that treat the same condition. Such products may have the same mechanism of action but use a different molecule, or they may offer a completely different method of treating patients with the same condition.

development process leads to two conclusions. First, profits for these firms are not as high as the margins for each product sold because of the fixed costs of developing drugs. This fact is especially true in light of the failures in the sector broadly—described below—and the need to provide significant returns on the portfolio of investments to attract risk-based capital. Second, high prices that are the result of monopoly protections for innovative products are a necessary part of the system of developing drugs.<sup>7</sup>

However, while the need to attract and incentivize investment implies the need for a degree of price setting above marginal cost, the optimal policy is not one that allows unbounded markup. Two considerations are at play. First, certain factors (beyond those alluded to above) are driving up prices, specifically market failures and other features of the pharmaceutical value chain, described below. The policy suggestions in this report attempt to address these other sources of high prices—many of which increase spending without a commensurate positive impact on social welfare or patient health.

Second, optimal pharmaceutical innovation policy is not simply about allowing an unending amount of investment in new products and ever higher prices. Instead, it involves acknowledging and managing the fundamental tradeoff at the center of drug development. This tradeoff involves the cost of reduced access today from higher prices and the benefit of ensuring future access by increasing firms' incentives to develop new products. To understand this tradeoff, we must know the answers to two questions: (1) How much would demand go down if prices were higher? (2) How does investment in developing new products respond to changes in expected revenue? Ignoring this tradeoff will lead to lower social welfare.

The answers to these questions are also country-specific. It is well known that pharmaceutical prices in the United States are often quite higher than they are in other developed countries. In fact, one of the few bipartisan sources of agreement about pharmaceutical prices in the United States is clear frustration over the divergence between prices in the US and those in other countries. This frustration certainly was an impetus for the passage of the IRA as well as for several earlier drug-

*Drug pricing in the United States involves a tradeoff: allowing high prices today provides firms with the incentive to make the large, fixed and sunk investments necessary to bring future new products to market.*

<sup>7</sup> A broader reform of the system—so that it no longer relies on private firms or risk capital and instead uses only government funding—is conceptually possible. However, such a broader reform is beyond the scope of this paper (and the authors have great skepticism that it would lead to a more efficient outcome).

pricing reforms supported by both Speaker Nancy Pelosi and President Trump that explicitly linked prices in the United States and those in other European countries.<sup>8</sup>

Why are these other developed markets able to charge low prices and avoid the fundamental tradeoffs described above? While insurance systems vary across countries, a unifying feature of all markets' lower prices is a willingness by governments to more directly set pharmaceutical prices for their citizens. These other countries, however, have not somehow "solved" the difficult question of drug pricing. Instead, these governments enjoy a freedom that is unavailable to the United States. Given the relatively small size of European countries, very few pharmaceutical firms concentrate on any particular one when determining whether to make the large, fixed, and sunk investment in developing a new product. As a result, these countries are free to demand lower prices and to free ride off United States profits (Lakdawalla 2018).

In this way, as long as countries offer a price that is above the marginal cost of production, marketing, and distribution, they can enjoy lower prices and access to medicines that generally match that in the United States.<sup>9</sup> Therefore, the implications of the United States adopting the more European types of pricing systems would be quite different from any individual European country making the same decision because it would create a much larger decrease in profits and therefore have a larger impact on the investment decisions of pharmaceutical firms (Garthwaite, Sachs, and Stern 2022).

Differences between the impacts of price-setting policies in the United States and Europe demonstrate that determining optimal policy depends on understanding the nuances of the health care and pharmaceutical markets. In particular, it is important to focus on how prices are set and how those prices result in revenue for innovative firms or impact access for patients. While no area of US health care is uncomplicated, few parts of the broader sector rival price setting for pharmaceuticals in their opacity. In this paper, we provide a description of the main elements of drug pricing in the US that need to be understood in order to promote smart policy reform. By demystifying the complexities of the pharmaceutical pricing system, we hope to illuminate policies that increase the value the system creates as well as the proportion of that value captured by patients. The purpose of this policy brief is therefore twofold:

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8 The ultimate price response to these policies is unclear. It is almost certain that prices in the United States would not fall to those currently charged in Europe. Instead, pharmaceutical prices would determine a profit-maximizing price that balanced reduced sales in Europe (from higher prices) with reduced profits in the United States (from lower prices).

9 It is, however, clear that countries that tend to demand lower prices get later and less generous access to new medications than those offering higher prices do. This pattern holds particularly true when these lower-paying countries are used as part of the reference price-setting process for the higher-paying countries. See Maini and Pammolli 2023; Kyle 2007.

1. Explain how drugs move from manufacturers to patients—with a focus on the economic relationships at each stage of the value chain.
2. Identify areas where the contractual structure of payments and/or actions by existing firms results in a disproportionate share of value being captured by various parts of the value chain—and offer solutions to these issues. That is, describe instances in which profits are likely to exceed the level necessary to generate socially efficient investments.

## **2. A Primer on Pharmaceutical Prices**

A key feature of the pharmaceutical sector that makes it different from many other markets is that most purchasers of pharmaceuticals are insured customers. This state of affairs weakens the relationship between the prices manufacturers charge and the demand for their products (Lakdawalla and Sood 2013). Understanding how demand changes in response to prices requires understanding (a) the role of insurers in determining patient access to drugs, and (b) the role of prices in determining how manufacturers invest in new products. It is also important to understand the revenues firms expect to capture should their investments in new-product development be successful. Both processes are complicated in the pharmaceutical sector because what is meant by “price” is ambiguous.

In pharmaceutical markets, “price” is at best an elusive term. Insured patients must often make out-of-pocket payments at the pharmacy counter. This specific cost is the price most consumers react to, even though it almost always represents a small fraction of overall spending on the product. The majority of spending is dictated by the “net price,” which is what the plan sponsor (i.e., the employer or insurance company responsible for medical spending) pays to gain access to the product. However, even this net price may vary depending on factors including who the payer is and how the patient gains access to the drug. For example, Medicare will pay a different price for patients to receive the immuno-oncology product Keytruda than private insurers UnitedHealth or CVS will pay for their patients to receive the same product in the same setting. Similarly, a Medicare patient purchasing the biologic product Humira to inject subcutaneously at home would access it through a different payment system than would a Medicare patient receiving Humira as an infusion in a provider’s office. Much of this variation is based on the nature of the value chain through which products move from manufacturers to patients. Different products reach patients via various intermediaries and, based on the type of product, patients have a variety of forms of insurance coverage.

There are three broad categories of economically important pharmaceutical prices:

1. The public list price common across all payers in the system. This price is most similar to the sticker price at a car dealer that is the starting point for a negotiation and is almost never actually paid by any customer.
2. The net price actually paid by a plan sponsor or government insurer. This price is negotiated by a pharmacy benefit manager or dictated by regulation. The net price for a product is different for every plan, and the size of the discount varies within plans across products.
3. The out-of-pocket payment from the consumer, which varies based on the plan, the product, and the patient's other medical spending throughout the year.

The first price is largely chosen by the manufacturer and has little bearing on the actual net price paid—however, as we describe below, it has meaningful implications for patient cost-sharing. The method by which the second and third prices above are determined primarily varies along three dimensions:

1. How many other products exist that treat the same underlying medical condition.
2. Whether the product is purchased in a retail setting or administered by a medical provider.
3. Who is paying for the product (e.g., a commercial insurer or a government program).

### **2.a. The Distribution of Pharmaceutical Spending**

Understanding the relative importance of these features of the price-setting process requires context about the distribution of pharmaceutical spending. To give some scope for understanding pharmaceutical prices, we begin by providing context across four categories.<sup>10</sup>

#### **2.a.1. Retail vs. Non-Retail Pharmaceuticals<sup>11</sup>**

One of the most important economic dimensions along which pharmaceutical products vary is whether they are purchased by a patient at a retail location (either an in-person store or a mail order pharmacy) or whether they were administered by

<sup>10</sup> While the following estimates of spending rely on imprecise pricing data, they are meant to provide broad context rather than explicit numbers.

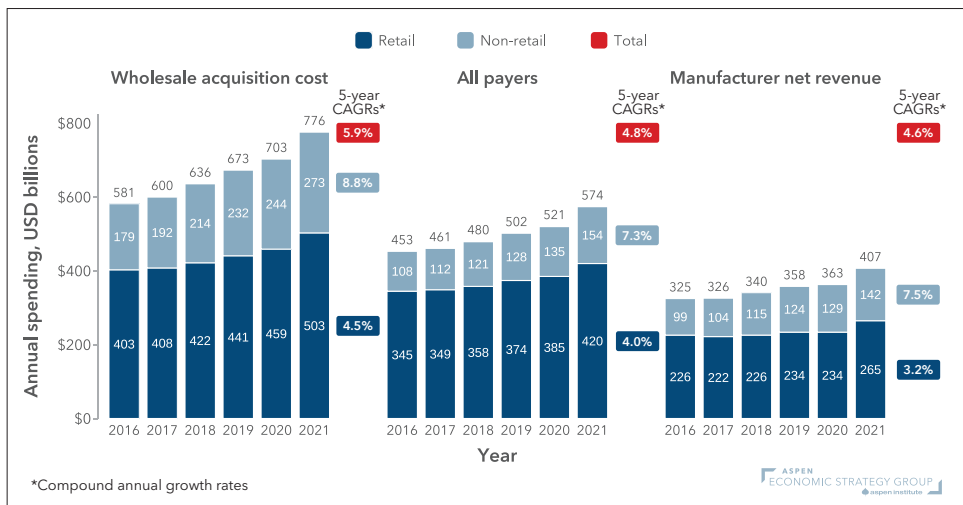
<sup>11</sup> In addition to physician administered outpatient drugs, products are also sold to hospitals for use in the inpatient settings as well as to be distributed through their outpatient pharmacies as part of the 340(B) system. Important reforms may be required in this area, but they are beyond the scope of this policy brief.



a medical provider in an outpatient setting. As will be discussed below, the price-setting process for these two situations is different in ways that have important impacts on both patient costs and provider profits.

Figure 1 charts retail spending by payers based on whether it occurred in the retail or physician administered (PAD) setting. In 2021, approximately 27 percent of pharmaceutical spending was for PADs—up from 14 percent in 2016—with the rest being purchased at a retail or mail order pharmacy.

**Figure 1. US Medicine Spending Levels and Segmentation by Channel, 2016-2021**



Source: IQVIA (2022).

Part of the reason for this growth is the rising importance of specialty medications—many of which are PADs. Specialty products are, broadly, more expensive products that treat more serious conditions and often require special handling or administration. From 2011 to 2021, specialty medications grew from 28 to 55 percent of overall drug spending (IQVIA 2022). This growth was driven by increased spending for autoimmune (459 percent) and oncology (326 percent) products.

### 2.a.2. Small-Molecule and Large-Molecule Products

While there is no consistent definition for a specialty medication, there is a clear scientific difference between products based on their underlying molecule type. This distinction between small- and large-molecule drugs impacts how patients access the product, how providers are paid, and the evolution of competition for the molecules.

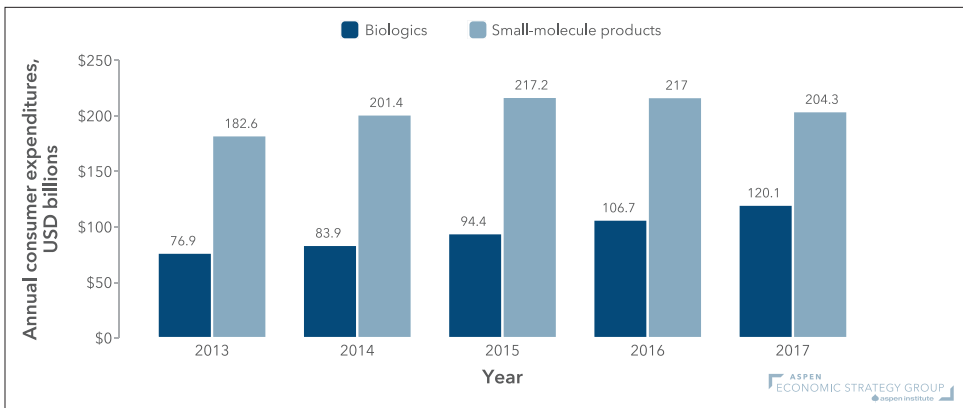
The most common view of pharmaceuticals is one of simple pills that are relatively inexpensive to produce and are sold to large numbers of customers. These products are almost invariably small-molecule products that are taken orally and sold at retail pharmacies.

Scientific advances, however, have allowed for the development of new types of large-molecule or biologic products. Large-molecule products are typically proteins that are grown rather than manufactured. Because they are grown, the marginal costs of manufacturing these products are far higher and require that firms have meaningfully more expertise. These proteins are often delicate and cannot survive in a patient's gastrointestinal tract. As a result, these products must be injected and are more likely to be infused as PADS, although subsequent development of these products at times allows for a subcutaneous version that a patient can administer in their own home.

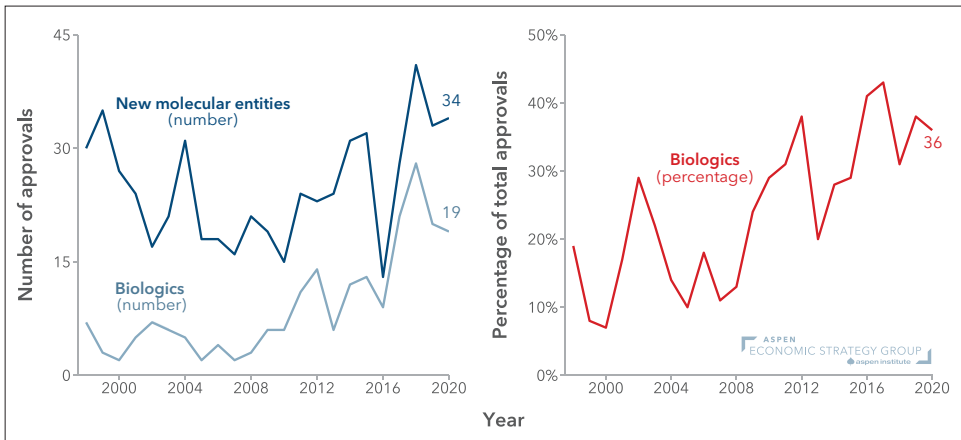
Finally, given their complexity, large-molecule products cannot be exactly replicated. As we discuss below, this impossibility has meaningful implications for the structure and nature of competition—in particular, it is hard for a new firm to enter and gain market share from an incumbent innovative firm.

Figure 2 shows consumer spending broken out by molecule type. In 2017, approximately 37 percent of pharmaceutical spending was for large-molecule products. This figure reflected nearly a 25 percent increase since 2014—and the share is likely to continue growing over time as large-molecule products come to make up a greater share of the set of approved drugs. Figure 3 charts FDA approvals by year based on product type. This number has risen steadily, and these biologic products now account for approximately 40 percent of all approvals each year.

**Figure 2. Consumer Spending in Billions, Small- vs. Large-Molecule Products, 2013-2017**



Source: Makurvet (2021).

**Figure 3. Annual FDA Drug Approvals by Product Type, 1998-2020**

Source: <http://www.nature.com/articles/s41587-022-01630-6>

### 2.a.3. Branded vs. Generic

Pharmaceutical products are intended to be a single-source branded product for a limited time period. These branded drugs have some form of market exclusivity (provided by either the Food and Drug Administration or a patent) and may not be imitated. Although “blockbuster” branded drugs capture much attention, most prescriptions are for generic drugs. A recent analysis of sales data shows that only 20 percent of *prescriptions* are for branded drugs; this number has remained fairly flat for the better part of a decade (Parasrampur and Murphy 2022). However, over 80 percent of *drug spending* is on branded drugs, because they are meaningfully more expensive than their generic counterparts.

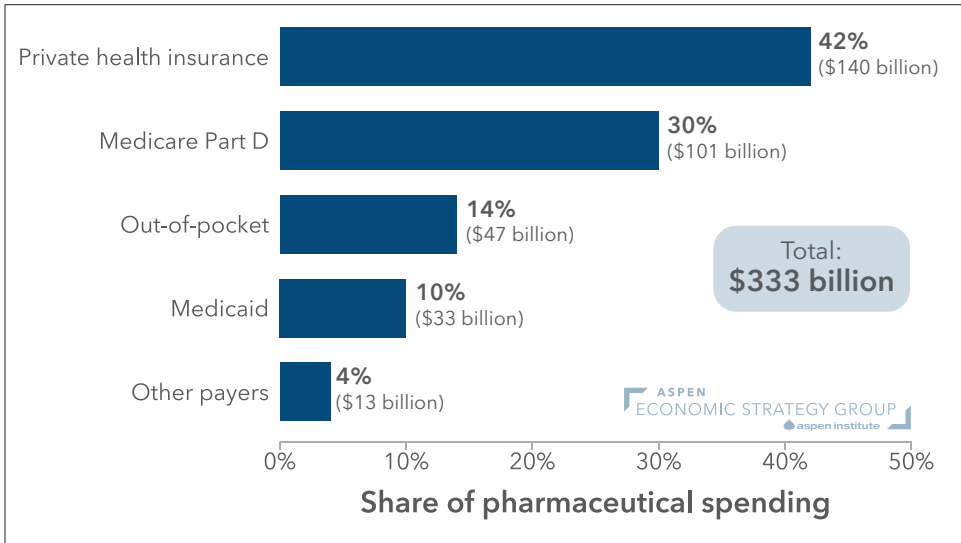
### 2.a.4. Spending by Payer Type

The final important distinction is whether the payer involved in a purchase is Medicare, Medicaid, or the commercial segment. Within each of these segments, prices vary across all the dimensions discussed above. But prices also vary within those categories based on payer type (i.e., Medicare prices for large molecules compared to prices for the same products in the commercial segment).

While the US health care system is often described as a free-market system dominated by private firms, in reality government payers of various types are a meaningful part of the payment system for pharmaceuticals. Figure 4 shows 2017 pharmaceutical spending by payer. The largest single payer is private health insurance, which accounts for 42 percent of all spending, while Medicare accounts

for 30 percent and Medicaid another 10 percent. Given their massive scale, the statutory payment rules implemented by these government payers can have wide-ranging implications.

**Figure 4. Total US Retail Prescription-Drug Spending, 2017**

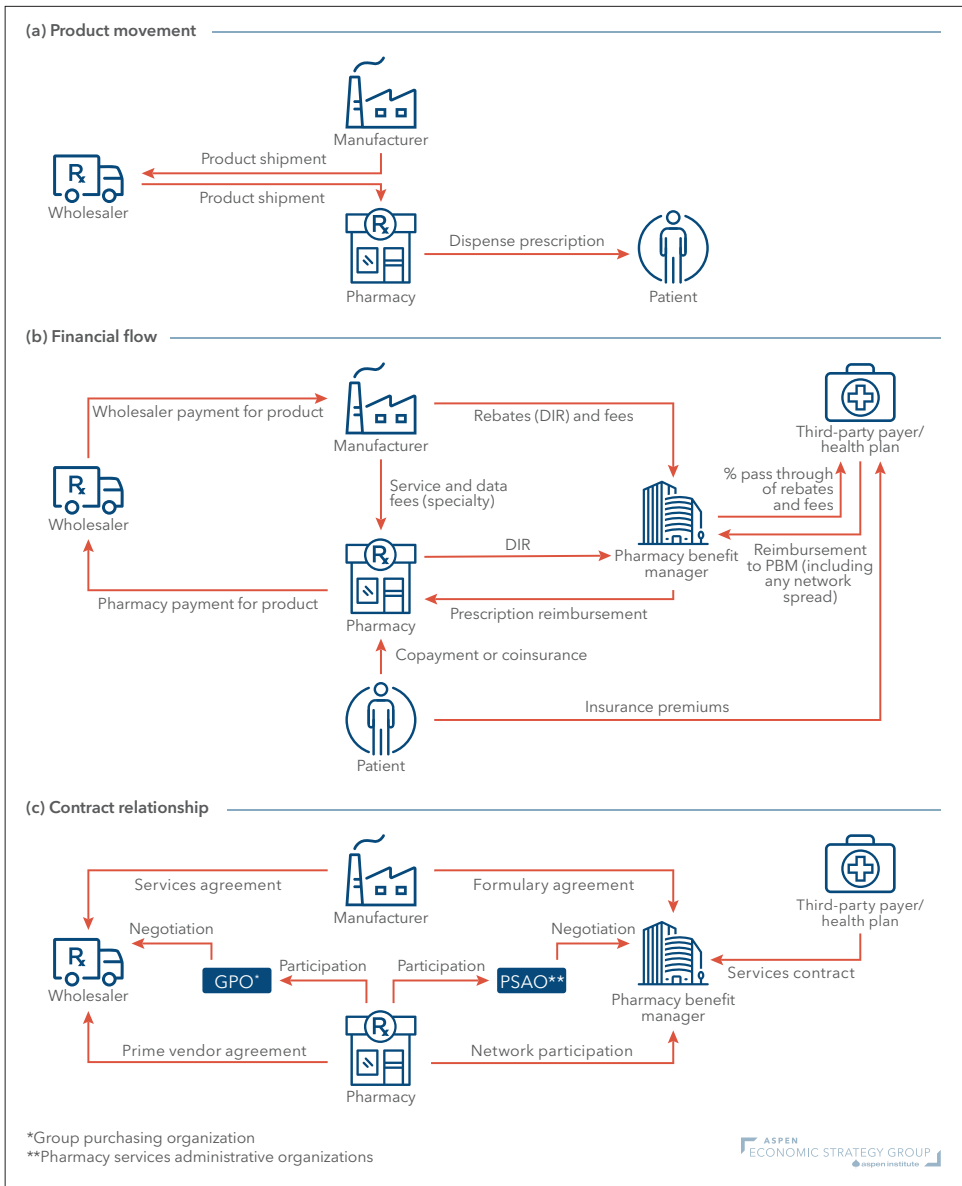


**Source:** Cubanski et al. (2019).

### 2.b. Price Setting for Branded Retail Pharmaceutical Products

As detailed above, the majority of pharmaceutical products are purchased at retail pharmacies. These products come to market through the value chain detailed in figures 5(a)—(c). To attempt to provide some clarity to what is often described as an opaque process, the panels of the figure depict the flow of products, the flow of funds, and the contractual relationship, respectively.

**Figure 5. The US Pharmacy Distribution and Reimbursement System for Patient-Administered, Outpatient Brand-Name Drugs**



Source: Fein (n.d.).

The path of a product from a manufacturer to the patient, depicted in figure 5a, is remarkably similar to paths found in nearly every other market that relies on wholesalers to serve as middlemen between manufacturers and retailers. The value chain starts with the manufacturers that are the patent holders selling branded products in the market.<sup>12,13</sup> In many cases, these manufacturers are innovative firms that received approval from the FDA to sell new products, but firms also acquire production rights at various points in a product's lifecycle.<sup>14</sup> As in many other markets, drug manufacturers provide wholesalers with products in return for payment.<sup>15</sup>

The largest wholesalers in the pharmaceuticals market are McKesson, Amerisource Bergen, and Cardinal. These firms represent over 90 percent of market volume (Mulcahy and Kareddy 2021). Wholesalers purchase products from manufacturers based on small discounts on the publicly available list price known as the wholesale acquisition cost (WAC). While almost no one ultimately pays this price for a drug, the WAC is the best-known price and is the one most commonly discussed in media reports about “high and rising” drug prices. The discounts negotiated by wholesalers are summarized by the average manufacturer price (AMP), which represents the average price paid by all wholesalers for each product. The discounts received by wholesalers are often for features such as prompt payments and generally amount to only a few percentage points off the WAC.

Wholesalers then sell branded products to pharmacies at approximately the prevailing WAC, that is, a price that is largely similar to a wholesaler's acquisition cost (Seeley 2022). Any spread between the acquisition cost and the price paid by pharmacies represents profit for the wholesalers.<sup>16</sup>

12 In some cases, manufacturers may use other firms to undertake the actual manufacturing. These firms are referred to as contract manufacturing organizations (CMOs). In addition, the actual patent holder for a given drug may be a combination of firms that hold various rights to the underlying intellectual property and may split up revenues based on various royalty agreements. While these arrangements are economically interesting when it comes to questions of capital allocation and drug development, they are beyond the scope of this brief.

13 In reality, the value chain starts even earlier, with the active product ingredients that are essential (but often commodity) inputs into product manufacturing. For the purposes of simplicity, we abstract away from this part of the value chain.

14 Additionally, the firm that ultimately receives FDA approval is often not the same firm that initially began developing the product. Often, products begin at smaller biotechnology firms and then are acquired at some point in their development. While this process is economically interesting, it is outside the scope of this brief. That said, it is important to realize that even if the firm selling the drug did not initially develop the product, it is the commercial opportunities available for products that dictate investment at all stage of product development.

15 That said, in the pharmaceutical industry manufacturers then provide separately negotiated discounts to plan sponsors (i.e., the insurance company or employer purchasing the product, rather than the actual consumer of the product). We discuss these nuances below after establishing how products move through the system.

16 Historically, this process included a practice of “forward buying,” that is, purchasing large amounts of drugs today, holding them in inventory, and then selling them later, after manufacturers raise the WAC and thereby mechanically increase the price paid by pharmacies. However, as the pace of price increases has declined, this strategy has proven far less lucrative for wholesalers.

Patients purchase pharmaceuticals from a pharmacy, either in a physical location or by mail. Over time, this market has become increasingly concentrated. In 2022, the five largest pharmacies were CVS Health (both mail order and retail), Walgreens Boots Alliance, Cigna (mail order), UnitedHealth Group (OptumRx mail order), and Walmart Stores. Together these five account for 64 percent of all retail sales (Fein 2023b). Larger pharmacies may have more leverage in negotiations with both wholesalers and buyers. This leverage could allow them to earn more margin on the spread between the acquisition price and the sales price of the drugs. It also allows them to demand greater dispensing fees for medications—fees that can represent the majority of the pharmacy profits from branded expensive drugs. Left behind in this pattern of consolidation are the remaining independent pharmacies that have little market power and therefore have experienced consistent decreases in reimbursements for their services.

In addition to traditional retail pharmacies, many patients now receive their prescriptions from specialty pharmacies distributing specialty medications. These medications are generally expensive, treat complex conditions, and often require more careful handling in terms of refrigeration and storage. Patients taking them also often need more intensive interactions with a pharmacist.

As a result of these features, specialty pharmacies likely generate additional value for patients who use these expensive medications. Increasingly, pharmacy benefit managers (PBMs)—that is, the entities responsible for managing the pharmaceutical benefits of health insurance programs—have moved into owning mail order or in-person specialty pharmacies. They have also been requiring enrollees to use these integrated pharmacies rather than independent providers. It is possible firms are doing so even if this decision decreases the quality of the insurance product for enrollees that value access to these pharmacies. PBMs may engage in this behavior because independent specialty pharmacies, compared to their retail counterparts, may generate more unique value for customers that specialty pharmacies can attempt to leverage into higher reimbursements. While in many markets such a strategy would be unlikely to create profits, many patients using these drugs are actually not profitable for insurers because such patients have exceptionally high medical costs. Underserving such patients on quality (even if doing so incentivizes them to move to another insurer) may result in a more advantageously selected insurance pool.

### **2.c. How Net Prices Are Determined for Retail Pharmaceutical Drugs**

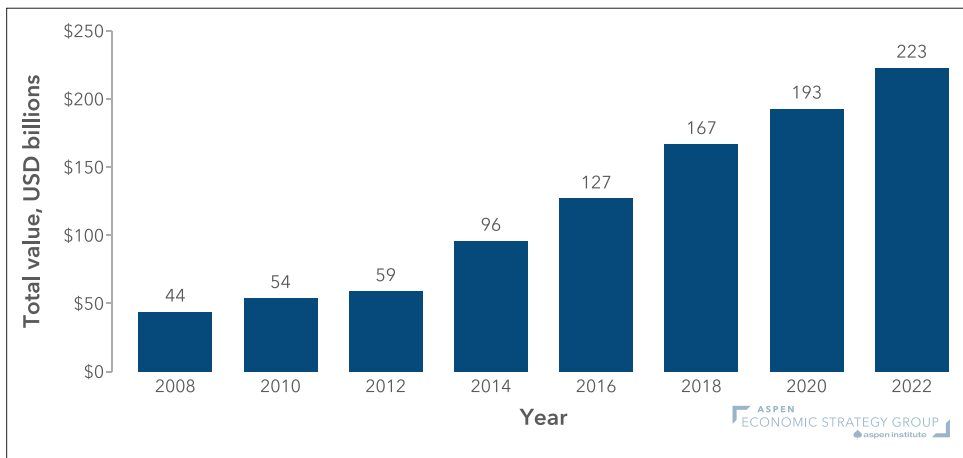
The prices paid on the distribution side of the drug market are largely divorced from both the profits of manufacturers and the payments by customers and plan sponsors (i.e., the employer, fully insured plan, union, or other entity responsible for paying for the drug). Figure 5b depicts the flow of funds and negotiations regarding retail prices in the pharmaceutical market.

### 2.c.1. The Role of Rebates in Determining Retail Pharmaceutical Prices

The actual prices paid for retail pharmaceuticals are largely determined by negotiations between PBMs and manufacturers (or by regulation). PBMs are the firms responsible for managing the pharmaceutical portion of a patient’s health insurance benefit. This management includes, among other activities, negotiating discounts (or “rebates”) off the WAC, negotiating prices paid to pharmacies, establishing networks of pharmacies, and establishing formularies (i.e., determining which products patients have access to and at what out-of-pocket price).

Negotiating rebates with plan sponsors is economically meaningful, as this process determines retail prices and thus profits for manufacturers. These profits provide incentives for firms to invest in new products and serve as an essential component to tradeoffs in the retail sector. As in the wholesale market, everything related to the PBM-manufacturer-pharmacy relationship begins with the WAC. However, the divergence of retail prices from WAC is greater than the divergence seen in the wholesaler market—evidence that rebates are economically significant. The role of rebates has also grown in recent years. Consider the evidence in figure 6, which charts total rebates paid in the system from 2007 to 2022. Over that period, these rebates have grown from \$43 billion to \$223 billion—a rate that far exceeds growth in drug spending. The biggest change in rebates happened after 2012, when the policy changes described below made increased Medicare list prices more advantageous.

**Figure 6. Pharmaceutical Manufacturers’ Off-Invoice Discounts, Rebates, and Price Concessions, 2008-2022**



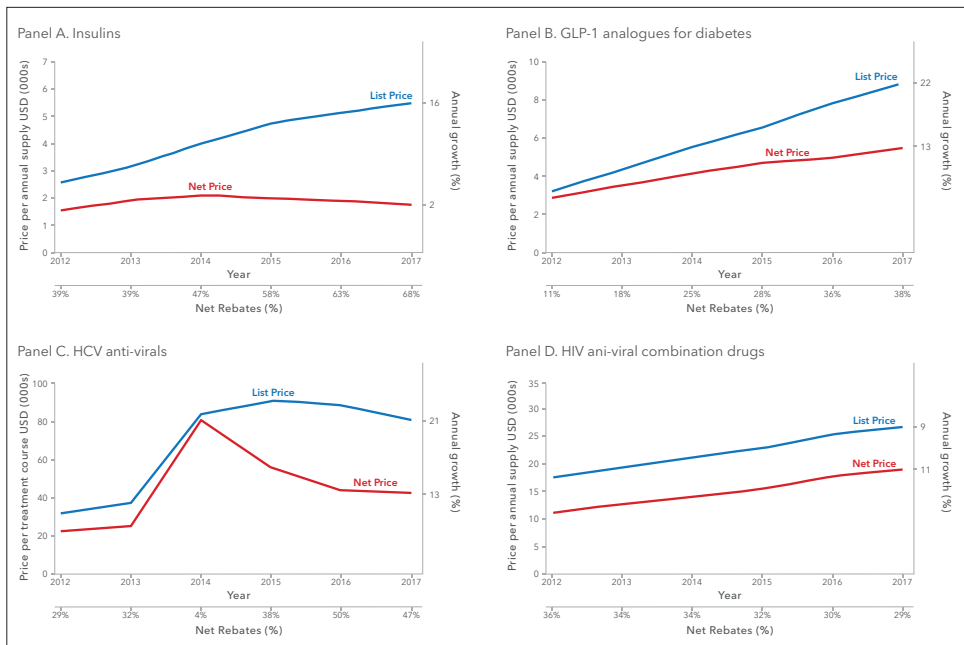
Source: Maas (2020).



Growing rebates reflect, in part, the ability of PBMs to credibly promise to move market share to alternative products. In therapeutic areas where many competing products are available to patients, there are more opportunities to move patients and, as a result, larger discounts. Consider figure 7 from Kakani, Chandra, and Chernew (2020), which shows net price and list prices for products that treat various conditions. In panels A and B, a growing gap is evident between net and list prices for insulins and GLP-1 analogues—both of which are drug categories containing multiple products that offer similar therapeutic benefits. In panel D, which represents prices for HIV antiviral products, there has been almost no divergence between these two prices. Over the time period depicted in the figure, there was almost no change in competitors; nor were any products introduced that offered meaningfully different clinical benefits for HIV antiviral drugs.

Perhaps the most interesting example is panel C, which contains prices for cures for hepatitis C (HCV). This class started as a near monopoly with the introduction of Sovaldi and Harvoni by Gilead in late 2013 as the only existing cures for this disease. For that reason, the list and the net price are exceptionally close. After competition emerged in 2015 (with the introduction of Abbvie’s Viekira Pak), there is a greater spread between these prices—reflecting the ability of PBMs to force manufacturers to negotiate when there are good substitutes.

**Figure 7. Growth in List and Net Prices Per Treatment Course or Annual Treatment Supply in Select Categories (2012-2017)**



Source: Kakani, Chandra, and Chernew (2020).

PBMs move market share across competing products using formularies that dictate what drugs patients may access. Formularies generally involve both financial and nonfinancial forms of utilization management. Nonfinancial utilization management includes processes such as prior authorization, step therapy, and at the extreme, complete exclusion from coverage. Prior authorization requires pharmacies to receive permission from the payer to dispense a drug to a particular patient. This process is often used for expensive products and involves consultations between the payer and the prescribing physician. Step therapy requires patients to try and fail on therapeutic substitutes before getting access to newer and more expensive treatments for their condition. At the extreme, some drugs are altogether excluded from coverage. As of 2022, the three largest PBMs each excluded more than 400 products—with each plan differing in its particular exclusions (Fein 2022a). The terms of nonfinancial utilization management are negotiated by the PBM, plan sponsor, and manufacturer. Providers offering larger discounts are managed less in this way than are those who refuse to concede on price. Therefore, even though patients are largely shielded from prices in this sector, utilization management of PBMs nevertheless drives a negative relationship between price and quantity.

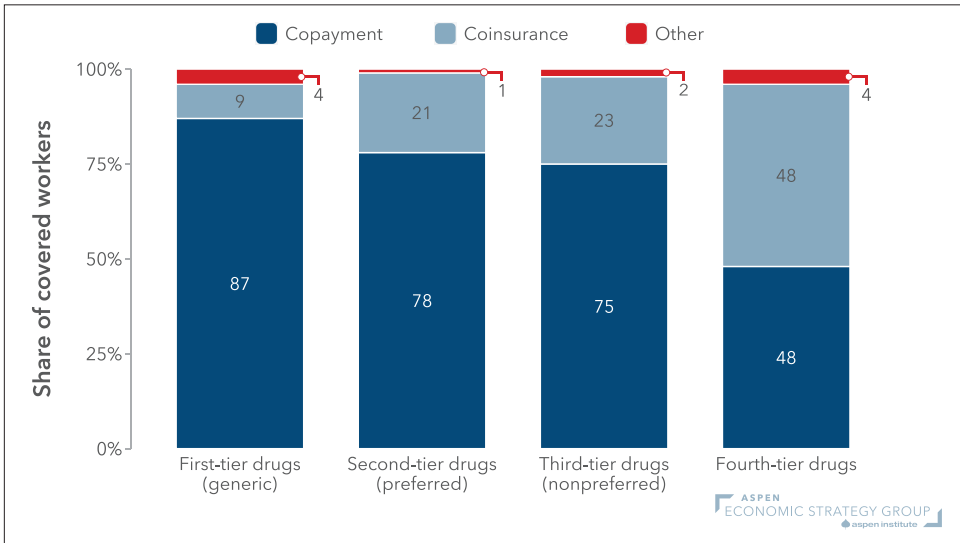
Patients are not entirely shielded from the cost of their prescriptions, however, because formularies also practice financial utilization management. Such management is implemented in the formulary through a series of tiers of increasing costs for patients. As part of the negotiation between PBMs and manufacturers, manufacturers who offer greater price concessions gain access to a greater number of formulary tiers in which patients face reduced cost sharing and out-of-pocket payments. Increasingly, PBMs are using more tiers in their formularies. Just over 60 percent of customers with high-deductible plans have four tiers of cost sharing for pharmaceuticals, compared to only 41 percent in more traditional health care plans (Fein 2023a). The majority of customers, regardless of plan type, have at least three tiers in their formulary.

Patient cost sharing comes in three main forms: (1) a deductible, or a pre-specified amount of medical spending wherein the patient is solely responsible for all costs; (2) a co-payment, or a fixed payment a patient makes to access a drug; and (3) coinsurance, or a percentage of a drug's costs that a patient must pay before gaining access to the product.

Figure 8 depicts the type of cost sharing applied to drugs based on their formulary tier. Drugs assigned to higher formulary tiers are more likely to be covered by coinsurance than by co-payments. This practice often exposes patients to greater out-of-pocket payments. Figure 9 shows average co-payment and coinsurance amounts by tier. For drugs on the fourth formulary tier, the average co-payment per prescription is over \$100 and the average coinsurance amount is 25 percent—figures that can result in

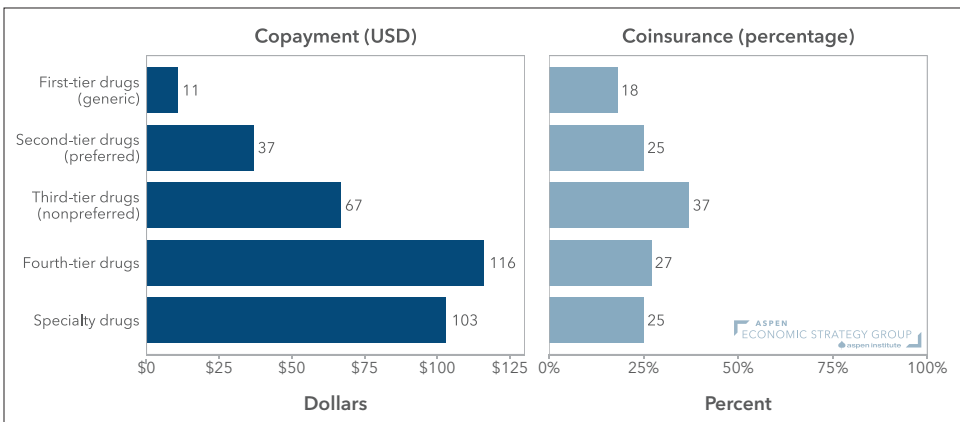
high cost sharing for exceptionally expensive drugs. For example, Revlimid—a drug that treats multiple myeloma—has a list price of approximately \$20,000 per month. Thus, patients with 25 percent coinsurance would be responsible for paying \$5,000 out of pocket each month to gain access to this life-saving medication.<sup>17</sup>

**Figure 8. Type of Cost Sharing for Prescription Drug Benefits, Employer-Sponsored Plans Without High Deductibles, by Benefit Tier, 2022**



Source: Fein (2023a).

**Figure 9. Average Cost Sharing by Prescription Drug Tier, Employer-Sponsored Plans, 2022**



Source: Fein (2023a).

<sup>17</sup> A patient’s ultimate charges are determined by any limits in the insurance contract on the enrollee’s out-of-pocket payment cap. Insurance contracts with lower limits on potential out-of-pocket payments tend to charge higher premiums.

This degree of cost sharing has implications beyond simply pharmaceutical pricing. Recent research shows that even small increases in cost sharing impact medication adherence in ways that negatively impact health, up to and including increasing mortality among affected patients (Chandra et al. 2023). There is little evidence that patients are responding to high cost sharing in a particularly well-informed manner; they appear to stop taking nearly all drugs when faced with higher out-of-pocket expenses. Given these broader effects of cost sharing, it is important that any discussion of pharmaceutical pricing contends with both the net price paid by plan sponsors and the out-of-pocket costs of consumers.

The degree of cost sharing is intrinsically linked to the publicly available WACs set by pharmaceutical firms. Given that the magnitude of negotiated rebates is meant to be confidential, any cost-sharing payments based on a drug's price (i.e., deductibles and coinsurance) are a function of the publicly available WAC and not of the drug's ultimate net price (i.e., the price after the negotiated rebate). For products with large rebates (i.e., those where there is a large difference between the WAC and the net price), this state of affairs can result in patients paying a meaningful fraction of the drug's net price as a cost-sharing payment. They are especially likely to do so in the more complicated formularies described above, wherein patients are expected to pay a significant percentage of the drug's price.

### ***2.c.2. Contract Structure and the Distribution of Profits***

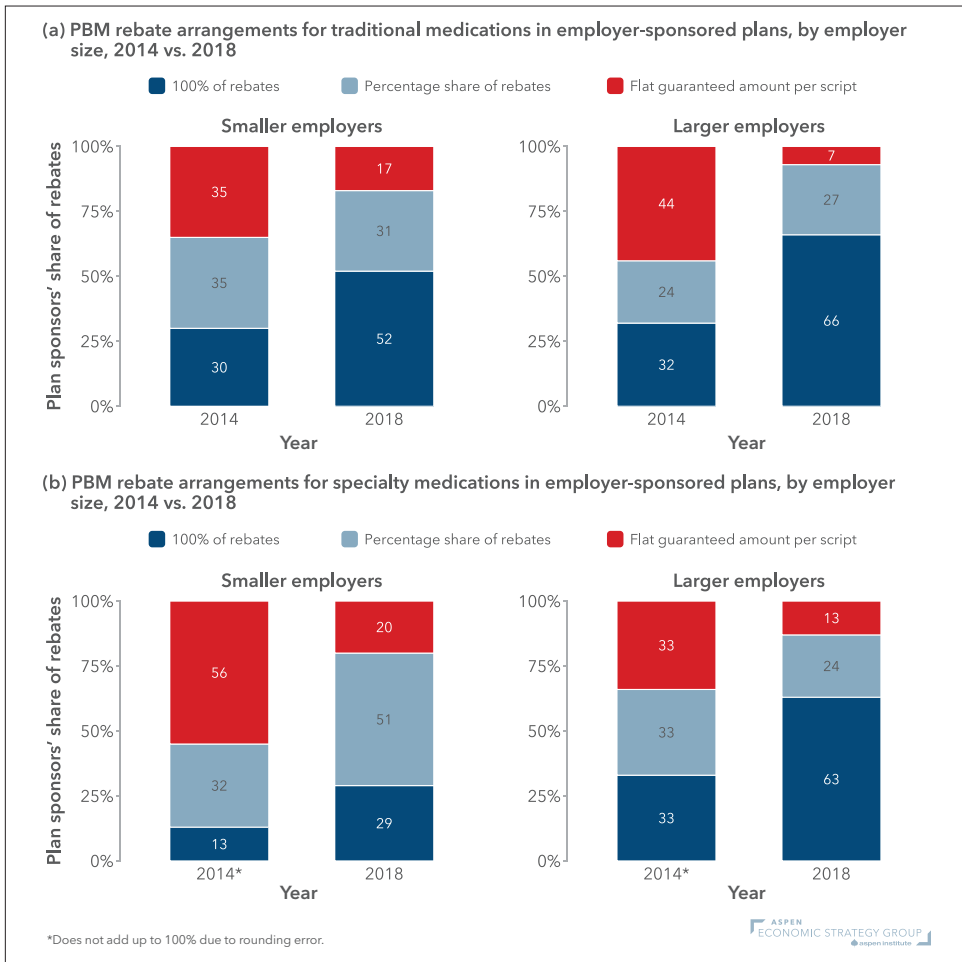
Given the relationship between list prices and rebates, this negotiation process has become an increasingly controversial part of the pharmaceutical value chain. The second area of bipartisan consensus, after the inequity of low European drug prices, is the view that PBMs are exploiting their position as middlemen to siphon money from both patients and pharmaceutical firms.

Understanding whether this belief is true requires knowing more about the PBM business model. PBMs are paid for their services through a variety of means, such as by charging a per-member-per-month (PMPM) fee, keeping a pre-specified portion of the negotiated rebate, and keeping the difference between what they pay the pharmacy for a drug and what the plan sponsor pays (i.e., spread pricing). Critics contend that because the PBM initially receives the rebate and/or keeps part of it as compensation, the market is broken. In point of fact, however, all of these contractual features are interrelated and reflect the specifics of the market structure.

In plans where the PBM keeps a portion of the rebate, they almost always earn a lower PMPM fee. Similarly, when they earn a higher PMPM fee they receive a smaller (or no) share of the rebate. Increasingly, plan sponsors are negotiating PBM contracts where they receive all or a substantial share of the rebates negotiated by the PBM. Figures 10(a) and 10(b) show estimates of the percentage of all rebates shared in part with plan sponsors. A growing fraction of plan sponsors, particularly for large plans, receive all their negotiated rebates from the PBM.

Plan sponsors might desire that PBMs receive a fraction of the rebate because such an arrangement provides managers an incentive to negotiate larger discounts. But for PBMs to keep a portion of the rebate is controversial—after all, these firms can generate larger rebates by allowing list prices to rise. Such cases would not result in greater savings for the plan sponsor (indeed, they might increase sponsor costs) but would increase the profits of the PBM. Similarly, PBMs can capture a portion of the spread between what the plan sponsor pays for a product and what the PBM pays the pharmacy. This practice, known as spread pricing, can provide the plan sponsor with certainty and insurance against volatile drug pricing. One risk, however (which we describe below), is that plan sponsors may be kept in the dark as to the true value they are bringing to the table when purchasing pharmaceuticals—and that PBMs may exploit that ignorance for their own profit.

**Figure 10.**



Source: Fein (2019).

### 2.c.3. PBM Concentration and Impact on Consumers

If a PBM increased list prices solely to capture more of a rebate, or if they were not putting sufficient effort into negotiating large rebates, total drug spending for plan sponsors would increase. Similarly, if a PBM were charging a plan much more than they themselves were paying pharmacies, pharmaceutical spending in that plan would rise.

Of course, if plan sponsors are concerned about PBMs manipulating prices to obtain higher rebates or spreads, they can move their contract to another PBM. The validity of this threat to discipline PBMs is a function of the level of competition in the PBM market. Therefore, concerns about pricing in this area should focus more on the amount of competition in this market than on the contractual arrangements between the parties.

There are valid reasons for concern about competition related to market concentration. The largest PBMs are CVS Caremark, OptumRx, and Express Scripts, which together represent over 80 percent of the market. Another 15 percent is accounted for by Humana Pharmacy Solutions, Prime Therapeutics, and Medimpact (Fein 2023c).

Beyond being concentrated, a set of vertical mergers over the last five years has transformed the PBM market. Currently, the four largest PBMs are wholly owned by large national insurance firms. After these mergers, a PBM using rebates to capture value from a plan sponsor would appear to just be taking money from another part of their commonly owned firm.

But if vertically integrated PBMs are not allowing rebates to increase solely to capture an inappropriate amount of value from plan sponsors, why do we continue to see rebates rise even after such extensive vertical integration? For one, the integration of a PBM and an insurer may not have much impact on incentives for PBMs as they relate to plan sponsors. In turn, insurance companies in the commercial market increasingly serve simply as administrators of employer plans.<sup>18</sup> In those contractual settings, the PBM may still have an incentive to use rebates to capture more value as profit.

Another reason for these rising rebates, however, could be the interplay between cost sharing, list prices, rebates, and insurance premiums. For products with many customers and a wide list-to-net spread in prices, cost sharing can be used strategically to lower premiums and increase market competition.

#### *2.c.4. A Numerical Example of Strategic Cost Sharing*

Consider the cost of a monthly product with a \$1,000 list price and a \$600 rebate, where the patient has a \$2,000 deductible and 20 percent cost sharing. As mentioned above, given the desire to maintain the confidentiality of negotiated prices, price-based cost sharing is a function of the list price (before rebates) rather than the net price. For this product, the patient pays the full price for the first two prescriptions: meeting her \$2,000 deductible. Despite not paying anything, the plan sponsor still gets \$1,200 in rebates for those two prescriptions—money that can either be used to lower premiums for all customers (i.e., the larger number of healthy customers not buying expensive drugs) or kept as profits. The relative disposition of these funds will depend on the market structure.

For the next ten prescriptions that year, the patient would pay \$2,000 out of pocket (\$200 each: 20 percent cost sharing on a \$1,000 list-price drug), while the plan sponsor

<sup>18</sup> For these plans, the health insurer is operating as a third-party administrator (TPA) that offers an administrative-services-only (ASO) contract to the plan sponsor. While the TPA organizes the benefits, the plan sponsor is still responsible for drug spending. For example, approximately 70 percent of UnitedHealth's commercial business involves insurance plans where the firm administers the benefit but bears no risk of higher medical spending, including spending on pharmaceuticals. See UnitedHealth Group 2023.

would only pay \$4,000 for the drug (at \$400 each after the rebate). Ultimately, the patient would pay an annual cost of \$4,000. The plan sponsor would only pay a net cost of \$2,800, since the sponsor would also receive rebates of \$1,200 that were effectively paid by the sick patient. In this way, the rebate dollars have offset a massive fraction of the costs of insuring this patient.

This concern is not theoretical. A recent Senate Finance Committee report on insulin pricing contained emails between manufacturers and PBMs about the potential to offer a lower-list-price version of insulin. The report described the emails in this manner: “Two weeks prior to this email, Eli Lilly executives raised the possibility that PBMs would object to a list price reset because it would result in (1) a reduction in administrative fees for PBMs, (2) a reduction in rebates, which would impact PBMs’ ability to satisfy rebate guarantees with some clients, and (3) *impair their clients’ ability to lower premiums for patients, thereby impacting their market competitiveness*” (Grassley and Wyden 2021, emphasis added).

To examine this issue further, we use Medicare data to construct measures of expected spending for hypothetical consumers.<sup>19</sup> We begin with the best-selling drugs for 2021. To measure the extent to which they treat chronic conditions, we calculate medication position ratios (MPRs) using historical data. (MPRs are the number of days’ supply the patient fills in a year, divided by 365.) We note that the average MPR of these blockbuster drugs is over 0.8x. Using a comparison tool created by the federal government, we then calculate expected out-of-pocket costs for a patient taking these drugs.

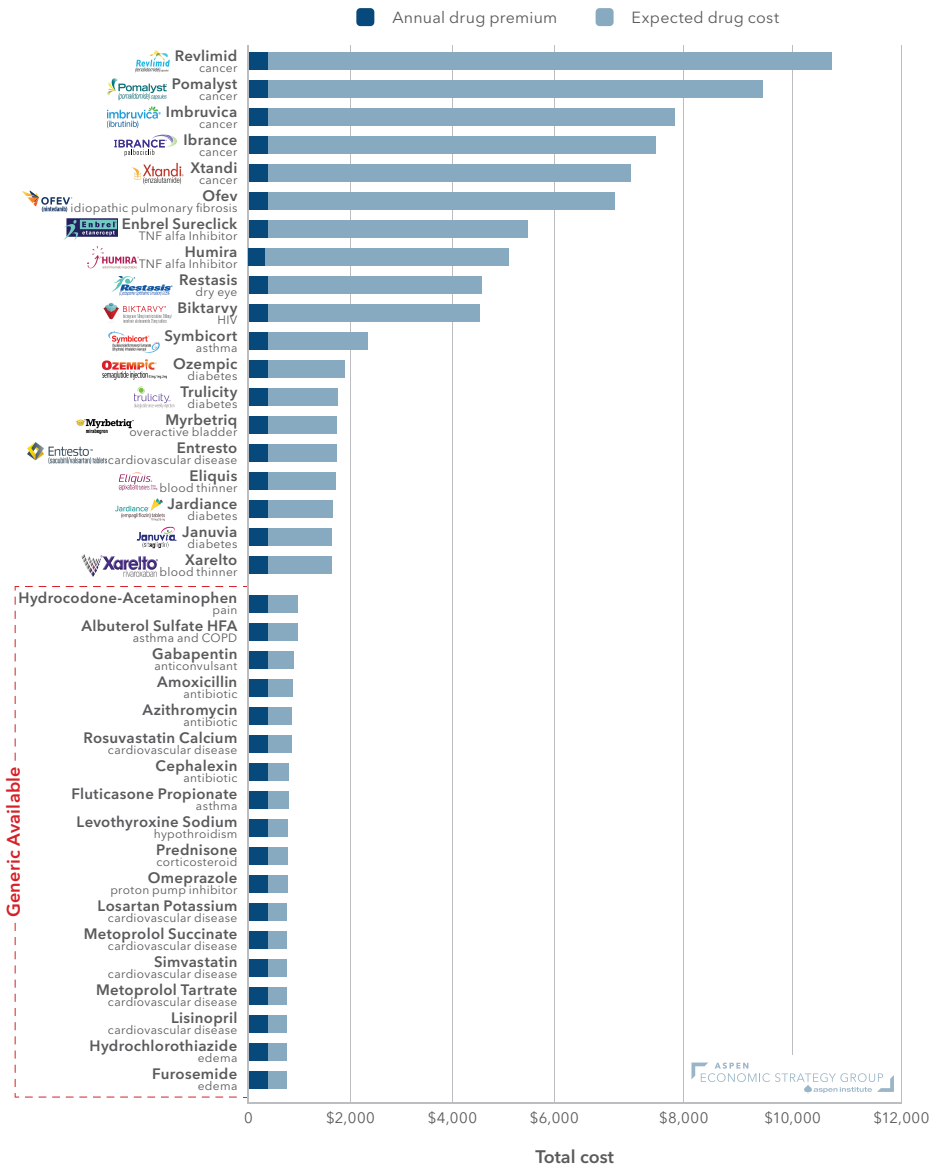
We input demographic information for a hypothetical consumer in Evanston, Illinois. We then collect premium and expected out-of-pocket costs by plan. We input this data first for the average consumer and then for a consumer taking each of the drugs described above. We then define “total expected spending” as the sum of (certain) premiums and expected out-of-pocket costs. We report this information for the lowest- and median-cost plans available to the consumer.

The results of this exercise are depicted in figure 11. The top of this figure includes branded drugs for which there are no generic or biosimilars available. It is immediately obvious that many patients with conditions such as cancer, autoimmune diseases, asthma, and HIV spend thousands of dollars out of pocket each year. For example, once we consider the known and certain cost sharing, patients taking ibrutinib (Imbruvica) for various types of leukemia could face an annual premium of \$7,495. If that patient took no prescription drugs for a medical condition, their premium would only be \$345. In this way, large cost sharing payments have introduced medical underwriting into insurance for prescription drugs.

<sup>19</sup> While we use Medicare data for this exercise, we do not mean to suggest that the problem is exclusive to Medicare.



**Figure 11. The Median Medicare Part D Plan: Total Cost by Drug**



Source: Authors' calculations.

As we discuss below, other concerns emerge because of a lack of transparency around payments. While PBMs negotiate with plan sponsors about the distribution of rebates, growing anecdotal evidence suggests that manufacturers and PBMs engage in meaningful transfers that are classified as administrative fees rather than as rebates. Like rebates, these payments are often determined as a percentage of WAC, but they are less apparent to plan sponsors who do not have insight into the financial arrangements between manufacturers and PBMs—even when those payments result from sponsor spending.

It is unclear whether such administrative fees represent bona fide services or are instead simply a renamed version of rebates that are designed to allow PBMs to take advantage of asymmetric information to capture more value from the supply chain—questions we come back to when we discuss policy solutions for drug pricing below.

#### **2.d. Prices in Medicare Part D**

The process for determining prices for commercial retail pharmaceuticals described above dictates spending for the largest purchasers of prescription drugs in the United States. The second largest purchaser is Medicare. Specifically, the Medicare Part D program provides retail prescription-drug coverage for the elderly and the disabled.

While Part D is a social insurance program that is primarily financed by the federal government, nearly all features of negotiation and administration in this program are handled by private firms. The five largest firms in the Medicare Part D market are UnitedHealth, Humana, CVS Health, Centene, and Cigna. Together, these plans account for 75 percent of Part D enrollment. Each of these firms is a large and sophisticated insurer that negotiates drug prices as part of its normal business model. In their role as Part D plan sponsors, they effectively operate as highly regulated commercial firms. That said, particular features of reinsurance and financing do influence prices and strategies in this market.

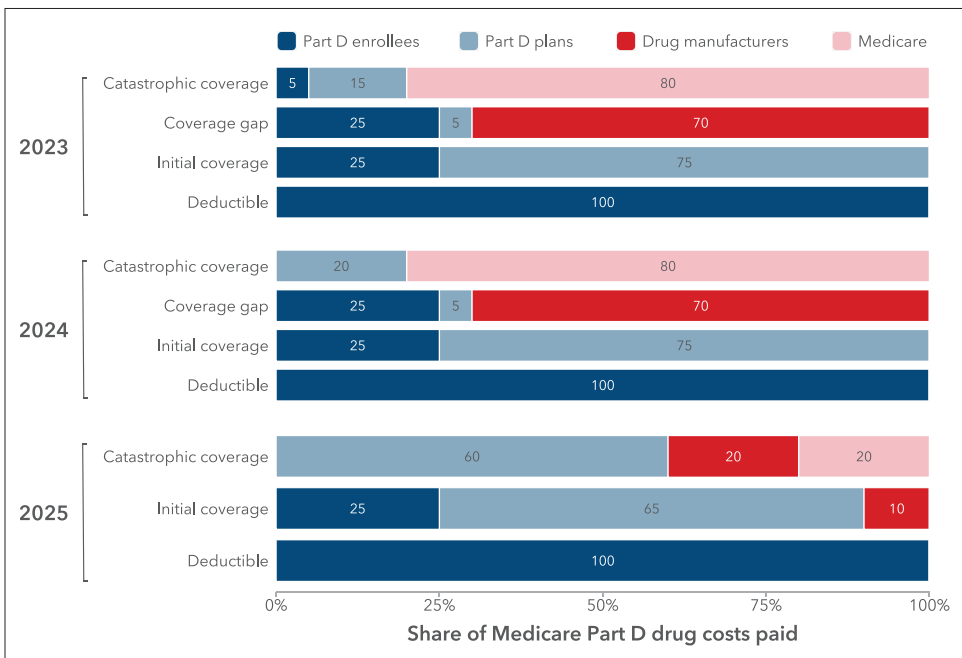
The financing of drug expenditures in Part D has evolved over time—and was meaningfully changed as part of the IRA. Figure 12 charts the structure of expenditures as of 2023 and forecasts it for after 2025—when the majority of IRA changes will have gone into effect. Key elements of the current Medicare Part D cost-sharing structure are as follows:

1. **Deductible period:** Enrollees are required to cover all prescription expenses for a deductible period.
2. **Initial coverage:** Following the deductible period, patients face coinsurance of 25 percent, with the remaining 75 percent of expenditures paid for by the Part D plan (e.g., UnitedHealth or CVS).

3. Coverage gap: After reaching a certain out-of-pocket threshold, individuals then pay 25 percent coinsurance, but the Part D plan’s responsibility falls to only 5 percent. The remaining 70 percent is paid by drug manufacturers.
4. Catastrophic phase: After \$7,400 in out-of-pocket spending, the enrollee contribution falls to only 5 percent. However, for individuals who have not secured supplemental insurance coverage, there is no upper limit on their expenditures. The government is responsible for 80 percent of these costs, and Part D plans pick up the remaining 15 percent.

Under this method of dividing expenses, high cost sharing for enrollees (which can be driven by higher list prices) increases their out-of-pocket share of total spending and reduces the expenditures of both plans and manufacturers. This reduction comes at the expense of both enrollees and taxpayers: work demonstrates that products with a higher share of patients on Medicare had greater list-price growth, as both manufacturers and Part D plans attempted to shift spending onto patients and the government (Ippolito and Levy 2023).

**Figure 12. Share of Medicare Part D Drug Costs Paid by Enrollees, Plans, Drug Manufacturers, and Medicare, 2023-2025**



Source: Cubanski and Neuman (2023).

These costs led to calls for additional reforms to Medicare Part D cost sharing in the IRA. The most salient of these changes, depicted in figure 12, was to remove any enrollee responsibility for spending in the catastrophic phase. In addition, the government share of spending in this period was reduced to 20 percent, while Part D plans are now responsible for 60 percent. The IRA reforms also include a cap on out-of-pocket expenditures of \$2,000. However, even if we examine the estimates in figure 11 there are still a number of drugs that would automatically put patients at this limit each year simply as a result of their chronic—and known—condition.

### **2.e. Prices for Retail Drugs in Medicaid**

The third-largest purchaser of prescription drugs is state Medicaid programs. Medicaid is the government insurance program for impoverished and disabled Americans. Unlike Medicare Part D, prices in this market are determined by regulation that guarantees that Medicaid pays the lowest or “best” price in the market. For branded drugs, this requirement is met by granting Medicaid a rebate equal to the greater of 23.1 percent of the AMP (i.e., the price paid by the wholesaler for the product) or the largest rebate available to any commercial-plan sponsor in the market.

The existence of these Medicaid rebates has implications for commercial price setting more widely, leading to higher prices for certain drugs. Effectively, this system of reference pricing across payers means that manufacturers who give large discounts to commercial payers will have to give similar discounts to Medicaid. The connection between discounts in the commercial market and Medicaid primarily exists for drugs in competitive therapeutic areas where the average rebate already exceeds the 23.1 percent of AMP minimum discount. In those categories, the existence of the Medicaid best-price rebate has been shown to increase commercial drug prices, as firms must now pass on their largest discounts in the private market to all patients in Medicaid. Larger discounts therefore become more costly, particularly for drugs with a large fraction of patients on Medicaid (Duggan and Scott-Morton 2006).

Medicaid also receives an inflationary rebate designed to shield the program from price increases that exceed inflation. Firms must provide a rebate to the government that represents the difference between the current list price (based on the first price for the drug in the market) and an inflation-adjusted reference (based on the consumer price index). For drugs that have been on the market for many years and/or experience large price increases, these inflationary rebates can be quite large. For example, the Congressional Budget Office (2021) estimates that an economically meaningful fraction of products in Medicaid are now sold at between 0 and 5 percent of the Medicare Part D price.

The role of these inflationary rebates will only grow due to policy changes in the 2021 American Rescue Plan Act. This legislation removed a cap on the size of the inflation rebate that had been equal to the list price of the drug. When a rebate equals the list price of a drug, the manufacturer receives no revenue for the product from Medicaid. As a result of this policy change, for drugs where the inflation rebate exceeds the list price of the drug, manufacturers would actually be required to pay a Medicaid agency each time a patient fills a prescription for the drug.<sup>20</sup>

Most Medicaid programs are administered by private managed care organizations (MCOs). Although Medicaid is already guaranteed the lowest price in the market, MCOs provide value primarily by negotiating with pharmacies to lower dispensing fees and ingredient costs (Dranove, Ody, and Starc 2021). The ability of private insurers to obtain discounts hinges on their ability to say no to high-cost drugs and pharmacies. To the extent that state Medicaid agencies can do the same, they may also be able to reduce costs. However, the federal government recently denied the Massachusetts Medicaid program's request to restrict the state-administered formulary and pharmacy network, limiting the negotiating power of these MCOs.

## **2.f. How Net Prices Are Determined for Physician Administered Drugs**

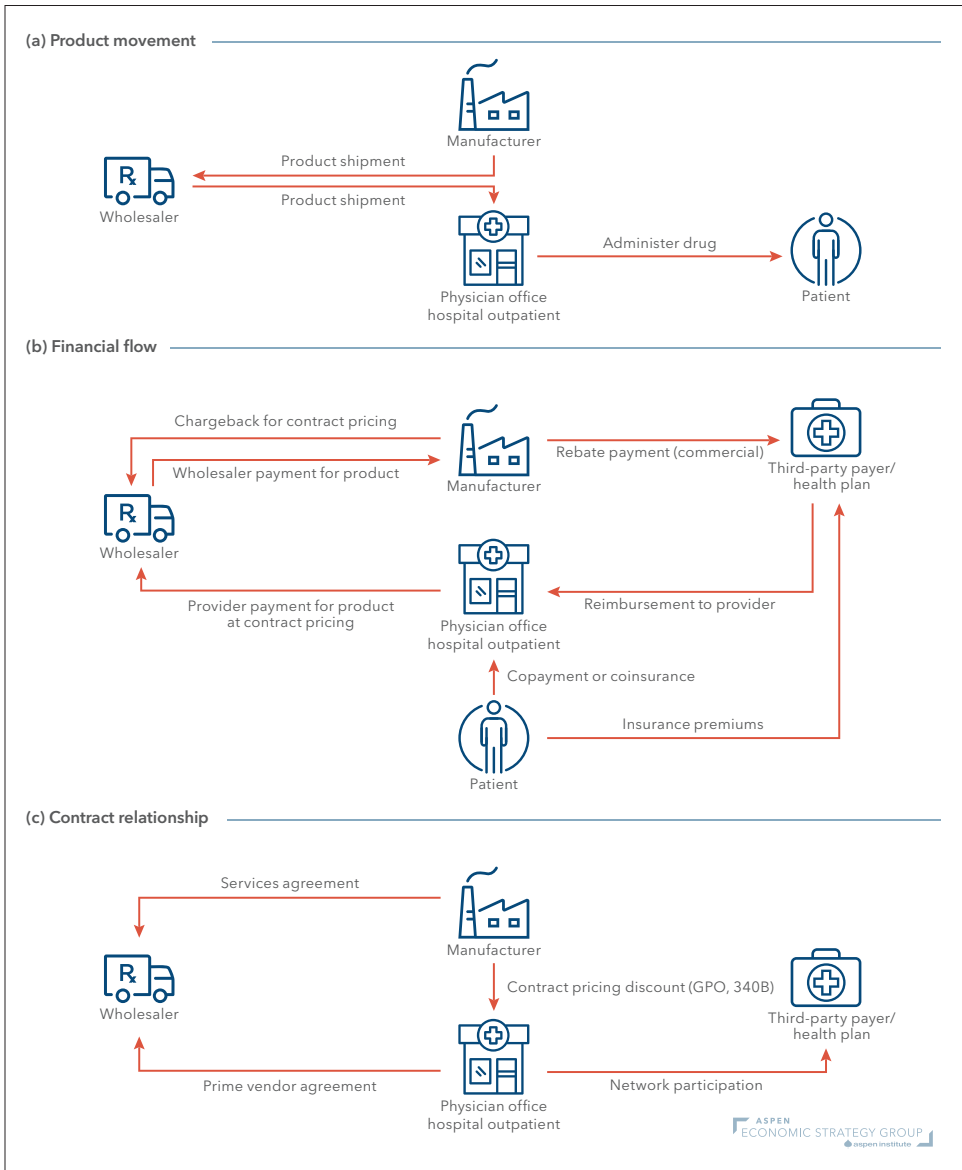
While most pharmaceuticals are obtained in a retail setting (i.e., a traditional or specialty pharmacy), an increasing fraction of drugs are administered to patients in a physician's office or outpatient clinic. These physician administered drugs (PADs) are paid for through a different system. The basics of this system are summarized in figure 13. Like figure 5, this graphic shows basic product-movement patterns within a distribution system, then shows financial flows and contract relationships within the same system.

Rather than being administered by PBMs under a plan's pharmacy benefit, PADs are negotiated and paid for through the medical benefit. These drugs exist under a buy-and-bill system in which medical providers first acquire drugs and are reimbursed only when they administer the product.

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<sup>20</sup> The interplay between the various parts of the Medicaid system is important. While previous work has shown that the existence of the Medicaid Best Price rebate increases commercial prices, Feng, Hwang, and Maini (2023) find that the combination of all features of the Medicaid pricing system lowers commercial prices. It may lower them even more when rebates can exceed list prices, as was seen by the recent move in the insulin market toward lower overall list prices (Wilkerson 2023).

**Figure 13. Distribution and Reimbursement of Provider-Administered Outpatient Drugs: Buy-And-Bill**



Source: Fein (2021).

Medical providers negotiate discounts on these products from a wholesaler. Such negotiation is carried out either directly by the health system or through a group purchasing organization (GPO), that is, an organization that pools demand across a variety of health systems to negotiate prices. Increasingly, these providers also implement formularies by which they constrain access to some products to obtain larger discounts (Pedersen et al. 2020).

The Medicare system is one of the largest purchasers of PADs, and their payment methodologies cast a long shadow over the payments by commercial payers in this market. PADs are paid through Medicare Part B—often described as the “medical benefit,”<sup>21</sup>—and pricing works as follows:

- For each drug, Medicare calculates the product’s average sales price (ASP), which represents the product’s price net of rebates and discounts. ASPs reflect the average prices paid two quarters prior, making them a lagging indicator of post-rebate prices.
- Providers are reimbursed, with providers normally receiving 106 percent of the drug’s ASP. Providers acquired this product at a negotiated price that could be above or below ASP based on the provider’s negotiating power.<sup>22</sup>
- Many commercial insurers also base their negotiations with providers on a percentage of the drug’s acquisition cost—though they often pay an add-on fee that is far greater than the 6 percent paid by Medicare.

As we discuss below, reimbursing providers in this way has immediate economic implications.

## **2.g. Prices for Small-Molecule Generic Products**

The discussion above describes how prices are determined for branded drugs. Such drugs are single-source products for which one firm has intellectual property protection giving it the exclusive right to manufacture a particular product.<sup>23</sup> Such firms have monopoly pricing power over their particular product, and they face competition from therapeutic substitutes (i.e., products that treat the same condition using a different product).

21 One consequence of the vertical integration in the commercial market is a merging of the medical and the pharmaceutical benefit into a single product. This merger could change how drugs are negotiated and formularies constructed.

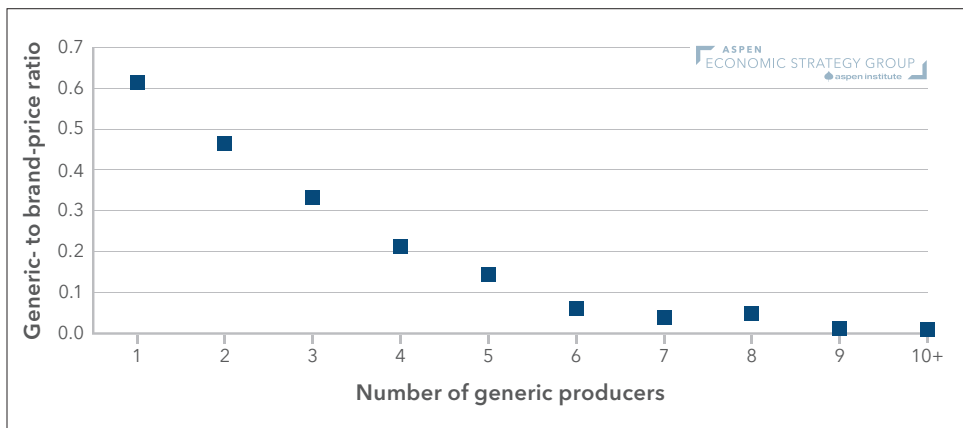
22 While providers are supposed to receive 106 percent of ASP, this figure was reduced to 104.3 percent during the budget sequester. In addition, a provider prescribing a qualified biologic can receive 108 percent of ASP for that drug.

23 In some situations, multiple firms have a financial stake in a product because of royalties, IP licensing, or other partnerships. Even in these settings, there is normally one firm acting as the manufacturer and supplying the product to the market.

While the majority of spending in the US is on such branded products, they represent a minority of the total pharmaceuticals sold in the market. In the United States, over 80 percent of prescriptions are filled by generic drugs. As a result, policies that affect generic competition have important consequences for consumers.

Since the passage of the 1984 Drug Price Competition and Patent Term Restoration Act (also known as the Hatch-Waxman Act), generic drugs have been a competition success story. After loss of exclusivity, generics capture a large fraction of the market at substantially lower prices (Scott-Morton 1999). Figure 14 shows how prices fall based on the number of generic providers that enter the market. By the time the fourth firm has entered a product market, prices have typically fallen by 80 percent.

**Figure 14. Median Generic Prices Relative to Brand Price Before Generic Entry: Average Manufacturer Price (AMP)**



**Source:** Conrad and Lutter (2019).

The success of generics in lowering prices can be attributed to several supply-side factors. First, insurers steer consumers to lower-cost generics through formulary design. Second, many states require automatic substitution at the point of sale, often a retail pharmacy. Such automatic substitution provides a means for low-cost entrants to capture market share without investing much in marketing or other costs. It also provides strong incentives for generic firms to produce at a low cost.

Retail pharmacies play an important role in the generic supply chain. As in other industries, retailers purchase drugs directly from manufacturers or from wholesalers. The decision of which manufacturers' products to stock is an important strategic choice, as consumers are largely indifferent to or ignorant about the supplier of these medications. Unlike buyers in other industries, however, pharmacies negotiate



reimbursement directly from third-party payers such as insurers. Pharmacy prices and rebates are set separately using different mechanisms.

Pharmacies often sign contracts that pay them a fixed dispensing fee plus an ingredient cost proportional to wholesale costs. Unlike dispensing fees, ingredient costs typically vary across drugs. Historically, average wholesale costs have been misestimated and manipulated (Alpert et al. 2013).<sup>24</sup> As a result, these contracts can distort behavior.

Many payers (insurers) have introduced new contractual arrangements, including provisions for maximum allowable costs. Under such contracts, payers set a ceiling price for specific active ingredients. Pharmacies profit by negotiating discounts from wholesalers for selling a particular version of a generic product.

Several factors threaten the competitiveness of generic drug markets. As discussed above, the retail and mail-order pharmacy market is increasingly concentrated and vertically integrated. In addition, shortages can reduce quantity, and anticompetitive behavior can increase prices.

Recent developments in generic markets have affected both the quantity and prices of generics sold. Drug shortages are increasingly commonplace. Manufacturer investments in reliability and quality depend on expected returns. Because price competition is so fierce in these markets, investments may be inefficiently low. Leibman et al. (2017) note that shortages are especially common for generic and injectable drugs—products that require more sophisticated and expensive manufacturing capabilities. They further show that reimbursement policy—which generates savings for payers—impacts supply. A policy change lowering reimbursement for some generic injectables led to greater shortages.

Alleged anticompetitive behavior has also led to skyrocketing prices. For example, an active collusive ring of generic manufacturers led to price hikes for over 100 drugs. The scheme generated \$12 billion of additional profit for drugmakers (Cuddy 2020). Harms from the cartel likely persisted even beyond a formal investigation—the cartel was remarkably stable and appeared to persist without active collusion even after intervention.

Collusive prices are stable in the years following the formation of a cartel, even after investigation. The market becomes more attractive to entrants following price hikes. Starc and Wollmann (2022) find that entry plays an important role in disciplining the cartel. Cartelized markets experience a 30–40 percent increase in entry compared

<sup>24</sup> Ingredient costs are often inflated, and as a result reimbursed point-of-sale prices can meaningfully exceed pharmacies' marginal costs.

to un-cartelized markets. However, largely due to delays at the FDA, the time from regulatory filing to approval typically exceeded two years. Yet simulations show that entry is beneficial to consumers, reducing cartel harms by a third. Taken together, the structure of the market for generic drugs generates low returns to both entry and investment in quality.

The stability of this cartel demonstrates that firms do not need to engage in active collusion in order for generic drug prices to remain elevated. In small markets and/or those where entry is difficult, it is possible for firms to *tacitly collude* to maintain high prices across multiple products.

Recently, several entrants into the generic industry have attempted to deal with high prices. These entrants include both Mark Cuban's CostPlus Drugs and CivicaRx. The potential effects of these two entities differ. CostPlus Drugs is currently serving as a middleman that is acquiring drugs from the lowest-cost owner of an abbreviated new drug application (ANDA—i.e., the FDA right to manufacture and market a product). Therefore, to the extent that high prices are the result of either formal or tacit collusion among ANDA holders, CostPlus Drugs can have little effect. It can, however, influence spread-pricing contracts and the resulting cost sharing for patients. That said, the ultimate effect is less clear, as changes to spread pricing will affect the equilibrium contract terms as PBMs negotiate to change those terms.

CivicaRx is a nonprofit organization that was started by a consortium of hospitals spearheaded by Intermountain Healthcare in Utah. Initially these hospitals were interested in addressing natural monopolies on small-market drugs and drug shortages for hospital administered pharmaceuticals—both of which dramatically increased hospital costs and limited profits. Civica initially engaged in contract manufacturing from existing ANDA holders (providing guarantees of demand for these products) and began construction of its own manufacturing and applications for its own ANDAs. It also partnered with the Blue Cross Blue Shield Association to undertake the same activities for drugs sold through retail channels.

## **2.h. Prices for Biosimilar Products**

Post-patent products for small molecules are referred to as generic products because they are exact bioequivalent copies of existing products. For biologic or large molecule products, however, the nature of the complexity of the molecule means that firms cannot simply make an exact copy of the product. Since 2010, firms have been allowed to develop and manufacture “biosimilar” products.<sup>25</sup> These

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<sup>25</sup> Firms were allowed to sell such biosimilar products in Europe in 2006 when Omnitrope entered as a biosimilar for human growth hormone.

products are intended to be broad replicas of the branded reference biologic product that provide an identical therapeutic benefit to the original product. However, since they don't represent an *exact bioequivalent copy*, biosimilar products do not enjoy the same rules regarding automatic substitution as small-molecule generics.

The lack of automatic substitution means that patients using a biosimilar require a specific prescription for the exact product. For example, one of the highest-grossing drugs in history is adalimumab (Humira). After a series of patent disputes, in 2023 Amgen released a generic version of Humira, adalimumab (Amjevita). Humira's 2022 list price of \$6,922 per month, with an average rebate of reportedly 40 percent, subjected this biologic to significant attention. Patients gaining access to the product would need a new prescription for Amjevita and not for Humira. A pharmacist would not be able to provide a patient with a Humira prescription for the lower-cost Amjevita unless a doctor provided a new prescription. Therefore, a US biosimilar manufacturer such as Amgen was required to negotiate with PBMs for formulary placement (and to market to consumers and physicians) in a manner more similar to that of a manufacturer of an innovative biologic product than that of a small-molecule generic manufacturer.

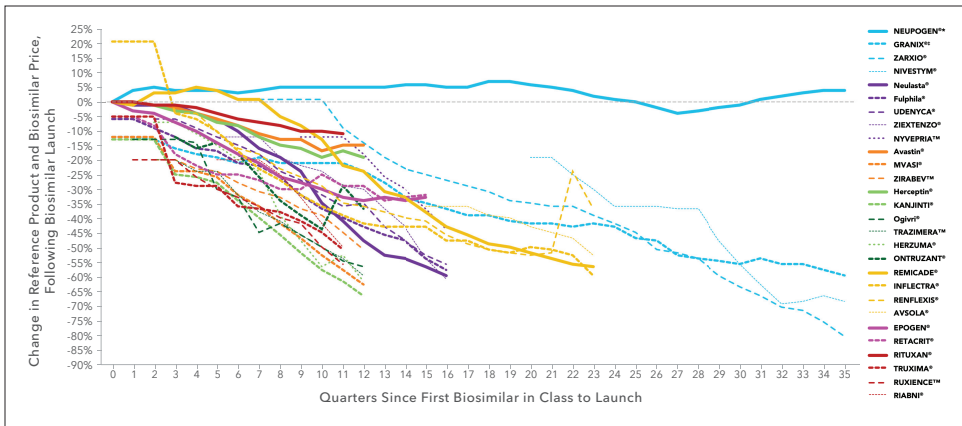
Historically, biosimilars were paid similarly to their reference products; that is, providers were reimbursed 106 percent of ASP. However, the biosimilars' add-on payment (i.e., the 6 percent additional payment above ASP) was based on the ASP of the reference product rather than on the biosimilar price. To increase the adoption of biosimilar products, the IRA increased this payment for biosimilars to 108 percent of ASP for the first five years following market entry.<sup>26</sup> Following this period, the biosimilars' reimbursement will return to the standard 106 percent.

While biosimilar entry in the United States has not been as robust as it has been in Europe, these products are gaining market share and competing on price with reference products. Consider figures 15 and 16, which show the ASP and market share for biosimilars and reference products based on the number of quarters since entry. The impact of these products varies, but in general they have reduced prices for the reference products. Some of this variation is based on the strategy of the reference product and the characteristics of the drug—which we discuss below.

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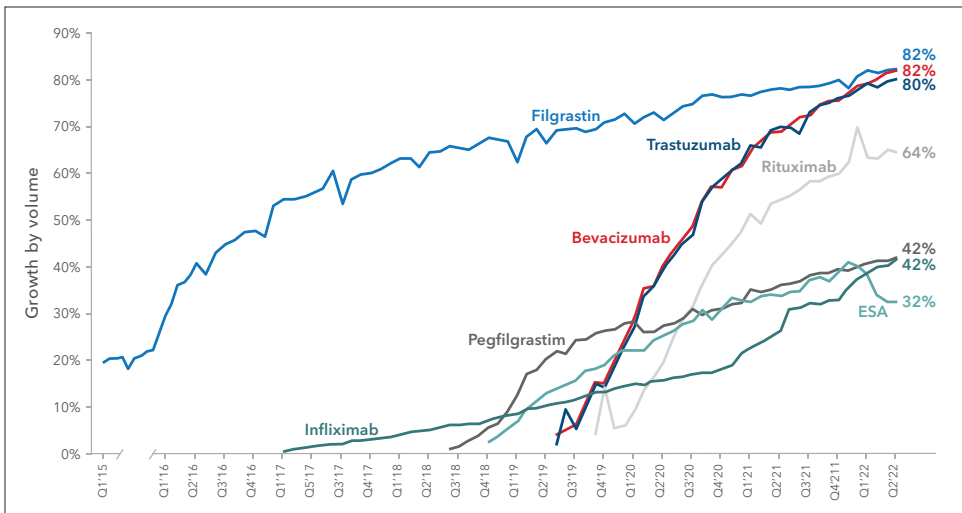
26 This payment is only available for biosimilar products with a price below the ASP of the reference product.

**Figure 15. Downward Trend in ASP for Biosimilars and Reference Products Over Time**



Source: Amgen (2022).

**Figure 16. Biosimilar Uptake Curve**



Source: Amgen (2022).

### 3. Economic Concerns Regarding Pharmaceutical Prices<sup>27</sup>

As discussed above, controversy over the high and rising prices of prescription drugs has resulted in legislative and policy activity including the passage of the IRA. The evidence is clear that such legislation will reduce the level of investment in

<sup>27</sup> Some of this text also appears in previous congressional testimonies by Craig Garthwaite.

new products and the pace of new biopharmaceutical product entry.<sup>28</sup> In addition, the blunt nature of such reforms often ignores valuable benefits that come from ongoing research into existing products. This phenomenon holds particularly true in the more complicated world of modern pharmaceuticals, in which products receive multiple indications (i.e., they are often approved by the FDA to treat multiple conditions). Such approvals can only be obtained through continued clinical trials and investment after a product launches. Regulations that shorten the period of exclusivity, for example, could impact welfare not only through the extensive margin of fewer products being introduced but also via the intensive margin of a decreased use of existing drugs resulting from reduced information about the potential clinical applications of those products.

The mere fact that innovation will decrease is not a reason to ignore questions regarding optimal drug prices. Our goal is not to develop a system that creates as many products as possible but instead one that maximizes social welfare. Given that so many features of the pharmaceutical market are dictated by government policy—in particular, the length and strength of intellectual property protection—the question of how much we pay for drugs is ultimately a policy decision.

Optimal policy should focus on identifying areas where the existing systems for acquiring or purchasing drugs and/or financing their purchase are causing unnecessary inefficiencies that decrease access to products today without providing sufficient incentives for firms to invest in future innovation. We detail several such areas for policy reform below.

*Optimal policy should focus on identifying areas where the existing systems for acquiring or purchasing drugs and/or financing their purchase are causing unnecessary inefficiencies that decrease access to products today without providing sufficient incentives for firms to invest in future innovation.*

### **3.a. Implementing Price Negotiation in Medicare Part B**

“Medicare,” defined as the Centers for Medicare and Medicaid Services (CMS), has historically been barred from directly negotiating the price of retail drugs. This proscription is often referred to as the *non-interference* provision of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), that is, the

<sup>28</sup> The exact magnitude of this effect is surrounded by a great deal of uncertainty. However, a clear body of research shows a strong connection between expected profits of new products and firm investments in research and development.

enabling legislation for Medicare Part D.<sup>29</sup> However, Part D relies on private firms that construct prescription drug plans and negotiate prices (Kirchhoff 2022).

As part of the IRA, CMS will now have a more direct hand in setting prices for the most expensive drugs in the Medicare program. CMS will effectively have an unfettered ability to set prices for small-molecule products beginning nine years after market entry and large-molecule drugs after 13 years. Such price setting power could have meaningful implications on the investment decisions of firms, particularly for the small-molecule products that may face price setting after a shorter period of time.

Even before the IRA, Part D had benefitted from price negotiations by private firms engaged in the retail prescription drug market. However, many policymakers and health policy experts have concerns that the physician administered drugs covered by Medicare Part B face less stringent negotiations. As detailed above, Medicare reimburses physicians under a buy-and-bill system that is governed by the price negotiated for the product in the commercial market. The purpose of this system is to provide doctors with simplicity and predictable reimbursement. In addition, Medicare hopes that this system will allow the government to leverage private-sector negotiations to secure lower prices with government involvement. Unfortunately, these attractive features come at a cost for the entire system, as Part B procurement rules increase prices for public and private markets while also potentially shifting market share at the margin to more-expensive treatment options.<sup>30</sup>

To understand the widespread effects of Part B, consider the motivations of a pharmaceutical manufacturer negotiating with GPOs and providers to determine a drug's optimal price. These profit-maximizing manufacturers set prices at a point that earns the greatest profits. Higher prices will, by definition, *decrease* the firm's total profits. They will do so because the increased margin per product sold will not make up for the lost quantity resulting from greater use of prior authorization, step therapy, increased cost sharing, or other utilization management tools. If such a decrease does not come about, then the profit maximizing firm was charging an inefficiently low price in the first place.

By linking public and private prices, however, the Part B purchasing rule distorts the optimal pricing decision in the private market. Firms are now willing to increase

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29 Specifically, the relevant clause states that “the Secretary: (1) may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors; and (2) may not require a particular formulary or institute a price structure for the reimbursement of covered part D drugs.”

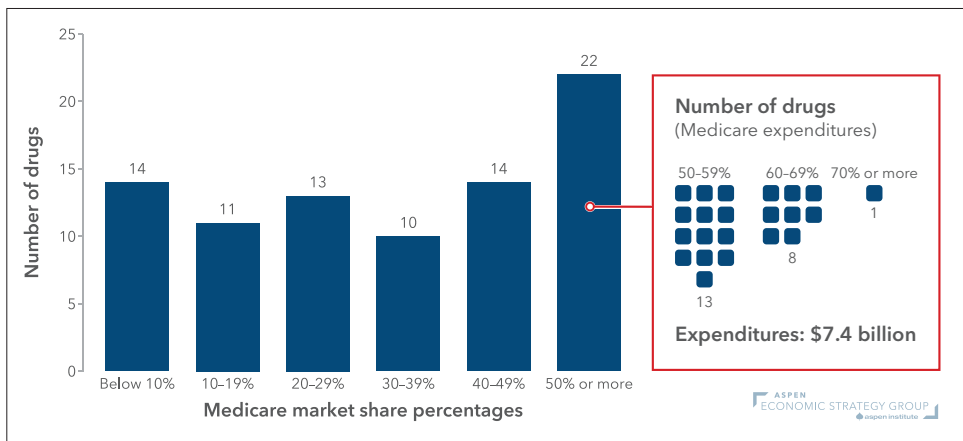
30 This pressure on prices is particularly acute in the case of launch prices. Given that the ASP is a lagging indicator of price, manufacturers face some difficulty in quickly raising prices because the actual price paid by physicians would start to outpace ASP updates. However, this phenomenon does not hold true for the initial launch price (Acquatella, Ericson, and Starc 2023).

private prices and suffer declining profits in the private market—if they calculate they can make up those lost profits and more from the public market. In addition, because they know physicians earn more money from administering a higher-priced drug, they have an additional incentive related to Part B for raising prices—because the profit motives of providers could increase demand for the product.

The combination of these factors means that the existing 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, Part B rules for purchasing physician administered drugs likely result in higher prices in both public and private markets.

Furthermore, these incentives to raise prices increase with Medicare’s market share in each drug, and (given the age and disease profile of Part B enrollees) many high-cost drugs already have a large Medicare market share. A larger Medicare market means the potentially higher reimbursement from the public payers is more important for determining profits than the lost sales in the private market. Figure 17 depicts Medicare’s 2015 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 (the categories overlap). For 22 of these drugs, Medicare is responsible for a majority of sales. As biologics continue to make up a larger share of newly approved products, the Medicare Part B system will become an even larger part of how prices in the pharmaceutical market are determined.

**Figure 17. Medicare’s Market Share for the 84 Most Expensive Part B Drugs in 2015**



Source: Government Accountability Office (2017).

Part B can cause higher prices not only because manufacturers have an incentive to raise private prices to influence the public market, but also because physicians have an incentive to prescribe higher-priced drugs (as they earn more for administering such products).

To address physician incentives, however, we must not create perverse incentives to inappropriately prescribe lower-cost drugs that don't provide sufficient clinical benefit for patients. We also must be careful about creating a situation where it is no longer economically viable for physicians to practice in particular areas or organizational forms. For example, reforming Part B procurement rules to simply pay physicians a flat fee for each administered drug would ignore the fact that physicians face 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 the liquidity needed to maintain sufficient stock of medications and may make prescription choices to limit these costs. At the extreme, such reforms could push further consolidation of the provider market, which could contribute to pricing and access concerns.

One policy solution is to adopt more of a vendor model for the distribution of physician administered drugs. Such a model would transform the existing buy-and-bill market system to one in which physicians have little financial incentive to prescribe particular medications. The details of such a fundamental shift in the market are important and must be worked out. In doing so, we must better understand why previous attempts to establish a similar model under the Competitive Acquisition Program (CAP) did not successfully attract vendors and providers.

Certainly, this failure came about in part because many providers are dependent on revenues from the buy-and-bill system. This dependency, however, is not a good reason to avoid such policies. If firms obtain an inappropriately large share of revenues from the existing system, that fact is *precisely why* we need reforms.

The political and practical reality is that any successful reform must figure out how to attract physicians and other providers into the system. In addition, such a program would need to be attractive enough to vendors to induce new entrants to the market. Achieving this aim would likely require empowering vendors to walk away from particular drugs to secure greater discounts. Absent such power it would be difficult to make the vendor model sufficiently attractive to potential entrants. This change may limit some patients' access to Medicare drugs, but we must be honest that some degree of reduced access is a necessary part of any price negotiation process.



### 3.b. Promoting Small-Market Generic Competition

Promoting competition in generics is likely to produce substantial gains for consumers because generics are produced in such large quantities. Reducing barriers to entry is especially important in this market. For example, entrants into the cartelized markets described above faced high costs and long delays before beginning production. While the FDA has introduced reforms to reduce delays, new abbreviated new drug applications (ANDAs) have also grown over time.<sup>31</sup> The financial and time costs reduce returns to entry. In turn, many firms may decide not to enter these markets. Additional reform is necessary, which may require more funding for regulatory agencies or other means of decreasing regulatory costs for firms.

Even so, not all markets will attract new entrants. Small product markets may simply be unable to support more firms. Since firms compete on price, profits are determined by a firm's ability to manufacture products at the lowest marginal cost. Price competition incentivizes entrants to produce enough to reach the minimum efficient scale of their production process. Absent sufficient quantity, entrants will find themselves at a perpetual cost disadvantage relative to incumbent firms. For sufficiently small markets, there is only enough demand for a single manufacturer to reach this scale. A natural monopoly and associated pricing are the result.

In recent years, several firms appear to have recognized the pricing power available to ANDA holders for generic products with sufficiently small potential markets. A good example was the pricing strategies of Turing Pharmaceuticals and its now infamous CEO Martin Shkreli, who dramatically raised the price of a generic drug used mainly to treat toxoplasmosis, a parasite infection. Aspects of this strategy have also been implemented by other firms and documented in media outlets (see, e.g., Hopkins and Martin 2018; Pollack 2015; and Rockoff and Silverman 2015). The number of generic-market monopolies has increased over time. Prices have increased in these markets, although the increases could be due to a range of factors, including the growth of precision medicine, changes in product costs, consolidation, and anticompetitive behavior.

These firms' ability to charge monopoly prices for generic products is not a reflection of the tradeoff between access today and innovation tomorrow; society has long since paid for the innovation from these products. The high prices represent firms taking advantage of a market failure created by the small patient population and

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31 An ANDA is the process by which a small-molecule generic firm is able to develop and market a drug in the United States. This process was created as part of the 1984 Hatch-Waxman Act. Rather than requiring generic firms to undertake the entire clinical-trial process required of innovative medicines, these firms must only demonstrate that their products are bioequivalent (i.e., chemically identical) to the reference products. This process was an attempt to lower entry costs for and increase the number of entrants into these generic markets.

relatively high costs of entry. While large pharmaceutical firms were historically either unwilling or unable to exploit this pricing power, the practice of firms charging high prices without fear of entry in small generic markets is now widespread throughout the industry.<sup>32</sup> Solutions to this problem will need to come either from firms being harmed by this practice or through government action.

If high, fixed entry costs make it difficult for multiple firms to profitably produce small-market generics, one potential solution is to lower these fixed costs. Doing so would make it easier for new entrants to reach scale and compete with incumbent manufacturers. In recent years, the FDA has focused on accomplishing this goal through programs such as streamlining and harmonizing the generic application process across developed countries (Gottlieb 2018). 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 (Elvidge 2018).

The FDA should 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 spending to demonstrate the safety and bioequivalence of the product—and this spending will always represent a meaningful fixed-cost investment. Therefore, another potential solution to promote entry is to increase the size of some generic markets. While such an increase can't be accomplished by finding more patients with relevant conditions, we could 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 the total quantity and the number of products that could successfully be produced by multiple manufacturers.

Even after efforts to decrease costs and increase market sizes, some markets will still be unable to support multiple firms. In these cases, further regulations are likely necessary to reach an efficient outcome. For example, lawmakers could empower the FDA to provide a new form of market exclusivity for generic products with market sizes that do not support multiple competitors.

The specifics of such exclusivity would need to be worked out, but a first step would be to examine how many potential patients are necessary for a market to support multiple generic firms. While most generic prescriptions are for molecules that can support multiple competitors, there are potentially many molecules with small

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<sup>32</sup> It is important to note that this practice is largely limited to smaller firms at the periphery of the market. While larger biopharma firms do at times sell generic products, they have largely avoided this type of pricing behavior.

patient populations that can't support multiple manufacturers. For example, the number of exits by ANDA holders has increased in recent years, with many firms citing a lack of profitability. The median generic market currently has only two manufacturers, and approximately 40 percent of markets have a single manufacturer, likely due to limited market potential (Berndt, Conti, and Murphy 2017).

The current number of firms participating in a market in equilibrium does not definitively tell us whether the market could support multiple firms. 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 (Silverman 2019). Therefore, it is important for agency economists to determine the market size and structure that would indicate that the market for the generic product is a natural monopoly where the incumbent firms possess significant pricing power. Ideally this investigation would incorporate the potential market-expanding policies of decreasing entry costs and increasing the market size to include some foreign markets.

After establishing the market characteristics likely to lead to natural monopolies, the FDA would undertake a request for proposal (RFP) process for those markets. Any private firm could thereby apply for the rights to be the exclusive manufacturer of a natural-monopoly generic medicine at a certain fixed percentage above manufacturing costs. Firms would compete on the margin they would require to serve the market. The winning firm would be granted the exclusive rights to sell the drug at this regulated price for a time sufficient to recover the fixed costs of entry. At that time, the FDA could react to market exclusivity. To ensure the efficient operation of this process, the FDA may also need to set a maximum percentage that they will accept before they turn to a nonprofit or government supplier for the product. This cap would limit the ability of firms to collude to divide up the markets they choose to enter.

Creating competition in small-market generics is important to undertake now, as this problem will only grow. Recent scientific advances have allowed for greater personalization of medicine. A well-documented and rising share of clinical trials involve patient-specific biomarkers to determine either efficacy or safety (Chandra, Garthwaite, and Stern 2018). In recent years, trials for these types of products have increased. Almost by definition, personalized medicine will involve products with limited patient populations, and we should be worried about whether robust generic competition will emerge for these products.<sup>33</sup> It will be easier to address the problem

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<sup>33</sup> The problem of competition for precision medicine will be further complicated in situations where the patented product is a biologic.

of small-market generics now than it will be when the number of powerful interests manufacturing such products increases.

At the same time, it is important to maintain quality. Generic quality for foreign products is especially problematic. If it is not profitable to provide quality, production quality requires rigorous inspection. Such inspection will require additional funding for regulatory agencies, such as the FDA. Research suggests that the consumer benefits of such funding are likely to outweigh their costs. Rather than relying on inspections and enforcement actions, Congress and the FDA should also consider rules that create more transparency about sources and quality in the generic market. Currently, the market is cleared on only one dimension: price. This circumstance rests on the belief that every product in the market is of similar quality and therefore competitive. Several high-profile examples in the generic market suggest that this untested belief may not be true. Introducing more information about product origin and manufacturing would allow generics manufacturers to aim not simply for the cheapest possible production process but for the most *efficient* process, that is, one that provides a specific level of quality at the lowest price. In the current market, where customers have little information about the source of their drugs, this incentive is almost absent.

### **3.c. 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 could 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 anticompetitive 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 many potential products are competing 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, "We told [companies], we're going to be pitting you all against each other. Who is going to give us the best price? If you give us the best price, we will move the market share to you. ... We'll exclude the other products" (Wehrwein 2015).

In situations where manufacturers are competing for access to the PBM's entire patient population, these types of contracts are likely to be pro-competitive, leading to large discounts and increased welfare. However, large portions of some product markets are not truly contestable, so PBMs will not be able to effectively move patients to lower-price products. For example, patients who are currently medically

stable on a biologic product are unlikely to switch to a competing biosimilar at almost any price. In addition, PBMs might find that plan sponsors would not be happy with strategies that forced their patients to move across biologic products.<sup>34</sup>

When 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 manufacturer finds that it cannot offer the PBM a large enough rebate on its products (which represent a relatively small share of its 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 hard to gain meaningful market share. Perhaps more concerning, rival-referencing contracts may induce potential biosimilar firms never 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 Novartis CEO Vas Narasimhan (Liu 2018; Narasimhan 2018). These concerns were also the subject of antitrust litigation between reference products and biosimilar firms that was recently settled (Biosimilars Council 2018; United States District Court for the Eastern District of Pennsylvania 2017).

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 a new entrant—for example, for a first biosimilar entering against a reference product—regulators may want to create additional restrictions on rebate contracts referencing the position of rival products on the formulary. In particular, it may be necessary to consider separate rules for contracts and rebates based on whether patients are treatment naïve (i.e., have been diagnosed with a condition but not initiated a biologic treatment for it) or medically stable on a particular biologic product, as well as whether the product is for a chronic or acute condition. While it may be hard to write rules for biologic treatments for chronic conditions with a large installed base, doing so should be the goal of such policies.

Some may ask why government intervention is needed here if these rebate walls raise prices in the market. In considering why government intervention may be necessary to address these contract structures, it is important to note that even if exclusive contracts limit entry and raise market-wide prices in equilibrium, for each PBM demanding that contract, they receive a lower price today. As a result, each

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<sup>34</sup> Plan sponsors are not simply looking for the lowest-cost plan, but instead the plan that best balances costs and benefits for their customers or employees.

PBM has an incentive to demand a bid from a manufacturer for exclusive formulary placement. Constructing such an exclusive formulary could maximize the rebate for the PBM and allow for a more competitive product. Any individual PBM would benefit from such a contract and may not be able to influence the individual entry decision for any particular product. This state of affairs could result in a commons problem that might be best solved by government action. Absent a government solution, in the future there will be less product entry, but there is no existing entity that can internalize the externality of the demands for exclusive contracts.

### ***3.d. Addressing Potentially Excessive Cost Sharing and the Value of Insurance***

As described above, features of the existing market have resulted in high cost sharing for some of the most expensive medications. This circumstance is in part the result of explicit decisions to raise contractual cost sharing for enrollees. The growing spread between list and net prices interacts with this cost sharing (which is often a function of the list rather than the net price) to further increase cost sharing.

While some of the spread between list and net prices results from more robust negotiation by PBMs, some also appears to be driven by the same economic incentives detailed in the discussion of rebates above. Specifically, that differential cost sharing can transfer resources from sick to healthy patients in the form of lower premiums and decrease the attractiveness of the plan to potentially expensive patients (Geruso, Layton, and Prinz 2019). In that way, high cost sharing undermines the community-rating and guaranteed-issue regulations that are popular among consumers and policymakers, and it does so in a way that may not be obvious to customers until they have purchased the insurance product and suffered a negative health shock. At this point, these customers may find that they have less insurance coverage than they anticipated.

In response to this increasing high cost sharing, pharmaceutical companies have implemented a variety of co-payment assistance and coupon programs. While these programs increase access to expensive pharmaceuticals, they have also been shown to increase overall drug spending (Dafny, Ody, and Schmitt 2017). They are especially likely to do so when coupons are available for products that have a bioequivalent generic product on the market. In such a setting, the coupons undo efficient financial-utilization management and shift customers away from less-expensive generic alternatives.

While it is tempting to view coupon programs as an attempt to undermine utilization management by payers, the reality is more complicated. Manufacturers offer co-payment assistance partly because these payments have gotten so large that they restrict access to medications for liquidity constrained customers—and thus may undermine the very purpose of health insurance in the first place (Besanko,

Dranove, and Garthwaite 2020). This position is not magnanimous on the part of manufacturers; when customers are unable to access drugs because of cost sharing, it decreases their revenue.

Cost sharing is used for a few reasons, including that it can be used to control moral hazard in the form of the overconsumption of drugs that don't provide sufficient value. It can also be used to move patients across products as part of price negotiations. Both rationales can increase the efficiency of health insurance markets.

However, when plan sponsors implement high cost sharing on products that do not have therapeutic substitutes or on all products in a class, their strategies can undermine the generosity of the insurance contract. This circumstance likely decreases the welfare created by the insurance contract. This type of high cost sharing on particular products is particularly concerning if customers are not aware of this incompleteness when they make their purchasing decisions—which is quite possible given the complexity of pharmaceutical products. This lack of awareness is even more apparent if the terms of the formulary—specifically, which products are on which tiers—change during the middle of the contract period.<sup>35</sup>

Excessive cost sharing has historically been particularly problematic in Medicare Part D, where (as we discuss above) patients who use expensive pharmaceuticals face high exposure to the cost of their drugs throughout the catastrophic period. These Medicare patients also are unable to use manufacturer coupons because of federal anti-kickback statutes and as a result, they find themselves trapped between manufacturers and insurers.

A fraction of this excessive exposure was addressed by the payment redesign of Medicare Part D in the IRA, but large amounts of cost sharing in both Part D and commercial plans remain. It does not appear that this cost sharing is about addressing moral hazard or shifting share across competing products. In addition, many manufacturers have offered expanded payment-assistance programs that seem more designed to subvert the negotiation process and blunt PBM bargaining power than to provide access to liquidity-constrained patients.

Therefore, policymakers should jointly address the questions of cost sharing and coupons in the prescription drug market. One possibility would be to create upper limits on both (a) the amount of cost sharing that can be charged to consumers, and (b) co-payment assistance in the commercial market. This compromise could address both sides of this issue and deserves more consideration.

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35 Depending on the plan contract, enrollees may be able to switch contracts within the year. For example, Medicare Part D enrollees are able to switch plans each quarter. However, for some commercial and individual market plans, enrollees are unable to switch plans mid-contract.

### **3.e. Improving the Flow of Information between PBMs and Plan Sponsors**

A second concern about the current system of confidential rebates and other payments between manufacturers and PBMs is that it creates an incentive for a PBM to give a preference to a higher-list-price drug that offers greater rebates and other fees—even if it has a higher net price for the plan sponsor. Effectively, the concern is that the PBM will not be a good agent for its principal, the final payer. As we discuss above, this concern reflects a fundamental question about the amount of competition in the market for PBM services.

As we discussed above, 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 state of affairs reflects a lack of competition for these services rather than an inherent problem with this contractual form. Policies to address this practice should then focus on the market structure for PBMs rather than the contractual form of particular payment arrangements.

Whether or not the PBM market is competitive remains unclear. Even in cases where PBMs are earning excess profit, new competitors are unlikely to successfully enter the market if there are large barriers to entry, perhaps because scale is necessary for competition. Furthermore, strong competition is less likely to emerge given that plan sponsors 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 practice provides information about the surplus created by their prescriptions. That said, despite these efforts, payers remain unaware of all the funds flowing between PBMs and manufacturers. In addition to rebates, PBMs receive administrative fees and other payments from manufacturers, as described above. These fees are often structured as a function of the list price, a state of affairs that further calls into question the distinction between a “fee” and a “rebate.” Part D plans are often not required to report rebates to CMS. This lack of transparency in the Medicare program has been one area of concern; another has been the competing interests that arise for PBMs and manufacturers when administrative fees are based on WAC prices (Grassley and Wyden 2021: 81).

Sophisticated payers hoping to gather more information about the flow of funds between PBMs and manufacturers often face restrictions on auditing their PBM-payer contracts (Weinberg and Langreth 2017). These constraints may entail excluding particular auditors that are deemed to hold views 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 (Advisory Council on Employee Welfare and Pension Benefit Plans 2014). While many of these restrictions can be cast as attempts to maintain rebate confidentiality, they also create information asymmetry between PBMs and payers about the amount of available surplus. In turn, such asymmetry negatively affects the efficiency of their bargaining.

Given these concerns, there have been numerous policy efforts to end confidential rebates based on drug price and to shift the market to a series of up-front price discounts and flat fees negotiated between PBMs and manufacturers (United States Department of Health and Human Services 2019). Such a reform would effectively end the confidentiality of negotiated prices while not decreasing the amount of surplus captured by PBMs, since a PBM with market power can calculate a flat fee as easily as it can figure out its take under the current percentage-based rebate system.

Both major political parties are coalescing on ending rebates. Frustrated by rising drug prices, people are looking for a scapegoat, and a system of shrouded prices set by large firms makes a convenient target. However, it would be unwise to limit the ability of PBMs to negotiate large discounts. Instead, we should move to a system where all payments between manufacturers and PBMs flow first to payers before being split with PBMs (Garthwaite and Scott Morton 2017). PBMs and payers would be free to negotiate any split of the rebates, fees, and other funds paid by manufacturers, but such a negotiation would then occur between two parties with equal information about the amount of money at stake. One possible way to move to such a system would be for regulators to end the safe harbor for payments between manufacturers and PBMs and create a separate safe harbor for payments between manufacturers and payers. If the current PBM market is competitive, this proposed solution should have little effect on the distribution of surplus.

### **3.f. Increased Pharmacy Competition**

A recurring theme in our proposals is encouraging robust competition at all stages of the value chain. The retail pharmacy market is increasingly concentrated due to a variety of factors.

1. Independent pharmacies have declined in importance. Today, two-thirds of establishments are retail chains, supermarkets, or mass retailers. Mass retailers can often undercut independent pharmacies by using prescription drugs as a loss leader to drive traffic, increasing sales of other products.

2. The past several decades have been marked by vertical and horizontal consolidation. For example, CVS has been vertically integrated with a PBM for over a decade and has acquired a number of smaller regional chains.
3. The growth of use networks by payers has led to lower generic reimbursement, making it difficult for independent pharmacies to remain financially solvent.

Despite greater concentration, consumers are fairly willing to switch pharmacies. Switching to lower-cost pharmacies can lead to cost savings from selective contracting. Because consumers do not have strong preferences for a particular pharmacy or chain, payers can threaten to exclude pharmacies from their networks. To avoid exclusion, pharmacies must offer substantial discounts.

As a result, the retail pharmacy market is competitive today despite higher levels of concentration throughout the value chain. However, the balance between a small number of buyers and a small number of sellers is fragile, especially given barriers to entry. This fragility is especially problematic given that there are a small number of wholesalers and therefore there is always a possibility of tacit collusion emerging (AmeriSource Bergen, Cardinal Health, and McKesson) in addition to the small number of PBMs.

In focusing on the structure of the pharmacy market, policymakers should separately consider retail and specialty pharmacies. Firms in these two markets generate value for customers in different ways—with independent specialty pharmacies potentially having ways to generate unique value for patients compared to their chain counterparts. As plan sponsors, PBMs, and specialty pharmacies become more vertically integrated, there are concerns about how these relationships may weaken competition and decrease welfare. These risks become particularly acute when independent pharmacies attract patients with particularly expensive conditions—thereby enabling plan sponsors to restrict patient access to specific pharmacies in order to create advantageous selection at the expense of sick people.

Beyond considering market structure and competition between pharmacies, we should continue to encourage the use of lower-cost generic drugs. While most prescriptions are filled with generics, additional savings are possible—perhaps particularly so in government programs that traditionally do less steering of consumers. For example, as more states transferred oversight of Medicaid drug benefits to private firms, private insurers generated savings by shifting patients from branded drugs to their generic equivalents or to closely related generics (Dranove, Starc, and Ody 2021).

Private insurers can negotiate lower point-of-sale prices at pharmacies. We should also encourage competition among retail pharmacies, where savings are achievable. We might, for example, encourage the adoption of preferred pharmacy networks. Prices can vary up to 40 percent for generics across retail pharmacies; preferred networks encourage consumers to fill their prescriptions at locations with the lowest prices. In turn, when insurers have greater bargaining leverage over pharmacies, prices are further reduced (Starc and Swanson 2021). Of course, such arrangements could involve important access tradeoffs. Yet evidence from the Medicare Part D context suggests that patients don't travel substantially farther under these plans and do benefit from reduced out-of-pocket costs at preferred pharmacies.

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