



Prescription Drug Pricing: An Overview of the Legal, Regulatory, and Market Environment

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Policy attention is now focused on prescription drug prices, which in some cases have grown sharply in recent years, and the financial burden that high prices can sometimes place on patients. The Trump administration has announced its intention to pursue changes in various policies to bring down prices or to slow their growth. The protection of intellectual property is an important component of dynamic economic growth and medical progress in the US. However, it does create pricing power for the inventors of new therapies, which in turn makes it difficult for policymakers to ensure access to effective care is within reach for all patients and is affordable for tax-subsidized programs. The pricing of prescription drugs occurs in a market influenced by a complex web of public policies and private-sector conventions that were assembled over many years on an ad hoc basis. These policies secure somewhat lower prices for some purchasers but likely raise the prices for others. While there are no simple solutions, policymakers should study the existing arrangements carefully and consider what can be done to promote more supply competition (thus minimizing monopolistic pricing) in all drug categories. They should also think creatively about how to promote more pricing leverage for consumers rather than adopt government price controls. The policy goal is to strengthen countervailing pressure from purchasers to negotiate better prices for consumers, rather than provide preferential pricing for narrow segments of the market.

American consumers and policymakers are increasingly concerned about the high cost of prescription drugs. In a recent survey, 40 percent of respondents said that lowering prescription drug prices should be Congress' top priority (Demko 2017). Lower prescription prices paid in other advanced economies are frequently cited as evidence that new policies are needed to address this issue (Council of Economic Advisers 2018).

Policies to moderate the cost of prescription drugs should be based on an understanding of the

complex web of federal and state laws and regulations that govern the manufacture, sale, distribution, and pricing of pharmaceuticals. The interaction of governmental rules, payment regulations, and industry practices is complex and often opaque, making it difficult for policymakers to develop proposals to promote lower costs while maintaining incentives for scientific research that leads to new, more effective treatments.

This report provides an overview of the major factors that affect the prescription drug prices paid by purchasers and patients.

The issues addressed are complex, involve a long history of legal and commercial precedents, and interact with each other in ways that complicate the policy process. This report introduces a topic that can sometimes attract solutions that sound straightforward but that may have serious unintended consequences.

The Starting Point: Patent Law, the Food and Drug Administration, and Hatch-Waxman

There is an ongoing tension between promoting pharmaceutical innovation and maintaining access to affordable, safe, and effective medical treatments. Pharmaceutical research is a high-cost, high-risk venture that can take years of work with no guarantee that the process will end with a product that a company can sell in the marketplace. Intellectual property protection through the patent system and other regulations is needed to foster that kind of research. But such protection also gives the innovator significant market power to set prices and reduces competition that can result in lower prices. The policy challenge is where to set the balance between promoting innovation and ensuring affordable access to effective medical therapies.

The US Constitution established intellectual property protection as a core responsibility of government. Article I, Section 8 of the Constitution grants Congress the power “to promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries” (United States Senate 2017). President George Washington signed the first patent law in 1790, and Thomas Jefferson, then secretary of state, sat on the original board vested with the authority to grant patents (Patent and Trademark Office 2002).

The Constitution made patent protection temporary to ensure there would be incentives for continuous progress and to prevent inventions that would be broadly beneficial to society from being held back permanently from widespread use (Walterscheid 2002).

Companies that develop new drugs or biologic products typically secure patents protecting the intellectual property associated with the potential therapies. Patents are granted by the Patent and Trademark Office to applicants who discover any new, useful, and novel “process, machine, manufacture, or composition of matter.” Patents last for 20 years from the date of the application and prohibit competitors from making and selling products that infringe on the inventor’s property rights (Congressional Research Service 2016).

The Food and Drug Administration (FDA) regulates the sale and use of all pharmaceutical products, including those with patent protection. In 1962, amendments to the Federal Food, Drug, and Cosmetic Act codified the requirement that all new drugs must be deemed “safe and effective” to be marketed and used in treating patients. Safety and effectiveness are determined through clinical trials. Once completed, the pharmaceutical company can seek approval to sell the drug in the US market by filing a new drug application (NDA) with the FDA.

The Drug Price Competition and Patent Term Restoration Act of 1984—commonly referred to as the Hatch-Waxman Act after its chief sponsors, Sen. Orrin Hatch (R-UT) and Rep. Henry Waxman (D-CA)—provided protections for drug innovators while facilitating and providing incentives for introducing generic competitors to brand-name drugs. The new law was, in part, a reaction to federal court decisions in a patent infringement case, *Roche Products v. Bolar Pharmaceutical*. Bolar’s use of the active ingredient in Dalmane, a treatment for insomnia, to develop a generic version was ruled a violation of Roche’s patent for the compound even though the use was said to be experimental and noncommercial.

Hatch-Waxman struck a compromise intended to establish clearer rules for the entry of generic competitors into the market. The law includes the following provisions:

- Generic competitors are permitted to begin work on generic versions of drugs at any time during the term of a drug product patent so long as that work is related to meeting FDA regulatory requirements for the eventual marketing of a generic version of the drug.
- Generic competitors are allowed to rely on the safety and efficacy findings reported in a brand-name NDA when filing for approval

of a generic version. This new type of drug approval application—an abbreviated new drug application (ANDA)—can be filed when there is bioequivalence between the generic and patented products.

- Drug companies are given an additional period of patent protection. Patents for drug products can be extended for one-half of the time between the initial drug application (called an investigational new drug application) and the filing of an NDA, plus the full time between the filing of an NDA and FDA approval of the drug. The patent term extension cannot exceed five years, and the full period of the patent after FDA approval cannot exceed 14 years.
- Applicants with an approved NDA are granted a period of “data exclusivity.” Data exclusivity means the FDA will not accept applications from generic competitors using clinical data that were the basis for FDA approval of the innovator drug. Data exclusivity is granted for three years for new indications for an existing drug, five years for new chemical entities, and 12 years for biologics (MedPAC 2016).
- The FDA also confers “market exclusivity,” which promotes introducing generics by not approving a similar product for a period of time. Market exclusivity is granted for 180 days to the first generic drug competing with a branded product, for seven years for “orphan drugs” (with a targeted patient population of no more than 200,000 patients), and for six months for certain pediatric products.

Hatch-Waxman substantially lowered the cost of bringing generic drugs to market, mainly by allowing generic competitors to piggyback on the clinical data submitted with an innovator drug’s NDA. Estimates of the costs of developing a new drug and getting it through the FDA approval process are controversial, with various studies providing widely diverging estimates (MedPAC 2017). One recent study estimates that developing a new drug costs an average of \$2.6 billion. The time from drug discovery to FDA approval is likely to take 10 years or more. In contrast, the cost of getting a generic approved is estimated at between \$1 million and

\$5 million, over a period of three to five years. The costs of bringing a new drug to market are clearly far higher than for a generic drug.

The Biologics Price Competition and Innovation Act, which was incorporated in the Affordable Care Act (ACA), created an approval process for “biosimilar” products that is roughly parallel to the process for generic drugs (Johnson 2017). Biologic products are large-molecule therapies, generally derived from living biological organisms or tissues. Although making exact generic copies of biologics is not possible, clinical data from innovator biologics can be used to produce products that are biosimilar and do not have clinically meaningful differences from the FDA-approved product. The 2010 law confers data exclusivity on innovator biologic products of 12 years, after which companies seeking to produce biosimilars can use the innovator’s clinical data to begin the FDA approval process themselves (MedPAC 2016). The FDA has approved 10 biosimilar products since the 2010 law went into effect (FDA 2018).

Detailed information on FDA drug approvals is available in the agency’s compendia, the *Approved Products with Therapeutic Equivalence Evaluations* (commonly known as the Orange Book), for small molecule drugs and their generic competitors and the Purple Book for biologics and biosimilars. For generic drugs, the FDA provides a code of “A” to those that are therapeutically equivalent to patented drugs, while the FDA does not consider those coded with a “B” to be equivalent to the innovator product.

Patent protection and exclusivity rights provide incentives for innovators to make sizable investments and take substantial financial risks to develop new products. Those protections give innovators significant bargaining power in the market. If there are no branded or generic competitors with similar therapeutic benefits, demand will be inelastic, and prices will be higher than if there were competing products. Hatch-Waxman and the Biologics Price Competition and Innovation Act created regulatory pathways to promote introducing generics and biosimilars, which would limit the market power of the innovator firm and put downward pressure on prices.

No simple metrics exist for determining if the current mix of laws and regulations strike the right balance between promoting innovation and promoting competition in the pharmaceutical market. That question is further complicated by two important

facts. First, the pharmaceutical supply chain is complex, with various intermediaries, each of whom have a financial interest and considerable influence over the distribution and pricing of prescription drugs. Second, third-party payers—including private insurance and public programs—have their own financial incentives that determine their willingness and ability to negotiate prices and control access to drugs. The interaction between intermediaries on both sides of the market must be carefully weighed when developing policies intended to moderate price growth for prescription drugs.

The Industry and Its Practices: Manufacturers, Wholesalers, Pharmacy Benefit Managers, Formularies, and Rebates

According to the Congressional Budget Office (CBO), consumers obtain about three-quarters of their prescription drugs from retail pharmacies and the remainder from nonretail providers (CBO 2007). Retail pharmacies include storefront operations (such as chain pharmacies and pharmacies in food stores) and mail-order pharmacies. Nonretail providers include hospitals, clinics, other health care providers, and federal facilities. Consumers typically pay part of the cost of prescriptions, with the rest covered by third-party payers (including private health plans, Medicaid, Medicare, and the Departments of Veterans Affairs and Defense). The price of the product depends on a complex set of rules, rebates, discounts, and other cross-subsidies that vary depending on whether the consumer is paying fully out of pocket or is purchasing the prescription through a third party.

Figure 1 illustrates the product and payment flows associated with the production and distribution of pharmaceutical drugs. Moving pharmaceutical products from manufacturers to patients is heavily influenced by the need to maintain product security throughout the supply chain. The FDA has long imposed chain of custody rules on the

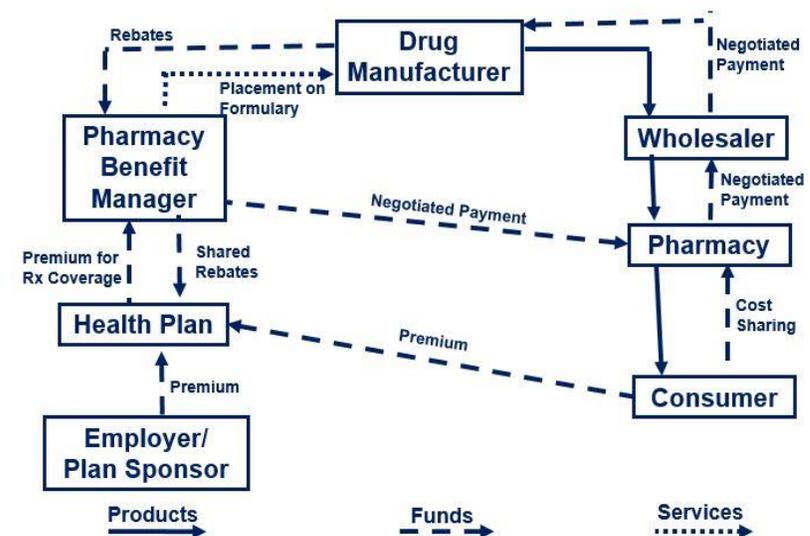
manufacturers and distributors of pharmaceutical products to ensure patients receive only authorized products that have been shipped and dispensed under proper conditions.

In 2007, Congress passed amendments to drug safety laws authorizing the FDA to impose risk evaluation and mitigation strategies (REMS) on prescribing and distributing certain drugs. Products with a REMS requirement in place may limit the number of physicians authorized to issue prescriptions for these products, as well as the number of pharmacies allowed to dispense them. REMS protocols can also impose restrictions on the manner in which the drugs move from manufacturer to patient (Congressional Research Service 2018).

Manufacturers can sometimes ship their products directly to retail pharmacies and nonretail providers, but they often rely on wholesalers for distribution. Wholesalers buy drugs from the manufacturers and resell them to the nation’s retail and mail-order pharmacies, as well as to hospitals, physician offices, nursing homes, and other licensed medical institutions and organizations. Wholesalers play an important role in the distribution system since they reduce the number of transactions that would be necessary if every retail pharmacy and nonretail provider had to independently order from hundreds of manufacturers.

In contrast, pharmacy benefit managers (PBMs) do not purchase drugs from manufacturers or deliver

Figure 1. Illustration of the Typical Movement of Products and Payments in the Prescription Drug Market



Source: Congressional Budget Office (2007).

them to pharmacies or other providers. They are hired by employers and health insurers to negotiate lower prices from manufacturers and retail pharmacy chains.

PBMs gain leverage in pricing negotiations with manufacturers mainly through using drug formularies. A formulary is a list of drugs available to enrollees in a health plan. Most formularies have tiers tied to how much the enrollee must pay out of pocket. Generic drugs are typically in the lowest tier with the lowest cost sharing. Branded products may be in higher tiers requiring higher cost-sharing amounts. Placement on the formulary depends on the price negotiated with the manufacturer, the availability of rebates, the availability of therapeutic substitutes, and other factors.

Because they represent many potential customers enrolled in different health plans, PBMs have considerable bargaining power to extract discounts from drug manufacturers, paid in the form of price rebates. In return for agreeing to make these rebate payments, the PBM agrees to place the drugs manufactured by the company on lower formulary tiers requiring lower cost sharing from patients. That incentive helps steer patients to preferred drugs, and greater sales volumes increase the amount of rebates.

Relying on rebates rather than upfront price discounts is controversial. Manufacturers are willing to offer discounts through rebates, which more closely align pricing discounts with actual product sales. PBMs and health plans also have an incentive to prefer rebates over price discounts.

Rebates lower the net prices paid by insurers for prescription drugs, but they do not necessarily lower the cost sharing required from the consumer. Rebates are typically paid to PBMs after the sales of the drugs to patients have been completed, and a share of those rebates is passed on to the employer or health plan. That payment to the plan can be used to lower premiums, reducing the employer's cost of sponsoring health plans for its workers. Rebates might not be used by plans to lower the cost-sharing requirements of patients consuming the highest-cost drugs.

When considering policies intended to slow drug cost growth, it is important to recognize that market concentration varies greatly across the different actors. Despite numerous competitors among drug manufacturers, and a robust market of

startup companies investing in experimental therapies, the corporate landscape for distributing and paying for drugs is highly concentrated, as shown in Table 1.

The significant regulatory requirements associated with the handling, storage, and distribution of pharmaceutical products, along with the benefits associated with scale, have led to consolidation in the drug wholesaler sector. Three wholesalers account for 90 percent of the revenue associated with the distribution of prescription drugs in the US: McKesson, AmerisourceBergen, and Cardinal Health.

The PBM and pharmacy industries are also highly concentrated. Three companies (CVS Caremark, Express Scripts, and OptumRx) control about two-thirds of the drug benefit management market, while four companies (CVS retail and mail order, Walgreens, Express Scripts mail order, and Walmart) control about half of the pharmacy market (Sood et al. 2017).

Federal Programs and Pricing Policies

The following are the major federal programs and policies that influence the pricing of prescription drugs, both within these programs and in the larger marketplace.

The Medicaid Drug Rebate Program. All state Medicaid programs cover outpatient prescription drugs. Concern about the rising cost of drugs and the impact on Medicaid budgets led to enacting the mandatory “best-price” rebate provision in the Omnibus Budget Reconciliation Act of 1990.

Best-price rebates are not tied to the actual prices paid by the states to pharmacies. Instead, manufacturers pay states a rebate on brand-name drugs equal to 23.1 percent of AMP or the difference between the best price for the drug and AMP, whichever is greater. Manufacturers of generic drugs must pay rebates of 13.1 percent of AMP. To discourage manufacturers from raising their prices to wholesalers, an additional rebate amount is required if the AMP for a drug rises more rapidly than general consumer inflation. The total amount of rebates cannot exceed 100 percent of AMP (Medicaid and CHIP Payment and Access Commission 2017).

The best-price requirement includes a strong enforcement mechanism. Only manufacturers who have entered into rebate agreements with the federal government are eligible to have their drugs or

Table 1. Pharmaceutical Sector Market Leaders (Percentage of Total Market)

Manufacturers (2016)	
Pfizer	12%
Roche	10%
Sanofi	8%
Johnson & Johnson	8%
Merck	8%
Novartis	7%
AbbVie	6%
Gilead Sciences	6%
GlaxoSmithKline	5%
Amgen	5%
PBM (2017)	
CVS Caremark	25%
Express Scripts	24%
OptumRx	22%
Wholesalers (2016)	
McKesson	34%
AmerisourceBergen	31%
Cardinal Health	24%
Pharmacies (2017)	
CVS	24%
Walgreens	16%
Express Scripts	11%
Optum Rx (United)	5%
Walmart	5%

Source: Statistics Portal (2018); Fein (2017); Fein (2018a); and Fein (2018b).

biologic products paid for by state Medicaid programs. In exchange for paying these rebates, manufacturers are protected from having their drugs excluded from coverage by Medicaid.

The introduction of the Medicaid rebate program changed pricing incentives in the pharmaceutical

market. Manufacturers must now include in their pricing decisions how offering steep discounts to certain purchasers will affect the rebate calculation in Medicaid. If a manufacturer offers a more heavily discounted price to a private purchaser, that new lower price must be extended to Medicaid. The resulting loss of revenue from Medicaid programs nationwide will almost always be larger than the revenue gain from expanded private sales.

The Medicaid rebate program has reduced the incentive for manufacturers to offer steep discounts to private purchasers and may have resulted in somewhat higher launch prices, particularly for drugs that are likely to have a significant market share in Medicaid (CBO 1996). The prices some private purchasers of brand-name drugs pay are probably higher than they would have been absent the rebate program.

The federally required best-price rebates are shared by the states and the federal government based on the Federal Medical Assistance Percentage used to determine the federal contribution to each state’s Medicaid program. Many states have separately negotiated with manufacturers for supplemental rebates, which are not shared with the federal government. Manufacturers who decline to pay these additional rebates run the risk of having barriers, such as prior authorization, imposed on the use of their products. (Prior authorization requires a physician to obtain approval from Medicaid before prescribing a particular medication.) Currently, 46 states plus the District of Columbia are collecting supplemental rebates from manufacturers through agreements of varying types (Centers for Medicare and Medicaid Services 2018).

The 340B Program. The Medicaid rebate program predictably discouraged manufacturers from offering deep discounts to private purchasers. After 1990, manufacturers quickly became sensitive to tracking their average prices (as measured by AMP) and their “best prices” because both can trigger large rebate requirements in Medicaid. Soon after the rebate program took effect, some of the discounts manufacturers had previously extended to purchasers serving lower-income populations were pulled back (Mulcahy et al. 2014).

Commonly Used Pricing Terms

Several pricing concepts are frequently used as the starting points for determining the actual prices various purchasers pay in the pharmaceutical market. The following are some of the more important pricing terms commercial purchasers and public programs use.

Average Wholesale Price (AWP). The AWP is a published list price for sales by wholesalers to retail pharmacies. It does not represent what pharmacies actually pay. Instead, it is sometimes used as the reference price for payments to pharmacies from payers such as Medicaid, PBMs, and insurers (CBO 2007).

Wholesale Acquisition Cost (WAC). The WAC is a publicly available manufacturers' list price for sales of drugs to wholesalers. However, it is not the price wholesalers pay to acquire drugs from manufacturers. For single-source drugs (which are brand-name drugs still under patent protection), the WAC often reflects what retail pharmacies pay wholesalers (CBO 2007).

Average Manufacturer Price (AMP). The AMP is the average price paid to manufacturers for drugs dispensed through retail pharmacies, after accounting for rebates and discounts paid to wholesalers or pharmacies. It does not include rebates paid to PBMs, Medicaid, or other insurers. Federal law requires drug manufacturers to disclose this information to the Centers for Medicare and Medicaid Services (CMS). The AMP is the reference price used to calculate rebates under the Medicaid program (CBO 2007).

Average Sales Price (ASP). Medicare Part B pays an amount equal to ASP plus 6 percent for Part B drugs and biologic products administered in physician offices and outpatient settings (described in more detail below). ASP was defined in law when Congress created the prescription drug benefit in 2003 to reflect the average sales price received by manufacturers from most purchasers, net of rebates, and discounts. Sales to Medicaid, Medicare Part D plans, and federal or 340B-covered purchasers are excluded from the calculation (Medicare Payment Advisory Commission 2017).

Best Price. Best price is the lowest manufacturer price (net of discounts and rebates) paid for a drug by any purchaser (excluding certain federal and state purchasers). Best price is used to calculate rebates from manufacturers to ensure that state Medicaid programs are, in fact, receiving the best price available in the market (other than sales to government purchasers, Medicare Part D plans, and entities purchasing under the 340B program (Medicaid and CHIP Payment and Access Commission 2017)).

The Patient's Price. While many different pricing terms are used in the industry, the price beneficiaries pay at the retail pharmacy is most politically salient. That price is a function of many different factors and depends heavily on the insurance coverage of the patient. For example, a patient needing a drug early in the year who has not yet paid the annual deductible may have to pay the full cost of the prescription. After that, the patient typically pays coinsurance or a fixed-dollar copayment. The amount of the patient's liability depends on whether the prescription can be filled by a generic, which formulary tier the drug is on, and other factors.

In 1992, Congress responded to the abrupt price hikes some purchasers faced by enacting Section 340B of the Public Health Service Act. The aim of 340B is to provide preferential drug pricing for safety-net facilities serving large numbers of lower-income households.

The 340B program does not require rebates. Instead, it places a ceiling on the prices that manufacturers can charge to “covered entities.” The price ceiling is set at AMP less the Medicaid rebate: 23.1 percent of AMP for brand-name drugs and 13 percent for generics (with some exceptions based on inflation and for certain types of drugs). The 340B ceiling is often below the net price state Medicaid programs pay for the same products because state Medicaid programs usually pay an initial price (before rebates) that exceeds AMP (Mulcahy et al. 2014).

Manufacturers are not required to participate in 340B, but most do because participation is a condition of participating in Medicaid and for selling to the Departments of Defense and Veterans Affairs (Mulcahy et al. 2014).

Sixteen categories of “covered entities” are eligible to purchase drugs under the 340B price ceiling. The main categories of covered entities are hospitals and clinics meeting eligibility standards, including federally qualified health centers and other clinics receiving federal grants, such as those providing care to HIV-positive patients. Not-for-profit and publicly owned hospitals with substantial low-income patient loads (disproportionate share hospitals or DSH) also qualify.

The ACA expanded the definition of “covered entities” to include facilities with special designations under the Medicare program, including critical access hospitals, sole community hospitals, rural referral centers, and cancer centers. About one-third of all hospitals are public or not-for-profit and have DSH percentages exceeding the 340B threshold.

Federal rules limit which patients receiving care from a covered entity are qualified to receive prescription drugs at 340B discounted prices. The benefits of 340B are confined to patients being treated in an outpatient setting (as opposed to patients admitted on an

inpatient basis). The 340B program allows all outpatient clinics associated with a qualified hospital to participate in the price ceiling program.

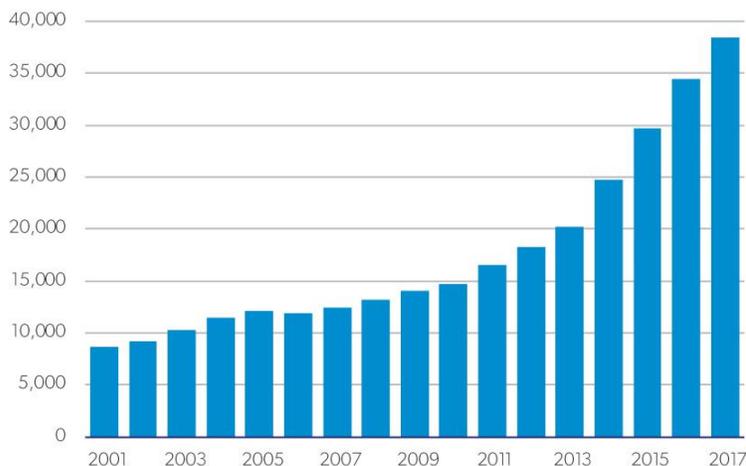
In general, eligible patients must be receiving care from someone who has a clear and recognizable professional affiliation with the covered entity. As a practical matter, there is little restriction on the types of patients who can be prescribed drugs purchased under the program.

Participating facilities can purchase drugs using 340B pricing directly from manufacturers or wholesalers and then store the drugs themselves at their sites. Alternatively, covered entities can contract with participating pharmacies to dispense the drugs to their patients.

Covered entities are not restricted in the prices they charge insurers or patients for the drugs they purchase under 340B. Consequently, covered entities can buy prescription drugs at discounted prices under 340B and then receive reimbursements from insurers and patients based on prices that exceed the price ceiling. For instance, hospital outpatient departments can purchase oncology drugs under the 340B price ceiling and charge Medicare higher rates when treating elderly patients covered by Part B (discussed below).

In response to the attractive discounts under 340B pricing and the ACA’s expanded list of covered entities, the number of covered entities participating in the program has exploded. Figure 2 shows that only 8,605 sites participated in the program in 2001. By 2017, the number had grown to nearly 38,400.

Figure 2. Growth in 340B Covered Entities



Note: The 2012 data are an approximation.
Source: Government Accountability Office (2011); and Government Accountability Office (2017).

Medicare Part B Payments for Prescription Drugs.

The Medicare program pays for prescription drugs under two separate programs. Drugs administered in physician offices and hospital outpatient departments are covered under Part B. These drugs generally require professional administration because they are injected or infused rather than consumed orally. Drugs that can be taken by the patient without professional assistance are covered under Part D (discussed below).

Providers (either physician offices or hospital outpatient departments) purchase Part B–covered drugs directly from wholesalers or manufacturers at prices that are negotiated privately and not tied to Medicare’s payment. The Medicare reimbursement rate is ASP plus 6 percent, which might exceed the price the provider pays.

Because providers keep the difference between the Part B payment and the price they actually pay, providers have a strong incentive to negotiate low prices for Part B drugs. The Medicare Payment Advisory Commission (MedPAC) analyzed invoice prices for 34 high-expenditure drugs purchased by providers under Part B. In most cases, the providers were paying a price that was below 102 percent of ASP, while Medicare was paying 106 percent of ASP for the products.

Further, because Medicare pays a 6 percent add-on to ASP, physicians and outpatient departments have an incentive to prescribe higher-priced products when lower-priced alternatives are available. A higher ASP creates a larger add-on payment from the Medicare program, giving suppliers more room to negotiate prices with purchasers.

Single-source drugs (for which there are no generics or biosimilars) are paid under their own unique billing code at ASP plus 6 percent. For multiple-source drugs, Medicare pays 106 percent of the weighted average ASP for all the products in the category. Payment for biosimilar products is 100 percent of the weighted average ASP for all the biosimilars in the therapeutic category plus 6 percent of the ASP for the particular biosimilar being used (Medicare Payment Advisory Commission 2017).

The Medicare Part D Program. In 2003, the Medicare Prescription Drug, Improvement, and Modernization Act (also called the Medicare Modernization Act or MMA) established a new

Part D prescription drug benefit—decades after many private health plans offered such coverage. Part D, which covers prescription drugs prescribed by physicians and dispensed at pharmacies, became available in 2006. Previously, beneficiaries obtained coverage through retiree plans sponsored by former employers, private supplemental insurance plans, or Medicaid—each of which provides wraparound coverage to Medicare and provides benefits beyond prescription drugs. Part D is voluntary and requires enrollees to pay a monthly premium.

The design of the prescription drug benefit is unusual. First, it is an insurance benefit that covers only prescription drugs rather than a wider range of medical services. Drug-only coverage is not available in the private insurance market.

Second, Part D is available only through private plans rather than through the government-administered insurance coverage model of the rest of the Medicare benefit. Beneficiaries have the option to choose their drug benefit coverage each year and are free to select from the competing options in their market area. (The country is divided into 34 drug plan markets.) Those options include stand-alone prescription drug plans (PDPs) or Medicare Advantage (MA) plans that cover the full range of Medicare benefits plus drug coverage, known as MA-PD plans.

Third, the MMA includes a noninterference provision that prohibits the Department of Health and Human Services (HHS) from involving itself in drug price contracts. Unlike Medicare Part A and Part B, which pay providers using detailed federally determined fee schedules, drug prices under Part D are set through private negotiation rather than public price controls.

This structure of private plans makes PBMs the primary competitors in the drug benefit marketplaces. The PBMs and other plan sponsors have strong incentives to negotiate prices that are as low as possible for the drugs on their formularies. Further, they are able to reduce their costs by encouraging patients to use generic products whenever possible. The law requires PBMs to cover at least two products in every drug class on their formularies, and there are six protected classes for which the PBMs must cover all available therapies.

Medicare pays a fixed monthly contribution toward Part D coverage based on premiums submitted by the private plans in a bidding process. Beneficiaries pay the difference between the government’s contri-

bution and the plan’s total premium. Consequently, beneficiaries have an incentive to select low-premium plans to minimize their monthly premium payments.

Private plan participation in the program has been robust from the benefit’s introduction in 2006. Although the law provides for a federally administered “fallback” plan if fewer than two privately administered plans are in a region, that provision has never been invoked. In 2018, 782 stand-alone PDPs are competing for enrollment across the country, and beneficiaries in every state have at least 19 options to choose from. Most MA offerings also include the prescription drug benefit.

The Medicare drug benefit has an unusual benefit design, reflecting Congress’ need to provide an attractive benefit while limiting the cost of the program (Figure 3). The standard benefit provides some upfront insurance protection (after an initial deductible) and catastrophic protection for high-expense cases. There is a coverage gap, or “donut hole,” requiring higher payments from enrollees. In the first years of the benefit, enrollees paid the entire costs of their drugs in the coverage gap.

Although the law specifies a standard structure for the Part D benefit, PDP and MA-PD plans are allowed to adjust the benefit parameters so long as the total value of what they will cover is actuarially equivalent to the value of the standard package.

The ACA adopted policies to close the donut hole. Beginning in 2011, brand-name manufacturers were required to provide a 50 percent discount on prescriptions filled in the coverage gap. Part D plans would gradually cover more of the costs in the donut hole. For generic drugs, the ACA gradually increased the portion of prescription costs covered by the Part D plans until it reached 75 percent in 2020. The beneficiary share fell commensurately, to 25 percent in 2020.

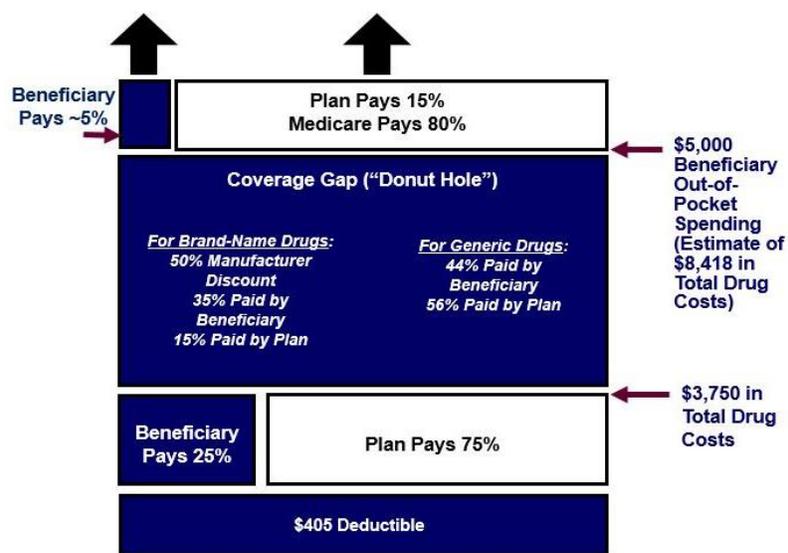
In 2018, the coverage gap is not yet fully closed. The initial deductible is \$405, and beneficiaries pay a 25 percent coinsurance rate on drug purchases above the deductible and below \$3,750 in total drug costs. Higher coinsurance rates are required in the coverage gap,

which runs from \$3,750 to \$5,000 in out-of-pocket costs (referred to as true out-of-pocket costs or TrOOP). Discounts from brand-name manufacturers in the coverage gap count as beneficiary payments when calculating TrOOP. Above that threshold, beneficiaries pay 5 percent of their drug expenses, while Part D plans pay 15 percent of the total. The other 80 percent is covered by the Medicare program (in effect, by general taxpayers).

Under the ACA, the coverage gap would have closed in 2020, with beneficiaries paying 25 percent coinsurance for all drug purchases between the deductible and the catastrophic spending threshold. Once the catastrophic threshold was reached, beneficiaries were to pay 5 percent of the cost of each prescription, with no cap on the total amount that the beneficiary would be expected to pay.

The Bipartisan Budget Act (BBA) of 2018 accelerated the closing of the coverage gap to 2019 by adjusting the distribution of payment obligations. Beginning next year, brand-name manufacturers must pay 70 percent of a beneficiary’s expenses in the coverage gap, and Part D plans must cover 5 percent of the costs. Beneficiaries will pay a 25 percent coinsurance rate on drug purchases in the gap (Kaiser Family Foundation 2018).

Figure 3. Medicare Prescription Drug Benefit, 2018



Source: Kaiser Family Foundation (2017).

In addition to phasing down beneficiary payments in the coverage gap, the ACA made a change that will allow beneficiaries to reach the catastrophic threshold more quickly—but only for a few years. Previously, this threshold and other program parameters were tied to the growth rate in overall per capita program expenditures. Under the ACA, for 2016–19, the catastrophic threshold is indexed to the lesser of the Consumer Price Index (CPI) plus 2 percentage points or the increase in average spending per Part D enrollee. Slowing annual increases in the threshold amount in this manner lowers the 2019 threshold by about \$1,000 compared with what it would have been without the change.

In 2020, the ACA will restore the threshold to the level it would have been if the indexing had not changed. As a result, the threshold will increase from \$5,100 in 2019 to \$6,350 in 2020 (Board of Trustees, Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, 2018). Such a large increase in the catastrophic threshold will mean delaying the financial relief from the lower cost-sharing percentage for large numbers of beneficiaries. That is likely to pressure Congress to provide a smoother, multiyear transition to the higher thresholds that would have occurred under pre-ACA law.

Part D spending growth has been relatively moderate since enactment, particularly compared to the initial projections of program spending. As shown in Figure 4, real per enrollee spending has risen at an annual average rate of just 0.9 percent since the program went into effect in 2006.

Part D plans or their PBMs have a strong incentive to seek rebates and other incentive payments from manufacturers and pharmacies. However, Part D plans have less incentive to bargain for lower drug prices at the point of sale. That is because the plan’s liability for drug costs drops significantly once the beneficiary has reached the catastrophic threshold. Medicare covers 80 percent of the cost (called “reinsurance”), while the plans pay only 15 percent (with the remaining 5 percent

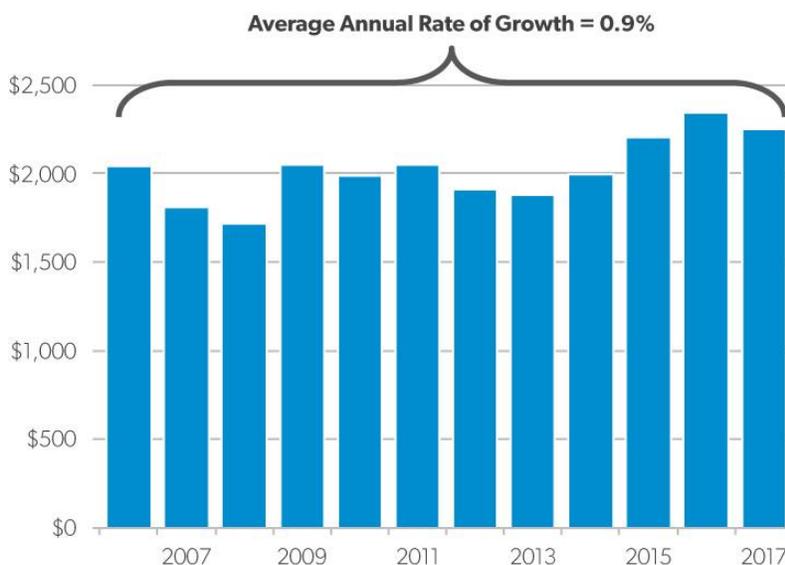
paid by beneficiaries). Given a choice between a lower gross price and a larger rebate, Part D plans generally prefer the larger rebate.

This incentive for large rebates has resulted in “a growing disparity between gross Part D costs, calculated based on cost of drugs at the point-of-sale, and net Part D drug costs,” which account for what CMS terms direct and indirect remuneration (Centers for Medicare and Medicaid Services 2017a).

Plans offering lower premiums are likely to attract greater enrollment, and large manufacturers’ rebates can help keep plan costs and premiums down. The issue is not rebates per se but rather what form those rebates take and how they affect beneficiary and program cost.

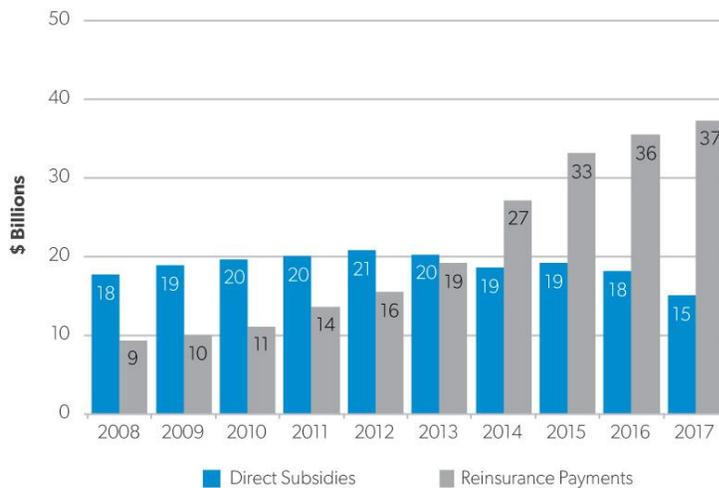
The program’s cost data show a pronounced trend toward higher gross prices for therapies used by patients with the highest annual drug costs. The Medicare program pays for 74.5 percent of the total cost of the program, split between direct subsidies to the plans, reinsurance for the catastrophic phase of the benefit, and payment of cost sharing for low-income beneficiaries. The other 25.5 percent is covered by beneficiary premiums. As shown in Figure 5, the plans have opted to get more and more of the overall subsidy from Medicare in the form of reinsurance payments.

Figure 4. Medicare Drug Benefit Per Enrollee Spending (2017 Dollars)



Source: Board of Trustees, Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds (2018).

Figure 5. Medicare Drug Benefit Direct Subsidy and Reinsurance Payments



Source: Board of Trustees, Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds (2018).

While the beneficiary premium is capped at 25.5 percent of program costs, there is no limit on the overall cost sharing that beneficiaries must pay. Cost-sharing amounts are based on the gross price charged for drugs at the pharmacy, not the net price that takes rebates into account. Consequently, the structure of the Part D benefit design may inadvertently provide an incentive for shifting more costs onto the beneficiaries in the form of higher cost sharing. Higher cost sharing might make the beneficiaries more price sensitive and thus also more willing to consider less costly therapies and interventions. On the other hand, some patients may find it difficult to pay the high prices, which could lead them to stop using therapies that would improve their health status.

The Department of Veterans Affairs. The Department of Veterans Affairs (VA) runs an integrated health system serving about nine million former members of the US armed forces. Most of the care is provided through facilities owned and operated by the VA and by clinicians who are directly employed by the agency.

For many years, the VA used formularies established by its many dispersed pharmacies to negotiate prices from drug manufacturers. Those arrangements were disrupted by the 1990 Medicaid rebate provisions, which led many drug companies to cancel the preferential prices they had extended to the VA, fearing that those discounts would also need to be extended to the entire Medicaid program.

In 1992, Congress responded to the canceled discounts by placing a ceiling on prices for the VA, the Department of Defense health system, the Public Health Services, and the Coast Guard. (These four federal agencies are sometimes referred to as the “big four.”) Drug companies are required to agree to these price ceilings as a condition of their participation in Medicaid.

The 1992 law specifies that these four systems can purchase drugs at a price that is no higher than the “non-federal AMP,” less a 24 percent discount. The nonfederal AMP is the AMP for all purchasers, not counting federal entities and federal programs. This price ceiling is roughly equal to the price the Medicaid program typically pays for branded drugs,

after the required rebate is included in the net price. If a drug has a “best price” for a nonfederal purchaser that is lower than the nonfederal AMP minus 24 percent, then the big four can purchase that drug at the lower price. As with Medicaid, the law also increases the discounting that applies if a drug has price inflation exceeding the CPI (McCaughan 2017).

Beyond this ceiling, the VA was also fully exempted from the Medicaid best-price calculation, which freed the agency to once again aggressively negotiate prices with manufacturers. In 1997, the VA moved to a single national formulary system for all its pharmaceutical purchases. This change substantially increased the agency’s leverage in price negotiations with manufacturers.

Several studies have shown that the VA generally gets lower prices for prescription drugs compared to other large purchasers. One study found that the VA paid an average of 38 percent of the average price paid for branded products, as measured by a survey of retail pharmacy invoices (McKinsey and Company Inc. 2015).

The Administration’s Initiatives

President Trump has stated on many occasions his intention to pursue policies that would lower the price of prescription drugs for consumers and the federal government. The administration included

numerous proposals aimed at drug pricing in the president’s annual budget submission to Congress (Office of Management and Budget 2018). The Department of Health and Human Services made a series of additional recommendations in May 2018 (Department of Health and Human Services 2018). The department also requested the public’s feedback on several additional concepts that might be pursued at a later date.

The following are the administration’s major themes and initiatives regarding prescription drug pricing. Table 2 provides a summary of the CBO’s estimates of the most significant proposals that appear in the president’s 2019 budget.

Improving Product Competition. A primary theme of the administration’s effort is to encourage, whenever possible, stronger product competition in the market for prescription drugs. Pricing for drugs clearly falls when multiple effective therapies are available for treating patients. The administration would like to promote stronger competition by lowering regulatory barriers to generic drug approvals, closing regulatory loopholes that allow brand-name and generic manufacturers to limit competition, and improving the payment environment for competing biosimilar products. These changes can be implemented without new legislation.

Rebate Reform. The administration argues that the current practice of using rebates to lower the net price of drugs distorts the market and needs reform. Rebates encourage manufacturers to raise

their list prices, which causes many consumers to pay more at the pharmacy counter by raising the retail price (for cash customers) or increasing cost-sharing amounts (for those with insurance). At the same time, rebates lower the overall prices insurers pay, but the administration argues that lower net prices are not passed onto the patients.

The administration is calling for a thorough review of the use of rebates in the pharmaceutical market and has proposed that a portion of rebates collected by Medicare Part D plans be passed onto Medicare beneficiaries at the pharmacy. The CBO estimates this latter proposal will increase Medicare spending because it will push premiums for Part D coverage higher (and thus push up the government’s costs) and may induce additional use of drugs by lowering the cost sharing required from beneficiaries. It is not clear if the administration has the authority under current law to require rebates at the point of sale. The overall effect of the administration’s rebate proposals is ambiguous, as it could increase or decrease total spending on prescription drugs depending on its details and responses of drug companies, PBMs, and consumers.

Other Medicare Part D Changes. In addition to redirecting a portion of PBM rebates, the administration proposes several structural changes to the Part D program.

The administration wants to redesign the standard Part D benefit. Both the ACA and the BBA of 2018 require that the discounts for brand-name drugs in the coverage gap count as payments by the beneficiary

Table 2. CBO Estimate of the Prescription Drug Proposals Contained in the Administration’s 2019 Budget

	Proposal	Change in Federal Outlays 2019–28 Billion Dollars
Medicare Part D Proposals	Allow More Plan Flexibility	–6.3
	Eliminate Cost Sharing on Generic Drugs for Low-Income Beneficiaries	+18.7
	Exclude Manufacturer Discounts from Beneficiary Out-of-Pocket Calculations	–58.5
	Establish a Maximum Beneficiary Cost	–1.5
Medicare Part B Proposals	Establish an Inflation Limit on Pricing	–1.5

Source: Congressional Budget Office (2018).

for purposes of TrOOP. The administration proposes to exclude these discounts from TrOOP, which would substantially increase the amount of spending required of some beneficiaries to reach the catastrophic threshold. The CBO estimates this change would reduce federal costs by \$58.5 billion over 10 years. To partially compensate for this change, the administration's budget also recommends eliminating the beneficiary's costs once the TrOOP calculation reaches the threshold, now set at 5 percent. The administration proposes to redistribute the costs of drugs above the catastrophic threshold by increasing the Part D plan liability from 15 to 80 percent of costs and lowering the program's share from 80 to 20 percent. The CBO estimates the net effect of these changes would be an increase in federal costs of \$1.5 billion over 10 years.

The 2019 budget also proposes to give drug benefit sponsors the ability to limit the number of drugs in each category or class to just one rather than two, as required under current law, and to eliminate cost-sharing requirements entirely for low-income beneficiaries when they are purchasing generic drugs.

Medicare Part B Reforms. Both the Bush and Obama administrations attempted to reform how Part B pays for covered drugs, but their proposals failed to gain traction and were largely set aside. The Trump administration is now attempting a reform of the program's drug payment system. The Department of Health and Human Services has announced that it plans to resuscitate the approach taken during the Bush years, called the Competitive Acquisition Program (CAP).

Under CAP, physicians can voluntarily enroll in a drug acquisition program, which allows vendors (presumably wholesalers and others) to negotiate pricing directly with the manufacturers. Medicare would pay these prices for drugs instead of the current rate of ASP plus 6 percent. Physicians would retain the ability to buy drugs themselves and get paid ASP plus 6 percent, as is the current practice. If vendors can negotiate lower prices, the savings could be shared among the physicians, beneficiaries, and the Medicare program. The Trump budget also called for putting an annual inflation limit on the growth of ASP.

The administration is exploring moving some prescription drug coverage from Part B to Part D of the program. Switching from Part B to Part D

would shift responsibility for pricing the products to the Part D plan sponsors, who would negotiate prices for these products and Part D products. Beneficiary cost-sharing requirements might fall if the Part D plans were able to secure lower pricing than is the case today under Part B. The CBO provided no cost estimate for this proposal because it is not yet clear which drugs might be targeted for the switch or if HHS has the authority to change coverage of certain products under current law.

Medicaid Demonstration. The administration has proposed to give up to five states the ability to test direct price negotiations with prescription drug manufacturers. States would be given the authority to establish formularies, with tiered pricing, and to exclude drugs from coverage when alternative therapies are available. These demonstrations are permissible under current law and would test whether states could secure lower net prices than occurs today with the statutory rebate program.

International Pricing. Member countries in the Organisation for Economic Co-operation and Development generally pay lower costs for brand-name prescription drugs than do insurance plans and consumers in the US. The Trump administration argues that these other countries are underpaying for drugs, which forces the drug manufacturers to charge higher prices in the US to fully cover their research costs and to compensate investors for the high risk of such investments. The administration-suggested remedy is to make this discrepancy an issue in international trade talks by demanding a fairer distribution of relative prices across all advanced economies.

Although this argument is featured prominently in the administration's drug pricing plan, it is unlikely to produce tangible results. Other countries with lower prices are unlikely to unilaterally agree to pay higher prices for the products they purchase simply because the Trump administration has demanded that they do so. And even if they were to raise their prices, there is no guarantee that pharmaceutical companies would lower US prices. The market for drugs in the US is unrelated to markets in other countries, and there is no direct relationship between prices paid here and prices paid for the same products

elsewhere. Prices would likely remain higher in the US because the demand for pharmaceuticals is driven by consumers and tends to be inelastic.

Considerations for Balancing Innovation with the Consequences of Single-Source Pricing Power

The pricing of pharmaceutical products is a difficult subject for public officials because society has an interest in both medical progress and affordable access to beneficial treatments. Patent protection provides a strong financial incentive for innovators to develop new medications, but high prices could limit patient access to effective care. The law's long-standing protection of intellectual property is an important reason that the US remains the world's largest and most dynamic economy. Although attaching patent protection to therapies can unquestionably help thousands—sometimes millions—of people, it also creates economic tensions that can be resolved only through political processes.

The question for public officials is how to create the right balance of incentives, restraint, regulation, and public subsidies to achieve the best combination of ever-improving care and reasonably affordable access for patients. The policies now in place are coming under increasing pressure because growing segments of society believe they are not striking the right balance.

The current mix of policies was assembled over a long period of time, and not systemically. Legal and regulatory changes have been made on an ad hoc basis to correct for the perceived problems of the moment. The result is a complex mix of public purchasing rules that works in some ways but that also produces distortions and problematic side effects. Among other things, the current mandatory discounts required for Medicaid, 340B covered entities, and large federal purchasers have left a smaller slice of the market to face higher, unregulated prices. Enrollees in employer-sponsored plans and other private insurance are now paying much higher prices than those who gain access through the mandatory public discounts, which is likely one reason for growing discontent.

As policymakers consider what might be done to strike a new balance of laws and regulations

affecting the market for prescription drugs, they should keep in mind the following considerations.

Supply Competition. Manufacturers of pharmaceutical products have maximum leverage over pricing when they face little or no competition. Patent law and exclusivity rights are the primary reasons manufacturers gain pricing power. But government regulation can also affect how quickly a product will face competition from another effective therapy. It is important to encourage generic competition as much as possible. But it is also critical to have more than one brand-name therapy available during the period of patent protection to prevent full monopoly pricing power for one manufacturer.

The Trump administration remains focused on improving the regulatory environment for introducing effective, competitive therapies. The FDA, in particular, has announced several measures aimed at speeding the introduction of competing products. The administration should also look at what can be done with research funding to speed up the development of competing therapies when one product dominates a drug class.

Rebates. The Trump administration is focused on reforming the rebate system, which is the predominant way manufacturers provide discounted net prices to purchasers. The financial benefits of rebates are seen in lower premiums for insurance plans. Efforts to shift some of the savings from rebates into the prices paid at the point of sale would benefit the patients with the greatest need. However, there is no evidence to date that this shift will lower overall spending on drugs. Lowering the price at the point of sale could increase overall drug spending, pushing up total costs to taxpayers and consumers.

Making Sense of Discounting. There is a strong temptation for policymakers to ensure that public programs and the beneficiaries participating in them have access to drugs at discounted prices. However, guaranteed discounts for one or several purchasers is likely to mean even higher prices for those who do not benefit from public regulation. The overall goal should be to strengthen countervailing pressure that can be brought to bear on pricing on behalf of all purchasers and consumers, not just a favored

segment of the market. This is likely to require rethinking the current discount system in a systematic way. One option would be to consolidate consumer demand through competing nongovernmental third parties, who would negotiate prices on behalf of large numbers of public and private insurance enrollees. The CAP that the administration plans to test for Part B drugs is one such model. Large PBMs play this role, although questions have been raised about how much consumers benefit from the rebates negotiated between PBMs, insurers, and drug manufacturers (Klein, Leonard, and King 2018). Privately negotiated prices on behalf of millions of consumers can better balance the interests of both the supply and demand sides of the markets, particularly when an effective brand-name therapy is still under patent protection and no competing alternative therapy is on the horizon.

Conclusion

The research needed to develop and bring to market effective medical therapies can take many years and billions of dollars. It often starts with basic research, funded largely through the National Institutes of

Health. When a promising idea or scientific approach is identified, biotechnology companies secure venture capital to test new concepts and hypotheses. A fraction of those efforts results in a real breakthrough, which leads to the introduction of a therapy that can dramatically improve the health status of many patients. The US has a vibrant ecosystem of researchers, private-sector entrepreneurs, and capital investors that leads to the introduction of more new therapies than any other country in the world. This system is built on a foundation of legal protection for intellectual property. In this regard, current public policy has been incredibly successful and should not be put at risk under any circumstances.

There is no question, however, that conferring market exclusivity rights on an important therapy will lead to high prices for purchasers or consumers in some circumstances. That's basic economics. The challenge for policymakers is to try to ensure there is strong supply competition to minimize the number of monopolistic pricing situations and then to create the proper balance of financial burdens when supply competition is limited. There are no simple fixes to these challenges, but it is likely that a more systematic approach would improve on today's ad hoc framework.

About the Authors

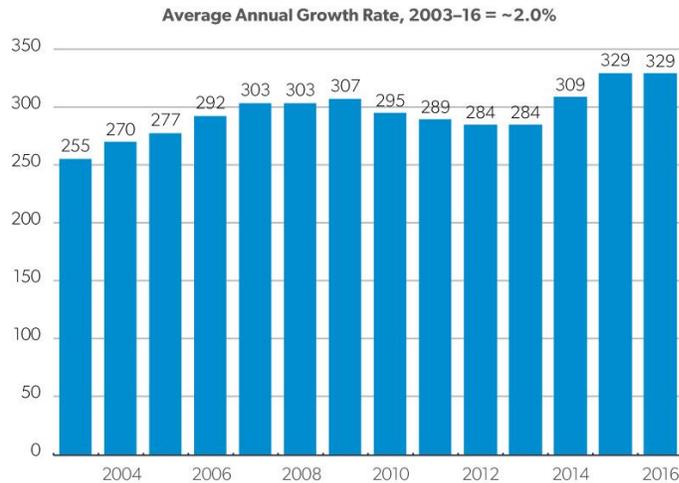
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Appendix

Aggregate spending on prescription drugs has grown at rates that roughly follow the pattern of overall national health expenditures. As shown in Figure A1, from 2000 to 2016, real spending on drugs dispensed through retail pharmacies grew at an average annual rate of about 2.0 percent after controlling for inflation, (National Health Expenditure Data Historical Tables 2017). During this period, overall spending in the health system grew at a similar rate. Prescription drug spending as a percentage of overall spending has thus remained fairly constant, at roughly 10 percent.

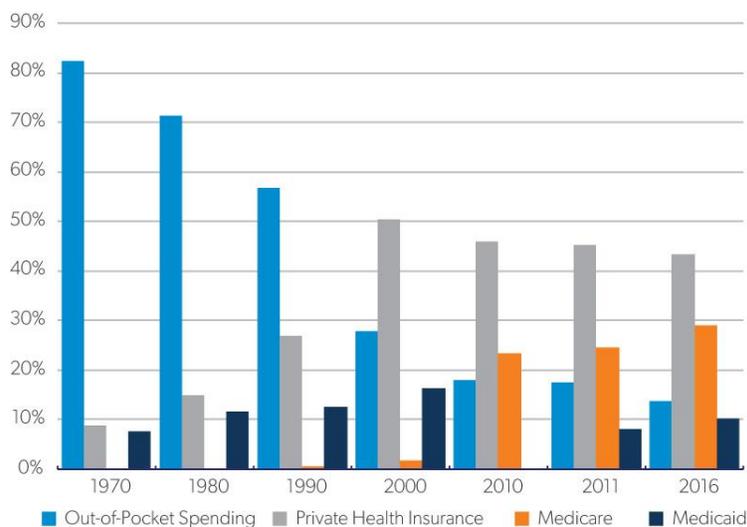
Figure A1. Aggregate National Spending on Retail Prescription Drugs (2016 Dollars)



Source: Centers for Medicare and Medicaid Services (2017b).

The distribution of prescription drug spending, by source of payment, has shifted over the past 40 years. As shown in Figure A2, in 1970, consumers directly paid for the vast majority of prescriptions. That began to change in the 1970s as more employers covered drug costs in the insurance plans they provided to workers and their families. The enactment of the Medicare drug benefit in 2003 provided public insurance coverage for seniors for the first time. Medicare now accounts for 25 percent of all payments for prescription drugs. While patients see rising prices for drugs, especially when they must pay for the costs themselves while fulfilling their insurance deductibles, overall out-of-pocket spending by consumers has fallen consistently over the years. Patients now pay for about only 14 percent of overall prescription drug costs.

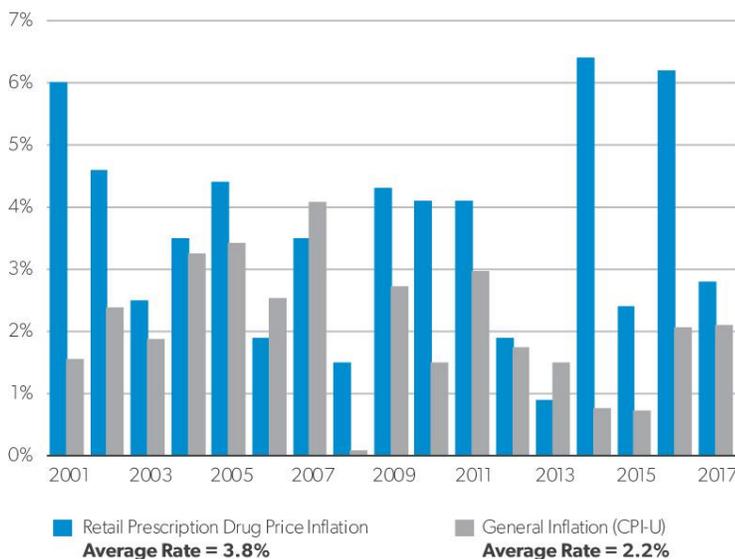
Figure A2. Sources of Payments for Prescription Drugs



Source: Centers for Medicare and Medicaid Services (2017b).

The Bureau of Labor Statistics tracks consumer inflation using survey methods. As shown in Figure A3, the retail prices for prescription drugs have risen more rapidly than the overall inflation rate for all consumer goods and services. From 2001 to 2017, retail drug prices rose at an average annual rate of 3.8 percent compared to 2.2 percent for all goods and services.

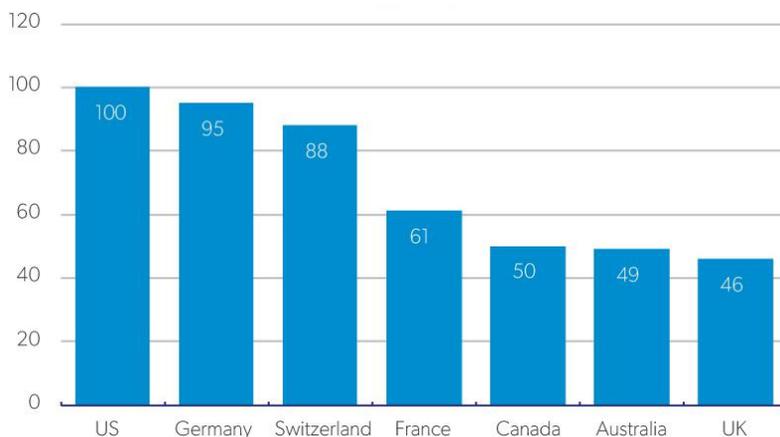
Figure A3. Comparison of Price Inflation Trends 2011–17



Source: Bureau of Labor Statistics (2018).

Other advanced economy countries have more centralized governmental control over their health systems than is the case in the US, and they typically use that control to extract pricing for prescription drugs that is below what purchasers pay in the US. As shown in Figure A4, based on a sample of drug prices, the US pays retail prices for brand-name drugs that are about 5 percent more than the prices Germany pays and more than double the prices Australia and the UK pay (Kavanos et al. 2013). This, and other similar studies, do not fully account for the large rebate system prevalent in the US, which lowers the net prices in the US.

Figure A4. Index of Retail Prices Paid for Selected Brand-Name Drugs in the US and Comparison Countries, 2010



Note: Index is from a sample of retail drug prices and may not fully reflect rebates and other discounting.

Source: Kavanos et al. (2013).

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