



Alternative Approaches to Reducing Prescription Drug Prices



At a Glance

In this report, the Congressional Budget Office discusses the factors underlying prescription drug prices and examines a set of policy approaches aimed at reducing those prices. The agency assesses how each approach, if implemented in 2025, would affect average drug prices for purchasers in the United States in 2031. Inclusion or exclusion of any approach does not imply an endorsement or a rejection by CBO.

Some of the approaches that CBO examined aim to reduce prescription drug prices by capping them or limiting their growth; others would reduce prices by promoting price competition or affecting the flow of information.

One examined approach would reduce prices by more than 5 percent—and possibly substantially more. That approach would set maximum allowed prices based on prices outside the United States.

An approach that expanded the Medicare Drug Price Negotiation Program would lead to a small reduction (1 percent to 3 percent) or a very small reduction (less than 1 percent) in average prices. An approach requiring manufacturers to pay inflation rebates for sales in the commercial market would lead to a small price reduction.

Four approaches would lead to a very small price reduction, no reduction, or a price increase. Those approaches would:

- Allow commercial importation of prescription drugs distributed outside the United States,
- Eliminate or limit direct-to-consumer prescription drug advertising,
- Facilitate earlier market entry for generics and biosimilar drugs (which are analogous to generic drugs but are made from living organisms), or
- Increase transparency in brand-name drug prices.

Reducing drug prices would save money for patients and payers, but reducing manufacturers' expected revenue from drugs that are not yet on the market would make investments in pharmaceutical research and development less profitable, thus decreasing the number of new drugs developed and introduced. Larger reductions in expected revenue would have a greater effect than smaller reductions.

Some approaches would have smaller effects on the prices of drugs launched after the approach was implemented than on those that were on the market beforehand. Additionally, some approaches would disrupt the availability of drugs in other countries, increase foreign drug prices, or both.

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Notes About This Report

This report focuses on prescription drugs purchased through retail channels, such as from local brick-and-mortar pharmacies and mail-order pharmacies. Because insurers use different payment mechanisms for prescription drugs that are administered by physicians or other health care professionals in outpatient settings or hospitals, prices for those drugs are not within the scope of this report. In the Medicare program, prescription drugs purchased in retail settings (and thus within the scope of this report) are covered under Part D, whereas drugs administered by physicians or other health professionals are covered under Part B.

Unless otherwise specified, in this report, a “prescription drug price” refers to the net retail price of a single unit of a prescription drug dispensed to a patient. The prescription drug price includes the amount paid to the pharmacy at the point of sale, including any cost-sharing obligation paid by patients, plus any payments by insurers or pharmacy benefit managers and minus any subsequent rebates or other payments from manufacturers or pharmacies to the purchasers of the drug.

The Congressional Budget Office examined how each policy approach in the report would affect the average net retail prices of prescription drugs in the United States—including prices for brand-name, generic, and biosimilar drugs—compared with prices under current policies in 2031. CBO characterized each approach as leading to a large, moderate, small, or very small reduction in the average prices of all retail prescription drugs or as causing no change or an increase in prices. An average estimated price reduction of more than 5 percent (whether substantially or slightly more than 5 percent) is referred to as large; a reduction of 3 percent to 5 percent is categorized as moderate; a reduction of 1 percent to 3 percent is small; and a reduction of 0.1 percent to 1 percent is very small. Any smaller price reduction or any price increase is described as no change or as an increase.

Summary

In this report, the Congressional Budget Office discusses the economics of prescription drug prices and the global pharmaceutical market and evaluates a set of policy approaches aimed at reducing the average prices of prescription drugs distributed through the retail channels in the United States. CBO selected the approaches examined in the report because they have been included in proposed legislation, discussed in the academic public policy community, or used in high-income foreign countries. Inclusion or exclusion of any approach does not imply an endorsement or a rejection by CBO.

This report focuses on the average prices that public and private purchasers pay for drugs in retail settings, net of postsale rebates and discounts. To the extent that approaches reduced manufacturers' expected revenue or increased their investment costs, those approaches would reduce manufacturers' incentives to engage in research and development (R&D) and would slow the pace of innovation in the pharmaceutical industry; those effects are discussed in the last section of this report.

What Determines the Prices of Brand-Name Prescription Drugs?

Several factors determine the prices of brand-name prescription drugs in the United States. One is the exclusive sales rights conferred under current law to manufacturers of newly approved brand-name drugs. In addition, prices in different market segments are influenced by regulations and other factors such as the prevalence and characteristics of health insurance coverage for prescription drugs. Competition from drugs with similar clinical effects can often reduce brand-name prices for all buyers.

Exclusive sales rights are conferred through patents and through rules governing drug approvals by the Food and Drug Administration (FDA). The period of exclusive sales rights for new drugs can vary in length because of patent litigation and other factors. Among a sample of brand-name drugs examined in a recent study, exclusivity periods lasted less than 12 years for a quarter of the drugs, 12 to 17 years for half of the drugs, and longer

than 17 years for the remaining quarter.¹ Those exclusive sales rights give manufacturers leverage in negotiating brand-name drug prices with insurers and other purchasers of prescription drugs. Manufacturers earn most of their profits from a typical brand-name drug during the period of exclusivity, and the prices they charge are higher than they would be if consumers could obtain the same drugs from competing manufacturers.

Insurance coverage, another factor affecting brand-name drug prices, insulates consumers from much of the cost of the drugs they use, making demand less sensitive to prices for insured patients. In some cases, federal law requires insurers to cover some or all drugs in a therapeutic class (a group of drugs that treat the same condition), which increases manufacturers' leverage in negotiating prices with insurers.

Manufacturers maximize their global revenue by charging different prices in different market segments, depending on the demand characteristics of those segments. Those demand characteristics reflect differences both in buyers' willingness to pay and in the regulations affecting prices in various markets. Differences in drug prices paid in different countries in part reflect that market segmentation, as do differences in prices paid by various purchasers within the United States.

The presence of multiple competing products in prescription drug markets puts downward pressure on prices faced by payers. For example, if a brand-name drug in its exclusivity period faces competition from at least one alternative brand-name product with similar clinical effects, its price will tend to be lower than it would be if the drug faced no such competition. At the end of that brand-name drug's exclusivity period, the availability of a generic equivalent or a biosimilar creates even more competitive pressure; when several generic or biosimilar

1. Benjamin N. Rome, ChangWon C. Lee, and Aaron S. Kesselheim, "Market Exclusivity Length for Drugs With New Generic or Biosimilar Competition, 2012–2018," *Clinical Pharmacology & Therapeutics*, vol. 109, no. 2 (February 2021), pp. 367–371, <https://doi.org/10.1002/cpt.1983>.

versions of the drug become available, consumers obtain them at significantly lower prices.²

How Would Different Policy Approaches Affect Prescription Drug Prices?

In this report, CBO examines seven policy approaches to reduce the net prices of retail prescription drugs in the United States. Broadly, three of the approaches would operate by capping the prices of prescription drugs or limiting price growth:

- Setting maximum allowed prices based on prices outside the United States;
- Expanding the Medicare Drug Price Negotiation Program, either to increase the number of drugs that undergo price negotiation each year or to make negotiated prices available in the commercial market; and
- Requiring manufacturers to pay inflation rebates for sales in the commercial market.

Four other approaches would operate by promoting price competition or by affecting the flow of information:

- Allowing commercial importation of prescription drugs distributed abroad;
- Eliminating or limiting direct-to-consumer (DTC) advertising of prescription drugs;
- Facilitating earlier market entry for generic and biosimilar drugs; and
- Increasing transparency in brand-name drug prices.

CBO assessed how each of the seven approaches included in the report would affect average retail drug prices in 2031, when the total retail prescription drug market is projected to surpass \$690 billion.³ For each approach, the effects would depend on the specifics of the policy (see Table S-1). The estimated effects of the approaches on price are characterized by size: An average

price reduction of more than 5 percent is considered large; a reduction of 3 percent to 5 percent is moderate; a reduction of 1 percent to 3 percent is small; a reduction of 0.1 percent to 1 percent is very small; and a reduction of less than 0.1 percent or a price increase is described as no change or as an increase.

CBO found that most of the approaches examined would have small or very small effects on prices. One approach—setting maximum allowed prices based on prices outside the United States—would have a large effect. None of the approaches examined would have an effect falling within the moderate range. Because of the size of the retail prescription drug market, even very small price changes could reduce drug spending by billions of dollars. The amount of savings that would accrue to any particular payer or program would depend on the specifics of the policy.

The effects of the approaches on average prices would change over time. For example, policies that exerted a greater effect on the prices of drugs already on the market than on future drugs would tend to have diminishing effects over time as more new drugs were launched and made up a greater share of the total market.

Many of the approaches would affect one or more subsets of retail drug sales and leave other sales unaffected. For example, in CBO's estimation, making negotiated prices available in the commercial market would lower the prices paid by commercial payers for drugs whose prices are subject to negotiation under current law by the Secretary of Health and Human Services (HHS), as well as the prices they pay for some other drugs that are therapeutic competitors of those selected for price negotiation. That same policy would also affect the prices of those sets of drugs in Medicare Part D and Medicaid. Prices of other drugs would be unaffected.

The overall price effect of such a policy would be a weighted average of the resulting price changes for affected sales and a price change of zero for unaffected sales. That policy would have a diminishing effect on prices over time because the prices of new drugs would decrease by less than those of drugs already on the market.

This report discusses other considerations relating to the approaches beyond their effects on average prices and on the development of new drugs. Some approaches could involve logistical or legal challenges that would need to be resolved before they could be implemented; others would affect the prices or availability of prescription drugs in foreign countries. CBO did not estimate the specific

2. A generic equivalent of a brand-name drug is a version of the drug with the same active ingredients, dosage form, strength, and intended use as the brand-name drug, but it is manufactured by a different company. A biosimilar is a biologic drug (one produced from living organisms rather than chemically synthesized) that is similar enough to a biologic drug approved by the Food and Drug Administration that it can be used in place of the original biologic drug.

3. Centers for Medicare & Medicaid Services, "National Health Expenditure Data: Projected," NHE Projections, Table 2, <https://tinyurl.com/2fht96ts>.

Table S-1.

Approaches to Reducing Prescription Drug Prices

Approach	Anticipated effect on average drug prices
Cap prices or limit their growth	
Set maximum allowed prices based on prices outside the United States	Large reduction: more than 5 percent (potentially substantially more)
Expand the Medicare Drug Price Negotiation Program	
Increase the number of drugs whose prices get negotiated each year	Small or very small reduction: 0.1 percent to 3 percent
Make negotiated prices available to all commercial purchasers	Small reduction: 1 percent to 3 percent
Require manufacturers to pay inflation rebates for sales in the commercial market	Small reduction: 1 percent to 3 percent
Promote price competition or affect the flow of information	
Allow commercial importation of prescription drugs distributed outside the United States	Very small reduction: 0.1 percent to 1 percent
Eliminate or limit direct-to-consumer prescription drug advertising	Very small reduction: 0.1 percent to 1 percent
Facilitate earlier market entry for generic and biosimilar drugs	Very small reduction: 0.1 percent to 1 percent ^a
Increase transparency in brand-name drug prices	
Require public reporting of net prices for brand-name drugs	No change (less than 0.1 percent) or a slight increase
Require pharmacy benefit managers to disclose net prices to insurers	Very small reduction: 0.1 percent to 1 percent

Data source: Congressional Budget Office.

a. CBO examined several policies for its analysis of this approach. In the agency's estimate, one policy would reduce average drug prices by less than 0.1 percent, and each of the others would reduce average drug prices by 0.1 percent to 1 percent.

effects of the different approaches on the federal budget, though the report includes a general discussion of the budgetary effects of changes in prescription drug prices.

How Would Different Policy Approaches Affect the Development of New Prescription Drugs?

Policies concerning prescription drugs involve a tradeoff between lowering prices for brand-name prescription drugs and fostering development of new prescription drugs for the future. The effect an approach would have on manufacturers' incentives to engage in research and development largely depends on how it would affect those manufacturers' expectations of future revenue or their cost of financing investment capital.

Manufacturers decide whether to invest in pharmaceutical R&D by weighing the expected revenue from new drugs against their expected development costs, which include financing costs. Manufacturers base their expected revenue on worldwide sales and not just those in the United States. But because the U.S. prescription drug market is larger than that of any other country, it plays an important role in manufacturers' decisions about R&D investments.

Policies that would lower the net prices paid to manufacturers for new prescription drugs would reduce manufacturers' expectations of future revenue. Policies that would lower their current revenue from products already on the market would, in some cases, make it harder for them to finance R&D investments without borrowing, thereby increasing their investment costs. Either of those effects would discourage manufacturers from investing in pharmaceutical R&D, and policies that induced larger changes in expected revenue or capital costs would have more pronounced effects on drug development.

Because revenue earned earlier in a drug's product cycle has a greater present value than the same amount of revenue earned later, reductions in expected revenue that occurred earlier in a drug's life cycle would tend to dampen incentives to develop new products more than reductions occurring later would. (A present value expresses the flows of current and future income or payments as a single number. That number, in turn, depends on the discount factor used to translate future cash flows into current dollars.)



Chapter 1: Factors That Determine Prescription Drug Prices

Once a drug has been developed and approved for sale, drug manufacturers set the price to maximize their revenue. Resources that have already been expended on research and development (R&D) activities represent sunk costs and are not a relevant consideration for manufacturers in determining that price. Pharmaceutical firms considering an R&D project assess the project's expected costs, along with the likelihood of success in developing a new marketable drug and—if it is approved for sale—the revenue it would earn. The prices that maximize manufacturers' revenues from brand-name drugs depend on factors such as exclusive sales rights for newly approved brand-name products, the prevalence of health insurance coverage for prescription drugs, and buyers' willingness to pay for brand-name drugs in various market segments. Regulations also often affect the prices of brand-name drugs, particularly in developed foreign countries. Brand-name drugs often face competition from other drugs with similar clinical effects, which can put downward pressure on prices.

The exclusive sales rights conferred under current law to manufacturers of brand-name drugs are a key factor determining prescription drug prices in the United States. Exclusive sales rights enable those manufacturers to charge higher prices than they could if their drugs faced direct competition from generic or biosimilar versions, particularly when those brand-name drugs have no close therapeutic substitutes. They are less able to charge higher prices when other drugs on the market confer similar clinical benefits. Manufacturers make most of their total revenue from a brand-name drug during its period of exclusivity. After that period ends, other manufacturers are permitted to sell competing generic or biosimilar versions, and the resulting competition puts downward pressure on the prices consumers pay.

Another factor influencing brand-name drug prices is insurance coverage for prescription drugs, which insulates consumers from some of the cost of drugs,

dampening the incentive for patients or providers to economize.¹ When a patient has reached an annual limit on out-of-pocket spending, all further drug costs are borne by the insurer, so the patient no longer has any incentive to economize. The combination of exclusive sales rights and insurance can give drug manufacturers considerable leverage in their price negotiations with purchasers, leading to higher prices.²

In many high-income foreign countries, drug manufacturers' ability to set prices is limited by regulations or greater sensitivity to prices, even when those manufacturers have exclusive sales rights and patients are covered by insurance. As a result, the foreign price for a particular brand-name prescription drug is often less than half the corresponding price in the United States. For generic drugs, prices in the United States and other high-income countries are more comparable.

Trends in Prescription Drug Prices

Growth in average prices for brand-name drugs in the United States has outpaced inflation in recent years. In Medicare Part D, for example, the average price for a one-month supply of a brand-name drug, calculated in 2018 dollars net of rebates and discounts, rose from \$149 in 2009 to \$353 in 2018—an average annual increase of about 10 percent.³ In Medicaid, the average

1. In some cases, coupons from drug manufacturers further insulate consumers from drug costs.
2. For some drugs—particularly generic ones—an insurance plan's cost-sharing requirement exceeds what a consumer would pay to purchase the same drug without insurance from certain large retailers. See Erin Trish and others, "Comparison of Spending on Common Generic Drugs by Medicare vs Costco Members," *JAMA Internal Medicine*, vol. 181, no. 10 (July 2021), pp. 1414–1416, <http://tinyurl.com/3emmxu67>; and Patrick Liu and others, "Medicare Beneficiaries' Out-of-Pocket Costs for Commonly Used Generic Drugs, 2009–2017," *American Journal of Managed Care*, vol. 26, no. 3 (March 2020), pp. 112–117, <https://doi.org/10.37765/ajmc.2020.42635>.
3. For more details about price increases, see Congressional Budget Office, *Prescription Drugs: Spending, Use, and Prices* (January 2022), www.cbo.gov/publication/57050.

net price increased from \$147 to \$218 (in 2018 dollars) during the same period, an average annual increase of about 4 percent. Part of that rise reflects year-to-year growth in prices of existing drugs on the market. Another important part of that rise reflects increased utilization of newly launched brand-name drugs with initial launch prices that were higher than those for drugs introduced in earlier years.

Greater use of generic drug products has restrained growth in total spending on prescription drugs, even as brand-name drug prices have risen. Generic drugs, which are usually priced much lower than their brand-name counterparts, accounted for 90 percent of all prescriptions in 2018, compared with 75 percent in 2009. Largely because of that greater share, average prescription costs have fallen, even though brand-name drugs have become more expensive. In Medicare Part D, for example, the average price of a prescription in 2018 dollars fell from \$57 in 2009 to \$50 in 2018; in Medicaid, the average price fell from \$63 to \$48 during that period.⁴

Exclusive Sales Rights

Manufacturers of new brand-name prescription drugs are protected from direct competition with generic or biosimilar products during the period of exclusive sales rights granted under current law. The leverage that manufacturers possess during that period results in consumers' paying higher prices than they would if the drug faced direct competition. Such leverage can be substantial if a drug is in high demand and confers unique therapeutic benefits. Some brand-name drugs—even those not subject to generic or biosimilar competition—face competition from other drugs that are partial substitutes with similar therapeutic effects. In such cases, manufacturers have less negotiating leverage with payers, placing downward pressure on prices.

In the United States, exclusive sales rights are conferred through a combination of patent protection, which is also granted for many other types of innovations, and regulatory exclusivity granted by the Food and Drug Administration (FDA), which is specific to prescription drugs.⁵ The primary statute governing small-molecule

drugs—that is, chemically synthesized drugs—is the Drug Price Competition and Patent Term Restoration Act of 1984 (known as the Hatch-Waxman Act). The effective period of exclusive sales rights for new small-molecule brand-name drugs varies, depending on factors such as the stage of development the drug was in when the manufacturer applied for a patent. The period of exclusivity tends to last for 12 to 17 years after approval for small-molecule products.⁶ For biologic drugs—those produced from living organisms—the primary statute is the Biologics Price Competition and Innovation Act of 2009 (BPCIA). On average, biologics have longer periods of exclusivity than small-molecule drugs.

Market Segmentation

Instead of charging one price everywhere, manufacturers maximize their total revenue by charging different prices in different market segments according to the particular demand characteristics of each segment—a practice known as price discrimination. Price differences among purchasers within the United States, as well as the different prices paid in different countries, are in part a reflection of that practice. If price discrimination (by country and within the United States) was not possible, manufacturers would charge a revenue-maximizing price reflecting the demand characteristics of the overall market. In such a hypothetical scenario, prices would be higher and the quantity of prescription drugs consumed would be lower than they currently are in some market segments (such as in foreign countries with lower income than the United States); in other segments, prices would be lower. Manufacturers' global revenue and profits would be less, reducing their incentive to develop new products.

manufacturing processes. The exclusivity rights granted by the FDA prevent generic or biosimilar versions of a drug from being approved for sale for a specified period. See Kevin J. Hickey and Erin H. Ward, *The Role of Patents and Regulatory Exclusivities in Drug Pricing*, Report R46679, version 6 (Congressional Research Service, January 30, 2024), <https://crsreports.congress.gov/product/pdf/R/R46679>.

4. The average price for a generic prescription also fell in Medicare Part D and Medicaid during that period. Those statistics do not include biosimilar drugs, which were not widely available through retail channels during that period.

5. Patents for a drug can cover its active ingredients as well as other characteristics, such as formulations, delivery mechanisms, and

6. One recent analysis examined 105 small-molecule drugs for which generic versions first entered the market between 2012 and 2018. Of those, a quarter had generic competitors after less than 12 years, half had generic competitors after 12 to 17 years, and a quarter had market exclusivity for more than 17 years. See Benjamin N. Rome, ChangWon C. Lee, and Aaron S. Kesselheim, "Market Exclusivity Length for Drugs With New Generic or Biosimilar Competition, 2012–2018," *Clinical Pharmacology & Therapeutics*, vol. 109, no. 2 (February 2021), pp. 367–371, <https://doi.org/10.1002/cpt.1983>.

Brand-Name Drug Prices in the United States

Some of the many purchasers of prescription drugs in the United States include commercial insurers, participating Part D plans, Medicaid, direct federal purchasers such as the Department of Veterans Affairs, and people who have cost-sharing obligations or who purchase drugs without insurance. The different prices paid by those parties have different effects on the federal budget (see Box 1-1). When drug manufacturers sell to a private payer, they have broad discretion to set prices, though regulations exert some influence on those prices. When manufacturers sell to a public payer, statutory rules and regulations strongly influence prices.

In the commercial market, net prices for brand-name drugs are determined through negotiations between the drug manufacturers and insurers or their pharmacy benefit managers (PBMs). Manufacturers are often willing to offer rebates that reduce net prices in exchange for a greater volume of sales when insurers or PBMs can steer patients toward specific drugs. Insurers or PBMs have the greatest leverage to obtain such rebates when a brand-name drug faces competition from similar products within a therapeutic class.⁷ For example, they can use formularies—lists of covered drugs and their cost-sharing requirements—that place a preferred drug on a formulary tier with lower cost sharing. Insurers and PBMs can also steer patients to particular drugs through utilization management tools like required step therapy.⁸ Commercial purchasers who do that more effectively can obtain lower prices than purchasers who are less able to influence utilization choices. But cost-based utilization management may also increase the likelihood that a patient does not receive the most clinically appropriate therapy.

In some circumstances, regulations influence the prices that emerge from negotiations between commercial insurers and brand-name drug manufacturers. For example, most insurance plans in the nongroup and small-group markets are required to cover at least one drug

in every therapeutic class of drugs as an essential health benefit, which reduces insurers' leverage in negotiating discounts.

In Medicare Part D, which is delivered through private plans, the insurer or PBM negotiates prices with manufacturers under market conditions similar to those for other commercial insurers, but their leverage in negotiating prices for some drugs is limited by a statutory requirement that plans cover all available products in certain classes of drugs as well as at least two drugs in other classes.⁹ Since October 2022, manufacturers have been subject to an inflation rebate policy for their Part D sales. Under that policy, if a drug's average manufacturer price (AMP) rises faster than the consumer price index for all urban consumers (CPI-U), then the manufacturer owes a rebate to Medicare.¹⁰ Beginning in 2026, under the Medicare Drug Price Negotiation Program, Part D plans will also be able to purchase certain drugs at prices determined in negotiations between manufacturers and the Secretary of Health and Human Services.

Prices paid by other public insurers in the United States vary substantially, reflecting factors such as statutory pricing rules, regulations, and whether and how drug formularies are used.¹¹ Some public payers, including Medicaid, receive rebates or other discounts that are specified by statute. In Medicaid, drug prices are lower than they are for many other payers. The Medicaid Drug Rebate Program specifies a minimum rebate amount that drug manufacturers must pay to state Medicaid agencies. The rebate has two components. The first is the basic rebate, which is the larger of either 23.1 percent of a brand-name drug's AMP or the difference between the AMP and the lowest net price available to any private-sector purchaser (the "best price"). The second component is an inflation rebate similar to the one recently introduced in Medicare:

7. Craig Garthwaite and Amanda Starc, "Why Drug Pricing Reform Is Complicated: A Primer and Policy Guide to Pharmaceutical Prices in the US," in Melissa S. Kearney, Justin Schardin, and Luke Pardue, eds., *Building a More Resilient US Economy* (Aspen Institute, 2023), pp. 74–128, <https://tinyurl.com/mu56dxjh>.

8. In step therapy, the insurer covers a costlier treatment only if the patient starts therapy with a cheaper alternative but that initial treatment is not successful. Insurers often use step therapy when more than one drug is available to treat a condition and those drugs differ in cost.

9. Plans participating in Medicare Part D are required to cover all drugs in six "protected" therapeutic classes: immunosuppressant, antidepressant, antipsychotic, anticonvulsant, antiretroviral, and antineoplastic (cancer) drugs.

10. The average manufacturer price is the average price paid to a manufacturer for a drug distributed to retail pharmacies, either through wholesalers or through sales directly from manufacturers to pharmacies. It is not adjusted to account for rebates or other price concessions that manufacturers extend to pharmacy benefit managers or health insurers.

11. Congressional Budget Office, *A Comparison of Brand-Name Drug Prices Among Selected Federal Programs* (February 2021), www.cbo.gov/publication/56978.

Box 1-1.

How Would Lower Prescription Drug Prices Affect the Federal Budget?

A general decline in prices for retail prescription drugs would reduce the federal budget deficit through a combination of different mechanisms. Four main mechanisms operate in different programs and segments of the market:

- A decline in prices would reduce federal outlays on prescription drug purchases, both for federal agencies and for state Medicaid agencies using federal matching funds.
- Lower prescription drug prices would reduce federal payments that subsidize private health insurance plans that cover those drugs as a benefit.
- Lower drug prices would reduce the share of employees' compensation that is in the form of nontaxable benefits for employment-based health insurance, thereby increasing the tax base and revenues to the federal government.
- Lower prices would reduce patients' out-of-pocket costs, increasing their use of and spending on prescribed medications; their increased use of medications would reduce their use of other health care services, thereby lowering costs.

Those four mechanisms would operate to different degrees in Medicare Part D, Medicaid, and the commercially insured segment of the market, as well as in other federal programs.

Medicare Part D

Medicare Part D is the largest federal program supporting access to prescription drugs in the retail market. The Part D benefit is administered through private insurance plans that receive subsidies from the federal government. Drug prices affect the total cost of the Part D program, which in turn affects the amount of federal subsidies and the premiums paid by enrollees.

The overall federal subsidy to Part D plans has three components: First, the federal government covers a portion of total spending in the catastrophic phase of the Part D benefit, which is the last benefit phase. Enrollees enter that phase only after incurring thousands of dollars in drug costs in a calendar year.¹ Second, the plans receive a direct federal subsidy that is based on the number and risk profile of the plans' enrollees as well as the average amount that plans expect to spend for a Part

D enrollee of average health. That average amount reflects both the prices that Part D plans expect to pay for prescription drugs and the amount of prescription drugs that plans expect enrollees to purchase. Third, a low-income subsidy covers most premiums and cost sharing for about a quarter of Part D enrollees who have low incomes and few assets. Together, those three components of the federal subsidy accounted for about two-thirds of all spending in Part D in 2022 at net prices, and the remainder is financed by enrollees' cost-sharing payments and premiums.

Lower average prices for prescription drugs would reduce federal spending for all three components of the federal subsidy. In particular, lower prices would reduce the amount that Part D plans expect to spend on enrollees, which would reduce the direct subsidy that the federal government pays. Lower prices would also reduce the out-of-pocket costs that Medicare beneficiaries have to pay, both through reduced cost sharing for prescriptions and through lower premiums. Lower cost sharing would increase the quantity of covered drugs that they use, partially offsetting the reduction in federal spending. At the same time, when Medicare beneficiaries use more prescription drugs, they use fewer hospital and other medical services, which lowers federal spending on Medicare Parts A and B.²

Medicaid

Drug prices in Medicaid affect federal outlays both through states' direct purchases of drugs and through payments to managed care organizations that provide prescription drug coverage. State Medicaid agencies sometimes elect to cover prescription drugs on a fee-for-service basis, paying pharmacies directly for drugs dispensed to beneficiaries. State Medicaid agencies may also contract with private managed care organizations that pay pharmacies for beneficiaries' prescriptions in exchange for a fixed payment per beneficiary. For both types of arrangements, the federal government makes matching payments to the states, and lower average prescription drug prices would reduce federal outlays on those matching payments.

Under fee-for-service and managed care arrangements, the price that Medicaid pays for prescription drugs is heavily

1. Through 2024, the federal government will continue to cover 80 percent of spending in the catastrophic phase of the benefit. Starting in 2025, the federal government will cover 20 percent of total spending on brand-name drugs and 40 percent of total spending on generics in the catastrophic phase.

2. For more information about the relationship between prescription drug use and medical spending among Medicare beneficiaries, see Congressional Budget Office, *Offsetting Effects of Prescription Drug Use on Medicare's Spending for Medical Services* (November 2012), www.cbo.gov/publication/43741.

Box 1-1.

Continued

How Would Lower Prescription Drug Prices Affect the Federal Budget?

influenced by statutory rebates that manufacturers are required to pay under the Medicaid Drug Rebate Program, as well as supplemental rebates that manufacturers negotiate with states and managed care organizations. The statutory rebate obligation for each drug is calculated as the sum of two components, known as the basic rebate and the inflation rebate. The formulas used to calculate both components of the statutory rebate rely on the price that a manufacturer receives for a drug that is distributed to retail pharmacies (the average manufacturer price, or AMP, which does not account for rebates or discounts after the point of sale). The formula for the basic rebate additionally relies on the lowest net price paid by a commercial purchaser (known as the “best price”). The rebate formula thereby links Medicaid’s prices to prices paid by commercial purchasers.

Because of the formula for calculating the statutory rebate, a lower AMP for some drugs would increase prices in Medicaid, increasing federal spending in turn. That is because the drug’s AMP is used to calculate both components of Medicaid’s statutory drug rebate such that their sum (the total statutory rebate) can change by more than the change in AMP that precipitated it. If a manufacturer owes both a basic rebate and an inflation rebate for a particular drug and the AMP decreases by less than the size of the inflation rebate, then the inflation rebate will fall by the same amount as the reduction in the AMP. Under most circumstances, the amount of the basic rebate would also fall, meaning that the total statutory rebate would decrease by more than the reduction in the AMP, resulting in a higher net price in Medicaid.³

Commercial Insurance

A reduction in average drug prices in the commercial market would put downward pressure on health insurance premiums, which would both increase tax revenues for enrollees with employment-based insurance and reduce federal subsidies for people with nongroup insurance.⁴ In 2022, an estimated

163 million people had employment-based coverage for which the premiums were excluded from income and payroll taxes.⁵ Changes in employees’ wages and taxable benefits tend to offset changes in premiums, so any reduction in premiums resulting from lower drug prices would tend to enlarge the tax base and increase tax revenues.⁶

Among the people with employment-based commercial coverage in 2022 were millions of federal employees, annuitants, and their dependents. In addition to those people’s premiums being excluded from taxable income, a portion of their premiums is paid by the federal government through the Federal Employees Health Benefits (FEHB) program. Lower drug prices would reduce those payments.

Other Federal Programs

Other federal programs purchase prescription drugs and dispense them to their beneficiaries. Some of the largest are administered by the Veterans Health Administration, the Department of Defense (TRICARE), and the Indian Health Service.⁷ Lower prescription drug prices would reduce the cost of delivering benefits under those programs but would directly reduce federal outlays only in programs that are financed by mandatory spending, meaning spending governed by statutory criteria rather than appropriation acts. For programs financed through appropriations, such as the Indian Health Service, a reduction in drug prices would not itself change the amount of federal spending on those programs, which would depend on future Congressional decisions about the programs’ funding. Similarly, in the FEHB program, the federal government’s share of the premiums for active federal employees and their dependents is financed through appropriations, but for annuitants, that spending is mandatory. Accordingly, lower prescription drug prices would directly reduce federal spending on annuitants but not on active employees or their families.

3. The basic rebate is equal to the difference between the AMP and the best price if that difference exceeds a specified percentage of the AMP (equal to 23.1 percent for most brand-name drugs). The basic rebate might not decrease when a particular drug’s AMP decreases if the best price falls by the same amount as the AMP.

4. If reductions in average prices were accompanied by reductions in the lowest prices paid for certain drugs by commercial purchasers, then statutory rebates in Medicaid could increase, lowering federal spending.

5. Congressional Budget Office, *Federal Subsidies for Health Insurance: 2023 to 2033* (September 2023), www.cbo.gov/publication/59273.

6. Congressional Budget Office, *Policy Approaches to Reduce What Commercial Insurers Pay for Hospitals’ and Physicians’ Services* (September 2022), www.cbo.gov/publication/58222.

7. For more information about the prices paid for prescription drugs in different federal programs, see Congressional Budget Office, *A Comparison of Brand-Name Drug Prices Among Selected Federal Programs* (February 2021), www.cbo.gov/publication/56978.

A larger rebate is required if a drug's AMP grows by more than the CPI-U.¹² The design of the Medicaid rebate therefore links net prices in Medicaid to prices paid in other markets. Many state Medicaid programs or managed care organizations also negotiate supplemental rebates with manufacturers.

The ways that prices are determined for different payers vary, but the flow of prescription drug products from manufacturers to patients is roughly similar for Medicare and Medicaid as well as for patients in commercial insurance plans. Prescription drug products and their payments flow between several different parties. Those parties include manufacturers, wholesalers, pharmacies, PBMs, public and private purchasers, and patients:

- Manufacturers of brand-name and generic drugs distribute their products to wholesalers or other distributors at a wholesale price.
- Pharmacies obtain their drug products from wholesalers or distributors at another wholesale price.
- PBMs make direct payments to pharmacies for prescriptions dispensed to patients. After the point of sale to a patient, the PBM receives a payment from the pharmacy that is based on contractual arrangements between those parties. For brand-name drugs, the PBM often also receives a rebate payment from the manufacturer that is based on negotiations between the PBM and the manufacturer; such rebates often reflect volume incentives (see Figure 1-1).

Brand-Name Drug Prices in High-Income Foreign Countries

Direct regulation of the prices that drug manufacturers are paid plays a greater role in influencing prices in most high-income foreign countries than it does in the United States. In many foreign countries, the main purchaser is a national health insurance program that has substantial leverage in price negotiations with brand-name drug manufacturers. That leverage is even greater if the purchaser is willing to exclude a drug from coverage.

Some countries set explicit limits on the prices that manufacturers receive for prescription drug products. Prices may be based in part on the prices paid for those same drugs in other countries—a practice known as

12. For a discussion of how prescription drug prices are determined in various federal programs, see Congressional Budget Office, *A Comparison of Drug Prices Among Selected Federal Programs* (February 2021), www.cbo.gov/publication/56978.

international reference pricing. For example, regulation of brand-name drug prices in Canada is influenced by prices in several other countries. Under another reference pricing approach, known as therapeutic reference pricing, prices are based on the cheapest available brand-name or generic drug within a therapeutic class. In France, regulators determine whether a new drug product confers significant added health benefits compared with existing products and then set a maximum allowed price based in part on that assessment.

In some countries, such as the United Kingdom, drug coverage and pricing decisions are influenced by cost-effectiveness analysis, in which the costs and clinical benefits of alternative approaches to treating a particular condition are evaluated together. Those analyses identify a specific criterion as a benchmark indicator of whether a particular drug is sufficiently cost-effective to be covered. If the manufacturer charges a price that does not meet the cost-effectiveness criterion, the drug might not be covered by the health care system.¹³ In some countries, the regulatory approval process integrates price considerations with safety and efficacy. To have the cost of a drug reimbursed by a national health care system, the manufacturer must negotiate directly with a government agency, and that process often involves presenting cost-effectiveness data in addition to clinical evidence. In some cases, a drug that is not covered by a foreign country's public insurer is available for purchase out of pocket.¹⁴

Generic and Biosimilar Competition

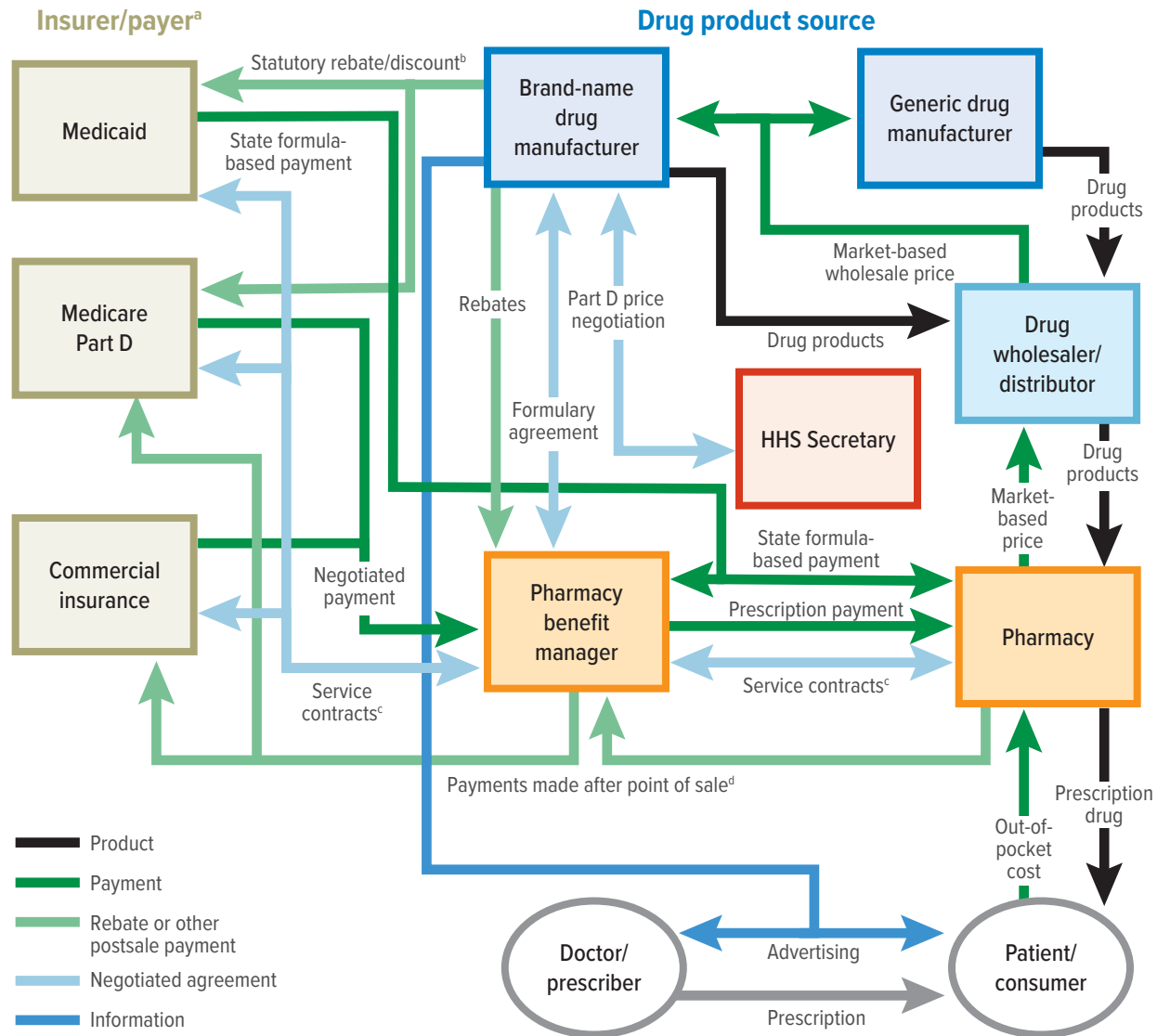
The availability of competing products can often reduce brand-name prices for buyers. For example, if a brand-name drug in its exclusivity period faces competition from another brand-name product with similar clinical effects, its price will tend to be lower than it would be if the drug faced no such competition. At the end of

13. For some examples, see Catherine Pham and others, "Assessment of FDA-Approved Drugs Not Recommended for Use or Reimbursement in Other Countries, 2017–2020," *JAMA Internal Medicine*, vol. 183, no. 4 (February 2023), pp. 290–297, <https://tinyurl.com/asmfcfdm>. For a discussion of cost-effectiveness analysis (also called technology assessment) in prescription drug coverage in foreign countries, see Olivier J. Wouters, Huseyin Naci, and Irene Papanicolas, "Availability and Coverage of New Drugs in 6 High-Income Countries With Health Technology Assessment Bodies," *JAMA Internal Medicine*, vol. 184, no. 3 (January 2024), <https://tinyurl.com/2wya76fx>.

14. For an example, see Ian Johnston, "Novo Nordisk 'Surprised' by High European Demand for Weight-Loss Drugs," *Financial Times* (February 4, 2024), <https://tinyurl.com/5ee7r22n>.

Figure 1-1.

Financial, Product, and Information Flows in the U.S. Prescription Drug Market



Data source: Congressional Budget Office.

HHS = Department of Health and Human Services.

- The figure does not include direct federal purchasers such as the Department of Veterans Affairs, the Department of Defense, the Public Health Service, the Coast Guard, and the Bureau of Prisons.
- For Medicare Part D, “statutory rebate/discount” includes the Part D inflation rebate and statutory discounts. For Medicaid, it includes the statutory Medicaid rebate, consisting of the basic rebate plus the inflation rebate. (Manufacturers may also pay supplemental rebates.)
- The relationships between commercial insurers, pharmacy benefit managers (PBMs), and pharmacies are depicted here as contracted arrangements. PBMs are sometimes integrated with the insurer, the pharmacy, or both.
- Price concessions from pharmacies after the point of sale take the form of periodic payments from pharmacies to the plans or to PBMs.

that brand-name drug's exclusive sales rights period, the availability of a generic equivalent or a biosimilar creates even more competitive pressure; when several generic or biosimilar versions of the drug become available, consumers obtain them at significantly lower prices.

Generic Drugs

In addition to establishing a period of exclusive sales rights for new brand-name drugs, the Hatch-Waxman Act created a regulatory pathway for makers of small-molecule generic drugs to bring their products to market. As part of that pathway, the manufacturer of a generic drug must demonstrate that the product is bioequivalent to its brand-name counterpart, meaning that it has the same active ingredients and produces the same clinical effect.¹⁵ Another part lays out a process for resolving patent disputes. Through that process, the generic drug manufacturer can challenge a brand-name drug's patents by asserting that they are invalid or would not be infringed by generic competition. The first generic drug manufacturer to bring a successful challenge to a brand-name drug's patent is granted 180 days of exclusive generic sales rights when its drug enters the market, which creates an incentive for generic drug manufacturers to undertake the patent challenge process.¹⁶ The process established through the Hatch-Waxman Act addresses the dual interests of encouraging new drug development (by conferring exclusive sales rights for brand-name drugs) and promoting competition between brand-name and generic drugs to lower drug prices after brand-name drugs lose sales exclusivity.

At the end of its period of sales exclusivity, a small-molecule brand-name drug can face direct competition from one or more generic versions of the same compound, leading to a large loss of market share for the brand-name manufacturer and lower prices for consumers.¹⁷ In CBO's estimation, generics accounted

for roughly 85 percent of a drug's total sales volume, on average, in Medicare Part D four years after a first generic product entered the market; in that same year, the average price in Part D for those generics was about 60 percent lower than the net price of the brand-name counterpart before generic competition began.¹⁸ Generic drugs currently account for roughly 90 percent of all prescriptions dispensed in pharmacies among all payers. Many private payers and PBMs encourage the use of available generic products, and pharmacists are permitted to automatically substitute a generic drug for its brand-name counterpart when filling prescriptions.¹⁹

Biosimilar Drugs

The BPCIA created an abbreviated pathway for regulatory approval of biosimilar drugs like that for generic small-molecule drugs. Unlike generic drugs, biosimilar drugs have active ingredients that are not identical (but that are very similar) to the active ingredients in their reference biologic drugs. To market a biosimilar, the manufacturer must demonstrate that it has no clinically meaningful differences from the original biologic in its safety, purity, or potency.

Biosimilars have not generated as much competition to date as generic small-molecule drugs have. Biosimilars are costlier to develop than generic drugs, and unlike small-molecule generics—most of which can be automatically substituted at the pharmacy if a patient is prescribed the brand-name version—they cannot be substituted for

Responses: Patterns in Prices and Sales Following Loss of Exclusivity," in Ana Aizcorbe and others, eds., *Measuring and Modeling Health Care Costs* (University of Chicago Press, 2018), pp. 243–271, <http://tinyurl.com/4d59uz66>.

15. For more information about bioequivalence, see Food and Drug Administration, "Orange Book Preface," in *Approved Drug Products With Therapeutic Equivalence Evaluations* (known as the "Orange Book") (September 11, 2024), <https://tinyurl.com/yjpkdeub>.

16. If more than one generic drug manufacturer challenges the same brand-name drug on the same day, and they are the first manufacturers to do so, then they share the 180-day exclusivity period for the generic version of the drug.

17. For a discussion of pricing and market share dynamics following a drug's loss of exclusivity, see Murray L. Aitken and others, "The Regulation of Prescription Drug Competition and Market

18. CBO used data on Medicare Part D claims and rebates for brand-name small-molecule drugs that lost their exclusive sales rights between 2011 and 2022. Net prices in those estimates reflect rebates from manufacturers but do not reflect payments from pharmacies after the point of sale. Estimates of generic market share in CBO's calculations exclude authorized generics marketed with the brand-name manufacturer's approval.

19. One recent analysis found that, in 2019, laws in 19 states required pharmacists to substitute eligible generic drugs for small-molecule brand-name drugs, and the remaining 31 states and the District of Columbia permitted but did not require such substitution. A small number of generic drugs are ineligible for substitution because they are not considered therapeutically equivalent to their brand-name counterparts. See Chana A. Sacks and others, "Assessment of Variation in State Regulation of Generic Drug and Interchangeable Biologic Substitutions," *JAMA Internal Medicine*, vol. 181, no. 1 (January 2021), pp. 16–22, <http://tinyurl.com/yptk69pj>.

their reference biologics in such broad circumstances.²⁰ Some policymakers have shown interest in making all biosimilars substitutable for their reference biologics.²¹

Biosimilar competition remains limited, but uptake of biosimilars appears to be increasing. According to one source, by the end of 2023 biosimilars represented 23 percent of the total volume of prescriptions among biologic drugs for which a biosimilar was available,

compared with 14 percent in 2018.²² Biosimilars are more established in the physician-administered drug market than in the retail market: Since the enactment of the BPCIA in 2010, a total of 26 biosimilars have entered the retail market, of which 17 entered in 2021 or later.²³ As a consequence, data are relatively scarce on how the effects of biosimilar competition over time compare with the effects of generic competition in the small-molecule market.

The available evidence on physician-administered drugs indicates that biosimilar competition lowers prices for consumers in two ways. In some cases, cheaper biosimilars capture market share from the original product; in other cases, prices of the original biologic products fall, and adoption of biosimilars is more limited. By contrast, generic competition in the small-molecule market most often follows that first pattern: Market share shifts to cheaper generic versions and away from the original brand-name products.

20. The reference biologic is the original brand-name drug that a biosimilar is compared with during the approval process to ensure that it is highly similar and has no clinically meaningful differences. A biosimilar may be substituted at the pharmacy for the reference product without the intervention of the prescribing physician if it is designated by the FDA as an interchangeable biosimilar; see Hassan Z. Sheikh, *Biologics and Biosimilars: Background and Key Issues*, Report R44620, version 14 (Congressional Research Service, June 6, 2019), <http://tinyurl.com/mskawt2c>. Prescribers' preferences for original biologics or reluctance to try biosimilars may also have led to limited uptake; see Allison R. Kolbe and others, "Physician Understanding and Willingness to Prescribe Biosimilars: Findings From a US National Survey," *BioDrugs*, vol. 35, no. 3 (May 2021), pp. 363–372, <https://doi.org/10.1007/s40259-021-00479-6>.

21. See, for example, the Biosimilar Red Tape Elimination Act, S. 3405, 118th Cong. (2023).

22. IQVIA Institute for Human Data Science, *The Use of Medicines in the U.S. 2024: Usage and Spending Trends, and Outlook to 2028* (IQVIA, May 2024), p. 58, <https://tinyurl.com/34rbr29w>. Prescription volume is measured as "defined daily doses," as defined by the World Health Organization and implemented by IQVIA.

23. Those numbers include some biosimilars that are also sold outside the retail market as physician-administered drugs.

Chapter 2: Policy Approaches That Would Cap Prescription Drug Prices or Limit Price Growth

For this report, the Congressional Budget Office examined seven policy approaches that aim to reduce the prices of prescription drugs. This chapter focuses on three of those approaches that would cap drug prices or limit price growth. Those approaches, along with their projected outcomes, are as follows:

- **Set maximum allowed prices based on prices outside the United States.** In CBO's assessment, a policy approach that used the prices of brand-name prescription drugs in high-income foreign countries to set maximum prices for those drugs would lower average prices in the United States by a large amount (more than 5 percent).
- **Expand the Medicare Drug Price Negotiation Program.** CBO examined two policies: The first would increase the number of drugs whose prices get negotiated each year, leading to a very small (0.1 percent to 1 percent) or a small (1 percent to 3 percent) reduction in average drug prices in 2031. The second would make negotiated prices available to all commercial purchasers, lowering average prices by a small amount (1 percent to 3 percent).
- **Require manufacturers to pay inflation rebates for sales in the commercial market.** CBO estimates that extending the Medicare Part D inflation rebate to sales in the commercial market would result in a small reduction (1 percent to 3 percent) in average drug prices in 2031.

See Box 2-1 for details about how CBO selected the approaches examined in this report and organized the discussion of each approach.

Set Maximum Allowed Prices Based on Prices Outside the United States

In many high-income foreign countries, the price of a brand-name prescription drug is partly determined by

international reference pricing. In Canada, for example, the Patented Medicines Prices Review Board examines the prices of brand-name prescription drugs sold in several other high-income countries; that comparison is used to evaluate manufacturers' prices when they first enter the Canadian market and on an ongoing basis.¹ International reference pricing is also common in health care systems in Europe and elsewhere, where countries' pricing policies are based in part on observed prices in other countries or on the lowest prices observed.

International reference pricing has also been the subject of proposals in the United States. The Elijah E. Cummings Lower Drug Costs Now Act of 2019 would have required the Secretary of Health and Human Services (HHS) to negotiate prices for selected drugs so that prices did not exceed 120 percent of the average in six foreign countries (Australia, Canada, France, Germany, Japan, and the United Kingdom).² The Centers for Medicare & Medicaid Services also proposed a rule for Part B drugs under which payments for certain high-cost drugs would have been based on observed prices in certain foreign countries.³ Key considerations for such proposals include which drugs would be subject to reference pricing, which foreign countries would be used as references, and how the prices observed in foreign countries would be used to determine prices in the United States.

1. Patented Medicine Prices Review Board, *PMPRB Guidelines*, <https://tinyurl.com/3cpdffb8>.

2. For CBO's analysis of that proposal, see Congressional Budget Office, cost estimate for H.R. 3, the Elijah E. Cummings Lower Drug Costs Now Act (December 10, 2019), www.cbo.gov/publication/55936.

3. International Pricing Index Model for Medicare Part B Drugs, 83 Fed. Reg. 54546 (October 30, 2018), pp. 54546–54561. That proposed rule was blocked on procedural grounds and did not go into effect. Part B drugs are outside the scope of this report.

Box 2-1.

CBO's Selection of Policy Approaches to Reducing Drug Prices

To generate a list of policy approaches to analyze for this report, the Congressional Budget Office searched current and previous Congressional legislative proposals, major proposals from the policy community, and the academic literature on health policy and prescription drug markets. CBO also examined various prescription drug pricing policies that are used in other high-income countries. Together, the seven policy approaches included in this report reflect a range of alternatives in two broad categories: approaches that would reduce the prices that drug manufacturers charge by capping those prices or limiting their rate of growth (see Chapter 2), and approaches that would promote price competition or affect the flow of information (see Chapter 3). The report focuses on prescription drugs purchased in retail settings, such as local brick-and-mortar pharmacies and mail-order pharmacies. Prices for drugs that are administered by physicians or other health care professionals in outpatient settings or hospitals are not within the scope of this report.

The discussion of each approach includes a description of the policy scenario, the effects of each approach on prescription

drug prices, and other related considerations, such as anticipated effects on foreign drug markets. The effects of each approach on pharmaceutical research and development are discussed together in Chapter 4. (See Box 1-1 on page 8 for a general discussion of the federal budgetary effects of changes in prescription drug prices.)

Within each broad category, the approaches appear in descending order of their estimated effect on average drug prices. Those overall averages reflect net prices paid by all public and private purchasers for prescription drugs distributed to patients through retail channels. Approaches are described as having large effects if they would reduce average prices for the whole retail drug market in 2031 (projected to exceed \$690 billion in that year) by more than 5 percent in CBO's estimation. Average price reductions of 3 percent to 5 percent are categorized as moderate, reductions of 1 percent to 3 percent are small, and reductions of less than 1 percent are very small. Approaches with estimated effects falling in the same range are listed in alphabetical order.

Policy Approach

CBO examined a policy scenario that would impose a maximum allowed price for single-source brand-name prescription drugs. It would be based on transaction prices in the reference countries of Australia, Austria, Belgium, Canada, France, Germany, Italy, Japan, the Netherlands, Sweden, Switzerland, and the United Kingdom.⁴ Manufacturers would be required to report to the HHS Secretary foreign net prices for all such products that they sell both domestically and in at least one of the foreign reference countries. Drug prices charged by manufacturers in the United States would be capped at a level reflecting the observed net prices in the reference countries (see Figure 2-1).

Specifically, the maximum allowed price would be an average of the reference countries' prices weighted to reflect each country's respective gross domestic product per capita; prices in wealthier reference countries would therefore exert more influence on the maximum allowed

U.S. price than prices in less wealthy countries would. For drugs not available in the reference countries, manufacturers would be able to set prices as they do under current law.

Estimated Effect: A Large Reduction in Average Prices

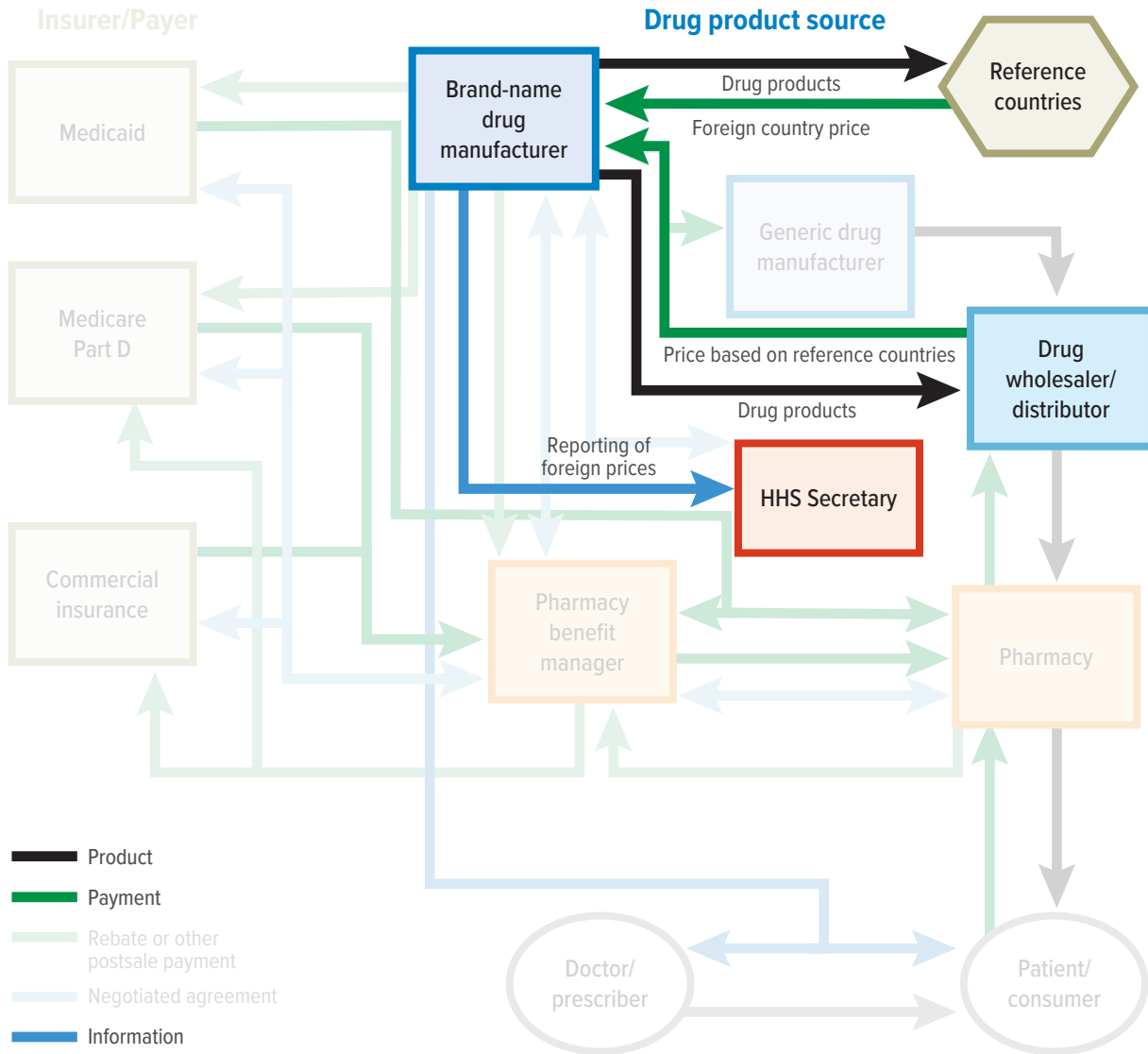
Setting a maximum price based on prices outside the United States would lead to a large reduction (more than 5 percent) in prescription drug prices in the United States. The price reduction would occur shortly after implementation but would probably diminish over time as manufacturers adjusted to the new policy by altering prices or distribution of drugs in other countries. Even after accounting for such strategic responses, the expected price reduction would exceed 5 percent in 2031.

In estimating the possible effect of this policy approach, CBO considered a range of values representing international price differences for brand-name prescription drugs. Specifically, CBO based its analysis on an estimated ratio of foreign prices to U.S. prices ranging from 30 percent to 55 percent for brand-name drugs in the

4. CBO chose those countries because, among countries for which bilateral price comparisons were available, they were comparable to the United States in their gross domestic product per capita.

Figure 2-1.

Set Maximum Allowed Prices Based on Prices Outside the United States



Data source: Congressional Budget Office.

HHS = Department of Health and Human Services.

retail market. In other words, prices in foreign countries are estimated to be 45 percent to 70 percent lower than those in the United States.⁵ Because not all brand-name

drugs are available in all countries, the prices of many drugs that are available in the United States cannot be compared with international prices. CBO’s estimate of the effects of this approach reflects an assessment that

5. That range is based on CBO’s calculations using data from Andrew W. Mulcahy, Daniel Schwam, and Susan L. Lovejoy, *International Prescription Drug Price Comparisons: Estimates Using 2022 Data*, RR-A788-3 (RAND Corporation, 2024), <https://doi.org/10.7249/RR788-3>; Andrew W. Mulcahy and others, *International Prescription Drug Price Comparisons:*

Current Empirical Estimates and Comparisons With Previous Studies, RR-2956-ASPEC (RAND Corporation, 2021), <https://doi.org/10.7249/RR2956>; and Council of Economic Advisers, *Funding the Global Benefits to Biopharmaceutical Innovation* (February 2020), <http://tinyurl.com/yc758365>.

a reference-price comparison is currently available for drugs representing 50 percent to 70 percent of spending on brand-name drugs.⁶

In CBO's estimation, if brand-name drug prices in the United States were linked to their corresponding prices in foreign countries, manufacturers would respond in ways that would reduce access to and availability of those drugs for patients in those foreign countries to mitigate the effect on prices in the United States. Manufacturers would probably delay brand-name product launches in foreign countries to delay the availability of a reference price, and they might withdraw from some markets they currently serve—particularly smaller countries—to avoid having a comparison price. Manufacturers could also prevent a comparison price from being available by altering the product distributed in other countries to make it less directly comparable to the U.S. version.

The threat of market withdrawal would give manufacturers leverage to increase prices in the foreign reference countries, though explicit price regulations in some countries might limit manufacturers' ability to do so. Any increase in foreign drug prices would reduce the price gap and thereby enable manufacturers to charge higher prices in the United States. They could also obscure transaction prices for prescription drugs in reference countries with rebates or other financial offsets that are hard to observe. As an example, donations from drug manufacturers to other sectors of a reference country's health system, such as hospitals, might effectively reduce that drug's cost to that health system without directly changing that drug's observed price.

Other Considerations

Patients in the reference countries would probably have delayed access to newly approved prescription drugs under this policy approach, and they might lose access

to some existing drugs.⁷ In CBO's assessment, prices for prescription drugs would also be higher for some patients or payers in the reference countries because manufacturers would have greater leverage to raise prices in those countries, though some countries' price regulations might limit manufacturers' ability to do so. The possibility of reduced access and higher prices would be particularly great if the reference country or countries made up a relatively small prescription drug market—for example, if a reference pricing policy was based only on prices in Canada. Manufacturers would then have great leverage to increase prices there because of the credible threat that they would abandon the entire market rather than allow large price reductions in the much larger U.S. market.

Expand the Medicare Drug Price Negotiation Program

Under the Medicare Drug Price Negotiation Program, which was authorized by the 2022 reconciliation act (Public Law 117-169), certain drugs will be made available in Medicare Part B or Part D at prices negotiated between manufacturers and the HHS Secretary. Each year, the Secretary will select a number of drugs (up to 20 beginning with the fourth cohort) for price negotiation on the basis of total Medicare spending on the drugs and certain other criteria. Eligibility for price negotiation is limited to small-molecule drugs that have been on the market for at least 7 years and have no generic competitors, as well as to biologic drugs (those produced from living organisms) that have been on the market for at least 11 years and have no biosimilar competitors. Each drug's negotiated price is subject to a ceiling amount that is based on its previous price, rebate amount, and length of time on the market.

The first cohort of drugs to undergo price negotiation was announced in August 2023, their negotiated prices were announced in August 2024, and the negotiated prices will take effect in 2026. Beginning with the second cohort of drugs to undergo price negotiation (which will

6. CBO's calculations are based on Andrew W. Mulcahy, Daniel Schwam, and Susan L. Lovejoy, *International Prescription Drug Price Comparisons: Estimates Using 2022 Data*, RR-A788-3 (RAND Corporation, 2024), <https://doi.org/10.7249/RR788-3>; Andrew W. Mulcahy and others, *International Prescription Drug Price Comparisons: Current Empirical Estimates and Comparisons With Previous Studies*, RR-2956-ASPEC (RAND Corporation, 2021), <https://doi.org/10.7249/RR2956>; and Council of Economic Advisers, *Funding the Global Benefits to Biopharmaceutical Innovation* (February 2020), <http://tinyurl.com/yc758365>.

7. For a discussion of how international reference pricing affects the timing of drug entry, see Dominic Voehler and others, "The Impact of External Reference Pricing on Pharmaceutical Costs and Market Dynamics," *Health Policy OPEN*, vol. 4 (December 2023), <https://doi.org/10.1016/j.hpopen.2023.100093>; and Panos Kanavos and others, "Does External Reference Pricing Deliver What It Promises? Evidence on Its Impact at National Level," *European Journal of Health Economics*, vol. 21, no. 1 (February 2020), pp. 129–151, <https://doi.org/10.1007/s10198-019-01116-4>.

be selected in 2025), negotiated prices will take effect at the start of the second calendar year following selection. Part D plans will then be able to purchase the drug at its negotiated price, and enrollees' cost sharing for the drug will be based on that price.

Policy Approach

CBO separately considered two policies that would each broaden the scope of the price negotiation program. The first would increase the number of drugs whose prices got negotiated each year. Under current law, 15 drugs will be selected for negotiation in 2025, with negotiated prices taking effect in 2027, and each subsequent negotiation cohort will include up to 20 drugs. Drugs are excluded from for price negotiation if they account for less than a specified minimum level of annual Medicare spending, which is \$200 million for the first negotiation cohort and adjusted thereafter by the rate of increase in the consumer price index for all urban consumers (CPI-U). Under the first policy, that exclusion would be lifted, and the number of drugs in each cohort would be increased to 50, beginning with those selected in 2025 (see Figure 2-2, policy 1).

The second policy would extend access to Medicare Part D's negotiated prices to commercial insurers. Under that policy, any retail drug that had a negotiated Part D price in effect would have to be offered to commercial purchasers at the same price (see Figure 2-2, policy 2). Unlike Part D plans, commercial insurers would not be obligated to cover drugs with negotiated prices.

Estimated Effect: A Small or Very Small Reduction in Average Prices

In CBO's estimation, increasing the number of drugs whose prices are negotiated each year would reduce average drug prices in 2031 by either a small amount (1 percent to 3 percent) or a very small amount (0.1 percent to 1 percent), and extending access to Medicare Part D's negotiated prices to the commercial market would reduce average prices by a small amount. CBO expects that, in subsequent years, the effect of either policy would diminish because price negotiation would have less-pronounced effects on the prices of drugs launched in the future than on drugs currently on the market.

Both policies would affect different market segments differently. Increasing the number of drugs negotiated annually would reduce the Part D and Medicaid prices of the additional drugs that got negotiated—along with

the prices of their therapeutic competitors—and would not significantly affect prices in the commercial market. Extending negotiated prices to the commercial market would lower commercial prices for negotiated drugs and their therapeutic competitors, but, in CBO's estimation, that policy would also increase average prices for those same drugs in Part D and Medicaid.

Under either policy, the overall price effect would depend on the magnitude of the price changes in different market segments, as well as the total sales volume of affected drugs. The price effect would also depend on how manufacturers, insurers, and other market participants changed their behavior in response to the policy, which in turn would depend on how the details of the policy were specified.

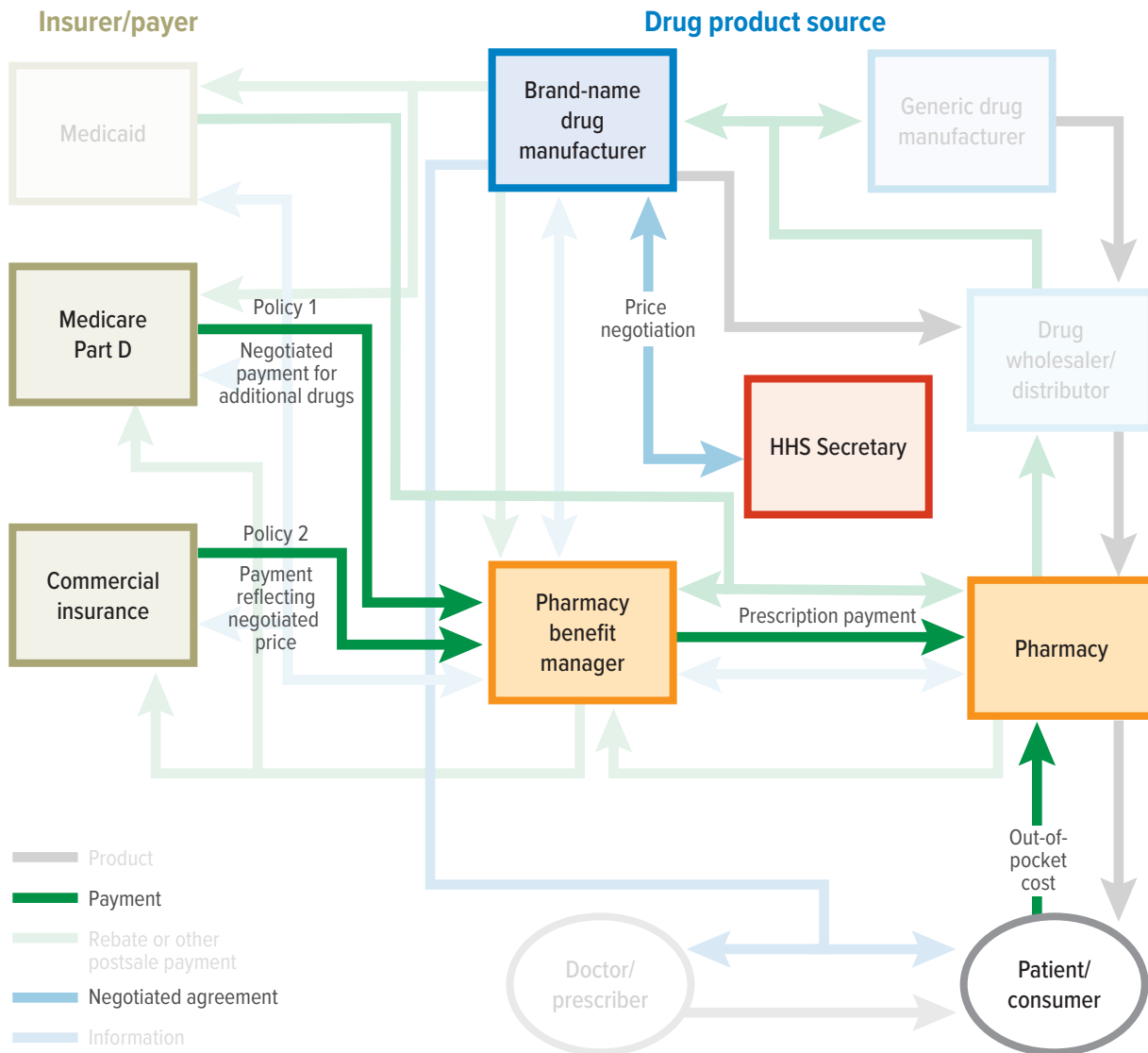
CBO estimates that negotiating prices for an additional set of drugs each year would reduce those drugs' net prices in Part D by 25 percent to 40 percent in 2031. (In that year, Part D spending is projected to account for more than 40 percent of all retail prescription drug spending.) In its analysis of the 2022 reconciliation act, CBO estimated that the Medicare Drug Price Negotiation Program would reduce the net prices of negotiated drugs in Part D by roughly 50 percent in 2031 relative to the prices projected under current law at that time, but the negotiated prices that were announced in August 2024 are 22 percent below the average net prices for those drugs in 2023.⁸ Consequently, CBO is updating its estimate of the price reductions from the Medicare Drug Price Negotiation Program and now expects the net prices of negotiated drugs to be 25 percent to 50 percent lower in 2031 as a result of that program.

The estimated price reduction (25 percent to 40 percent) for the drugs whose prices are newly negotiated under this policy is smaller because those additional drugs are subject to other policies under current law, such as the Part D inflation rebate policy, which is expected to slow price growth. CBO's assessment that the policy would

8. For CBO's earlier estimate of the price reduction resulting from negotiation, see Congressional Budget Office, "How CBO Estimated the Budgetary Impact of Key Prescription Drug Provisions in the 2022 Reconciliation Act" (February 2023), p. 10, www.cbo.gov/publication/58850. For the comparison between net prices in 2023 and the negotiated prices announced in August 2024, see Centers for Medicare & Medicaid Services, "Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026" (August 2024), <https://tinyurl.com/2u2rxyu3>.

Figure 2-2.

Expand the Medicare Drug Price Negotiation Program



Data source: Congressional Budget Office.

HHS = Department of Health and Human Services.

lead to either a small or a very small reduction in average prices in 2031 reflects that range of possible price reductions from negotiation.

Enabling commercial purchasers to buy drugs at the prices negotiated by the HHS Secretary would lower the prices of those drugs in the commercial market, but it would also cause the negotiated prices to be higher than they would be under current law. The law imposes significant costs (in

the forms of an excise tax and civil monetary penalties) on manufacturers whose drugs are selected for negotiation if those manufacturers do not agree to a negotiated price or if they do not make the drug available at the negotiated price they had previously agreed to. CBO's modeling reflects the expectation that manufacturers will comply with the negotiation process because refusing to do so would be costlier than reaching a negotiated price for their Part D sales of a particular drug. If commercial sales

were also subject to negotiated prices, that would increase the cost to the manufacturer of agreeing to a negotiated price relative to the cost of refusing. For that reason, the Secretary would have less leverage in the negotiations, and CBO expects that the resulting price reductions would be about 15 percent smaller, on average, than they would be under current law.

Each of the two policies would also affect prices in Medicaid by changing the “best price” for some drugs. The best price is the lowest net price available to any private-sector purchaser for a drug and is used in the calculation of each drug’s statutory Medicaid rebate. For most brand-name drugs, the smallest Medicaid rebate that a manufacturer can owe is the greater of 23.1 percent of the drug’s average manufacturer price (AMP) or the difference between the AMP and the best price.⁹ Prices paid by Part D plans are not included in the calculation of the best price, except for drugs whose prices are negotiated with the HHS Secretary. Those negotiated prices will therefore affect Medicaid prices for the group of drugs whose negotiated price becomes the best price (because the negotiated price is lower than the lowest private-sector price) and is lower than 76.9 percent of the AMP.

CBO expects that the two policies would have opposing effects on average prices in Medicaid in 2031: Increasing the number of drugs negotiated annually would introduce negotiated prices for some drugs that would not otherwise have them by 2031, thus lowering average Medicaid prices. Conversely, because extending negotiated prices to the commercial market would raise negotiated prices compared with current law, prices in Medicaid would also increase.

The effects of either policy on overall average drug prices would be more modest than its effects on the prices of negotiated drugs in particular, mainly because the drugs whose prices changed would account for a minority of overall drug spending. (For the policy that extended negotiation to the commercial market, the decrease

in commercial prices would also be partially offset by the price increases in Part D and Medicaid.) In CBO’s baseline projection, Part D and the commercial market each account for more than 40 percent of retail drug spending at net prices in 2031, and Medicaid accounts for about 10 percent. In that year, CBO estimates, drugs with negotiated Part D prices in effect would account for about 10 percent of spending in Part D (and about the same share of spending in the commercial market). The set of drugs whose prices would be negotiated if prices for 50 drugs were negotiated each year, but that would not be negotiated under current law, would make up an additional 5 percent of Part D spending.

Beyond 2031, the effects of both policies would diminish. CBO expects that negotiation would not reduce the prices of drugs launched in the future as much as it would reduce prices of drugs already on the market at the policy’s outset because manufacturers of new drugs would be able to mitigate the policy’s effect on net prices by setting higher list prices at launch. They could do so without changing net prices by increasing the rebates they pay to insurers, and doing so could result in a higher negotiated price years later. That is because each drug’s negotiated price will be subject to a ceiling based in part on its average price in 2021 (not accounting for rebates or discounts after the point of sale) if it was on the market in that year or, if the drug was launched after 2021, its average price during its first year on the market.

Other Considerations

One source of uncertainty about the effects of these policies stems from ongoing litigation by manufacturers who are challenging the constitutionality of the Medicare Drug Price Negotiation Program. If that litigation results in changes to the program, the policies’ effects on drug prices could be significantly affected.

Extending access to negotiated prices to commercial purchasers could alter the structure of the pharmacy benefits management industry. One function of pharmacy benefit managers (PBMs)—in addition to such activities as developing formularies and negotiating with pharmacies—is to negotiate net drug prices with drug manufacturers on behalf of commercial insurers. If the commercial insurers had access to the prices negotiated by the HHS Secretary, then part of the role played by PBMs would be supplanted as the number of drugs with negotiated prices increased over time. The timing of any resulting changes in the PBM industry is uncertain: In 2031, drugs with

9. That rebate amount, known as the Medicaid basic rebate, is what the manufacturer would owe in rebates if it did not pay supplemental rebates and the drug’s AMP had not increased faster than the CPI-U since the drug was launched. For some drugs, including blood clotting factors and exclusively pediatric drugs, the floor on the basic rebate is set at 17.1 percent of the AMP rather than at 23.1 percent. See Congressional Budget Office, *A Comparison of Brand-Name Drug Prices Among Selected Federal Programs* (February 2021), www.cbo.gov/publication/56978.

negotiated prices would make up only about 10 percent of commercial spending in CBO's estimation, suggesting that the largest potential effects of this policy on the PBM industry would manifest in later years. Changes to the industry could occur earlier than 2031 if market participants anticipate more widespread negotiation.

Extending the negotiation program to the commercial market—depending on how the policy was specified—could also increase net prices in Medicaid and the 340B Drug Pricing Program by changing the set of drug sales used to calculate the AMP.¹⁰ Such a price increase would be in addition to the increase in net Medicaid prices caused by an increase in the best price. Net prices in Medicaid and the 340B program depend in part on a drug's AMP. Under the 2022 reconciliation act, sales of negotiated drugs in Part D at the negotiated price are not included in the calculation of the AMP. If, under the policy, neither Part D nor commercial sales were included in the AMP calculation for negotiated drugs, then for some drugs Medicaid and the 340B program themselves could account for the large majority of sales used to calculate the AMP. In that case, manufacturers could set the AMP at the level that maximized their revenue in Medicaid and the 340B program (increasing net prices in those programs) without affecting their revenue in other market segments.

Require Manufacturers to Pay Inflation Rebates for Sales in the Commercial Market

Manufacturers are required to grant discounts or pay rebates for their sales in certain segments of the market if their products' average manufacturer prices increase faster than the CPI-U. In both Medicaid and Medicare Part D, the manufacturers are required to pay inflation rebates after the point of sale (at specified intervals that are based on recent sales).¹¹ Inflation rebates were introduced in Medicaid in the early 1990s as part of the Medicaid Drug Rebate Program, and they were

introduced in Part D in October 2022 as part of the 2022 reconciliation act.

In both programs, each drug is assigned a benchmark price that is based on the drug's AMP in an earlier period and adjusted by the rate of increase in the CPI-U after that benchmark period. If the drug's AMP exceeds the benchmark, the manufacturer is required to pay a rebate—equal to the difference between the AMP and the benchmark—for each unit of the drug sold in the relevant program. The inflation rebate policy thus imposes a penalty on manufacturers when a drug's AMP increases faster than economywide inflation.

The AMP does not reflect manufacturers' rebates to insurers or PBMs after the point of sale. Manufacturers who pay such rebates can increase net prices either by charging a higher price to the pharmacy or wholesaler or by paying smaller rebates to insurers and PBMs afterward, but only the first option would result in a higher AMP and potentially trigger a mandatory inflation rebate. So, when an inflation rebate policy is in effect, manufacturers who pay larger rebates have greater flexibility to increase net prices by reducing those rebates. For that reason, CBO expects manufacturers of new drugs that come to market after 2022 to respond to the Medicare inflation rebate policy introduced that year by setting higher list prices at launch—with correspondingly higher initial rebates to insurers and PBMs—than they otherwise would have.

Manufacturers of drugs already on the market are expected to reduce the rebates they pay to plans in the coming years because of the Part D inflation rebate policy. Once the rebates paid to plans for a drug fall to zero, the manufacturer cannot increase its net price faster than inflation without increasing the AMP (triggering an inflation rebate obligation) and has to choose whether to constrain net price increases, which avoids the inflation rebate, or raise the AMP faster than inflation and pay the inflation rebate.¹² Either option has a cost for the manufacturer: Limiting increases in the AMP means that commercial insurers can purchase the drug at lower prices, reducing the manufacturer's profit. Alternatively, raising the AMP faster than inflation preserves the manufacturer's profit in the commercial market but raises the drug's price for Part D plans and uninsured patients (reducing

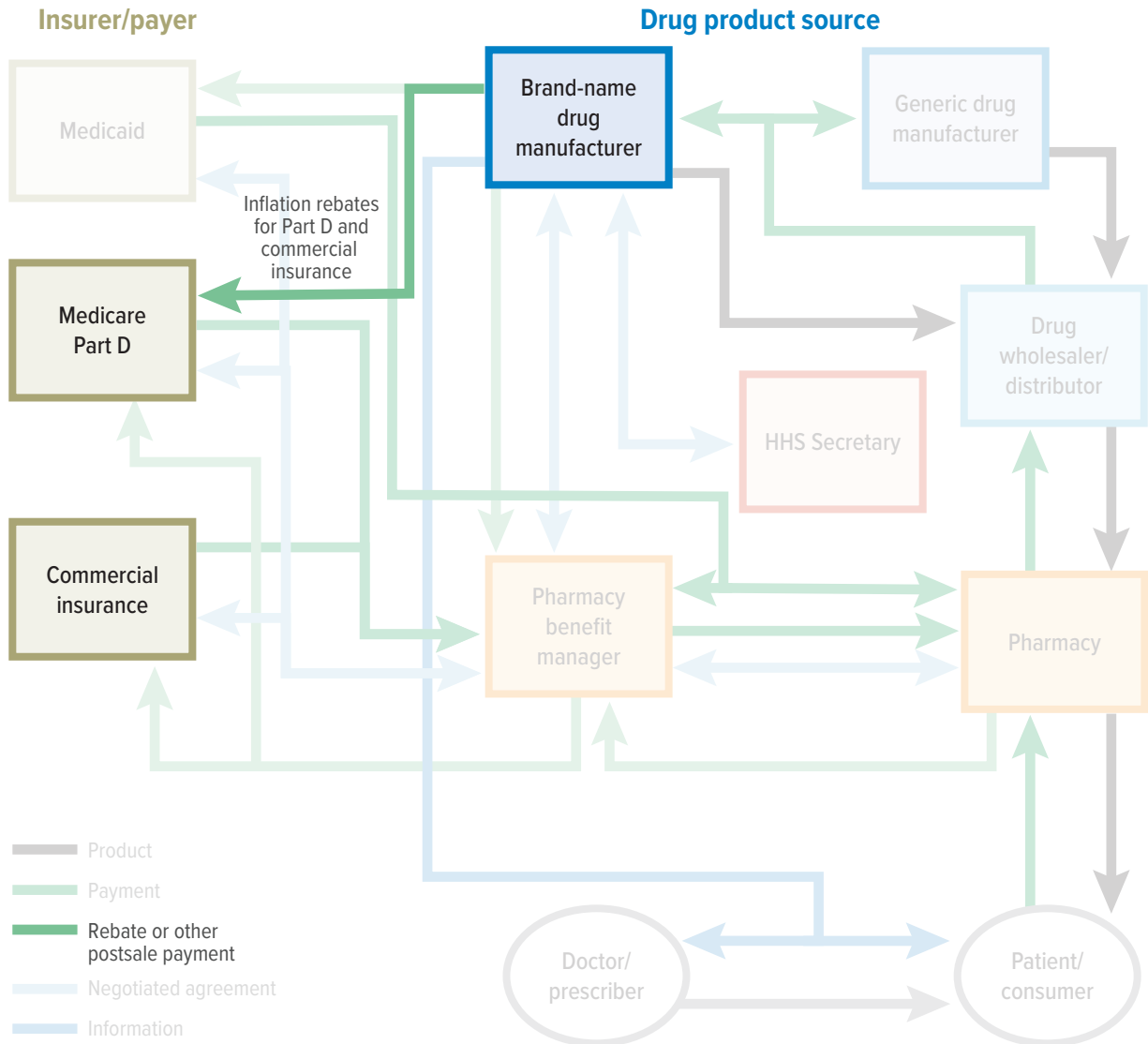
10. The federal 340B Drug Pricing Program enables eligible providers to obtain prescription drugs at discounted prices. See Government Accountability Office, *340B Drug Discount Program: Increased Oversight Needed to Ensure Nongovernmental Hospitals Meet Eligibility Requirements*, GAO-20-108 (December 2019), www.gao.gov/products/GAO-20-108.

11. Medicare Part B also uses an inflation rebate, but drugs covered under Medicare Part B are beyond the scope of this report. The 340B Drug Pricing Program incorporates a required discount when a drug is sold to a provider or pharmacy rather than a rebate from the manufacturer.

12. For a detailed explanation, see Congressional Budget Office, "How CBO Estimated the Budgetary Impact of Key Prescription Drug Provisions in the 2022 Reconciliation Act" (February 2023), pp. 13–17, www.cbo.gov/publication/58850.

Figure 2-3.

Require Manufacturers to Pay Inflation Rebates for Sales in the Commercial Market



Data source: Congressional Budget Office.

total sales) without raising the manufacturer’s profits in Part D, since any additional revenue is captured by the inflation rebate. As a result, in CBO’s analysis, drugs whose sales are mostly concentrated in the commercial market are more likely to experience net price increases that are faster than inflation, and thus to incur inflation rebate obligations, than drugs that are mostly sold in Medicare and Medicaid.

Policy Approach

CBO analyzed an extension of the inflation rebate policy recently adopted in Medicare Part D to sales in the

commercial market. Under the policy, the benchmarks and reference prices already used to calculate the Part D inflation rebates would still apply, but the manufacturer would be required to pay rebates for the sum of the Part D and commercial units sold, rather than for the Part D units alone.¹³ For any drugs sold in the commercial market that are not also sold in Part D, benchmarks and reference prices would be assigned following the same criteria already used in Part D (see Figure 2-3).

13. As under current law, manufacturers would pay those rebates into the Medicare Supplementary Medical Insurance Trust Fund.

Estimated Effect: A Small Reduction in Average Prices

Extending the Medicare Part D inflation rebate to sales in the commercial market would result in a small reduction (1 percent to 3 percent) in average drug prices in 2031. Average net prices in Part D and the commercial market would be lower in 2031 as a result of the policy. That reduction would be partially offset by higher net prices in Medicaid. The policy's effect on average prices would diminish over time.

Under the policy, manufacturers of most drugs would have to pay inflation rebates for nearly all domestic sales if their drugs' AMP increased faster than inflation. CBO expects that, faced with that prospect, manufacturers would choose to avoid paying inflation rebates for nearly all drugs, even when that would mean limiting net prices.

In particular, many manufacturers who would pay Medicare Part D's inflation rebate under current law would begin limiting their net price increases to avoid owing larger rebate obligations under the policy. By inducing those manufacturers to constrain the prices of their drugs, the policy would reduce average drug prices in the Part D and commercial markets. A drug whose Part D and commercial prices would be most affected would have all of these characteristics:

- The drug was launched before 2022,
- The price of the drug was not negotiated under the Medicare Drug Price Negotiation Program,
- Its sales are concentrated in the commercial market, and
- The manufacturer of the drug does not pay large rebates to insurers.

The drugs with those characteristics would experience similar price declines in Part D and the commercial market under this approach. Because those drugs would account for a larger share of commercial spending than of Part D spending, the policy would have a larger effect on average commercial prices than on average Part D prices. CBO estimates that the average price across all prescription drugs in Part D would be 2 percent lower in 2031 under this approach and that the average commercial price would be 3 percent lower.

CBO expects average net prices in Medicaid to be higher as a result of the policy—by less than 1 percent in 2031. For

drugs launched before 2022, Medicaid would pay lower retail prices, on average, under this approach, but reductions in the average AMP would cause Medicaid rebates to fall by more than the corresponding reductions in retail prices. Medicaid would pay higher net prices for some drugs launched after 2022. In particular, the approach would lead some manufacturers to introduce their new drugs with higher list prices at launch and pay larger rebates to insurers and PBMs so they could minimize the policy's effect on the drugs' net prices. (Other drugs would be unaffected because their manufacturers would have already set launch prices to fully account for Part D's inflation rebates.) Higher initial list prices, even when paired with larger rebates to insurers, would cause net Medicaid prices to rise, on average, because Medicaid rebates would increase by less than the increase in the AMP. (See Box 1-1 on page 8 for further discussion of the relationship between the AMP and net prices in Medicaid.)

The effects of this approach on overall average drug prices would attenuate over time because net price reductions would be concentrated among drugs launched before 2022. Manufacturers of new drugs can insulate their net prices from the effects of an inflation rebate policy by launching their products at a higher initial AMP and by paying correspondingly larger rebates to insurers and PBMs. CBO does not expect drugs launched after 2022 to have lower average prices in Part D or the commercial market under the approach, but some of those drugs would be launched with a higher initial AMP and would therefore have higher net prices in Medicaid.

Other Considerations

The policy would increase net federal costs for some drugs in Medicare Part D, even as the net prices of those drugs decreased. The manufacturers who lowered their drugs' prices in response to the policy would, under current law, have paid inflation rebates to the federal government based on their Part D sales. By instead constraining net prices under the policy, those manufacturers would not have to pay those inflation rebates. Because the benefits of the price reductions are split between the federal government and Part D enrollees through lower premiums and cost sharing—but reduced inflation rebate payments affect only the government—the reduction in rebate payments to Medicare would exceed the federal government's share of savings from the lower net price, resulting in a larger federal deficit.

Chapter 3: Policy Approaches That Would Promote Price Competition or Affect the Flow of Information

Four of the seven policy approaches that the Congressional Budget Office analyzed aim to reduce prescription drug prices by introducing more market competition or affecting the flow of information in the market. Specifically, those approaches and their projected outcomes are as follows:

- **Allow commercial importation of prescription drugs distributed outside the United States.** This policy, which would require the Secretary of Health and Human Services (HHS) to allow the large-scale importation of prescription drug products from other countries, would lead to a very small reduction (0.1 percent to 1.0 percent) in average drug prices in the United States.
- **Eliminate or limit direct-to-consumer prescription drug advertising.** CBO examined policies that would either eliminate direct-to-consumer prescription drug advertising or prohibit it for three years after a drug's initial approval for sale; the result would be a very small reduction (0.1 percent to 1.0 percent) in average drug prices.
- **Facilitate earlier market entry for generic and biosimilar drugs.** A diverse set of policies embodied in legislation recently introduced in the Congress and analyzed by CBO would accelerate market entry for generic and biosimilar drugs and reduce average drug prices by a very small amount (0.1 percent to 1.0 percent) or by less than 0.1 percent.
- **Increase transparency in brand-name drug prices.** CBO looked at two policies: The first, which would require manufacturers to publicly disclose rebates that they pay to insurers or pharmacy benefit managers (PBMs) in Medicare Part D and commercial insurance, would probably cause the net prices that those purchasers pay to rise slightly. The second policy, which would require PBMs to share their drug price information with health insurers, would lead to a very small reduction (0.1 percent to 1.0 percent) in average drug prices.

See Box 2-1 on page 16 for details about how CBO selected the approaches examined in this report and organized the discussion of each approach.

Allow Commercial Importation of Prescription Drugs Distributed Outside the United States

Purchasers of prescription drugs in foreign countries often pay substantially lower prices than purchasers in the United States, even when the product is the same. Some individual U.S. consumers save money by purchasing prescription drugs in another country, such as Canada or Mexico. Since the enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, the Department of Health and Human Services (HHS) has had the authority to permit prescription drugs to be imported from Canada if the Secretary of HHS certifies that doing so would pose no additional risk to public health and would result in significant savings to consumers. The Food and Drug Administration (FDA) has expressed concerns about the safety of imported products under such a scenario but has recently established a process by which states can submit proposals for importation programs to the FDA for review and authorization.¹

The Congress has considered legislative proposals that would allow prescription drugs that were distributed in a foreign market (regardless of where they were manufactured) to be diverted and sold to consumers in the

1. The FDA has developed two pathways for allowing importation of drugs distributed in foreign countries. In the first, states and Native American tribes can submit a proposal to the FDA under section 804 of the Federal Food, Drug, and Cosmetic Act for review. Such procedures apply only to Canada, and certain categories of drugs, such as biological drugs, infused drugs, and intravenously injected drugs, are not eligible. On January 5, 2024, the FDA approved a two-year Section 804 Importation Program for Florida. The FDA also issued a guidance for a second pathway under section 801(d)(1)(B) that would apply to drug manufacturers. See Amanda Sarata, *Prescription Drug Importation*, Report IF11056, version 7 (Congressional Research Service, January 22, 2024), www.crs.gov/reports/pdf/IF11056/IF11056.pdf.

United States, a practice known as parallel trade. Such proposals would affect wholesalers or other intermediaries, pharmacies, and, potentially, patients.

Some proposals include a wide set of developed countries as potential sources of products that could be redistributed in the United States, and others have been limited to Canada. The proposals also differ in the set of drugs that would become eligible for importation and distribution. Some proposals would make all brand-name drugs eligible or specify a subset of drugs to be made eligible; others would exclude drugs requiring special handling. Alternatively, a policy could confer eligibility on individual products or classes of drugs used to treat a particular condition. Most proposals are concerned with brand-name drugs because prices for generic drugs in the United States are more comparable to generic prices elsewhere.

One important consideration in the design of any importation policy is whether it would compel the HHS Secretary to issue regulations permitting importation or simply extend existing authority under current law to permit importation from a broader set of countries than Canada alone. CBO's cost estimates for legislative proposals that would allow parallel trade of prescription drugs that were distributed outside the United States have been based on an expectation that, without a concrete requirement, the Secretary would be unlikely to act; those policies would probably not affect the domestic market for prescription drugs.

Another key consideration is whether the policy would prevent manufacturers from attempting to limit the volume of drugs imported for redistribution in the United States. For example, manufacturers could differentiate drug products sold outside the country so that they were not identical to their U.S. counterparts and therefore not approved for sale in the United States, they could limit shipments of drugs to a foreign country or countries, or they could make contracts with foreign purchasers that restrict resale of products.²

Policy Approach

CBO examined a policy under which small-molecule prescription drugs that are distributed by manufacturers or their licensees in a specific set of countries could be

redistributed by licensed wholesalers to purchasers in the United States. (Biologic drugs, which are produced from living organisms, or other drugs requiring special handling would not be eligible.) Those countries would include Canada, France, Germany, Italy, Sweden, Switzerland, and the United Kingdom.³ This policy would not prevent manufacturers from limiting the volume of drugs distributed in foreign markets in order to reduce the potential volume of drugs available for redistribution in the United States (see Figure 3-1).

Estimated Effect: A Very Small Reduction in Average Prices

Requiring the HHS Secretary to allow parallel trade in certain prescription drug products would lead to a very small reduction (0.1 percent to 1.0 percent) in average drug prices in the United States. CBO's assessment of the potential price reductions under this approach is based on an estimate that prices for the set of drugs that could be subject to parallel trade are about 60 percent lower in the source countries than in the United States.⁴ The overall effect of this approach on average drug prices in the United States would be limited by several factors. CBO expects manufacturers to distribute only enough drug products to foreign countries to meet their needs. In the short run, intermediaries might be able to obtain significant volumes of prescription drugs for resale in the United States, but in the longer run the affected countries would probably intervene to prevent large amounts of drugs from being diverted.

Another factor that would limit the effect on average prices is the share of any price difference that would be retained by intermediaries. It is possible that little or no savings would be passed on to consumers, though that is difficult to predict because such an importation policy has not been implemented on a large scale. In CBO's estimation, at least half of the price difference would be retained by firms engaging in parallel trade.

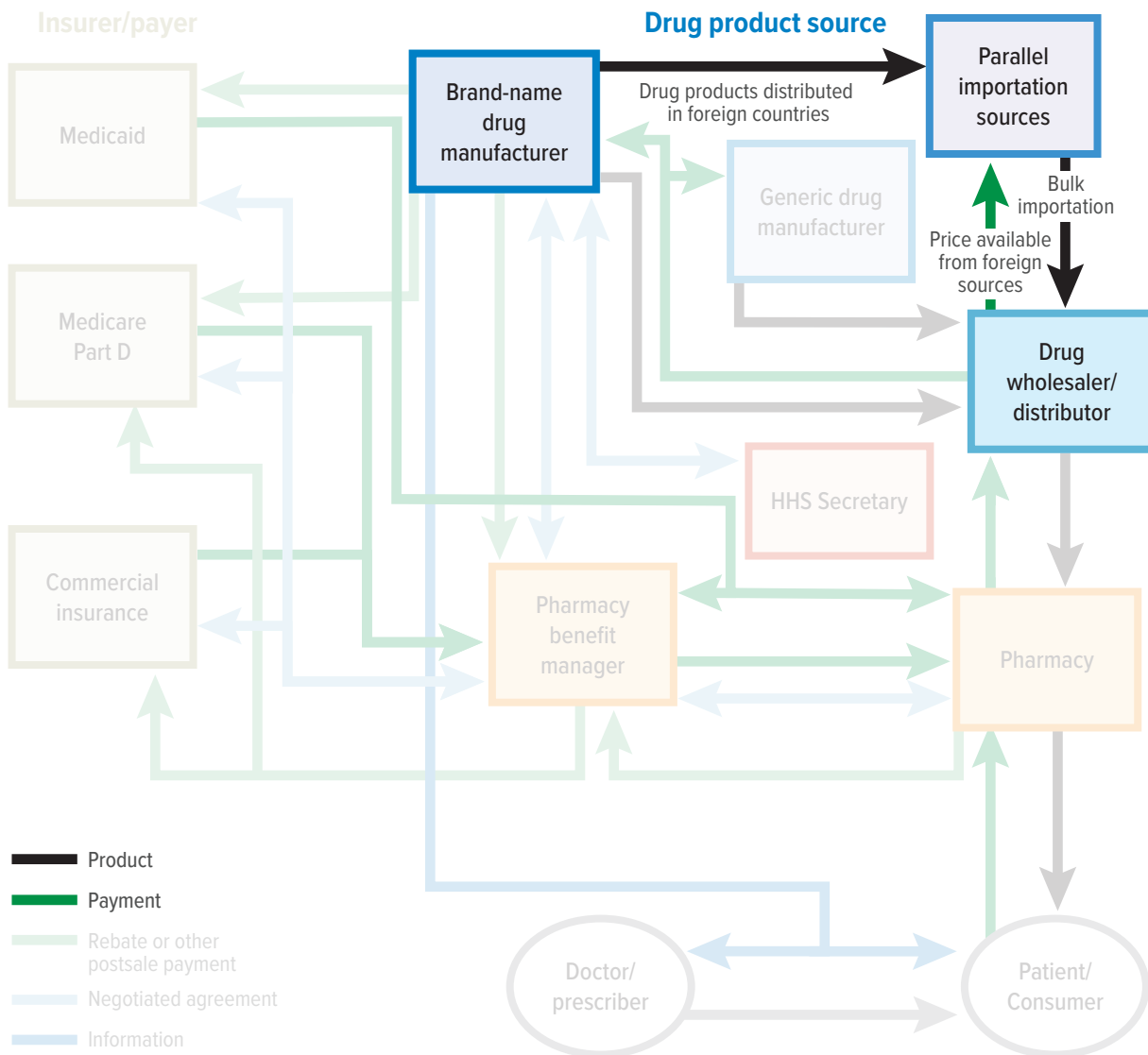
2. Margaret Kyle, "Strategic Responses to Parallel Trade," *B.E. Journal of Economic Analysis and Policy: Advances*, vol. 11, no. 2 (December 2011), pp. 1–34, <https://doi.org/10.2202/1935-1682.2629>.

3. Canada's Patented Medicine Prices Review Board includes that set of countries (plus the United States) in its price comparisons.

4. That figure is based on the difference between U.S. and foreign prices estimated for nonbiological drugs in Andrew W. Mulcahy, Daniel Schwam, and Susan L. Lovejoy, *International Prescription Drug Price Comparisons: Estimates Using 2022 Data*, RR-A788-3 (RAND Corporation, 2024), <https://doi.org/10.7249/RR-A788-3>; and Andrew W. Mulcahy and others, *International Prescription Drug Price Comparisons: Current Empirical Estimates and Comparisons With Previous Studies*, RR-2956-ASPEC (RAND Corporation, 2021), <https://doi.org/10.7249/RR2956>.

Figure 3-1.

Allow Commercial Importation of Prescription Drugs Distributed Outside the United States



Data source: Congressional Budget Office.

Other Considerations

Allowing parallel trade could reduce the availability of prescription drugs in the source countries if substantial amounts of drugs distributed in those countries were diverted for sale in the United States. In particular, that could occur if manufacturers sought to limit imports by restricting overseas distribution. Placing limits on manufacturers' ability to restrict overseas distribution would probably result in legal challenges, the outcomes of which would be uncertain. Patients' access to drugs in

the selected source countries could also be diminished if manufacturers raised prices in those countries.

Eliminate or Limit Direct-to-Consumer Prescription Drug Advertising

Manufacturers advertise brand-name prescription drugs to boost the quantity of drugs they sell, particularly during the period when they have exclusive sales rights and earn nearly all of their profits. They advertise through direct-to-physician marketing, which includes

advertisements in medical journals, physician detailing (in which a sales representative shares information with a physician), and promoting their products to opinion leaders or at conferences and in other settings. Manufacturers also boost sales through direct-to-consumer (DTC) advertisements on television or in other media aimed at patients.

The two types of advertising target different parts of the process by which patients and their medical providers make decisions about drug consumption.⁵ During that process, the patient must seek medical care, the provider must make a diagnosis and prescribe a drug, and the patient must fill the prescription and comply with treatment over time if required.

Unlike drug advertising aimed at physicians, which has a long history in the United States, large-scale direct-to-consumer advertising emerged relatively recently, in the 1990s.⁶ Since then, spending on DTC advertising has risen substantially, though it remains far below the amount directed at medical providers. Among high-income countries, only the United States and New Zealand allow DTC advertising of prescription drugs.

DTC advertising can prompt people to seek care that they would not have otherwise and can encourage them to adhere to prescribed therapy longer than they would have otherwise. As a result, it may improve the health of some people who would not have sought care or who would have been less adherent in the absence of DTC advertising. At the same time, DTC advertising might lead patients to request and receive a new, expensive drug when a less costly option could offer similar clinical benefits; in such cases, limiting or eliminating advertising activity could reduce spending without a loss of clinical benefits, improving the efficiency of health care spending. Because rare adverse outcomes from new drugs are sometimes not detected in safety and efficacy trials, faster take-up of a new drug resulting from DTC advertising may lead to a larger number of adverse outcomes.

5. Insurers also play a role in the selection of prescription drugs for consumption, for example, by setting favorable cost-sharing requirements for preferred drug products.

6. In 1997, the FDA released a draft guidance to manufacturers on how to comply with existing regulatory requirements for advertising drugs on television and radio; a final rule was issued in 1999. See Susan Thaul, *Direct-to-Consumer Advertising of Prescription Drugs*, Report R40590, version 2 (Congressional Research Service, May 20, 2009), p. 10, <http://tinyurl.com/4zut47mf>.

Policy Approach

CBO analyzed two alternative policies. The first would prohibit all DTC advertising for individual brand-name prescription drugs in electronic (TV, radio, internet) and print (newspapers, magazines) media. The second would prohibit DTC advertising for a brand-name drug in the three years after its initial approval. The temporary ban would allow time for possible adverse effects of a new drug to be identified before it became more widely used. Under both policies, marketing efforts aimed at physicians would be permitted as they are now, and manufacturers could publish scientific information in other settings, as they do under current law (see Figure 3-2).

Estimated Effect: A Very Small Reduction in Average Prices

Both of the alternative policies that CBO examined—eliminating DTC advertising and prohibiting it for three years after a drug's initial approval for sale—would lead to a very small reduction (0.1 percent to 1.0 percent) in drug prices. That reduction would occur because prohibiting DTC advertising would reduce patients' demand for drugs, which would lower the ability of manufacturers to negotiate higher prices with insurers.

According to one estimate, manufacturers spent about \$6 billion on DTC advertising of brand-name drugs in the United States in 2018.⁷ That spending tends to be highly concentrated on a small number of brand-name drugs; most drug products are not heavily advertised to consumers. CBO estimates that drugs with substantial DTC advertising accounted for roughly one-fifth of retail spending on prescription drugs that year.⁸

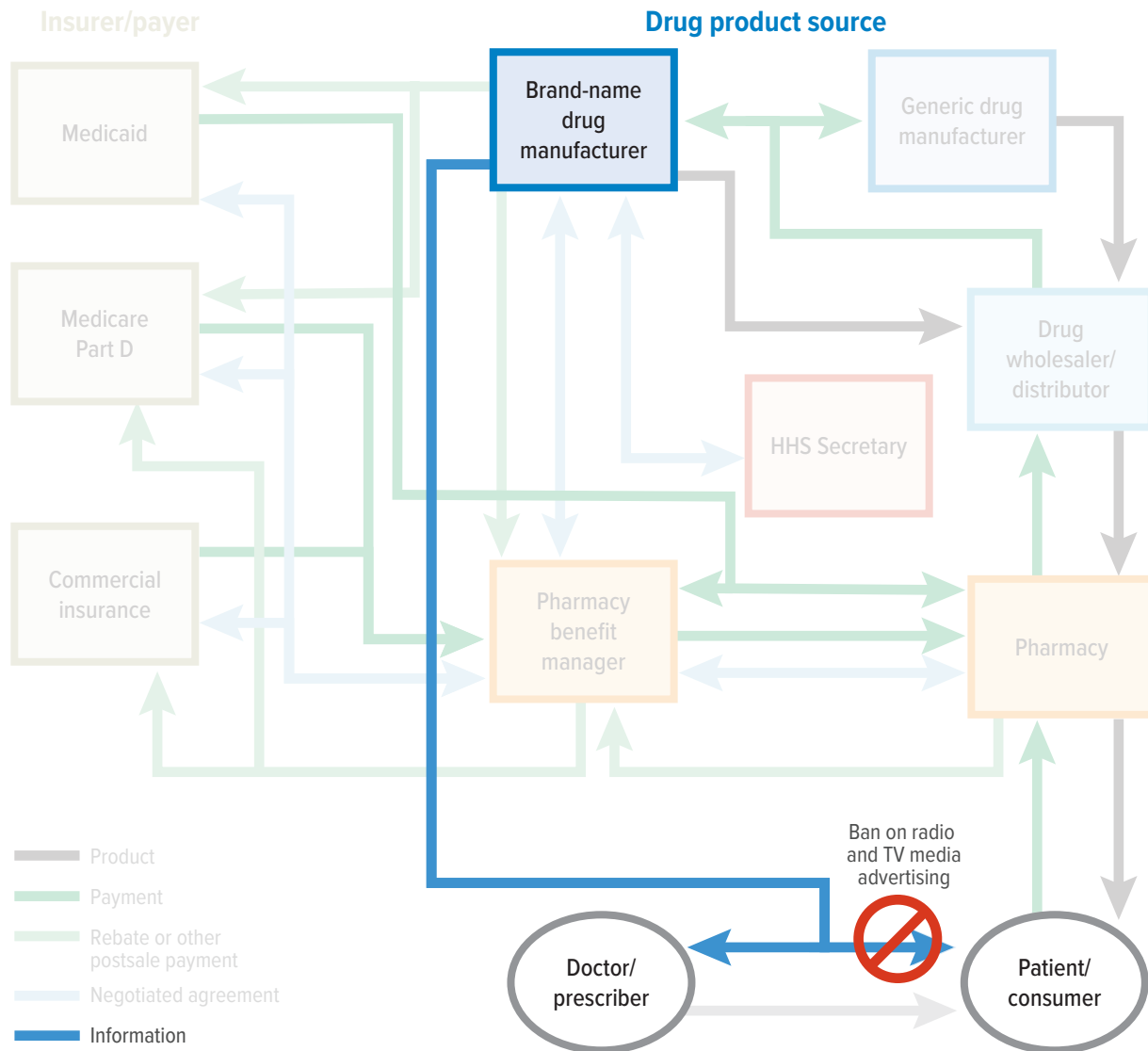
Manufacturers advertise products to increase their revenue, so reductions in advertising expenditures would be expected to reduce that revenue. Empirical analyses of the relationship between DTC advertising and spending on prescription drugs have found that a change of 10 percent in DTC advertising expenditures is associated

7. That estimate was steady from 2016 to 2018. See Government Accountability Office, *Prescription Drugs: Medicare Spending on Drugs With Direct-to-Consumer Advertising*, GAO-21-380 (May 2021), www.gao.gov/assets/gao-21-380.pdf.

8. For that estimate, CBO used data from the Government Accountability Office about direct-to-consumer advertising expenditures for the 25 most advertised brand-name prescription drugs in 2018, along with total U.S. sales figures publicly reported by manufacturers. See Government Accountability Office, *Prescription Drugs: Medicare Spending on Drugs With Direct-to-Consumer Advertising*, GAO-21-380 (May 2021), p. 23, www.gao.gov/assets/gao-21-380.pdf.

Figure 3-2.

Eliminate or Limit Direct-to-Consumer Prescription Drug Advertising



Data source: Congressional Budget Office.

with a change of 1.0 percent to 2.3 percent in prescription drug spending. The change in drug spending measured in relation to the change in advertising expenditures is called the elasticity of drug spending to spending on DTC advertising; thus, estimates of that elasticity range from 0.10 to 0.23.⁹

Those estimates reflect analyses of relatively small changes in DTC spending, and they may understate how a larger change—for example, eliminating all DTC advertising—would affect drug spending. CBO’s calculations of the effects of this approach are therefore based on an elasticity of 0.23, which is at the high end of the range

9. Abby Alpert, Darius Lakdawalla, and Neeraj Sood, “Prescription Drug Advertising and Drug Utilization: The Role of Medicare Part D,” *Journal of Public Economics*, vol. 221 (2023), pp. 1–17, <https://pubmed.ncbi.nlm.nih.gov/37275770/>; Dhaval Dave and Henry Saffer, “Impact of Direct-to-Consumer Advertising on Pharmaceutical Prices and Demand,” *Southern Economic*

Journal, vol. 79, no. 1 (July 2012), pp. 97–126, www.jstor.org/stable/41638864; and Meredith B. Rosenthal and others, “Demand Effects of Recent Changes in Prescription Drug Promotion,” in David M. Cutler and Alan M. Garber, eds., *Frontiers in Health Policy Research* (MIT Press, 2003), pp. 1–26, www.nber.org/system/files/chapters/c9862/c9862.pdf.

of published estimates, reflecting CBO's expectation that a large change in DTC advertising would have a greater effect than that suggested in empirical studies that are based on analyses of relatively small changes.

Those changes in spending would be driven primarily by changes in quantities of drugs consumed, not prices for those drugs, so existing empirical evidence provides only a partial guide for assessing how this approach would affect prices. In addition to increasing sales quantities and therefore manufacturers' revenue, DTC advertising may enable manufacturers to charge higher prices by reducing consumers' sensitivity to a drug's price; if so, the absence of DTC advertising might mean that manufacturers would set prices that are lower than they otherwise would. However, the exact contributions of quantities versus prices to such spending changes are unclear. CBO's estimates of the effects of this approach reflect an assessment that price changes would account for one-fifth or less of the reduction in drug spending that would result from it.¹⁰

Brand-name drugs often have exclusive sales periods of 12 to 17 years. In CBO's estimation, prohibiting DTC advertising during the first three years after approval for sale would roughly correspond to reducing DTC expenditures by a quarter, resulting in a much smaller reduction in average prices than would occur with a prohibition of all DTC advertising.

Other Considerations

Disallowing direct-to-consumer advertising for three years after a product's initial approval could allow the identification of adverse outcomes or long-term risks from new products while also permitting manufacturers to use advertising as a means of boosting revenue when additional follow-up data have been made available.

Drug manufacturers would probably challenge a policy aimed at eliminating or limiting DTC advertising on constitutional grounds, and the outcome of such a legal challenge would be uncertain. An alternative approach to limiting DTC advertising directly would be to limit the tax deductibility of manufacturers' expenses on that advertising activity.

Facilitate Earlier Market Entry for Generic and Biosimilar Drugs

When a brand-name drug faces competition from a newly launched generic or biosimilar version of that drug, its manufacturer often permanently loses a large share of the market and profits on that drug. Delaying the availability of an inexpensive generic or biosimilar alternative, even for a short time, can increase profits by allowing the manufacturer of the brand-name drug to retain market share without reducing prices.

As a result, manufacturers have used various tactics to effectively prolong the period of exclusive sales rights. One method involves obtaining multiple additional patents—creating a “patent thicket”—in the later years of a drug's market exclusivity, which can make it costlier and more difficult for a manufacturer of generic or biosimilar drugs to challenge the patents protecting the brand-name drug. Another method is “product hopping,” in which the brand-name manufacturer introduces a modified version of a drug (such as an extended-release version) that will remain under exclusivity protections after the original formulation is at risk of generic competition; the manufacturer then encourages or forces physicians and patients to switch to the new version, possibly by discontinuing production of the old version.

Two other strategies that brand-name manufacturers have used to delay generic entry are settlement agreements with “pay-for-delay” provisions and efforts to obstruct the generic version's regulatory approval process. In most cases, patent disputes between manufacturers of generic or biosimilar drugs and brand-name drug manufacturers involve litigation that has to be resolved before the generic or biosimilar can launch, and those disputes are often resolved through settlement agreements.¹¹ “Pay-for-delay” refers to settlement agreements in which the brand-name manufacturer compensates the generic or biosimilar manufacturer in exchange for an agreement to delay generic or biosimilar entry. Manufacturers of brand-name drugs have also used parts of the regulatory approval process for generic drugs to delay that process, such as by submitting citizen petitions to the Federal Drug Administration, or FDA (which can delay regulatory approval of generic and

10. In other words, 80 percent of the reduction in drug spending on DTC-advertised drugs (which account for roughly one-fifth of prescription drug expenditures) would be related to reduced sales quantities, not lower prices.

11. Generic drug manufacturers sometimes launch their products before patent litigation is resolved—a practice known as launching at risk—but can incur large penalties if they are later found to be infringing on a valid patent.

biosimilar drugs) just before the generic drug's expected approval date.¹²

Policy Approach

Rather than examine a specific policy, CBO instead considered a diverse set of policies recently introduced in the Congress and analyzed by CBO that address a variety of practices used to delay generic or biosimilar entry. In recent years, the Congress has considered several bills aimed at accelerating the market entry of generic and biosimilar drugs. Those bills target different practices that delay generic and biosimilar entry, such as patent thickets, pay-for-delay arrangements, and citizen petitions. Another policy would address the delay in generic competition that can occur when a manufacturer holds the 180-day exclusive generic sales rights for a product but does not make it available for sale. CBO examined the spectrum of policies proposed in this area because they are so diverse that examining a specific policy would not adequately represent the breadth of policies proposed (see Figure 3-3).

Estimated Effect: A Very Small Reduction in Average Prices for Most Policies

In CBO's estimation, recent proposals to accelerate generic and biosimilar entry that have been introduced in the Congress and analyzed by CBO would each reduce average drug prices in 2031 by a very small amount (0.1 percent to 1.0 percent) or by less than 0.1 percent.¹³ The extent of the overall price reduction would depend on the amount by which generic or biosimilar competition reduced the average price paid for any particular drug, the amount of time by which entry would be accelerated for the affected drugs, and the per-

centage of total spending that would be subject to earlier entry under the policy.

Policies like the ones CBO considered would reduce the prices of affected drugs by hastening generic and biosimilar entry relative to current law. The affected drugs would have eventually faced such competition anyway, so the price reductions from the policy would be temporary relative to current law for the affected drugs.¹⁴

The expected price reduction for drugs affected by a particular policy would depend on whether they were small-molecule or biologic drugs. CBO estimates that the net prices of small-molecule drugs are about three-quarters lower, on average, in the fourth year following generic entry than in the year before generic entry.¹⁵ In CBO's assessment, which is based on the limited data available in the biologics market, prices of biologics (including their biosimilars) fall by about one-third over the same period, on average. That difference results from sharper price reductions and more rapid uptake of generic drugs than of biosimilars. As a result, in CBO's estimation, earlier generic entry reduces the prices of affected small-molecule drugs more than earlier biosimilar entry reduces the prices of affected biologic drugs.

A policy's effect on prices would also depend on how much earlier the competing generic or biosimilar entered the market. The temporary price reductions for affected drugs (compared with their prices under current law) would be larger and last longer if the policy hastened generic or biosimilar entry by a greater amount. When a price reduction persists for longer, a greater fraction of total drug spending at any time goes toward drugs with lower prices, so total spending is lower. In CBO's estimation, recent legislative proposals in this area would hasten entry by between six months and two years for different sets of drugs.

Policies that CBO examined would affect a very small percentage of overall drug spending for two reasons. First, brand-name drugs that become subject to generic or biosimilar competition in a given year account for only a limited share of total spending. For example, in CBO's estimation, drugs experiencing first generic or biosimilar entry in 2031 would account for less than

12. Delays in generic or biosimilar market entry can also result from other aspects of the regulatory approval process, such as the FDA's rules governing disclosure of a brand-name drug's inactive ingredients to generic manufacturers. Under current law, generic versions of certain medicines are required to match their brand-name version in both active and inactive ingredients, but the FDA is not permitted to divulge the concentrations of the inactive ingredients to generic manufacturers. CBO expects that allowing the FDA to disclose that information would sometimes lead to earlier generic entry. See Congressional Budget Office, cost estimate for H.R. 5378, the Lower Costs, More Transparency Act (December 8, 2023), www.cbo.gov/publication/59825.

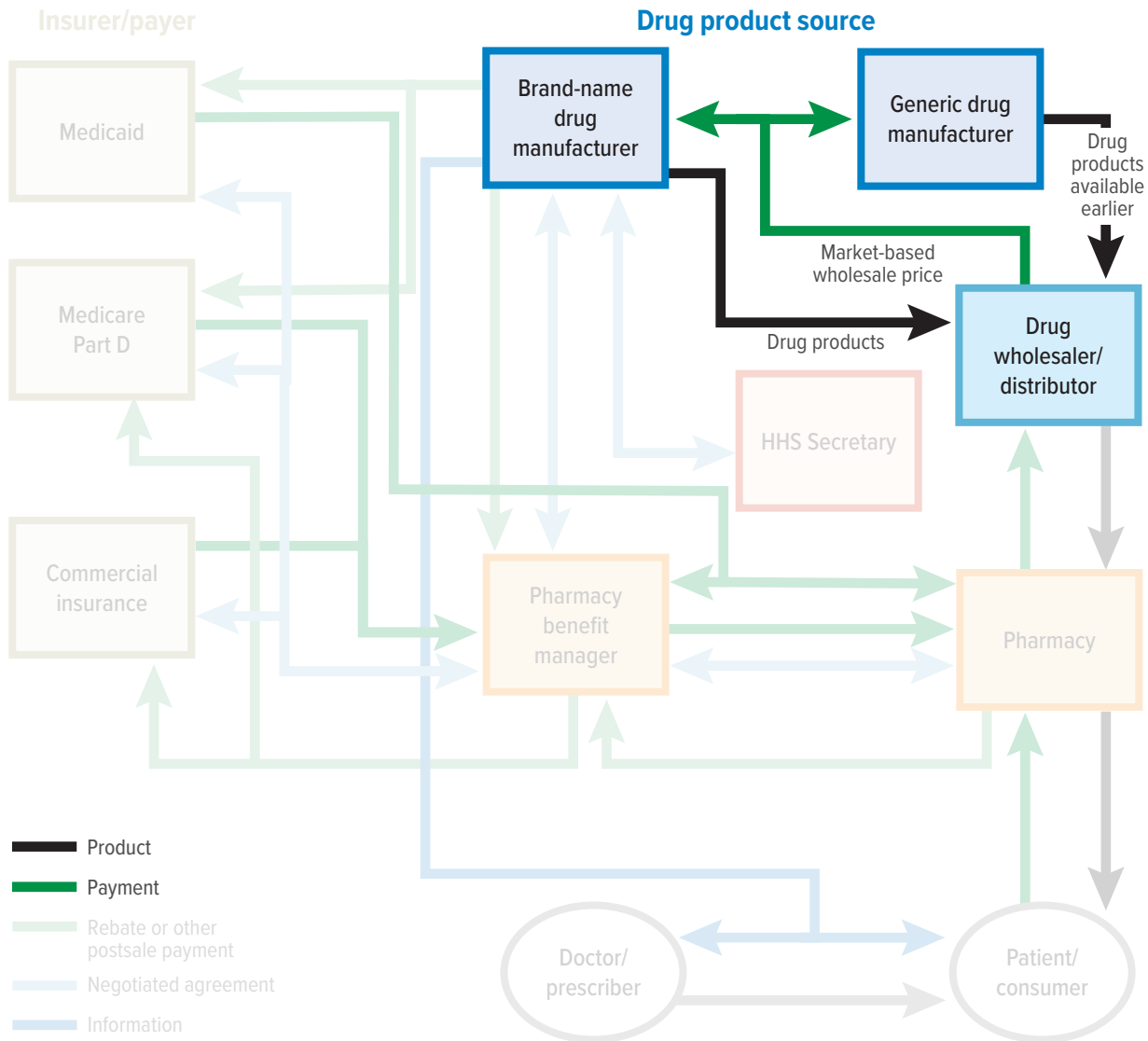
13. CBO analyzed the individual effects of the policies as if they were each implemented alone. The agency estimates that each policy would reduce average prices in 2031 by 0.1 percent to 1 percent, except for restricting citizen petitions, which would reduce average prices by less than 0.1 percent. Multiple policies could be implemented at the same time, and their combined effects on prices could be larger or smaller than the sum of their individual effects.

14. Although price reductions for individual drugs are temporary, the effect of a policy on average drug prices may not diminish over time. An effect could remain constant over time if the affected drugs accounted for a constant fraction of total drug spending over time.

15. That estimate reflects a weighted average price for brand-name and generic sales combined.

Figure 3-3.

Facilitate Earlier Market Entry for Generic and Biosimilar Drugs



Data source: Congressional Budget Office.

5 percent of total drug spending in that year. Second, only a fraction of the drugs experiencing entry each year would be affected by any particular policy. Different barriers to entry prove binding for different drugs, so a policy that aims to address only one particular barrier to entry is unlikely to affect a large number of drugs. Of the proposals that CBO examined for this report, none would affect more than 10 percent of spending on the drugs experiencing entry each year.

Other Considerations

CBO estimated the effects of policies that facilitate earlier market entry for generic and biosimilar drugs relative to a current-law baseline under which federal regulators—principally, the FDA and the Federal Trade Commission (FTC)—already possess authority to bring certain antitrust enforcement actions or to take other steps to facilitate earlier entry. In CBO’s view, antitrust enforcement tools affect prices primarily by deterring anticompetitive behavior. If the antitrust enforcement

tools available to the FTC changed, as they did following the Supreme Court's decisions in *FTC v. Actavis* (2013) and *AMG Capital Management v. FTC* (2021), CBO's assessment of the effects of certain policies relative to current law would also change.¹⁶

For this report, CBO considered only proposals that were recently introduced in the Congress and for which CBO published a cost estimate.¹⁷ Another potential tool available to policymakers is compulsory licensing (see Box 3-1).

Increase Transparency in Brand-Name Drug Prices

The prices that private insurers or pharmacy benefit managers (PBMs) pay for brand-name prescription drugs are known only to those parties and the drug manufacturers. List prices for prescription drugs are publicly available, but they do not reflect rebates or other price concessions after the point of sale that purchasers often negotiate with manufacturers. Manufacturers agree to such rebates in exchange for preferred formulary placement with lower cost sharing or fewer restrictions on utilization than competing products. Additional rebates may be provided to purchasers who reach specified drug sales volumes.

The rebates that PBMs or insurers receive from manufacturers are often substantial. Larger rebates mean lower net prices, or final transaction prices, for payers. Those rebates and net prices are commercially sensitive information. Some recent legislative proposals have focused on greater transparency in drug prices in order to make lower prices available to some purchasers—for example,

by increasing the leverage they might have in negotiations with manufacturers.

Policy Approach

CBO examined two policies. Under the first, manufacturers of brand-name prescription drugs would be required to publicly report, for individual drugs, the overall average amounts per prescription of any rebates, discounts, or other price concessions that they provide to insurers or PBMs. That information, along with publicly reported list prices, would make a drug's average net price publicly known. The policy would apply to retail sales to commercial insurers and Medicare Part D plans, as well as to PBMs acting on their behalf. (Medicaid sales would not be included.) The numbers that manufacturers would report under the policy would reflect the net prices charged to each commercial or Part D purchaser during the reporting period, weighted by each buyer's total purchase volume. Purchasers could use that information to compare their rebate agreements with average market rebates (see Figure 3-4 on page 36).

Under the second policy, PBMs would be required to provide sponsors of group health plans with information about the prices they pay for individual drugs. That price information would reflect all rebates or other payments made after the point of sale for drugs provided to the health plans' enrollees. (Under current law, Part D insurers already have access to such information from PBMs.)

Estimated Effect: A Slight Increase or a Very Small Reduction in Average Prices

Requiring manufacturers to publicly disclose rebates that they pay to insurers or PBMs in Medicare Part D and commercial insurance would probably cause the net prices that those purchasers pay to rise slightly. That assessment is grounded in the expectation that such disclosure would reduce the variation in existing rebates among purchasers, with larger and smaller rebates tending to converge. Purchasers who had not previously received large rebates could use the newly revealed pricing information to bargain for lower prices. At the same time, manufacturers would be more reluctant to offer large rebates because of the resulting pressure on pricing arrangements with other purchasers.

In CBO's estimation, average rebates would fall, meaning that insurers and PBMs would face higher net prices and greater average drug costs, though that assessment is uncertain because the effect would depend on the

16. In *FTC v. Actavis*, the Supreme Court held that when patent settlement agreements between manufacturers of brand-name and generic drugs include the transfer of something of value from the brand-name to the generic manufacturer, those agreements can be subject to antitrust scrutiny. In *AMG Capital Management v. FTC*, the Court curtailed the FTC's ability to collect monetary damages from brand-name manufacturers who engage in anticompetitive practices. In CBO's assessment, the *Actavis* decision made it easier for the FTC to challenge and deter pay-for-delay arrangements, and the *AMG Capital Management* decision diminished the FTC's enforcement power as a deterrent against anticompetitive behaviors.

17. See, for example, Congressional Budget Office, cost estimate for S. 150, the Affordable Prescriptions for Patients Act of 2023 (June 13, 2024), www.cbo.gov/publication/60412, and cost estimate for S. 142, the Preserve Access to Affordable Generics and Biosimilars Act (March 13, 2024), www.cbo.gov/publication/60083.

Box 3-1.

Compulsory Licensing for Brand-Name Prescription Drugs

Compulsory licensing refers to an action by the federal government that would allow a party other than the patent-holding manufacturer—for example, a generic drug manufacturer—to produce a patented prescription drug without that manufacturer’s consent before the expiration of the drug’s exclusive sales rights under the Hatch-Waxman Act and related laws.

Two possible sources for such authority exist under current law in the United States.¹ First, the Patent and Trademark Law Amendments Act of 1980 (sometimes called the Bayh-Dole Act) gives the federal government “march-in rights,” which allow the Secretary of Health and Human Services (HHS) to withdraw a manufacturer’s exclusive sales rights if the relevant drug was developed using federal funds and the manufacturer does not make the drug available for purchase on “reasonable” terms. Experts have expressed differing views about the extent to which agencies can or should consider price when applying the statutory criteria that allow the use of march-in rights.²

A second possible source of compulsory licensing authority is 28 U.S.C. §1498, which enables the government to allow some party other than the patent-holding drug manufacturer to produce the patented product without the consent of the patent holder in exchange for “reasonable and entire compensation.” That law does not specify a means of determining such compensation.

No Secretary of HHS has exercised march-in rights under the Bayh-Dole Act, and the authority under 28 U.S.C. §1498 has not

been invoked for prescription drugs for several decades.³ In recent years, some legislative proposals, such as the Prescription Drug Price Relief Act of 2019 (S. 102, 116th Cong.), have included provisions that would have made use of compulsory licensing of prescription drugs. In December 2023, the National Institute of Standards and Technology released a draft interagency guidance on the use of march-in rights under the Bayh-Dole Act.⁴

The use of compulsory licensing could have a wide range of possible effects on prescription drug prices and research and development (R&D) investments, depending greatly on how such a policy was implemented. The effects would depend on both the likelihood that a given drug would be subject to the policy and the ability of other manufacturers to produce the drug and drive prices down through direct competition. On the one hand, if compulsory licensing was unlikely to be applied or if competition from other manufacturers was limited for a given product, then the effects of such a policy would be limited. On the other hand, if a policy required extensive use of compulsory licensing and several other manufacturers were able to enter the market, then the effects of that policy on prices and R&D investments would be larger. The amount of compensation paid to the brand-name manufacturer could mitigate the effect of the policy on R&D investments.

When a brand-name drug faces direct competition from one or more equivalent generic products, market share shifts rapidly to cheaper generic versions, and prices paid by consumers fall

1. Kevin J. Hickey and Erin H. Ward, *The Role of Patents and Regulatory Exclusivities*, Report R46679, version 6 (Congressional Research Service, January 30, 2024), pp. 25–27, <https://crsreports.congress.gov/product/pdf/R/R46679>.

2. See Amy Kapczynski and others, letter to the Honorable Elizabeth Warren (April 20, 2022), <https://tinyurl.com/2cvkhkxe>; and Jonathan M. Barnett and others, letter to the Honorable Bernie Sanders, the Honorable Dr. Bill Cassidy, the Honorable Jason Smith, and the Honorable Richard Neal (September 28, 2023), <https://tinyurl.com/2r8uh7ru>.

3. In 2001, the HHS Secretary considered using the authority under 28 U.S.C. §1498 for Cipro but declined to do so. See Kevin J. Hickey and Erin H. Ward, *The Role of Patents and Regulatory Exclusivities*, Report R46679, version 6 (Congressional Research Service, January 30, 2024), pp. 25–27, <https://crsreports.congress.gov/product/pdf/R/R46679>.

4. National Institute of Standards and Technology, Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-in Rights, 88 Fed. Reg. 235 (December 8, 2023), pp. 85593–85605.

Continued

current distribution of rebates across drugs.¹⁸ Not all brand-name drug prices would be equally affected by a convergence in average rebates. Disclosure of rebates could have a greater effect on brand-name drugs with

competitors in their therapeutic class than on unique drugs, because drugs facing competition tend to have larger rebates and therefore more room for variation in net prices.

18. For a discussion of the effects of disclosing rebates, see Congressional Budget Office, letter to the Honorable Joe Barton and the Honorable Jim McCrery on the potential effects of disclosing price rebates on the Medicare drug benefit (March 12, 2007), www.cbo.gov/publication/18421.

A disclosure requirement might also increase net prices by allowing manufacturers to better monitor other manufacturers’ prices, making it easier for them to maintain high prices. For some types of goods—particularly those

Box 3-1.

Continued

Compulsory Licensing for Brand-Name Prescription Drugs

substantially. Subjecting a brand-name prescription drug to compulsory licensing could produce a similar effect on prices, though that is uncertain.

Several practical factors could prevent a compulsory licensing policy from replicating the price dynamic of ordinary generic drug competition. For example, it could take time for generic drug manufacturers to prepare to produce a new generic product and enter the market, which could substantially delay price competition. (The historical price dynamics after generic entry reflect market outcomes when generic manufacturers could anticipate years in advance that a brand-name drug was going to lose its exclusive sales rights.) More generic competitors create more price competition, so compulsory licensing would have greater potential to reduce prices if it led to multiple generics entering the market.

The effect on overall drug prices of exercising compulsory licensing would critically depend on the specifics of the policy being implemented. Parameters on which the policy's effects would ultimately depend include the following:

- Would the HHS Secretary be required to act and, if so, under what specific circumstances? A Secretary might continue to choose not to use compulsory licensing authority if not required to do so. Would there be a specific, predictable point in the timing of a brand-name drug's product cycle at which the Secretary would exercise that authority, and would generic manufacturers know beforehand when generic entry would be allowed?
- For what set of brand-name drugs would compulsory licensing be exercised? Compulsory licensing would have a greater effect on average prices if it was applied to a larger number of drugs representing a greater share of spending.
- Would all dosage forms, strengths, and routes of administration of a patented drug be subject to compulsory licensing at the same time, or only some versions?
- How much competition would be introduced? For example, would a first generic entrant be given 180 days of exclusive generic rights as under current policy following a successful patent challenge, or would more than one generic manufacturer be permitted to enter immediately? Greater numbers of generic competitors would lead to greater price reductions.
- What remaining barriers to generic entry would exist, and how would they be addressed?
- How would such a policy address the likely strategic responses by patent-holding manufacturers? For example, manufacturers could try to shift patients to newer versions of a drug that are not subject to compulsory licensing; they could also adjust their prices to avoid triggering action from the Secretary.
- How much compensation would be provided to patent-holding manufacturers, and how would the amount be determined?

The use of compulsory licensing authority could substantially slow the pace of new drug development. The actual effect on drug innovation would depend on the amount of compensation provided to the patent-holding manufacturer. If drug manufacturers expected that their future products would probably be subject to compulsory licensing and that the compensation would be inadequate, then the expected returns on R&D investments would decline, making such investments less attractive. An additional consideration is that an attempt by the Secretary to exercise compulsory licensing authority—even if specifically called for in new legislation—would probably be subject to legal challenges. Under current law, the patent holders would be owed reasonable compensation, and litigation could relate to other aspects of the program or process. The outcome of such litigation is uncertain.

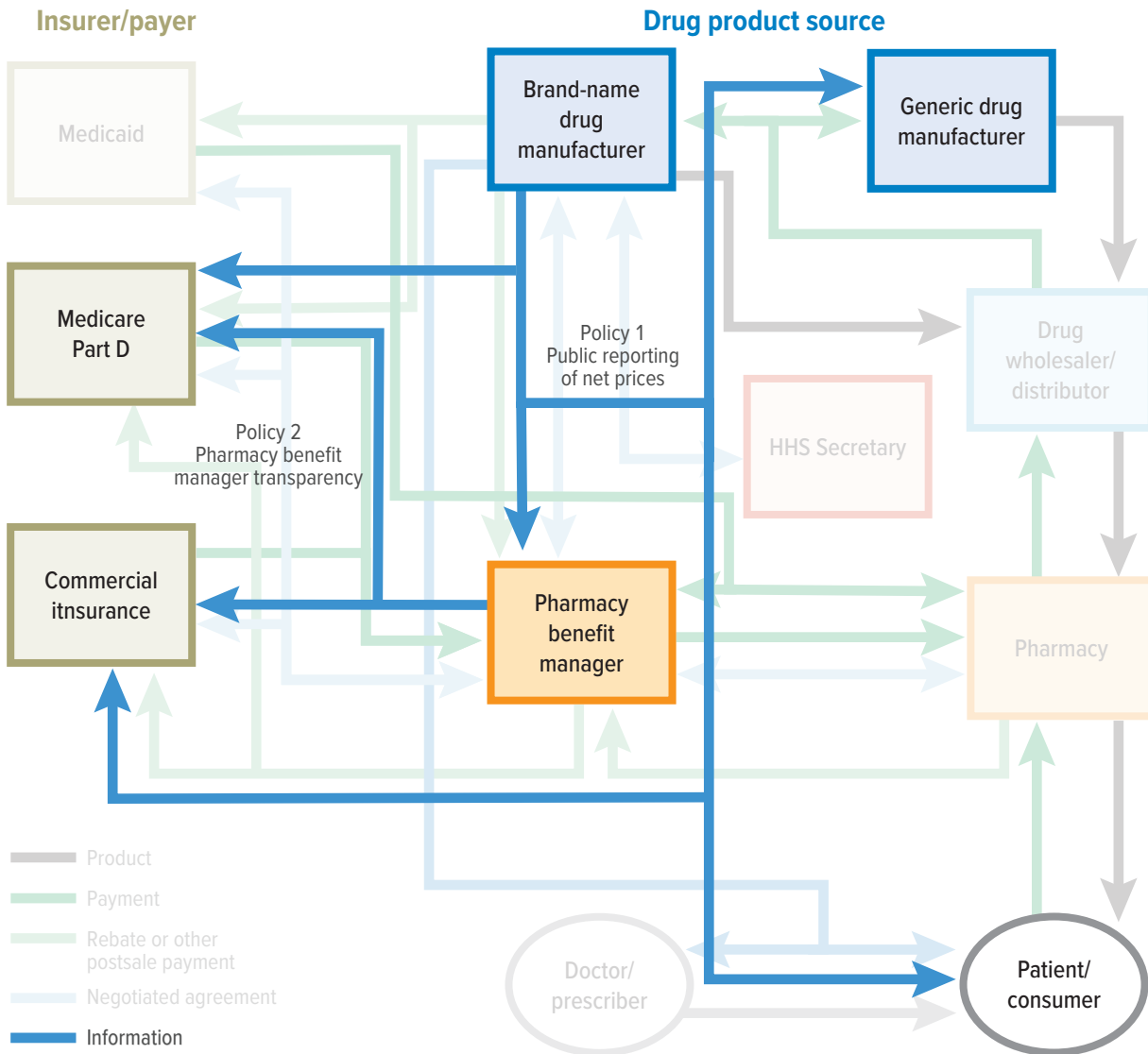
that can be substituted with competing products and that are produced by only a few firms—price transparency creates an incentive for those firms to keep prices higher than they would if the prices were unknown to competitors. That might also apply to some prescription drugs. For example, for some medical conditions, only a few drugs that confer substantial clinical benefits are available in a therapeutic class. In such cases, disclosure of drug-specific rebates could facilitate tacit collusion among makers of competing products, leading to higher

drug prices by giving manufacturers additional information about competitors' net prices. However, current empirical evidence is not sufficient to provide a basis for estimating that effect in the prescription drug market.

The second approach, requiring PBMs to share their drug price information with health insurers, would lead to a very small reduction (0.1 percent to 1.0 percent) in average drug prices. In CBO's estimation, disclosure of that information would help some clients of PBMs obtain

Figure 3-4.

Increase Transparency in Brand-Name Drug Prices



Data source: Congressional Budget Office.

better terms in contract negotiations. In particular, sponsors of smaller plans would benefit because many currently have only limited access to such information, and under this policy they would be in a better position in negotiations with PBMs. The overall effect of the policy would be limited, however, because a large portion of the market would not be significantly affected. Under current law, in CBO’s assessment, a large share of contracts between PBMs and plan sponsors in the private health insurance market are likely to include terms that require such information sharing even without this policy.

Other Considerations

If manufacturers were required to publicly disclose the rebates they pay to insurers or PBMs, some payers who receive substantial rebates under current law would face slightly higher net prices for prescription drugs. If prices increased, on average, CBO expects that manufacturers would sell smaller quantities of their drugs and earn less revenue under that scenario.

Chapter 4: Factors That Affect Manufacturers' Incentives to Develop New Drugs

The incentive to undertake pharmaceutical research and development (R&D) depends on the prospect of future global profits for manufacturers who develop new drugs and obtain approval for sale. Policies concerning prescription drugs involve a tradeoff between the desire for lower prices for brand-name prescription drugs—which can expand patients' access to existing drug therapies—and the pace of new drug development. Lower drug prices in the United States would reduce the amount that patients pay for prescription drugs, reduce health insurance premiums, and reduce health care spending by the federal and state governments. At the same time, patients and policymakers want new and better drug therapies for current and future patients, and policies that reduced manufacturers' expectations of future global revenue would dampen the incentive to invest in R&D.¹

Most policies that would reduce drug prices would also reduce manufacturers' expected total revenue, and larger reductions in revenue would have greater effects on R&D incentives than smaller reductions. Broadly, among the policy approaches that the Congressional Budget Office examined for this report, those that would reduce average prices by larger amounts would have more-pronounced effects on drug development. Price reductions occurring earlier in a drug's life cycle would dampen R&D incentives more than those occurring later. An approach could have a more- or less-pronounced effect on drug development than on average prices if it would change the total quantity of new brand-name drugs that manufacturers could expect to sell, or if its effect on the prices of new drugs would differ from its effect on the prices of drugs already on the market.

1. For a discussion of CBO's modeling of new drug development, see Christopher P. Adams, *CBO's Simulation Model of New Drug Development*, Working Paper 2021-09 (Congressional Budget Office, August 2021), www.cbo.gov/publication/57010.

The U.S. market is an especially important source of revenue for the global pharmaceutical industry because of its large size and the substantially higher drug prices in the United States than in other countries. Accordingly, drug sales in the U.S. market are a particularly important determinant of the pace of global innovation in prescription drugs, and policies that would reduce manufacturers' prices in the United States would dampen the pace of new drug innovation more than such policies in other countries would.²

Manufacturers of new brand-name drugs engage mainly in applied research, which focuses on particular compounds that can be patented and sold commercially. Many of those commercial investments in R&D are informed, directly or indirectly, by scientific knowledge generated by publicly funded research. For instance, research funded by the National Institutes of Health (NIH) identifies mechanisms of disease and describes biological processes, highlighting potential drug targets that offer the promise of valuable new strategies for therapy. Private firms have little incentive to engage in that kind of research—often referred to as “basic science”—because its economic benefits are difficult for a firm to retain. Knowledge gleaned from basic science research is often a public good available to all parties for use.³ The

2. For a discussion of how changes in drug prices in the United States could affect the global market for prescription drugs, see Darius N. Lakdawalla and others, “U.S. Pharmaceutical Policy in a Global Marketplace,” *Health Affairs*, vol. 27, no. S1 (December 2008), pp. 138–150, <https://doi.org/10.1377/hlthaff.28.1.w138>.

3. One recent analysis examined the contribution of public funding to the development of new prescription drug products and found that NIH funding contributed to every one of the new drug compounds approved from 2010 to 2016. See Ekaterina Galkina Cleary and others, “Contribution of NIH Funding to New Drug Approvals 2010–2016,” *Proceedings of the National Academy of Sciences of the United States of America*, vol. 115, no. 10 (March 6, 2018), pp. 2329–2334, <https://doi.org/10.1073/pnas.1715368115>.

relationship between public investment in basic science and private investment in applied commercial product development is complex. Publicly funded basic science research is not a substitute for private investments in applied drug R&D, but advances in basic science can make commercial R&D investments more productive by introducing opportunities for product development that had not been previously understood.

The various approaches to reducing drug prices discussed in this report would not affect publicly funded basic science research, but by reducing manufacturers' expected future revenue they could reduce their incentive to invest in privately funded applied research aimed at developing new marketable products.

Expectations of Future Revenue and Development Costs

Drug manufacturers compete to be first on the market with breakthrough drug products and to introduce alternatives to existing products. The process of developing new drugs and getting approval for sale is a risky and time-consuming enterprise: Only 12 percent of drugs that enter clinical trials are ultimately approved, and those that reach the market take about 11 years, on average, to develop.⁴

Manufacturers of new drugs invest in R&D because of the prospect of future profits. For such investments to be appealing, expectations of future global revenue must compare favorably with expected development costs, including the opportunity costs of alternative investment possibilities. If expected future returns on R&D investment are high enough to justify the time and risk involved in trying to develop new drugs, then those investments will be seen as productive; if the expected returns are lower than expected costs, investment capital will be directed

toward some activity other than drug R&D, meaning that fewer new drug products will be developed.

Manufacturers' Revenue

Expectations of future revenue are influenced by several factors. One is the likelihood of scientific success in finding and testing new compounds. Most attempts at drug development are unsuccessful, and only drugs that are successfully brought to market generate revenue for the manufacturer. Areas of research that are less likely to yield an approved product require the prospect of particularly high revenue to offset that risk. The expected market size for a new drug is also an influential factor. A drug's potential sales volume depends on the prevalence of the disease that it would treat, its expected length of exclusivity, and its safety and effectiveness compared with any competitors' products.

Other drivers of manufacturers' revenue expectations are future buyers' willingness to pay for new products and the policies to which manufacturers must adhere when setting prices. Policies that would limit prescription drug prices in the future would tend to reduce manufacturers' expectations of future revenue and, therefore, their expectations of the profitability of potential R&D investments. In response, manufacturers could decide to invest less in new product development.

Two of CBO's recent analyses of major prescription drug legislation illustrate the relationship between manufacturers' expected revenue and drug development. The Elijah E. Cummings Lower Drug Costs Now Act included provisions that, in CBO's estimate, would have reduced manufacturers' future global revenue from new drugs by 19 percent and reduced the number of new drugs introduced to the market in the third decade after implementation by 10 percent.⁵ CBO estimated that the drug-related provisions of the 2022 reconciliation act would reduce manufacturers' global revenue by 1 percent to 3 percent and would reduce the number of drugs that come to market in the third decade by 1 percent.⁶

4. The 11-year average time to develop a drug includes both preclinical and clinical phases of the drug development process. According to one study, the preclinical phase takes an average of about 31 months, followed by 95 months, on average, for clinical trials; see Joseph A. DiMasi, Henry G. Grabowski, and Ronald W. Hansen, "Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs," *Journal of Health Economics*, vol. 47 (May 2016), pp. 20–33, <https://doi.org/10.1016/j.jhealeco.2016.01.012>. In another study using data on clinical trials for more than 20,000 drugs, the clinical trials were estimated to take 8.4 years, or about 100 months, at the median; see Chi Heem Wong, Kien Wei Siah, and Andrew W. Lo, "Estimation of Clinical Trial Success Rates and Related Parameters," *Biostatistics*, vol. 20, no. 2 (April 2019), pp. 273–286, <https://doi.org/10.1093/biostatistics/kxx069>. See also Congressional Budget Office, *Research and Development in the Pharmaceutical Industry* (April 2021), pp. 13–14 and footnote 14, www.cbo.gov/publication/57025.

5. Congressional Budget Office, cost estimate for H.R. 3, the Elijah E. Cummings Lower Drug Costs Now Act (December 10, 2019), www.cbo.gov/publication/55936. For updated global revenue and drug development estimates, see Congressional Budget Office, "CBO's Model of New Drug Development" (presentation to the Dartmouth Institute for Health Policy and Clinical Practice, January 13, 2022), www.cbo.gov/publication/57450.

6. Congressional Budget Office, letter to the Honorable Jodey Arrington and the Honorable Michael C. Burgess, providing additional information about drug price negotiation and CBO's simulation model of drug development (December 21, 2023), www.cbo.gov/publication/59792.

Development Costs

Development costs fall into one of two categories: The first category includes the direct costs of laboratory work, clinical trials, and navigating the regulatory process, as well as the direct financing cost of investment capital, such as interest that the manufacturer has to pay on loans. The second category includes the opportunity cost of investment capital, which arises from forgone investments—including safer investments yielding relatively consistent returns—that could have been made in place of comparatively risky R&D investments. Because of the high rate of failure, and because capital is tied up for years during the development and approval stages for compounds that are ultimately successful, manufacturers or other investors in biopharmaceutical R&D find such investments to be attractive options only if the expected return from a successful drug is high enough.

The timing of expected development costs and future revenue flows plays an important role in whether prospective R&D investments appear profitable. Drug development costs occur in the relative near term; expected revenue for a successful product appears later in a manufacturer's time horizon. To compare favorably on a present-value, discounted basis, that future revenue must be substantially larger than the more immediate development costs.

Effects of the Policy Approaches on Manufacturers' Incentives to Develop New Drugs

Changes to policies affecting the prescription drug market will affect the pace of drug development if they lead to changes in any of the drivers of expected revenue or development costs. The policy approaches examined in this report would not affect the costs of biomedical research or the likelihood of success in developing a drug.

Any effects of these approaches on the amount of total R&D investment or the pace of new drug launches would result from changes either in manufacturers' expectations of future global revenue or in the cost of financing investment capital. Reductions in expected revenue would make R&D investments less attractive, and reductions in manufacturers' current revenue from products already on the market would reduce the amount of cash on hand that they can invest, which could increase their cost of capital.⁷

7. In a 2021 study that used the policy changes in the Elijah E. Cummings Lower Drug Costs Now Act to demonstrate the key features of CBO's drug development simulation model, CBO evaluated the effects of the policy with and without

Policies that would have larger effects on manufacturers' revenue expectations or their cash on hand would affect R&D investments to a greater extent. Expected revenue in the near future has a higher present value than that in the more distant future, so expected revenue early in a drug's product cycle exerts more influence on the decision to invest in R&D than revenue that would be realized later. Accordingly, a reduction of any given size in manufacturers' expected revenue at the end of a future drug's product cycle would have less of a dampening effect on current R&D investments than would a similar reduction earlier in the product cycle.

Certain policies could also affect the allocation of R&D investment across different types of projects, in addition to any effect those policies would have on the overall level of R&D investment.⁸ For instance, some R&D projects aim to modify or improve an existing product, such as by introducing an extended-release version of a tablet or capsule, whereas other projects aim to develop entirely new therapies. Compared with modifying an existing product, developing an entirely new drug is costlier and entails a greater risk of failure. Some of the approaches CBO examined could change the relative payoff between those different types of R&D projects.

Policy Approaches That Would Cap Prices or Limit Their Growth

Of the approaches examined in this report, the international reference pricing policy would dampen private investment in pharmaceutical R&D the most. It would greatly limit manufacturers' ability to charge revenue-maximizing prices for affected drugs in the large U.S. drug market, reducing both current revenue and expected future revenue. If prices increased in reference countries in response to the use of international reference pricing in the United States, that could offset part of the reduction in manufacturers' revenue; the size of that offset would depend on the size of the international price response.

accounting for its effects on manufacturers' current revenue. When those effects were accounted for, the policy reduced estimated new drug launches by 9 percent in the second decade after enactment, compared with 8 percent when manufacturers' current revenue was not accounted for. See Christopher P. Adams, *CBO's Simulation Model of New Drug Development*, Working Paper 2021-09 (Congressional Budget Office, August 2021), pp. 24–26, www.cbo.gov/publication/57010.

8. CBO's drug development model predicts changes in the number of new prescription drugs brought to market but does not predict their characteristics, such as therapeutic class, patient population, or clinical effectiveness.

Expanding the Medicare Drug Price Negotiation Program in Part D would reduce manufacturers' revenue from existing drugs as well as their expected future revenue from drugs developed later. The negative effect on R&D incentives would be limited, however, because drugs would be eligible for price negotiation only after they had been on the market for several years. In CBO's assessment, drugs developed later would experience smaller price reductions from negotiation than drugs currently on the market would.

Extending the Medicare Part D inflation rebate policy to the commercial market would have a smaller effect than expanding price negotiation would. It would not affect manufacturers' expected revenue from new drugs developed in the future, but it would reduce their revenue from drugs already on the market, which would reduce their cash on hand and potentially increase their cost of investment capital. That policy could also create incentives for manufacturers to develop new versions of existing products, because the new products would be tied to new benchmark prices.

Policy Approaches That Would Promote Price Competition or Affect the Flow of Information

Allowing the commercial importation of prescription drugs that manufacturers distributed outside the United States would have a slight negative effect on R&D incentives. Brand-name drug manufacturers would lose revenue on sales of drugs that were redistributed under such a policy, reflecting the share of the price difference between the United States and foreign countries that would be retained by intermediaries and any savings passed on to drug purchasers. Because only a small volume of drugs would be available for redistribution under this approach, that revenue loss—and the policy's effect on R&D investments—would be modest.

Eliminating or limiting direct-to-consumer (DTC) advertising would have a very small effect on prices but would have a much larger effect on manufacturers' future

revenue. That is because, unlike other policy approaches examined in this report, restricting DTC advertising would affect the quantities of drugs consumed more than it would their prices, and manufacturers' revenue depends on both quantities and prices. Consumers of prescription drugs would see only very small price reductions, similar in magnitude to those from other approaches such as allowing commercial importation, but manufacturers would experience larger reductions in revenue. As a result, this approach would dampen R&D incentives much more than other approaches with similarly sized effects on prices.

The policies that CBO examined that would promote earlier market entry for generic and biosimilar drugs would have very small effects on average prices. But the reduction in manufacturers' revenue would primarily occur only after the drugs had been on the market for several years, which would attenuate any effect that such a policy would have on R&D. The composition of R&D could change if a policy discouraged the practice of product hopping, in which brand-name manufacturers develop modified versions of existing drugs to extend exclusivity protections.

The two policies aimed at transparency in prescription drug prices would each have a small dampening effect on R&D incentives. The first scenario that CBO examined, requiring manufacturers to publicly disclose rebates that they pay to insurers or pharmacy benefit managers (PBMs), would reduce the variation in the net prices paid by different purchasers and probably cause the average net price to rise slightly. In CBO's estimation, because manufacturers maximize their revenue by charging a wide range of prices to different purchasers, a policy that compressed net prices would cause total revenue to fall. The second scenario, requiring PBMs to share their drug price information with health insurers, would lower average prices by less than 1 percent and lead to a small decline in revenue.

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About This Document

This report was prepared at the request of the Chairman of the Senate Committee on the Budget and the Chairman of the Senate Committee on Health, Education, Labor, and Pensions. In keeping with the Congressional Budget Office's mandate to provide objective, impartial analysis, the report makes no recommendations.

Colin Baker and Scott Laughery prepared the report with guidance from Tamara Hayford and Chapin White. Austin Barselau, Ezra Cohn, Ryan Greenfield, Kaylee Nielson, Aaron Pervin, Lara Robillard, Asha Saavoss, and Noah Zwiefel contributed to the analysis. Christopher Adams, David Austin, Ann E. Futrell, Wendy Kiska, Kevin Laden, Noah Meyerson, Chad Shirley, and James Williamson offered comments. Kaylee Nielson and Joyce Shin fact-checked the report.

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CBO seeks feedback to make its work as useful as possible. Please send comments to communications@cbo.gov.



Phillip L. Swagel
Director
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