



March 2021

PRESCRIPTION DRUGS

U.S. Prices for
Selected Brand Drugs
Were Higher on
Average than Prices
in Australia, Canada,
and France



A Century of Non-Partisan Fact-Based Work

GAO@100 Highlights

Highlights of [GAO-21-282](#), a report to the Chairman, Committee on the Budget, U.S. Senate

Why GAO Did This Study

While spending on prescription drugs continues to grow worldwide, studies indicate the U.S. spends more than other countries. However, various factors—such as country-specific pricing strategies, confidential rebates to payers, and other price concessions—may obscure the actual prices of prescription drugs.

GAO was asked to review U.S. and international prescription drug prices. This report (1) examines how prices at the retail and manufacturer levels in the U.S. compare to prices in three selected comparison countries—Australia, Canada, and France, and (2) provides information on consumers' out-of-pocket costs for prescription drugs in these countries.

GAO analyzed 2020 price data for a non-generalizable sample of 41 brand-name drugs among those with the highest expenditures and use in the U.S. Medicare Part D program in 2017. Twenty of these drugs had price data available in all four countries. For U.S. prices, GAO estimated the net prices paid using data from various sources, including estimates of Medicare Part D rebates and other price concessions, and commercially available data.

Prices for the selected comparison countries were obtained from publicly available government sources. National prices were not available for Canada, so GAO used the prices from Ontario, Canada's most populous province, as a proxy for Canadian prices. GAO also reviewed country-specific guidance and other relevant information and interviewed researchers, manufacturers, and government officials.

View [GAO-21-282](#). For more information, contact John E. Dicken at (202) 512-7114 or dickenj@gao.gov.

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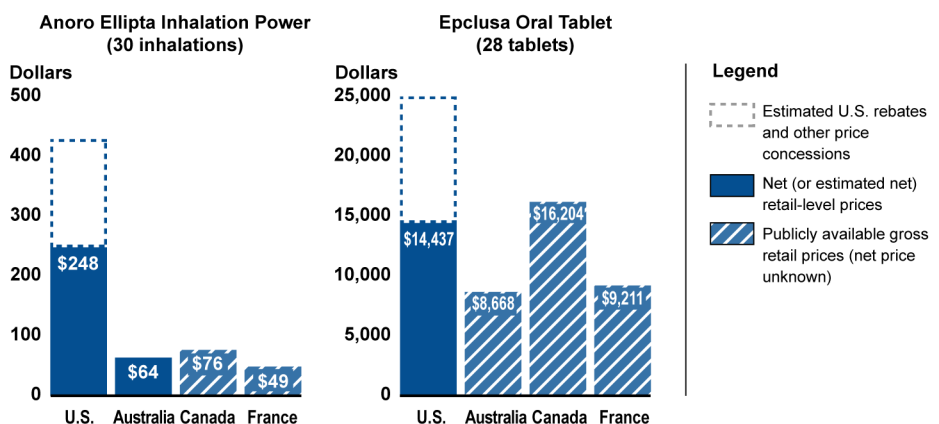
PRESCRIPTION DRUGS

U.S. Prices for Selected Brand Drugs Were Higher on Average than Prices in Australia, Canada, and France

What GAO Found

GAO's analysis of 2020 data found that, for 20 selected brand-name prescription drugs, estimated U.S. prices paid at the retail level by consumers and other payers (such as insurers) were more than two to four times higher than prices in three selected comparison countries. The U.S. prices GAO estimated for comparison reflect confidential rebates and other price concessions, which GAO refers to as net prices. Publicly available prices for the comparison countries were gross prices that did not reflect potential discounts. As a result, the actual differences between U.S. prices and those of the other countries were likely larger than GAO estimates. The price differences varied by drug. Specifically, while estimated U.S. net prices were mostly higher than the gross prices in other countries (by as much as 10 times), some were lower. The following figure illustrates comparisons for two of GAO's selected drugs. GAO found similar differences in estimated prices paid by final payers at the manufacturer level.

Estimated U.S. Net Prices and Selected Comparison Countries' Gross Prices at the Retail Level for Two Selected Drugs and Package Sizes, 2020



Source: GAO analysis of data from Medicare Part D, a commercially available compendium, and national pricing sources. | GAO-21-282

GAO's analysis found consumers' out-of-pocket costs for prescription drugs varied across and within all four countries but likely more within the U.S. and Canada where multiple payers had a role setting prices and designing cost-sharing for consumers, and not all consumers had prescription drug coverage. In Australia and France, prescription drug pricing was nationally regulated and prescription drug coverage was universal; thus, consumers' out-of-pocket costs within these countries for each drug were generally less varied. For example, in Australia, consumers typically paid one of two amounts for prescription drugs—either about 5 or 28 U.S. dollars in 2020. In the U.S., potential out-of-pocket costs for consumers could have varied much more widely depending on the type of coverage they had. For example, for one drug in GAO's analysis, considering only a few coverage options, consumers' out-of-pocket costs in 2020 could have ranged from a low of about 22 to a high of 514 U.S. dollars.

GAO provided a draft to the Department of Health and Human Services for review and incorporated the Department's technical comments as appropriate.

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Abbreviations

AUD	Australian Dollar
CAD	Canadian Dollar
DOD	Department of Defense
EUR	Euro
GDP	gross domestic product
IQVIA	IQVIA Institute for Human Data Science
OECD	Organisation for Economic Co-operation and Development
OPM	Office of Personnel Management
PBAC	Pharmaceutical Benefits Advisory Committee
PBS	Pharmaceutical Benefits Scheme
USD	U.S. Dollar
VA	Department of Veterans Affairs
VHA	Veterans Health Administration
WAC	wholesale acquisition cost

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March 29, 2021

The Honorable Bernard Sanders
Chairman
Committee on the Budget
United States Senate

Dear Mr. Sanders:

Spending on prescription drugs continues to grow in the United States and throughout the world. One research study found that global net spending on prescription drugs grew from 628 billion U.S. Dollars (USD) in 2009 to USD 955 billion in 2019 (a 4.3 percent average annual increase) and is projected to exceed USD 1.1 trillion by 2024.¹ New and expensive specialty drugs, an aging population, and increased drug use due to improved management of chronic conditions all contribute to the increased spending on prescription drugs. Although spending is increasing worldwide, the United States spends more on prescription drugs both as a share of its economy and per person than most of the other Organisation for Economic Co-operation and Development (OECD) countries.²

¹Data are reported in constant USD.

See IQVIA Institute for Human Data Science, *Global Medicine Spending and Usage Trends: Outlook to 2024* (Parsippany, New Jersey: 2020). The IQVIA Institute for Human Data Science (IQVIA) conducts research and analysis and provides scientific expertise in human health. IQVIA collects and maintains a variety of data assets (including information on prescription drugs), often referenced by researchers.

²Among the 34 OECD countries reporting drug expenditures, the United States ranks third overall in pharmaceutical spending as a percentage of gross domestic product (GDP) and first overall with respect to USD per capita. Pharmaceutical spending as a percent of GDP was highest in Greece and Japan at 2.02 percent (2018) and 1.97 percent (2017), respectively. The median among the 34 OECD countries with data was 1.35 percent for the most recent available year. United States pharmaceutical spending was 1.95 percent of GDP and approximately USD 1,229 per capita in 2018. The second highest spending per capita was Switzerland at about USD 894, and the 34 OECD countries with data had a median of about USD 542 for the most recent available year.

The 37 OECD member countries are Australia, Austria, Belgium, Canada, Chile, Colombia, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Israel, Italy, Japan, Korea, Latvia, Lithuania, Luxembourg, Mexico, Netherlands, New Zealand, Norway, Poland, Portugal, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Turkey, the United Kingdom, and the United States.

Comparing prescription drug prices across different countries presents a number of challenges. Some countries have universal prescription drug coverage that relies on varying centralized price negotiation strategies with manufacturers resulting in clearly defined prices for each drug. Conversely, the United States primarily has a decentralized system resulting in multiple prices among different payers for each drug. Negotiations over prices may occur at various points within the drug supply chain as drugs move from the manufacturer, through wholesalers, to pharmacies, and ultimately to consumers and the prices paid at each of these levels can vary from country to country.³ Further, it is difficult to know the actual prices paid within each country's supply chain because of a lack of transparency in some aspects of pricing. For example, the prices paid to manufacturers are often subject to confidential rebates and other price concessions, which obscure the final net cost paid by various payers for each drug. Although many countries make publicly available the prices the government pays manufacturers for prescription drugs on their national formularies, information on rebates and other price concessions affecting these prices are generally not publicly available.

You asked us to review how U.S. prices for drugs compared to prices for the same drugs in other countries. This report

(1) examines how prices at the retail and manufacturer levels for selected brand-name prescription drugs in the United States compare to prices in other countries, and

(2) provides information on consumers' out-of-pocket costs for prescription drugs in the United States and other countries.

To examine how brand-name prescription drug prices at the retail and manufacturer levels in the United States compare to publicly available retail and manufacturer level prices in other countries, we compared estimated 2020 net prices in the United States to publicly available 2020 prices in three countries with similar income levels to the United States:

³In addition, the supply chain and entities involved in distributing and paying for drugs can vary by country. For example, in the United States, the supply chain can include different types of entities, in addition to wholesalers and pharmacies, and often includes pharmacy benefit managers. Pharmacy benefit managers are organizations that help manage drug benefits.

Australia, Canada (Ontario), and France.⁴ To conduct this analysis we used a variety of data sources and methods, as summarized below and described in more detail in appendix I.

While our work for this report was limited to single-source, brand-name prescription drugs, these drugs do not represent other types of drugs, such as generics. Studies have found that use of generic drugs is more prevalent in the United States than in other countries, and the prices for generic drugs in the United States are often lower than prices for these drugs in other countries.

Source: GAO, the Millbank Quarterly, and Food and Drug Administration. | GAO-21-282

- We obtained and analyzed prescription drug pricing data for a non-generalizable sample of 41 brand-name, single-source prescription drugs that were among those with the highest expenditures and use in the U.S. Medicare Part D program in 2017.⁵ Twenty of the 41 drugs had publicly available prices on each of the selected country's formularies. We defined a prescription drug as single-source if the drug had no generic or biosimilar alternative as of January 2020.
- To estimate net prices paid at the retail and manufacturer levels in the United States, we analyzed data from various sources, including estimates of Medicare Part D rebates and other price concessions and data from a commercially available compendium, among others.
 - To estimate the net prices paid at the retail level (the final amount paid to a retailer by all payers, such as a consumer and their insurer, less rebates and other price concessions the payers receive from any source), we estimated the average price a Medicare Part D plan might pay at the retail level after any rebates or price concessions have been applied.⁶ To calculate this estimated net price, we subtracted Medicare Part D confidential

⁴We selected the comparison countries based on the following characteristics: OECD status, GDP per capita, geography, population size, health care system (pharmaceutical coverage and pricing), and the availability of publicly reported prescription drug pricing data. Because prescription drug coverage in Canada is decentralized, we used Ontario (Canada's most populated province) as a proxy for Canada when examining prescription drug pricing in that country. Throughout this report, references to drug prices in Canada are based on prices in Ontario.

⁵Medicare is the federally financed health insurance program for persons aged 65 and over, certain individuals with disabilities, and individuals with end-stage renal disease. Medicare Part D is the voluntary program that provides outpatient prescription drug coverage for Medicare beneficiaries who enroll in Part D drug plans. When we started selecting our non-generalizable sample of 41 prescription drugs, the most recent Medicare Part D cost and usage full-year data was from 2017.

Physician-administered drugs are outside the scope of this work.

⁶Research suggests that the range of net prices paid at the retail level in the United States might vary widely depending on the payer, and that net prices under Medicare Part D generally might fall in the middle of that range. For example, on average, rebates and other price concessions for Medicaid may be larger than those for Medicare Part D plans and might be smaller for private plans.

rebate and price concession data from the estimated gross prices Medicare Part D plan sponsors paid to retailers.⁷

- To estimate net prices paid at the manufacturer level in the United States (the final amount a manufacturer receives from all payers, such as wholesalers or retail chains, less any rebates and other price concessions the manufacturer provides to those payers), we used prescription drug wholesale acquisition cost (WAC) data—a price point commonly used by researchers as a proxy for U.S. manufacturer-level prices.⁸ In conducting this work, we determined that, in many cases, WAC was not markedly different from U.S. retail-level prices, so we adjusted these data to account for the estimated amount of the rebates and price concessions offered at the manufacturer level.⁹ (See appendix II for more information on how we determined that WAC was not markedly different from U.S. retail-level prices.) We estimated these rebate and price concession amounts based on the Medicare Part D confidential rebate and price concession data we obtained, along with estimated additional price concession amounts reported by the IQVIA Institute for Human Data Science (IQVIA).¹⁰ The confidential rebate and other price concession data used in our

⁷Medicare beneficiaries can obtain coverage for outpatient prescription drugs by choosing from multiple competing plans offered by plan sponsors that contract with the Centers for Medicare & Medicaid Services to offer the prescription drug benefit. Plan sponsors are responsible for paying retail pharmacies for drugs dispensed to Medicare Part D beneficiaries, and beneficiaries may be responsible for applicable cost-sharing. Drug plans may differ in the premiums charged to the Centers for Medicare & Medicaid Services and beneficiaries; beneficiary deductibles and copayments (i.e., beneficiary-paid amounts); the drugs covered; pharmacies available to beneficiaries for filling prescriptions; and the drug prices, rebates, and other price concessions negotiated with manufacturers and pharmacies.

When we calculated price estimates, 2018 Medicare Part D payment data were the most recent full-year data available. We projected the gross prices forward to 2020. See appendix I for a detailed description of this methodology.

⁸The manufacturer-level price is often referred to as the ex-factory price, ex-manufacturer price, or WAC. We obtained 2020 WAC from a commercially available compendium, Red Book. Because manufacturer-level data are not publicly available in the United States, WAC is commonly used by researchers as a proxy to represent manufacturer prices paid by wholesalers, before discounts and rebates.

⁹WAC is a list price set by manufacturers that does not reflect actual transactions with wholesalers and is generally considered to overstate actual prices paid to manufacturers by wholesalers.

¹⁰See IQVIA Institute for Human Data Science, *Medicine Use and Spending in the U.S.: A Review of 2018 and Outlook to 2023* (Parsippany, New Jersey: 2019).

estimates reflect price concessions (such as those made by manufacturers, pharmacies, or other sources), which decrease the cost of the drug for Part D plan sponsors. However, these data do not necessarily reflect rebates and other price concessions that may be received by other government programs or by other prescription drug payers in the United States.¹¹

- We obtained January 2020 retail- and manufacturer-level data for the selected comparison countries from national pricing sources that the countries make publicly available.¹² We did not discount these publicly available retail and manufacturer prices for the comparison countries, as estimates of rebates and other price concessions are confidential.¹³ As a result, the publicly available prices for the other countries generally represent gross prices, rather than net prices that reflect rebates and other price concessions. We converted all foreign prices to USD using the January 2020 United States Federal Reserve average monthly foreign exchange rates.¹⁴

¹¹In 2018, Medicare Part D accounted for approximately USD 107 billion in retail prescription drug sales—nearly one-third of total U.S. expenditures. Other studies, including a prior GAO report, found that, on average, rebates by other public or private payers in the United States were higher or lower than Medicare Part D. For example, Medicaid (which accounted for about USD 33 billion in retail prescription drug sales in 2018) had average rebates representing a larger share of gross prices as a result of statutorily defined rebate requirements. In contrast, private insurers (which accounted for USD 134 billion in retail prescription drug sales) had rebates averaging a smaller share of gross prices than Medicare Part D. See GAO, *Prescription Drugs: Comparison of DOD, Medicaid, and Medicare Part D Retail Reimbursement Prices*, GAO-14-578 (Washington, D.C.: June 30, 2014). See appendix I for more information.

¹²Data were obtained from the following formularies: Australia's Pharmaceutical Benefits Scheme (PBS); the Database for Medication and Pricing Information, maintained by France's national health insurance program; and the Ontario Ministry of Health's Drug Benefit Program Formulary or the Ontario Exceptional Access Program.

¹³Based on information from national pricing sources, the publicly available pricing data used in our review for selected comparison countries—Australia, Canada (Ontario), and France—represent the gross price paid before confidential discounts and rebates. However, according to Australian officials and based on our review of Australia's formulary, some drugs are not subject to confidential discounts and rebates, so the publicly available price is both the gross and net price for those drugs. In our review, 32 of our 41 selected drugs were listed on Australia's formulary in 2020; among these 32 drugs, 14 were not subject to confidential discounts and rebates.

¹⁴January 2020 average monthly rates were accessed from the Federal Reserve on July 7, 2020, at <https://www.federalreserve.gov/releases/g5/20200203/>; USD 1.00 was equal to 1.3089 Canadian Dollar (CAD), Euro (EUR) 1.00 was equal to USD 1.1098, and Australian Dollar (AUD) 1.00 was equal to USD 0.6851.

To provide information on consumers' out-of-pocket costs for prescription drugs in the United States and selected comparison countries, we compared publicly available 2020 data and other information on what consumers pay out-of-pocket for prescription drugs in general (including a detailed look at five drugs within our sample) for all four countries in our analysis. Specifically, to determine the amount insured and uninsured (or cash-paying) consumers may pay out-of-pocket for prescription drugs in the United States, we obtained and reviewed data from the Centers for Medicare & Medicaid Services, which administers the Medicare Part D program; reviewed published literature on consumer cost-sharing for prescription drugs for other public and private options; obtained and reviewed data from a nationally recognized prescription drug discount service in the United States (GoodRx) that may be utilized by uninsured (or cash-paying) consumers; and called 20 U.S. pharmacies.

Similarly, to determine the amount insured and uninsured consumers may pay out-of-pocket for prescription drugs in Canada, we obtained and reviewed data from national pricing sources, reviewed published literature on consumer cost-sharing, and called 21 Canadian pharmacies.¹⁵ To determine the amount insured consumers may pay out-of-pocket for prescription drugs in Australia and France, we reviewed information from each country's publicly available national pricing source. Because prescription drug pricing is nationally regulated and prescription drug coverage is universal in Australia and France, we did not perform a similar analysis for uninsured consumers in these countries.

For both objectives, we also reviewed country-specific guidance and other relevant information on prescription drug coverage and price controls in the United States and select comparison countries and interviewed government officials—including officials from the United States Department of Health and Human Services' Office of the Assistant Secretary for Planning and Evaluation—and other industry and academic researchers with expertise in conducting international price comparisons in recent years. We also obtained information from several manufacturers with prescription drugs included in our comparisons regarding their perspectives on differences in prescription drug prices across countries. We assessed the reliability of the data sets used in our analyses by

¹⁵When judgmentally selecting pharmacies for direct calls in both the United States and Canada, we selected a mix of prescription drug retailers from geographically diverse areas. Our United States calls included pharmacies from six different states and both urban and rural areas. Our Canadian calls included pharmacies from five different cities (both smaller and larger) within the province of Ontario.

reviewing related documentation and interviewing officials, among other steps. We determined the data were sufficiently reliable for the purposes of our reporting objectives.

We conducted this performance audit from May 2019 to March 2021 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

The United States, Australia, Canada, and France all have developed economies with relatively large gross domestic products (GDP) and similar GDP per capita, but these countries vary in population size and in two pharmaceutical spending measures—pharmaceutical spending per capita and pharmaceutical spending as a percentage of GDP.¹⁶

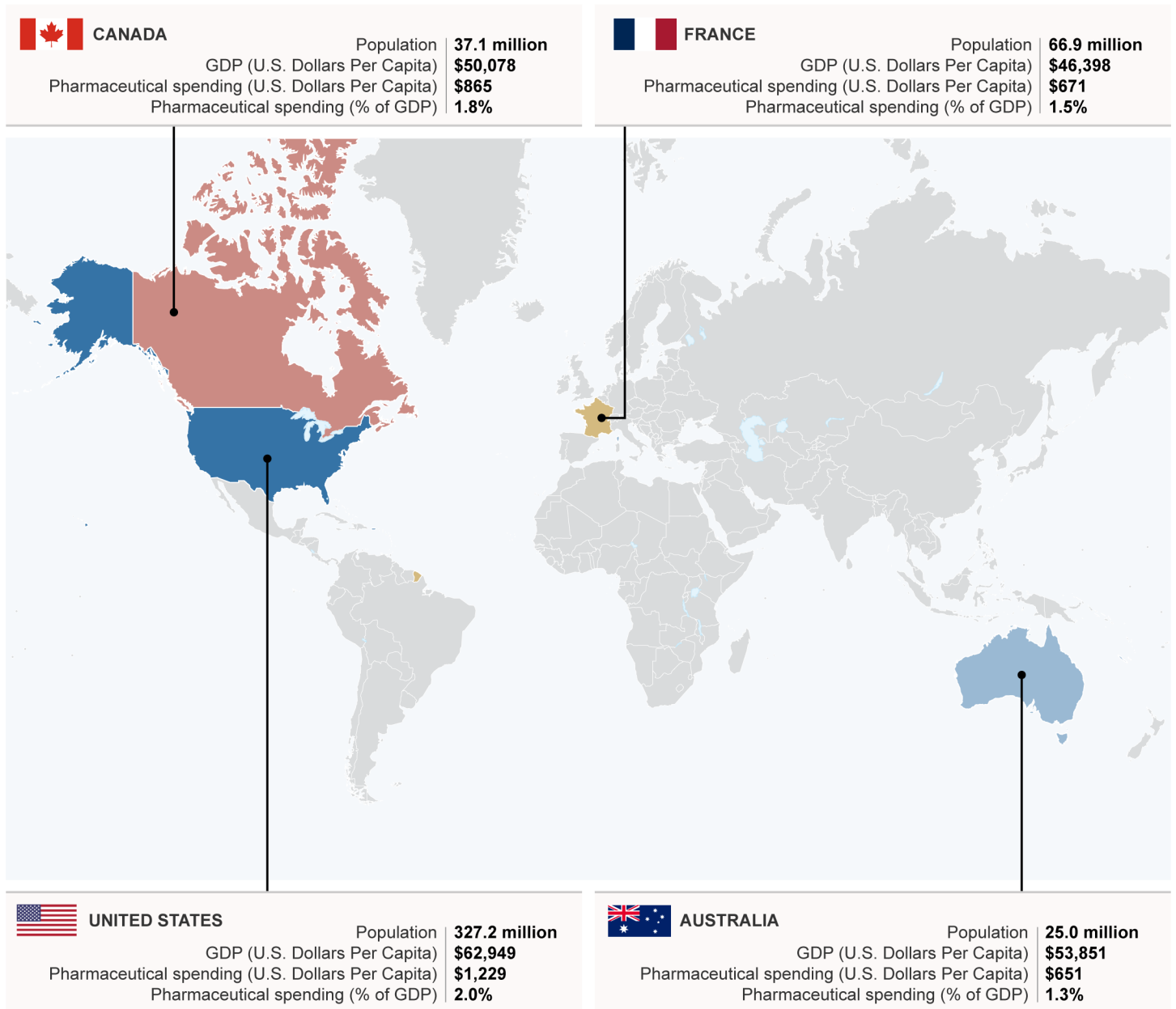
According to the OECD, the United States has the largest population and leads the four countries in each of the economic and pharmaceutical measures. Australia has the smallest population of the four countries but the highest GDP per capita after the United States; Canada has the highest pharmaceutical spending, both per capita and as a percent of GDP, after the United States; and France has a larger population than both Australia and Canada and falls between Canada and Australia in GDP and the pharmaceutical spending measures.¹⁷ (See fig. 1.)

¹⁶GDP is the standard economic measure of the value added created through the production of goods and services in a country during a certain period of time. As such, it also measures the income earned from that production, but is not a measure of people's material well-being.

According to the OECD, pharmaceutical spending covers expenditure on prescription drugs and over-the-counter products, but excludes drugs provided in hospitals or other care settings. Final expenditure on pharmaceuticals includes wholesale and retail margins and value-added tax. Total pharmaceutical spending refers in most countries to “net” spending—that is, adjusted for possible rebates payable by manufacturers, wholesalers, or pharmacies.

¹⁷See Organisation for Economic Co-operation and Development, “Population”, accessed November 17, 2020, <https://data.oecd.org/pop/population.htm>; “Gross Domestic Product”, accessed December 2, 2020, <https://data.oecd.org/gdp/gross-domestic-product-gdp.htm>; and “Pharmaceutical Spending” accessed November 17, 2020, <https://data.oecd.org/healthres/pharmaceutical-spending.htm>.

Figure 1: Selected Countries and Relevant Economic Data, 2018 or Most Recent Year



Sources: GAO summary of Organisation for Economic Co-operation and Development (OECD) data; Map Resources (map). | GAO-21-282

Note: Population and gross domestic product (GDP) data were from 2018 for each country. Pharmaceutical spending data, both per capita and as a percent of GDP, were from 2018 for the United States, Canada, and France and from 2017 for Australia. According to the OECD, pharmaceutical spending covers expenditure on prescription drugs and over-the-counter products but excludes drugs provided in hospitals or other care settings. Final expenditure on pharmaceuticals

includes wholesale and retail margins and value-added tax. Total pharmaceutical spending refers in most countries to “net” spending—that is, adjusted for possible rebates payable by manufacturers, wholesalers, or pharmacies.

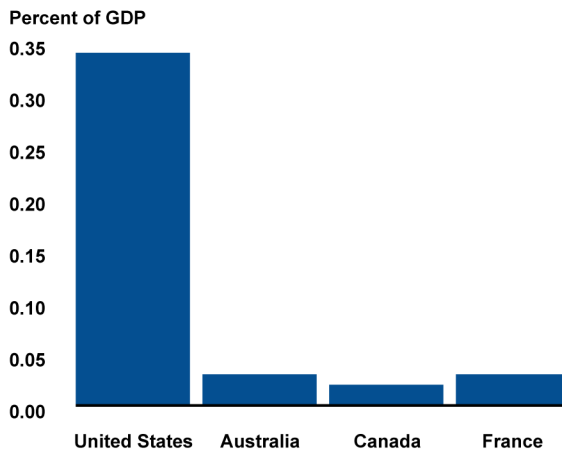
Further, spending on research and development in the pharmaceutical sector varies among our selected countries. According to the OECD, pharmaceutical research and development are funded from a complex mix of private and public sources—governments mainly support basic and early-stage research, and the pharmaceutical industry, while active across all phases of research and development, makes the largest contribution to translating and applying knowledge to develop products.¹⁸ Among OECD member countries with available data, nearly two-thirds of pharmaceutical research and development expenditures occur in the United States.¹⁹ In addition, among our selected countries, the pharmaceutical industry research and development expenditures as a share of GDP are highest in the United States. Specifically, according to OECD data for the most recent year available, pharmaceutical industry research and development expenditures in the United States were 0.34 percent of GDP compared to 0.03, 0.02, and 0.03 percent of GDP in Australia, Canada, and France, respectively.²⁰ (See fig. 2).

¹⁸According to the OECD, government support is provided through direct budget allocations, research grants, publicly owned research institutions, and higher education institutions. In addition, clinical trials required to gain market approval are largely funded by industry; however, industry also receives direct research and development subsidies or tax credits in many countries. See Organisation for Economic Co-operation and Development, “Research and Development in the Pharmaceutical Sector”, *Health at a Glance 2019: OECD Indicators*, (Paris, France: 2019).

¹⁹We have also reported that pharmaceutical company-reported research and development spending in the United States grew slightly from 2008 through 2014, while federally funded spending decreased slightly over the same period. In addition, industry spending focused on drug development rather than earlier-stage research, whereas direct federal spending, such as through grants from the National Institutes of Health, funded a greater amount of basic research. See GAO, *Drug Industry: Profits, Research and Development Spending, and Merger and Acquisition Deals*, [GAO-18-40](#) (Washington, D.C.: Nov. 17, 2017).

²⁰Pharmaceutical research and development in this context refers to expenditures on research and development by businesses classified in the pharmaceutical industry, known as the business enterprise expenditure for research and development, and covers research and development carried out by corporations, regardless of the origin of the funding, which can include government subsidies. See Organisation for Economic Co-operation and Development, “Research and Development in the Pharmaceutical Sector.”

Figure 2: Pharmaceutical Industry Research and Development Expenditure as a Share of Gross Domestic Product (GDP), 2017 or Most Recent Year Available



Source: GAO analysis of Organisation for Economic Co-operation and Development (OECD) data. | GAO-21-282

Notes: Data for the United States, Canada, and France were from 2017. The most recent data available for Australia was from 2013. Pharmaceutical research and development in this figure refers to expenditures on research and development by businesses classified in the pharmaceutical industry, known as the business enterprise expenditure for research and development, and covers research and development carried out by corporations, regardless of the origin of the funding, which can include government subsidies.

Prescription Drug Coverage

Prescription drug coverage varies by country. Australia and France provide centralized universal public coverage for prescription drugs and have established national formularies—a list of prescription drugs approved for coverage. Prescription drug coverage in Canada and the United States is not universal, although both countries have various publicly funded coverage options for some segments of their populations—such as the elderly or veterans. In addition, all of the countries in our review have private prescription drug coverage options available. For example, France has voluntary private coverage that complements the public system by covering the out-of-pocket costs from the public plan, and Australians can purchase private health coverage that may pay for drugs not included on the national formulary. Private coverage in Canada and the United States is generally used by consumers who do not have access to publicly funded coverage. In general, those without prescription drug coverage in both Canada and the United States pay the full retail-level cost of prescription drugs out-of-pocket. See table 1 for summary information about prescription drug coverage in each of the four countries.

Table 1: Summary of Prescription Drug Coverage in the United States, Australia, Canada, and France

United States	Australia	Canada	France
<p>Not universal</p> <p>The United States does not have universal public health insurance or prescription drug insurance coverage. Instead, Americans generally receive prescription drug coverage either through a publicly or privately funded plan (or both), or do not have coverage.</p> <p>For example, the United States has several federal agencies and programs, including the Department of Veterans Affairs' (VA) Veterans Health Administration (VHA), which provide health care to veterans. These also include Medicare, which generally covers the elderly, and Medicaid, a joint federal and state program that covers qualifying low-income adults and children. In addition, private coverage is available, obtained through employers or purchased on the individual market.</p>	<p>Universal</p> <p>Australia has a universal, publicly funded health insurance system that includes coverage for prescription drugs included on its national formulary—a list of covered prescription drugs.</p> <p>Ancillary</p> <p>Australia also has voluntary, private health coverage that covers ancillary treatment not covered by the universal public system. This ancillary coverage may include coverage for prescription drugs not included on Australia's national formulary.</p>	<p>Not Universal</p> <p>Canada has a universal, publicly funded health insurance system, but this system does not include coverage for prescription drugs. Instead, Canadians receive prescription drug coverage either through a publicly or privately funded plan (or both), or they do not have coverage.</p> <p>Specifically, each of Canada's provinces and territories have their own public prescription drug coverage options with varying eligibility requirements and consumer costs. The federal government also has a public plan for eligible groups, including eligible indigenous peoples. In addition, private prescription drug coverage is available for many Canadians, often through employers.</p>	<p>Universal</p> <p>France has a universal, publicly funded health insurance system that covers prescription drugs included on its national formulary.</p> <p>Complementary</p> <p>France also has voluntary, private health coverage that complements the universal public system by covering out-of-pocket costs incurred under the public system.</p>

Source: GAO summary of documentation from each country. | GAO 21-282

Prescription Drug Pricing Strategies

Each of the four countries uses varying pricing strategies to limit the price of prescription drugs. However, the United States is the only country in our review that does not have an overarching national pricing strategy for prescription drugs, although some of its publicly funded coverage, such as Medicaid and the Department of Veterans Affairs' (VA) Veterans Health Administration (VHA), use pricing strategies.²¹ Some researchers have noted that cross-country differences in the introduction and uptake of new prescription drugs are likely influenced by country specific pricing strategies—specifically, countries' processes for assessing the therapeutic value of new medicines. See table 2 for summary information about prescription drug pricing strategies used in each of the four

²¹Medicaid is the joint federal-state program that finances health care coverage for qualifying low-income adults and children. VA provides prescription drug coverage to eligible veterans and their eligible dependents.

selected countries. For more detailed information on each country's prescription drug pricing strategies, see appendix III.

Table 2: Summary of Prescription Drug Pricing Strategies in the United States, Australia, Canada, and France

United States	Australia	Canada	France
<p>No overall national strategy but various strategies at plan level</p> <p>The United States does not have a national prescription drug pricing strategy, but the various publicly funded coverage options available use a range of prescription drug pricing strategies. These include statutorily defined rebates and other price concessions and pricing formulas for some federal options like Medicaid and the Veterans Health Administration (VHA).^a In addition, private health plans that participate in Medicare Part D negotiate prices and rebates and other price concessions and apply utilization management, tiered formularies, and benefit design to prefer, discourage, or exclude certain prescription drugs. Further, other private plans, including employer-sponsored plans, employ similar strategies.</p>	<p>Negotiated national prices</p> <p>Australia's national formulary is limited to prescription drugs for which the government and manufacturers have agreed to prices. First, each prescription drug is assessed by a number of factors, including comparing the effectiveness of two or more prescription drugs that are therapeutically equivalent. If a drug is recommended for inclusion, the government then negotiates with the manufacturer the price it will pay. If no agreement is reached on a price, the prescription drug is not included on the formulary.</p>	<p>Regulated maximum national prices</p> <p>Canada regulates the maximum price at which manufacturers can sell patented prescription drugs in Canadian markets. Upon introduction and thereafter, as required until the patent expires, a prescription drug's price is reviewed against guidelines, such as the prescription drug's median international price in comparator countries, to determine if its price is excessive. When prices are determined to be excessive, manufacturers must decrease the prescription drug's price, pay back the excess to the government, or both.</p> <p>Joint negotiations</p> <p>Canada's public (federal, provincial, and territorial) prescription drug plans collectively negotiate—through the pan-Canadian Pharmaceutical Alliance—with manufacturers to determine prices paid by the public plans.</p>	<p>Negotiated national prices</p> <p>France negotiates a price for each drug based on its added therapeutic value. The added therapeutic value of a new prescription drug is given a price classification that is established in relation to a comparator prescription drug. This classification determines the parameters in place for the government's price negotiation with the manufacturer. If agreement can be reached on the price, the prescription drug is added to the national formulary.</p> <p>Cap on drug manufacturers' sales growth</p> <p>Each year, France caps the growth of drug companies' total sales. When manufacturer sales exceed the cap, manufacturers must pay the government a "clawback"—a rebate set based on sales revenue.</p>

Source: GAO summary of documentation from each country. | GAO 21-282

^aFor example, Medicaid uses mandatory prescription drug price rebates and other price concessions, and the Department of Veterans Affairs (VA) has access to statutory discounts on its drug purchases and receives additional discounts if drug prices rise faster than general inflation. In addition, VA may negotiate further price discounts for drugs included on its formulary through blanket purchase agreements or other national contracts with manufacturers.

Prescription Drug Supply Chain

The prescription drug supply chain within the United States, Australia, Canada, and France includes a number of entities, with differing prices paid to each entity.

- **Manufacturer:** The drug manufacturer develops and produces prescription drugs that are purchased by other entities within the supply chain. The manufacturer-level price (sometimes referred to as

the ex-manufacturer price or ex-factory price) generally refers to the amount the manufacturer receives for a prescription drug by entities such as the wholesaler or retailer; however, the manufacturer may provide rebates or other price concessions to the various entities within the supply chain. For the purpose of this report, we generally refer to the manufacturer price as the gross price at the manufacturer level, and we refer to the amount received by manufacturers from entities such as the wholesaler and retailer, less rebates and other price concessions, as the net manufacturer price.

- **Wholesaler:** The wholesaler is a distributor that may purchase prescription drugs directly from a manufacturer and sell them to other entities later in the supply chain.
- **Retailer:** The retailer is the pharmacy or other public or private distributor through which consumers may directly obtain prescription drugs. Retailers may purchase prescription drugs from a wholesaler or directly from the manufacturer. Consumers and other payers, such as insurance plans (see below), pay a retail price to retailers when purchasing prescription drugs—for the purpose of this report, we refer to this as the gross price at the retail level. The net price at the retail level is the total amount the retailer is paid for the prescription drug less discounts and other price concessions that may be passed along to payers. For example, a private insurer may have an agreement with a manufacturer to receive volume discounts for sales of its drugs within a given plan year—the price the insurer and the insured consumer pay a retailer, less these discounts, represents the net price at the retail level.
- **Consumer:** The consumer is the prescription drug user. Consumers purchase prescription drugs from a retailer and may be responsible for some or all of the prescription drug's cost out-of-pocket.
- **Other payers:** Other payers include entities such as private insurers, employers, or government programs that may pay for or contribute to the cost of consumers' prescription drugs. For example, other payers may pay for a set percentage of the retail price of the drug and require the consumer to pay the balance. (See fig. 3.)

Figure 3: Summary of Prescription Drug Supply Chain and Relevant Price Points

Manufacturer Price

The drug manufacturer develops and produces prescription drugs that are purchased by other entities within the supply chain. The manufacturer-level price (sometimes referred to as the ex-manufacturer price or ex-factory price) generally refers to the amount the manufacturer receives for a prescription drug by entities such as the wholesaler or retailer; however, the manufacturer may provide rebates or other price concessions to the various entities within the supply chain. For the purpose of this report, we generally refer to the manufacturer price as the gross price at the manufacturer level, and we refer to the amount received by manufacturers from entities such as the wholesaler and retailer, less rebates and other price concessions, as the net manufacturer price.

Wholesaler

The wholesaler is a distributor that may purchase prescription drugs directly from a manufacturer and sell them to other entities later in the supply chain.

Retailer

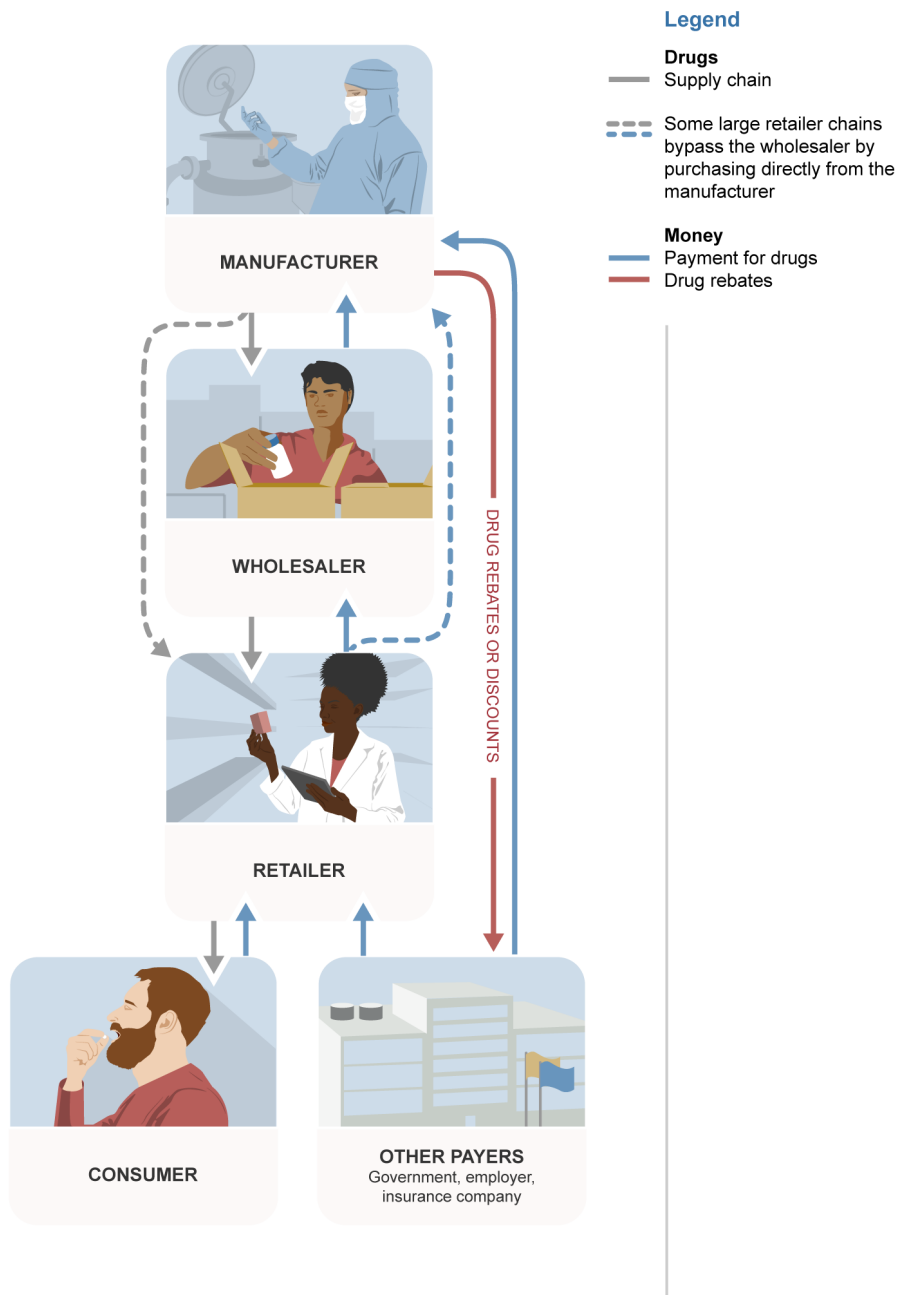
The retailer is the pharmacy or other public or private distributor through which consumers may directly obtain prescription drugs. Retailers may purchase prescription drugs from a wholesaler or directly from the manufacturer. Consumers and other payers, such as insurance plans, pay a retail price to retailers when purchasing prescription drugs—for the purpose of this report, we refer to this as the gross price at the retail level. The net price at the retail level is the total amount the retailer is paid for the prescription drug less discounts and other price concessions that may be passed along to payers. For example, a private insurer may have an agreement with a manufacturer to receive volume discounts for sales of its drugs within a given plan year—the price the insurer and the insured consumer pay a retailer, less these discounts, represents the net price at the retail level.

Consumer

The consumer is the prescription drug user. Consumers purchase prescription drugs from a retailer and may be responsible for some or all of the prescription drug's cost out of pocket.

Other payers

Other payers include entities such as private insurers, employers, or government programs that may pay for or contribute to the cost of consumers' prescription drugs. For example, other payers may pay for a set percentage of the retail price of the drug and require the consumer to pay the balance.



Source: GAO analysis of information from GoodRx, the Kaiser Family Foundation, and other public sources. | GAO-21-282

U.S. Net Prices for Selected Drugs Were, on Average, More than Two to Four Times Higher than Publicly Available Prices in Australia, Canada (Ontario), and France

For the selected drugs in our review, estimated U.S. net prices at the retail level were, on average, more than two to four times higher than publicly available retail prices in Australia, Canada (Ontario), and France. At the manufacturer level, the comparisons between U.S. net prices and publicly available prices in our selected comparison countries followed a very similar trend—estimated U.S. net prices were also more than two to four times higher.

At the Retail Level, U.S. Net Prices for Selected Drugs Were, on Average, More than Two to Four Times Higher than Publicly Available Prices in Selected Comparison Countries

On average, the estimated U.S. net prices at the retail level for the selected brand-name, single-source prescription drugs included in our review were higher than publicly available (gross) prices in all three selected comparison countries.²² For example, for the 20 drugs in our review for which we had pricing data for all three selected comparison countries in 2020, estimated U.S. net prices at the retail level were over four times higher, on average, than gross prices paid at the retail level in Australia and France and about 2.8 times higher than gross prices in Canada (Ontario).²³ (See table 3.)

Table 3: Ratios of Estimated U.S. Net Prices to Selected Comparison Countries' Gross Prices at the Retail Level, for Selected Drugs, in 2020

	U.S. estimates were on average:
Australia	4.25 times higher
Canada (Ontario)	2.82 times higher
France	4.36 times higher

Source: GAO analysis of Centers for Medicare & Medicaid Services data and selected countries' formularies. | GAO 21-282

Notes: Our analysis was based on 20 brand-name, single-source prescription drugs that were among those with the highest total expenditures and use in the U.S. Medicare Part D program in 2017 and included on the formularies of all three selected comparison countries in 2020. U.S. net prices at the retail level are the final amount paid to a retailer by all payers, such as a consumer and insurer, less rebates and other price concessions the payers receive from any source. Estimates were calculated by applying confidential, first quarter 2018 Medicare Part D rebate and price concession data, at a

²²While the estimated U.S. net prices reflect confidential rebates and other price concessions, information on such discounts was not publicly available for the comparison countries, so we used gross prices that do not reflect discounts.

²³Of the 41 drugs included in our review, 20 were available on each relevant formulary in all three other countries—Australia, Canada (Ontario), and France—in 2020.

per-drug level, to each drug's projected gross price at the retail level in 2020. Prices for selected comparison countries—Australia, Canada (Ontario), and France—were prices listed on their respective public formularies from January 2020 and were converted to U.S. dollars at the relevant monthly Federal Reserve rates.

While research has found that confidential rebates and other price concessions are generally higher in the United States, rebates and price concessions are also used in all three of our selected comparison countries, according to public reporting and officials in Australia, Canada, and France that we interviewed. However, data on these rebates and price concessions were not publicly available at the time of our review. Without accounting for these rebates and other price concessions, U.S. gross prices at the retail level were higher than all equivalent gross prices in Australia, Canada (Ontario), and France. Because our analysis could not account for these rebates and other price concessions, actual net price differences between U.S. net prices and net prices in our comparison countries were likely larger than those identified in our comparison.²⁴

Some of the retail prices on Australia's formulary represented both the gross and net prices for that country, because, according to Australian officials, certain drugs listed on their formulary are not subject to rebates or price concessions. The Australian government confirms the existence of special pricing arrangements on a per-drug basis via their public website. These special pricing arrangements include, but are not limited to, confidential rebates and other price concessions. Of the 32 of our 41 selected drugs included in our analysis that were listed on Australia's formulary in 2020, 14 did not have special pricing arrangements. As a result, Australia's formulary prices for these drugs represented both the gross and net prices. The one drug (Zepatier) for which the estimated U.S. net price at the retail level was lower than Australia's gross price was among those subject to rebates or price concessions.

Source: GAO analysis of information from Australian government officials and country-specific data. | GAO-21-282

At the retail level, the drug-by-drug difference in U.S. net prices compared to the gross prices in all three selected comparison countries varied. While the U.S. net prices were mostly higher (by as much as 10 times), some were lower. Specifically, four of the 41 drugs in our review had estimated U.S. net prices at the retail level that were lower than a gross price available at the retail level in one or more of the selected comparison countries. For these four drugs, the lower estimated U.S. net prices ranged from less than 1 percent to 70 percent lower than the gross prices in the selected comparison countries.²⁵ However, it is possible that these drugs were subject to confidential rebates and other price concessions in these countries. As a result, we do not know how the estimated U.S. net prices for these four drugs compared to the actual net prices at the retail level in Australia, Canada (Ontario), and France. Using Australia as an example, of the 41 drugs included in our analysis, 32 were included on Australia's formulary in 2020, and the U.S. net prices were higher than Australia's gross prices for all but one of these 32 drugs.

²⁴For the 41 selected drugs, U.S. net prices at the retail level were lower than U.S. gross prices by about 28 percent, on average.

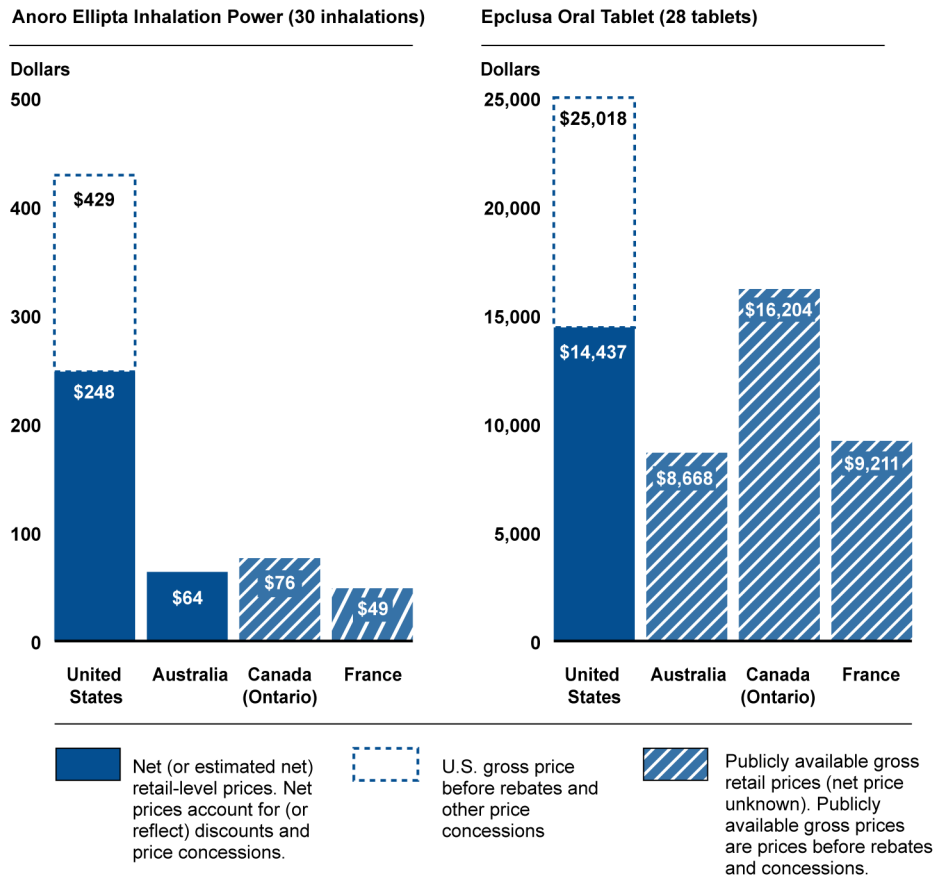
²⁵Three of the four drugs had estimated U.S. net prices at the retail level that were lower than the gross prices in Canada (Ontario); two were lower than gross prices in France, and one was lower than the gross price in Australia.

Figure 4 illustrates examples of the retail-level price comparisons for two of our selected prescription drugs—Anoro Ellipta Inhalation Powder and Epclusa Oral Tablet.²⁶ For these two drugs, we found that one—Anoro Ellipta Inhalation Powder—had a higher estimated U.S. net price than the gross prices at the retail level in all three of our selected comparison countries. For the second drug, Epclusa Oral Tablet, our estimated U.S. net price was lower than the gross price in Canada (Ontario). The estimated rebates and price concessions in the United States for this drug were substantial—about 42 percent of the gross price. We do not know the amount of confidential rebates and price concessions for this drug in Canada (Ontario), but if it was only about one third the level of the U.S. rebates and price concessions—12 percent of the gross price—the net prices in Canada (Ontario) would have been lower than the estimated net price in the U.S.²⁷ (See fig. 4. App. IV contains details on all 41 selected prescription drugs.)

²⁶In order to permit public reporting on a per-drug basis, estimated U.S. net prices reported in fig. 4 were developed using a methodology that was different than that used to develop the summary statistics above. See appendix I for additional details.

²⁷The estimated rebates and price concessions in the United States for Epclusa Oral Tablet were 42 percent off its \$25,018 gross retail price—or \$10,581—resulting in an estimated net retail price of \$14,437. If the rebates and price concessions in Canada (Ontario) for Epclusa Oral Tablet were 12 percent of its gross price of \$16,204—or \$1,944—the resulting net price would have been \$14,260.

Figure 4: Estimated U.S. Prices Compared to Selected Comparison Countries' Prices at the Retail Level for Two Selected Drugs and Package Sizes, 2020



Source: GAO analysis of data from Medicare Part D, a commercially available compendium, and national pricing sources. | GAO-21-282

Notes: Prices for Australia, Canada (Ontario), and France were effective January 2020. Local currencies were converted to U.S. dollars (USD) using the United States Federal Reserve average foreign exchange rates for the month of January 2020. Estimated U.S. net prices at the retail level were calculated by projecting 2018 Medicare Part D gross prices to 2020 using commercially available data and adjusted using confidential calendar year 2018 Medicare Part D rebates and other price concessions at a per drug level to arrive at an estimated net price. In order to permit public reporting on a per-drug basis, drugs were grouped into four quartiles, and projected 2020 Medicare Part D gross prices were discounted using the average percentage rebate and other price concessions from each relevant quartile.

At the Manufacturer Level, U.S. Net Prices for the Drugs We Reviewed Were, on Average, More than Two to Four Times Higher than Publicly Available Prices in Selected Comparison Countries

Similar to prices at the retail level, on average, the estimated U.S. net prices at the manufacturer level for the selected single-source, brand-name prescription drugs included in our review were higher than publicly available (gross) prices in all three selected comparison countries. Specifically, for the 20 drugs in our review for which we had pricing data for all three selected comparison countries in 2020, estimated U.S. net prices at the manufacturer level were about four times higher than gross prices in Australia and France and about 2.5 times higher compared to Canada (Ontario).²⁸ However, our estimates of prices in the three selected comparison countries do not account for confidential rebates or price concessions. As a result, the actual price differences are likely larger than what we estimated.²⁹ (See table 4.)

Table 4: Ratios of Estimated U.S. Net Prices to Selected Comparison Countries' Gross Prices at the Manufacturer Level, in 2020

	U.S. best estimates were ^a :	U.S. alternate estimates were ^b :
Australia	4.19 times higher	3.77 times higher
Canada (Ontario)	2.71 times higher	2.46 times higher
France	4.36 times higher	3.94 times higher

Source: GAO analysis data from Centers for Medicare & Medicaid Services, Red Book, and selected countries' formularies. | GAO 21-282

Notes: Our analysis was based on 20 brand-name, single-source prescription drugs that were among those with the highest total expenditures and use in the U.S. Medicare Part D program in 2017 and included on the formularies of all three selected comparison countries in 2020. Prices for selected comparison countries—Australia, Canada (Ontario), and France—are from January 2020, and were converted to U.S. dollars at the relevant monthly Federal Reserve rates.

^aU.S. best estimates of net prices at the manufacturer level were calculated by discounting wholesale acquisition cost (WAC) by 12 percent and then adjusting each drug's discounted price by the 2018 per-drug Medicare Part D rebates and other price concessions. Net prices at the manufacturer level are the final amounts a manufacturer receives from all payers, such as wholesalers or retail chains, less rebates and other price concessions the manufacturer pays.

²⁸Net prices at the manufacturer level are the final amounts a manufacturer receives from all payers, such as wholesalers or retail chains, less any confidential rebates and other price concessions the manufacturer provides to those payers. To estimate net prices paid at the manufacturer level in the United States, we reduced 2020 WAC by estimates of rebates and price concessions offered at the manufacturer level.

In conducting this work, we determined WAC—the price point used in our manufacturer-level comparisons—was not markedly different from gross retail prices; for more information on this issue, see appendix II.

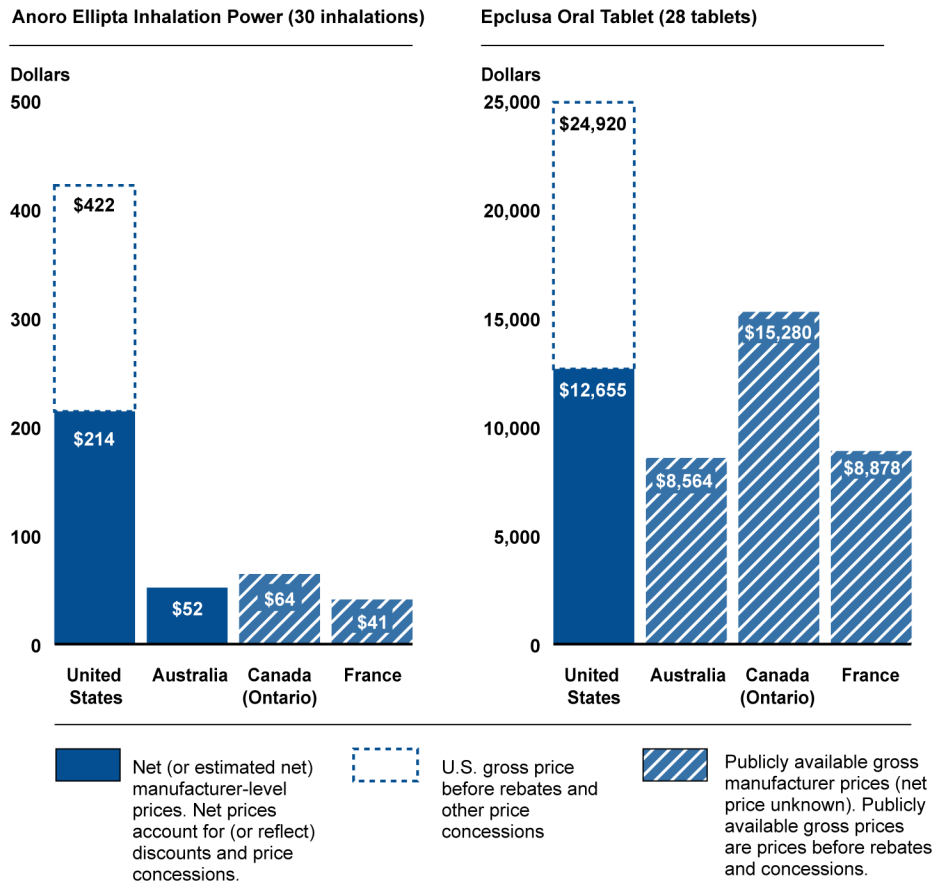
²⁹As with retail-level prices, payers in the United States, Australia, Canada, and France negotiate and receive confidential rebates and other price concessions, which manufacturers pay; however research has found that these rebates and price concessions are generally higher in the United States than in other countries.

^bU.S. alternate estimates of net prices at the manufacturer level were calculated from WAC using a general discount of 43 percent (the amount the IQVIA Institute for Human Data Science estimated WAC overstates net manufacturer prices).

Similar to our findings at the retail level, at the manufacturer level the drug-by-drug difference in U.S. net prices compared to the gross prices in the comparison countries varied, with most being higher, though to varying degrees. Just as with the retail level, of the 32 drugs for which we were able to compare U.S. prices to Australian prices, the U.S. net manufacturer prices were higher than Australia's gross manufacturer prices for all but one of the 32 drugs (Zepatier). As with the retail-level prices, the same four of the 41 drugs in our review had estimated U.S. net prices at the manufacturer level that were lower than the gross prices in selected comparison countries.

Figure 5 illustrates manufacturer-level price comparisons for the two selected prescription drugs described earlier in figure 4. The pricing at the manufacturer level follows the same patterns that we found at the retail level: once again, Anoro Ellipta Inhalation Powder had a higher estimated U.S. net price than gross prices in all three of our selected comparison countries; in contrast, our estimated U.S. net price for Epclusa Oral Tablet was lower than the gross price in Canadian (Ontario). (See fig. 5.)

Figure 5: Estimated U.S. Prices Compared to Selected Comparison Countries' Prices at the Manufacturer Level for Two Selected Drugs and Package Sizes, 2020



Source: GAO analysis of data from Medicare Part D, a commercially available compendium, national pricing sources, and IQVIA. | GAO-21-282

Notes: Prices for Australia, Canada (Ontario), and France were effective January 2020. Local currencies were converted to U.S. dollars (USD) using the United States Federal Reserve average foreign exchange rates for the month of January 2020. U.S. estimates of net prices at the manufacturer level were calculated by discounting wholesale acquisition cost (WAC) by 12 percent and then adjusting each drug's discounted price by an average 2018 Medicare Part D rebate and other price concession amount.

Manufacturers told us that a number of factors could contribute to higher prices in the United States compared to prices in our selected comparison countries. Two noted that, in addition to factors associated with differences in health care financing systems, price differentials across countries could reflect factors such as differences in demographics and disease prevalence. Another manufacturer also noted, as a factor for higher drug prices in the United States, the competitive influences that may not be replicated in other markets. In addition, all three

manufacturers noted that the lower prices in other countries could have implications for access to certain drugs in those countries, including no or delayed access. For example, one manufacturer cited a Pharmaceutical Research and Manufacturers of America study that showed that, compared to patients in France, Canada, and Australia, patients in the United States have access to 37, 41, and 48 percent more new medicines, respectively.

Consumers' Out-of-Pocket Prescription Drug Costs Vary within and across Countries, but Likely Vary More within the United States and Canada

Our analysis found that out-of-pocket prescription drug costs paid by consumers vary within the United States and each of the three selected comparison countries but likely vary more within the United States and Canada. In the United States and Canada, multiple payers have a role in price setting and designing cost-sharing for consumers, and some consumers do not have prescription drug coverage. By contrast, in Australia and France, prescription drug pricing is nationally regulated, and prescription drug coverage is universal; as a result, the amount consumers pay out-of-pocket within these countries is generally publicly available and less varied.³⁰ For example, our analysis of publicly available 2020 data shows that, in Australia, consumers typically paid one of two amounts per prescription—up to AUD 41.00 (or USD 28.09) for consumers with general benefits or AUD 6.60 (or USD 4.52) for consumers with concessional benefits—for prescription drugs listed on Australia's national formulary.³¹ In the United States, potential out-of-pocket costs for consumers can vary much more widely depending on the type of prescription drug coverage they have. (See fig. 6.)

³⁰Consumers in Australia and France could pay less out-of-pocket if they have private insurance, such as employer-sponsored supplemental insurance, that pays for their out-of-pocket costs. However, for the purposes of our report, we did not evaluate the effect of this coverage on consumers' out-of-pocket costs.

³¹In Australia, certain groups (generally seniors and veterans, among others) are eligible for concessional benefits. If consumers do not qualify for concessional benefits, they are typically eligible for general benefits.

Figure 6. Information on Consumer Out-of-Pocket Drug Costs in the United States and Selected Comparison Countries



UNITED STATES

Variation in Consumer Costs

Consumer out-of-pocket costs vary greatly depending on the type of coverage and levels of cost-sharing (e.g., copayments, coinsurance, and deductibles). For uninsured consumers, the cost of a specific drug can also vary between pharmacies.

Americans with prescription drug coverage obtain it through public coverage (such as Medicare) or private plans (such as employer-based plans). For example, in its 2019 survey, the Kaiser Family Foundation found that, among covered workers with prescription drug coverage:

- Average copayments for plans with three or more drug tiers ranged from USD 11.00 to USD 123.00 per prescription.
- Average co-insurance rates ranged from 18 to 34 percent per prescription.^a

Americans without prescription drug coverage must pay the entire cost of prescription drugs out-of-pocket, not benefiting from negotiated discounts available to those with coverage. However, consumers may lower their costs through publicly available discounts.



AUSTRALIA

Variation in Consumer Costs

Consumers pay one of two possible copayments.

In 2020, for drugs included on the national formulary, Australians paid one of two possible copayments:

- Up to AUD 41.00 (USD 28.09) per prescription for those covered by general benefits.
- AUD 6.60 (USD 4.52) per prescription for those covered by concession benefits, generally for seniors and veterans, among other groups.

Australians may also have access to voluntary, private health coverage that covers ancillary treatment not covered by the universal public system. This ancillary coverage may include coverage for prescription drugs not included on Australia's national formulary.



CANADA

Variation in Consumer Costs

Consumer out-of-pocket costs vary greatly depending on the type of coverage. For uninsured consumers, the cost of a specific drug can also vary between pharmacies.

Canadians with prescription drug coverage obtain it through public coverage (typically provincial plans) or private plans (typically through employers). For example, in Ontario's public plan, out-of-pocket costs per prescription for consumers varied by eligibility group. Specifically, in 2020:

- Higher income seniors: Up to CAD 6.11 (USD 4.67) per prescription after meeting a CAD 100.00 (USD 76.40) annual deductible.
- Lower income seniors: Up to CAD 2.00 (USD 1.53) per prescription and no deductible.
- Children and young adults less than age 25 without private coverage: No out-of-pocket costs.

Canadians without prescription drug coverage must pay the entire cost of prescription drugs out-of-pocket, not benefiting from negotiated discounts available to those with coverage. However, consumers may benefit from maximum drug prices set by the national government.



FRANCE

Variation in Consumer Costs

While there is no variation in the out-of-pocket cost for a specific drug, there is variation across drugs.

French consumers pay a percentage of a drug's cost, varying based on the drug's medical benefit designated by the government. Specifically, in 2021:

- No cost: Drugs recognized as irreplaceable or costly.
- 35%: Drugs designated as having major or important medical benefit.
- 70%: Drugs designated as having a moderate medical benefit.
- 85%: Drugs designated as having a low medical benefit.
- Full cost: Drugs designated as having insufficient medical benefit.

Most French consumers also have access to private coverage that complements the universal public system by covering mainly out-of-pocket costs.

Source: GAO summary of documentation from national pricing sources, the Kaiser Family Foundation, and other published literature on consumer cost-sharing. | GAO-21-282

Notes: Cost-sharing generally refers to the share of costs covered by beneficiaries' insurance that are paid out-of-pocket. While cost-sharing generally includes copayments, coinsurance, and deductibles, it does not include other costs such as payments for premiums or for non-covered services. A copayment is usually a fixed dollar amount paid by the plan beneficiary, while coinsurance is a percentage of the cost. A deductible is typically a fixed dollar amount plan beneficiaries are required to pay annually for healthcare services before the insurance plan contributes.

^aSee the Kaiser Family Foundation, Employer Health Benefits, 2019 Annual Survey (San Francisco, California: the Kaiser Family Foundation, 2019).

The wide range of possible coverage scenarios in the United States and Canada—both within and outside of public options—means there is also a wide range of consumer out-of-pocket costs for prescription drugs in these countries. For example, in the United States, consumers may obtain publicly funded prescription drug coverage through Medicaid, Medicare Part D, or VHA, among others. Each of these programs includes varying levels of cost-sharing—generally in the form of copayments, coinsurance, and deductibles.³² For example, out-of-pocket costs for Medicaid are often zero or nominal, while out-of-pocket costs for Medicare may vary widely because prescription drug coverage is offered through plan sponsors (primarily private health insurers) that may offer different beneficiary cost-sharing arrangements that can also vary by drug tier.³³ While some VHA beneficiaries do not pay for any prescription drugs, other beneficiaries may pay a fixed copayment for outpatient prescription drugs that varies by drug tier—in 2020 ranging from USD 5.00 (generics) to USD 11.00 (brand-name) for a 30-day supply.

Variation in private plan options in the United States also results in the potential for wide variation in consumer out-of-pocket costs for prescription drugs. In its 2019 survey, the Kaiser Family Foundation found that, among covered workers with prescription drug coverage, average copayments for plans with three or more drug tiers ranged from USD 11.00 to USD 123.00 for a single drug, and average coinsurance rates ranged from 18 to 34 percent.³⁴ Similarly, a separate analysis by the Kaiser Family Foundation on prescription drug coverage under private plans offered through Healthcare.gov in 2015 indicated consumer

³²Cost-sharing generally refers to the share of costs covered by beneficiaries' insurance that are paid out-of-pocket. While cost-sharing generally includes copayments, coinsurance, and deductibles, it does not include premiums, amounts paid to non-network providers, or for the cost of non-covered services. A copayment is usually a fixed dollar amount paid by the plan beneficiary, while coinsurance is a percentage of the cost. A deductible is typically a fixed dollar amount plan beneficiaries are required to pay annually for healthcare services before the insurance plan contributes.

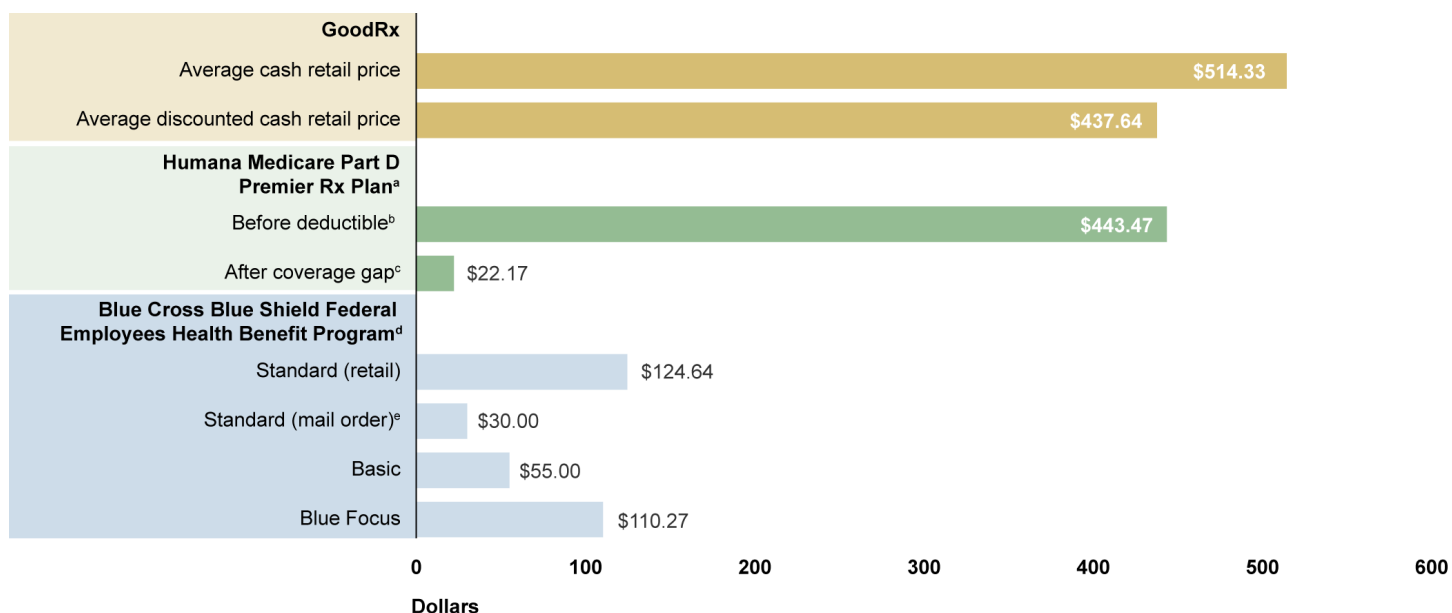
³³Health plans typically include prescription drug formularies that classify drugs into categories or tiers—e.g., generic, preferred, non-preferred, and specialty drugs—that are subject to different cost-sharing or management. Preferred drugs typically include brand-name drugs without an available generic.

³⁴See the Kaiser Family Foundation, *Employer Health Benefits, 2019 Annual Survey* (San Francisco, California: the Kaiser Family Foundation, 2019).

copayments for prescription drugs also varied by plan type and within plans by drug tier.³⁵

To illustrate this variation, we researched information on consumers' out-of-pocket costs in 2020 for a sample Medicare Part D plan and a Federal Employees Health Benefits Program plan, as well as for those without prescription drug coverage, for the prescription drug Anoro Ellipta, which is used to treat chronic obstructive pulmonary disease, including chronic bronchitis and emphysema. We found significant variability in consumers' out-of-pocket costs for a typical monthly supply (30 inhalations) ranging from a high of about USD 514 to a low of USD 22. (See fig. 7.)

Figure 7: Illustrative Example of Consumers Out-of-Pocket Costs in the United States for Anoro Ellipta (30 inhalations), 2020



Source: GAO analysis of information from GoodRx, Centers for Medicare & Medicaid Services, and Federal Employee Health Benefit Program prescription drug pricing resources. | GAO-21-282

Notes: When prices were provided for multiple months (e.g., a 90-day supply), we adjusted these prices to reflect a monthly supply. Pricing data were current at the time of our data pull and were extracted from July 2020 to November 2020. U.S. cash retail price data were obtained from the website of a nationally recognized prescription drug discount program (GoodRx) but may not represent all discounts available to consumers through other programs. Sample Medicare Part D plan amounts were obtained via the Medicare Part D plan finder on Medicare.gov. Federal Employee Health Benefit Program data were obtained from the plan's prescription drug pricing resources. As estimates, these values may not account for all plan specific fees, discounts, or deductibles. These

³⁵See the Kaiser Family Foundation, *The Cost of Care with Marketplace Coverage* (San Francisco, California: the Kaiser Family Foundation, February 11, 2015), accessed August 20, 2020, <https://www.kff.org/health-costs/issue-brief/the-cost-of-care-with-marketplace-coverage/>.

estimates are also not representative of all available plan options and actual prices may vary based on a number of different factors (including beneficiaries' locale).

^aMedicare is the federally financed health insurance program for persons aged 65 and over, certain individuals with disabilities, and individuals with end-stage renal disease. Medicare Part D is the voluntary program that provides outpatient prescription drug coverage for Medicare beneficiaries who enroll in Part D drug plans.

^bA deductible is typically a fixed dollar amount plan beneficiaries are required to pay annually for healthcare services before the insurance plan contributes. In 2020, Humana's Medicare Part D Premier Rx plan required patients to meet a one-time deductible of USD 435.00 before coverage began. Not all Medicare Part D plans require patients to meet a deductible before coverage begins.

^cMost Medicare Part D drug plans have a coverage gap (also commonly referred to as the "donut hole"), or temporary coverage limit. The coverage gap begins after the beneficiary and their Medicare Part D prescription drug plan spends a certain amount for covered drugs—USD 4020.00 in 2020. The donut hole ends when the spending for the covered drugs reaches USD 6250.00 and catastrophic coverage begins. These amounts may change each year. While in the coverage gap, beneficiaries pay no more than 25 percent of the cost for covered prescription drugs.

^dThe Federal Employees Health Benefit Program is the largest employer-sponsored health insurance program in the United States, providing coverage to about 8.2 million federal employees, retirees, and their dependents. The Office of Personnel Management (OPM) administers this program in part by entering into contracts with qualified health insurance carriers, negotiating plan benefits and premiums as part of that process. Eligible enrollees can use OPM's Plan Comparison Tool to compare the cost of different plans' monthly premiums, deductibles, and annual out-of-pocket maximums.

^eAll Standard plan members, as well as certain Basic plan members, are eligible to have their prescription drugs delivered directly to their home via Blue Cross Blue Shield's Mail Service Pharmacy Program. This includes maintenance or long-term drugs, such as those for high blood pressure, arthritis, or other chronic conditions. Members may get up to a 90-day supply for a single copay. If the cost of the prescription is less than the applicable copay, the enrollee will only pay the cost of the prescription.

In Canada, we similarly found variability across public and private plans. While public programs and plans are offered at the provincial level, each province includes its own formulary and eligibility requirements, and levels of cost-sharing may vary by province and consumers' ability to pay.³⁶ For example, most eligible seniors enrolled in Ontario's Drug Benefit program have a CAD 100.00 annual deductible and a maximum copayment of CAD 6.11 per prescription, while low-income seniors do not have a deductible and have a maximum CAD 2.00 copayment. According to a 2017 report by Canada's Parliamentary Budget Office, there was variation in the amounts of out-of-pocket costs for consumers covered by private plans. For example, in 2012, 17 percent of plan members paid a fixed copayment amount for prescription drugs, 67 percent paid amounts

³⁶Canada is divided into 10 provinces and three territories, each with their own public prescription drug coverage options that have varying eligibility requirements and consumer costs. Canada's 10 provinces are Alberta, British Columbia, Manitoba, New Brunswick, Newfoundland and Labrador, Nova Scotia, Ontario, Prince Edward Island, Quebec, and Saskatchewan. Canada's three territories are the Northwest Territories, Nunavut, and Yukon.

that varied depending on the price of the drug (coinsurance), and 16 percent paid nothing.³⁷

In addition, unlike in Australia and France (where prescription drug coverage is universal), a significant number of consumers in the United States and Canada do not have prescription drug coverage.³⁸ Out-of-pocket costs for these consumers are likely the highest compared to Australia and France, as consumers without prescription drug coverage (or cash-paying consumers) typically do not benefit from negotiated discounts available to insured consumers; as a result, consumers without prescription drug coverage likely also pay more than their insured counterparts. See figure 8 for a comparison of the potential range of out-of-pocket-costs for consumers across the four countries for two of the selected drugs included in our analysis.

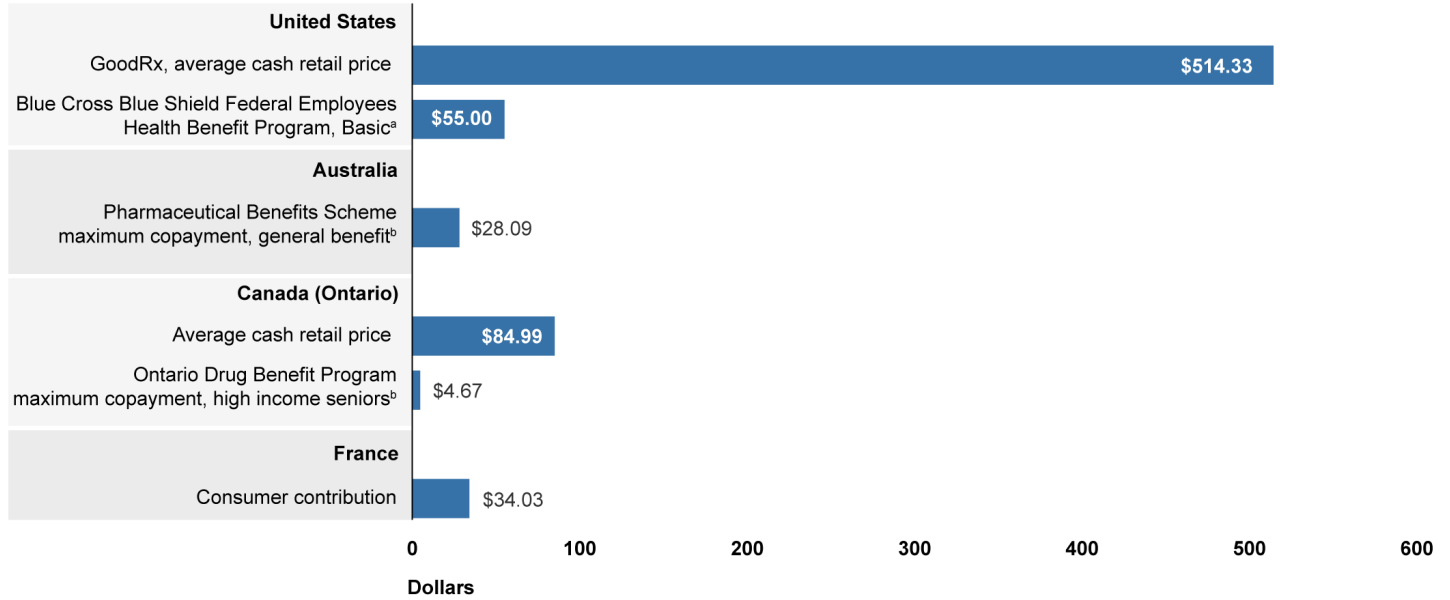
³⁷See Canada Office of the Parliamentary Budget Officer, *Federal Cost of a National Pharmacare Program* (Ottawa, Canada: 2017).

³⁸According to a May 2019 report by the National Center for Health Statistics, approximately 13.3 percent of U.S. adults aged 18 through 64 were uninsured in 2018. See Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics, *Health Insurance Coverage: Early Release of Estimates From the National Health Interview Survey, 2018* (May 2019).

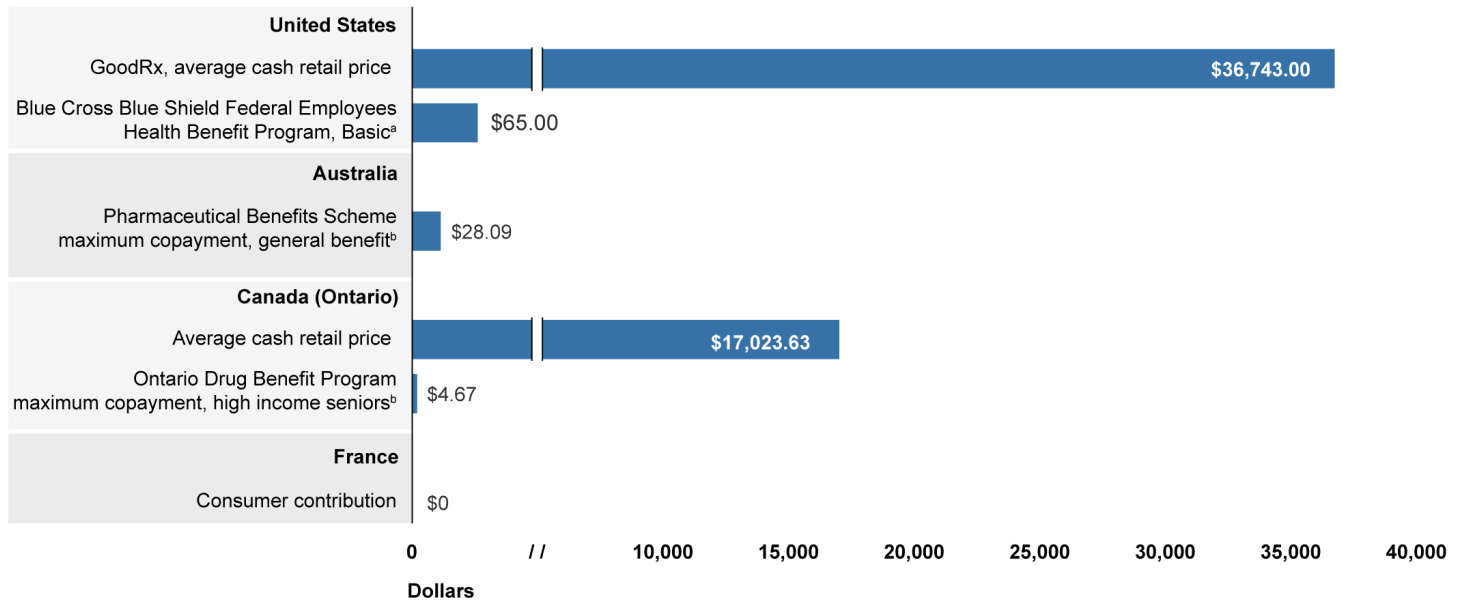
According to a 2015/2016 report from Ontario's Ministry of Health, approximately 16 percent of Canadian consumers were uninsured in 2015. See Ontario Ministry of Health, Ministry of Long Term Care, *2015/16 Report Card for the Ontario Drug Benefit Program*.

Figure 8: Illustrative Examples of Consumers Out-of-Pocket Costs for Two Selected Drugs and Package Sizes in the United States and Selected Comparison Countries, 2020

Anoro Ellipta Inhalation Powder (30 inhalations)



Epclusa Oral Tablet (28 tablets)



Source: GAO analysis of information from GoodRx, Centers for Medicare & Medicaid Services, and Federal Employee Health Benefit Program prescription drug pricing resources. | GAO-21-282

Notes: Prices for selected comparison countries were converted to U.S. dollars, using the United States Federal Reserve average foreign exchange rates for January 2020 and harmonized to match

U.S. package quantities. Pricing data were current at the time of our data pull and were extracted from April to November 2020. U.S. cash retail price data were obtained from the website of a nationally recognized prescription drug discount program (GoodRx). Canadian cash prices were obtained via direct calls to pharmacies in Ontario, Canada. Federal Employee Health Benefit Program data were obtained from the plan's prescription drug pricing resources. All other data were obtained from national pricing sources. As estimates, these values may not account for all plan-specific fees, discounts, or deductibles.

^aThe Federal Employees Health Benefit Program is the largest employer-sponsored health insurance program in the United States, providing coverage to about 8.2 million federal employees, retirees, and their dependents. The Office of Personnel Management (OPM) administers this program in part by entering into contracts with qualified health insurance carriers, negotiating plan benefits and premiums as part of that process. Eligible enrollees can use OPM's Plan Comparison Tool to compare the cost of different plans' monthly premiums, deductibles, and annual out-of-pocket maximums.

^bA copayment is usually a fixed dollar amount paid by the plan beneficiary.

Although not generalizable, our analysis of cash retail prices for five of the selected prescription drugs in our review found that the full cash prices quoted for consumers without prescription drug coverage or other discounts at retail pharmacies in the United States were approximately two to eight times higher than cash retail prices obtained for the same drugs from pharmacies in Canada.³⁹ In Canada, consumers without prescription drug coverage (again, cash-paying consumers) likely benefit from national price controls that regulate the maximum price at which manufacturers can sell patented drugs. In the United States, consumers without prescription drug coverage do not share a similar benefit, as the United States does not have an overall national strategy to control drug prices. However, in the United States, these consumers could have access to various discount programs, such as those offered by prescription drug manufacturers. For example, some prescription drug manufacturers may offer patient assistance programs that provide financial assistance or free prescription drugs to low income individuals; these programs may augment eligible consumers' existing prescription drug coverage, such as Medicare Part D. For more information on consumers' out-of-pocket costs in the United States and selected comparison countries, see appendix V.

³⁹U.S. cash retail prices were primarily obtained from GoodRx and supplemented by direct pharmacy calls for 10 drugs in our sample as a reliability check. Canadian cash retail prices were obtained via direct calls to pharmacies in Ontario, Canada, and are reported for five of the 10 prescription drugs used from our U.S. pharmacy calls and that were also available in the United States and each selected comparison country: Anoro Ellipta Inhalation Powder, Harvoni Oral Tablet 90MG-400MG, Xarelto Oral Tablet 15MG, Eplusea Oral Tablet 400MG-100MG, and Incruse Ellipta Inh Pwd 62.5MCG/1ACT.

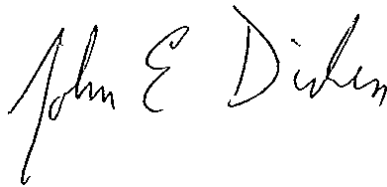
Agency Comments and Our Evaluation

We provided a draft of this product to the Department of Health and Human Services for comment. The agency provided technical comments, which we incorporated as appropriate.

As agreed with your office, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies of this report to the Secretary of Health and Human Services and to the appropriate congressional committees. The report also will be available at no charge on the GAO Web site at <http://www.gao.gov>.

If you or your staff have any questions about this report, please contact me at (202) 512-7114 or dickenj@gao.gov. Contact points for our Office of Congressional Relations and Office of Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix VI.

Sincerely yours,



John E. Dicken
Director, Health Care

Appendix I: Methods Used to Select Drug Sample, Conduct International Price Comparisons, and Estimate U.S. Prices

This appendix describes additional detail on our methodology for selecting our non-generalizable sample of 41 prescription drugs; performing price comparisons to prices in Australia, Canada (Ontario), and France; and estimating U.S. drug prices.

Drug Sample Selection

We created our sample of brand-name, single-source prescription drugs by selecting from highest cost and highest use prescription drugs covered in the Medicare Part D program in 2017.¹ We selected our sample of prescription drugs by applying the following judgmental criteria:

- top 30 drugs by highest total number of claims;
- top 30 drugs by highest total quantity;
- top 30 drugs by highest total cost;
- top 10 drugs by highest cost per unit; and
- top three drugs for each therapeutic class.²

Accounting for duplicates across these criteria resulted in a list of 63 prescription drugs. We then removed prescription drugs that were, as of January 2020, no longer brand-name, single-source drugs (13 prescription drugs with a generic or biosimilar equivalent approved for marketing in the United States), which reduced our list to 50.

¹Medicare is the federally financed health insurance program for persons aged 65 and over, certain individuals with disabilities, and individuals with end-stage renal disease. Medicare Part D is the voluntary program that provides outpatient prescription drug coverage for Medicare beneficiaries who enroll in Part D drug plans.

The Medicare Part D prescription drug event data include records of individual drug transactions that Part D plan sponsors submit to the Centers for Medicare & Medicaid Services each time a beneficiary obtains a prescription drug. We excluded claims billed under programs exempted from certain Part D requirements, including Programs of All-Inclusive Care for the Elderly plan contracts, employer-sponsored plans, and demonstration or special needs plans. We also excluded compounded drugs, which are tailor-made by a pharmacist or other health care practitioner for an individual patient; over-the-counter drugs, as they generally are not covered by Medicare Part D; and physician-administered drugs covered under Medicare Part B. Finally, we excluded drugs with payments made by third parties outside of Medicare.

²Our prescription drug selections were made at the National Drug Code 11-Digit level, which is specific to one strength, form, and package size of a prescription drug. We use the term package size to denote a drug at the National Drug Code 11-Digit level.

Appendix I: Methods Used to Select Drug Sample, Conduct International Price Comparisons, and Estimate U.S. Prices

We also removed five prescription drugs that were not available on any of the relevant formularies in Australia, Canada (Ontario), or France.³ An additional four drugs were removed because the strengths or formulations of the versions in the comparison countries were not medically equivalent to those available in the United States.⁴ This resulted in our final list of 41 prescription drugs, 20 of which were listed on the relevant formularies in all three selected comparison countries. These 20 drugs were used for cross-country summary statistics.

Table 5. Availability of Prescription Drugs Included in Selected Comparison Countries, in January 2020

Legend: ● = available, ○ = not available

Drug name	International price availability by country		
	Australia	Canada (Ontario)	France
Anoro Ellipta Inhalation Powder 62.5MCG-25MCG/1ACT	●	●	● ^a
Breo Ellipta Inh Pwd 100MCG/1ACT	●	●	● ^a
Cosentyx Subcutaneous Solution 150MG/1ML	●	●	●
Descovy Oral Tablet 200MG-25MG	●	○	○
Dupixent Subcutaneous Solution 300MG/2ML	○	○	●
Entresto Oral Tablet 24MG-26MG	●	●	●
Epclusa Oral Tablet 400MG-100MG	●	●	●
Esbriet Oral Capsule 267MG	●	●	●
Harvoni Oral Tablet 90MG-400MG	●	●	●
Ibrance Oral Capsule 100MG	●	●	●
Ibrance Oral Capsule 125MG	●	●	●
Imbruvica Oral Capsule 140MG	●	●	●
Incruse Ellipta Inh Pwd 62.5MCG/1ACT	●	●	● ^a
Invokana Oral Tablet 100MG	○	●	○
Invokana Oral Tablet 300MG	○	●	○
Janumet XR Oral Tab ER 1000MG-50MG	●	●	○
Myrbetriq Oral Tablet 25MG	○	●	○
Myrbetriq Oral Tablet 50MG	○	●	○
Ofev Oral Capsule 150MG	●	●	●

³These five drugs were: Arcalyst SubQ Pwd For Soln 220MG, Auryxia Oral Tablet 1GM, Linzess Oral Capsule 290MCG, ProSol Intravenous Solution 20%, and Zinbryta SubQ Solution 150MG/1ML.

⁴These four drugs were Creon Oral Cap DR 180000U-36000U-114000U, Creon Oral Delayed Release Capsule, Evzio Injection Solution 0.4MG/0.4ML, and Evzio Injection Solution 2MG/0.4ML.

Appendix I: Methods Used to Select Drug Sample, Conduct International Price Comparisons, and Estimate U.S. Prices

Legend: ● = available, ○ = not available

Drug name	International price availability by country		
	Australia	Canada (Ontario)	France
Opsumit Oral Tablet 10MG	●	○	○
Plegridy Pen SubQ Soln 125MCG/0.5ML	●	●	●
Pradaxa Oral Capsule 75MG	●	○	●
Praluent Subcutaneous Solution 75MG/1ML	○	●	●
Revlimid Oral Capsule 10MG	●	●	○ ^b
Revlimid Oral Capsule 5MG	●	●	○ ^b
Signifor LAR IM Pwd for Susp 40MG	●	○	●
Simponi SubQ Solution 50MG/0.5ML	●	●	●
Spiriva Respimat Inh Spray 2.5MCG/1Act	●	●	●
Strensiq Subcutaneous Solution 80MG/0.8	○	●	○
Taltz Subcutaneous Solution 80MG/1ML	●	●	●
Tecfidera Oral Cap DR 240MG	●	●	●
Tradjenta Oral Tablet 5MG	●	●	○
Tremfya Subcutaneous Solution 100MG/1ML	●	○	●
Tresiba Subcutaneous Solution 200U/1ML	○	●	●
Trulicity SubQ Soln 1.5MG/0.5ML	●	○	●
Trulicity SubQ Solution 0.75MG/0.5ML	○	○	●
Vimpat Oral Solution 10MG/1ML	●	○	●
Vimpat Oral Tablet 200MG	●	●	●
Xarelto Oral Tablet 15MG	●	●	●
Xtandi Oral Liquid Filled Capsule 40MG	●	○	●
Zepatier Oral Tablet 50MG-100MG	●	●	●

Legend: ● = available, ○ = not available

Source: GAO Analysis of data from national pricing sources. | GAO 21-282

Note: Prescription drugs are listed as available if they appeared on the relevant formulary in January 2020: Australia's Pharmaceutical Benefits Scheme (PBS); the Ontario Ministry of Health's Drug Benefit Program; the Ontario Ministry of Health's Exceptional Access Program; or the Database for Medications and Pricing Information, maintained by the Medical Insurance division of French Social Security.

^aU.S. prescription drug selection and its labeled formulation or strength differed in the comparison country, but the prescription drug was medically equivalent.

^bAccording to officials, Revlimid Oral Capsule 10MG and Revlimid Oral Capsule 5MG are available in France to outpatients through hospital pharmacies.

International Comparisons

To examine publicly available retail and manufacturer-level prices in Australia, Canada (Ontario), and France, we collected pricing information for the 41 selected prescription drugs on the following national formularies, in January 2020:

Appendix I: Methods Used to Select Drug Sample, Conduct International Price Comparisons, and Estimate U.S. Prices

- Australia’s Pharmaceutical Benefits Scheme (PBS);⁵
- the Ontario Ministry of Health’s Drug Benefit Program;
- the Ontario Ministry of Health’s Exceptional Access Program;⁶ and
- France’s national health insurance’s Database for Medications and Pricing Information.⁷

We collected several pieces of data for each drug. Using information contained in the formularies above, we collected January 2020 manufacturer-level prices.⁸ For France and Australia, we were able to collect retail-level prices from the formularies; for Canada, we were able to estimate retail-level prices for drugs available in Ontario using public information from the Ontario Ministry of Health and the Canadian government.⁹

For certain prescription drugs, individual drug package sizes—which contain various quantities of drug units—differed in the United States and Australia, Canada (Ontario), and France. The definition of drug unit also differed. We defined drug units by the dosage form; for example, one pre-

⁵We accessed the following pricing source for Australia: Australian Government Department of Health, The Pharmaceutical Benefits Scheme Publications Archive, January 1, 2020, accessed June 1, 2020, <https://www.pbs.gov.au/info/publication/schedule/archive>.

⁶We accessed the following pricing sources for Canada (Ontario): Ontario Ministry of Health, Drugs Funded by Ontario Drug Benefit Program, accessed January 13, 2020, http://www.health.gov.on.ca/en/pro/programs/drugs/edition_43.aspx; and the Ontario Ministry of Health, Formulary—Exceptional Access Program, accessed July 30, 2020, http://www.health.gov.on.ca/en/pro/programs/drugs/odbf/odbf_except_access.aspx.

⁷We accessed the following pricing source for France to determine prices on January 13, 2020: Social Security Database for Medications and Pricing Information, accessed April 16, 2020, http://www.codage.ext.cnamts.fr/codif/bdm_it/index_presentation.php.

⁸Prices collected were: for Australia, approved ex-manufacturer and proportional ex-manufacturer prices from Australia’s PBS; for Ontario, drug benefit prices from the Ontario Ministry of Health’s Drug Benefit Program Formulary or the Ontario Exceptional Access Program; and, for France, prices obtained from France’s national health insurance’s Database for Medication and Pricing Information.

⁹Prices collected were: for Australia, dispensed price for maximum quantity from Australia’s PBS; for Ontario, retail prices calculated using public information from the Ontario Ministry of Health’s Drug Benefit Program Formulary or the Ontario Exceptional Access Program; and, for France, retail prices including all markups, taxes, and dispensing fees obtained from the Database for Medication and Pricing Information.

filled syringe, tablet, capsule, or inhalation.¹⁰ To verify that the drug units in the foreign countries matched those in the United States, we consulted DailyMed, the official provider of Food and Drug Administration label information maintained by the National Institutes of Health's National Library of Medicine. For each prescription drug, where necessary, we harmonized drug units to be consistent in each country, and we also harmonized the quantity of drug units to match the quantity contained in each U.S. prescription drug package selection.¹¹

We converted all foreign prices to U.S. dollars (USD) using the United States Federal Reserve average foreign exchange rates for the month of January 2020.¹²

United States Price Estimates at the Retail and Manufacturer Levels

To estimate net prices paid at the retail and manufacturer levels in the United States, we analyzed data from various sources, including estimates of Medicare Part D rebates and other price concessions and data from a commercially available compendium, among others. Specifically, to estimate the net prices paid at the retail level—the final amount paid to a retailer by all payers—such as a consumer and their insurer—less rebates and other price concessions the payers receive from any source, we took steps to estimate the average price a Medicare Part D plan might pay at the retail level, less any rebates or price concessions. To do so, we projected first quarter 2018 Medicare Part D prices forward for each drug by an amount equivalent to the change between first quarter 2018 and 2020 wholesale acquisition cost (WAC). We then discounted those prices for each drug in our selection by the amount of rebates and other price concessions for that drug using confidential 2018 Medicare Part D data.¹³ The resulting discounted prices were used to inform summary analyses included in the body of this report.

¹⁰One exception to this was for Vimpat Oral Solution. For this, we counted the quantity on a per-milliliter basis, or 465 units, because the individual drug package is one bottle of 465 ml and the package does not contain individual drug units.

¹¹For example, a drug may be supplied in 4-week doses abroad (i.e., 28 tablets), while in the United States it is supplied in 1-month supplies (i.e., 30 tablets).

¹²January 2020 average monthly rates were accessed from the Federal Reserve on July 7, 2020, at <https://www.federalreserve.gov/releases/g5/20200203/>; USD 1.00 was equal to 1.3089 CAD, EUR 1.00 was equal to USD 1.1098, and AUD 1.00 was equal to USD 0.6851.

¹³The rebate and price concession data used in our analyses are not inclusive of Coverage Gap Discount Program payments from manufacturers of brand-name drugs.

The confidential rebate and other price concession data from Medicare Part D utilized in our estimates reflect those received by Part D plan sponsors; however, these data may not reflect rebates and other price concessions that may be received by other government programs or other prescription drug payers in the United States. For example, in 2014, we found that rebates for the brand-name subset of the sample analyzed ranged from about 19 percent of the gross price for Medicare Part D to nearly 39 percent for the Department of Defense and 62 percent for Medicaid.¹⁴ Similarly, a 2018 study examining overall prescription drug expenditures found that rebates represented about 22 percent of the gross price for Medicare Part D, 51 percent for Medicaid, and 12 percent for private insurers.¹⁵ In 2018, Medicare Part D accounted for approximately USD 107 billion in retail prescription drug sales—nearly one-third of total U.S. expenditures—while expenditures from DOD and Medicaid were significantly lower: DOD accounted for approximately USD 5 billion in retail prescription drug sales, and Medicaid—approximately USD 33 billion. Private health insurance accounted for approximately USD 134 billion in retail prescription drug sales.

To estimate the U.S. net prices paid at the manufacturer level—the final amount a manufacturer receives from all payers, such as wholesalers or retail chains, less rebates and other price concessions the manufacturer provides to those payers—we used two different methods. For the first method, we discounted January 2020 WAC for each drug in our selection by the actual amount of Medicare Part D rebates and other price concessions, and then we discounted each drug by an additional 12 percent—which the IQVIA Institute for Human Data Science (IQVIA) has estimated to be the average difference between WAC and the invoice price.¹⁶ For the second method, we discounted January 2020 WAC for each drug in our selection by 43 percent, which IQVIA has estimated to be the average difference between WAC and the net manufacturer

¹⁴See GAO, *Prescription Drugs: Comparison of DOD, Medicaid, and Medicare Part D Retail Reimbursement Prices*, [GAO-14-578](#) (Washington, D.C.: June 30, 2014).

¹⁵See Charles Roehrig, *The Impact of Prescription Drug Rebates on Health Plans and Consumers*. (Altarum, April 26, 2018), accessed January 8, 2021, <https://altarum.org/publications/impact-prescription-drug-rebates-health-plans-and-consumers>.

¹⁶IQVIA researches and publishes reports on, pharmaceutical usage and pricing in the United States and throughout the world, among other topics. See IQVIA Institute for Human Data Science, *Medicine Use and Spending in the U.S.: A Review of 2018 and Outlook to 2023* (Parsippany, New Jersey: 2019).

Appendix I: Methods Used to Select Drug Sample, Conduct International Price Comparisons, and Estimate U.S. Prices

price.¹⁷ These prices were used to inform summary analyses included in the body of this report.

Because the actual amounts of rebates and other price concessions from 2018 Medicare Part D data are confidential, we developed an alternate method for reporting any U.S. per-drug prices in the report body and included in our appendices. For reporting per-drug estimated U.S. net prices paid at the retail level, we grouped our 41 prescription drugs into four quartiles based on the total amount of rebates and other price concessions for each drug divided by the gross retail price for that drug—establishing a percentage for each drug. We then calculated the average percentage for all the drugs in each quartile. We then discounted the projected first quarter 2020 gross Medicare Part D prices for the drugs in each quartile by the average percentage for each relevant quartile. For reporting per-drug estimated U.S. net prices paid at the manufacturer level, we discounted January 2020 WAC for each drug in our selection by the same average percentage from each relevant quartile, and then by an additional 12 percent—which IQVIA estimated to be the average difference between WAC and the invoice price. For more information on WAC, see appendix II.

We did not discount the publicly available retail and manufacturer pricing data for selected comparison countries, as rebates and other price concessions in those countries are confidential.

¹⁷See IQVIA Institute for Human Data Science, *Medicine Use and Spending in the U.S.*

Appendix II: Additional Details on Wholesale Acquisition Cost (WAC)

During our work examining prices in the United States at the manufacturer level, we found WAC—a price point commonly used by researchers as a proxy for U.S. manufacturer-level prices—was not markedly different from gross retail prices.

Specifically, we found that for the 41 drugs in our analysis, WAC was in many cases not markedly different from U.S. gross prices at the retail level. Because WAC is intended to describe a manufacturer price point, the retail price should be higher, allowing for wholesaler and pharmacy margins. However, for our selection of prescription drugs, our analysis of first quarter 2018 Medicare Part D gross retail prices—which did not reflect confidential rebates and other price concessions—showed they were on average only 2 percent higher than the published WAC for the same period and were lower for two drugs.¹ Accounting for confidential rebates and other price concessions to estimate a net price would have reduced these retail-level prices by an additional 28 percent on average, further widening the gap between WAC and the retail-level prices.

Third-party researchers have previously reported that WAC is overstated. For example, a 2016 study evaluating prices charged by prescription drug manufacturers in the United States and the United Kingdom found that WAC did not reflect the actual prices paid to manufacturers. Specifically, the study found that WAC, as reported, was too high, because it was too close to retail prices to allow for wholesaler and pharmacy margins, which the study indicated were about 3 and 22 percent of the prescription drugs' retail prices, respectively.² Another study by the IQVIA Institute for Human Data Science (IQVIA), for a broader group of brand prescription drugs, estimated that net prices at the manufacturer level were 43 percent lower than WAC in 2018.³

We accounted for WAC potentially being overstated in our estimates. To estimate the U.S. net prices paid at the manufacturer level—the final amount the drug manufacturer would receive from payers such as

¹Medicare is the federally financed health insurance program for persons aged 65 and over, certain individuals with disabilities, and individuals with end-stage renal disease. Medicare Part D is the voluntary program that provides outpatient prescription drug coverage for Medicare beneficiaries who enroll in Part D drug plans.

²See Jesper Jørgensen and Panos Kefalas, “A Price Comparison of Recently Launched Proprietary Pharmaceuticals in the U.K. and the U.S.,” *Journal of Market Access & Health Policy*, (2016).

³See IQVIA Institute for Human Data Science, *Medicine Use and Spending in the U.S.: A Review of 2018 and Outlook to 2023* (Parsippany, New Jersey: 2019).

**Appendix II: Additional Details on Wholesale
Acquisition Cost (WAC)**

wholesalers and retailers, less any rebates and other price concessions—we used two different methods. For the first method, we discounted January 2020 WAC for each drug in our selection by the actual amount of Medicare Part D rebates and other price concessions, and then we discounted each drug by an additional 12 percent—which IQVIA has estimated to be the average difference between WAC and the invoice price. For the second method, we discounted January 2020 WAC for each drug in our selection by 43 percent, identified by IQVIA as the difference between net prices at the manufacturer level and WAC.

Appendix III: Prescription Drug Pricing Strategies in Selected Countries

The following country profiles in this appendix describe in more detail the prescription drug pricing strategies used in each selected country—the United States, Australia, Canada, and France. For each of the foreign countries, we focused this appendix primarily on pricing strategies for new prescription drugs to align with the methodology of this report.¹ To describe prescription drug pricing strategies for the selected countries, we reviewed governmental reports and websites, reviewed reports from relevant national and international organizations, and interviewed government representatives. Specifically, we interviewed representatives from the following foreign governmental departments:

- Australia: The Department of Health and the Pharmaceutical Benefits Advisory Committee
- Canada: The Patented Medicine Prices Review Board and Ontario’s Ministry of Health
- France: The Comité Économique des Produits de Santé (The Economic Committee for Health Products)

Table 6 summarizes the key points about each country’s prescription drug pricing strategies.

Table 6: Summary of Key Points about Prescription Drug Coverage and Pricing Strategies in the United States, Australia, Canada, and France

United States	Australia	Canada	France
No universal prescription drug coverage.	Universal public prescription drug coverage.	No universal prescription drug coverage.	Universal public prescription drug coverage.
Array of publicly and privately funded coverage and portion of the population without drug coverage.	Federal government determines whether to cover drugs and negotiates prices. Drugs not included on the national formulary are not covered and prices can be set without regulation.	Array of publicly and privately funded coverage and portion of the population without drug coverage.	Federal government determines whether to cover drugs, negotiates prices, and caps drug manufacturers’ sales growth.
No overall national prescription drug pricing strategy.		Federal regulation of maximum patented drug prices.	Drugs not covered can be sold on the French market without price regulation.
Variety of prescription drug pricing strategies at the plan level.		Joint drug price negotiation for public coverage.	

Source: GAO summary of documentation from the United States, Australia, Canada, and France. | GAO-21-282

¹The variety of drug pricing strategies at the plan level that we describe for the United States are not necessarily specific to new drugs.

Physician-administered drugs are outside the scope of this report.



Prescription Drug Pricing Strategies in Selected Countries

The United States

Key Points

- No universal prescription drug coverage.
- Array of publicly and privately funded coverage and portion of the population without drug coverage.
- No overall national prescription drug pricing strategy.
- Variety of prescription drug pricing strategies at the plan level.

Prescription Drug Coverage

The United States does not have universal public health insurance or prescription drug coverage. Instead, the United States has a mix of public sector and private sector health insurance programs. This results in varying types of coverage for prescription drugs across the country and leaves some Americans without drug coverage. Those without coverage pay for their prescription drugs entirely out-of-pocket.

Publicly Funded Coverage

Publicly funded prescription drug coverage is available to qualifying individuals.

Medicare Part D. Medicare—the federal health insurance program that, in 2019, served about 61 million elderly and disabled individuals, as well as individuals with end-stage renal disease—offers an outpatient prescription drug benefit known as Medicare Part D. Medicare beneficiaries may choose a Part D plan from multiple competing plans run by private companies—largely commercial insurers—under contract with the federal government. In 2019 there were nearly 45.4 million beneficiaries enrolled in these plans.

Medicaid. Medicaid—a joint federal-state health insurance program that

Prescription Drug Pricing Strategies

The United States does not have a national prescription drug pricing strategy, but the various prescription drug coverage options available, including federal programs and private payers, use a range of prescription drug pricing strategies.

Medicare Part D

Medicare Part D follows a model that relies on competing prescription drug plans to control prescription drug spending. The program is structured to provide plans the incentive to offer benefits that will meet beneficiaries' prescription drug needs at competitive premiums.² The larger a plan's market share, the more leverage it has for obtaining favorable drug prices on behalf of its enrollees and controlling prescription drug spending. To generate prescription drug savings for beneficiaries, and to help contain drug spending, plans often contract with pharmacy benefit managers to negotiate rebates with drug manufacturers, discounts with retail pharmacies, and other price concessions on behalf of the plan sponsor. Other methods to help contain drug spending include assigning covered drugs to distinct tiers, each of which carries a different level of beneficiary cost sharing, as well as utilization management practices, such as requiring physicians to obtain authorization from the plan prior to prescribing a drug, and step therapy, which requires beneficiaries to first try a less costly drug to treat their condition. Federal law specifically prohibits the federal government from interfering with negotiations between plans and drug manufacturers and pharmacies.³

Medicaid

State Medicaid programs do not negotiate drug prices with manufacturers to control prescription drug spending but pay retail pharmacies for drugs dispensed to beneficiaries at set prices.⁴ In addition to these retail pharmacy payments, Medicaid programs also control prescription drug spending through the Medicaid drug rebate program. Under the drug rebate program, drug manufacturers are required to provide quarterly rebates for covered outpatient prescription drugs purchased by state Medicaid programs, which helps Medicaid receive manufacturers' lowest prices.⁵ States can also negotiate additional rebates with manufacturers.

²While Part D plans vary in their monthly premiums, annual deductibles, and cost sharing for drugs, all plan formularies generally must cover at least two drugs in each therapeutic category, with certain exceptions. See 42 C.F.R. § 423.120(b)(2)(i) (2019). Plans are required to cover drugs in six protected classes, unless an exception applies.

³See 42 U.S.C. § 1395w-111(i). The government may also not require a particular formulary or institute a price structure for the payment of Medicare Part D drugs.

⁴The federal government sets aggregate payment limits—known as the federal upper limit—for certain outpatient, multiple-source prescription drugs and also provides guidelines regarding drug payment.

⁵See 42 U.S.C. § 1396r-8.

covers qualifying low income adults and children—includes prescription drug coverage. In fiscal year 2018, all states and the District of Columbia provided Medicaid prescription drug coverage to about 75 million beneficiaries. States establish and administer their own Medicaid programs within broad federal guidelines, so Medicaid prescription drug programs can vary from state to state. In addition, most states require a nominal beneficiary copayment for prescription drugs.

DOD and VA. DOD provides prescription drug coverage to TRICARE beneficiaries, including active-duty personnel, certain reservists, retired uniform service members, and their eligible dependents. VA's Veterans Health Administration (VHA) provides prescription drug coverage to eligible veterans and their eligible dependents. In fiscal year 2019, the departments provided prescription drug coverage to approximately 18.8 million beneficiaries. Both DOD and VA pay for prescription drugs on behalf of their beneficiaries through a direct purchase approach, where the programs purchase drugs directly from manufacturers—through intermediaries known as prime vendors—and distribute them to beneficiaries through their own medical facilities and pharmacies.

Privately Funded Coverage

Private health insurance is the most common form of health coverage in the United States, covering over two-thirds of the insured population in 2018, according to the U.S. Census Bureau. The majority of privately insured individuals are covered through group plans, either small group (for small employers) or large group (for large employers).

Americans without access to group health coverage, such as those with employers that do not offer health coverage, may choose to purchase coverage directly as part of the individual market or go without coverage.

In addition, Medicaid programs use other utilization management methods to control prescription drug spending, including prior authorization and utilization review programs, dispensing limitations, and cost-sharing requirements.

Department of Defense and Department of Veterans Affairs

The Department of Defense (DOD) and the Department of Veterans Affairs (VA) are both health care providers and prescription drug purchasers—relying on statutory discounts and further negotiations with drug suppliers to obtain lower prices for drugs covered on their formularies. DOD and VA have access to a number of prices when purchasing drugs and receive additional discounts if drug prices rise faster than general inflation.⁶ In addition, DOD and VA may negotiate further price discounts for drugs included on their formularies through blanket purchase agreements or other national contracts with manufacturers. Both DOD and VA use their own national, standard formularies to obtain more competitive prices from manufacturers with drugs included on the formularies. Their formularies also encourage the substitution of lower cost drugs determined to be as or more effective than higher cost drugs.

Private Payers

Private health plans use a range of strategies to control drug prices, including negotiating prices and rebates and other price concessions with other market participants. They also apply utilization management, tiered formularies, and benefit design to prefer, discourage, or exclude certain prescription drugs. Private payers in the United States, including employer-based health plans and private insurers, typically contract with pharmacy benefit managers that negotiate rebates or payments with manufacturers and prices with retail pharmacies. These benefit managers compete in the private market based on their ability to negotiate reduced prices and contain costs. The benefit managers influence price negotiations with manufacturers through formulary development and management and through the large number of health plan enrollees they typically represent. Manufacturers pay benefit managers through rebates or other payments to be included on plan formularies and to capture greater market shares for their drugs. For example, many mail-order pharmacies are owned by pharmacy benefit managers, and benefit managers can obtain greater manufacturer rebates or payments by dispensing a high volume of the manufacturer's drug.

The extent to which pharmacy discounts and manufacturer rebates or payments are shared with health plans and enrollees depends on contractual arrangements with the health plan and the plan's benefit design. For example, pharmacy benefit managers negotiate contracts with health plans and their networks of pharmacies separately, which means that health plans may pay higher prices for drugs than those the benefit manager negotiated with the pharmacy.

⁶Under 38 U.S.C. § 8126, DOD and VA have access to (1) Federal Supply Schedule prices—intended to be no more than the prices manufacturers charge their most-favored nonfederal customers under comparable terms and conditions; and (2) federal ceiling prices—mandated by law to be 24 percent lower than nonfederal average manufacturer prices.



Prescription Drug Pricing Strategies in Selected Countries

Australia

Key Points

- Universal public prescription drug coverage.
- Federal government determines whether to cover drugs and negotiates prices.
- Drugs not included on the national formulary are not covered and prices can be set without regulation.

Prescription Drug Coverage

Australia has a publicly funded health care system—known as Medicare—that provides universal coverage of a range of health care services including medical services by doctors, hospital treatment, and prescription drugs. Australian Medicare has a safety net structure in place for both medical services and drugs that provides consumers with higher benefits once an annual threshold of out-of-pocket costs is met.

The Australian state, territory, and local governments share responsibility for administering the health system, with the Australian government managing benefits' schedules and regulating private insurance, and the state, territory, and local governments managing and administering public hospitals, among other responsibilities.

Public prescription coverage is available to all Australian individuals with a Medicare card. The national formulary, known as the PBS schedule, lists all of the drugs available to Medicare consumers at a government-subsidized price. Most consumers pay one of two copayments for drugs on the PBS. In 2020, the copayment for consumers with general benefits was up to AUD 41.00 (USD 28.09), and the copayment for consumers with concession benefits—seniors and some veterans, among other

Prescription Drug Pricing Strategies

The Australian government employs national strategies to regulate and negotiate prescription drug prices. Specifically, either during or after drugs are authorized for marketing, drugs are assessed for comparative and cost effectiveness by the Pharmaceutical Benefits Advisory Committee (PBAC). If a drug receives a positive recommendation from the PBAC to be included on the Pharmaceutical Benefits Scheme (PBS) schedule for coverage, the federal government then negotiates with drug manufacturers to determine the price the government will pay. If no agreement is reached on a price, the prescription drug is not included on the PBS schedule. The Minister for Health makes final coverage decisions based on many factors, including budget impact, but a drug cannot be added to the PBS without a positive recommendation from the PBAC.

Drug Coverage Recommendation

The PBAC is an independent expert committee whose primary role is to make recommendations to the Minister for Health regarding which prescription drugs should be covered under the PBS.⁷ Drug manufacturers that want their prescription drugs to receive reimbursement under PBS submit an application to the PBAC following published guidelines. For each submission to the PBAC, which includes requests to list new drugs or new indications of existing drugs on the PBS, the committee considers both the comparative effectiveness and cost effectiveness of each drug during its evaluation.⁸ The PBAC has subcommittees that assist with analysis and provide advice on technical items.

- **Economics subcommittee.** For each submission of this type, the subcommittee assesses clinical and economic evaluations of the drug and identifies important uncertainties and key issues for the PBAC to consider.
- **Drug utilization subcommittee.** For selected submissions of this type, the subcommittee evaluates use and financial forecasts and advises the PBAC and the drug manufacturer on important related matters.⁹

⁷Other roles include recommending vaccines to the Minister for Health for funding under the National Immunisation Program, recommending maximum quantities and refills of drugs and any restrictions on the indications covered, and regularly reviewing the list of PBS items.

⁸There are other types of submissions, such as requests to list new forms or strengths of an already-listed therapeutically equivalent drug.

⁹Generally, the subcommittee does not consider submissions where the estimated use and cost of the drug for the indication have already been reviewed. The drug utilization subcommittee also assists with post-market evaluation of PBS drugs.

groups—was AUD 6.60 (USD 4.52). Additional fees were applicable in certain cases.

In addition, Australia has voluntary, private health coverage which may cover some or all of private hospital care, ancillary treatments not covered by the universal public system, or ambulance services. Coverage for ancillary treatments may include prescription drugs not included on the PBS schedule, as well as other services such as dental and vision.

After receiving input from the subcommittees, the PBAC holds its meeting and makes one of three possible recommendations—a positive recommendation, a deferral of a recommendation, or a decision to not recommend. When a submission is not recommended, the drug manufacturer may choose to reapply.

Agreement of Drug Subsidy Parameters

Following a positive PBAC recommendation to the Australian Minister for Health to cover a prescription drug under the PBS schedule, the drug manufacturer takes a number of steps.¹⁰ First, the drug manufacturer submits a notice of intent and then a pricing offer package to start the negotiation process with the Department of Health. The offer package includes support for the proposed ex-manufacturer price and a proposed special pricing agreement request, if applicable, among other items. In addition to price, the manufacturer and the department must agree on the expected utilization of the drug and the budget cost to the government, as well as any restrictions for prescribing the drug.¹¹ When the manufacturer and the department have agreed in principle on the drug's price and the budget impact is finalized, all relevant information is provided to the Minister for Health to make a PBS listing decision.¹²

Minister for Health Decision

The Minister for Health's final decision on whether to add a prescription drug to the PBS takes several factors into account. Specifically, the Minister will consider not only the final pricing and budget information but will also consider costs in relation to any other area affected by a listing on the PBS schedule, such as the Medicare Benefits Schedule that lists all covered health services. Where the net cost to the Australian government of listing a drug is projected to be greater than AUD 20 million (USD 13.7 million) in any year, the Minister refers the listing to the Cabinet for consideration before making the determination. An Australian Department of Health report noted that all of the drugs that received a positive recommendation by the PBAC and were approved by the Minister in 2018 and 2019 were listed on the PBS schedule within 6 months of agreement of budget impact and price, meeting the agency's goal.

¹⁰On July 1, 2019, the Australian Department of Health implemented improvements to the efficiency, transparency, and timeliness of the PBS listing processes, which were a part of the first stage of a Strategic Agreement with Medicines Australia, a pharmaceutical industry group.

¹¹In addition, special patient contribution arrangements can be made, where patients must pay a premium on top of the PBS reimbursement price in addition to the applicable PBS copayment.

¹²According to Australian officials, drug manufacturers that either choose not to list a prescription drug on the PBS or who reject the PBAC recommendation can set their prices for drugs not covered through the PBS without regulatory intervention.



Prescription Drug Pricing Strategies in Selected Countries

Canada

Key Points

- No universal prescription drug coverage.
- Array of publicly and privately funded coverage and portion of the population without drug coverage.
- Federal regulation of maximum patented drug prices.
- Joint drug price negotiation for public coverage.

Prescription Drug Coverage

Canada has a publicly funded health care system that provides universal coverage for a broad range of medically necessary services. However, Canada's health care system excludes coverage of drugs prescribed outside of hospitals. This results in varying types of coverage for prescription drugs across the country and leaves some Canadians without drug coverage.

Publicly funded prescription drug coverage is available to some individuals. Specifically, the 10 provinces and three territories provide prescription drug coverage to certain groups of people—typically including seniors and low-income individuals. In addition, the federal government delivers health services and provides prescription drug coverage to certain populations, including eligible indigenous peoples. Those who do not qualify for or enroll in prescription coverage through a public plan are either covered by private plans, which are provided by employers or purchased individually, or go without coverage and pay for their prescription drugs out-of-pocket.

According to data from the Canadian public drug plans that provided prescription drug data to a national database from April 1, 2017 through March 31, 2018, these plans paid for about 277 million

Prescription Drug Pricing Strategies

The Canadian government employs national strategies to control the prices of prescription drugs. Specifically, the federal government regulates the maximum potential prices for which patented drugs can be sold by drug companies nationwide. In addition, Canada's publicly funded prescription drug plans negotiate prices with drug companies jointly, leveraging their resources and market share to pay lower prices.

Nationally Regulated Ceiling Prices

Through the Patented Medicine Prices Review Board (hereafter referred to as the Board), Canada regulates the maximum average potential price, or ceiling price, at which drug companies can sell patented drugs in any Canadian market.¹³ The Board—an independent and autonomous, quasi-judicial body made up of Board members and Board staff—has a regulatory role to ensure that the prices charged by drug companies for patented drugs are not excessive.¹⁴ According to Board staff, the specific ceiling prices for each drug are not publicly reported. The Board does not set the actual prices at which patented drugs are sold, but it takes steps to ensure that the prices paid do not exceed the ceiling price.

When introducing a new patented drug in the Canadian market and thereafter, as required, until the patent expires, drug companies must file price and sales information to the Board.¹⁵ There are different review processes for new patented drugs and existing patented drugs.¹⁶

- **New patented drugs.** For new patented drugs being introduced to the Canadian market, the Board conducts two types of reviews—a scientific review to determine the drug's level of therapeutic improvement and a price review to establish the drug's ceiling price. The method used to review the price is dependent on the level of therapeutic improvement determined during the scientific review. For example, when the scientific review categorizes a drug as breakthrough—the first drug to be sold in Canada that treats a particular disease effectively—the drug's ceiling price is determined

¹³The Board does not have authority over the prices of off-patent drugs, the prices charged by wholesalers or retailers, or pharmacists' professional fees.

¹⁴The Board also has a mandate to report on pharmaceutical trends and on the research and development spending by drug companies.

¹⁵In the years following a drug's introduction, while the drug is under patent, drug companies with a drug containing controlled substances must report its price and sales information to the Board every 6 months, while companies with a drug that does not contain controlled substances must report upon receiving a request from the Board.

¹⁶In August 2019, the Canadian government significantly amended its regulations for patented drugs; it plans to implement the changes on July 1, 2021. We describe the Board's process that was in effect in 2020 to align with the prescription drug prices used in our analysis.

prescriptions during that time period, which were filled by nearly 7 million active beneficiaries (out of Canada's total population of 37 million in 2018). In addition, the Canadian Life and Health Insurance Association estimated that in 2018 approximately 26 million Canadians had private prescription drug coverage. Some Canadians are eligible for both public and private coverage, and coordination of benefits varies by province.

For example, in 2020, Ontario—the most populous province—had six prescription drug programs. The Ontario Drug Benefit program was the primary program. It covered all Ontario residents age 65 and older, as well as other groups, including young adults and children less than age 25 without private coverage. The amount enrollees paid out of pocket for their covered prescription drugs varied. Specifically

- a higher income senior had a copayment of up to CAD 6.11 (USD 4.67) for each prescription filled after meeting a CAD 100.00 (USD 76.40) annual deductible;
- a lower income senior had a copayment of up to CAD 2.00 (USD 1.53) for each prescription filled and no deductible; and
- an enrollee less than age 25 had no out of pocket payment.

Another one of Ontario's public programs provided catastrophic coverage for individuals whose prescription drug costs were high in relation to their household income. The remaining drug programs in Ontario were specific to drugs that treat certain diseases.

by a median international price comparison test that determines the median manufacturer-level price of the same strength and dosage form of the drug for a specific list of seven comparator countries.¹⁷ Conversely, when the scientific review categorizes a drug as providing substantial improvement, the drug's ceiling price is the higher of either (1) the highest priced domestic therapeutic class comparator or (2) the median international price comparison test just described.

- **Existing patented drugs.** For existing patented drugs, the Board conducts only a price review to assess whether the price of the drug appears to be excessive. Generally, the price of the drug is presumed to be excessive if the national average transaction price of the drug exceeds the lower of either: (1) the change in the consumer price index, or (2) the highest international price in comparator countries. If the Board determines that the price may be excessive, it can trigger an investigation, which includes an analysis of the pricing history of the patented drug and reviews prices for each class of customer, such as the hospital or wholesaler, and for each province and territory.¹⁸ There are three possible outcomes to an investigation:
 - the prices do not appear to be excessive;
 - the prices appear to be excessive and the drug company voluntarily submits an acceptable proposal to offset any excess revenue accrued; or
 - the prices appear to be excessive and the drug company does not submit an acceptable voluntary proposal, resulting in a formal hearing in front of the Board and a final determination.

When prices are determined to be excessive, drug companies face remedies that are either proposed by the company and accepted by the Board during the voluntary process or ordered by the Board following a hearing. Remedies include the reduction of the price of the drug, payment to the Canadian government in the amount of the excess revenues earned, or both.¹⁹ The most recent results of these determinations, which pertain to patented drugs sold in 2018, resulted, as of May 31, 2019, in drug price reductions for certain drugs and approximately CAD 2.6 million (USD 2.0 million) in repayment of excess revenues through accepted voluntary proposals for 12 drugs.²⁰

On July 1, 2021, amendments to the Patented Medicines Regulations and the Board's guidelines will go into effect. According to the Board, three key changes were made to the regulations.²¹ First, the list of comparator countries will be updated. There are currently seven comparator countries. Two countries—the United States and Switzerland—will be

¹⁷In 2020, the seven comparator countries were France, Germany, Italy, Sweden, Switzerland, the United Kingdom, and the United States.

¹⁸When the Board determines that the drug's price appears to be excessive but not by enough to trigger an investigation, the drug company is notified and the Board's website will report the results as "does not trigger investigation."

¹⁹In cases where the Board determines there has been a policy of excessive pricing, it can double the amount of the monetary payment.

²⁰At the time of the Board's report, 21 total drugs were subject to voluntary compliance undertakings, of which nine were still in process. In addition, two drugs were subject to an upcoming hearing and one drug had a completed hearing that resulted in a price reduction order.

removed from the list because, according to Board staff, their drug prices were the highest among comparable countries. Six countries will be added for a total of 11 comparator countries.²² Second, the factors that the Board is allowed to consider when determining the maximum ceiling price will be updated. New factors include the market size, gross domestic product, and pharmacoeconomic value (a measure of cost per quality-adjusted year of life).²³ Finally, the amendments will change the reporting requirements for patentees. Patentees will be required to report prices and net revenue information of all price adjustments to the Board.²⁴

Price Negotiations in Public Plans

Canada's publicly funded prescription drug plans (public plans) conduct joint negotiations with drug companies for brand-name and generic drugs. Through the pan-Canadian Pharmaceutical Alliance (the Alliance), federal, provincial, and territorial governments combine their negotiating power. According to the Alliance, this allows these public plans to both increase access to, and decrease the price of, drugs, as well as reduce duplication of effort, improve resource use, and improve consistency of decisions among plans. In addition, according to officials in Ontario, drug companies may negotiate a confidential rebate with the Alliance, resulting in a public list price that is higher than the programs actually pay. In these cases, federal, provincial, and territorial governments pay the pharmacy the drug benefit price and then drug companies refund the governments through a rebate.

²¹According to the Board, the guidelines seek to operationalize the amended regulations. The regulations have the force of law, while the guidelines are nonbinding.

²²As a part of its amended regulations, the comparator countries will change on July 1, 2021, to Australia, Belgium, France, Germany, Italy, Japan, the Netherlands, Norway, Spain, Sweden, and the United Kingdom. Of these 11 countries, France, Germany, Italy, Sweden, and the United Kingdom are on the list of seven comparator countries. The other six countries are new to the list.

²³According to a Board official, one of the factors that will be considered are the results of the Canadian Agency for Drugs and Technologies in Health's drug reimbursement review and recommendations. The Agency is an independent, not-for-profit organization that, among other things, conducts objective evaluations of the clinical, economic, patient, and clinician evidence on drugs and uses these evaluations to provide reimbursement recommendations to federal, provincial, and territorial public drug plans. The recommendations are non-binding but are used by public plans when making reimbursement decisions.

²⁴According to the Board, this requirement has been struck down by the Federal Court and the Quebec Superior Court. As of February 2021, these decisions were under appeal.

Prescription Drug Pricing Strategies in Selected Countries

France

Key Points

- Universal public prescription drug coverage.
- Federal government determines whether to cover drugs, negotiates prices, and caps drug manufacturers' sales growth.
- Drugs not covered can be sold on the French market without price regulation.

Prescription Drug Coverage

France has national health insurance that provides universal coverage of a range of health care services, including hospital care, outpatient care provided by doctors, and prescription drugs. The national insurance system has a safety net in place for low income people, providing them with free or discounted insurance.

The French national formulary lists the drugs for which the national health insurance will reimburse consumers. The percentage of the co-insurance varies depending on the government's determination of the value or benefit of the drug. If approved for marketing, drugs that are not on France's formulary can be purchased but are not reimbursed.

In addition, France has voluntary, private health insurance that complements the national health insurance by covering mostly out-of-pocket expenses incurred under the public plan. This private insurance is provided by employment-based associations or purchased by individuals from insurance companies. In 2017, approximately 95 percent of the French population was covered by voluntary insurance either through employers or via France's safety net system.

Prescription Drug Pricing Strategies

France's pharmaceutical price control strategy has two parts. First, the actual benefit of each new drug is determined, which is how the reimbursement rate is set, and then the added clinical, or therapeutic, value of each new drug is determined, which serves as the basis for negotiating the drug's price. Second, a budget cap is used to limit the national health insurance's spending on drugs.

Determining Therapeutic Value, Setting Reimbursement Rates, and Negotiating Drug Prices

France's Transparency Commission—an independent scientific committee associated with the French National Authority for Health—conducts scientific and medical appraisal of prescription drugs for reimbursement purposes. Specifically, the commission first assesses actual therapeutic benefit of the new drug, which determines whether the drug should be reimbursed by France's national health insurance and, if so, by how much. There are four levels of actual benefit:

- Important actual benefit: 65 percent reimbursement rate (35 percent co-insurance for consumers).
- Moderate actual benefit: 30 percent reimbursement rate (70 percent co-insurance for consumers).
- Mild actual benefit: 15 percent reimbursement rate (85 percent co-insurance for consumers).
- Insufficient actual benefit: Not covered.²⁵

In addition, France's national health insurance reimburses 100 percent of the cost for drugs that are recognized as irreplaceable or costly.

Second, for drugs with sufficient actual benefit, the Transparency Commission then assesses the relative value of the new drug compared to existing treatment alternatives, which is known as the added therapeutic value. Determining the added therapeutic value begins with the selection of a clinically relevant comparator.²⁶ The Commission reviews the quality of the research evidence provided, looks at both the new drug's effect compared to the comparator (which is usually described in terms of morbidity and mortality, quality of life or safety for patients, and its clinical relevance) and considers the medical need for the new drug. After reviewing the application based on these criteria, the Commission rates the new drug to a five-level scale:

²⁵There are a number of reasons why the actual benefit of a drug may be considered insufficient. For instance, the new drug may have a therapeutic alternative with similar efficacy, more important efficacy, or less serious adverse events.

²⁶A clinically relevant comparator may be another drug, a placebo drug, a medical device, a procedure, or any other non-drug therapy or diagnostic method.

- Major added therapeutic value (level one): A therapeutic breakthrough that saves or changes the lives of patients with serious disease.
- Important added therapeutic value (level two): A new drug with progress over existing therapies.
- Moderate added therapeutic value (level three): A new drug with progress over existing therapies, but with a smaller effect or for a less severe disease than level two.
- Minor added therapeutic value (level four): A new drug with small progress over existing therapies.
- No added therapeutic value (level five): A new drug that is a generic or biosimilar alternative to existing drugs or biological products, or a new drug with uncertainty related to the quality of the research evidence, among other reasons.

The drug's rating is the basis for negotiating the drug's price. From 2009 through 2016, the Transparency Commission evaluated about 85 new drugs per year, according to The Commonwealth Fund. Each year, most of those new drugs (an average of 51 drugs per year) were rated as adding no therapeutic value, and only about one new drug per year, on average, was rated as adding a major, or breakthrough, therapeutic value.²⁷

The added therapeutic value rating sets parameters for the price negotiations between the drug manufacturers and the Economic Committee for Health Products—an inter-agency government body with insurance sector representation located within the French Ministries of Health, Social Security and Economy.

- Prices for drugs with level one, two, and three ratings—which represent major, important, and moderate added therapeutic value, respectively—can be set higher than the comparator price. The Committee negotiates a list price that is neither higher nor lower than the highest or lowest prices in four comparator countries—the United Kingdom, Germany, Italy, and Spain—known as the European list price.²⁸
- Prices for drugs with a level four rating, which represents minor added therapeutic value, generally match the French price of their comparator.
- Prices for level five drugs, which have no added therapeutic value, are priced lower than the French price of their comparator.

According to French officials, for each new drug the Committee negotiates a contract with the drug manufacturer that specifies the drug price. These negotiations take into account anticipated sales volume. The contracts may change year-to-year as a drug can be subject to reassessment at any time or be valid for the entire commercialization cycle of the product.²⁹ Prescription drugs that are not listed for reimbursement on France's formulary are priced freely without regulation.

²⁷See Marc Rodwin, *Issue Brief: What Can the United States Learn from Pharmaceutical Spending Controls in France?* (New York, N.Y.: The Commonwealth Fund, Nov. 2019).

²⁸According to French officials, certain drugs with level one, two, or three ratings may also be assessed by the Economic and Public Health Committee.

²⁹French officials noted that either the Committee or the drug manufacturer may request a new technical assessment and subsequent update to the contract for a number of reasons. For instance, there may be a new indication for the drug that the drug manufacturer believes warrants a price change or the Committee may want to improve their pricing for the drug.

Further, the Committee may negotiate a confidential discount, which is paid as a rebate to the government. According to French officials, the average discount typically ranged from 9 to 37 percent depending on the therapeutic class of the drug. Further, when the Committee renegotiates a price contract, it typically results in lower prices that are in line with a drug's brand-name and generic comparators or therapeutic class. It is mainly through this reduction of older drugs' prices that France is able to then finance new drugs.

Budget Caps

According to The Commonwealth Fund, annual legislation in France sets a target for National Health Insurance spending growth rates, including a target growth rate for drug manufacturers that caps their total sales. When manufacturer sales exceed the cap, manufacturers must pay a rebate to the government based on sales revenue, referred to as a "clawback." Each manufacturer pays 50 to 70 percent of its sales revenue after the budget cap is surpassed depending on the amount of overspending.³⁰

³⁰Each drug manufacturer's clawbacks are capped at 10 percent of revenue. In addition, manufacturers can cut their clawback payments by about 20 percent if they join a voluntary framework agreement, which sets rules for price negotiations. See Rodwin, *What Can the United States Learn*.

Appendix IV: Data on Prescription Drug Prices in the United States and Selected Comparison Countries

This section provides additional data from our analyses of prescription drug prices in the United States and our selected comparison countries—Australia, Canada (Ontario), and France.

Table 7. Estimated U.S. Net and Selected Comparison Countries' Gross Prices Paid at the Retail Level for Selected Drugs and Package Sizes, 2020

Prescription drug name	Drug units per package ^a	2020 price, per individual drug package (USD) ^b				
		United States gross price ^c	United States estimated net price ^d	Australia gross price ^e	Canada (Ontario) gross price ^f	France gross price ^g
Anoro Ellipta Inhalation Powder 62.5MCG-25MCG/1ACT	30	429	248	64	76	49 ^h
Breo Ellipta Inh Pwd 100MCG/1ACT	30	369	146	39	77	36 ^h
Cosentyx Subcutaneous Solution 150MG/1ML	2	5,623	5,066	999	1,353	1,127
Descovy Oral Tablet 200MG-25MG	30	1,872	1,686	496	—	—
Dupixent Subcutaneous Solution 300MG/2ML	2	3,171	3,080	—	—	1,594
Entresto Oral Tablet 24MG-26MG	60	552	319	146	190	170
Epclusa Oral Tablet 400MG-100MG	28	25,018	14,437	8,668	16,204	9,211
Esbriet Oral Capsule 267MG	270	10,214	9,920	2,101	2,986	2,491
Harvoni Oral Tablet 90MG-400MG	28	31,895	12,642	8,668	18,093	13,743
Ibrance Oral Capsule 100MG	21	12,811	11,542	2,905	4,325	3,176
Ibrance Oral Capsule 125MG	21	12,809	11,541	2,905	4,325	3,176
Imbruvica Oral Capsule 140MG	90	14,218	13,809	6,019	7,120	6,011
Incruse Ellipta Inh Pwd 62.5MCG/1ACT	30	351	139	43	48	28 ^h
Invokana Oral Tablet 100MG	30	519	206	—	76	—
Invokana Oral Tablet 300MG	30	518	206	—	76	—
Janumet XR Oral Tab ER 1000MG-50MG	60	475	188	40	90	—
Myrbetriq Oral Tablet 25MG	30	413	164	—	43	—
Myrbetriq Oral Tablet 50MG	30	412	163	—	43	—
Ofev Oral Capsule 150MG	60	10,806	10,495	2,322	2,768	2,480
Opsumit Oral Tablet 10MG	30	10,274	9,256	2,003	—	—
Plegridy Pen SubQ Soln 125MCG/0.5ML	2	7,169	6,963	720	2,780	769
Pradaxa Oral Capsule 75MG	60	393	227	75	-	65
Praluent Subcutaneous Solution 75MG/1ML	2	1,140	658	-	430	642
Revlimid Oral Capsule 10MG	28	22,008	21,375	4,941	8,193	—
Revlimid Oral Capsule 5MG	28	22,048	21,414	4,723	7,716	—
Signifor LAR IM Pwd for Susp 40MG	1	13,278	12,895	2,688	—	3,085
Simponi SubQ Solution 50MG/0.5ML	1	5,095	4,949	891	1,266	893

**Appendix IV: Data on Prescription Drug Prices
in the United States and Selected Comparison
Countries**

Prescription drug name	Drug units per package ^a	2020 price, per individual drug package (USD) ^b				
		United States gross price ^c	United States estimated net price ^d	Australia gross price ^e	Canada (Ontario) gross price ^f	France gross price ^g
Spiriva Respimat Inh Spray 2.5MCG/1Act	60	433	250	36	52	30
Strensiq Subcutaneous Solution 80MG/0.8	12	71,205	64,153	—	58,688	—
Taltz Subcutaneous Solution 80MG/1ML	1	5,717	5,552	1,169	1,288	1,020
Tecfidera Oral Cap DR 240MG	60	8,499	7,657	945	1,707	1,047
Tradjenta Oral Tablet 5MG	30	470	186	41	73	—
Tremfya Subcutaneous Solution 100MG/1ML	1	11,437	11,108	2,594	—	1,991
Tresiba Subcutaneous Solution 200U/1ML	3	616	244	—	117	66
Trulicity SubQ Soln 1.5MG/0.5ML	4	796	459	90	—	89
Trulicity SubQ Solution 0.75MG/0.5ML	4	798	460	—	—	89
Vimpat Oral Solution 10MG/1ML	465 ⁱ	766	690	103	—	67
Vimpat Oral Tablet 200MG	60	969	873	243	294	166
Xarelto Oral Tablet 15MG	30	471	272	64	78	67
Xtandi Oral Liquid Filled Capsule 40MG	120	12,076	10,880	2,720	—	3,522
Zepatier Oral Tablet 50MG-100MG	28	7,393	4,266	5,859	15,130	7,322

Legend: — = not applicable

Source: GAO Analysis of data from national pricing sources. | GAO 21-282

^aIndividual drug packages contain various quantities of drug units. Drug units are per the dosage form (i.e., one pre-filled syringe, tablet, capsule, or inhalation). Quantities of drug units per package and prices for selected comparison countries—Australia, Canada (Ontario), and France—were harmonized to match the U.S. quantity of drug units per package.

^bPrices effective January 2020. Local currencies were converted to U.S. dollars (USD) using the United States Federal Reserve average foreign exchange rates for the month of January 2020. January 2020 average monthly rates were accessed from the Federal Reserve on July 7, 2020, at <https://www.federalreserve.gov/releases/g5/20200203/>; USD 1.00 was equal to 1.3089 Canadian Dollar (CAD), Euro (EUR) 1.00 was equal to USD 1.1098, and Australian Dollar (AUD) 1.00 was equal to USD 0.6851.

^cProjected first quarter 2020 gross Medicare Part D prices.

^dEstimated net U.S. prices paid at the retail level were calculated using confidential calendar year 2018 Medicare Part D rebates and other price concessions at a per-drug level. In order to permit public reporting on a per-drug basis, drugs were grouped into four quartiles, and projected 2020 Medicare Part D gross prices were discounted using the average percentage rebate and other price concessions from each relevant quartile.

^eDispensed Price for Maximum Quantity from Australia's Pharmaceutical Benefits Scheme for January 2020. Price does not account for confidential rebates or other price concessions.

^fRetail prices for January 2020 calculated using public information from the Ontario Ministry of Health's Drug Benefit Program Formulary or the Ontario Exceptional Access Program. This price includes the amounts reimbursed to the pharmacy, pharmacy markup, and dispensing fees. Price does not account for confidential rebates or price concessions.

^gRetail prices including all markups, taxes, and dispensing fees for January 2020 obtained from the Database for Medication and Pricing Information, maintained by the Medical Insurance division of French Social Security. Price does not account for confidential rebates or price concessions.

**Appendix IV: Data on Prescription Drug Prices
in the United States and Selected Comparison
Countries**

^hU.S. prescription drug selection and its labeled formulation or strength differed in the comparison country, but the prescription drug was medically equivalent.

ⁱPackage is one bottle of 465 ml; the package does not contain individual dosages.

Table 8. Estimated U.S. Net and Selected Comparison Countries' Gross Prices Paid at the Manufacturer Level for Selected Drugs and Package Sizes, 2020

Prescription drug name	Drug units per package ^a	2020 price, per individual drug package (USD) ^b				
		United States gross price ^c	United States estimated net price ^d	Australia gross price ^e	Canada (Ontario) gross price ^f	France gross price ^g
Anoro Ellipta Inhalation Powder 62.5MCG-25MCG/1ACT	30	422	214	52	64	41 ^h
Breo Ellipta Inh Pwd 100MCG/1ACT	30	362	126	29	65	30 ^h
Cosentyx Subcutaneous Solution 150MG/1ML	2	5,518	4,375	949	1,270	1,017
Descovy Oral Tablet 200MG-25MG	30	1,842	1,461	480	—	—
Dupixent Subcutaneous Solution 300MG/2ML	2	3,104	2,653	—	—	1,453
Entresto Oral Tablet 24MG-26MG	60	542	275	127	170	146
Epclusa Oral Tablet 400MG-100MG	28	24,920	12,655	8,564	15,280	8,878
Esbriet Oral Capsule 267MG	270	9,850	8,418	1,997	2,811	2,287
Harvoni Oral Tablet 90MG-400MG	28	31,500	10,987	8,564	17,063	13,318
Ibrance Oral Capsule 100MG	21	12,449	9,870	2,801	4,074	2,430
Ibrance Oral Capsule 125MG	21	12,449	9,870	2,801	4,074	2,430
Imbruvica Oral Capsule 140MG	90	13,861	11,847	5,915	6,711	5,744
Incruse Ellipta Inh Pwd 62.5MCG/1ACT	30	344	120	32	38	23 ^h
Invokana Oral Tablet 100MG	30	504	176	—	64	—
Invokana Oral Tablet 300MG	30	504	176	—	64	—
Janumet XR Oral Tab ER 1000MG-50MG	60	472	165	30	77	—
Myrbetriq Oral Tablet 25MG	30	400	139	—	33	—
Myrbetriq Oral Tablet 50MG	30	400	139	—	33	—
Ofev Oral Capsule 150MG	60	10,485	8,961	2,218	2,605	2,287
Opsumit Oral Tablet 10MG	30	9,821	7,787	1,971	—	—
Plegridy Pen SubQ Soln 125MCG/0.5ML	2	7,064	6,038	644	2,617	684
Pradaxa Oral Capsule 75MG	60	401	203	63	—	55
Praluent Subcutaneous Solution 75MG/1ML	2	1,120	569	—	391	565
Revlimid Oral Capsule 10MG	28	21,364	18,259	4,897	7,723	—
Revlimid Oral Capsule 5MG	28	21,364	18,259	4,679	7,273	—
Signifor LAR IM Pwd for Susp 40MG	1	12,678	10,836	2,672	—	2,878
Simponi SubQ Solution 50MG/0.5ML	1	4,893	4,182	809	1,188	799

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Countries**

Prescription drug name	Drug units per package ^a	2020 price, per individual drug package (USD) ^b				
		United States gross price ^c	United States estimated net price ^d	Australia gross price ^e	Canada (Ontario) gross price ^f	France gross price ^g
Spiriva Respimat Inh Spray 2.5MCG/1Act	60	455	231	26	41	25
Strensiq Subcutaneous Solution 80MG/0.8	12	68,640	54,421	—	55,360	—
Taltz Subcutaneous Solution 80MG/1ML	1	5,378	4,597	1,117	1,209	918
Tecfidera Oral Cap DR 240MG	60	8,276	6,561	858	1,604	941
Tradjenta Oral Tablet 5MG	30	462	161	31	61	—
Tremfya Subcutaneous Solution 100MG/1ML	1	11,065	9,457	2,490	—	1,823
Tresiba Subcutaneous Solution 200U/1ML	3	610	213	—	102	56
Trulicity SubQ Soln 1.5MG/0.5ML	4	761	386	76	—	76
Trulicity SubQ Solution 0.75MG/0.5ML	4	761	386	—	—	76
Vimpat Oral Solution 10MG/1ML	465 ⁱ	737	584	92	—	56
Vimpat Oral Tablet 200MG	60	943	748	215	266	143
Xarelto Oral Tablet 15MG	30	456	232	52	66	57
Xtandi Oral Liquid Filled Capsule 40MG	120	11,823	9,374	2,608	—	3,296
Zepatier Oral Tablet 50MG-100MG	28	7,280	3,697	5,755	14,267	7,029

Legend: — = not applicable

Source: GAO Analysis of data from national pricing sources. | GAO 21-282

^aIndividual drug packages contain various quantities of drug units. Drug units are per the dosage form (i.e., one pre-filled syringe, tablet, capsule, or inhalation). Quantities of drug units per package and prices for selected comparison countries—Australia, Canada (Ontario), and France—were harmonized to match the U.S. quantity of drug units per package.

^bPrices effective January 2020. Local currencies were converted to U.S. dollars (USD) using the United States Federal Reserve average foreign exchange rates for the month of January 2020. January 2020 average monthly rates were accessed from the Federal Reserve on July 7, 2020, at <https://www.federalreserve.gov/releases/g5/20200203/>; USD 1.00 was equal to 1.3089 Canadian Dollar (CAD), Euro (EUR) 1.00 was equal to USD 1.1098, and Australian Dollar (AUD) 1.00 was equal to USD 0.6851.

^cWholesale acquisition cost (WAC) was obtained from a commercially available compendium, Red Book.

^dU.S. estimates of net prices at the manufacturer level were calculated from WAC using a discount of 12 percent and per-drug Medicare Part D rebates and other price concessions. In order to permit public reporting on a per-drug basis, drugs were grouped into four quartiles, and projected 2020 Medicare Part D gross prices were discounted using the average percentage rebate and other price concessions from each relevant quartile.

^eApproved ex-manufacturer prices from Australia’s Pharmaceutical Benefits Scheme for January 2020. Price does not account for confidential rebates or other price concessions.

^fDrug benefit prices for January 2020 from the Ontario Ministry of Health’s Drug Benefit Program Formulary or the Ontario Exceptional Access Program. This price is the amount reimbursed to the pharmacy, and does not include any markups, copayments, or dispensing fees. Price does not account for confidential rebates or other price concessions.

^gEx-manufacturer prices for January 2020 obtained from the Database for Medication and Pricing Information, maintained by the Medical Insurance division of French Social Security. Price does not account for confidential rebates or other price concessions.

**Appendix IV: Data on Prescription Drug Prices
in the United States and Selected Comparison
Countries**

^hU.S. prescription drug selection and its labeled formulation or strength differed in the comparison country, but the prescription drug was medically equivalent.

ⁱPackage is one bottle of 465 ml; the package does not contain individual dosages.

Appendix V: Data on Consumer Out-of-Pocket Costs in the United States and Selected Comparison Countries

The following tables included in this appendix provide additional detail on our analyses on consumer out-of-pocket costs in the United States and selected comparison countries.

Table 9: Estimates of Consumers' Varying Out-of-Pocket Costs in the United States for Selected Brand-Name, Single-Source Prescription Drugs and Package Sizes, 2020

Prices are in U.S. dollars (USD)

Drug name	GoodRx, average cash retail price	GoodRx, average discounted cash retail price	Humana Medicare Part D Premier Rx plan, before deductible ^a	Humana Medicare Part D Premier Rx plan, after coverage gap ^b	Blue Cross Blue Shield Federal Employees Health Benefit Program, Standard (retail) ^c	Blue Cross Blue Shield Federal Employees Health Benefit Program, Standard (mail order or specialty pharmacy) ^d	Blue Cross Blue Shield Federal Employees Health Benefit Program, Basic	Blue Cross Blue Shield Federal Employees Health Benefit Program, Blue Focus
Anoro Ellipta Inhalation Powder 62.5MCG-25MCG/1ACT	514.33	437.64	443.47	22.17	124.64	30.00	55.00	110.27
Epclusa Oral Tablet 400MG-100MG	36,743.00	25,924.95	7,658.33 ^e	1308.33	5000.00	50.00	65.00	350.00
Harvoni Oral Tablet 90MG-400MG	46,570.33	32,767.93	8,003.78 ^f	1,653.78	5000.00	50.00	65.00	350.00
Incruse Ellipta Inhalation Powder 62.5MCG/1ACT	411.33	349.74	361.48	18.07	169.32	41.67	Not covered	Not covered
Xarelto Oral Tablet 15MG	558.33	503.46	493.94	24.70	104.27	30.00	55.00	122.11

Source: GAO analysis of information from GoodRx, Centers for Medicare & Medicaid Services, and Federal Employee Health Benefit Program prescription drug pricing resources. | GAO 21-282

Notes: Prices are for varying drug quantities: Anoro Ellipta Inhalation Powder (30 inhalations), Epclusa Oral Tablet (28 tablets), Harvoni Oral Tablet (28 tablets), Incruse Ellipta Inhalation Powder (30 inhalations), and Xarelto Oral Tablet (30 tablets). When prices were provided for multiple months (e.g., a 90-day supply), we adjusted these prices to reflect a monthly supply. Pricing data were current at the time of our data pull and were extracted from July 2020 to November 2020. U.S. cash retail price data were obtained from the website of a nationally recognized prescription drug discount program (GoodRx) but may not represent all discounts available to consumers through other programs. Sample Medicare Part D plan amounts were obtained via the Medicare Part D plan finder on Medicare.gov. Federal Employee Health Benefit Program data were obtained from the plan's prescription drug pricing resources. As estimates, these values may not account for all plan specific fees, discounts, or deductibles. These estimates are also not representative of all available plan options and actual prices may vary based on a number of different factors (including beneficiaries' locales).

^aMedicare is the federally financed health insurance program for persons aged 65 and over, certain individuals with disabilities, and individuals with end-stage renal disease. Medicare Part D is the

**Appendix V: Data on Consumer Out-of-Pocket
Costs in the United States and Selected
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voluntary program that provides outpatient prescription drug coverage for Medicare beneficiaries who enroll in Part D drug plans.

A deductible is typically a fixed dollar amount plan beneficiaries are required to pay annually for healthcare services before the insurance plan contributes. In 2020, Humana's Medicare Part D Premier Rx plan required patients to meet a one-time deductible of USD 435.00 before coverage began. Not all Medicare Part D plans require patients to meet a deductible before coverage begins.

^bMost Medicare Part D drug plans have a coverage gap (also commonly referred to as the "donut hole"), or temporary coverage limit. The coverage gap begins after the beneficiary and their Medicare Part D prescription drug plan spends a certain amount for covered drugs—USD 4020.00 in 2020. The donut hole ends when the spending for the covered drugs reaches USD 6350.00 and catastrophic coverage begins. These amounts may change each year. While in the coverage gap, beneficiaries pay no more than 25 percent of the cost for covered prescription drugs.

^cThe Federal Employees Health Benefit Program is the largest employer-sponsored health insurance program in the United States, providing coverage to about 8.2 million federal employees, retirees, and their dependents. The Office of Personnel Management (OPM) administers this program in part by entering into contracts with qualified health insurance carriers, negotiating plan benefits and premiums as part of that process. Eligible enrollees can use OPM's Plan Comparison Tool to compare the cost of different plans' monthly premiums, deductibles, and annual out-of-pocket maximums.

^dAll Standard plan members, as well as certain Basic plan members, are eligible to have their prescription drugs delivered directly to their home via Blue Cross Blue Shield's Mail Service Pharmacy Program. This includes maintenance or long-term drugs, such as those for high blood pressure, arthritis or other chronic conditions. Members may get up to a 90-day supply for a single copay. If the cost of the prescription is less than the applicable copay, the enrollee will only pay the cost of the prescription.

Members with complex health conditions who need specialty drugs may also access Blue Cross Blue Shield's Specialty Drug Program, administered by AllianceRx Walgreens Prime. Medications handled by the specialty pharmacy include oral, inhaled, injected, and infused drugs, and often require complex care, a high level of support, and specific guidelines for shipment and storage. These drugs are identified on the plan's Specialty Drug List. For plan year 2020, only two of the five drugs included in this table were included on this list—Harvoni and Eplclusa.

^ePer the Medicare Part D plan finder, the 2020 pre-deductible cost for Eplclusa Oral Tablet under this specific Medicare Part D plan is USD 26,166.50. However, according to other plan information, after beneficiaries' yearly out-of-pocket prescription drug costs (both retail and mail order) reach USD 6350.00 (in 2020), the beneficiary will pay no more than the greater of 5 percent of the cost of the drug, or a USD 3.60 copay for generic (including brand-name drugs treated as generic) and a USD 8.95 copayment for all other drugs. Therefore, the maximum out-of-pocket cost for this drug cannot exceed USD 7658.33—the plan cap (USD 6350.00) plus 5 percent of the drug cost (USD 1308.33).

^fPer the Medicare Part D plan finder, the 2020 pre-deductible cost for Harvoni Oral Tablet under this specific Medicare Part D plan is USD 33,075.50. However, according to other plan information, after beneficiaries' yearly out-of-pocket prescription drug costs (both retail and mail order) reach USD 6350.00 (in 2020), the beneficiary will pay no more than the greater of 5 percent of the cost of the drug, or a USD 3.60 copay for generic (including brand-name drugs treated as generic) and a USD 8.95 copayment for all other drugs. Therefore, the maximum out-of-pocket cost for this drug cannot exceed USD 8003.78—the plan cap (USD 6350.00) plus 5 percent of the drug cost (USD 1653.78).

**Appendix V: Data on Consumer Out-of-Pocket
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Table 10: Estimates of Consumers' Out-of-Pocket Costs in the United States and Selected Comparison Countries for Selected Brand-Name, Single-Source Prescription Drugs and Package Sizes, 2020

Prices are in U.S. dollars (USD)

Drug name	United States: GoodRx, average cash retail price	United States: Blue Cross Blue Shield Federal Employees Health Benefit Program, Basic^a	Australia: Pharmaceutical Benefits Scheme maximum copayment, general benefit^b	Canada: average cash retail price	Canada: Ontario Drug Benefit Program maximum copayment, high income seniors^b	France: consumer contribution
Anoro Ellipta Inhalation Powder 62.5MCG- 25MCG/1ACT	514.33	55.00	28.09	84.99	4.67	34.03 ^c
Epclusa Oral Tablet 400MG- 100MG	36,743.00	65.00	28.09	17,023.63	4.67	0
Harvoni Oral Tablet 90MG- 400MG	46,570.33	65.00	28.09	19,084.54	4.67	0
Incruse Ellipta Inhalation Powder 62.5MCG/1ACT	411.33	Not covered	28.09	53.31	4.67	9.88 ^c
Xarelto Oral Tablet 15MG	558.33	55.00	28.09	85.44	4.67	23.29

Source: GAO analysis data from GoodRx, Federal Employee Health Benefit Program prescription drug pricing resources, direct pharmacy calls, and documentation from national pricing sources. | GAO 21-282

Notes: Prices are for varying drug quantities: Anoro Ellipta Inhalation Powder (30 inhalations), Epclusa Oral Tablet (28 tablets), Harvoni Oral Tablet (28 tablets), Incruse Ellipta Inhalation Powder (30 inhalations), and Xarelto Oral Tablet (30 tablets). Prices for selected comparison countries were converted to USD using the United States Federal Reserve average foreign exchange rates for January 2020 and harmonized to match United States package quantities. Pricing data were current at the time of our data pull and were extracted from April to November 2020. U.S. cash retail price data were obtained from the website of a nationally recognized prescription drug discount program (GoodRx). Canadian cash prices were obtained via direct calls to pharmacies in Ontario, Canada. Federal Employee Health Benefit Program data were obtained from the plan's prescription drug pricing resources. All other data were obtained from national pricing sources. As estimates, these values may not account for all plan specific fees and discounts.

^aThe Federal Employees Health Benefit Program is the largest employer-sponsored health insurance program in the United States, providing coverage to about 8.2 million federal employees, retirees, and their dependents. The Office of Personnel Management (OPM) administers this program in part by entering into contracts with qualified health insurance carriers, negotiating plan benefits and premiums as part of that process. Eligible enrollees can use OPM's Plan Comparison Tool to compare the cost of different plans' monthly premiums, deductibles, and annual out-of-pocket maximums.

^bA copayment is usually a fixed dollar amount paid by the plan beneficiary.

^cU.S. prescription drug selection and its labeled formulation or strength differed in the comparison country, but the prescription drug was medically equivalent.

Appendix VI: GAO Contacts and Staff Acknowledgments

GAO Contacts

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Staff Acknowledgments

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