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Frequently Asked Questions About Prescription Drug Pricing and Policy

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Prescription drugs play an important role in the U.S. health care system. Innovative, breakthrough drugs are providing cures for diseases such as hepatitis C and helping individuals with chronic conditions lead fuller lives. Studies show that prescription drug therapy can produce health care savings by reducing the number of hospitalizations and other costly medical procedures.

Congress and presidential administrations have attempted to ensure that Americans have access to pharmaceuticals by, among other legislation, enacting the Medicare Part D prescription drug benefit as part of the Medicare Modernization and Prescription Drug Act of 2003 (MMA; P.L. 108-173) and expanding drug coverage under the 2010 Patient Protection and Affordable Care Act (ACA; P.L. 111-148, as amended). Congress also has enacted laws to encourage manufacturing of lower-cost generic drugs, as well as cutting-edge biologics and biosimilars. Americans are using more prescription drugs, and for longer periods of time, than in past decades. Still, access to prescription drugs remains an issue for a number of consumers, particularly those without insurance; those prescribed expensive *specialty drugs* for treating serious or rare diseases; or those enrolled in private insurance or public health plans that impose high cost-sharing requirements, such as drug deductibles and coinsurance.

The pace of U.S. retail prescription drug spending has varied through the decades. Drug spending growth moderated in the early 2000s due in part to an economic recession and the expanded use of lower-cost generic drugs. Drug spending spiked in 2014, due in part to the introduction of expensive new hepatitis C drugs, increasing 13.5% in 2014 and 8.8% in 2015, before slowing to an average of 3.4% annual growth from 2016 through 2019. Although the pace of spending has declined from the 2014 peak, the Centers for Medicare & Medicaid Services (CMS) forecasts that retail drug spending could average 5.5% annual growth from 2020 through 2028, which would be faster than some other areas of U.S. health care spending in this period. The CMS projections for 2020-2028 are based on a model developed prior to the Coronavirus Disease 2019 (COVID-19) pandemic. Future CMS reports will measure the impact of the pandemic.

This CRS report addresses frequently asked questions about government and private-sector policies that affect drug prices and availability. Among the prescription drug topics covered are spending trends, federally funded research and development, regulation of direct-to-consumer advertising, legal restrictions on prescription drug reimportation, and federal price negotiation. The report provides a broad overview of the issues, as well as references to more in-depth CRS products.

The **Appendix** provides references to relevant congressional hearings and documents.

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Introduction

Prescription drugs play an important role in the U.S. health care system. Innovative, breakthrough drugs are providing cures for diseases such as hepatitis C and helping individuals with chronic conditions lead fuller lives. Studies show that prescription drug therapy can produce savings for the broader health care system by reducing the number of hospitalizations and other costly medical procedures.

Americans are using more prescription drugs, and for longer periods of time, than in past decades. Still, access to prescription drugs remains an issue for a number of consumers, particularly those without insurance; those enrolled in private insurance or public health plans that impose high cost-sharing requirements, such as drug deductibles and coinsurance; and those prescribed expensive *specialty drugs* for treating serious or rare diseases. Specialty drugs, which can cost tens of thousands of dollars or more for a course of treatment, made up less than 3% of total prescriptions, but nearly 40% of retail and mail-order prescription drug spending, net of rebates in 2016-2017, according to one study.¹ (See “Drug Price Transparency” **textbox** below.)

Retail prescription drug spending has varied over the years. Spending moderated in the early 2000s due in part to an economic recession, and the expanded use of lower-cost generic drugs. Spending has increased at a faster rate in recent years, as manufacturers have introduced new drugs at a record rate and have raised prices for existing brand-name products. (See “What Is Behind the Recent Volatility in Retail Drug Spending?”)

Overall, annual spending for outpatient (retail) drugs jumped 13.5% in 2014 and 8.8% in 2015, before slowing to an average 3.4% annual rate of growth from 2016-2019, including an increase of 5.7% in 2019.² Although the pace of spending has declined from the 2014 peak, the Centers for Medicare & Medicaid Services (CMS) forecasts that retail drug spending could average 5.5% annual growth from 2020 through 2028, which is faster than some other areas of U.S. health care spending in this period.³ However, the CMS projections for 2020-2028 are based on models developed prior to the COVID-19 pandemic. Future CMS reports will measure the impact of the pandemic.

This CRS report addresses frequently asked questions about government and private-sector policies that affect drug prices and availability. Among the prescription drug topics covered are spending trends, federally funded research and development, regulation of direct-to-consumer advertising, legal restrictions on drug reimportation, and federal price negotiation. The report provides a broad overview of the issues and references to more in-depth CRS products. The **Appendix** provides references to relevant congressional hearings.

¹ Steven Hill, Edward Miller, and Yao Ding, “Net Spending On Retail Specialty Drugs Grew Rapidly, Especially For Private Insurance And Medicare Part D,” *Health Affairs*, vol. 39, no. 11, November 2020, <https://www.healthaffairs.org/doi/10.1377/hlthaff.2019.01830>. The research looks at net spending after rebates. The authors said their work complemented other research, such as findings by the IQVIA Institute for Human Data Science that in 2018 specialty drugs accounted for approximately half of combined *gross* spending on retail, mail-order, and provider-administered drugs.

² Centers for Medicare & Medicaid Services (CMS), “National Health Expenditure Data: Historical,” Table 16, available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical>, and “National Health Expenditure Data: Projected,” Table 11, <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected>. Also see Sean Keehan et al., “National Health Expenditure Projections, 2019–28: Expected Rebound in Prices Drives Rising Spending Growth,” *Health Affairs*, March 24, 2020, <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2020.00094>.

³ *Ibid.*

Table I. Commonly Used Prescription Drug Terms

| Term | Definition |
|----------------------------------|---|
| Biologic | Pharmaceuticals derived from a living organism that can be many times the size of a conventional (small-molecule) drug and have a more complex structure. ^a |
| Biosimilar | A follow-on to a biologic that is “highly similar,” notwithstanding minor differences in clinically inactive components. There are no clinically meaningful differences between a biosimilar and the reference biologic product in terms of safety, purity, and potency of the product. The Patient Protection and Affordable Care Act (ACA; P.L. 111-148, as amended) provided a period of exclusivity for manufacturers of certain biologic brand-name drugs and biosimilar products. |
| Brand-Name Drug | A drug marketed under a proprietary, trademark-protected name. |
| Coinsurance | The percentage share that an enrollee in a health insurance plan pays for a product or service covered by the plan. For example, an insurer may charge 10% coinsurance for a \$100 prescription drug, meaning the consumer’s out-of-pocket cost is \$10. |
| Co-payment | A fixed dollar amount that an enrollee in a health insurance plan pays for a product or service covered by the plan. For example, an insurer may charge a \$20 co-payment for a physician visit or a \$5 co-payment for a prescription drug. |
| Deductible | The amount an enrollee is required to pay for health care services or products before his or her insurance plan begins to provide coverage. An enrollee in an insurance plan with a \$500 deductible would be responsible for paying for the first \$500 in health care services. In some insurance plans, the deductible does not apply to certain services, such as preventive care. Insurance plans vary regarding whether beneficiaries must meet a deductible for prescription drug coverage. |
| Generic Drug | A drug that is identical to a traditional (small molecule) brand-name drug in dosage, safety, strength, route of administration, quality, performance characteristics, and intended use. Generic drugs generally cost significantly less than their brand-name counterparts. ^b |
| Formulary | A list of prescription drugs covered by an insurance plan. In an effort to control costs, insurers are imposing partially closed formularies, which include a more limited number of drugs than open formularies. Insurers use tiered cost sharing for formulary drugs, meaning patients are charged lower co-payments or coinsurance for less expensive generic drugs and certain brand-name drugs that are designated by the plan as preferred drugs, based on the price the plan has negotiated with the manufacturer and the effectiveness of the product. At the same time, patients are charged higher co-payments or coinsurance for more expensive drugs or drugs that the plan deems to be less effective. |
| Orphan Drug | A traditional drug or biologic for the treatment of rare diseases and disorders that affect fewer than 200,000 people in the United States or that affect more than 200,000 people but where manufacturers are not expected to recover the costs of developing and marketing a treatment drug. Manufacturers of orphan drugs are eligible for federal tax, marketing, and other incentives. ^c |
| Out-of-Pocket Costs | The total amount an insured consumer pays each year for covered health care services that are not reimbursed by an insurance plan. Out-of-pocket costs can include deductibles, co-payments, and coinsurance. |
| Out-of-Pocket Maximum | The maximum amount an enrollee must pay before his or her health insurance plan covers 100% of health benefits. Certain costs, such as premiums, generally are not counted toward an out-of-pocket maximum, or cap. |
| Pharmacy Benefit Managers (PBMs) | Intermediaries between health plans and pharmacies, drug wholesalers, and manufacturers. PBMs perform functions such as designing drug formularies, negotiating prices, and administering prescription drug payment systems. |

| Term | Definition |
|------------------|---|
| Pharmacy Network | A group of retail, mail-order, and specialty pharmacies that contract with PBMs and health insurers to dispense covered drugs at set prices. Network pharmacies also may provide other services under contract, such as monitoring patient adherence to drugs. |
| Premium | The amount an enrollee pays for health insurance coverage. Many plans charge monthly premiums, but premiums also can be assessed on a quarterly or annual basis. |
| Specialty Drug | There is no one set definition of specialty drugs, although insurers and other health care payers often characterize them as prescription products requiring extra handling or administration that are used to treat rare and/or complex diseases, such as cancer. High cost can trigger a specialty drug designation. Biologics are often deemed specialty drugs. ^d |
| Underinsured | Refers to people who have insurance but still have financial difficulty paying for prescription drugs or medical treatments. ^e |

Source: CRS.

- a. See CRS Report R44620, *Biologics and Biosimilars: Background and Key Issues*.
- b. U.S. Food and Drug Administration (FDA), “Generic Drugs,” at <https://www.fda.gov/drugs/buying-using-medicine-safely/generic-drugs>. In 1984, Congress enacted the Hatch-Waxman Act (P.L. 98-417), which provided manufacturers of innovative prescription drugs with patent protection and a period of marketing exclusivity, created a generic drug approval process to help companies bring products to market more quickly once the patent for an original brand-name drug expired, and established procedures for resolving patent disputes arising from applications to market generic drugs. Generic drugs make up 90% of filled prescriptions and 20% of total drug spending. See Association for Accessible Medications, *2020 Generic Drug & Biosimilars Access & Savings in the U.S.*, at <https://accessiblemeds.org/2020-Access-Savings-Report>.
- c. FDA, “Developing Products for Rare Diseases & Conditions,” at <https://www.fda.gov/industry/developing-products-rare-diseases-conditions>.
- d. See CRS Report R44132, *Specialty Drugs: Background and Policy Concerns*.
- e. There are different definitions of *underinsurance*. For example, the Commonwealth Fund defines individuals as underinsured if they had health insurance but still had total out-of-pocket costs or deductibles that were high relative to their incomes. See Commonwealth Fund, “Underinsured Rate Rose From 2014-2018, With Greatest Growth Among People in Employer Health Plans,” February 7, 2019, at <https://www.commonwealthfund.org/press-release/2019/underinsured-rate-rose-2014-2018-greatest-growth-among-people-employer-health>.

U.S. Prescription Drug Spending

How Much Does the United States Spend on Prescription Drugs?

The most commonly cited data on prescription drug spending come from the National Health Expenditures (NHE) accounts compiled by CMS.⁴ The NHE accounts track annual spending by all payers for prescription drugs purchased in retail settings, such as pharmacies, mail-order outlets, grocery stores, warehouse clubs, and similar businesses. The NHE data do not include

⁴ CMS, “National Health Expenditure Projections 2019-2028,” at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected>. The National Health Expenditures (NHE) data incorporate information from the U.S. Census Bureau and IQVIA, a private firm that provides consulting, technology, and other services for the health care industry. The figures include retail sales of prescription drugs, subtract manufacturer rebates, and add in government spending for drugs provided by government-owned mail-order facilities.

drugs dispensed in institutions including hospitals, long-term care facilities, and clinics,⁵ nor do they include over-the-counter products such as aspirin purchased without a prescription.⁶

According to the most recent NHE data, the United States spent \$369.7 billion on prescription drugs in 2019 and a projected \$358.7 billion in 2020, or about 9% of the forecast of \$4 trillion in 2020 national health care spending.⁷ Prescription drug spending is forecast to remain at about 9% of national health care spending through 2028, down slightly from a prior average of about 10% of health care spending (see **Figure 1**).

Retail drug spending has ranged from about 5% to 10% of total health care expenditures since 1960, when the NHE accounts began compiling prescription spending data.⁸ (See “How Does Current Drug Spending Compare to Other Years?”) Because the NHE data provide information about retail drug sales only, a number of analysts say the data do not offer a complete picture of U.S. drug spending. The Department of Health and Human Services (HHS) in April 2016 issued a study that attempted to estimate *total* U.S. prescription drug spending—retail plus institutional use in hospitals and other health facilities.⁹

⁵ Although spending for drugs in institutional settings is not included in the NHE retail prescription drug category, it is included in other categories of spending and in overall national health care spending. For example, drugs dispensed in hospitals are included in the NHE hospital spending category.

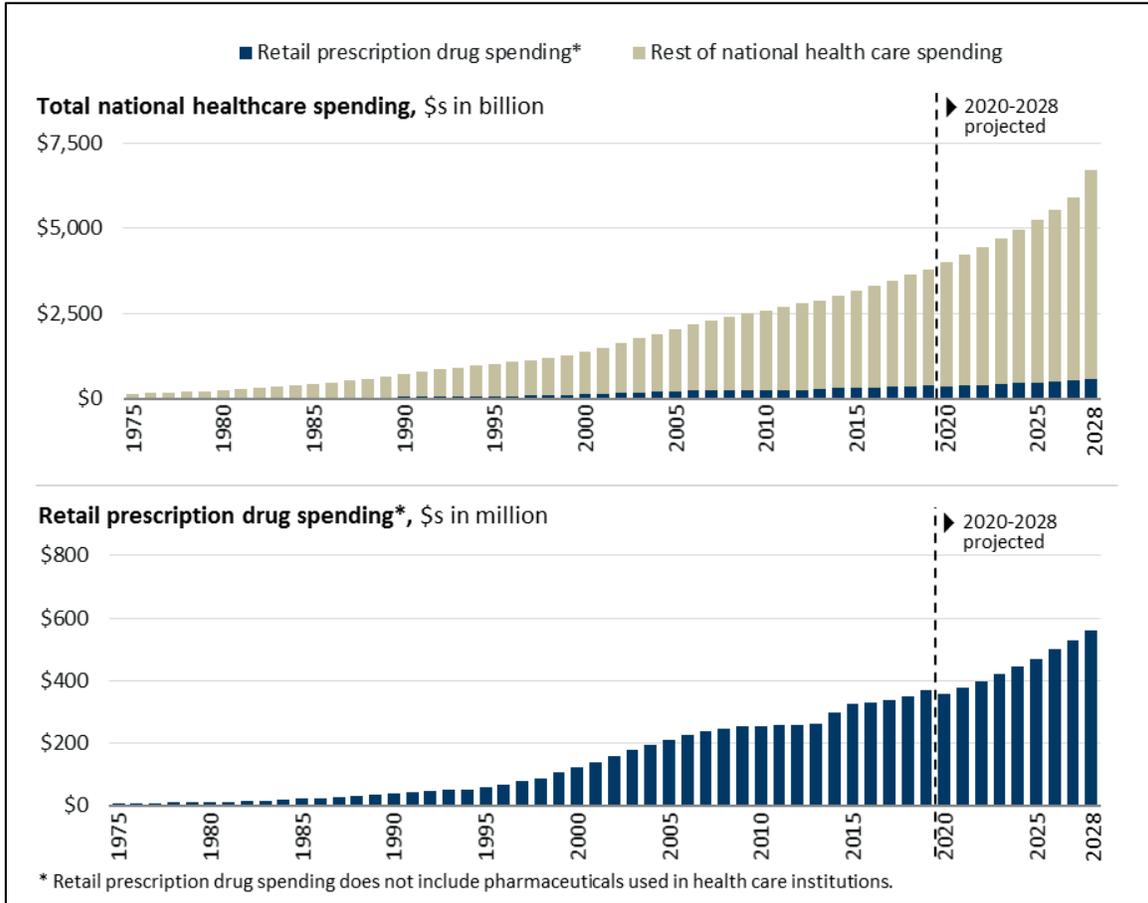
⁶ Many over-the-counter products originally were prescription products, such as some antihistamines. See U.S. Food and Drug Administration (FDA), “Now Available without a Prescription,” at <https://www.fda.gov/drugs/drug-information-consumers/now-available-without-prescription>.

⁷ CMS, “National Health Expenditure Projections 2019-2028,” at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected>; and “National Health Expenditure Data: Historical,” at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical>. The NHE projects national health care spending of \$6.2 trillion in 2028, including \$560 billion in retail drug spending. Sean Keehan et al., “National Health Expenditure Projections, 2019–28: Expected Rebound in Prices Drives Rising Spending Growth,” *Health Affairs*, March 24, 2020, <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2020.00094>. (CMS updated its historic spending data after the *Health Affairs* article was published to provide actual data, rather than projections, for 2019. This report uses the most updated historic data for prescription drug spending. The historic data showed higher drug spending for 2019 than had been earlier projected by CMS, while the 2020-2028 projections are based on data developed prior to the COVID-19 pandemic.)

⁸ According to the NHE, retail prescription drug spending was 10% of national health expenditures in 1960. Retail drug spending declined to less than 5% of national health expenditures from 1960 to 1982. During this period, other areas of medical spending were increasing more quickly than drug spending due to the creation of government health programs such as Medicare and Medicaid and the expansion of private health insurance. Retail drug spending began to increase as a share of national health spending in the mid-1980s, due to price inflation and growing consumption. By the early 2000s, retail drug spending had once again reached about 10% of national health care expenditures. See Cynthia Smith, “Retail Prescription Drug Spending in the National Health Accounts,” *Health Affairs*, vol. 233, no. 1 (January/February 2004), pp. 160-167, at <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.23.1.160>.

⁹ Department of Health and Human Services (HHS), Office of the Assistant Secretary for Planning and Evaluation, “Observations on Trends in Prescription Drug Spending,” March 8, 2016, at <https://aspe.hhs.gov/pdf-report/observations-trends-prescription-drug-spending>. The HHS estimate is based on NHE retail prescription drug data and an outside analysis by the Altarum Institute, a nonprofit health systems research and consulting organization. According to Altarum, nonretail, or institutional, drug spending accounts for 28% of prescription drug spending and retail drugs account for 72%. The HHS study provided estimates of total prescription drug spending as a share of U.S. personal health expenditures. Personal health expenditures are a subset of the NHE accounts that measure the amount spent each year to treat people with specific medical conditions. Personal health expenditures do not include some areas of spending included in the broader definition of national health expenditures, such as industry investment and public health activity. According to HHS, total prescription drug spending was projected to account for nearly 17% of personal health expenditures in 2016. The comparable measure for retail prescription drugs was 12%.

Figure 1. National Retail Prescription Drug Spending
(Annual spending for retail drugs as a percentage of total health spending)



Source: Centers for Medicare & Medicaid Services (CMS), National Health Expenditure (NHE) data: Historical and Projected.

Note: Figures through 2019 are actual; 2020-2028 are forecasts.

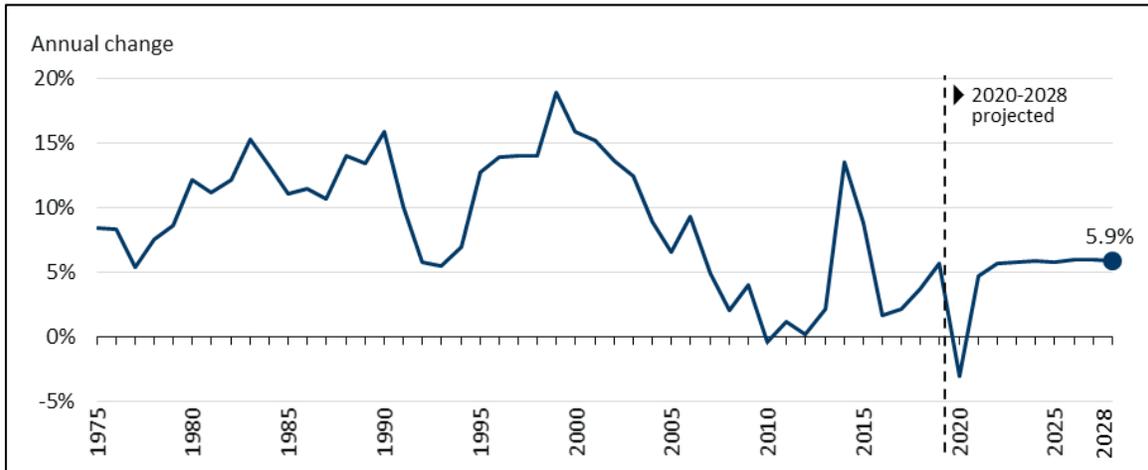
In addition to the NHE data, private consultants and academics publish their own forecasts of U.S. prescription drug spending.¹⁰ National estimates vary for a number of reasons, including assumptions about the dollar value of rebates that pharmaceutical manufacturers provide to health payers, as well as the value of coupons offered to consumers, and whether the forecasts include both retail and institutional use. However, the different studies show similar spending trends in recent years.

¹⁰ IQVIA estimates that prescription drug spending, based on list prices set by manufacturers, was \$671 billion in 2019, growing at a 7.1% compound annual growth rate (CAGR) over the previous five years. According to IQVIA, payer net spending is calculated after supply chain discounts, manufacturer rebates, and patient out-of-pocket costs are deducted, and markups and margins by intermediaries are added. Total net payer spending in 2019 was \$509 billion and had increased at a CAGR of 4.1% over the previous five years. See IQVIA Institute, “Medicine Spending and Affordability in the United States,” Overview, p. 2, August 2020. Available at <https://www.iqvia.com/insights/the-iqvia-institute/reports/medicine-spending-and-affordability-in-the-us>. Also see Eric Tichy et al., “National Trends in Prescription Drug Expenditures and Projections for 2020,” *American Journal of Health System Pharmacies*, vol. 77 (May 15, 2020), at <https://academic.oup.com/ajhp/article-abstract/77/15/1213/5837520>.

How Does Current Drug Spending Compare to Other Years?

The pace of U.S. retail prescription drug spending has varied through the decades. For much of the 1980s through the early 2000s, retail drug spending grew at a double-digit annual pace. From 2003 through 2013, drug spending slowed to a historically low average annual growth rate of about 5%.¹¹ (See **Figure 2.**) Drug spending growth moderated for a number of reasons during this period, including a deep economic recession from 2007 to 2010, a reduction in the number of expensive new drugs coming to the market compared to earlier years, and a continued expansion in the use of lower-cost generic drugs.¹² (See **Table 1.**)

Figure 2. Annual Percentage Change in Retail Prescription Drug Spending



Source: Centers for Medicare & Medicaid Services (CMS), National Health Expenditure (NHE) data: Historical and Projected.

Note: Figures through 2019 are actual; 2020-2028 are forecasts.

Spending for retail prescription drugs accelerated in 2014, jumping by 13.5%—the largest annual increase in more than a decade. Drug spending rose by 8.8% in 2015 before slowing to a pace of a 3.4% annual rate of growth from 2016 to 2019.¹³ (See “What Is Behind the Recent Volatility in Retail Drug Spending?” below.) According to CMS, a 5.7% increase in spending in 2019 was influenced by growing utilization, including use of drugs for autoimmune disorders, cancer, and diabetes.¹⁴

¹¹ Aaron Catlin and Cathy Cowan, *History of Health Spending in the United States, 1960-2013*, *Health Affairs*, November 23, 2015, at <https://www.healthaffairs.org/doi/10.1377/hblog20151123.051904/full/>. The implementation of Medicare Part D in 2006 caused a spike in prescription drug spending that year.

¹² *Ibid.*, p. 23.

¹³ Centers for Medicare & Medicaid Services (CMS), “National Health Expenditure Data: Historical,” at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical>, and “National Health Expenditure Data: Projected,” <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected>. Also see Sean Keehan et al., “National Health Expenditure Projections, 2019–28: Expected Rebound in Prices Drives Rising Spending Growth,” *Health Affairs*, March 24, 2020, <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2020.00094>.

¹⁴ Anne Martin, Micah Hartman, David Lassman, Aaron Catlin, “National Health Care Spending In 2019: Steady Growth for the Fourth Consecutive Year,” *Health Affairs*, December 16, 2020, <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2020.02022>.

Retail drug spending is projected to grow by about 5.5% a year on average from 2020 through 2028, according to the NHE, due partly to faster projected drug price growth and growing intensity of use.¹⁵ That is in line with NHE projections for overall U.S. health care spending to grow at a 5.4% annual rate from 2019 to 2028. The CMS projections are based on data developed prior to the COVID-19 pandemic.

During recent Congresses, lawmakers held a series of hearings on prescription drugs in response to the mid-2010's acceleration in spending and continued, sharp increases in prices for certain drugs. (See partial list of hearings in **Appendix**. The list focuses on hearings most relevant to drug pricing issues.)

What Is Behind the Recent Volatility in Retail Drug Spending?

As discussed below, retail prescription drug spending can be affected by (1) changes in the mix of available drugs in the marketplace, (2) changes in the price of drugs, and (3) changes in the volume of drugs used. The rapid increase in retail drug spending in 2014 and 2015 was driven largely by the introduction of new high-cost drugs, price increases for existing drugs, and the diminishing impact of generic substitution, as fewer brand-name drugs lost patent protection than in previous years. Implementation of the ACA (P.L. 111-148, as amended) also helped to boost drug demand.¹⁶ The slower pace of prescription drug spending since 2015 is due to factors that include reduced use and prices for expensive hepatitis C drugs.¹⁷

Looking forward, CMS expects retail prescription drug spending to be propelled by faster drug price increases and higher growth in use and intensity. Other factors contributing to this projected increase include the aging of the population and the expected introduction of new drugs for such conditions as cancer, diabetes, and Alzheimer's disease.¹⁸

Changes in Drug Mix

Drug mix refers to the composition of the different types of drugs being utilized in the retail marketplace, specifically focused on the availability and cost of new drugs versus those of older drugs being used. New, innovator brand-name drugs often are more expensive than older drugs and do not have lower-cost equivalents. Likewise, newly introduced generic drugs, which are less expensive than brand-name products, can reduce the cost of certain therapies.

During the past several years, the U.S. Food and Drug Administration (FDA) has approved a large number of novel new drugs, including a number of specialty drug products.¹⁹ The

¹⁵ Sean Keehan et al., "National Health Expenditure Projections, 2019–28: Expected Rebound in Prices Drives Rising Spending Growth," *Health Affairs*, March 24, 2020, <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2020.00094>. (CMS updated its historic spending data after the *Health Affairs* article was published to provide actual data, rather than projections, for 2019. This report uses the most updated historic data for prescription drug spending.)

¹⁶ Anne B. Martin et al., "National Health Spending In 2014: Faster Growth Driven by Coverage Expansion and Prescription Drug Spending," *Health Affairs*, vol. 35, no.1 (December 2, 2015), pp. 150-160, at <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2015.1194>; and Anne Martin et al., "National Health Spending: Faster Growth In 2015 As Coverage Expands and Utilization Increases," *Health Affairs*, vol. 26, no. 1 (January 2017).

¹⁷ Sean Keehan et al., "National Health Expenditure Projections, 2019–28: Expected Rebound in Prices Drives Rising Spending Growth," *Health Affairs*, March 24, 2020, <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2020.00094>.

¹⁸ Andrea Sisko et al., "National Health Expenditure Projections, 2018-27: Economic and Demographic Trends Drive Spending and Enrollment Growth," *Health Affairs*, February 20, 2019, at <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2018.05499>.

¹⁹ FDA approved 53 novel drugs in 2020, 48 novel drugs in 2019, 59 novel drugs in 2018, 46 novel drugs in 2017, 22 in 2016, and 45 in 2015. See FDA, "Novel Drug Approvals for 2020," at <https://www.fda.gov/drugs/new-drugs-fda->

introduction of a new generation of hepatitis C drugs alone, which can cure the disease, accounted for nearly 40% of the net growth in total U.S. drug spending in 2014 and two-thirds of increased brand-name prescription drug spending by employer-sponsored health plans that year.²⁰ The outsized impact of the hepatitis drugs is diminishing as fewer new patients are treated with the products and new competing products come on the market, affecting prices. However, growth in the number of newly introduced drugs and increased use of high-cost specialty drugs, continue to have an outsized impact on spending.

For example, according to the analytics and consulting firm IQVIA, U.S. net pharmaceutical revenues rose from \$300 billion in 2014 to \$356 billion in 2019. There were partially offsetting trends in pricing and utilization during that period. For example, new drug launches contributed \$68 billion to net manufacturer revenue growth during the period, price increases for brand drugs with marketing or patent protection²¹ contributed \$21 billion, and volume growth for protected brands contributed \$40 billion. At the same time, a loss of marketing and patent exclusivity, paving the way for generic production, and changes in the volume and price of generics reduced manufacturer net revenues by \$73 billion.²² Many protected brand drugs are specialty drugs.

Changes in drug mix will continue to play an important role in spending going forward. Many drugs now in the development pipeline are biologics, which often have a high introductory price and initially may not have many lower-cost alternatives.²³ Although the FDA has approved nearly 30 biosimilar substitutes for biologics that have lost patent and marketing protection, there has been a lag in bringing many of these biosimilars to the market.²⁴ In addition, biosimilars so far have not reduced prices for biologic products as significantly as lower-priced generics have done for traditional, chemical drugs.

Changes in Drug Prices

Although there have been annual fluctuations, prescription drug prices have risen faster than prices for overall U.S. goods and services in most years from 2000 to 2020, according to the U.S. Department of Labor Consumer Price Index (CPI), which measures retail inflation.²⁵ (See **Figure**

cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2020.

²⁰ Murray Aitken et al., “Has the Era of Slow Growth for Prescription Drug Spending Ended?” *Health Affairs*, vol. 35, no. 9 (September 2016), p. 1601. The study looked at retail and institutional drug spending. Health Care Cost Institute, *2014 Health Care Cost and Utilization Report*, October 2015, p. ii, at <https://www.healthcostinstitute.org/research/annual-reports>. The report, based on claims data from three major commercial insurers, found that per capita brand-name drug spending in employer-sponsored plans rose by \$45 from 2013 to 2014. About two-thirds of the increase, \$29.60, was for newly introduced drugs for hepatitis C.

²¹ Most often driven by brands in the three-to-five-year period since their launch.

²² IQVIA Institute, “Medicine Spending and Affordability in the United States,” p. 7, August 2020. Available for download at <https://www.iqvia.com/insights/the-iqvia-institute/reports/medicine-spending-and-affordability-in-the-us>.

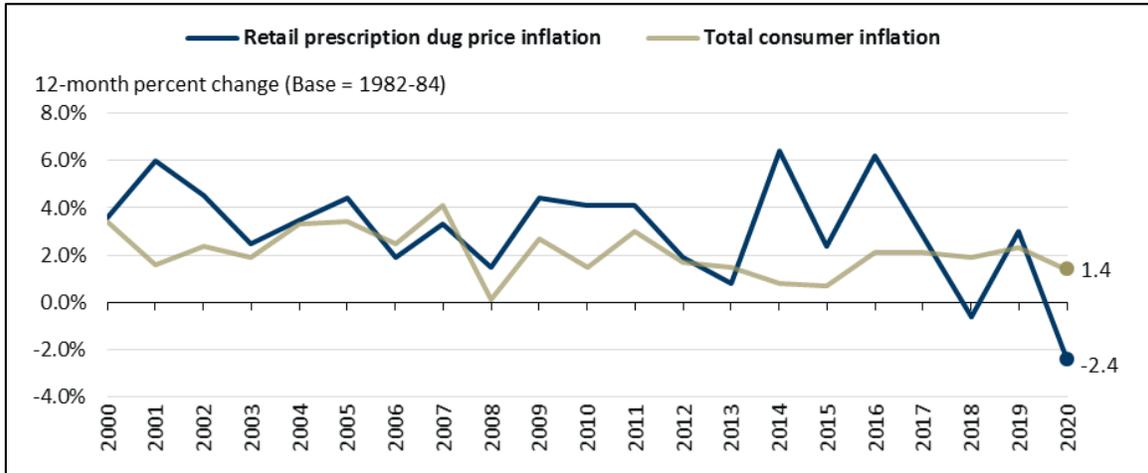
²³ CRS Report RL34045, *FDA Regulation of Follow-On Biologics*, and CRS Report R42890, *The Role of Patents and Regulatory Exclusivities in Pharmaceutical Innovation*. Federal law has provided 12 years of marketing exclusivity for certain biologic drugs, which limits manufacturers’ initial market competition and increases their pricing power. Lawmakers also have attempted to spur development of lower-cost biosimilar products, similar to earlier efforts to stimulate development of generic products. Congress and the President enacted the Biologics Price Competition and Innovation Act of 2009 (BPCIA) as Title VII of the Patient Protection and Affordable Care Act (ACA; P.L. 111-148, as amended). The ACA/BPCIA gives the FDA authority to license products shown to be biosimilar to or interchangeable with an FDA-licensed biological product.

²⁴ FDA, “Biosimilar Product Information,” <https://www.fda.gov/drugs/biosimilars/biosimilar-product-information>.

²⁵ Retail inflation is a measure of the average change over time in prices for a set list of consumer goods and services. The Consumer Price Index (CPI) is based on a market basket of goods and services. For prescription drugs, Department of Labor analysts survey a sample of drug stores and a list of the last 20 drugs dispensed. See BLS, “Measuring Price

3.) U.S. retail drug inflation, as measured by the CPI-U,²⁶ has fluctuated from annual increases of greater than 6% to a 2020 price decline.

Figure 3. U.S. Retail Prescription Drug Price Inflation
(Annual percentage CPI-U change in retail prescription drug prices compared to all retail inflation)



Source: U.S. Department of Labor, Bureau of Labor Statistics, Consumer Price Index, All Urban Consumers (CPI-U).

Notes: Non-seasonally adjusted data are for 12 months ending in December. The data do not include drugs dispensed through Medicaid or workers’ compensation programs. The CPI-U prescription drug index is based on a survey of filled prescriptions in U.S. drug stores. It captures price reductions associated with use of generic drugs, with a lag, as well as prices of new drugs.

Drug inflation has been driven mainly by price increases for existing brand-name drugs and adoption of expensive new innovator brand-name drugs.²⁷ (See “Changes in Drug Mix.”) Within the brand-name drug category, biologics and specialty drugs have driven much of the price inflation.²⁸

Change in the CPI: Medical care,” <https://www.bls.gov/cpi/factsheets/medical-care.htm#A3>.

²⁶ The CPI-U is the CPI value for urban consumers. It excludes rural populations and represents approximately 80% of the population.

²⁷ Murray Aitken et al., “Has the Era of Slow Growth for Prescription Drug Spending Ended?” *Health Affairs*, vol. 35, no. 9 (September 2016), pp. 1595-1603. The study looked at retail and institutional drug spending.

²⁸ Ibid. There is wide variation in estimates of specialty drug spending depending on how the specialty drug category is defined. For example, see HHS, Office of the Assistant Secretary for Planning and Evaluation, “Observations on Trends in Prescription Drug Spending,” March 8, 2016, at <https://aspe.hhs.gov/pdf-report/observations-trends-prescription-drug-spending>.

Drug Price Transparency

It can be difficult to determine the final price of a prescription drug due to a lack of transparency in the marketplace. Drug companies price discriminate, meaning they sell the same drug to different buyers (wholesalers, health plans, pharmacies, hospitals, government purchasers, and other providers) at different prices. The final price of a drug may include rebates and discounts to health plans and pharmacy benefit managers that are not publicly disclosed. Market participants, such as wholesalers, add their own markups and fees. Complicating the picture even more, pharmaceutical manufacturers offer direct consumer discounts, such as prescription drug coupons that can be redeemed when filling a prescription at a pharmacy. Drug companies also offer charitable aid through patient assistance programs for individuals who cannot afford their prescriptions. Eligibility is often based on income. The most commonly published drug prices do not include these discounts and rebates, which appear to be growing in size and importance according to government and private analyses.

Source: CRS Report R44264, *Prescription Drug Discount Coupons and Patient Assistance Programs (PAPs)*; IQVIA Institute, “Medicines Use and Spending in the U.S. A Review of 2018 and Outlook to 2023,” May 2019, Exhibit 14, p. 20, HHS OIG, “Increases in Reimbursement for Brand-Name Drugs in Part D,” June 2018, <https://oig.hhs.gov/oei/reports/oei-03-15-00080.asp>.

Drug Utilization

Total prescription drug use has been rising in recent years. According to the Centers for Disease Control and Prevention (CDC), the percentage of people in the United States using at least one prescription drug in the previous 30 days rose to 48.4% from 2013 to 2016, compared with 39.1% from 1988 to 1994.²⁹ Total U.S. prescriptions, adjusted for length, rose to 6.4 billion in 2019 from 6.02 billion in 2017.³⁰

The ACA expansion of prescription drug coverage has helped to boost demand for prescription drugs. Beginning in 2014, the ACA provided tax credits for the purchase of ACA exchange-based health plans and required many private insurance plans to cover prescription drugs as part of a package of essential health benefits.³¹ Studies of health insurance plans sold through ACA exchanges showed a nearly 15% annual increase in drug spending for those insured consumers from 2014 to 2015, driven mainly by higher utilization.³² Medicaid coverage was also expanded under the ACA, providing more drug coverage for non-elderly, low-income individuals.³³ In

²⁹ CDC, “*Health United States, 2018*,” Table 38, <https://www.cdc.gov/nchs/fastats/drug-use-therapeutic.htm>.

³⁰ IQVIA Institute, “*Medicine Spending and Affordability in the United States*,” Exhibit 29, p. 32, August 2020. Available for download at <https://www.iqvia.com/insights/the-iqvia-institute/reports/medicine-spending-and-affordability-in-the-us>. According to IQVIA, prescription counts are adjusted for length of prescriptions and are reaggregated. Prescriptions referred to as 90-day are calculated based on transactions with 84 days supply or more to include medicines with up to one week fewer treatment days. Prescriptions for 84 days supply or more are factored by three, and those under 84 days are unchanged. The figure includes both retail and long-term care prescriptions.

³¹ The essential health benefits are 10 categories of services required by private plans offered in the nongroup and small-group markets. The requirement to offer the essential health benefits does not apply to large-group plans, self-insured plans, or grandfathered plans. CRS Report R44163, *The Patient Protection and Affordable Care Act’s Essential Health Benefits (EHB)*.

³² Express Scripts, “*Exchange Pulse*,” June 2016, <https://docplayer.net/126670164-Exchange-pulse-public-health-exchanges-report-june-2016.html>.

³³ The ACA raised the income threshold used to qualify individuals for the Medicaid program, thereby expanding coverage to more people. The ACA originally made the state Medicaid expansion mandatory, but the Supreme Court found that the enforcement mechanism for the expansion was unconstitutional, basically rendering it voluntary. Although prescription drug coverage is an optional Medicaid benefit, all states include drug coverage. See CRS In Focus IF10399, *Overview of the ACA Medicaid Expansion*.

2014, the ACA changes to Medicaid contributed to an 8% jump in Medicaid prescription drug claims and a 20% rise in gross Medicaid prescription drug spending.³⁴

The aging of the baby boomers also has contributed to increased demand, as Americans over age 65 have significantly higher rates of prescription drug use than their younger counterparts.³⁵

During the past several years, utilization has been affected by government and health payer efforts to reduce abuse of prescription opioids. For example, opioid use in the Medicare Part D program has been declining due to tighter program controls, although it still remains at high levels. According to the HHS Office of the Inspector General (OIG), Part D covered nearly 67 million opioid prescriptions in 2019—an average of 5.3 prescriptions per beneficiary receiving opioids. By comparison, Part D covered 71 million opioid prescriptions in 2018, 76 million in 2017, and 79 million in 2016.³⁶

Are U.S. Consumer Out-of-Pocket Drug Costs Rising?

As recently as 1990, consumer out-of-pocket spending—cash payments, health plan deductibles, coinsurance, and co-payments—for filled prescriptions made up 57% of U.S. retail drug spending, whereas commercial payers and taxpayer-financed health programs accounted for about 43%, according to NHE data. However, in the ensuing years, commercial payers and taxpayer-financed health programs have covered a growing share of the nation’s retail prescription drug bill. (See **Figure 4.**) According to the latest NHE data, out-of-pocket spending declined to about 14% of retail drug spending in 2019, versus about 86% for these other payers.³⁷ By 2028, out-of-pocket spending is forecast to account for 12% of retail drug costs.

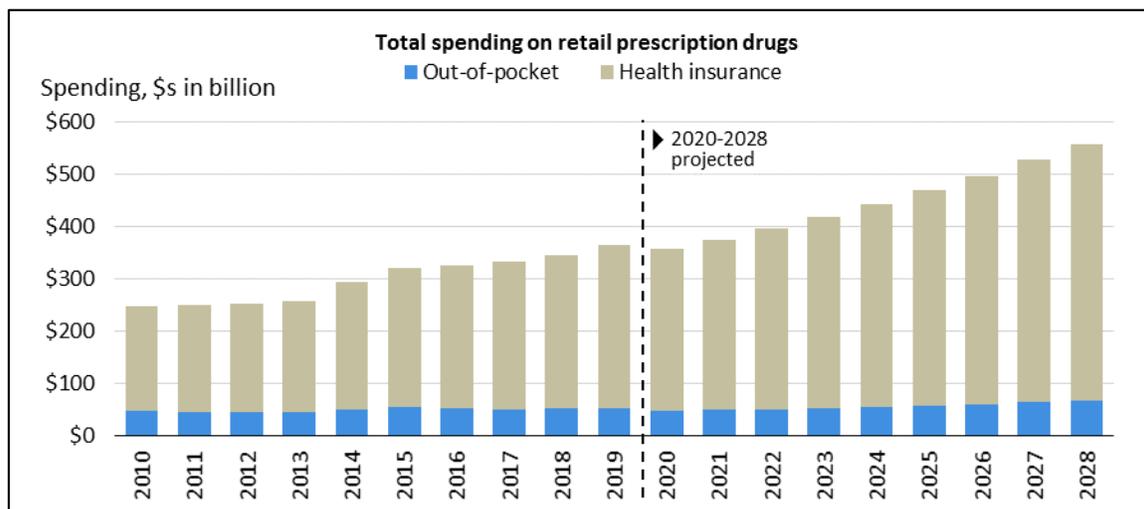
³⁴ MACPAC, “Medicaid Spending for Prescription Drugs,” January 2016, p. 6, at <https://www.macpac.gov/publication/medicaid-spending-for-prescription-drugs/>. Drug spending rose 24.6% in expansion states compared to 14.1% in non-expansion states in 2014. Also see “National Health Spending: Faster Growth In 2015 As Coverage Expands and Utilization Increases,” *Health Affairs*, vol. 26, no. 1 (January 2017).

³⁵ Centers for Disease Control and Prevention, *Health United States, 2018*, Table 38, <https://www.cdc.gov/nchs/fastats/drug-use-therapeutic.htm>.

³⁶ HHS OIG, “Opioid Use in Medicare Part D Continued To Decline in 2019, but Vigilance Is Needed as COVID-19 Raises New Concerns,” OEI-02-20-00320, August 13, 2020, <https://oig.hhs.gov/oei/reports/OEI-02-20-00320.asp/>.

³⁷ CMS, “National Health Expenditure Projections 2019-2028,” Table 11, at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected>. “National Health Expenditure Data: Historical,” at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical>. The NHE accounts spell out how much consumers pay each year to fill retail prescriptions including cash purchases and insurance deductibles, co-payments, and coinsurance. Annual insurance premiums are not included in out-of-pocket spending.

Figure 4. Consumer Out-of-Pocket Spending as a Share of Retail Drug Spending
(2020-2028 is projected)



Source: Centers for Medicare & Medicaid Services (CMS), National Health Expenditure (NHE) data: Historical and Projected.

Notes: Out-of-pocket spending includes cash payments, deductibles, co-payments, and coinsurance but does not include insurance premiums. Consumer out-of-pocket spending rose from \$22.9 billion in 1990 to \$54 billion in 2019 and is projected to reach \$67 billion in 2028.

Although consumer cost sharing represents a smaller share of overall prescription drug spending than in the past, consumers can still face high out-of-pocket expenses depending on the specific drugs they are prescribed (generic versus brand-name), whether they have insurance, the policies of their health plans, and their eligibility for manufacturer drug discount coupons or charitable assistance programs.

In general, health plans have been imposing higher levels of cost sharing for more expensive or less preferred prescription drugs in an effort to control spending and costs. There has been a continued increase in the use of formulary tiered pricing and in the practice of imposing coinsurance, as opposed to flat co-payments, for more expensive or less preferred drugs. In tiered pricing, a consumer may pay a \$10 co-payment for a generic drug on a formulary low-cost price tier; the same consumer may be charged 30% coinsurance for an expensive specialty drug on a high-priced tier. The differential between health plan price tiers has been widening, imposing a greater financial burden on consumers who use higher-priced drugs.³⁸

In 2020, enrollees in employer-sponsored health plans with three or more drug tiers had an average co-payment of \$116 for a high-priced tier-four drug, compared with an \$11 co-payment for a tier-one generic drug. Coinsurance for covered workers in plans with three or more tiers averaged 18% for first-tier drugs, 25% second-tier preferred drugs, 37% third-tier nonpreferred drugs, and 28% for fourth-tier drugs.³⁹ Nearly all covered workers at large firms had coverage for

³⁸ Kaiser Family Foundation, *2020 Employer Health Benefits Survey*, Section 9, at <https://www.kff.org/report-section/ehbs-2020-section-9-prescription-drug-benefits/>. The Kaiser data indicate that the differential has increased, but 2018 is not directly comparable to some previous years due to a change in methodology.

³⁹ *Ibid.*, Kaiser. According to Kaiser, preferred drugs are drugs included on a formulary or preferred drug list; for example, a brand-name drug without a generic substitute. Nonpreferred drugs are drugs not included on a formulary or preferred drug list; for example, a brand-name drug with a generic substitute. Fourth tier drugs refer to new types of cost-sharing arrangements that typically build additional layers of higher co-payments or coinsurance for specifically

specialty drugs, including 45% of workers who are in a plan with at least one cost-sharing tier just for specialty drugs. Insurers often base enrollee coinsurance on a list price for a drug, rather than the insurer's net price after accounting for manufacturer rebates and other price discounts. Some health plans have begun to base enrollee co-insurance on net prices.⁴⁰ However, insurers may increase premiums or set higher deductibles to make up for lost revenue from such a change.

Increases in prescription drug cost-sharing for specific drugs have been partially moderated by other developments. The ACA capped total annual out-of-pocket spending in many commercial health plans, eliminated cost sharing for contraceptives, and reduced average cost sharing for Part D enrollees.⁴¹ (There is no annual cap on out-of-pocket spending in Part D.) Pharmaceutical manufacturers have expanded patient assistance via discount coupons (which cover a portion of required health plan cost sharing) and patient assistance programs (which provide aid based on health condition and annual income).⁴² Generic drug-use rates, for which cost sharing is low, have continued to increase.

According to some recent studies of insured consumers, average out-of-pocket spending for retail drugs has declined in the past several years. However, the number of consumers with high out-of-pocket costs—such as those with serious conditions or those prescribed specialty drugs—has increased.⁴³

Caps on Annual Out-of-Pocket Spending

Many private health insurance plans place an annual cap, or maximum, on enrollee out-of-pocket spending for covered health care services, after which the payer covers the cost. For 2021, the Patient Protection and Affordable Care Act (ACA; P.L. 111-148, as amended) caps out-of-pocket spending at \$8,550 for self-only coverage and \$17,100 for family coverage. The spending limit includes out-of-pocket payments for prescription drugs. Medicare Part D does not have an absolute out-of-pocket cap. For 2021, Medicare Part D enrollees who incur \$6,550 in annual out-of-pocket spending enter the catastrophic portion of the benefit, in which they pay the greater of 5% coinsurance or a nominal, set co-payment.

Source: Healthcare.gov, <https://www.healthcare.gov/glossary/out-of-pocket-maximum-limit/>, and CRS Report R40611, *Medicare Part D Prescription Drug Benefit*.

Notes: Only certain grandfathered private plans do not have to comply with the out-of-pocket cap.

There are differing reports regarding trends in consumer out-of-pocket spending. For example, a 2016 study of enrollees in large employer-sponsored health plans found that average out-of-pocket spending on prescription drugs declined to \$144 in 2014 from a recent high of \$167 in

identified types of drugs, such as lifestyle drugs or biologics.

⁴⁰ Unitedhealthcare, "Successful Prescription Drug Discount Program Expands to Benefit More Consumers at Point-of-sale," March 12, 2019, <https://www.unitedhealthgroup.com/newsroom/2019/2019-03-12-prescription-drug-program-expands-to-benefit-consumers-point-of-sale.html>.

⁴¹ Departments of Labor, HHS, and the Treasury, "FAQs about Affordable Care Act Implementation Part 36," January 9, 2017, at https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/ACA-FAQs-Part36_1-9-17-Final.pdf.

⁴² See IQVIA Institute, "Medicine Spending and Affordability in the United States," p. 18, available at <https://www.iqvia.com/insights/the-iqvia-institute/reports/medicine-spending-and-affordability-in-the-us>; and CRS Report R44264, *Prescription Drug Discount Coupons and Patient Assistance Programs (PAPs)*.

⁴³ *Ibid.*, IQVIA, p. 3. According to the IQVIA Institute, Part D enrollees paid \$16.1 billion out of pocket in 2019, up 27% over the previous five years. The change included an 8.3 million (18.2%) increase in the over-65 population and a 13.7% increase due to greater use of medicines and shifts to drugs that may have higher out-of-pocket costs. The higher spending was offset 5.2% by lower per-prescription costs. Patients covered by commercial insurance paid \$36 billion out of pocket in 2019, down 5% from 2014, reflecting mix and volume changes, as well as greater use of coupons and vouchers provided by manufacturers. By law, coupons are not allowed to be used by patients using government programs.

2009.⁴⁴ But nearly 3% of enrollees had out-of-pocket costs of more than \$1,000 in 2014, accounting for about one-third of drug spending and also one-third of all out-of-pocket spending. The share of people with high drug costs grew 2.5 times between 2004 and 2014. More recently in Medicare Part D, the unit cost of a specialty drug claim rose from \$1,151 in 2007 to \$4,455 in 2018. Beneficiaries can pay up to 33% coinsurance for Part D specialty drugs.⁴⁵

A separate 2020 study by HHS on spending for outpatient prescription drugs found that from 2009 to 2018, median annual out-of-pocket spending per user in the United States declined to \$54 from \$93. The general finding held across different age groups and across different forms of insurance coverage, with some differences in degree.⁴⁶

According to the NHE data, per person out-of-pocket spending for retail prescription drugs fluctuated from \$145 in 2012 to \$148 in 2016, before declining to \$144 in 2018. Out of pocket spending is forecast to gradually increase to \$190 by 2028⁴⁷ (see **Figure 5**). Because out-of-pocket spending is expected to rise more slowly than overall U.S. retail drug spending in the next decade, out-of-pocket spending is forecast to continue to decline as a share of retail drug expenditures (see **Figure 5**).

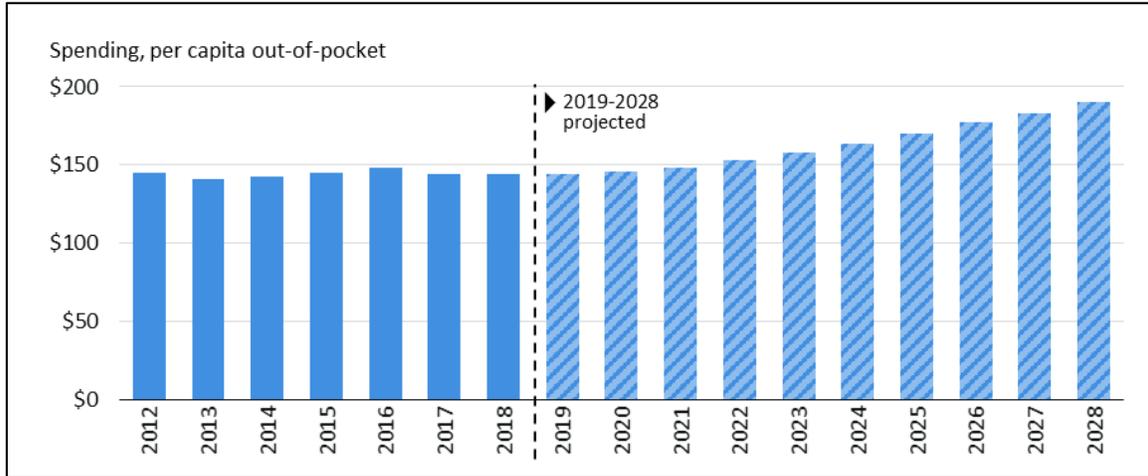
⁴⁴ Peterson-Kaiser Health System Tracker, “Examining High Prescription Drug Spending for People with Employer Sponsored Health Insurance,” October 27, 2016, at <http://www.healthsystemtracker.org/insight/examining-high-prescription-drug-spending-for-people-with-employer-sponsored-health-insurance/>. The 2009 figure of \$167 is about \$185 in 2014 dollars.

⁴⁵ MedPAC, *Report to the Congress: Medicare Payment Policy*, March 2019, p. 414, http://medpac.gov/docs/default-source/reports/mar19_medpac_ch14_sec.pdf?sfvrsn=0. Part D specialty drugs are defined as those with a negotiated price of \$670 or more per month. If a Part D enrollee has sufficient out-of-pocket spending to reach the catastrophic portion of the benefit, cost-sharing is reduced to a maximum of 5% coinsurance.

⁴⁶ William Carroll, G. Edward Miller, and Steven Hill, “Out-of-Pocket Spending for Retail Prescribed Drugs by Age and Type of Prescription Drug Coverage, 2009 to 2018,” HHS Agency for Healthcare Research and Quality (AHRQ), December, 2020, https://meps.ahrq.gov/data_files/publications/st532/stat532.pdf. Study based on data from the Medical Expenditure Panel Survey, Household Component, 2009–2018. Annual figures were inflated to 2018 dollars using the all-item Consumer Price Index.

⁴⁷ CMS, “National Health Expenditure Projections 2019-2028,” Table 11, at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected.html>.

Figure 5. Per Capita Out-of-Pocket Spending for Retail Prescription Drugs
(projected increases in out-of-pocket spending)



Source: CMS, National Health Expenditure, Projected Data.

Government Role in Prescription Drug Spending

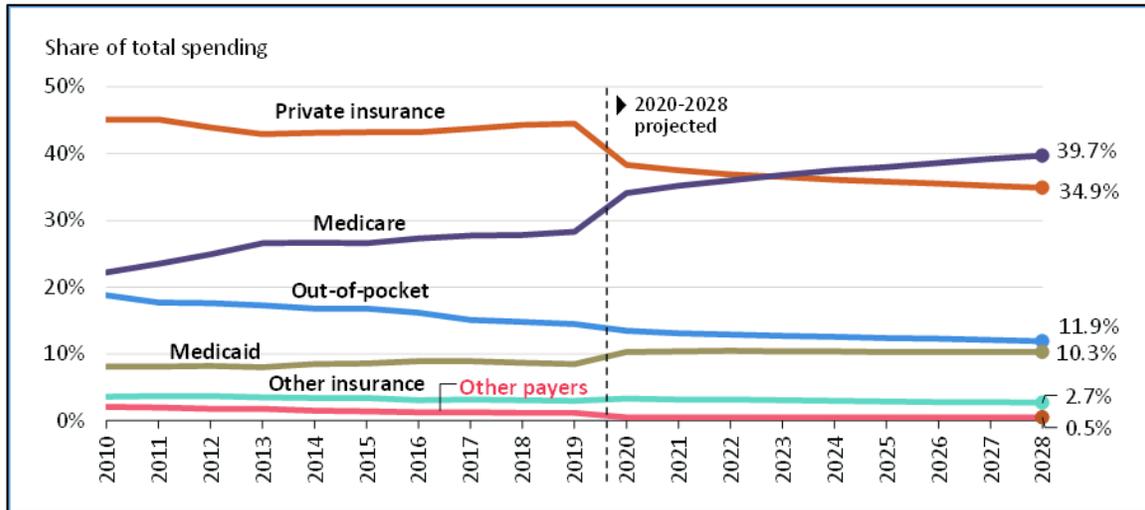
How Much U.S. Drug Spending Is Paid by Government Programs?

Congress and presidential administrations have expanded subsidized drug coverage to tens of millions of consumers by implementing Medicare Part D (Medicare Modernization Act, 2003) and expanding eligibility for Medicaid as part of the ACA.⁴⁸ As a result, the government share of U.S. retail prescription drug spending (federal, state and local) rose from about 25% in 2005—the year before Part D took full effect—to 41% in 2019. The government share of drug spending is forecast to rise to 53% by 2028.⁴⁹ (See **Figure 6.**)

⁴⁸ For example, the federal government subsidizes about 75% of the basic Medicare Part D benefit. See CRS Report R40611, *Medicare Part D Prescription Drug Benefit*.

⁴⁹ CMS, “National Health Expenditure Projections 2019-2028,” Table 11.

Figure 6. Share of Spending for Retail Prescription Drugs by Source
(total retail prescription drug spending broken down by payer share)



Source: CMS, National Health Expenditure (NHE) data: Historical and Projected.

Notes: The “other payers insurance” category includes the State Children’s Health Insurance Program, the Department of Defense, and the Department of Veterans Affairs. The other payers category includes worksite health care, other private revenues, Indian Health Service, workers’ compensation, general assistance, maternal and child health, vocational rehabilitation, Substance Abuse and Mental Health Services Administration, other federal programs, other state and local programs, and school health.

How Does the Federal Government Pay For Prescription Drugs?

Unlike many other industrialized nations, the United States does not operate a single, centralized system for administering government-sponsored drug benefits, procuring pharmaceuticals, or setting drug prices.⁵⁰ Instead, the various departments and agencies that oversee federal health programs operate a range of congressionally mandated drug discount and contracting systems, including market-based negotiations in Medicare Part D, direct procurement in the Veterans Health Administration, and a combination of mandatory rebates and negotiations in Medicaid. Separately, FDA regulates the safety and effectiveness of prescription drugs.⁵¹ Congress has not given FDA authority to set drug prices or to consider prices as part of its drug approval process.

Federal agencies can secure substantial discounts for prescription drugs under this decentralized system. However, price discounts vary widely among federal programs. For example, according to a recent Congressional Budget Office (CBO) report on the prices of 176 drugs (net of applicable rebates and discounts), the average price ranged from \$118 in Medicaid to \$343 in Medicare Part D. According to CBO, the lower net prices in Medicaid were due to higher manufacturer rebates for that program than for Medicare Part D.⁵² The Department of Veterans Affairs (VA) and Department of Defense had average prices between the average prices in

⁵⁰ See “Is U.S. Prescription Drug Spending Higher Than in Other Nations?”

⁵¹ Beginning with the Food and Drugs Act of 1906, Congress has incrementally refined and expanded FDA’s responsibilities regarding drug approval and regulation. CRS Report R41983, *How FDA Approves Drugs and Regulates Their Safety and Effectiveness*. See, in particular, Federal Food, Drug, and Cosmetic Act (FFDCA) §§505 (new drugs), 501 (adulteration), and 502 (misbranding).

⁵² Congressional Budget Office, “A Comparison of Brand-Name Drug Prices Among Selected Federal Programs,” February 18, 2021, <https://www.cbo.gov/publication/56978>.

Medicaid and Medicare Part D. CBO also found a wide range of prices for specialty drugs. The CBO report builds on previous studies, including a 2015 HHS OIG report, which found that Medicaid rebates were equal to 47% of Medicaid spending in 2012, while rebates made up a smaller 15% of Part D spending that same year.⁵³ Medicaid rebates for some drugs were more than 10 times larger than Part D rebates for the same products. Members of Congress have introduced legislation to give the HHS Secretary more power to negotiate Medicare Part D drug prices. (See “Can the HHS Secretary Negotiate Medicare Part D Drug Prices?”)

Table 2 outlines prescription purchasing systems for four federal health care programs: Medicare Part D, Medicare Part B, Medicaid, and the Veterans Health Administration health system.⁵⁴ These programs were chosen because they are among the largest federal health programs. The table is not a complete list of federal prescription drug coverage.

Table 2. Selected Federal Programs Providing Prescription Drug Coverage
(overview of drug purchasing and payment methods by government programs)

| | |
|---------------------------------------|---|
| Medicare Part D | Medicare Part D is a voluntary drug benefit offered through private health care plans that contract with HHS. The Part D program relies on market competition to limit spending. Plan sponsors, which compete for enrollees, negotiate rebates, discounts, and other price concessions with manufacturers. The ACA amended Part D to require additional price discounts from manufacturers. Starting in 2011, manufacturers that choose to participate in Part D have been required to provide a 50% discount on brand-name drugs purchased by enrollees who incur a certain level of drug expenses and are in the coverage gap, with higher out-of-pocket spending. Congress increased the manufacturer discount to 70%, effective in 2019. Total annual manufacturer coverage gap discounts are about \$5 billion, according to available data. ^a |
| Medicare Part B | Medicare Part B covers physician services and durable medical equipment, as well injectable or intravenous drugs administered as part of a service in a doctor’s office or hospital outpatient department. ^b Part B also covers specific drugs, such as immunosuppressant products, certain vaccines, transplant drugs, and oral end stage renal disease medications. Under Part B, physicians who purchase prescription drugs for administration are reimbursed by Medicare for the Average Sales Price of a drug, plus 6%. |
| Medicaid | Medicaid is a federal-state entitlement program that pays for health care services on behalf of certain low-income individuals. ^c Prescription drugs are an optional benefit but are covered by all states. Manufacturers that choose to sell their drugs to state Medicaid agencies must enter into a national rebate agreement with the HHS Secretary and provide information on their lowest or “best” drug prices. Manufacturer rebates vary depending on the specific product. For example, manufacturers must provide at least a rebate of 23.1% the Average Manufacturer Price (AMP) on new innovator drugs and a rebate of 13.1% of AMP on generic drugs. States may limit formularies and require use of generic drugs when possible. Drug manufacturers that participate in Medicaid must sell their products at a discounted price to health providers covered by the 340B program. ^d |
| Veterans Health Administration | The Department of Veterans Affairs (VA) through the Veterans Health Administration (VHA) operates the nation’s largest integrated direct health care delivery system, including outpatient clinics and hospitals. To reduce variability in access to pharmaceuticals, VHA has implemented a national formulary process. The VA uses multiple contracting mechanisms to acquire pharmaceuticals supplies, including the federal supply schedule (FSS); performance-based incentive agreements, or blanket purchase agreements (BPAs); temporary price reductions; pricing under the Veterans Health Care Act of 1992 (P.L. 102-585); and national standardization contracts. On a drug-by-drug basis, the VHA selects the mechanism that offers the best value at the lowest price. VHA also can use a Wholesale Acquisition Cost-Based Priced Generics mechanism to buy drugs from its Pharmaceutical Prime Vendor (PPV) contract in the absence of |

⁵³ HHS, Office of Inspector General (OIG), “Medicaid Rebates for Brand-Name Drugs Exceeded Part D Rebates by a Substantial Margin,” April 2015, at <http://oig.hhs.gov/oei/reports/oei-03-13-00650.pdf>.

⁵⁴ Other government health programs not in **Table 2** include those run by the Department of Defense and the Indian Health Service.

other government contracting vehicles. If drugs are not available through these various contract vehicles, using applicable government procurement processes, VHA can procure them through the Government Purchase Card program or by having a warranted contracting officer execute the procurement.^e

Source: CRS Analysis of federal agency information, including contracts, and federal statutes.

Notes: ACA = Patient Protection and Affordable Care Act (P.L. 111-148, as amended); CMS = Centers for Medicare & Medicaid Services; HHS = Department of Health and Human Services.

- a. CMS, “Coverage Gap Discount Program,” at <http://www.cms.gov/Medicare/Medicare-Advantage/Plan-Payment/CGDP.html>. The Bipartisan Budget Act of 2018, P.L. 115-123, increased the manufacturer discount.
- b. See CRS Report R40425, *Medicare Primer*.
- c. See CRS Report R43778, *Medicaid Prescription Drug Pricing and Policy*.
- d. *Ibid.* Under the 340B program, manufacturers agree to provide outpatient drugs to covered entities, including qualifying hospitals, at significantly reduced prices.
- e. See CRS Report R42747, *Health Care for Veterans: Answers to Frequently Asked Questions*.

Can the HHS Secretary Negotiate Medicare Part D Drug Prices?

Congress designed Medicare Part D as a market-oriented program in which commercial health payers compete for enrollees based on the price and scope of their drug coverage.⁵⁵ Part D plan sponsors, which include health plans, unions, employers, and pharmacy benefit managers (PBMs), negotiate drug rebates and discounts with manufacturers and contract with retail pharmacies to dispense drugs to Part D enrollees at set reimbursement rates.⁵⁶

To bolster market competition, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA; P.L. 108-173), which created Medicare Part D, contains a “noninterference provision.”⁵⁷ This provision prohibits the HHS Secretary from intervening in negotiations between Part D plan sponsors, drug manufacturers, and pharmacies or from requiring a specific Part D formulary.⁵⁸

In the years since Part D was enacted, Congress has debated whether the market-based model has been effective in controlling drug prices and enrollee costs. Part D plan sponsors have been successful in increasing drug rebates. Part D direct and indirect remuneration (which consists mainly of prescription drug rebates but also includes other remuneration that affects net drug prices, such as certain pharmacy fees) rose from 11.1% of total Part D drug costs in 2008 to an estimated 28.4% in 2020.⁵⁹ However, HHS, the Medicare Payment Advisory Commission

⁵⁵ Part D plans must provide coverage that is at least equivalent to a set standard benefit, which is set and updated annually by HHS. Part D plans also may offer more generous coverage.

⁵⁶ CRS Report R40611, *Medicare Part D Prescription Drug Benefit*. Unions and employers may sponsor special Part D Employee Group Waiver Plans to provide retiree drug coverage.

⁵⁷ The noninterference provision is §1860D-11(i) of the Social Security Act. The actual wording of the noninterference provision states, “In order to promote competition under this part and in carrying out this part, the Secretary (1) may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors; and (2) may not require a particular formulary or institute a price structure for the reimbursement of covered Part D drugs.” A PDP is a stand-alone Part D drug plan. Medicare beneficiaries also may obtain Part D benefits as part of a Medicare Advantage plan, or an MA-PD.

⁵⁸ Although Part D does not have a central formulary, Part D plans are required to cover at least two distinct drugs in each class and category, as defined by U.S. Pharmacopeial Convention (USP), an independent scientific organization, or a like organization. In addition, all Part D plans must cover substantially all drugs in six protected classes: immunosuppressant, antidepressant, antipsychotic, anticonvulsant, antiretroviral, and antineoplastic.

⁵⁹ CMS, “The 2020 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal

(MedPAC) and other analysts say the higher rebates may not be indicative of successful price negotiations. Manufacturers have continued to increase list prices or set high list prices for brand-name drugs in Part D. Rebates have grown, but not as fast as prices, and the gap between Part D reimbursement for brand-name drugs and total rebates to plan sponsors has increased. For example, the HHS OIG found total reimbursement for Part D brand-name drugs, net of rebates, rose 62% from 2011 to 2015, even as the number of brand-name prescriptions fell 17%.⁶⁰ In addition, a series of studies have found that Part D pays higher average net prices for brand-name drugs than other federal programs.⁶¹

Lawmakers have made repeated proposals to repeal or modify the noninterference provision to give the Secretary the authority to negotiate Part D drug prices. Supporters of Secretarial negotiation maintain that by leveraging the combined purchasing power of tens of millions of Part D enrollees, the Secretary could secure larger discounts and rebates than can be obtained by plan sponsors. Opponents note that Part D enrollment is concentrated among a few large insurers that already have substantial bargaining power, and that changing the noninterference provision could result in more limited plan formularies.

In 2007, the House approved H.R. 4, the Medicare Prescription Drug Price Negotiation Act of 2007, which would have allowed the Secretary to negotiate Part D drug prices but not to craft a formulary.⁶² The measure was not approved by the Senate. A CBO analysis said that the bill would produce negligible savings unless the Secretary were given authority to create a central formulary, set prices administratively, or take other regulatory actions against firms that failed to offer price reductions.⁶³ A number of patient and consumer groups have opposed proposals to give the Secretary more control of the Part D formulary, contending it could lead to reductions in drug coverage.⁶⁴

In a May 2019 letter to the Chairman of the Senate Finance Committee regarding Part D price negotiation, CBO continued to conclude that “(n)egotiation is likely to be effective only if it is accompanied by some source of pressure on drug manufacturers ... providing broad negotiating

Supplementary Medical Insurance Trust Funds,” April 22, 2020, Table IV.B8, p. 142, at <https://www.cms.gov/files/document/2020-medicare-trustees-report.pdf>. Direct and Indirect Remuneration (DIR) is an accounting system that Part D plans use to report to CMS all prescription drug price concessions that take place after the point of sale. Rebates are the vast majority of reported DIR, but various Part D plan sponsor-imposed fees on pharmacies have been growing rapidly.

⁶⁰ HHS OIG, “Increases in Reimbursement for Brand-Name Drugs in Part D,” June 2018, <https://oig.hhs.gov/oei/reports/oei-03-15-00080.asp>.

⁶¹ CBO, “A Comparison of Brand-Name Drug Prices Among Selected Federal Programs,” February 18, 2021, <https://www.cbo.gov/publication/56978>; “Prices for and Spending on Specialty Drugs in Medicare Part D and Medicaid,” June 2018, <https://www.cbo.gov/publication/53929>; and “Competition and the Costs of Medicare’s Prescription Drug Program,” July 2014, p. 29, at <https://www.cbo.gov/sites/default/files/113th-congress-2013-2014/reports/45552-PartD.pdf>. See also HHS OIG, “Medicaid Rebates for Brand-Name Drugs Exceeded Part D Rebates by a Substantial Margin,” April 2015, at <http://oig.hhs.gov/oei/reports/oei-03-13-00650.pdf>; and Government Accountability Office, “Comparison of DOD, Medicaid, and Part D Retail Reimbursement Prices,” June 2014, at <http://www.gao.gov/assets/670/664521.pdf>.

⁶² The House passed the measure by a vote of 255-170 on January 12, 2007. See <http://clerk.house.gov/evs/2007/roll023.xml>. For a text of the bill, see <https://www.congress.gov/bill/110th-congress/house-bill/4/text>.

⁶³ CBO Letter to Rep. John Dingell, January 10, 2007, at <https://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/77xx/doc7722/hr4.pdf>. See also CBO letter to Senator Ron Wyden, April 10, 2007, at <https://www.cbo.gov/sites/default/files/110th-congress-2007-2008/reports/drugpricenegotiation.pdf>.

⁶⁴ Letter to Congress from Coalition of Consumer and Health Care Groups, March 18, 2013, at [http://www.nam.org/Issues/Health-Care/Letter-to-Congress-to-Protect-Medicare-Part-D\(1\)](http://www.nam.org/Issues/Health-Care/Letter-to-Congress-to-Protect-Medicare-Part-D(1)). See also <https://www.cbo.gov/sites/default/files/110th-congress-2007-2008/costestimate/s30.pdf>.

authority by itself would likely have a negligible effect on federal spending.”⁶⁵ CBO indicated that the Secretary might achieve savings by negotiating prices for select drugs, such as those with no close substitutes or with relatively high prices that are needed to address a public health emergency; however, such negotiations may have only a modest impact on federal spending.

During the 116th and 117th Congresses, a number of bills were introduced to allow the Secretary to negotiate Part D drug prices. The bills have varied widely in approach. Some would retain noninterference provision language barring a central Part D formulary, while others would repeal the entire noninterference opening the way for the Secretary to take a more active role in setting plan formularies. Some bills were prescriptive regarding possible price negotiation, such as directing the Secretary to prioritize negotiations on Part D drugs with the highest cost, the largest price increase, or the least market competition.

Still another approach has been to set fallback pricing and/or penalties to be triggered if the Secretary and manufacturers could not reach agreement. Examples include basing Part D prices on (1) prices charged to the VHA, (2) prices in selected industrialized nations, or (3) Medicaid’s best price, which is the lowest price that a manufacturer offers to a U.S. buyer. One bill using fallback pricing and penalties, H.R. 3, would require the Secretary to negotiate prices for certain single-source drugs in Part D and commercial plans, which could not exceed a benchmark based on prices in six countries.⁶⁶ Manufacturers would be subject to an excise tax on drug sales if they declined to negotiate or failed to agree on a price. CBO estimated this approach would result in significant changes in drug prices and reductions in federal spending.⁶⁷

What Are U.S. States Doing to Address Drug Costs?

State governments play an active role in regulating prescription drug use and pricing. States are the main regulators of health insurance, administer and fund Medicaid jointly with the federal government, and offer health insurance plans to state employees. Some states have their own patient assistance programs that provide free prescription drugs to low-income residents.

States are using various approaches to address prescription drug spending and access, including passing laws to allow for importation of drugs from abroad, limiting consumer cost-sharing for high-priced drugs, and requiring transparency in drug pricing by requiring manufacturers to justify drug price increases or provide data about research, advertising and other costs.⁶⁸ States are also imposing additional regulation on pharmacy benefit managers, such as requiring them to register with the state as third party benefit administrators; prohibiting so-called gag clauses in pharmacy contracts with PBMs that bar pharmacists from telling consumers about less expensive options for filling a prescription; and making public PBM bids for services to provide more transparency.⁶⁹

⁶⁵ CBO, “Effects of Drug Price Negotiation Stemming From Title 1 of H.R. 3, the Lower Drug Costs Now Act of 2019, on Spending and Revenues Related to Part D of Medicare,” October 11, 2019. <https://www.cbo.gov/publication/55722>.

⁶⁶ An earlier version of H.R. 3 passed in the House in December 2019. The bill was reintroduced in the 117th Congress.

⁶⁷ For spending estimate, see CBO, H.R. 3, Elijah E. Cummings Lower Drug Costs Now Act, December 6, 2019, <https://www.cbo.gov/publication/55936>.

⁶⁸ For directories of state legislation on prescription drugs, see National Conference of State Legislatures, “Prescription Drug Policy Research Center,” <http://www.ncsl.org/research/health/ncsl-prescription-drug-policy-resources-center.aspx>; and Deloitte, “State Drug Pricing Policies: Drug Companies and PBMs Should Prepare for Continued Activity,” July 16, 2020, <https://www2.deloitte.com/us/en/insights/industry/life-sciences/state-drug-pricing-legislation.html>.

⁶⁹ LaVita Tuff, “Trending Now: State Legislation that Bans Pharmacy Benefit Managers’ ‘Gag Clauses,’” National

For example, in 2016 Vermont approved a first-in-the nation law requiring manufacturer disclosure for drugs that underwent large percentage price increases.⁷⁰ Each year, this law requires state regulators to compile a list of drugs used by Vermont residents that experience the largest annual price increases. Manufacturers are required to justify the price increase to the state attorney general. The idea behind the Vermont act, and similar bills, is to force drug companies to justify prices, based on costs.

Maine in 2013 enacted a law allowing its citizens to import prescription drugs from Canada, New Zealand, Australia, and the United Kingdom. A federal district court ruled the law unconstitutional in 2015.⁷¹ Six states have laws that would allow for importation of drugs through state-run drug wholesaling operations.⁷² (See “May U.S. Consumers Import Drugs from Abroad?” for information on federal policy.)

Is U.S. Prescription Drug Spending Higher Than in Other Nations?

The United States spends more for prescription drugs than other industrialized nations, as measured by both total spending and spending per person. The U.S. share of global drug spending was estimated at about 41% in 2019, according to one forecast.⁷³ By comparison, the top five European nations combined are projected to account for 14% of global drug spending in 2019.⁷⁴

Similarly, a study by the Organisation for Economic Co-operation and Development (OECD) found that U.S. per capita spending for retail prescription drugs was \$1,220 in 2017, compared to the OECD average of \$564. U.S. spending was higher than spending in any of the other 30 industrialized nations examined.⁷⁵ (See **Figure 7**.)

Academy for State Health Policy, January 30, 2018, at <https://nashp.org/trending-now-state-legislation-that-bans-pharmacy-benefit-managers-gag-clauses/>. See also from the National Academy for State Health Policy: “States Save on Rx Spending by Using Reverse Auctions for Pharmacy Benefit Manager Service Procurement,” August 24, 2020, <https://www.nashp.org/states-save-on-rx-spending-by-using-reverse-auctions-for-pharmacy-benefit-manager-service-procurement/>; “2020 State Legislative Action to Lower Pharmaceutical Costs,” updated December 8, 2020, <https://www.nashp.org/rx-legislative-tracker/>; and State Drug Pricing Laws: 2017-2020, updated December 3, 2020, <https://www.nashp.org/rx-laws/>. There are also recent federal laws banning gag clauses in Medicare and commercial insurance: P.L. 115-262 and P.L. 115-263.

⁷⁰ Ed Silverman, “Vermont Becomes First State to Require Drug Makers to Justify Price Hikes,” *Pharmalot/STAT*, June 6, 2016, at <https://www.statnews.com/pharmalot/2016/06/06/vermont-drug-prices-transparency/>. See also <http://legislature.vermont.gov/bill/status/2016/S.216>. The law directs the state to identify up to 15 prescription drugs annually on which the state spends significant health care dollars and for which the wholesale acquisition cost has increased by 50% or more over the previous five years, or by 15% or more over the previous 12 months.

⁷¹ Eric Russell, “Judge Strikes Down Maine Law Allowing Residents to Buy Drugs from Foreign Pharmacies,” *Portland Press Herald*, February 25, 2015, at <http://www.pressherald.com/2015/02/24/maine-residents-cant-order-drugs-from-foreign-pharmacies-judge-rules/>. See also State of Maine, An Act to Facilitate the Personal Importation of Prescription Drugs from International Mail Order Prescription Pharmacies, at <http://www.mainelegislature.org/legis/bills/getPDF.asp?paper=SP0060&item=4&num=126>.

⁷² National Academy for State Health Policy, “With Federal Rule Issued, States Advance Prescription Drug Importation Programs,” October 19, 2020, <https://www.nashp.org/with-federal-rule-issued-states-advance-prescription-drug-importation-programs/>.

⁷³ IQVIA, *Global Medicine Spending and Usage Trends*, March 2020, at <https://www.iqvia.com/insights/the-iqvia-institute/reports/global-medicine-spending-and-usage-trends>. The data include drugs dispensed in retail pharmacies and drugs used in hospital or clinic settings. Adoption of specialty medicines is driving spending increases globally as well, with such products account for 36% of global spending.

⁷⁴ *Ibid*.

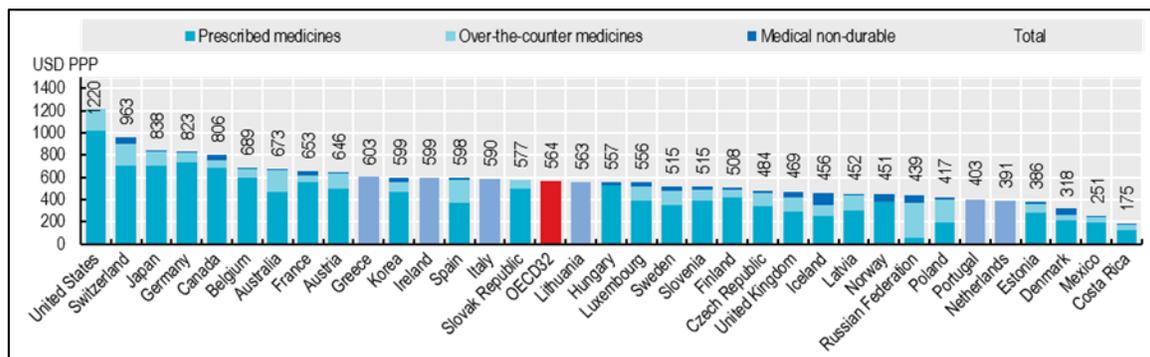
⁷⁵ Organisation for Economic Co-operation and Development (OECD), *Health at a Glance 2017*, Chapter 10, at <https://www.oecd-ilibrary.org/docserver/4dd50c09-en.pdf?expires=1614023061&id=id&accname=ocid195520&>

Other studies have found large differences in the price for specific drugs in the United States and other countries.⁷⁶ In one study, researchers at the University of Liverpool examined a class of cancer drugs known as tyrosine kinase inhibitors and found that the U.S. price in most cases was at least double that charged in the European Union (EU).⁷⁷

Academic studies have posited a number of reasons for the higher U.S. spending and prices. These reasons include the faster adoption of breakthrough, or newly introduced, drugs in the United States and patent and other protections that give U.S. manufacturers market exclusivity during the early years a product is on the market.⁷⁸

Another difference is that OECD countries may operate government-run health care systems that are the main purchasers of drugs and that set price limits for the products they buy. Most EU nations use external reference pricing, defined by the European Commission as using the price of a medicine in one or several countries to derive a benchmark, or reference price, for setting or negotiating the price of that medicine in another country.⁷⁹

Figure 7. Per Capita Spending on Retail Drugs in U.S. and Other Countries
(2017 or nearest year of available data, in dollars)



Source: Organisation for Economic Co-operation and Development (OECD), *Health at a Glance 2019*, Chapter 10.

Notes: Data include retail prescription drugs and over-the-counter medications. Data are based on purchasing power parity, which accounts for different currency exchange rates among countries. OECD 32 is average across

checksum=B5A3E1BC855F7B02EE7D996E657E4628. OECD numbers include retail drug spending, including both prescribed drugs and over-the-counter products. According to the OECD, prescription drugs accounted for 75% of spending, with the remainder spent on over-the-counter (OTC) medicines (19%) and medical nondurables (5%).

⁷⁶ Government Accountability Office, “Prescription Drugs: U.S. Prices for Selected Brand Drugs Were Higher on Average than Prices in Australia, Canada, and France,” GAO-21-282, March 29, 2021, <https://www.gao.gov/assets/gao-21-282.pdf>.

⁷⁷ University of Liverpool, “Americans Overpaying for Drugs Say Researchers,” September 24, 2015, at <https://news.liverpool.ac.uk/2015/09/24/americans-overpaying-for-cancer-drugs-say-researchers/>. Andrew Hill et al., “Target Prices for Mass Production of Tyrosine Kinase Inhibitors for Global Cancer Treatment,” *BMJ Open*, 2016, at <http://bmjopen.bmj.com/content/6/1/e009586.full>. Tyrosine kinase inhibitors are used to treat cancer by blocking a specific enzyme.

⁷⁸ Panos Kanavos et al., “Higher U.S. Branded Drug Prices and Spending Compared to Other Countries May Stem Partly from Quick Uptake of New Drugs,” *Health Affairs*, vol. 32, no. 4 (April 2013), pp. 753-761.

⁷⁹ European Commission, *Study on Enhanced Cross-Country Coordination in the Area of Pharmaceutical Product Pricing*, by Gesundheit Österreich Forschung-und Planungs GmbH, December 2015, at http://ec.europa.eu/health/sites/health/files/systems_performance_assessment/docs/pharmaproductpricing_frep_en.pdf. According to the report, reference pricing has limitations, including providing incentives for companies to launch medicines in countries with a high price level.

OECD nations. In some countries, other medical nondurable goods also are included. Total pharmaceutical spending refers in most countries to “net” spending (i.e., adjusted for possible rebates payable by manufacturers, wholesalers, or pharmacies).

National health programs may use value-based pricing, which bases payment for a drug on evidence of its effectiveness or therapeutic value.⁸⁰ In Canada, the Common Drug Review assesses the clinical and economic effectiveness of new drugs and of existing drugs approved for new uses.⁸¹ The assessments are passed on to federal, territorial, and provincial drug plans to use in setting reimbursement.

U.S. government and commercial payers are experimenting with alternative forms of pricing. For example, Harvard Pilgrim Health Care, a regional private health insurer, has announced deals with pharmaceutical firms under which the insurer will receive discounts if certain drugs do not meet specified goals for improving health or reducing hospitalizations.⁸² CMS has encouraged state Medicaid programs to move toward value-based purchasing and has offered guidance on addressing some associated technical issues.⁸³ There are questions about how far outcomes-based pricing can go in addressing drug price issues given difficulties in negotiating and administering such systems.⁸⁴

The Institute for Clinical and Economic Review (ICER), a private research organization, is producing public reports on the comparative effectiveness, cost-effectiveness, and potential budget impact of drugs that are newly approved by FDA.⁸⁵

Pharmaceutical Development and Marketing

How Much Does Publicly Funded Research Contribute to Drug Development?

In general, federally funded biomedical research tends to focus more on the early stages of drug development, including basic or preclinical research conducted or supported by the National Institutes of Health (NIH). In contrast, the pharmaceutical industry tends to concentrate more of its research funding on late-stage drug development, such as clinical trials, rather than on early-stage research activity.⁸⁶ When trying to assign credit for specific therapeutic advancements,

⁸⁰ Vallerie Paris and Annalisa Belloni, “Value in Pharmaceutical Pricing,” OECD Health Working Papers, No. 63, 2013, at <http://dx.doi.org/10.1787/5k43jc9v6kxn-en>.

⁸¹ CADTH Common Drug Review (CDR), at <https://www.cadth.ca/about-cadth/what-we-do/products-services/cdr>.

⁸² Harris Meyer, “As a Cure for High Drug Prices, Outcomes-Based Deals Aren’t Delivering Yet,” *Modern Healthcare*, March 23, 2019, <https://www.modernhealthcare.com/insurance/cure-high-drug-prices-outcomes-based-deals-arent-delivering-yet>.

⁸³ CMS, “Medicaid Drug Rebate Program Notice,” Release No. 99, July 14, 2016, at <https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Prescription-Drugs/Downloads/Rx-Releases/MFR-Releases/mfr-rel-099.pdf>. Also see John Armstrong and Colleen Becker, “Value-based Pricing to Address Drug Costs,” *Legis Brief*, National Conference of State Legislatures, vol. 27, no. 15, April 2019, <https://www.ncsl.org/research/health/value-based-pricing-to-address-drug-costs.aspx>.

⁸⁴ Harris Meyer, “As a cure for high drug prices, outcomes-based deals aren’t delivering yet,” *Modern Healthcare*, March 23, 2019, <https://www.modernhealthcare.com/insurance/cure-high-drug-prices-outcomes-based-deals-arent-delivering-yet>.

⁸⁵ Institute for Clinical and Economic Review (ICER), <https://icer.org/>.

⁸⁶ Hamilton Moses et al., “The Anatomy of Medical Research: U.S. and International Comparisons,” *Journal of the American Medical Association*, vol. 313, no. 2 (January 13, 2015), pp. 174-189.

drawing a line between basic and applied research can be challenging. For example, without major underlying basic scientific advances, such as recombinant DNA technology, the development of whole new classes of drugs would not have taken place.⁸⁷

Although the line can blur, public sector contributions to new drugs can generally be categorized as *direct* or *indirect*. Public funding *directly* contributes to drug development when publicly funded scientists—either through intramural or extramural research⁸⁸—develop a chemical compound or other invention specific to a particular drug. The intellectual property arrangements for these direct contributions to new drugs vary based on (1) the applicable laws and policies, (2) the nature of the funding or other agreement between the federal agency and the research institution, (3) whether the intellectual contribution is patentable, and (4) the research institution’s decision to patent the invention, among other factors.⁸⁹ Because of these factors, publicly funded researchers do not always seek or hold patents to the inventions they develop.⁹⁰ Government agencies also fund some clinical research (mostly early stage clinical trials) on new or existing drugs to assess their safety and effectiveness for purposes of FDA approval, but typically do not actually apply for FDA approval of the drug.⁹¹ In recent years, federal agencies and public research institutions have engaged in an increasing number of public-private research partnerships to facilitate the development of new drugs—most visibly during the COVID-19 pandemic. These partnerships further complicate the assessment of public sector contributions to new drugs, as they involve combined efforts by both the public and private sectors to jointly develop new drugs.⁹²

Since much of federal medical and health research funding supports basic research on fundamental mechanisms of biology and behavior (rather than applied research on specific products), much of publicly funded research generates scientific knowledge that *indirectly* aids in drug development.⁹³ NIH-funded research can lead to innovations in fundamental science that enable the development of new types of drugs. Federal science agencies also support the education and training of some biomedical scientists who then work for the pharmaceutical industry. It is difficult to assess and measure the indirect contribution of federal research and

⁸⁷ Recombinant DNA technology is the joining of DNA molecules from different sources in a host organism to produce a new genetic combination. Publicly funded research played an instrumental role in the development of recombinant DNA beginning in the 1970s. See Rajendra K. Bera, “The Story of the Cohen-Boyer Patents,” *Current Science*, vol. 96, no. 6 (March 2009), pp. 760-763.

⁸⁸ An example of intramural research is research performed by federal NIH scientists in the NIH-operated laboratories and Clinical Center. An example of extramural research is research performed by nonfederal scientists using NIH grant or contract funding.

⁸⁹ CRS Legal Sidebar LSB10422, *COVID-19 Medical Countermeasures: Intellectual Property and Affordability*.

⁹⁰ Rahul K Nayak, Jerry Avorn, and Aaron S. Kesselheim, “Public Sector Financial Support for Late-Stage Discovery of New Drugs in the United States,” *The BMJ*, vol. 367, no. 15766 (September 23, 2019).

⁹¹ Gillian K. Gresham, Stephan Ehrhardt, and Jill L. Meinhert, “Characteristics and Trends of Clinical Trials Funded by the National Institutes of Health Between 2005 and 2015,” *Clinical Trials*, vol. 15, no. 1 (2018), pp. 65-74.

⁹² CRS Report R46427, *Development and Regulation of Medical Countermeasures for COVID-19 (Vaccines, Diagnostics, and Treatments): Frequently Asked Questions*, and section on “Public-Private Partnerships” in CRS Report R41705, *The National Institutes of Health (NIH): Background and Congressional Issues*.

⁹³ CRS Report R46341, *Federal Research and Development (R&D) Funding: FY2021*, and GAO, *Drug Industry: Profits, Research and Development Spending, and Merger and Acquisition Deals*, GAO-18-40, November 2017, pp. 34-37, <https://www.gao.gov/assets/gao-18-40.pdf>. Specifically, GAO reported that “federal spending consistently funded a greater amount of basic research . . . NIH obligated 54 percent, or \$13.6 billion of its total \$25 billion of drug related spending, for basic research in fiscal year 2014. This is more than twice as much as the \$6.3 billion that the NSF [National Science Foundation] data show pharmaceutical companies reported spending domestically for basic research that year.”

training to new drugs, though several studies have found that it is greater than the direct contribution of public research funding to drug development.⁹⁴

Various studies have attempted to quantify the contribution of publicly funded research to the discovery of new drugs. Studies have characterized these contributions in several ways, including by quantifying (1) the number of FDA-approved drugs that are developed relying on federally owned or licensed intellectual property, (2) the number of drugs developed with key intellectual property or contributions from publicly funded research, (3) the contribution of publicly funded research to certain “innovative” drugs as defined in the studies, or (4) the total effect of public research funding on pharmaceutical drug development. These studies characterize publicly funded research differently—some focus on NIH funding (the largest government biomedical research agency in the United States and the world), others focus on all federally funded research, while others account for publicly funded research more broadly (e.g., funded by the philanthropic sector, foreign government agencies, and state governments). In summary, available research shows that a fraction (9%-25%) of new drugs approved by FDA in recent decades are based on patents or specific intellectual contributions of publicly funded researchers. Some studies find that drugs developed with public support tend to be more innovative and/or have a greater therapeutic impact (as defined by the researchers) than those drugs developed solely by the private sector. When accounting for broader indirect scientific contributions to new drugs, virtually all FDA-approved drugs are associated with NIH-funded research.

Federal intellectual property. For scientists and researchers employed by federal agencies (i.e., those conducting intramural research), federal law authorizes federal agencies to apply for patents and to grant licenses for inventions developed in the course of federal research.⁹⁵ While federal agencies, such as NIH, maintain websites and reports on their intellectual property broadly, commentators have noted a lack of consolidated and complete information by federal agencies about patents held by federal agencies specific to pharmaceutical drugs.⁹⁶ In October 2020, the Government Accountability Office (GAO) reported on NIH’s licensing of its intramural inventions. GAO found that “NIH provides limited information to the public about its licensing activities.” Based on an analysis of patents owned by HHS (NIH’s parent department), GAO found that HHS-funded research had led to 4,446 patents between 1980 through 2019, of which NIH had 93 patents (2%) that contributed to the successful development and FDA approval of 34 drugs. These 34 drugs were developed by drug companies and were associated with 32 NIH-granted licenses. GAO recommended that NIH make information about licensing of its inventions more publicly available; NIH concurred with the recommendation and committed to developing a plan for greater transparency of its licensed inventions.⁹⁷

Drugs with patents or key intellectual contributions from publicly funded research. For extramural research or federal partnerships through a funding or other agreement (e.g., a grant or contract), several laws allow for nonfederal institutions to seek and gain primary ownership of

⁹⁴ See section on “Publicly Funded Research and Pharmaceutical Drug Development” in CRS Report R41705, *The National Institutes of Health (NIH): Background and Congressional Issues*.

⁹⁵ 35 U.S.C. §§ 207-209.

⁹⁶ For federal agency information, see NIH Office of Intramural Research Office of Technology Transfer, “Reports/Stats,” <https://www.ott.nih.gov/> and National Institute of Standards and Technology (NIST), “Federal Laboratory (Interagency) Technology Transfer Summary Reports,” [nist.gov/tpo/reports-and-publications/annual-reports](https://www.nist.gov/tpo/reports-and-publications/annual-reports). Commentary on transparency around drug patents: Arti K. Rai and Bhaven N. Sampat, “Accountability in Patenting of Federally Funded Research,” *Nature Biotechnology*, vol. 30 (10 2012), pp. 953-956.

⁹⁷ U.S. Government Accountability Office, *Biomedical Research: NIH Should Publicly Report More Information about the Licensing of its Intellectual Property*, GAO-21-52, November 20, 2020, <https://www.gao.gov/products/GAO-21-52>.

patents to inventions developed in the course of federally funded or supported research.⁹⁸ Given that much of federal health research funding is extramural, patents or inventions held by extramural research institutions account for a greater share of public sector inventions used in pharmaceutical drugs than those held by federal agencies discussed above. Various studies have sought to measure and characterize the number of new drugs that originated from or were invented through publicly funded research (including both intramural and extramural federal research as well as nonfederal public research, depending on the study). Some studies have focused on drugs covered by patents held by publicly funded research institutions. Other studies sought to characterize critical intellectual contributions to new drugs beyond patents—particularly to account for issues with underreporting of government funding on patent information or because publicly funded researchers do not always seek patents for inventions derived from their research, among other factors.⁹⁹

Table 3 provides an overview of five studies that assessed direct contributions of public sector research institutions to new pharmaceutical drugs—mostly in the form of patents—but some also accounted for other direct involvement in development or discovery of a specific drug.¹⁰⁰ Most of the studies focused on new molecular entities (NMEs, i.e., new chemical compounds that FDA had not previously approved) approved by FDA within the study period, though the Stevens et al. study also explored all FDA-approvals (e.g., existing drugs for new clinical indications or uses). In summary, the studies generally show that when looking at mostly patents, about 9%-14% of drugs approved in recent decades (the percentage varies by time period and definition used) involve a patent or other critical intellectual property linked to a public sector research institution or publicly funded researcher, as shown in the Sampat and Lichtenberg (2011), Stevens et al., (2011), Long (2019), and Clearly et al. (2020) studies. When looking more broadly, as in the Nayak et al. (2019) study, about 25% of all FDA-approved drugs in recent decades were developed with public sector contributions (accounting for “spin-off” companies based on public sector research). The studies use different definitions for public sector research, characterizations of public sector research contributions to new drugs, and time periods; therefore, the studies are not directly comparable.

Table 3. Findings from Studies on Direct Public Sector Contributions to New Drugs

Presented in order of publication date

| Study | Time Period and Selection Criteria | Definition of “Public Sector Research Contribution” Used | Drugs Linked to Public Sector Contribution |
|------------------------------|------------------------------------|--|--|
| Sampat and Lichtenberg, 2011 | Drugs approved from 1988 to 2005 | Patents assigned to a government agency or with government interest statements (public sector patent). | 34 out of 379 (9.0%) new molecular entities (NME) approved by FDA. |

⁹⁸ CRS Legal Sidebar LSB10422, *COVID-19 Medical Countermeasures: Intellectual Property and Affordability*.

⁹⁹ Arti K. Rai and Bhaven N. Sampat, “Accountability in Patenting of Federally Funded Research,” *Nature Biotechnology*, vol. 30 (10 2012), pp. 953-956, and Rahul K Nayak, Jerry Avorn, and Aaron S. Kesselheim, “Public Sector Financial Support for Late-Stage Discovery of New Drugs in the United States,” *The BMJ*, vol. 367, no. 15766 (September 23, 2019).

¹⁰⁰ These studies were identified through a CRS literature review. They are shown to reflect findings based on different study methodologies, but may not comprehensively reflect all relevant studies.

| Study | Time Period and Selection Criteria | Definition of “Public Sector Research Contribution” Used | Drugs Linked to Public Sector Contribution |
|---------------------------------|--|---|--|
| Stevens et al., 2011 | Drugs approved from 1990 to 2007 | Public sector research institution (universities, research hospitals, etc.) solely or jointly created intellectual property specific to the drug, mostly but not entirely in the form of patents. | 143 out of 1541 (9.3%) of all FDA-approved drugs. 64 of 483 (13.6%) of NMEs. |
| Long, 2019 | Top-selling drugs in the United States from 2013 to 2017 (based on sales data) | Top-selling drugs from 2013-2017 (based on sales data) assigned to government agency or government interest statement | 20 of 197 (10.2%) of top-selling drugs (2013-2017) with patents listed in the Annual Editions of the FDA Orange Book for the period of 1985–2016. |
| Nayak et al., 2019 | Drugs approved from 2008 to 2017 | Major research contribution in late stage of development: public sector patent, or late stage development occurred in public sector research based on analysis of development history. Also included drugs developed in “spin-off” companies that originated from public sector research. | 48 of 248 (19%) of FDA-approved drugs containing NMEs had major public sector research contributions late in development. 14 of 248 (6%) were developed by spin-off companies based “wholly or in part” on publicly supported research. |
| Cleary et al., 2020 [pre-print] | Drugs approved from 2010 to 2019 | Drugs with patents listed in FDA’s Orange Book associated with NIH-funded projects and acknowledged in publications on the NME or biological target. | 27 of 256 (8.7%) of FDA-approved drugs containing NMEs. |

Source: Bhaven B. Sampat and Frank R. Lichtenberg, “What are the Respective Roles of the Public and Private Sectors in Pharmaceutical Innovation?,” *Health Affairs*, vol. 30, no. 2 (2011), pp. 332-339; Ashley J. Stevens, Jonathan J. Jensen, and Katrine Wyller, “The Role of Public-Sector Research in the Discovery of Drugs and Vaccines,” *New England Journal of Medicine*, vol. 364 (February 2011), pp. 535-541; Genia Long, “Federal Government-Interest Patent Disclosures,” *Journal of Medical Economics*, vol. 22, no. 12 (2019), pp. 1261-67; Rahul K. Nayak, Jerry Avorn, and Aaron S. Kesselheim, “Public Sector Financial Support for Late-Stage Discovery of New Drugs in the United States,” *The BMJ*, vol. 367, no. 15766 (September 23, 2019); and Ekaterina Galkina Cleary, Matthew J. Jackson, and Fred D. Ledley, “Government as the First Investor in Biopharmaceutical Innovation: 2010-2019,” *Institute for New Economic Thinking- Working Papers*, August 5, 2020.

Notes: The studies use different definitions for public sector research, characterizations of public sector research contributions to new drugs, and time periods; therefore, the studies are not directly comparable.

Public sector contributions to “innovative” drugs. Several studies have focused on the relative contribution of public sector research in developing the most “innovative” subset of drugs, characterized either as drugs that meet a previously unmet medical or health need or that have been determined to have a groundbreaking effect on patient care. For example, several studies explore the proportion of drugs developed by public sector researchers that received FDA priority review—a mechanism for expediting the review of certain drugs that treat serious conditions and

would provide a significant improvement in safety or effectiveness.¹⁰¹ The Stevens et al. 2011 study (see **Table 3**) found that 46% of new drug applications (NDAs) for drugs developed at public sector research institutions from 1990 to 2007 received priority review by the FDA, compared with 20% of NDAs for drugs developed solely by the private sector.¹⁰² A 2014 study on the NIH intramural research program found that 94% of drugs licensed by NIH intramural researchers had received FDA priority review (17 NDAs total).¹⁰³ These studies are consistent with the view that public sector contributions are particularly important for innovative drugs.

Some studies have focused on the public sector's role in developing a subset of drugs with the greatest health impact. A 2015 study focused solely on the public sector's role in "transformative" drug development from 1984 to 2009. The researchers defined a transformative drug as both innovative and having a groundbreaking effect on patient care, identified by surveying physicians from the top 30 U.S. academic medical centers. The researchers focused on 21 drugs and five drug classes that were identified as transformative and followed their development history through FDA documents and interviews with scientists and drug developers. The authors found that academic researchers played a central role in developing most of these transformative drugs, often by conceptualizing a therapeutic approach in basic research or by jointly developing the drug with commercial institutions.¹⁰⁴

Total direct and indirect contribution of publicly funded research to drug development.

Given that much of publicly funded research is basic research that indirectly aids in the development of new drugs, a few studies have aimed to ascertain the total impact of NIH funding on drug development (accounting for both direct and indirect contributions). A 2020 study found that NIH research funding contributed to every NME approved by the FDA from 2010 to 2019. The study determined that the 356 new drugs approved by the FDA, as well as their biological targets, in this time period were associated with a body of research comprising 2 million publications—494,000 of which were supported by NIH. The total NIH funding contribution to this body of research was determined to be \$230 billion.¹⁰⁵ Another 2019 study used patenting as an economic measure for the impact of NIH research funding on industry productivity from 1980 through 2012. The study determined that NIH investments in a particular research area increase subsequent private-sector patenting: a \$10 million increase in NIH funding for a given research area ultimately resulted in 2.7 additional patents. Alternatively phrased, one private-sector patent ultimately results from every two to three NIH grants. Though the authors faced difficulty measuring the economic value of such patents, they stated that "one rough calculation suggests that \$1 in NIH funding generates around \$2.34 in drug sales."¹⁰⁶

¹⁰¹ FDA, "Expedited Programs for Serious Conditions – Drugs and Biologics," Guidance for Industry, May 2014, pp. 24-25, <https://www.fda.gov/media/86377/download>. Specific statutory provisions may qualify drugs for priority review in other cases.

¹⁰² Priority review means that FDA aims to take action on an NDA 6 months after filing, compared to 10 months for standard review. Ashley J. Stevens, Jonathan J. Jensen, and Katrine Wyller, "The Role of Public-Sector Research in the Discovery of Drugs and Vaccines," *New England Journal of Medicine*, vol. 364 (February 2011), pp. 535-541.

¹⁰³ Sabarni K. Chatterjee and Mark L. Rohrbach, "NIH Inventions Translate to Drugs and Biologics with High Public Health Impact," *Nature Biotechnology*, vol. 32, no. 1 (January 2014), pp. 52-58.

¹⁰⁴ Aaron S. Kesselheim, Yongtian T. Tian, and Jerry Avorn, "The Roles Of Academia, Rare Diseases, And Repurposing In the Development of The Most Transformative Drugs," *Health Affairs*, vol. 34, no. 2 (2015), pp. 286-293.

¹⁰⁵ Ekaterina Galkina Cleary, Matthew J. Jackson, and Fred D. Ledley, "Government as the First Investor in Biopharmaceutical Innovation: 2010-2019," *Institute for New Economic Thinking - Working Papers*, August 5, 2020.

¹⁰⁶ Pierre Azoulay, Joshua S. Graff Zivin, Danielle Li, et al., "Public R&D Investments and Private-Sector Patenting: Evidence from NIH Funding Rules," *Review of Economic Studies*, vol. 86 (2019), pp. 117-152.

How Much Does It Cost to Develop New Drugs?

Although publicly traded pharmaceutical manufacturers release aggregate research and development (R&D) spending information, detailed information about the cost of developing specific drugs is generally not available. Many institutions (academic and nongovernmental organizations) have attempted to estimate the average R&D spending for a single representative FDA-approved drug. Different methodologies for the studies have led to conflicting estimates of drug R&D expenditures at every stage of drug development. Commonly cited estimates include the following:

- A 2016 Tufts Center for the Study of Drug Development report, based on proprietary data on 106 products from 10 large drug manufacturers, estimated that the pretax and preapproval cost of developing an FDA-approved prescription drug was \$2.6 billion, which included \$1.4 billion in clinical spending and \$1.2 billion in time costs (2013 dollars), where time costs were defined as “the cost of the delay between when R&D expenditures are incurred and when returns to the successes can first be realized (date of marketing approval).”¹⁰⁷
- A 2016 HHS study noted that estimates for new drug development range from \$1.2 billion to \$2.6 billion per drug and are highly sensitive to factors such as assumptions about development time, cost of capital, and whether the study includes orphan drugs, which are likely to have smaller trial sizes, higher success rates and which receive special federal tax breaks.¹⁰⁸
- A 2020 paper from the *Journal of the American Medical Association* (JAMA) found that the median capitalized R&D investment was estimated at \$985.3 million, and the mean investment was estimated at \$1,335.9 million, using publicly available industry financial and clinical trial data. These estimates changed based on the therapeutic area evaluated (e.g., nervous system agents differed from immunomodulating agents). As with the Tufts study, the authors accounted for the costs of failed trials and the time cost for development.¹⁰⁹

The different estimates reflect differences in the types of data used and study methodology. They also underscore the difficulty in measuring industry drug development costs. The 2016 estimate from Tufts Center for the Study of Drug Development, a partially industry backed initiative,¹¹⁰

¹⁰⁷ Joseph A. DiMasi, Henry G. Gabrowski, and Ronald W. Hansen, “Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs,” *Journal of Health Economics*, vol. 47 (2016), pp. 20-33. The study was based on data provided by 10 pharmaceutical companies on 106 randomly selected drugs that were first tested in human subjects anywhere in the world from 1995 to 2007. The figure rises to \$2.9 billion when FDA-mandated post-approval costs (such as additional testing and monitoring) are added, according to Tufts.

¹⁰⁸ HHS, *Prescription Drugs: Innovation, Spending and Patient Access*, Chapter 2, December 7, 2016, at <http://apps.who.int/medicinedocs/en/m/abstract/Js23128en/>. Also see FDA “Developing Products for Rare Diseases & Conditions,” at <http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/ucm2005525.htm>.

¹⁰⁹ Olivia Wouters, Martin McKee, and Jeroen Luyten, “Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018,” *Journal of the American Medical Association*, vol. 323, no. 9 (March 3, 2020), pp. 844-853.

¹¹⁰ See Tufts Center for the Study of Drug Development, “Financial Disclosure,” 2021, <https://csdd.tufts.edu/financial-disclosure>. “The Tufts Center for the Study of Drug Development (Tufts CSDD) at Tufts University School of Medicine is an independent, academic, nonprofit research center. Tufts CSDD receives unrestricted grants from pharmaceutical and biotechnology firms, as well as companies that provide related services to the research-based industry (e.g., contract research, consulting, and technology firms). These grants represent approximately 25% of Tufts CSDD’s operating expenses. The remainder comes from government and foundation support, grants for commissioned projects, registration fees for courses and conferences, and subscription fees for Tufts CSDD publications. Sponsoring

used data from 10 manufacturers to estimate R&D spending, based on the manufacturers' out-of-pocket clinical trial costs of drug development and time costs of development. The former cost is inclusive of the cost of compounds discontinued at any point during animal or human clinical trials (e.g., due to drug failure), while the second cost represents the “cost of the delay between when R&D expenditures are incurred and when returns to the successes can first be realized (date of marketing approval).”¹¹¹ The 2016 figure is an update of previous studies by the same authors, including a 2002 analysis that estimated the total cost at \$1.046 billion, and a 1991 study that estimated the total cost at \$415 million (in comparable 2013 dollars). The Tufts group concluded that these increases in R&D costs were due to “increases in the real out-of-pocket costs of development for individual drugs and by much higher failure rates for drugs that are tested in human subjects, but not particularly by changes in development times or the cost-of-capital.” The study indicates that the cost of developing a new drug has risen in the past few decades. Some observers attribute this increase, at least in part, to increased length and costs of both preclinical and clinical research,¹¹² while other researchers have found that length of clinical testing has remained stable over time. For example, Darrow et al. (2020) found that from 1983 through 2017, the time from the authorization of clinical testing to FDA approval remained at approximately eight years.¹¹³

Some experts and observers have questioned or critiqued the Tufts study's estimates, including its assumptions, small sample size, and lack of transparency about data used for analysis.¹¹⁴ Some have additionally criticized the integrity of the estimates given the fact the organization is partially funded by pharmaceutical industry partners, and its estimates are occasionally referenced by pharmaceutical firms to justify drug prices.¹¹⁵ Many also note that the estimates do not account for tax credits and deductions for R&D costs, such as the federal R&D tax credit or the Orphan Drug Tax credit.¹¹⁶ While detailed data on the use of R&D-related tax credits are not available, CRS analysis suggests that it can be significant—resulting in negative tax rates for

companies have no direct access to any of the Tufts Center's proprietary databases. Whereas sponsoring companies, regulators, academics, and others outside of Tufts CSDD may suggest topics for investigation, the research agenda of Tufts CSDD is set by the group's director and its research staff.”

¹¹¹ Joseph A. DiMasi, Henry G. Grabowski, and Ronald W. Hansen, “Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs,” *Journal of Health Economics*, vol. 47 (2016), pp. 20-33. The study was based on data provided by 10 pharmaceutical companies on 106 randomly selected drugs that were first tested in human subjects anywhere in the world from 1995 to 2007.

¹¹² Stuart O. Schweitzer and Z. John Lu, “Chapter 1: The Industry,” in *Pharmaceutical Economics and Policy: Perspectives, Promises, and Problems*, 3rd ed. (New York, NY: Oxford University Press, 2018), p. 47.

¹¹³ Johnathan Darrow, Jerry Avon, and Aaron Kesselheim, “FDA Approval and Regulation of Pharmaceuticals, 1983-2018,” *Journal of the American Medical Association*, vol. 323, no. 2 (January 14, 2020), pp. 164-179.

¹¹⁴ Vinay Prasad and Sham Mailankody, “Research and Development Spending to Bring a Single Cancer Drug to Market and Revenues After Approval,” *JAMA Intern Med*, vol. 177, no. 11 (2017), pp. 1569-1575; Narcyz Ghinea, Wendy Lipworth, and Ian Kerridge, “Propaganda or the Cost of Innovation? Challenging the High Price of New Drugs,” *BMJ*, March 11, 2016; and Stuart O. Schweitzer and Z. John Lu, “Chapter 1: The Industry,” in *Pharmaceutical Economics and Policy: Perspectives, Promises, and Problems*, 3rd ed. (New York, NY: Oxford University Press, 2018), p. 47-48.

¹¹⁵ See, for example, *New York Times*, “\$2.6 Billion to Develop a Drug? New Estimate Makes Questionable Assumptions,” press release, November 18, 2014, <https://www.nytimes.com/2014/11/19/upshot/calculating-the-real-costs-of-developing-a-new-drug.html>.

¹¹⁶ Wendy Lipworth, and Ian Kerridge, “Propaganda or the Cost of Innovation? Challenging the High Price of New Drugs,” *BMJ*, March 11, 2016, and Aaron E. Carroll, “\$2.6 Billion to Develop a Drug? New Estimates Makes Questionable Assumptions,” *New York Times*, November 18, 2014, <https://www.nytimes.com/2014/11/19/upshot/calculating-the-real-costs-of-developing-a-new-drug.html>.

pharmaceutical manufacturers in some cases.¹¹⁷ A 2017 GAO report also found rising use of both tax credits by the industry in recent years.¹¹⁸

In the more recent 2020 JAMA study, the authors used U.S. Securities and Exchange Commission (SEC) filings, the Drugs@FDA database, and ClinicalTrials.gov, alongside published data on clinical trial success rates to evaluate the mean and median R&D investment to bring a new drug to market.¹¹⁹ The authors noted that SEC filings are not available for “private US drug firms and foreign companies listed on non-US stock exchanges.” Products from these firms were thus excluded from the study estimates. Even if a firm did file with the SEC, however, this did not guarantee precise R&D data. For example, some firms reported aggregate R&D expenditures across all their drug candidates or therapeutic areas, instead of detailing individual drug candidates. An additional data barrier is that “certain companies only started tracking costs at late stages of preclinical development or at the start of phase I of development, resulting in an underreporting of preclinical costs.” The authors noted that the combination of these factors most likely led to “an overrepresentation of smaller firms, which may have run leaner operations than larger ones,” and thus may lead to a lower estimate of total development costs. The study authors used statistical methods to try to adjust for these issues.

The 2020 JAMA study noted that differences in its conclusions from previous studies could be explained by “the spectrum of products analyzed, the restricted availability of data in the public domain, and differences in underlying assumptions in the cost calculations.”¹²⁰ This JAMA study and the Tufts study both point out that difficulties in estimating R&D costs are primarily due to issues of transparency in drug development costs. The Tufts study notes that “some firms were not able to provide full phase cost data for every new drug sampled.” Phase I data in particular was missing most often, compared proportionally with Phase II and III reporting.¹²¹ The authors conclude that the result of this data gap is that their “cost estimates are likely to be somewhat conservative.” The JAMA study notes that in addition to SEC reporting issues, not every pharmaceutical firm records “cost” in the same way. For example, some firms choose to include overhead, administrative costs, and preclinical costs in their figures for direct R&D spending, while others separate out two or all of these as distinct line items.¹²² Still others report “costs associated with licensing deals, drug acquisitions, and collaboration agreements differently,”¹²³ leading to further complications in analysis of industry data and increased likelihood that such analysis will be inconsistent with real values.

¹¹⁷ See CRS Report R44522, *A Patent/Innovation Box as a Tax Incentive for Domestic Research and Development*, and CRS Report R45186, *Issues in International Corporate Taxation: The 2017 Revision (P.L. 115-97)*.

¹¹⁸ U.S. Government Accountability Office, *Drug Industry: Profits, Research and Development Spending, and Merger and Acquisition Deals*, GAO-18-40, November 2017, <https://www.gao.gov/assets/690/688472.pdf>.

¹¹⁹ Olivia Wouters, Martin McKee, and Jeroen Luyten, “Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018,” *Journal of the American Medical Association*, vol. 323, no. 9 (March 3, 2020), pp. 844-853.

¹²⁰ *Ibid.*

¹²¹ Joseph A. DiMasi, Henry G. Gabrowski, and Ronald W. Hansen, “Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs,” *Journal of Health Economics*, vol. 47 (2016), pp. 20-33. “[P]hase I cost data were available for 97 of the 106 new drugs in the dataset (92%). Of the 82 compounds in the dataset that had entered phase II, cost data were available for 78 (95%). For phase III, cost data were available for 42 of the 43 compounds that entered the phase (98%).”

¹²² Olivia Wouters, Martin McKee, and Jeroen Luyten, “Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018,” *Journal of the American Medical Association*, vol. 323, no. 9 (March 3, 2020), pp. 844-853.

¹²³ *Ibid.*

A 2017 report by GAO examined aggregate pharmaceutical industry spending on R&D. This report found that on average, R&D spending by the entire industry increased from 2008 to 2014. This increase represented an 8% change, from \$82 billion to \$89 billion, respectively.¹²⁴ At the same time as spending on R&D increased, however, the amount of R&D conducted within individual firms fell, and the amount of R&D paid for by the company and conducted by others (“purchased R&D services”)¹²⁵ increased. Many of the pharmaceutical firms surveyed in this report described a decrease over time in NIH spending on biomedical research as one of the driving factors of increasing development costs.¹²⁶ A 2021 Congressional Budget Office (CBO) publication also examined pharmaceutical industry spending on R&D, and found that in 2019 this number was \$83 billion.¹²⁷ This report indicates this number is nearly a 10 times real dollar value increase from the 1980 value. This change was accompanied by increases in the share of manufacturer revenue invested back into R&D and an increase in the number of new drugs approved by the FDA.

Transparency and more standardized accounting and reporting practices could allow for a better understanding of industry R&D spending to develop new drugs. Legislation has in the past been proposed to require detailed manufacturer reporting of pharmaceutical R&D,¹²⁸ but it is unclear how successful such efforts could be. As such, Congress may consider additional legislative action directed toward increasing transparency in pharmaceutical firm reporting. Congress may also consider specifying what costs should and should not be included in R&D figures reported in SEC filings, so that reporting may be uniform across pharmaceutical firms.

Is There a Relationship Between Development Costs and Drug Prices?

Many analyses have noted the lack of a relationship between the cost to develop a specific drug and its price.¹²⁹ Some experts contend there is strong economic evidence that drug prices are primarily influenced by demand-side factors—such as availability and price of competing or generic drugs for the same clinical indication, the size of the patient population, and drug payment or price regulation policies. Supply-side factors, such as the cost to develop drugs, are not as strongly associated with drug prices. This is because the cost to develop a drug is incurred

¹²⁴ U.S. Government Accountability Office, *DRUG INDUSTRY: Profits, Research and Development Spending, and Merger and Acquisition Deals*, GAO-18-40, November 17, 2017, <https://www.gao.gov/assets/690/688472.pdf>. These values were calculated based on “worldwide R&D spending by U.S.-owned pharmaceutical companies and U.S.-based R&D by foreign companies.” This 8% change was based on a real-dollar calculation (which accounts for inflation).

¹²⁵ *Ibid.*

¹²⁶ *Ibid.* GAO found that direct federal spending on biomedical research, primarily through NIH, aggregately decreased from “\$27 billion in fiscal year 2008 to \$26 billion in fiscal year 2014, after a peak of \$32 billion in 2010.” The 2014 value is 3.8% less than the 2008 value, and the calculation was based on real-dollar amounts (accounting for inflation).

¹²⁷ David Austin and Tamara Hayford, *Research and Development in the Pharmaceutical Industry*, Congressional Budget Office, April 2021, https://www.cbo.gov/publication/57126#_idTextAnchor036.

¹²⁸ H.R. 1391. See, for example, S. 1801 (116th Congress) Section 101, Drug Manufacturer Reporting. This would require drug manufacturers to submit annual reports to the HHS Secretary and to Congress their itemized R&D costs, including such costs related to marketing, preclinical research, and patenting and licensing.

¹²⁹ Salomeh Keyhani, Marie Diener-West, and Neil Powe, “Are Development Times for Pharmaceuticals Increasing or Decreasing?,” *Health Affairs*, vol. 25, no. 2 (March/April 2006), pp. 461-468; Sydney Costantini and Rochelle P. Walensky, “The Costs of Drugs in Infectious Diseases: Branded, Generics, and Why We Should Care,” *The Journal of Infectious Diseases*, March 19, 2019, pp. 1-7; and Vinay Prasad and Kevin R. De Jesus-Morales, “The High Price of Anticancer Drugs: Origins, Implications, Barriers, Solutions,” *Nature Reviews Clinical Oncology*, October 2017.

before a drug is ever sold, and therefore represents a “sunk cost” to the company.¹³⁰ CBO notes that such sunk costs (already incurred in developing the drug) do not influence drug prices; instead, “when drug companies set the prices of a new drug, they do so to maximize *future* revenues net of manufacturing and distribution costs.”¹³¹

A 2017 GAO report on drug development costs identifies market factors associated with drug prices.¹³² The report notes that the biggest factor influencing drug prices is the level of competition that a given drug may face. For example, based on economic principles of supply and demand, a brand-name drug with little or no competition essentially experiences more “inelastic demand,” where there are few or no alternatives (less competition), and these products are often able to be priced at the discretion of the pharmaceutical firm. Brand-name drugs with competition (i.e., therapeutic alternatives for treating the same condition) and/or generic drugs, on the other hand, may experience more “elastic demand,” where there are many alternatives (more competition) so products are priced based on consumer willingness to pay for a particular therapeutic and the prices of substitutable products.¹³³ This pricing consideration is described in GAO’s 2017 report, which states that

[b]rand-name companies producing drugs under patent or exclusivity protection have monopoly pricing power unless alternative drugs that treat the same condition are available. For brand-name products that face competition from such therapeutic alternatives, companies compete on price, differentiation from competitors, or both.¹³⁴

Generic drugs, on the other hand, compete with other brand-name and generic alternatives primarily on the basis of price when they are first introduced to a market. For these generic drugs, price tends to fall as more competitors enter the market. A 2019 FDA report further describes this phenomenon, finding that after the entry of a generic product to market, as competition increases, generic prices decrease.¹³⁵ This phenomenon is more pronounced based on the number of drug competitors in the generic market, such that the more competitors enter the market, the lower the generic Average Manufacturing Price (AMP) will be compared with brand drug prices.¹³⁶ This study found that

¹³⁰ Stuart O. Schweitzer and Z. John Lu, “The Pharmaceutical Industry,” in *Pharmaceutical Economics and Policy: Perspectives, Promises, and Problems*, 3rd ed. (New York, NY: Oxford University Press, 2018), pp. 8-11; and David H. Howard, Peter B. Bach, Ernst R. Berndt, et al., “Pricing in the Market for Anticancer Drugs,” *Journal of Economic Perspectives*, vol. 29, no. 1 (Winter 2015), pp. 139-162.

¹³¹ David Austin and Tamara Hayford, *Research and Development in the Pharmaceutical Industry*, Congressional Budget Office, April 2021, https://www.cbo.gov/publication/57126#_idTextAnchor036.

¹³² U.S. Government Accountability Office, *DRUG INDUSTRY: Profits, Research and Development Spending, and Merger and Acquisition Deals*, GAO-18-40, November 17, 2017, <https://www.gao.gov/assets/690/688472.pdf>.

¹³³ Other things equal, given two equally substitutable products, consumers are more likely to purchase the cheaper commodity.

¹³⁴ U.S. Government Accountability Office, *DRUG INDUSTRY: Profits, Research and Development Spending, and Merger and Acquisition Deals*, GAO-18-40, November 17, 2017, <https://www.gao.gov/assets/690/688472.pdf>.

¹³⁵ Ryan Conrad and Randall Lutter, *Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices*, Food and Drug Administration, Silver Spring, MD, December 2019, <https://www.fda.gov/media/133509/download>. This study evaluated “average manufacturer prices (AMP) reported to the Centers for Medicare and Medicaid Services (CMS) and invoice-based wholesale prices reflecting pharmacy acquisitions from IQVIA’s National Sales Perspective database (NSP)” to draw conclusions on generic drug pricing relative to increases in competition.

¹³⁶ The average manufacturer price (AMP) is the average price paid to the manufacturer by wholesalers for drugs distributed to retail community pharmacies. The AMP, which is used for payment purposes in the federal Medicaid program, is a statutory measure that is calculated based on actual sales transactions. The AMP is defined at 42 CFR §447.504.

for products with a single generic producer, the generic AMP is 39% lower than the brand AMP before generic competition, compared to a 31% reduction using invoice prices. With two competitors, AMP data show that generic prices are 54% lower than the brand drug price before generic competition, compared to 44% when calculated using invoice-based drug prices. With four competitors, AMP data show that the generic prices are 79% less than the brand drug price before generic entry, compared to 73% when calculated using invoice-based drug prices. With six or more competitors, generic prices using both AMP and invoice prices show price reductions of more than 95% compared to brand prices.¹³⁷

Competition in biologics markets may behave differently than in small molecule prescription drug markets, in part, due to differing regulatory requirements.¹³⁸ Generic drugs need only prove bioequivalence to an existing brand name product to receive FDA approval.¹³⁹ This circumvents the need to conduct expensive clinical trials. In contrast, generic biological products, called biosimilars, typically must undergo clinical trials to prove biosimilarity to an existing brand-name biologic. In addition, a generic drug is presumed to be therapeutically equivalent to, and thus interchangeable with, the brand-name drug of which it is a copy. All states have enacted laws that allow or require a pharmacist to substitute a generic for the brand-name drug without the intervention of the prescriber. A biosimilar, however, is not structurally identical to the brand-name biologic, and assessing interchangeability is a separate and more demanding process, which may come at a significant expense to a firm. To date, FDA has not approved any interchangeable biosimilars.¹⁴⁰ Given these considerations, market entry of biosimilars may not result in the same price decreases as seen with generic drugs.

Along with market competition, various other factors contribute to prescription drug competition and thus prices, including raw material shortages, the market demand for the drug (e.g., size of patient population), FDA review times, and consolidation among drug manufacturers and buyers (such as retail pharmacies), among others.¹⁴¹ There is some evidence that the relationship between drug pricing and drug development is bidirectional, meaning that overall drug prices may also influence industry R&D investments. For example, a 2005 paper found that a “10 percent increase in the growth of real drug prices is associated with nearly a 6 percent increase in the growth of R&D intensity.”¹⁴² This paper used both a theoretical microeconomic model and publically unavailable pharmaceutical R&D data, reported in the aggregate and not by individual firms,¹⁴³ from the Pharmaceutical Research and Manufacturers Association (PhRMA, pharmaceutical industry association). This theoretical model was based in part on the authors’ observation that “the variable costs of manufacturing drugs are very low. The sunk costs

¹³⁷ Ibid.

¹³⁸ Compared with small molecule drugs, which are typically chemically synthesized, biologics are relatively large and complex molecules. They may be composed of proteins (and/or their constituent amino acids), carbohydrates (such as sugars), nucleic acids (such as DNA), or combinations of these substances.

¹³⁹ CRS Report R46221, *Drug Pricing and Pharmaceutical Patenting Practices*, coordinated by Kevin T. Richards.

¹⁴⁰ See CRS Report R44620, *Biologics and Biosimilars: Background and Key Issues*, by Agata Bodie.

¹⁴¹ U.S. Government Accountability Office, *Generic Drugs Under Medicare: Part D Generic Drug Prices Declined Overall, but Some Had Extraordinary Price Increases*, 16-706, August 12, 2016, <https://www.gao.gov/products/gao-16-706>.

¹⁴² Carmelo Giaccotto, Rexford E. Santerre, and John A. Vernon, “Drug Prices and Research and Development Investment Behavior in the Pharmaceutical Industry,” *Journal of Law and Economics*, vol. 48, no. 1 (April 2005), pp. 195-214. The authors define R&D intensity as “pharmaceutical R&D expenditure as a percentage of sales.”

¹⁴³ Ibid. The authors write, “These R&D data are a measure of comprehensive R&D outlays and include the domestic and foreign R&D expenditures of U.S.-owned PhRMA member companies, the domestic (U.S.) R&D expenditures of foreign-owned PhRMA member companies, and the foreign R&D expenditures made by the U.S. divisions of non-U.S.-owned PhRMA member companies.”

associated with R&D make up a large proportion of overall costs; thus, rising drug prices reflect growing profit margins and greater internal cash flow, where, “[i]nternal cash flow represents a major source of financing for R&D.”¹⁴⁴ The results of this study support the conclusion that drug prices have a direct influence on R&D spending by industry.

Any analysis involving drug prices in the United States is complicated by many factors, the first of which is that list pricing does not always reflect what is actually paid for the drug. This is because wholesalers, retailers, and payers may receive rebates or discounts from manufacturers at different points along the distribution chain.¹⁴⁵ This consideration is similar to that of drug development, in that the lack of transparency in drug pricing may inhibit understanding of actual prices paid by consumers.

As part of the Consolidated Appropriations Act, 2021, Congress required commercial health plans to report information on prescription drug costs to the federal government.¹⁴⁶ Additional action through so-called transparency legislation, however, is being debated in Congress and a number of state legislatures (see “What Are U.S. States Doing to Address Drug Costs?”). This legislation would compel drug makers to provide data about research, marketing, and other costs for drugs that have a high price or have experienced a large price increase.¹⁴⁷ Price transparency legislation assumes a direct relationship between a drug’s development cost and its resulting price. Given that demand-side factors (competition) are considered more indicative of drug development prices, transparency legislation may shed some light on the business model of pharmaceutical companies, but may not be as useful in understanding the pricing rationale for a specific drug.¹⁴⁸

Can the FDA Regulate Prescription Drug Prices?

The FDA, pursuant to its authorities under the Federal Food, Drug, and Cosmetic Act (FFDCA) and the Public Health Service Act (PHSA), regulates the marketing of drugs (including biological products or biologics) in the United States.¹⁴⁹ Before a new drug can be marketed, it must be approved by the FDA. To obtain approval, a manufacturer must submit an application for marketing approval (i.e., a new drug application [NDA], an abbreviated NDA [ANDA], or a biologics license application [BLA]). A marketing application includes the required clinical data on a drug’s safety and effectiveness (or in the case of a generic drug, bioequivalence data),

¹⁴⁴ The authors specifically note that, “internal cash flow represents a major source of financing for R&D given external capital market imperfections such that the cost of using internal funds tends to be less than that of acquiring external funds.”

¹⁴⁵ The Medical Letter on Drugs and Therapeutics, “Prescription Drug Prices in the US,” *JAMA Network*, vol. 319, no. 10 (March 13, 2018), pp. 1042-1043.

¹⁴⁶ P.L. 116-260. See “Reporting on Pharmacy Benefits and Drug Costs” in Section 204 of Title II of Division BB in the Consolidated Appropriations Act, 2021.

¹⁴⁷ For example, S. 1391 (116th Congress), which would have required drug manufacturers to notify the HHS Secretary and provide cost data before increasing the price of certain drugs by more than 10%. In states, see National Conference of State Legislatures, “Recent Approaches and Innovations in State Prescription Drug Laws,” at <https://www.ncsl.org/research/health/rx-costs.aspx>.

¹⁴⁸ For more information on drug pricing, see CRS Report R46221, *Drug Pricing and Pharmaceutical Patenting Practices*, coordinated by Kevin T. Richards.

¹⁴⁹ FDA approves drugs under the authority of the FFDCA and licenses biologics under the authority of the PHSA. Biologics are subject to most FFDCA drug provisions, and FDA regulations often consider drugs and biologics together and refer to the group as *drugs*.

information about manufacturing procedures (supported by FDA inspection), and proposed labeling.¹⁵⁰

The FFDCA, PHSa, and FDA regulations specify the required contents of a premarket application,¹⁵¹ provide for the conditions under which the FDA may deny approval of an application,¹⁵² and prohibit certain acts with respect to drugs.¹⁵³ FDA law and regulations do not expressly require an application to include information about a drug's price, do not authorize FDA to deny approval of an application because of price, and do not prohibit the marketing of a drug whose price may be considered too high. While the FDA is not explicitly prohibited in statute from requiring drug manufacturers to submit pricing information as part of the approval process, the agency has consistently indicated that it does not have the authority to control or investigate drug prices.¹⁵⁴

Instead, the FDA (and Congress) have attempted to help reduce drug prices indirectly by facilitating competition, specifically by (1) increasing access to generic drugs and (2) decreasing so-called “gaming” of existing statutory and regulatory requirements.¹⁵⁵ For example, the FDA prioritizes review of certain generic drugs, thus allowing lower-priced alternatives onto the market more quickly. In its manual of policies and procedures, the FDA specifies which generic drug applications (i.e., ANDAs) it will prioritize for review, including those for “sole source” drugs or for drugs that are in shortage. The cost of the brand-name drug is not listed as a consideration for prioritization of generic drug review.¹⁵⁶ The FDA also publishes on its website a list of off-patent, off-exclusivity drugs for which there are no approved generics and aims to expedite the review of ANDAs for drugs on this list.¹⁵⁷ However, the generic drugs trade association has noted that the drugs on this list are not necessarily good candidates for development for a variety of reasons, including the capital investment required and low volume of sales because the drug treats a small population or is no longer the standard of care.¹⁵⁸ To further promote competition, the FDA has issued a final rule and guidance to allow for the importation of certain drugs intended for foreign markets. As described in the next section, the

¹⁵⁰ See, in particular, FFDCA §§505 (new drugs), 501 (adulteration), and 502 (misbranding), as well as PHSa §351. For an easier-to-read description, see CRS Report R41983, *How FDA Approves Drugs and Regulates Their Safety and Effectiveness*, and CRS Report R44620, *Biologics and Biosimilars: Background and Key Issues*.

¹⁵¹ The requirements for an NDA are specified in FFDCA §505(b) and 21 C.F.R. §314.50; the requirements for an ANDA are specified in FFDCA §505(j)(2) and 21 C.F.R. §314.94; and the requirements for a BLA are specified in 21 C.F.R. §601.2 and additional requirements specific to a BLA for a biosimilar are in PHSa §351(k)(2).

¹⁵² The requirements for denial of approval of an NDA are specified in FFDCA §505(d) and 21 C.F.R. §314.125; the requirements for denial of approval of an ANDA are specified in FFDCA §505(j)(4) and 21 C.F.R. §314.127; and the requirements for denial of licensure of a BLA are specified in 21 C.F.R. §601.3 and §601.4.

¹⁵³ Prohibited acts are listed in FFDCA §301.

¹⁵⁴ FDA, Frequently Asked Questions about CDER, <https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/FAQsaboutCDER/default.htm>.

¹⁵⁵ CRS In Focus IF11075, *FDA and Drug Prices: Facilitating Access to Generic Drugs*.

¹⁵⁶ FDA, Center for Drug Evaluation and Research, Office of Generic Drugs, Manual of Policies and Procedures (MAPP) 5240.3 Rev. 4, “Prioritization of the Review of Original ANDAs, Amendments, and Supplements,” <https://www.fda.gov/media/89061/download>.

¹⁵⁷ FDA initially published a list of off-patent, off-exclusivity drugs with no approved generics and announced its intent to expedite the review of ANDAs for drugs on this list until in June 2017 as part of the agency's Drug Competition Action Plan. These actions were codified by Section 801 of the FDA Reauthorization Act of 2017 (FDARA; P.L. 115-52) [FFDCA §505(j)(11) & (12)].

¹⁵⁸ Comments from the Association for Accessible Medicines (AAM) to Docket No. FDA-2017-N-3615: Administering the Hatch-Waxman Amendments: Ensuring a Balance Between Innovation and Access; Public Meeting; Request for Comments, November 17, 2017, pp. 8-9.

importation of unapproved drugs—including unapproved versions of FDA-approved drugs—has generally been prohibited.

The FDA and Congress also have taken action to address alleged practices used by brand companies to delay approval of generic competitors, including misuse of FDA-mandated risk evaluation and mitigation strategies (REMS). The FDA may require a REMS for certain drugs that it otherwise may have kept off the market due to safety risks.¹⁵⁹ As part of a REMS, a drug manufacturer may be required to impose restrictions on a drug’s distribution via one or more elements to ensure safe use (ETASU). A brand drug and its generic must use a single, shared system of ETASU, with some exceptions. The FDCA prohibits a brand company from using ETASU to block or delay approval of a generic application.¹⁶⁰ However, FDA and the Federal Trade Commission (FTC) have reported that some brand companies have used REMS and self-imposed restricted distribution systems to prevent or delay generic drugs from entering the market, primarily by withholding or refusing to sell samples of the brand drug to the generic company for testing.¹⁶¹ Although FDA has attempted to address misuse of REMS through guidance, stakeholders have described these efforts as ineffective.¹⁶² In December 2019, Congress passed legislation creating a private right of action to allow a generic product developer to bring a civil lawsuit against a brand-name drug manufacturer for failing to provide the generic developer with sufficient quantities of the drug on “commercially reasonable, market-based terms.” The law also provides the FDA with additional flexibility to waive the requirement for a single shared system of ETASU.¹⁶³ While the impact of this legislative change is not yet clear, CBO had scored similar legislation, estimating that its enactment would decrease the deficit by \$3.9 billion over 2019-2029.¹⁶⁴

May U.S. Consumers Import Drugs from Abroad?

Under current law, the importation of unapproved drugs, including foreign-made versions of FDA-approved drugs, is generally prohibited, with limited exceptions. As mentioned, before a drug may be sold in the United States, it must be approved by FDA. Because FDA’s premarket approval requirements are so detailed and explicit, no drug that a consumer might import would technically fulfill all the approval elements. (For example, a drug must include labeling that FDA has approved for U.S. sales; the labeling of a physically identical drug packaged for foreign sale would not have the U.S.-relevant packaging codes.) The Prescription Drug Marketing Act of 1987 (PDMA; P.L. 100-293) clarified that even for a drug that FDA had approved for U.S. sales that had been sold or transferred to a foreign country, only the manufacturer of that FDA-approved prescription drug may legally bring the drug back into the United States.¹⁶⁵

¹⁵⁹ FDCA §505-1[21 U.S.C. §355-1].

¹⁶⁰ FDCA §505-1(f)(8) [21 U.S.C. §355-1(f)(8)].

¹⁶¹ For additional information, see CRS In Focus IF11075, *FDA and Drug Prices: Facilitating Access to Generic Drugs*, and CRS Report R44810, *FDA Risk Evaluation and Mitigation Strategies (REMS): Description and Effect on Generic Drug Development*.

¹⁶² Comments from the Association for Accessible Medicines (AAM) to Docket No. FDA-2017-N-3615: Administering the Hatch-Waxman Amendments: Ensuring a Balance Between Innovation and Access; Public Meeting; Request for Comments, November 17, 2017, p. 23.

¹⁶³ §610 of P.L. 116-94; 21 U.S.C. §355-2.

¹⁶⁴ Congressional Budget Office (CBO), H.R. 965, CREATES [Creating and Restoring Equal Access to Equivalent Samples] Act of 2019, https://www.cbo.gov/system/files/2019-05/hr965_Judiciary.pdf.

¹⁶⁵ FDCA §801(d)(1)(A). The law was enacted to reduce the risk of adulterated or subpotent drugs entering the United States after concern about the resale of manufacturer drug samples and other situations. For additional information, see

The FDA has exercised enforcement discretion to permit personal importation of unapproved drugs on a case-by-case basis. As outlined in the agency's personal importation policy (PIP), the FDA generally allows individuals to bring into the United States a 90-day supply of unapproved drugs for personal use where effective treatment is not available in the United States, the drug is for the treatment of a serious medical condition, and there is no commercialization of the drug to U.S. residents.¹⁶⁶ While FDA's PIP is not intended to allow consumers to bring lower-priced prescription drugs into the United States,¹⁶⁷ the policy is used by consumers seeking lower foreign prices for FDA-approved drugs.

Over the years, Congress has introduced legislation that would authorize both personal and commercial importation of unapproved prescription drugs, subject to specified requirements, from countries where they may be less expensive. In the early 2000s, during a period of high prescription drug inflation, Congress enacted the Medicine Equity and Drug Safety Act (MEDS Act; P.L. 106-387), and subsequently the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA; P.L. 108-173), to allow pharmacists and wholesalers to import unapproved versions of FDA-approved prescription drugs from Canada.¹⁶⁸ Despite outlining procedures to do so, the law, in practice, has not allowed such importation. This is because the statute requires that before this provision (FFDCA §804) can take effect, the Secretary must first certify to Congress "that the implementation of this section will (1) pose no additional risk to the public's health and safety; and (2) result in a significant reduction in the cost of covered products to the American consumer."¹⁶⁹ Until recently, no HHS Secretary has been willing to make such certification.

However, on September 23, 2020, former HHS Secretary Alex Azar made the requisite certification in a letter to Congress. HHS and FDA subsequently promulgated a final rule to implement the MEDS Act provision and allow for the importation of certain prescription drugs from Canada, specifically Health Canada-approved versions of U.S.-approved drugs (i.e., drugs marketed under an NDA or ANDA).¹⁷⁰ The rule allows states and tribes to submit so called Section 804 Importation Program (SIP) proposals to FDA for review and authorization. Consistent with the statutory language, certain drugs are ineligible for importation, including biologics (e.g., insulin, monoclonal antibodies) and intravenously injected drugs, among others.¹⁷¹ While Secretary Azar made the necessary certification in a letter to Congress, the final rule requires SIP sponsors (i.e., states, tribes, and, in certain future circumstances, pharmacies and wholesalers) to demonstrate that their program will pose no additional risk to the public's health and safety and to explain how they will ensure their SIP will result in a significant reduction in the cost of covered products to consumers. Proposals must specify the eligible drugs to be included in the SIP, which would have to bear the required U.S. labeling and undergo testing for

CRS In Focus IF11056, *Prescription Drug Importation*.

¹⁶⁶ FDA, "Personal Importation Policy (PIP) Frequently Asked Questions (FAQs)," <https://www.fda.gov/media/83411/download>.

¹⁶⁷ *Ibid*.

¹⁶⁸ FFDCA §804 [21 U.S.C. §384], as added by §745 of the Medicine Equity and Drug Safety Act (MEDS Act; P.L. 106-387) and subsequently amended by §1121 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA; P.L. 108-173).

¹⁶⁹ FFDCA §804(1) [21 U.S.C. §384(1)].

¹⁷⁰ FDA, "FDA Takes Actions to Help Lower U.S. Prescription Drug Prices," September 24, 2020, <https://www.fda.gov/news-events/press-announcements/fda-takes-actions-help-lower-us-prescription-drug-prices>. HHS, FDA, "Importation of Prescription Drugs," 85 *Federal Register* 62094, published October 1, 2020.

¹⁷¹ FFDCA §804(a)(3) [21 U.S.C. §384(a)(3)].

quality and authenticity, in addition to meeting other supply chain security requirements. SIP proposals also must identify the foreign seller in Canada that will purchase the eligible prescription drug directly from its manufacturer, as well as the U.S. importer that will purchase the drug directly from the foreign seller. Both the foreign seller and importer would be subject to applicable U.S. registration and licensure requirements, as well as FFDCAs supply chain security requirements.

Concurrent with promulgation of the final rule, FDA also published a guidance to facilitate the importation by drug manufacturers of prescription drugs that are FDA-approved, manufactured abroad, and originally intended and authorized for sale in a foreign country (i.e., “multi-market approved [MMA] products”).¹⁷² Among other things, the guidance describes procedures for a drug manufacturer to obtain a National Drug Code (NDC) for an MMA product. According to FDA, “the use of an additional NDC for these products may allow greater flexibility for drug companies to offer these products at a lower price than what their current distribution contracts require.”¹⁷³ The guidance applies to drug manufacturers, offering them an option to import drugs that may provide lower cost alternatives to consumers. This is in contrast to the SIP final rule, which creates a mechanism for importation by entities other than the drug manufacturer and does not require the manufacturer to authorize the importation. Also unlike the SIP final rule, the policy outlined in the guidance applies to small molecule prescription drugs and biologics and is not limited to importation of drugs from Canada.

It is not clear how or if expanding legal drug importation would affect costs for U.S. consumers and payers. With respect to FDA’s final rule, to date, the agency has not authorized any SIPs, and at least one lawsuit has been filed challenging the rule.¹⁷⁴ Notably, high-cost biologics such as insulin are excluded from the program. With respect to the guidance, it provides an option for manufacturers, but it is not clear how many manufacturers are interested in importing drugs and biologics intended for foreign markets in order to offer them at a lower cost to U.S. consumers. Further, other countries may be reluctant to support U.S. importation policies, as it may affect their own domestic supply of drugs. For example, Canadian officials reportedly have opposed U.S. importation proposals, and in November 2020, the Canadian government announced that certain drugs intended for the Canadian market may not be sold outside of Canada if such sale would cause or worsen a drug shortage.¹⁷⁵ Proposals to expand drug importation also have been opposed by several former FDA Commissioners and HHS Secretaries, as well as by the pharmaceutical industry, citing safety concerns. Given these concerns and the change in Administration, the implementation of these importation policies remains uncertain.

In addition to the FDA rulemaking and guidance, some members of Congress have introduced legislation to authorize importation of unapproved prescription drugs, subject to specified

¹⁷² FDA, “Importation of Certain FDA-Approved Human Prescription Drugs, Including Biological Products, and Combination Products under Section 801(d)(1)(B) of the Federal Food, Drug, and Cosmetic Act Guidance for Industry,” September 2020, <https://www.hhs.gov/sites/default/files/importation-guidance.pdf>.

¹⁷³ FDA, “FDA Takes Actions to Help Lower U.S. Prescription Drug Prices,” September 24, 2020, <https://www.fda.gov/news-events/press-announcements/fda-takes-actions-help-lower-us-prescription-drug-prices>.

¹⁷⁴ *Pharmaceutical Research and Manufacturers of America v. U.S. Department of Health and Human Services*, 1:20-cv-03402 (United States District Court for the District of Columbia), filed November 23, 2020.

¹⁷⁵ Health Canada, “Canada announces new measures to prevent drug shortages,” November 28, 2020, <https://www.canada.ca/en/health-canada/news/2020/11/canada-announces-new-measures-to-prevent-drug-shortages.html>. Allison Martell, “Exclusive: Canada warns U.S. against drug import plans, citing shortage concerns,” *Reuters*, July 18, 2019, <https://www.reuters.com/article/us-canada-pharmaceuticals-exports-exclus/exclusive-canada-warns-u-s-against-drug-import-plans-citing-shortage-concerns-idUSKCN1UD2LN>.

requirements.¹⁷⁶ Some states have attempted to enact their own laws allowing prescription drug importation. (See “What Are U.S. States Doing to Address Drug Costs?”)

How are Prescription Drug Ads Regulated?

The United States is one of two nations (along with New Zealand) that allow direct-to-consumer (DTC) advertising of prescription drugs.¹⁷⁷ Congress has given FDA the authority to regulate DTC ads to ensure they are not false or misleading, fairly balance the benefits and risks of the specific drugs, and contain facts relevant to a drug’s intended uses.¹⁷⁸ Under current law, businesses, including pharmaceutical companies, may take a federal tax deduction for advertising expenses. Advertising expenditures generally are treated as ordinary and necessary business expenses in the tax code and can be fully deducted in the year they are incurred.

DTC advertising is just one facet of the industry’s promotion efforts. Pharmaceutical firms also market to physicians and other health care providers via professional journals, conferences, marketing calls, and samples.¹⁷⁹

Pharmaceutical advertising has evolved since 1962, when Congress gave FDA (rather than the Federal Trade Commission) authority (within limits) over prescription drug advertising. In 1969, when FDA issued regulations requiring manufactures to provide true and balanced information in drug advertising, most ads were in print journals directed at physicians.¹⁸⁰ During the 1980s, pharmaceutical firms began advertising to consumers; FDA addressed this in a 1985 *Federal Register* notice. In 1999, FDA issued guidance on broadcast ads.¹⁸¹ Since that time, FDA has published updated guidance on relevant issues, including internet advertising.¹⁸²

DTC prescription drug advertising expanded steadily over the decades, reaching more than \$5 billion in 2006.¹⁸³ Advertising dipped during the 2007 recession and did not rebound to the 2006 peak until about 2014. Recent data indicate that DTC advertising has been increasing at a more rapid pace during the past several years.¹⁸⁴ According to Kantar Media, a market research and

¹⁷⁶ See, for example, S. 920 (117th Congress), Affordable and Safe Prescription Drug Importation Act, H.R. 832 and S. 259 (117th Congress), Safe and Affordable Drugs from Canada Act of 2021.

¹⁷⁷ The Federal Food, Drug, and Cosmetic Act (21 U.S.C. §301) is the main source of the FDA authority to regulate drug ads. The 1962 Kefauver-Harris amendments (P.L. 87-871) gave FDA rather than the Federal Trade Commission main regulatory authority over *prescription* drug advertising.

¹⁷⁸ FDA has issued regulations over the years that have broadened drugmakers’ ability to advertise on television and other media. 21 C.F.R. §202.1. For a list of laws and regulations, see FDA, OPDP Regulatory Information, at <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductandTobacco/CDER/ucm109905.htm>.

¹⁷⁹ The ACA included “sunshine” provisions requiring reporting of industry payments for research, gifts, speaking fees, meals and other activities. See CMS, “Open Payments,” at <https://openpaymentsdata.cms.gov/summary>.

¹⁸⁰ Julie Donohue, “A History of Drug Advertising: The Evolving Roles of Consumers and Consumer Protection,” *The Milbank Quarterly*, vol. 84, no. 4 (2006), pp. 659–699, at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2690298/>.

¹⁸¹ See FDA, “OPDP Regulatory Information,” at <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductandTobacco/CDER/ucm109905.htm>.

¹⁸² *Ibid.*

¹⁸³ Pharmaceutical direct-to-consumer advertising is estimated by firms including IMS Health, Kantar Media, and Nielsen. Spending estimates vary, but the data sets show similar trends. See “Pharmaceutical Marketing,” *Advertising Age* and Kantar Media, October 11, 2011, at http://gaia.adage.com/images/bin/pdf/WPpharmmarketing_revise.pdf. See also Rachel Kornfield et al., “Promotion of Prescription Drugs to Consumers and Providers, 2001–2010,” *PLOS One*, March 4, 2013, at <http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0055504>.

¹⁸⁴ Elizabeth Wilner “The Side Effects of Drug Ads,” *Kantar U.S. Insights*, June 4, 2016, at <http://us.kantar.com/tech/tv/2016/ad-and-opinion-research-on-rx-drug-ads/>. Kantar, “The growth of DTC ad spend – where is the money going?” June 7, 2017, <https://www.kantarmedia.com/us/thinking-and-resources/blog/the-growth-of-dtc-ad-spend-where-is-the->

marketing firm, pharmaceutical DTC advertising rose to \$6.46 billion in 2018 (see **Figure 8**). According to Kantar, DTC pharmaceutical television advertising rose 11% percent in the first half of 2018 to \$2.29 billion and accounted for 73% of all DTC dollars in that period, while magazines accounted for 17%, and digital for 7%.¹⁸⁵

Figure 8. Direct-to-Consumer Prescription Drug Advertising
(annual spending in billions of dollars)



Source: Kantar Media, Fierce Pharma via Statista.

Notes: Kantar Media provides audience measurement, consulting, media planning, and other services. The 2019 figure is for the first nine months of the year. During the same nine-month period in 2018, pharmaceutical firms spent \$4.79 billion.

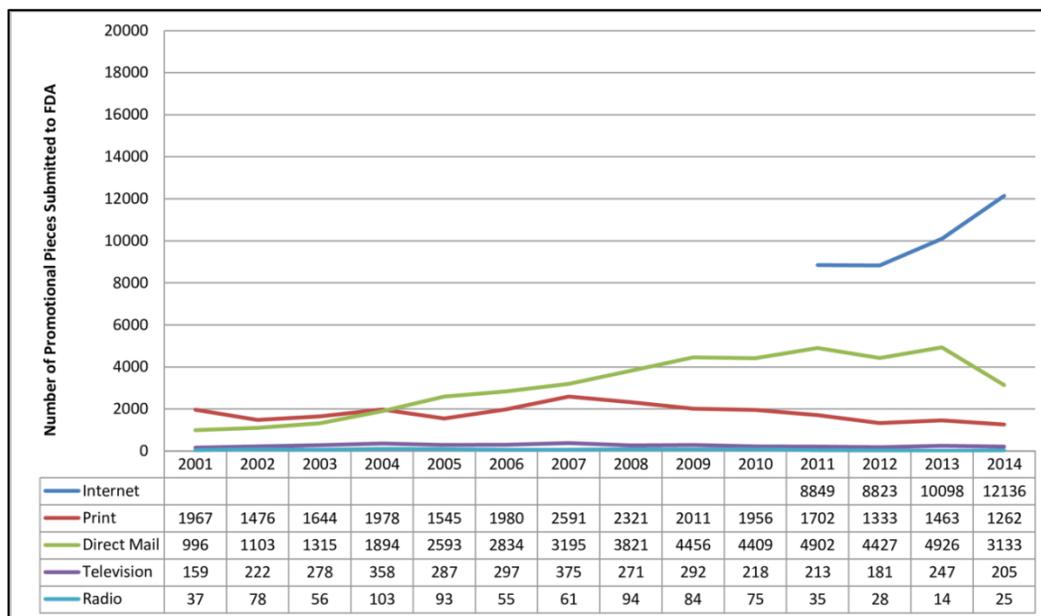
Federal regulations require that at the same time a drug company disseminates a prescription drug ad, it also submits the ad to FDA, which assesses whether it is fair, balanced, and meets other regulatory standards. According to an FDA analysis of materials submitted from 2001 to 2014 (more recent data not available), the number of internet prescription drug promotions was increasing, whereas television promotions were flat.¹⁸⁶ (The data tell how often ads are submitted to FDA but not how often the ads actually appear in different media outlets.) (See **Figure 9**.)

money-going.

¹⁸⁵ Anthony Crupi, “Big Pharma is Spending Lots of Money in Your Favorite Sitcom,” *AdAge*, November 12, 2018, <https://www.kantarmedia.com/us/newsroom/km-inthenews/big-pharma-is-spending-lots-of-money-in-your-favorite-sitcoms>. Kantar provides updated data on print advertising by pharmaceutical companies at Kantar’s “Healthcare Print Ad Spend Tracker,” <https://www.kantarmedia.com/us/thinking-and-resources/data-lab/kantar-media-healthcare-print-ad-spend-tracker>.

¹⁸⁶ Helen Sullivan et al., “Prescription Drug Promotion from 2001-2014: Data from the U.S. Food and Drug Administration,” *PLOS One*, May 5, 2016, at <http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0155035#pone-0155035-g002>.

Figure 9. Number of Prescription Drug Ads Reviewed by FDA
(review classified by type of media)



Source: U.S. Food and Drug Administration (FDA), Office of Prescription Drug Promotion.

The advertising of prescription drugs directly to consumers remains of considerable debate. Supporters of pharmaceutical advertising say it contributes to more informed consumers who then visit their doctors and become more involved in their own treatment, leading to better and earlier diagnosis of undertreated illnesses. Critics say the industry’s presentation of the balance of drug benefit and risk information may encourage inappropriate prescribing of advertised products and ultimately may lead to higher drug spending. Advertising for new brand-name drugs with higher prices may lead consumers to seek brand-name products, substituting them for lower-priced brand or generic drugs or beginning a course of treatment where previously no drug had been used. It is not clear, in some cases, that the new drugs are more effective or safer than other drugs or that they confer enough additional benefits compared to existing treatments to justify paying their higher prices.

Recent studies suggest a link between drug advertising and increased use of prescription drugs. A 2015 study suggested that a 10% rise in drug advertising views leads to a 5.4% increase in filled prescriptions for the advertised drugs.¹⁸⁷ A 2006 Government Accountability Office report found that advertising may have direct benefits but also may encourage use of advertised drugs even if alternatives may be more appropriate.¹⁸⁸ A recent government survey found that 46% of the public did not think the DTC advertisements included enough information about the benefits of the drugs and 52% thought they did not include enough information about the risks.¹⁸⁹

¹⁸⁷ Abby Alpert, Darius Lakdawalla, and Neeraj Sood, “Prescription Drug Advertising and Drug Utilization: The Role of Medicare Part D,” National Bureau of Economic Research, Working Paper 21714, November 2015, at <http://www.nber.org/papers/w21714.pdf>.

¹⁸⁸ Government Accountability Office, “Improvements Needed in FDA’s Oversight of Direct -to-Consumer Advertising,” November 2006, at <http://www.gao.gov/new.items/d0754.pdf>.

¹⁸⁹ Helen Sullivan and Margaret Campbell, “Do Prescription Drug Ads Tell Consumers Enough About Benefits and Side Effects? Results from the Health Information National Trends Survey, Fourth Administration,” *Journal of Health*

Congress has debated restricting DTC drug advertising in the past. The issue has received new attention with two distinct goals: protecting the public's health from unsafe or ineffective drugs and protecting the public's pocketbook from unnecessary higher spending. In November 2015, the American Medical Association voted to recommend a ban on DTC drug ads.¹⁹⁰ In January 2016, the American Society of Health-System Pharmacists followed suit.¹⁹¹ A ban could raise constitutional issues, given that courts in the past have ruled that product advertisements are “commercial speech” protected by the First Amendment.¹⁹²

Legislation introduced in the 116th Congress would have imposed a moratorium on advertising for new drugs.¹⁹³ The Kantar data indicating that manufacturers are focusing ad dollars on newly introduced products underscores a long-standing concern that new drugs are being promoted to consumers before there is long-term evidence about their safety and effectiveness.¹⁹⁴ In 2006, the Institute of Medicine recommended that FDA restrict DTC advertising of new drugs for two years after introduction.¹⁹⁵ Over the years, Congress has debated, but has not approved, a moratorium on advertising for new drugs.¹⁹⁶

Likewise, lawmakers during the 116th Congress introduced legislation to disallow federal tax deductions for pharmaceutical DTC advertising as a means to reduce drug spending.¹⁹⁷ Congress also has debated the issue in the context of broader tax reform.¹⁹⁸

Communication, vol. 20, no. 12 (2015), at <http://www.tandfonline.com/doi/full/10.1080/10810730.2015.1018635?scroll=top&needAccess=true>.

¹⁹⁰ American Medical Association, “AMA Calls for Ban on Direct to Consumer Advertising of Prescription Drugs and Medical Devices,” November 17, 2015, at <http://www.ama-assn.org/ama/pub/news/news/2015/2015-11-17-ban-consumer-prescription-drug-advertising.page>.

¹⁹¹ *States News Services*, “Pharmacist Association Calls for Ban on Prescription Drug Advertising,” January 14, 2016.

¹⁹² The Supreme Court has held that the Constitution affords less protection to commercial speech than other constitutionally safeguarded forms of expression. Commercial speech is “speech that proposes a commercial transaction.” The Court has further noted that the combination of speech in an advertising format, which references a specific product and for which the speaker has an underlying economic motivation is “strong support” for characterizing such speech as commercial speech.

¹⁹³ H.R. 4106, S. 3180 (116th Congress), the Responsibility in Drug Advertising Act of 2019.

¹⁹⁴ FDA reviews clinical evidence before approving drugs, but other indications and concerns can arise after drugs have been on the market. A 2016 study found that prescription drug television advertising increased online searches and clicks on information for advertised drugs, but there is also an association between DTC ads and consumer clicks on promotional, rather than informational, websites. See Matthew Chesnes and Ginger Zhe Jin, “Direct to Consumer Advertising and Online Search,” Bureau of Economics, Federal Trade Commission, August 2016, at https://www.ftc.gov/system/files/documents/reports/direct-consumer-advertising-online-search/working_paper_331.pdf.

¹⁹⁵ Institute of Medicine, “The Future of Drug Safety: Action Steps for Congress,” September 2006, at https://www.nationalacademies.org/hmd/~media/Files/Report%20Files/2006/The-Future-of-Drug-Safety/futureofdrugsafety_reportbrief.pdf.

¹⁹⁶ Ira Teinowitz, “Senate Moves Closer to Giving FDA Power to Ban Drug Ads,” *Advertising Age*, April 19, 2007, at <http://adage.com/article/news/senate-moves-closer-giving-fda-power-ban-drug-ads/116174/>. In a 2011 study, CBO analyzed the potential impact of restrictions on pharmaceutical advertising. See CBO, “Potential Effects of a Ban on Direct-to-Consumer Advertising of New Prescription Drugs,” May 2011, at <https://www.cbo.gov/sites/default/files/112th-congress-2011-2012/reports/5-25-prescriptiondrugadvertising.pdf>.

¹⁹⁷ H.R. 4711 (116th Congress), No Tax Breaks for Drug Ads Act.

¹⁹⁸ CRS In Focus IF10201, *The Tax Reform Act of 2014*.

Appendix. Relevant Congressional Drug Pricing Hearings in the 117th, 116th, 115th and 114th Congresses

Senate Special Committee on Aging

The Complex Web of Prescription Drug Prices, Part III: Examining Agency Efforts to Further Competition and Increase Affordability, 116th Cong., 1st sess., June 19, 2019, <https://www.aging.senate.gov/hearings/the-complex-web-of-prescription-drug-prices-part-iii-examining-agency-efforts-to-further-competition-and-increase-affordability>.

The Complex Web of Prescription Drug Prices, Part II: Untangling the Web and Paths Forward, 116th Cong., 1st sess., March 7, 2019, <https://www.aging.senate.gov/hearings/the-complex-web-of-prescription-drug-prices-part-ii-untangling-the-web-and-paths-forward>.

The Complex Web of Prescription Drug Prices, Part I: Patients Struggling with Rising Costs, 116th Cong., 1st sess., March 6, 2019, <https://www.aging.senate.gov/hearings/the-complex-web-of-prescription-drug-prices-part-i-patients-struggling-with-rising-costs>.

Insulin Access and Affordability: The Rising Cost of Treatment, 115th Cong., 2nd sess., May 8, 2018, <https://www.aging.senate.gov/hearings/insulin-access-and-affordability-the-rising-cost-of-treatment>.

Valeant Pharmaceuticals' Business Model: the Repercussions for Patients and the Health Care System, 114th Cong., 2nd sess., April 27, 2016, at <http://www.aging.senate.gov/hearings/valeant-pharmaceuticals-business-model-the-repercussions-for-patients-and-the-health-care-system>.

Sudden Price Spikes in Decades-Old Rx Drugs: Inside the Monopoly Business Model, 114th Cong., 2nd sess., March 17, 2016, at <http://www.aging.senate.gov/hearings/sudden-price-spikes-in-decades-old-rx-drugs-inside-the-monopoly-business-model>.

Sudden Price Spikes in Off-Patent Drugs: Perspectives from the Front Lines, 114th Cong., 1st sess., December 9, 2015, at http://www.aging.senate.gov/hearings/sudden-price-spikes-in-off-patent-drugs_perspectives-from-the-front-lines.

Senate Committee on Finance

Drug Pricing in America: A Prescription for Change, Part III, 116th Cong., 1st sess., April 9, 2019, <https://www.finance.senate.gov/hearings/drug-pricing-in-america-a-prescription-for-change-part-iii>.

Drug Pricing in America: A Prescription for Change, Part II, 116th Cong., 1st sess., February 26, 2019, <https://www.finance.senate.gov/hearings/drug-pricing-in-america-a-prescription-for-change-part-ii>.

Drug Pricing in America: A Prescription for Change, Part I, 116th Cong., 1st sess., January 29, 2019, <https://www.finance.senate.gov/hearings/drug-pricing-in-america-a-prescription-for-change-part-i>.

Prescription Drug Affordability and Innovation: Addressing Challenges in Today's Market, 115th Cong., 2nd sess., June 26, 2018, <https://www.finance.senate.gov/hearings/prescription-drug-affordability-and-innovation-addressing-challenges-in-todays-market>.

Examining the Proposed Medicare Part B Drug Demonstration, 114th Cong., 2nd sess., June 28, 2016; at <http://www.finance.senate.gov/hearings/examining-the-proposed-medicare-part-b-drug-demonstration>.

Senate Committee on Health, Education, Labor, and Pensions

Why Does the U.S. Pay the Highest Prices in the World for Prescription Drugs? 117th Cong., 1st sess., March 23, 2021, <https://www.help.senate.gov/hearings/why-does-the-us-pay-the-highest-prices-in-the-world-for-prescription-drugs>.

Vaccines: Saving Lives, Ensuring Confidence, and Protecting Public Health, 116th Cong., 2nd sess., September 9, 2020, <https://www.help.senate.gov/hearings/vaccines-saving-lives-ensuring-confidence-and-protecting-public-health>.

Vaccines Save Lives: What Is Driving Preventable Disease Outbreaks, 116th Cong., 1st sess., March 5, 2019, <https://www.help.senate.gov/hearings/vaccines-save-lives-what-is-driving-preventable-disease-outbreaks>.

Effective Administration of the 340B Drug Pricing Program, 115th Congress, 2nd sess., June 19, 2018, <https://www.help.senate.gov/hearings/effective-administration-of-the-340b-drug-pricing-program>.

The Cost of Prescription Drugs: Examining the President's Blueprint 'American Patients First' to Lower Drug Prices, 115th Congress, 2nd sess., June 12, 2018, <https://www.help.senate.gov/hearings/the-cost-of-prescription-drugs-examining-the-presidents-blueprint-american-patients-first-to-lower-drug-prices>.

Examining Oversight Reports on the 340B Drug Pricing Program, 115th Congress, 2nd sess., May 15, 2018, <https://www.help.senate.gov/hearings/examining-oversight-reports-on-the-340b-drug-pricing-program>.

Perspectives on the 340B Drug Pricing Program, 115th Congress, 2nd sess., March 15, 2018, <https://www.help.senate.gov/hearings/perspectives-on-the-340b-drug-pricing-program>.

The Cost of Prescription Drugs: An Examination of The National Academies of Sciences, Engineering, and Medicine Report "Making Medicines Affordable: A National Imperative" 115th Cong., 1st sess., December 12, 2017, at <https://www.help.senate.gov/hearings/the-cost-of-prescription-drugs-an-examination-of-the-national-academies-of-sciences-engineering-and-medicine-report-making-medicines-affordable-a-national-imperative>.

The Cost of Prescription Drugs: How the Drug Delivery System Affects What Patients Pay, Part II, 115th Cong., 1st sess., October 17, 2017, at <https://www.help.senate.gov/hearings/the-cost-of-prescription-drugs-how-the-drug-delivery-system-affects-what-patients-pay-part-ii>.

The Cost of Prescription Drugs: How the Drug Delivery System Affects What Patients Pay, 115th Cong., 1st sess., June 13, 2017, at <https://www.help.senate.gov/hearings/the-cost-of-prescription-drugs-how-the-drug-delivery-system-affects-what-patients-pay>.

EpiPen Price Increases: How Regulatory Barriers Inhibit Pharmaceutical Competition, field hearing, 114th Cong., 2nd sess., October 7, 2016, at <http://www.help.senate.gov/hearings/epipen-price-increases-how-regulatory-barriers-inhibit-pharmaceutical-competition/>.

Generic Drug User Fee Amendments: Accelerating Patient Access to Generic Drugs, 114th Cong., 2nd sess., January 28, 2016, at <http://www.help.senate.gov/hearings/generic-drug-user-fee-amendments-accelerating-patient-access-to-generic-drugs>.

Biosimilar Implementation: A Progress Report from FDA, 114th Cong., 1st sess., September 17, 2015, at <http://www.help.senate.gov/hearings/biosimilar-implementation-a-progress-report-from-fda>.

Continuing America's Leadership: Advancing Research and Development for Patients, 114th Cong., 1st sess., March 24, 2015, at <http://www.help.senate.gov/hearings/continuing-americas-leadership-advancing-research-and-development-for-patients>.

Senate Committee on Homeland Security & Governmental Affairs

Majority and Minority Staff Report - Combatting the Opioid Crisis: The Price Increase of an Opioid Overdose Reversal Drug and the Cost to the U.S. Health Care System, 115th Cong., 1st sess., November 18, 2018, https://www.hsgac.senate.gov/subcommittees/investigations/hearings/majority-and-minority-staff-report_-combatting-the-opioid-crisis-the-price-increase-of-an-opioid-overdose-reversal-drug-and-the-cost-to-the-us-health-care-system.

House Energy and Commerce Committee

"Pathway to Protection: Expanding Availability of COVID-19 Vaccines," 117th Cong., 1st sess., February 23, 2021, <https://energycommerce.house.gov/committee-activity/hearings/hearing-on-pathway-to-protection-expanding-availability-of-covid-19>.

Pathway to a Vaccine: Ensuring a Safe and Effective Vaccine People Will Trust, 116th Congress, 2nd sess., September 30, 2020, <https://energycommerce.house.gov/committee-activity/hearings/hearing-on-pathway-to-a-vaccine-efforts-to-develop-a-safe-effective-and>.

Pathway to a Vaccine: Efforts to Develop a Safe, Effective and Accessible COVID-19 Vaccine, 116th Congress, 2nd sess., July 21, 2020, <https://energycommerce.house.gov/committee-activity/hearings/hearing-on-pathway-to-a-vaccine-efforts-to-develop-a-safe-effective-and>

Improving Safety and Transparency in America's Food and Drugs, 116th Congress, 2nd sess., January 29, 2020, <https://energycommerce.house.gov/committee-activity/hearings/hearing-on-improving-safety-and-transparency-in-americas-food-and-drugs>.

Securing the U.S. Drug Supply Chain: Oversight of FDA's Foreign Inspection Program, 116th Congress, 1st sess., December 10, 2019, <https://energycommerce.house.gov/committee-activity/hearings/hearing-on-securing-the-us-drug-supply-chain-oversight-of-fda-s-foreign>.

Safeguarding Pharmaceutical Supply Chains in a Global Economy, 116th Congress, 1st sess., October 30, 2019, <https://energycommerce.house.gov/committee-activity/hearings/hearing-on-safeguarding-pharmaceutical-supply-chains-in-a-global-economy>.

Making Prescription Drugs More Affordable: Legislation to Negotiate a Better Deal for Americans, 116th Congress, 1st sess., September 25, 2019, <https://energycommerce.house.gov/committee-activity/hearings/hearing-on-making-prescription-drugs-more-affordable-legislation-to>.

Profits over Consumers: Exposing How Pharmaceutical Companies Game the System, 116th Congress, 1st sess., September 19, 2019, <https://energycommerce.house.gov/committee-activity/hearings/hearing-on-profits-over-consumers-exposing-how-pharmaceutical-companies>.

Improving Drug Pricing Transparency and Lowering Prices for American Consumers, 116th Congress, 1st sess., May 21, 2019, <https://energycommerce.house.gov/committee-activity/hearings/hearing-on-improving-drug-pricing-transparency-and-lowering-prices-for>.

Lowering Prescription Drug Prices: Deconstructing the Drug Supply Chain, 116th Congress, 1st sess., May 9, 2019, <https://energycommerce.house.gov/committee-activity/hearings/hearing-on-lowering-prescription-drug-prices-deconstructing-the-drug>.

Prescription Drug Coverage in the Medicare Program, 116th Congress, 1st sess., April 30, 2019, <https://energycommerce.house.gov/committee-activity/hearings/hearing-on-prescription-drug-coverage-in-the-medicare-program>.

Priced Out of a Lifesaving Drug: Getting Answers on the Rising Cost of Insulin, 116th Congress, 1st sess., April 10, 2019, <https://energycommerce.house.gov/committee-activity/hearings/hearing-on-priced-out-of-a-lifesaving-drug-getting-answers-on-the-rising>.

Priced Out of a Lifesaving Drug: The Human Impact of Rising Insulin Costs, 116th Congress, 1st sess., April 2, 2019, <https://energycommerce.house.gov/committee-activity/hearings/hearing-on-priced-out-of-a-lifesaving-drug-the-human-impact-of-rising>.

Lowering the Cost of Prescription Drugs: Reducing Barriers to Market Competition, 116th Congress, 1st sess., March 13, 2019, <https://energycommerce.house.gov/committee-activity/hearings/hearing-on-lowering-the-cost-of-prescription-drugs-reducing-barriers-to>.

Opportunities to Improve the 340B Drug Pricing Program, 115th Cong., 2nd sess., July 11, 2018, <https://energycommerce.house.gov/committee-activity/hearings/hearing-on-opportunities-to-improve-the-340b-drug-pricing-program>.

Examining the Drug Supply Chain, 115th Cong., 1st sess., December 13, 2017, at <https://energycommerce.house.gov/hearings/examining-drug-supply-chain/>.

Examining How Covered Entities Utilize the 340B Drug Pricing Program, 115th Cong., 1st sess., October 11, 2017, <https://energycommerce.house.gov/hearings/examining-covered-entities-utilize-340b-drug-pricing-program/>.

Examining Patient Access to Investigational Drugs, 115th Cong., 1st sess., October 3, 2017, at <https://energycommerce.house.gov/hearings/examining-patient-access-investigational-drugs/>.

Modernizing FDA's Regulation of Over-the-Counter Drugs, 115th Cong., 1st sess., September 13, 2017, <https://energycommerce.house.gov/hearings/modernizing-fdas-regulation-of-counter-drugs/>.

Examining FDA's Prescription Drug User Fee Program, 115th Cong., 1st sess., March 22, 2017, at <https://energycommerce.house.gov/hearings-and-votes/hearings/examining-fda-s-prescription-drug-user-fee-program>.

Examining FDA's Generic Drug and Biosimilar User Fee Program, 115th Cong., 1st sess., March 2, 2017, at <https://energycommerce.house.gov/hearings-and-votes/Hearing>.

The Obama Administration's Medicare Drug Experiment: The Patient and Doctor Perspective, 114th Cong., 2nd sess., May 17, 2016, at <https://energycommerce.house.gov/hearings-and-votes/hearings/obama-administration-s-medicare-drug-experiment-patient-and-doctor>.

House Judiciary Committee

Competition in the Pharmaceutical Supply Chain: The Proposed Merger of CVS Health and Aetna, 115th Cong., 2nd sess., February 27, 2018, <https://judiciary.house.gov/legislation/hearings/competition-pharmaceutical-supply-chain-proposed-merger-cvs-health-and-aetna>.

Antitrust Concerns and the FDA Approval Process, 115th Cong., 1st sess., July 27, 2017, at <https://judiciary.house.gov/hearing/antitrust-concerns-fda-approval-process/>.

The State of Competition in the Pharmacy Benefit Manager and Pharmacy Marketplaces, 114th Cong., 1st sess., November 17, 2015, at <https://judiciary.house.gov/hearing/the-state-of-competition-in-the-pharmacy-benefit-manager-and-pharmacy-marketplaces/>.

House Committee on Oversight and Government Reform

The Role of Purdue Pharma and the Sackler Family in the Opioid Epidemic, 116th Congress, 2nd sess., December 17, 2020, <https://oversight.house.gov/legislation/hearings/the-role-of-purdue-pharma-and-the-sackler-family-in-the-opioid-epidemic>.

Unsustainable Drug Prices: Testimony from the CEOs (Part II), 116th Congress, 2nd sess., October 1, 2020, <https://oversight.house.gov/legislation/hearings/unsustainable-drug-prices-testimony-from-the-ceos-part-ii>.

Unsustainable Drug Prices: Testimony from the CEOs (Part I), 116th Congress, 2nd sess., September 30, 2020, <https://oversight.house.gov/legislation/hearings/unsustainable-drug-prices-testimony-from-the-ceos-part-i-and-part-ii>.

The Patient Perspective: The Devastating Impacts of Skyrocketing Drug Prices on American Families, 116th Congress, 1st sess., July 26, 2019, <https://oversight.house.gov/legislation/hearings/the-patient-perspective-the-devastating-impacts-of-skyrocketing-drug-prices-on>.

HIV Prevention Drug: Billions in Corporate Profits after Millions in Taxpayer Investments, 116th Congress, 1st sess., May 16, 2019, <https://oversight.house.gov/legislation/hearings/hiv-prevention-drug-billions-in-corporate-profits-after-millions-in-taxpayer>.

Examining the Actions of Drug Companies in Raising Prescription Drug Prices, 116th Congress, 1st sess., January 29, 2019, <https://oversight.house.gov/legislation/hearings/examining-the-actions-of-drug-companies-in-raising-prescription-drug-prices>.

Federally Funded Cancer Research: Coordination and Innovation, 115th Cong., 1st sess., March 29, 2017, at <https://oversight.house.gov/hearing/federally-funded-cancer-research-coordination-innovation/>.

Examining the Impact of Voluntary Restricted Distribution Systems in the Pharmaceutical Supply Chain, 115th Cong., 1st sess., March 22, 2017, at <https://oversight.house.gov/hearing/examining-impact-voluntary-restricted-distribution-systems-pharmaceutical-supply-chain/>.

Reviewing the Rising Price of EpiPens, 114th Cong., 2nd sess., September 21, 2016, at <https://oversight.house.gov/hearing/reviewing-rising-price-epipens-2/>.

Developments in the Prescription Drug Market: Oversight, 114th Cong., 2nd sess., February 4, 2016, at <https://oversight.house.gov/hearing/developments-in-the-prescription-drug-market-oversight/>.

House Ways & Means Committee

More Cures for More Patients: Overcoming Pharmaceutical Barriers, 116th Congress, 2nd sess., February 5, 2020, <https://waysandmeans.house.gov/legislation/hearings/more-cures-more-patients-overcoming-pharmaceutical-barriers>.

Investing in the U.S. Health System by Lowering Drug Prices, Reducing Out-of-Pocket Costs, and Improving Medicare Benefits, 116th Congress, 1st sess., Oct 17, 2019, <https://waysandmeans.house.gov/legislation/hearings/investing-us-health-system-lowering-drug-prices-reducing-out-pocket-costs-and>.

Promoting Competition to Lower Medicare Drug Prices, 116th Congress, 1st sess., March 7, 2019, <https://waysandmeans.house.gov/legislation/hearings/promoting-competition-lower-medicare-drug-prices>.

The Cost of Rising Prescription Drug Prices, 116th Congress, 1st sess., February 12, 2019, <https://waysandmeans.house.gov/legislation/hearings/cost-rising-prescription-drug-prices>.

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