

Prescription Drug Price Transparency Results and Recommendations – 2021

As required by House Bill 4005 (2018)



About DCBS:

The Department of Consumer and Business Services is Oregon's largest business regulatory and consumer protection agency. For more information, visit https://www.oregon.gov/dcbs/.

About Oregon DFR:

The Division of Financial Regulation protects consumers and regulates insurance, depository institutions, trust companies, securities, and consumer financial products and services and is part of the Department of Consumer and Business Services. Visit dfr.oregon.gov.

About the Drug Price Transparency Program:

Oregon's Drug Price Transparency program provides accountability for prescription drug pricing through the notice and disclosure of specific drug costs and price information from pharmaceutical manufacturers, health insurers, and consumers. Visit https://dfr.oregon.gov/drugtransparency/.

Additional report information:

This report is based on all data submitted to the program through Oct. 15, 2021, and consumer survey responses received before the finalization of the report.

Throughout our report, we also reference drug prices and therapeutic class information extracted from the Medi-Span drug database.

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Acknowledgments

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Introduction



In 2018, the Oregon Legislature passed Oregon's Prescription Drug Price Transparency Act, which created the Oregon Drug Price Transparency Program. The Prescription Drug Price Transparency Act directs the Oregon Department of Consumer and Business Services to annually report to the legislature on the information it collects, as well as any recommendations for legislative changes to contain the cost of prescription drugs and reduce the impact of price increases. This report is intended to satisfy the department's annual reporting requirement, as well as provide the public information about prescription drug impacts and trends based on data received from prescription drug manufacturers, health insurance companies, and consumers.

We are providing information in the following sections:

- Background with an overview of prescription drugs and spending
- Oregon's Drug Price Transparency Program and consumer information
- Prescription drug manufacturer information and data collected from reports
- Insurance company reporting data
- Compliance information
- Policy recommendations to the Legislature

These topics are covered briefly in the executive summary, followed by detailed information in the appropriate sections, concluding with key findings.

Executive summary

Background

Prescription drugs are vital to both longevity and quality of life for many Oregonians. Not being able to afford these life-saving, life-improving prescriptions causes detriment to patients and their families, as well as additional burdens to our health care system. For those who can afford prescriptions only because they do without other needs, there is a reduction in quality of life, which can, and often does, affect overall health. Affordability and access remain of high concern to consumers and lawmakers alike.

In 2021, 60 percent of adults in the United States reported taking at least one prescription drug; that increases to a higher percentage with age.^{1,2} A poll by the Kaiser Family Foundation found that 1 in 4 adults and seniors say it is difficult or very difficult to afford their prescription drugs.³ More than 8 in 10 (83 percent) said that the cost of prescription drugs is "unreasonable." ⁴ Of the 30 percent of Americans who reported not taking their medications as prescribed due to cost, about 1 in 3 reported that their health worsened as a result of taking fewer doses.⁵

While several federal prescription drug policies are still at the beginning stages of implementation, Oregon has enacted several laws since the Prescription Drug Price Transparency Program was created. In 2021, the Oregon Legislature passed Senate Bill 763, which requires pharmaceutical representatives to obtain a license before marketing

pharmaceutical products to health care providers. Along with these policy initiatives, the Drug Price Transparency Program continues to learn more each year about new drugs and high-cost drugs that are reported to the program.



¹ Liz Hamel, et al, *KFF Polling – Public Opinion on Prescription Drugs and Their Prices*, October 2021. Retrieved at: https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices/, on Nov. 6, 2021.

² Centers for Disease Control and Prevention. *Prescription Drug Use Among Adults Aged 40-79 in the United States and Canada – NCHS Data Brief No. 347*, August 2019. Retrieved at: https://www.cdc.gov/nchs/products/databriefs/db347. htm, on Dec. 2, 2020.

³ Ashley Kirzinger, et al, *KFF Health Tracking Poll – February 2019: Prescription Drugs*, March 1, 2019. Retrieved at: https://www.kff.org/health-costs/poll-finding/kff-health-tracking-poll-february-2019-prescription-drugs/ on Dec. 3, 2020.

⁴ Liz Hamel, et al, KFF Polling – Public Opinion on Prescription Drugs and Their Prices, October 2021.

⁵ Ibid.



Program overview

and consumers.

In 2018, the Oregon Legislature passed the Prescription Drug Price Transparency Act (House Bill 4005) to increase prescription drug price transparency, creating Oregon's Drug Price Transparency Program.⁶ The goal of the Drug Price Transparency Program is to provide accountability for prescription drug pricing through transparency of specific drug costs and price information from pharmaceutical manufacturers, health insurers,

During the 2018 legislative process, Oregon legislators called the Prescription Drug Price Transparency Act the first step to understanding prescription drug cost and pricing through increased transparency.7 In 2019, the Legislature expanded the reporting requirements on manufacturers through passage of House Bill 2658. This law requires manufacturers to provide notice to the state 60 days before a planned price increase when the reporting thresholds are met or exceeded. This requirement applies regardless of whether the price increase ultimately goes into effect or not.

Two bills passed in 2021 that involve the program conducting a study and also providing assistance in the implementation of a drug affordability board. The Legislature passed Senate Bill 711, which required the Department of Consumer and Business Services to study the cost differences in hormone replacement drugs used by men and women and report findings to the Legislature by Sept. 15, 2022.

Additionally, the Legislature passed Senate Bill 844, which created the Prescription Drug Affordability Board. The board, which will be part of the Department of Consumer and Business Services, will review prices for selected prescription drugs reported to the Drug Price Transparency Program.

Prescription drug manufacturers are required to submit reports to the program for new prescription drugs and prescription drug price increases that exceed the threshold for that reporting requirement.

Each year, health insurance companies in Oregon report the drugs most prescribed to their policyholders, the drugs with the highest total health plan spending, and the drugs contributing to the greatest increases in total health plan spending.

⁶ House Bill 4005 (2018), https://olis.leg.state.or.us/liz/2018R1/Measures/Overview/HB4005.

⁷ Oregon House Majority, "Prescription Drug Price Transparency Passes House", Feb. 28, 2018; see: Quotes from Representatives Meek and Nosse: https://www.oregonlegislature.gov/housedemocrats/Documents/ PRESS%2RELEASE%20Prescription%20Drug%20Price%20Transparency%20Passes%20House.pdf

In addition to manufacturer and insurer reports, the program also asked Oregonians to submit their stories, comments, and questions about prescription drug pricing. We have received a number of responses, with a few consistent threads.

All of the consumer questions and stories we have received with permission to share be available in a separate document as exhibits 1 and 2. The submissions have light editing and names removed.

Results

Oregon's Drug Price Transparency Program is one of the first in the nation to be fully implemented and has been collecting data for nearly three years. By analyzing the information received from drug manufacturers, health insurers, and consumers, the program is working to deepen the state's understanding of the factors that influence prescription prices, and how drug prices affect Oregonians.

Based on the information collected, the program has made the following key findings in this 2021 report:

- The program received more reports for new high-cost cancer drugs than for any other class of therapy. The two most expensive drugs introduced in 2021 – Abecma, with a list price of \$419,500, and Breyanzi, with a list price of \$410,300 – are both CAR-T (gene therapy) cancer treatments produced by Bristol Myers Squibb.
- Biogen's new drug report for its Alzheimer's
 disease treatment, Aduhelm, indicated that
 its \$56,000 list price was driven by the "overall
 value this treatment is expected to bring to
 patients, caregivers, and society, while reflecting
 key principles such as innovation, access, and
 sustainability." However, the price has been
 criticized by patient advocates and drug pricing
 experts as unjustified. If Medicare elects not to
 cover Aduhelm, the cost of providing the drug
 could fall to Medicaid, potentially increasing state
 spending on the Oregon Health Plan.

- For the third year in a row, the most costly drug for Oregon's insurance companies was Humira, with insurers reporting spending \$93,544,597 on Humira prescriptions. Overall, more was spent on anti-inflammatory analgesics, including Humira, than any other drug class, with companies reporting \$153,753,608 on prescriptions in this class. The next most costly class of drugs was cancer therapies, with insurers reporting \$123,815,822 spent on prescriptions for antineoplastics and adjunctive therapies.
- The number of price increase reports received by the program continued to fall this year, a trend that is consistent with wider data showing that the number and magnitude of price increases fell sharply from 2015 to 2017. However, in the same period, the average launch price of new brand-name drugs more than doubled, from less than \$4,000 to more than \$10,000. This may suggest that manufacturers are avoiding making controversial price increases while a drug is on the market by setting a drug's launch price higher.
- The largest price increase reported to the program in 2021 was a 778 percent increase from an average of \$10.99 in 2019 to \$96.48 in 2020. This increase was for generic promethazine hydrochloride syrup, used to treat the symptoms of allergic reactions and nausea. Four out of five of the largest price increases were for generic drugs. The median price increase reported for generic drugs was 27 percent and the median price increase reported for brand-name drugs was 13 percent.
- Half of the generic drugs reported indicated a profit margin of 32 percent or higher, with one generic reporting a 93 percent profit margin. Thirty-eight percent of brand-name drugs with price increases reported that they lost money on the product, with the worst performing drug recouping only 22 percent of costs.

Recommendations

The Prescription Drug Price Transparency Act requires recommendations for legislative changes to contain the cost of prescription drugs and reduce the effect of price increases. Several of the recommendations offered are suggested improvements to the program to receive better quality data to inform policy recommendations.

Note: Not all recommendations require legislation

Manufacturer reporting

Recommendation 1: Expanded reporting requirements for patient assistance programs

We recommend removing patient assistance program reports from annual price increase reports, and, instead, requiring all reporting manufacturers to report to the department annually on all patient assistance programs supported by each manufacturer. This will avoid the problems identified with HB 2044 (2021) requiring manufacturers to report information that is unavailable, and will allow us to collect information on high-cost drugs that have not experienced a price increase of 10 percent or more. This will allow us to get a better picture of the overall landscape of patient assistance and to better inform the Legislature and the public about the market impacts of patient assistance when the issue arises in future legislative debates.

Recommendation 2: Clarify the threshold for annual price increase reports

The advance notice requirement (HB 2685, 2019) contains different threshold price reporting terms than the Prescription Drug Price Transparency Act.

We recommend changing the statutory language regarding the threshold for annual price increase reports to conform to HB 2658 terms:

A cumulative increase of 10 percent or more over the course of the previous year or

When, at any point in the previous calendar year, an increase or series of increases in the price of the drug results in a price 10 percent higher than the price of the drug at any previous time during the calendar year.

Health insurer reporting

Recommendation 3: Expand reporting to additional insurers

Under the Prescription Drug Price Transparency Act, health insurance companies are required to submit rate filings only if they offer individual or small group health benefit plans. Some health insurers that do not participate in these markets are not required to submit these reports. This may result in an incomplete picture of health plan spending on drugs in Oregon.

We recommend legislators consider separating the health insurance company reporting requirement from the rate review process and require it as a separate annual report from all health benefit plan issuers in Oregon.

Global recommendations

Recommendation 4: Transparency across the pharmaceutical supply chain

The price of a prescription drug is influenced by several factors. This includes the interactions and financial negotiations between pharmaceutical supply chain entities. Several of these entities can influence the price of the drug to consumers, either at the pharmacy counter, through consumers' health insurance premiums, or how drug costs contribute to overall health care system costs.

We recommend the Legislature consider transparency across the pharmaceutical supply chain entities to fully understand what influences and contributes to the price of the drug.

Consumer notification reporting

Recommendation 5: Protection of consumerreported information

Consumer reports on the price increases of the prescription drugs they take is an essential component to the program. When consumers report to the program, they submit specific information about the drug they are reporting on, which the program uses to compare against the information submitted by drug manufacturers and health insurers. Also, consumers report their ZIP code, health insurance information, and the reasons for the price increase.

This information is important for policymakers and stakeholders to know what is being reported to the department from the consumer perspective. However, collectively, the information could potentially identify a consumer. We recommend clarifying that the personally identifiable information collected will be protected from public disclosure.

Program improvements

Recommendation 6: Ongoing program evaluation

We will continue to evaluate the program and learn how to improve our processes. This may result in recommendations to the Legislature or changes the department can make to improve the overall program. Improvements may include changes to help manufacturers efficiently submit reports, internal changes to better administer the program and its deadlines, and any other changes that improve the program for the agency and its stakeholders. When evaluating any improvement to the program, the department will evaluate the time and resources needed to implement any change.



Background

Prescription drugs are vital to both longevity and quality of life for many Oregonians. Not being able to afford these life-saving, life-improving prescriptions causes detriment to patients and their families, as well as additional burdens to our health care system. For those who can afford prescriptions only because they do without other needs, there is a reduction in quality of life which can, and often does, affect overall health. Affordability and access remain of high concern to consumers and lawmakers alike.

In 2021, 60 percent of adults in the United States reported taking at least one prescription drug; that increases to a higher percentage with age.^{8,9} A poll by the Kaiser Family Foundation found that 1 in 4 adults and seniors say it is difficult or very difficult to afford their prescription drugs.¹⁰ More than 8 in 10 (83 percent) said that the cost of prescription drugs is "unreasonable." ¹¹ Of the 30 percent of Americans who reported not taking their medications as prescribed due to cost, about 1 in 3 reported that their health worsened as a result of taking fewer doses.¹²

Both the Trump and Biden administrations have released policy proposals to address affordability, such as plans to import drugs from Canada.¹³ It remains to be seen how this will roll out for the states that have passed laws to implement a drug importation plan.

In November 2021, lawmakers in Congress have proposed to address drug prices for people with health insurance. This includes a \$2,000 cap on out-of-pocket costs for Medicare Part D, capping cost sharing at \$35 for one insulin product in each dosage form, and rebates for drugs with a price that increases faster than inflation.¹⁴ Federal lawmakers have also proposed to allow for the negotiation of a fair price for drugs with the highest gross spending under Medicare policies.

While several federal prescription drug policies are still at the beginning stages of implementation, Oregon has enacted several laws since the Drug Price Transparency Program was created. In 2021, the Oregon Legislature passed Senate Bill 763, which requires pharmaceutical representatives to obtain a license before marketing pharmaceutical products to health care providers, as well as Senate Bill 844, which established the Prescription Drug Affordability Board. Along with these policy initiatives, the Drug Price Transparency Program continues to learn more each year about new drugs and high-cost drugs that are reported to the program.

⁸ Liz Hamel, et al, *KFF Polling – Public Opinion on Prescription Drugs and Their Prices*, October 2021. Retrieved at: https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices/ on Nov. 6, 2021.

⁹ Centers for Disease Control and Prevention. *Prescription Drug Use Among Adults Aged 40-79 in the United States and Canada – NCHS Data Brief No. 347*, August 2019. Retrieved at: https://www.cdc.gov/nchs/products/databriefs/db347. htm, on Dec. 3, 2020.

¹⁰ Ashley Kirzinger, et al, *KFF Health Tracking Poll – February 2019: Prescription Drugs*, March 1, 2019. Retrieved at: https://www.kff.org/health-costs/poll-finding/kff-health-tracking-poll-february-2019-prescription-drugs/ on Dec. 3, 2020.

¹¹ Liz Hamel, et al, KFF Polling – Public Opinion on Prescription Drugs and Their Prices, October 2021.

¹² Ibid.

¹³ Caleb J. Scheckel and S. Vincent Rajkumar, "Drug importation: limitations of current proposals and opportunities for improvement," *Nature: Blood Cancer* Journal, July 2021. Retrieved at: https://www.nature.com/articles/s41408-021-00522-3 on Nov. 6, 2021.

¹⁴ H.R. 5376, Build Back Better Act, Nov. 3, 2021. Retrieved at: https://rules.house.gov/sites/democrats.rules.house.gov/files/BILLS-117HR5376RH-RCP117-18.pdf on Nov. 6, 2021.

Overview of prescription drugs

Prescription drugs are substances used to provide a therapeutic benefit to people with specific diseases or conditions and are required to have a health care practitioner's approval to purchase. Prescription drugs can be either a brand-name drug or generic drug. Brand-name prescription drugs are covered by a patent, which provides protections to the drug developer for a set period of time in which no one else can produce the same drug. A generic drug is considered to be the same as a brand-name drug and competes with the brand-name drug once the patent has expired. Generic drugs typically cost less than brand-name drugs and are used more frequently due to their reduced cost.

Drugs can also be distinguished between "small molecule" and "biologic" drugs. Small molecule drugs are generally manufactured through a controlled chemical reaction, while biologics are generally manufactured through the manipulation of living cells.¹⁷ Many high-cost new prescription drugs and new innovative therapies, including technologies such as "CAR-T" and monoclonal antibodies, are considered biologics. However, even some well-established prescription compounds such as insulin and human growth hormone would technically be considered biologics under current law if they were developed today.¹⁸

All prescription drugs are initially priced by the drug manufacturer with a wholesale acquisition cost (WAC). WAC is sometimes referred to as the list price for a prescription drug and is the starting

point for the drug price, which does not include any rebates or discounts. There are several other ways prescription drugs can be priced, such as the average wholesale price (AWP) and the average manufacturer price (AMP), that are used as starting points for negotiating drug prices between pharmaceutical supply chain entities.

The price someone pays at the pharmacy is determined through a complex set of factors throughout the pharmaceutical supply chain, which works to supply consumers with drug products. Manufacturers, wholesale distributors, pharmacies, pharmacy benefit managers (PBM), health insurance companies, medical providers, and consumers make up the majority of the actors involved in the pharmaceutical supply chain.

The price a consumer pays at the pharmacy can be influenced by the industry practices and financial negotiations between pharmaceutical supply chain entities, as well as what type of health insurance coverage the consumer has.

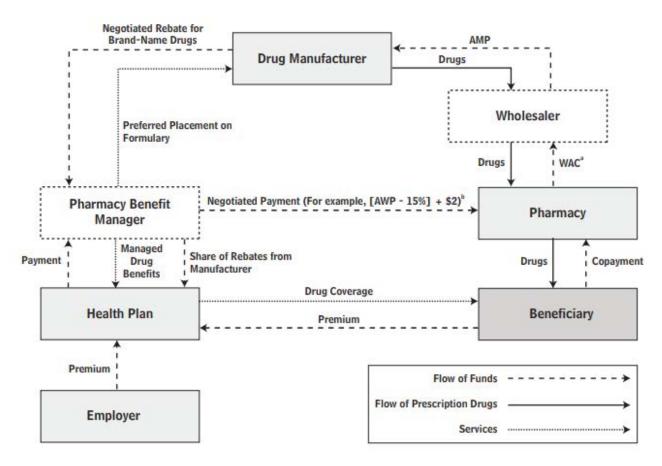


¹⁵ U.S. Food & Drug Administration. Prescription Drugs and Over-the-Counter (OTC) Drugs: Questions and Answers. https://www.fda.gov/drugs/questions-answers/prescription-drugs-and-over-counter-otc-drugs-questions-and-answers, visited November 2019.

¹⁶ U.S. Food & Drug Administration. *Questions, Answers, and Facts About Generic Drugs*. https://www.fda.gov/drugs/resources-you-drugs/questions-answers-and-facts-about-generic-drugs, visited November 2019.

¹⁷ Thomas Morrow, MD, Linda Hull Felcone, "Defining the difference: What Makes Biologics Unique," *Biotechnology Healthcare*, September 2004, retrieved at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3564302/ on Dec. 3, 2020. ¹⁸ Id.

Figure 1: Pharmaceutical supply chain for brand-name drug at retail pharmacy with employer health insurance plan



Source: Congressional Budget Office 19

People who are uninsured typically pay the list price of the drug, which can be changed by the drug manufacturer.

For people with health insurance, prescription drug costs are typically regulated through placement on a formulary tier determined by their insurance company. Placement on a higher tier typically results in a higher cost to purchase the drug. Many health insurance companies will require a co-pay or co-insurance payment when the consumer pays for the prescription drug at the pharmacy. A co-pay is a flat fee, such as \$5 per prescription, and co-insurance is a percentage of the drug cost, such as 20 percent of the drug price, that is paid to receive a prescription drug. Additionally, the negotiated reimbursement rate between the pharmacy and a health insurance

carrier can affect what the consumer pays for the drug.

There are several ways prescription drugs can be categorized: based on the disease they treat (therapeutic class), what type of pharmacy the prescription drug is obtained from (retail or nonretail), or by the specific national drug code (NDC) given to identify the dosage and packaging of the prescription drug. These types of categories will be used throughout this report to describe the data received from manufacturers, health insurers, and consumers.

¹⁹ Congressional Budget Office. Prescription Drug Pricing in the Private Sector, 2007, visited November 2019.

Prescription drug spending in the United States and Oregon

In 2019, U.S. health care spending reached \$3.8 trillion, which is approximately \$11,582 per person.

20 It is estimated that prescription drug spending accounts for approximately 13.9 percent of health care spending – 9.2 percent in retail pharmacies and an estimated 4.5 percent nonretail (by a physician or in a health care facility).

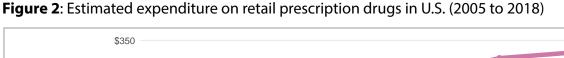
21 In the U.S., retail prescription drug spending accounts for approximately 10.9 percent of total health expenditures in 2018 and national spending has increased by \$130 billion from 2005 to 2018.

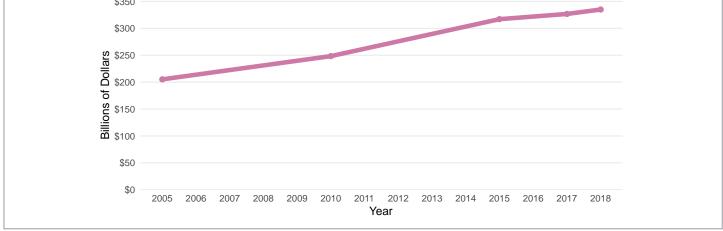
22 While growth in overall U.S. health care and prescription drug spending has slowed in recent years, many Americans continue to struggle paying for prescription drugs.

An estimated 19 million people are unable to pay for their prescription drugs in 2021.²³ Stories of how high costs affect people continue to be reported, particularly for those who need prescription drugs to treat cancer, manage diabetes, and address heart conditions.²⁴ These reports illustrate the effect that prescription drug costs have on households around the country and in Oregon.

Oregon prescription drug spending

Prescription drug spending and the effect of costs on Oregonians has been a growing interest for policymakers, health care providers, and the public in recent years. The state is a major purchaser of prescription drugs through health benefit plans





Source: Department of Consumer and Business Services, 2021.

Data: CMS National Health Expenditure Data – Accessed from www.cdc.gov November 2021.

²⁰ Anne B. Martin, Micah Hartman, David Lassman, and Aaron Catlin, "National Health Care Spending in 2019: Steady Growth for the Fourth Consecutive Year," *Health Affairs*, Dec. 2020. Retrieved at: https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2020.02022 on Nov. 6, 2021.

²¹ Conti RM, Turner A, Hughes-Cromwick P. Projections of US Prescription Drug Spending and Key Policy Implications. JAMA Health Forum. 2021. Retrieved at: https://jamanetwork.com/journals/jama-health-forum/fullarticle/2776040 on Nov. 6, 2021.

²² Centers for Disease Control document using data compiled from various sources by the Centers for Medicare and Medicaid Services (CMS) in 2019. https://www.cdc.gov/nchs/data/hus/2019/045-508.pdf visited November 2021.

Dan Witters, "In U.S., an Estimated 18 Million Can't Pay for Needed Drugs," *Gallup*, September 2021. Retrieved at: https://news.gallup.com/poll/354833/estimated-million-pay-needed-drugs.aspx on Nov. 6, 2021.

²⁴ Dena Bunis, "People Share Their Stories: The Human Cost of High Prescription Drug Prices," *AARP*, September 2021. Retrieved at: https://www.aarp.org/politics-society/advocacy/info-2021/high-prescription-drug-price-stories.html on Nov. 6, 2021.

or direct purchases for Oregonians. Reports from July 2019 through December 2020, show that the Oregon Health Authority (OHA) spent more than \$1.5 billion on prescription drugs for those enrolled in the Oregon Health Plan.²⁵ The biennium expectation is \$27 million for the CAREAssist program (Oregon's AIDS Drug Assistance Program - ADAP).²⁶ Prescription drug spending by the Public Employees Benefits Board (PEBB) was more than \$127 million in 2020 for 137,338 members. Oregon Educators Benefit Board (OEBB) with 134,108 members recorded \$110 million for the 2019-2020 plan year.²⁷ The Oregon Youth Authority, Oregon Department of Corrections, and Oregon State Hospital also purchase prescription drugs for the people in their care.

COVID-19 vaccines and therapeutics

When analyzing the specific issues affecting the prescription drug market in 2021, one of the biggest concerns is the cost and availability of vaccines and therapeutics developed to combat COVID-19. Several new pharmaceutical interventions were developed in 2020, and three vaccines are currently available in the U.S. to prevent illness or reduce the severity of COVID-19. These vaccines are available to all people

who are at least 5 years old and with no cost sharing under emergency use authorization.²⁸ Only one of these vaccines, Comirnaty (Pfizer-BioNTech)²⁹, has received full U.S. Food and Drug Administration (FDA) approval for use in people age 16 and older. The two other vaccines are produced by Moderna and Johnson & Johnson Janssen and are authorized for emergency use. The benefits of these vaccines have been realized with reduced COVID-19 hospitalizations and deaths.³⁰

Currently, vaccines are purchased by the federal government and are usually priced at a "pandemic price," which acknowledges the need for lower prices to distribute large quantities of an intervention. According to reports, the price paid by the federal government for the COVID-19 vaccines is about \$15 to \$20 per dose.³¹ Attention has turned to examining the potential disparities in the amount of profit that these companies have generated while concentrating distribution among higher income countries.³² Pfizer anticipates receiving \$36 billion in revenue from Comirnaty, and Moderna has reported a total revenue of \$11.3 billion for three quarters of 2021.³³

²⁵ Oregon Health Authority, "Pharmacy Utilization Summary Report: July 2019 – June 2020" "Pharmacy Utilization Summary Report: January 2020 – December 2020," Jan. 21, 2021, and July 22, 2021, see: "Total Amount Paid" on page 1. Retrieved at: https://www.orpdl.org/durm/reports/utilization/2020/DUR_Utilization_2020_Q4.pdf and https://www.orpdlorg/durm/reports/utilization_2021_Q2.pdf on Nov. 23, 2021.

²⁶ Legislative Policy and Research Office. Background Brief on Prescription Drugs. 2014. https://www.oregonlegislature.gov/lpro/Publications/BB2014PrescriptionDrugs.pdf, visited November 2019.

²⁷ "Oregon's PEBB July Utilization Report," see "Current" column on Page 16 of attachment 2. https://www.oregon.gov/oha/PEBB/MeetingDocuments/Board-Agenda-Attachment-20210719.pdf, visited November 2021. OEBB, see Page 46 of April 6, 2021, SEOW meeting attachments (slide 43): https://www.oregon.gov/oha/OEBB/Meeting%20Documents/SEOW-Attachments-20210406.pdf, visited December 2021.

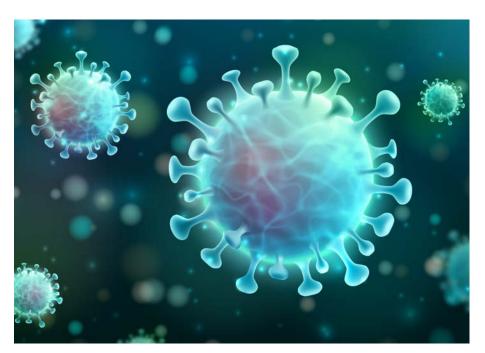
²⁸ Centers for Disease Control and Prevention, *COVID-19 vaccine dosing and schedule*, November 2021. Retrieved at: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#dosing-schedule on. Nov. 6, 2021. ²⁹ U.S. Food & Drug Administration, *Comirnaty*, October 2021. Retrieved at: https://www.fda.gov/vaccines-blood-biologics/comirnaty on Nov. 6, 2021.

³⁰ Centers for Disease Control and Prevention, *Rates of Cases and Deaths by Vaccination Status*, September 2021. Retrieved at: https://covid.cdc.gov/covid-data-tracker/#rates-by-vaccine-status on Nov. 6, 2021.

³¹ Rebecca Robbins and Peter S. Goodman, "Pfizer Reaps Hundreds of Millions in Profits from COVID Vaccine," *New York Times*, May 2021. Retrieved at: https://www.nytimes.com/2021/05/04/business/pfizer-covid-vaccine-profits.html on Nov. 6, 2021.

³² Rebecca Robbins, "Moderna, Racing for Profits, Keeps COVID Vaccine Out of Reach of Poor," October 2021. Retrieved at: https://www.nytimes.com/2021/10/09/business/moderna-covid-vaccine.html on Nov. 6, 2021.

³³ Pfizer, *Pfizer Reports Third-Quarter 2021 Results*, November 2021. Retrieved at: https://s21.q4cdn.com/317678438/files/doc_financials/2021/q3/Q3-2021-PFE-Earnings-Release.pdf and Moderna, *Moderna Reports Third-Quarter Fiscal Year 2021 Financial Results and Provides Business Updates*, November 2021. Retrieved at: https://investors.modernatx.com/node/13196/pdf on Nov. 6, 2021.



Therapeutics

Therapeutics for COVID-19 include one approved pharmaceutical treatment and others given emergency use authorization. Gilead Sciences' Veklury (remdesivir) attracted particular attention as the first new compound to win full FDA approval as a treatment for COVID-19. The company filed a new drug report for Veklury in late November 2020, because the drug meets Oregon's reporting threshold at a cost up to \$3,120 for a typical five-day course of treatment. We may receive reports about more COVID-19 therapeutics as they are approved, if they are within our filing thresholds.

Antivirals

Two antivirals are currently being evaluated for their efficacy at reducing hospitalizations and deaths as a result of COVID-19. One antiviral, Lagevrio

(molnupiravir), produced by Merck, was recently approved by the U.K.'s Medicines and Healthcare products Regulatory Agency (MHRA).³⁴ This accompanies news from Pfizer that its antiviral, PAXLOVID (ritonavir), significantly reduces hospitalization and death.³⁵ It remains to be seen if these antivirals will be approved for emergency use authorization, but the FDA is currently evaluating them.

Monoclonal antibodies

One other category of therapeutics for COVID-19 has drawn significant attention: monoclonal antibodies, a technology that uses engineered

human cells to generate antibody proteins similar to those naturally created by the immune system. Many of the innovative therapies developed by pharmaceutical companies over the past 20 years, including many treatments for cancers, are monoclonal antibody therapies. There are currently four monoclonal antibody therapies on the market for COVID-19 treatment, with one of the more notable manufacturers being Regeneron.³⁶ Clinical data indicates that these treatments may be effective in preventing severe complications from COVID-19-related illness.

Similar to vaccines, the federal government has been purchasing monoclonal antibodies for COVID-19 treatment and distributing them to states free of charge. The Centers for Medicare and Medicaid Services (CMS) has outlined

³⁴ Bill Chappell, "The U.K. approves Merck's COVID-19 antiviral pill, calling it a world first," *NPR*, November 2021. Retrieved at: https://www.npr.org/sections/coronavirus-live-updates/2021/11/04/1052281073/uk-merck-molnupiravir-covid-drug on Nov. 6, 2021.

³⁵ Pfizer, "Pfizer's Novel COVID-19 Oral Antiviral Treatment Candidate Reduced Risk of Hospitalization or Death by 89 percent in Interim Analysis of Phase 2/3 EPIC-HR Study," November 2021. Retrieved at: https://www.pfizer.com/news/press-release/press-release-detail/pfizers-novel-covid-19-oral-antiviral-treatment-candidate on Nov. 6, 2021.

³⁶ U.S. Dept. of Health & Human Services, "Monoclonal Antibody COVID-19 Infusion," June 2021. Retrieved at: https://www.hhs.gov/guidance/document/monoclonal-antibody-covid-19-infusion on Nov. 6, 2021.



that the payment rate for COVID-19 monoclonal antibodies is set the same way that is used for the COVID-19 vaccine. The example provided states, "Medicare will pay 95 percent of AWP for COVID-19 vaccines provided in the physician office setting, and pay hospital outpatient departments at reasonable cost for COVID-19 vaccines." ³⁷ Reports estimate the cost of monoclonal antibodies to be between \$1,250 and \$2,100, depending on the infusion received.

Other drugs

COVID-19 also disrupted the market for established prescription drugs due to demand for these drugs as COVID-19 cases increased. Many COVID-19 patients with severe illness require mechanical ventilation,

leading to concerns of shortages in multiple drugs used to support the process, such as paralytics, analgesics (painkillers), and sedatives. This trend continued into late 2021, when it was reported that many American hospitals were facing severe drug shortages as a result of supply chain disruptions caused by the pandemic.³⁸ In 2021, the massive promotion of Ivermectin as a treatment for COVID-19 led to shortages, despite the lack of evidence supporting its efficacy.³⁹ In the United States and Europe, 29 of 40 drugs commonly used to treat COVID-19 were in short supply in 2020.⁴⁰ Shortages like these, whether due to supply disruptions, unexpected demand, or both, can be a contributing factor to rising drug prices.

³⁷ U.S. Dept. of Health & Human Services, "Monoclonal Antibody COVID-19 Infusion," June 2021.

Mark Strassman, "Hospitals struggle with drug shortages as supply chain issues persist," *CBS Evening News*, October 2021. Retrieved at: https://www.cbsnews.com/news/hospitals-struggle-with-drug-shortages-as-supply-chain-issues-persist/ on Nov. 6, 2021.

³⁹ Oliver Milman, "U.S. horse owners face ivermectin shortage as human chase unproven COVID 'cure," *The Guardian*, September 2021. Retrieved at: https://www.theguardian.com/world/2021/sep/20/ivermectin-shortage-horse-owners-covid on Nov. 6, 2021.

⁴⁰ Ed Silverman, "As Covid-19 intensifies, shortages of staple drugs may grow worse," *STAT*, Oct. 21, 2020. https://www.statnews.com/pharmalot/2020/10/21/covid19-coronavirus-pandemic-shortages/ visited on Dec. 9, 2020.

Oregon Drug Price Transparency Program



Statutory authority

In 2018, the Oregon Legislature passed the Prescription Drug Price Transparency Act (House Bill 4005) to increase prescription drug price transparency, creating Oregon's Drug Price Transparency Program. The goal of the Drug Price Transparency Program is to provide accountability for prescription drug pricing through transparency of specific drug costs and price information from pharmaceutical manufacturers, health insurers, and consumers. The authority for Oregon's Drug Price Transparency Program is provided in Oregon Revised Statute (ORS) 646A.680 through 646A.692.

During the 2018 legislative process, Oregon legislators called the Prescription Drug Price Transparency Act the first step to understanding prescription drug cost and pricing through increased transparency.⁴² In 2019, the Legislature expanded the reporting requirements on manufacturers through passage of House Bill 2658. This law requires

manufacturers to provide notice to the state 60 days before a planned price increase when the reporting thresholds are met or exceeded. This requirement applies regardless of whether the price increase ultimately goes into effect or not.

Program information and activities

The program continues to engage manufacturers and collect information to inform the public hearing and legislative reports. In December 2021, the program held its third annual public hearing and released this report to the legislature.

Throughout the year, program staff members collect and analyze data from consumers, insurers, and pharmaceutical manufacturers. Program staff members help pharmaceutical manufacturers with questions, registration, billings, and filing required reports. Efforts to increase reporting compliance, review trade secret claims, and perform outreach to consumers have been reduced due to COVID-19. In spite of these challenges, the program continues to find ways to improve data reporting and analysis.

Two bills passed in 2021 that involve the program conducting a study and also providing assistance in the implementation of a drug affordability board. The Legislature passed Senate Bill 711, which required the Department of Consumer and Business Services to study the cost differences in hormone replacement drugs used by men and women and report findings to the Legislature by Sept. 15, 2022.

Additionally, the Legislature passed Senate Bill 844, which created the Prescription Drug

⁴¹ House Bill 4005 (2018), https://olis.leg.state.or.us/liz/2018R1/Measures/Overview/HB4005.

⁴² Oregon House Majority, "Prescription Drug Price Transparency Passes House", Feb. 28, 2018; see: Quotes from Representatives Meek and Nosse: https://www.oregonlegislature.gov/housedemocrats/Documents/PRESS%20 RELEASE%20Prescription%20Drug%20Price%20Transparency%20Passes%20House.pdf

Affordability Board. The board, which will be part of the Department of Consumer and Business Services, will review prices for selected prescription drugs reported to the Drug Price Transparency Program.

This report summarizes the findings from data collected since the 2020 annual legislative report. Any information directly identifiable to a particular drug or company was not claimed as a trade secret in the manufacturer's submission. Information covering multiple drugs has been de-identified and aggregated so that information claimed to be trade secret is not disclosed.

Consumer notifications and stories

The department has conducted outreach to provide Oregonians with information about the option to report a price increase. Direct program outreach to consumers has been limited due to the necessity of limiting in-person gatherings and maintaining physical distancing due to the COVID-19 pandemic. We also believe that such restrictions have limited consumer access to printed materials, such as program fliers posted in pharmacies.

Anyone from the public can provide notification of an increase in the cost of prescription drugs to the Drug Price Transparency Program via phone, email, or an online submission form. The notification form includes information about the consumer's insurance coverage, the drug that increased in price, and when and where the consumer experienced the price increase.

Price increase notices from consumers

Over the life of the program, the department has received 40 notifications of price increases from consumers. The vast majority of these reports (36) were received in the first year of the program, and likely coincided with pre-pandemic efforts. As of

October 2021, the department has received only one price increase notification from an Oregon consumer in 2021 (for NDC 50228-363, Omeprazole and Sodium Bicarbonate, a treatment for acid reflux and the generic equivalent of Prilosec). This decrease in consumer reports is likely due to the disruption of planned outreach efforts due to the COVID-19 pandemic as mentioned above.

It is also possible that the increasing shift of consumers to mail-order and online pharmacies has decreased the visibility of the program. Our outreach efforts to date have been focused on distributing print literature to retail pharmacies. However, the market share of mail-order and online pharmacy services accounted for 37 percent of retail prescription sales in 2017.⁴³ It is likely that the COVID-19 pandemic has accelerated the shift toward remote pharmacy delivery as consumers seek to limit in-person contacts.⁴⁴

Due to the limited data received from consumer reports this year, we are not publishing any new analysis based on consumer notice data. As the pandemic eases and we are able to resume more outreach, we are anticipating an increase in consumer reporting next year.

The department remains committed to maintaining consumer engagement with the program and views consumer reporting as an indispensable element of our data collection. The program will continue outreach to Oregonians using a variety of strategies, including virtual opportunities for people to connect with the program. Program materials are currently available in English, Russian, Spanish, and Vietnamese.

⁴³ Elizabeth Seeley, Surya Singh, "Competition, Consolidation, and Evolution in the Pharmacy Market," The Commonwealth Fund, Aug. 12, 2021, retrieved at: https://www.commonwealthfund.org/publications/issue-briefs/2021/aug/competition-consolidation-evolution-pharmacy-market, on Nov. 5, 2021.

⁴⁴ Id.

Stories from Oregonians

In addition to price increase reports, the program also asked Oregonians to submit their stories, comments, and questions about prescription drug pricing. We have received a number of responses, with a few consistent threads. Below is information on questions and stories received this year. Those shared below were edited for length. All of the consumer questions and stories we have received with permission to share will be available in a separate document as exhibits 1 and 2. The submissions have light editing and names removed.

This word cloud shows the density of words found in submissions to the program received in 2021 to provide a visual of the most common topics.

state continue prescribed medicine diabetes order profit doctor inhaler different changing allowed medicare last hospital long money use oregon available brand help every reasonable advertising

Some respondents in 2021 shared their experience with specific prescription drugs, such as these stories about Humira and Xarelto.

"After her immune suppressive drugs started having less effect and were no longer working effectively against Crohn's disease, my wife was switched to other progressively more expensive drugs to see if any of them worked. After several different drugs were considered, she was prescribed Humira, which is the most expensive drug regularly prescribed (I think) and it almost killed her with some of the worst side effects. . . .

The price of the Humira prescription was so outrageous that most people can't even afford it. . . . After the horrible side effects appeared, she was advised to stop

the drug and discard the unused auto injectors that were unopened. We contacted the pharmacy and they advised the unopened Humira auto injectors valued at more than \$30,000 could not be returned or reused for another patient.

... For some people it becomes a choice of do I try something that could save my life, but risk death if an adverse side effect happens? Or do I choose to spend money on a prescription instead of other things like rent, food, ... While the waste of unused, unopened drugs is sad, it is very common. Is this the best we can do as a society and modern civilization? We think not."

"The cost of our generic drugs have all doubled or tripled in just the last few years. Yes, for now we can afford them, but we wonder if this steep increase will

continue to the point we can no longer pay for all of them.

We copay almost \$600 for Xarelto for 90 days. Of course it's worth it because it keeps my husband alive, but again, we wonder what the future brings."

We also received stories about the expense of treating certain illnesses. Here is a story about a

price increase for an asthma treatment and the cost for Crohn's disease prescription drugs.

"When I moved to Oregon I was using an over-the-counter inhaler for asthma. The cost at Bi-Mart was \$12.00 for one atomizer that would last me for 3 or 4 weeks. That lasted for 3 or 4 years. Then one day I went in to buy another atomizer (spray for my lungs) and I was told I need a prescription. So I went to my doctor and got a prescription took it to Bi-Mart to get it filled. When I went to pick it up it was \$600.00 for one \$12.00 atomizer. And that happened overnight. There was no way I could afford that, so I had to do without.

My sister has Crohn's disease and was prescribed a drug to control it, the cost \$12,000 dollars a month."

We also received stories about the affect of insurance on treatment options.

"As a dialysis patient with end stage renal failure, I'm on Medicare in addition to my work-provided insurance. One of the side effects of dialysis is hyperthyroidism in dialysis patients. This is usually treated with an injection of Parsabiv at the end of treatment. However, around 6 months ago, my medical center decided, as a cost saving measure, to switch to a pill that I take, which, despite their best efforts, makes me nauseous every time I take it. This was done because the insurance companies didn't want to pay the high prices for Parsabiv when a pill "can do the same job for cheaper". Because of this, I now have to decide..."do I deal with being sick 3 days a week, or do I not take my meds?"

This story is about medical expenses and drug prices leading to financial struggles, including cancer treatment of a loved one who has since died from the disease.

"... my husband was being treated during his third & final bout of cancer. We were both retired, considered middleclass, owned a home ... We also were grateful we could afford good health coverages ... as we got older ... the costs became increasingly harder to cover ... [T] he day came when my husband needed a procedure to help him breathe. He was hospitalized & we were waiting ... for the procedure - when we were told he would have to wait one or two days before the specialist could be brought in or pay \$29,000 for an available doctor & get it done that day.

What would you do if a family member was gasping for each breath? I had no idea how I would pay for it, but at that moment I would do anything ... That procedure helped & made it possible for him to return home ... with 5 months actively interacting with friends & family; not just laying in bed thinking of his passing. What was just as disappointing as paying \$29,000 was the one pill he took the last month of his life - a whooping \$5,500! Yes, one pill per week.

I used ... life insurance to pay for what wasn't covered by insurance ... Medical issues ... put me in a situation that I no longer own a home, ... With my primary care provided by ... Nurse Practitioners ... (I haven't seen a medical doctor ... in well over 3 years) - they bill my health insurance the same for NP services as MD services, so you don't see an MD & they profit 80% more so why care about the patient?!

... Now I'm in the low-income population; unable to work, living on retirement & SSI. ... Costs of medications are equal to a trip to the grocery store each month & I shop only sales! ...; much of my working life was in the health industry ... I saw the waste & mishandling of medications by non-professionals & professionals.

The sad thing is there are people clumped together by their economic groups NOT by who needs medications that would be life changing for them; it's like companies making medications want money & if you're not making enough, then you're not worth it because you don't improve our bottom line."

A physician shared what their patients experience.

"As a physician who cares for people with multiple sclerosis, every week I meet a patient who cycles on and off disease modifying therapy due to job loss, excessive copays, and other logistical problems, like having to be home to sign for specialty pharmacy drug delivery and transportation barriers to getting infused therapies. MS has a therapeutic window early in the disease course to prevent or delay disability accumulation. Treatments later in the disease course don't work to slow disability, and there are no effective ways to repair the nervous system. It's not the occasional patient falling through the cracks, but nearly the norm. Healthcare is a patchwork blanket with major holes in it, and drug prices are one of those major holes. Society ends up paying multiple times the cost of medication later due to the costs of being highly disabled -- wheelchairs, home modifications, infections, hospitalizations, and caregiver pay."

We also saw respondents who spoke to the state and federal government.

"I ordered a prescription ointment from my mail order pharmacy and when it came I had been charged \$343. I later found out I could have purchased it at Fred Meyer for \$45 with the GoodRx discount card. I have since used GoodRx for all prescriptions, but still have to pay my monthly Part D plan premium. What a serious mistake on our government's part to be the only country not to negotiate prices. It is quite obvious who is winning here."

"Why will the government not place reasonable price controls on pharmaceutical companies and/or require insurers to negotiate lower prices?"

"They are absolutely ridiculous. My wife had medicine prescribed by a vet for our dog. The local pharmacy charged her \$150.00. The pharmacist later contacted us and apologized to us for charging us the HUMAN price. The dog price for the SAME drug was \$12.50 from the same pharmacy.

So, why the hell are human drugs so much more expensive? We are being ripped off by unnecessary mark ups! It's because the healthcare system is a for-profit criminal enterprise that completely rips off customers. And the federal and state governments are complicit in allowing this to occur."

A few consumers submitted questions and comments about advertising.

"One reason the price of prescriptions has skyrocketed over the last few years, is because of the media allowing drug companies to advertise over television and radios.

... Billions of dollars are spent by these Big Pharma companies to choose for a medical doctor to what drug they need for their patient. I have COPD end stage. Just one of my many prescriptions costs the public over \$600 per month and it's plastered all over media these days!

They use big name entertainers to do their misleading diagnosis of a drug to convince us that we need to be taking this celebrity's drug just the same way they do with other merchandise promoted! If we would impose like our country to the north (who doesn't allow any drug commercials), they would save billions on advertising and use that money for research. . . . "

The program also accepted questions from Oregonians about prescription drug pricing. This shows what people want to know about drug pricing, and will help guide analysis in the years to come.

"Why are they so high when they're cheaper in other countries?"

"Why do insurance companies keep buying up pharmacies? So, customers are stuck going through mail order with prices that are non-negotiable?"

"How can there be such a big difference in price between my insurance company and GoodRx? How can there be such huge differences in price between competing pharmacies?"

"How are you calculating if and how transparency about drug prices translates to lower consumer costs? How is this information being shared with the public?"

"How can prices be so outrageously high that people must choose between their medications, a place to live (rent or mortgage), or even their health?"

"Why does it feel like the price you pay depends on how much time you have to spend on the phone negotiating prices or scouring the internet for coupons? ... When will this get better?"

Other questions were more specific, such as the following about insulin, patents, and advertising.

"Why is insulin so expensive when the original patent was given to them for free? Simply adding buffers or a little saline does not constitute a whole new medicine. What are lawmakers afraid of?"

"Why is the United States still allowing the gouging of insulin prices?"

"Note that the most expensive and/or most prescribed drugs are the most advertised drugs. Some of these ads run multiple times in a half-hour program, especially during prime time, particularly on news and other programs watched mostly by seniors.

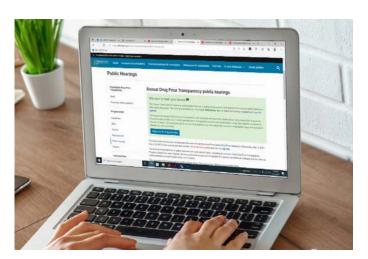
How much does this advertising add to the cost of the drugs? Also, how much do the drug companies pay to or for doctors to endorse and prescribe these drugs?"

This report contains significant detail on the drug pricing process, though it also describes how the price set by a manufacturer can be quite different from the price actually paid at the pharmacy counter. One challenge for Oregon may be working to translate reforms at the insurer and manufacturer level into reduced out-of-pocket costs at the pharmacy counter, as consumers have requested.

Other issues, such as the amount of money manufacturers spend on various types of marketing and its effect on a drug's list price, will take more time to address. While manufacturers are required to submit this information to the program, the quality of information provided has been extremely variable, and we are actively working with pharmaceutical companies to improve the quality of data provided. The level of detail we currently

have available does not allow for meaningful analysis of this information.

The questions and concerns presented by Oregonians are a vital part of our process and will guide our continuing implementation of the Prescription Drug Price Transparency Act and future legislative actions.



Prescription drug manufacturers

Prescription drug manufacturers are required to submit reports to the program for new prescription drugs and prescription drug price increases that exceed the threshold for that reporting requirement. The three reports received are:

New drug report: Manufacturers are required to submit a new prescription drug report within 30 days of introducing a new prescription drug with a list price of \$670 or more for a 30-day supply or for a course of treatment shorter than one month.

Annual price increase report: Manufacturers are required to annually submit a price increase report for each prescription drug with a list price of \$100 or more for a 30-day supply or for a course of treatment shorter than one month that experiences a net price increase of 10 percent or more during the previous calendar year.

Sixty-day notice price increase report:

Manufacturers are required to submit a price increase report 60 days before the planned increase takes effect when the threshold is met. A report is

required for a brand-name prescription drug when the cumulative price increase is at least 10 percent or \$10,000 within a 12-month period. A report is required for a generic prescription drug when the cumulative price increase is at least \$300, and the increase is also 25 percent or more, within a 12-month period.

Reporting is required for each qualifying national drug code (NDC) the manufacturer sells. Each unique formulation, dosage, and packaging of a manufacturer's drug gets its own NDC, so the program may receive multiple reports for a single drug if it is manufactured in a variety of dosages or sold in different package sizes.

This report is based on data submitted to the program through Oct. 15, 2021. Any information directly identifiable to a particular drug or company was not claimed as a trade secret in the manufacturer's submission. Information covering multiple drugs has been de-identified and aggregated so that information claimed to be trade secret is not disclosed.

New High-Cost Drug Reports

New high-cost drugs are reported to the program when they are priced at \$670 or more. This is the price threshold set by the federal government to categorize a drug as a "specialty drug" under Medicare Part D. Reports for new high-cost drugs come in continuously.

Between Oct. 15, 2020, and Oct. 3, 2021, the program received 300 New High-Cost Drug Reports, each one for a different NDC. These reports were submitted by 105 different manufacturers.

A single drug will generally be sold under several NDCs. For example, a manufacturer may sell two bottles of generic ibuprofen, one with 25 tablets and the other with 50 tablets. In that case, both bottles would have a different NDC, even though they are for the same drug. In our analysis, we group together NDCs for the same drug from the same manufacturer when describing our data.

We received New High-Cost Drug Reports for 121 generic drugs that came from 45 manufacturers reporting 193 NDCs. We also received reports for 72 brand-name drugs that came from 62 manufacturers reporting 107 NDCs.

The most common class of drug in these reports were antineoplastics and adjunctive therapies (drugs for the treatment of cancer). We received reports for 41 different antineoplastics and adjunctive therapies. Of these, 18 were generic drugs from 14 manufacturers (25 NDCs) and 23 were brand-name drugs from 21 manufacturers (33 NDCs).

The next most common classes were antivirals reporting 14 drugs from 10 manufacturers (19 NDCs) and dermatologicals reporting 13 drugs from 10 manufacturers (31 NDCs).

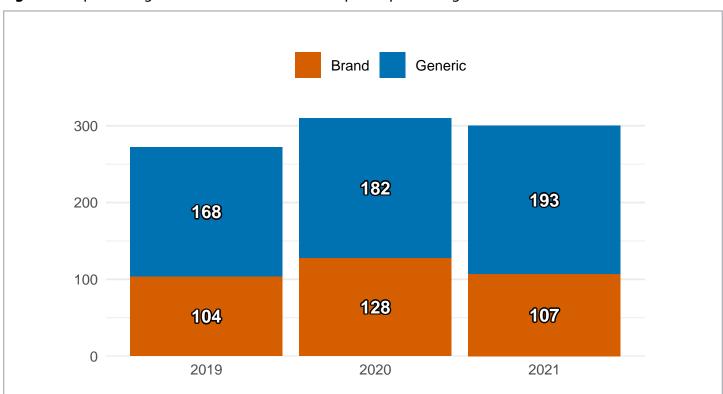
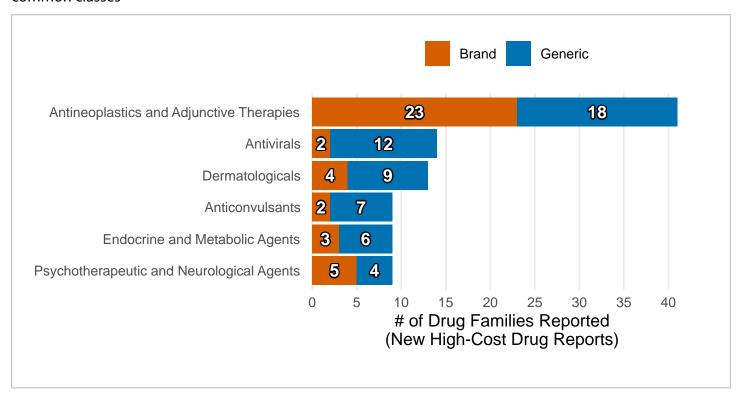


Figure 3: Reports for generic and brand-name new prescription drugs 2019-2021

Figure 4: Breakdown for brand-name and generic drugs from New High-Cost Drug Reports by most common classes





Aduhelm and Biogen's report to the department

Aduhelm (chemical name aducanumab), manufactured by Biogen, is the first new treatment in 18 years to be approved by the FDA for the treatment of Alzheimer's disease, and the first treatment intended to target the disease process rather than treating symptoms.⁴⁵ The drug, a monoclonal antibody that launched with a list price of \$56,000 per year, has been surrounded by controversy.

The drug reduces the presence of amyloid plaques in the brain. These plaques are associated with Alzheimer's disease, and their presence is the primary diagnostic criteria for Alzheimer's. It has been questioned whether eliminating these plaques actually improves brain function in Alzheimer's

⁴⁵ Pam Belluck and Rebecca Robbins, "FDA Approves Alzheimer's Drug Despite Fierce Debate Over Whether It Works," *The New York Times*, June 7, 2021, retrieved at: https://www.nytimes.com/2021/06/07/health/aduhelm-fda-alzheimers-drug.html, on Nov. 2, 2021.

patients, and nearly two dozen drugs targeting amyloid plaques have failed in clinical trials due to a lack of evidence of any clinical benefit.⁴⁶

In November 2020, the FDA's scientific advisory panel voted unanimously that the clinical evidence was insufficient to demonstrate a benefit from administration of Aduhelm (the vote was 10 "no," 1 "uncertain.")^{47 48} Despite this, the FDA approved the drug for the treatment of Alzheimer's disease in June 2021 with no population restrictions – even though Biogen's own clinical trials had been limited to patients in the earliest stages of Alzheimer's.⁴⁹ In response to subsequent criticism, the FDA narrowed its original approval for Aduhelm to patients with mild cognitive impairment or mild dementia, the same class of patients that had been tested in trials.⁵⁰

Aduhelm has also been associated with potentially dangerous brain swelling and brain bleeding.⁵¹ While these side effects are generally controllable, patients taking Aduhelm require regular brain

monitoring through potentially expensive positron emission tomography (PET) scans and magnetic resonance imaging (MRI) tests.⁵²

With a list price of \$4,312 per infusion, Aduhelm is expected to cost around \$56,000 a year for a typical patient (not including clinical costs associated with infusion or the cost of brain scans to monitor side effects).53 Due to the age of Alzheimer's patients, most of the cost of administering Aduhelm in the United States will probably be paid by Medicare – if Medicare chooses to cover the drug. If 500,000 patients were covered annually for Aduhelm infusion through Medicare, slightly less than 10 percent of the estimated 6 million Americans with Alzheimer's, the cost would reach \$29 billion per year, or almost as much as Medicare Part B currently spends on all drugs (\$37 billion in 2019).54 Given this potential budget impact, the Centers for Medicare and Medicaid Services has begun

⁴⁶ Harris Meyer, "FDA Weighs Approval of a Lucrative Alzheimer's Drug, but Benefits Are Iffy," *Kaiser Health News*, June 4, 2021, retrieved at: https://khn.org/news/article/fda-weighs-approval-of-a-lucrative-alzheimers-drug-but-benefits-are-iffy/?utm_campaign=KHN%3A on Nov. 3, 2021.

⁴⁷ Dylan Scott, "The new alzheimer's drug that could break Medicare, *Vox*, June 10, 2021, retrieved at: https://www.vox.com/policy-and-politics/22524608/new-alzheimers-drug-cost-fda-approval-biogen, on Nov. 2, 2021.

⁴⁸ Matthew Herper, Adam Feurstein, and Damian Garde, "Expert panel votes down Biogen's Alzheimer's drug, and rebukes the FDA in the process," *STAT*, Nov. 6, 2020, retrieved at: https://www.statnews.com/2020/11/06/expert-panel-votes-down-biogens-alzheimers-drug-and-rebukes-the-fda-in-the-process/, on Nov. 2, 2021

⁴⁹ Andrew Joseph, "An extra twist in the FDA's Alzheimer's decision: no limits on which patients can get the drug," *STAT*, June 7, 2021, retrieved at: https://www.statnews.com/2021/06/07/twist-fda-alzheimers-decision-no-limits-on-patients/?utm_source=STAT+Newsletters&utm_campaign=b22996b9%E2%80%A6, on Nov. 3, 2021.

⁵⁰ Manas Mishra, "US FDA narrows use of Biogen Alzheimer's drug; shares rise," *Reuters*, July 12, 2021, retrieved at: https://www.reuters.com/business/healthcare-pharmaceuticals/us-fda-updates-label-biogens-alzheimers-drug-specify-disease-stage-2021-07-08/, on Nov. 3, 2021.

⁵¹ Id.

⁵² Id.

⁵³ Hawken Miller, "Aduhelm Approval Greeted with Joy, Concern in Alzheimer's Community," *Alzheimer's News Today*, June 17, 2021, retrieved at: https://alzheimersnewstoday.com/2021/06/17/aduhelm-approval-biogen-greeted-joy-concern-alzheimer-community/, on Nov. 3, 2021.

⁵⁴ Zachary B. Wolf, "The hard math on the new \$56,000 Alzheimer's drug," CNN, July 20, 2021, retrieved at: https://www.cnn.com/2021/07/20/politics/aduhelm-alzheimers-drug-cost-what-matters/index.html on Nov. 3, 2021.

reviewing the evidence for Aduhelm's efficacy, and is expected to issue a determination of whether, and how, Medicare will cover Aduhelm.⁵⁵

While Medicare may choose not to cover Aduhelm, state Medicaid programs who participate in the Medicaid Drug Rebate Program are required to cover all FDA-approved drugs (currently all states participate).⁵⁶ The National Association of Medicaid Directors has projected that a decision by the Center for Medicare and Medicaid Services not to cover Aduhelm through Medicare could cost the Medicaid program \$1.9 billion in additional spending.⁵⁷ If this happened, some of these costs would be paid by the state, due to its required contributions to fund the Oregon Health Plan, Oregon's version of Medicaid.

In Biogen's report to the program on Aduhelm, the company provided the following information to describe the company's methodology for pricing the drug (this information was not claimed as trade secret):

"[Biogen has] engaged extensively with health economists, public health experts, and payers about ADUHELM – and we have examined other recent biologic drug innovations. Consistent with our pricing principles, we have established a price for ADUHELM that reflects the overall value this treatment brings to patients, caregivers and society – and one that will enable continuous innovation. We have determined the launch price of ADUHELM based on our belief in the impact of treatment as well as the size of the appropriate patient population based on the entry criteria of our clinical trials. Biogen has established the price of ADUHELM based

on the overall value this treatment is expected to bring to patients, caregivers, and society, while reflecting key principles such as innovation, access and sustainability. The wholesale acquisition cost (WAC) of ADUHELM, which is an infusion once every four weeks, is \$4,312 per infusion for a patient of 74 kg—the average weight of a U.S. patient with mild cognitive impairment (MCI) or mild dementia. The yearly cost at the maintenance dose (10 mg/kg) would be \$56,000. The cost during the first year of treatment will be lower due to the titration period. WAC is a list price and not the net price or the price paid by patients with insurance.

Biogen has a set of Pricing Principles that inform pricing decisions for its products. Those principles are: 1. Value to Patients, 2. Present and Future Benefit to Society, 3. Fulfilling our commitment to Innovation, 4. Evolution toward Value Based Care, and 5. Affordability & Sustainability."

While Biogen's explanation references value, access, and sustainability, the high price of Aduhelm has drawn criticism even from organizations such as the Alzheimer's Association, which supported the FDA's approval of the drug. In its press release following the FDA's decision, the Alzheimer's Association stated:

"This price is simply unacceptable. For many, this price will pose an insurmountable barrier to access, it complicates and jeopardizes sustainable access to this treatment, and may further deepen issues of health equity. We call on Biogen to change this price." 58

⁵⁵ Center for Medicare & Medicaid Services, "CMS Opens National Coverage Determination Analysis on Treatment for Alzheimer's Disease," July 12, 2021, retrieved at: https://www.cms.gov/newsroom/press-releases/cms-opens-national-coverage-determination-analysis-treatment-alzheimers-disease, on Nov. 3, 2021.

⁵⁶ Kaiser Family Foundation, "Medicaid's Prescription Drug Benefit: Key Facts," May 1, 2019, retrieved at: https://www.kff.org/medicaid/fact-sheet/medicaids-prescription-drug-benefit-key-facts/, on Nov. 5, 2021.

⁵⁷ Matt Salo, "Much Adu(helm) about nothing: New Alzheimer's drug threatens state Medicaid budgets," *STAT*, Oct. 12, 2021, retrieved at: https://www.statnews.com/2021/10/12/new-alzheimers-drug-threatens-state-medicaid-budgets/on Nov. 3, 2021.

⁵⁸ The Alzheimer's Association, "Alzheimer's Association Statement: Next Steps For New Alzheimer's Treatment,", retrieved at: https://www.alz.org/news/2021/next-steps-for-new-alzheimers-treatment

The Institute for Clinical and Economic Review (ICER), an independent nonpartisan research organization that objectively evaluates the economic and clinical benefits of health care innovations, has reviewed the clinical and economic case for Aduhelm. ICER's analysis, which took into account not only the potential clinical benefit of the drug, but also benefits to the health system and society, suggested a price between \$1,030 and \$11,500 per year for Aduhelm based on the current evidence.⁵⁹ This is less than one-fifth of the price set by Biogen.

Interest in Aduhelm has been slow so far, despite the large potential patient population. As of Sept. 11, 2021, only about 100 patients had received Aduhelm infusions.⁶⁰ Several private insurance companies, including a number of Blue Cross/Blue Shield affiliates, have announced that they will not provide coverage for Aduhelm.⁶¹ Additionally, a

number of health systems, including the Cleveland Clinic, New York City's Mount Sinai, and Washington-statebased Providence Health Systems (a major provider of care in Oregon) have all announced that they will not administer Aduhelm to their patients.⁶²

Given the potential budget impact for the Oregon Health Plan, the approval of Aduhelm by the FDA, its pricing, and possible coverage or noncoverage by private insurers should be discussed by state policymakers. It is unclear how many Oregonians with Alzheimer's disease will seek an Aduhelm prescription, if they will be able to pay for it, or even be able to find a clinic that is willing to administer the drug.

Trade secret claims in New High-Cost Drug Reports

When a manufacturer fills out a report for the program, it can mark individual data elements (such as cost and profit data and the narrative description of the factors contributing to the price increase) as "trade secret." This prevents the Drug Price Transparency Program from immediately publishing it. In order to publicly release an individual data element claimed to be trade secret, the program must conduct a lengthy review of the manufacturer's provided justification for the trade secret claim, make



⁵⁹ Grace A. Lin, et al, "Aducanumab for Alzheimer's Disease: Effectiveness and Value Draft Evidence Report", Institute for Clinical and Economic Review, May 5, 2021.

⁶⁰ Adam Feuerstein, Damian Garde, "Biogen's Aduhelm sales slower than disclosed, forcing company to consider cost-cutting measures," STAT, Sept. 22, 2021, retrieved at: https://www.statnews.com/2021/09/22/biogens-aduhelm-sales-slower-than-disclosed-forcing-company-to-consider-cost-cutting-measures/ on Nov. 3, 2021.

⁶¹ Max Gelman, "Private insurers decline to cover Biogen's new Alzheimer's drug in escalating standoff – report," *Endpoints News*, July 14, 2021, retrieved at: https://endpts.com/private-insurers-decline-to-cover-biogens-new-alzheimers-drug-in-escalating-standoff-report/ on Nov. 3, 2021.

⁶² Katie Adams, "Providence joins opposition to Aduhelm administration," *Becker's Hospital Review*, July 16, 2021, retrieved at: https://www.beckershospitalreview.com/pharmacy/providence-joins-opposition-to-aduhelm-administration.html on Nov. 3, 2021.

a determination that the data element should be released, and give the manufacturer an opportunity to appeal the program's decision.

Across the 300 New High-Cost Drug Reports we received, manufacturers claimed 475 individual data elements as trade secret. That's an average of 1.6 trade secret claims per report, much lower than the rate we found this year for the annual price increase reports (10.5 claims per report – see page 40).

Out of all possible data elements that could be claimed as trade secret in their New High-Cost Drug Reports, manufacturers claimed 13 percent of them to be trade secret.

The following data elements were frequently claimed to be trade secret this year:

- The description of the marketing used in the introduction of the new drug, including dollars spent
- The methodology used to establish the price of the drug
- The estimated number of patients per month for the drug

Highest WAC prices in New High-Cost Drug Reports

The program received New High-Cost Drug Reports for drugs with wholesale acquisition costs (WACs) ranging from \$18 to \$419,500. It is possible that a WAC less than \$670 may still require a report to the program, depending on the length of a course of treatment. For example, a drug with a WAC of \$335 for a single dose that requires two doses in one month would cost \$670 for a course of treatment, prompting a report. However, it is likely that some of the reports we received with lower WACs have been submitted in error.

The chart below shows the 10 highest WAC prices for new brand-name drugs reported to the program this year. It is important to note that this is not the price that will be billed to most patients or their insurance company, but is a factor in that price, which is typically calculated as a set percentage of a drug's WAC.

The two highest WACs reported this year were for chimeric antigen receptor T-cell (CAR-T)

Figure 5: Highest Reported WACs for New Brand-name Drugs

Drug	WAC	Therapeutic Class	Manufacturer
Abecma	\$419,500	Antineoplastics and Adjunctive Therapies	Bristol Myers Squibb
Breyanzi	\$410,300	Antineoplastics and Adjunctive Therapies	Bristol Myers Squibb
Oxlumo	\$55,000	Genitourinary Agents	Alnylam Pharmaceuticals
Bylvay	\$6,600 - \$39,600	Gastrointestinal Agents	Albireo Pharma
Evkeeza	\$10,781 - \$37,500	Antihyperlipidemics	Regeneron Pharmaceuticals
Orladeyo	\$37,308	Hematological Agents	BioCryst Pharmaceuticals
Zokinvy	\$21,510 - \$32,265	Progeria Treatment Agents	Eiger Biopharmaceuticals
Welireg	\$26,400	Antineoplastics and Andjunctive Therapies	Merck & Co
Fotivda	\$24,150	Antineoplastics and Andjunctive Therapies	AVEO Oncology
Zynlonta	\$23,500	Antineoplastics and Andjunctive Therapies	ADC Therapeutics

therapies, both manufactured by Bristol Myers Squibb. This mirrors the reports from last year, when the highest reported WAC was also for a CAR-T therapy (Tecartus, \$373,000). CAR-T therapies are a relatively new technology that uses engineered versions of a patient's own white blood cells to destroy targeted substances in the body, such as cancer cells.⁶³

This year's highest reported WAC was for Abecma, with a per-dose price of \$419,500. This is a CAR-T treatment for multiple myeloma, a cancer of plasma cells that affects the immune system.⁶⁴

The second highest reported WAC was for Breyanzi, with a per-dose price of \$410,300. This is a CAR-T treatment for large B-cell lymphoma, also a cancer of the immune system.⁶⁵

The chart below shows the 10 highest WAC prices for new generic drugs reported to the program this year. Again, these prices are not necessarily the same as the price billed to patients or insurance.

The highest WAC reported this year among generic drugs was for an NDC of artesunate, an antimalarial drug manufactured by Amivas

Figure 6: Highest Reported WACs for New Generic Drugs

Drug	WAC	Therapeutic Class	Manufacturer
Artesunate	\$9,960 - \$19,920	Antimalarials	Amivas (US)
Sunitinib Malate	\$5,093 - \$17,732	Antineoplastics and	Sun Pharmaceutical Industries
Icatibant Acetate	\$15,250	Adjunctive Therapies	Cipla USA
Strontium Chloride Sr-89	\$15,000	Hematological Agents	Q BioMed
Flucytosine	\$6,566 - \$12,704	Antineoplastics and	Aurobindo Pharma USA
Everolimus	\$12,013 - \$12,565	Adjunctive Therapies	Hikma Pharmaceuticals
Vigabatrin	\$10,512	Antifungals	Dr. Reddy's Laboratories
Abiraterone Acetate	\$9,396	Antineoplastics and	Mylan Pharmaceuticals
Pyrimethamine	\$8,775	Adjunctive Therapies	Dr. Reddy's Laboratories
Isoproterenol HCI	\$8,495	Antiasthmatic and Bronchodilator Agents	Micro Labs USA

⁶³ American Cancer Society, "CAR T-cell Therapy and Its Side Effects," retrieved at: https://www.cancer.org/treatment/treatments-and-side-effects/treatment-types/immunotherapy/car-t-cell1.html on Dec. 2, 2020.

⁶⁴ Bristol Myers Squibb, Abecma Patient Website, retrieved at: https://www.abecma.com/ on Oct. 26, 2021; American Cancer Society, "What Is Multiple Myeloma?" retrieved at: https://www.cancer.org/cancer/multiple-myeloma/about/what-is-multiple-myeloma.html on Oct. 26, 2021.

⁶⁵ Bristol Myers Squibb, Breyanzi Patient Website, retrieved at: https://www.breyanzi.com/ on Oct. 26, 2021; American Cancer Society, "Types of B-Cell Lymphoma," retrieved at: https://www.cancer.org/cancer/non-hodgkin-lymphoma/about/b-cell-lymphoma.html on Oct. 26, 2021.

(NDC 73607000110). This NDC has a WAC price of \$19,920 and contains four vials of the drug. Amivas also reported a second NDC for this drug (NDC 73607000111) that contains two vials and has a WAC price of \$9,960.

The highest reported WAC for a single dose of a generic drug was for strontium chloride Sr-89, manufactured by Q BioMed, with a per-dose price of \$15,000. This anti-cancer drug is an injection of a radioactive compound and is indicated for the relief of bone pain in patients with bone cancer.⁶⁶

Public funds in New High-Cost Drug Reports

Manufacturers are required to report any funding provided by national, state, local, or foreign government entities that was used in the basic or applied research for the drug, including funding for preclinical and clinical trials.

Manufacturers overwhelmingly reported receiving no public funding for the drugs reported. Out of the 300 New High-Cost Drug Reports we received, only three reported nonzero amounts of public funding that were not marked as trade secret.

A report for Welireg (NDC 00006533101), an anti-cancer drug manufactured by Merck & Co., reported \$3,201,002 of public funding and stated the following:

The Cancer Prevention & Research Institute of Texas (CPRIT) provided a grant to Peloton Therapeutics, Inc. (later acquired by Merck) in support of small molecule discovery programs. This grant was awarded on June 18, 2010, however funds were received when Peloton commenced operations in August 2011. This information was obtained from the developer of the molecule used to manufacture WELIREG, Peloton Therapeutics, Inc. To the best of our knowledge, there is no other public funding received by Peloton that we are aware of.

A report for Dificid (NDC 52015070022), an antibiotic drug also manufactured by Merck & Co., reported \$1,734,965 of public funding and stated the following:

The Small Business Innovation Research (SBIR) program provided a grant to Optimer (later acquired by Merck) in support of microbiological and preclinical research of fidaxomicin, the active pharmaceutical ingredient of the DIFICID product line including the oral suspension; the amounts for the two phases of the grant were \$734,965 and \$1,000,000 over the period 2005-2008.

Finally, a report for Xcopri (NDC 71699010456), an anti-seizure drug manufactured by SK Life Science, reported receiving \$9,200,000 from the Korea Drug Development Fund between 2012 and 2016.

All other New High-Cost Drug Reports either indicated \$0 in public funding or marked their public funding as trade secret (or both). Of the 193 product families we received reports for, 18 of them (across 29 NDCs from 10 manufacturers) claimed their public funding data as trade secret.

These manufacturers marked their public funding data as trade secret in every New High-Cost Drug Report they submitted this year:

Ascend Laboratories (8 NDCs)

Eton Pharmaceuticals (3 NDCs)

Gilead Sciences (1 NDC)

Myovant Sciences (2 NDCs)

Pharmacosmos Therapeutics (1 NDC)

Servier Pharmaceuticals (1 NDC)

These manufacturers marked their public funding data as trade secret in some, but not all, of their reports:

⁶⁶ Q BioMed, Strontium 89 Webpage, retrieved at: https://qbiomed.com/pipeline/sr89 on Oct. 26, 2021.



Almirall – 8 NDCs with trade secret public funding, 1 NDC without

Biogen – 2 NDCs with trade secret public funding, 1 NDC without

Fresenius Kabi USA – 2 NDCs with trade secret public funding, 1 NDC without

HRA Pharma Rare Diseases – 1 NDC with trade secret non-U.S. public funding, all other public funding (USA, state, and local public funding) not trade secret, and 1 NDC with all public funding not trade secret

Marketing description

Manufacturers are required to submit a description of their planned marketing for a new prescription drug as part of any new drug reports submitted. This includes the amount the company expects to spend on marketing directly to consumers, as well as on marketing to health care providers. The narrative description is required to include what marketing activities a company plans to engage in, including, but not limited to, advertising on TV and in magazines, using peer-to-peer communications such as sponsored speakers at medical seminars, and employing sales representatives.

Here are samples from submissions for the marketing description data element that included the amount spent:

"Total Marketing Spend for Xtandi
Tablets is \$586,973. The total spend
noted above includes total marketing
spend for channel, payer, organized
provider, and reimbursement audiences
for "available soon" and "now available"
tablet materials. Marketing is for both
40mg and 80mg tablet. Marketing
resources include: interactive PDF,
leave behind PDF resources, e-blasts to
managed care professionals and GPO
audiences, internal resource to track EHR
adoption of tablet NDC codes." (Xtandi ®
filed by Astellas Pharma US, Inc.)

"To market this new indication, Neurocrine will increase awareness with physicians of more dosing options for patients. There will be DTC media at the time of the INGREZZA® (valbenazine) 60 mg launch for the INGREZZA brand as a whole. This will include TV, print, digital media (streaming video, banner, and search advertising). Neurocrine's existing free trial and assistance offers apply as they are not specific to INGREZZA 60 mg. There will be professional detailing, sampling, conferences, and peer-to-peer promotion to HCPs across the INGREZZA brand. Updating marketing materials related to the new dosage is budgeted at \$400,000. Free drug samples for INGREZZA 60 mg is budgeted at \$243,000." (Ingrezza ® filed by Neurocrine Biosciences, Inc.)

"Direct to consumer via social and various digital media including paid search totaling in sum of \$935,143.00. Direct to Prescriber Marketing via Representatives, ad campaigns and website totaling in sum of \$4,797,485.00" (ZYNLONTA ® filed by ADC Therapeutics)

"AKYNZEO for injection and AKYNZEO injection are indicated in combination with dexamethasone in adults for the prevention of acute and delayed

nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy. They have not been studied for the prevention of nausea and vomiting associated with anthracycline plus cyclophosphamide chemotherapy. Print materials or brochures targeted at HCPs - \$10,030" (AKYNZEO ® for injection filed by Helsinn Therapeutics)

While the program collects this information for all new drug reports, both generic and brandname, we have found that most companies do not engage in any marketing for generic drugs. The scope of promotion for generics is typically limited to listing the drug in wholesaler catalogs. However, biosimilars, which are roughly equivalent to generics in the market for biologics, tend to be marketed more like a brand-name.

The quality of information submitted by manufacturers was extremely variable, ranging from refusals to provide any information to detailed descriptions of a company's plans for a drug's lifecycle. While the program frequently sends requests for more information or clarification to companies with insufficient filings, staff members are still working through the process of integrating responses to these questions with previous submissions and providing consistency in the review process.

The program will continue to work with manufacturers to ensure improved data quality of a larger proportion of submissions by integrating information received through follow-up requests and outreach and education to manufacturer representatives. We expect our future reports to contain analysis of marketing strategies based on a more comprehensive set of collected data.

Pricing methodology

Manufacturers are also required to submit an explanation of the methodology they used to establish the price of the new prescription drug, including a narrative description and explanation of all major financial and nonfinancial factors

that influenced the initial price. We found that the price of generic drugs is commonly set as a fixed percentage of the price of the drugs' brand-name equivalent, while most brand-name manufacturers described a holistic multi-factor analysis of economic and clinical factors.

Here are samples from submissions for the pricing methodology data element:

"Prices are set forth by our pricing committee whom take into account a range of variables such as market dynamics, discounting strategy, etc." (Phenoxybenzamine HCl, generic for Dibenzyline ® filed by Amneal Pharmaceuticals)

"Alexion follows a rigorous and comprehensive process to align on the price for each medicine in each disease context for a specific country. We consider local disease burden, health care systems, and societal values in addition to the comprehensive benefits of our medicines. We seek input from our stakeholders and take steps to evolve our pricing practices as the dynamic health care ecosystem evolves. We grow through innovation, not arbitrary price increases, preserving our ability to invest in future medicines to address the rare disease patients that have suboptimal treatment options today." (ULTOMIRIS ® filed by Alexion Pharmaceuticals)

"Based on meaningful market research, which looks at comparative products within the same clinical indication and patient population, a cross functional team evaluates how the product differentiates from its competition in the market and, based on the entirety of the data available, assesses a product baseline fair market value. Following interactions with payers, internal methodology is used to forecast a realistic cost of rebates and other instruments designed to facilitate patient access. Product price at launch reflects the sum of the data analysis in the light of all the principles outlined above, coupled with the Company's assessment of its fair market value when compared with similar products already on the market." (Klisyri ® filed by Almirall, LLC)



"Based on manufacturing, sales, marketing and distribution cost." (Artesunate for Injection ™ filed by Amivas (US), LLC)

"When setting the price of medicines AstraZeneca aims to reflect its value to patients, to payers, and to society in general as well as the cost of research and development (R&D). AstraZeneca's pricing decisions are based on many factors that reflect our commitment to patients and the US Healthcare System as well as our obligation to shareholders. We are mindful of healthcare costs and are working to explore innovative opportunities and solutions

working with others in the US Healthcare system to deliver innovative medicines while considering cost and value." (Saphnelo $^{\mathsf{TM}}$ filed by AstraZeneca)

The program plans to continue working with manufacturers to ensure improved data quality of a larger proportion of submissions by integrating information received through follow-up requests and outreach and education to manufacturer representatives. We expect our future reports to contain analysis of pricing methodology based on a more comprehensive set of collected data.

Annual Price Increase Reports

Manufacturers are required to annually submit a Price Increase Report for any of their drugs with a list price of \$100 or more for a 30-day supply or a shorter course of treatment that experience a net price increase of 10 percent or more from the previous year. Price Increase Reports are due March 15 each year. Reports are filed for price increases that occurred over the preceding calendar year, so reports received in 2021 reflect increases from the average price of the drug in 2019 to the average price of the drug in 2020.

In 2021, the program received 143 Annual Price Increase Reports, each one for a different NDC, from 31 different manufacturers. This is slightly fewer than the 160 reports we received in 2020.

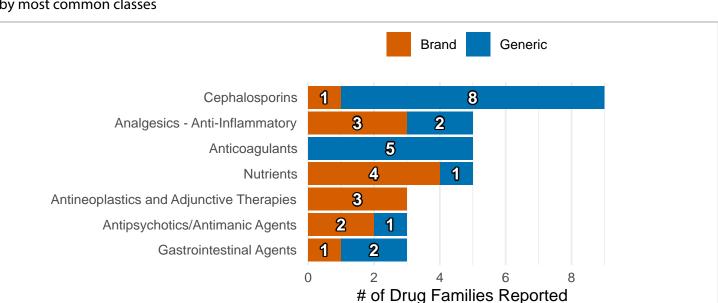
As also described earlier, a single drug will generally be sold under several NDCs. For example, a manufacturer may sell two bottles of generic ibuprofen, one with 25 tablets and the other with 50 tablets. In that case, both bottles would have a different NDC, even though they are for the same drug. In our analysis we will group together NDCs for the same drug from the same manufacturer when describing our data.

We received Annual Price Increase Reports for 40 generic drugs from 13 manufacturers reporting 86 NDCs. We also received reports for 31 brandname drugs from 21 manufacturers reporting 57 NDCs. Patient assistance programs were reported for 13 of the brand-name drugs from 10 manufacturers (26 NDCs).

The median reported price increase was 27 percent for generic drugs and 13 percent for brand-name drugs.

The most common class of drug in these reports was cephalosporins, a type of antibiotic. We received reports for nine different cephalosporins, including eight generic drugs (15 NDCs from three manufacturers) and one brandname drug (one NDC for Zerbaxa, manufactured by Merck & Co.).

The next most common classes, each with reports for five different drugs, were anti-inflammatory analgesics (eight NDCs from four manufacturers), anticoagulants (18 NDCs from four manufacturers), and nutrients (12 NDCs manufactured by B Braun Medical Inc.).



(Annual Increase Reports)

Figure 7: Breakdown for brand-name and generic drugs from annual price increase reports by most common classes

Long-term trends and market dynamics

The total of 143 price increase reports received in 2021 represents an approximately 10 percent decrease from the 160 received in 2020, following a much larger decline of about 71 percent from 2019. This trend is generally consistent with long-term data from the overall market, which has a seen a decline in total WAC increases from a peak of 2,311 in 2013 to a low of 1,060 in 2020. However, there have been 1,244 net WAC increases in 2021 as of Nov. 1, the highest number since 2018.

At the same time, the average percentage increase in WAC price for brand-name drugs with net price increases has fallen from a peak of 14.4 percent in

Figure 8: Annual price increase reports from manufacturers 2019-2021

Brand Generic 37 500 400 300 515 200 57 90 100 86 70 0 2019 2020 2021

Data Source: Oregon Drug Price Transparency Program

2012, to an average of about 5 percent from 2019 through 2021. This follows commitments from a number of prominent drug manufacturers, including AbbVie, Allergan, Novo Nordisk, and Valeant, to keep price increases below 10 percent annually.⁶⁷

However, these reductions in the frequency and magnitude of price increases corresponds with a steep increase in the launch price of new drugs. Figure 11 charts the number of net price increases per year against the average launch price for new brand-name drugs. In 2017, the average launch price of new brand-name drugs rose to around \$10,000, accelerating a much slower trend over the previous decade. This sudden change directly coincides with industry pledges to slow down price increases. In 2019, the average launch price of new branded drugs was \$267,816 – largely driven by the list price of

\$2,125,000 for AveXis' gene therapy Zolgensma.⁶⁹

This suggests that by building costs and profits into a high launch price, drug companies can retain similar revenue while avoiding the large price increases that trigger political scrutiny and state reporting requirements. Since our reporting requirements are tied to a 10 percent price increase threshold, many drugs can avoid reporting while increasing their prices every

⁶⁷ Jeroen Van Meijgaard, PhD, "Drug Makers Keep Promises to Limit Price Increases to 10 percent - But Barely," GoodRx Blog, accessed at: https://www.goodrx.com/blog/drug-manufacturers-keep-price-increase-pledge-ten-percent-barely/, on Nov. 2, 2021.

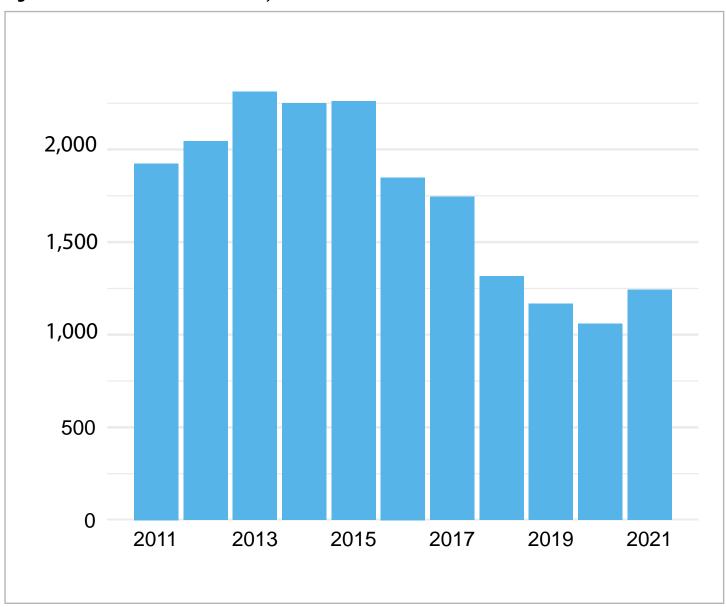
⁶⁸ Bob Herman, "New drugs are launching with ever-higher prices," *Axios*, Oct. 16, 2019, accessed at: https://www.axios.com/drug-prices-launch-brand-generic-4f40d7e7-37fa-4d0d-bc98-64cc71e531e1.html, on Nov. 2, 2021.

⁶⁹ 2019 is not included on the chart to preserve readability and to restrict outliers.

year. AbbVie's Humira, which has been the most costly drug for Oregon's health system for every year the program has data, increased its WAC price by 7.3 percent in 2019 and 7.4 percent in 2020, with no new evidence of safety or efficacy.^{70,71} This price increase is estimated to have cost the United

States health system an additional \$1.4 billion in new spending for Humira prescriptions in 2020.⁷² Unfortunately, since this change falls below our reporting threshold, the program cannot provide any additional insight into Humira's price increase.

Figure 9: Number of WAC increases each year

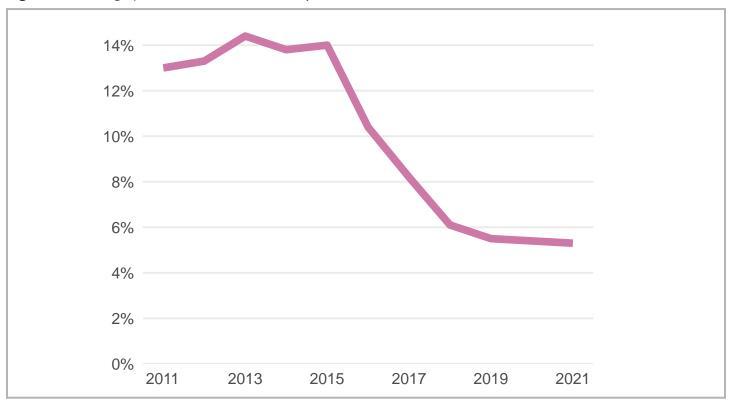


⁷⁰ David M. Rind, et al, "Unsupported Price Increase Report," Institute for Clinical and Economic Review, Nov. 16, 2021.

 $^{^{71}}$ 2019 data is from Institute for Clinical and Economic Review and 2020 data comes from Medi-Span's price database.

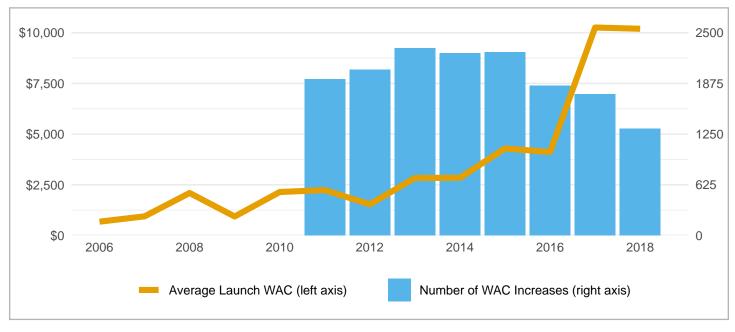
⁷² Id.

Figure 10: Average percent WAC increase each year



Data Source: 46Brooklyn Brand Drug List Price Change Box Score 73

Figure 11: Launch prices of new branded drugs vs. number of price increases each year⁷⁴



⁷³ "Brand Drug List Price Change Box Score," 46Brooklyn, Oct. 12, 2021, accessed at: https://www.46brooklyn.com/branddrug-boxscore, on Nov. 2, 2021

⁷⁴ "Drug Price Launchpad," Oct. 15, 2019, Accessed at: https://www.46brooklyn.com/launch-price-viz, on Nov. 2, 2021.

Trade secret claims in Annual Price Increase Reports

When a manufacturer fills out a report for the program, it may mark individual data elements (such as cost and profit data and the narrative description of the factors contributing to the price increase) as "trade secret." This prevents the Drug Price Transparency Program from immediately publishing it. In order to publicly release an individual data element claimed to be trade secret, the program must conduct a lengthy review of the manufacturer's provided justification for the trade secret claim, make a determination that the data element should be released, and give the manufacturer an opportunity to appeal the program's decision.

Across the 143 Annual Price Increase Reports we received, manufacturers claimed 1,508 individual data elements as trade secret. That is an average of 10.5 trade secret claims per Annual Price Increase Report – much higher than the rate we found this year for the New High-Cost Drug Reports (1.6 claims per report – see page 30).

Out of all possible data elements that could be claimed as trade secret, manufacturers claimed 53 percent of them to be trade secret.

The following data elements were generally claimed to be trade secret:

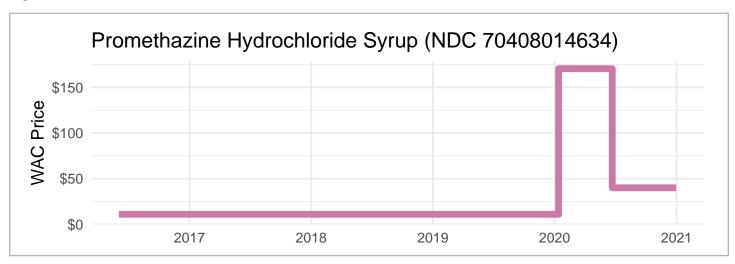
- The narrative description of the factors that contributed to the price increase
- The direct costs of the drugs (manufacturing, marketing, distribution, and ongoing safety and effectiveness research costs)
- The total sales revenue of the drug
- The total profit from the drug
- The participant count of a patient assistance program
- The total dollar value of the assistance provided by a patient assistance program

Largest reported price increases

Manufacturers reported the net percent increase in the WAC price of the drug from 2019 to 2020 in their Annual Price Increase Reports this year. To validate the reported percentages, we checked them against the Medi-Span price history database.

The highest reported net price increase percentage was 265 percent for a generic of promethazine hydrochloride syrup manufactured by Nostrum Laboratories (NDC 70408014634). According to Medi-Span, the WAC price for this drug remained at \$10.99 from 2016 until Jan. 13, 2020, when it increased to \$170.55. Its WAC price then decreased to \$40 on June 22, 2020, and hasn't changed since. So, according to these numbers, the average price of the drug in 2019 was \$10.99, and its average price in 2020 was \$96.48, representing an actual net increase percentage of 778 percent from 2019 to 2020.





Nostrum Laboratories also reported the secondhighest price increase percentage: an increase of 250 percent for a generic of pindolol (NDC 29033002801). According to Medi-Span, the WAC price for this drug was \$105.58 in 2016. On Jan. 6, 2020, Nostrum Laboratories raised its price to \$369.06. It remained at that price for all of 2020.

Nostrum Laboratories also submitted a report for a different NDC of pindolol (NDC 29033002901) that increased in price by 200 percent. It did not report any factors that contributed to any of its WAC price increases.

The third-highest reported price increase percentage was 230 percent for the brand-name drug Mytesi, manufactured by Napo Pharmaceuticals (NDC 70564080260). Its WAC price was \$652.21 in 2017, and Napo Pharmaceuticals raised it to \$668.52 on Jan. 1, 2019. On April 9, 2020, Napo Pharmaceuticals increased the price by exactly 230 percent to \$2,206.12. As justification for this increase, Napo Pharmaceuticals submitted the following: "The rise in prices can be attributed to a number of factors, including overhead, supply chain changes, storage of product, changes to market access to ensure patients can get relief and market pricing trends."

The fourth- and fifth-highest reported price increase percentages, 218 percent and 211 percent, were for two NDCs of generic naproxen manufactured by Virtus Pharmaceuticals (NDCs 69543042510 and 69543042610). Virtus Pharmaceuticals claimed that the factors that

Figure 13:

contributed to this price increase are a trade secret, so the program is unable to reveal them in this report.

Across all reports, the median price increase was 27 percent for generic drugs and 13 percent for brandname drugs.

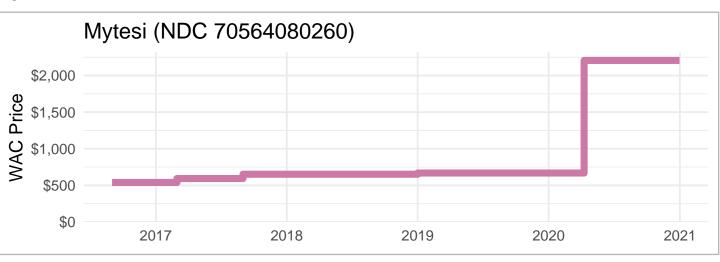
Profits and revenues in Annual Price Increase Reports

Manufacturers are required to include the drug's profits and revenues in the previous year in each Annual Price Increase Report they file with the program. This year, we analyzed the reported profits and revenues for 53 drug product families (29 generic and 24 brand-name) from 21 manufacturers.

Among the generic drugs, 83 percent reported positive profits (24 product families). Half of the generic drugs reported profit margins of 32 percent or higher. The best performing generic drug had a profit margin of 93 percent.

A 93 percent profit margin means that, for every dollar of revenue brought in by the drug, 93 cents was pure profit. A drug with a 93 percent profit margin would make back its annual costs 14 times over.

Among the brand-name drugs, 62 percent reported positive profits (15 product families). Half of the brand-name drugs reported profit margins of 28 percent or higher. The best performing brand-name drug had a profit margin just under 60 percent.



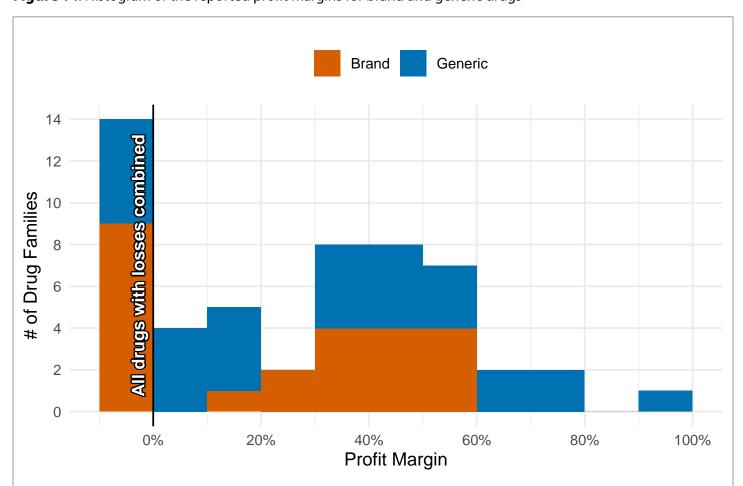


Figure 14: Histogram of the reported profit margins for brand and generic drugs

We see from the histogram that most of the brandname drugs that turned a profit have profit margins between 20 percent and 60 percent, while the generic drugs' profit margins are more spread out. One possible explanation for some generic drugs' high profit margins is that marketing and research costs for generic drugs are generally low compared to brand-name drugs. See the section of this report titled **Direct Costs in Annual Price Increase Reports** for more on this.

This year, 17 percent of the generic drugs reported losing money (five product families), with revenues that did not cover their costs. The worst performing generic drug recouped only 51 percent of its costs.

For the brand-name drugs, 38 percent reported losing money (nine product families). The worst performing brand-name drug recouped only 22 percent of its costs.

A single manufacturer may have drugs that turn a profit and drugs that lose money, as was the case with several reporting manufacturers. Other manufacturers reported only positive profits for their drugs, and others reported only losses for their drugs.

Overall, about three-quarters of the drug product families reported positive profits (39 product families). In other words, about one-quarter of the drug product families (14 product families) reported negative profits. Half of the drugs reported profit margins of 31 percent or higher.

We can compare this year's numbers to the ones in last year's report. Last year, one-quarter of the drugs also reported negative profits, but six out of 62 drugs reported profit margins higher than 80 percent, compared to only one out of 53 this year. Last year, the median profit margin was 37 percent, compared to 31 percent this year.

Figure 15: Changes in reports showing negative profit and profit margins over 80 percent

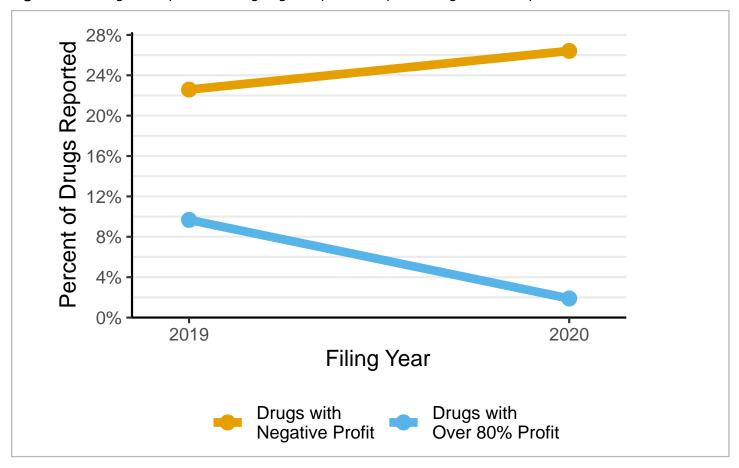
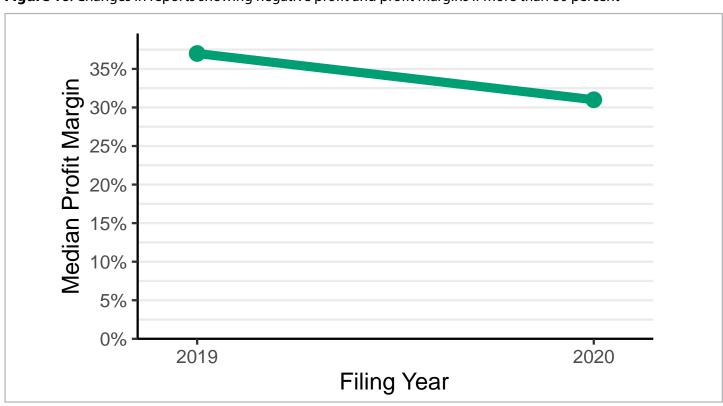


Figure 16: Changes in reports showing negative profit and profit margins if more than 80 percent



In total, the 29 generic drugs we analyzed this year reported \$316 million in revenue and \$50 million in profit, with an overall profit margin of 16 percent. The 24 brand-name drugs we analyzed reported \$1.69 billion in revenue and \$289 million in profit, with an overall profit margin of 17 percent. Last year, the 62 drugs we analyzed reported \$1.96 billion in revenue and \$374 million in profit, with an overall profit margin of 19 percent.

Direct costs in Annual Price Increase Reports

Pharmaceutical manufacturers are also required to report the direct costs they incurred in the previous year in each Annual Price Increase Report they file with the program. They are required to report direct costs across four potential categories:

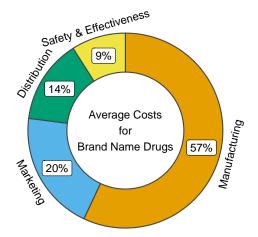
- Manufacturing
- Marketing
- Distribution
- Ongoing safety and effectiveness research

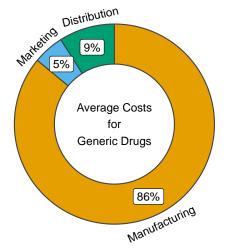
This year, we analyzed the reported costs for 55 drug product families (29 generic and 26 brandname) from 22 manufacturers.

As we saw last year, manufacturers tend to spend more on manufacturing than on marketing, distribution, or safety and effectiveness research. Manufacturers tend to spend the least on ongoing safety and effectiveness research.

Among the brand-name drugs, manufacturing accounted for 57 percent, marketing accounted for 20 percent, distribution accounted for 14 percent, and ongoing safety and effectiveness research

Figure 17 and 18: Averages of direct costs from annual price increase reports – brand-name and generic





accounted for 9 percent of a product family's reported costs, on average.⁷⁵

Among the generic drugs, manufacturing accounted for 86 percent, marketing accounted for 5 percent, distribution accounted for 9 percent, and ongoing safety and effectiveness research accounted for little to none of a product family's reported costs, on average.

⁷⁵ In some parts of this report, we analyze information for a drug at the "product family" level, which includes all of the national drug codes for the same brand-name or active chemical agent, rather than individual NDCs. We found that many manufacturers do not track costs, revenues, or profits for individual NDCs. Instead, they aggregate and track information by product family. Consequently, they provide identical numbers in the costs, revenue, and profit fields in all reports they submit for NDCs in the same product family. When we say "drug product family," we are referring to a set of NDCs from a manufacturer with the same reported trade name, and "drug" in the same context may be used to refer to a product family, rather than an individual NDC.

In total, the 26 brand-name drugs reported \$683 million in manufacturing costs, \$193 million in marketing costs, \$155 million in distribution costs, and \$45 million in ongoing safety and effectiveness research costs. The 29 generic drugs reported \$185 million in manufacturing costs, \$5 million in marketing costs, \$23 million in distribution costs, and \$101,000 in ongoing safety and effectiveness research costs.

Public funds in Annual Price Increase Reports

Manufacturers are required to report any funding provided by national, state, local, or foreign government entities that was used in the basic or applied research for the drug, including funding for preclinical and clinical trials.

Just as in the submitted New High-Cost Drug Reports, manufacturers overwhelmingly reported receiving no public funding for the drugs reported. Out of the 143 Annual Price Increase Reports we received, none reported nonzero amounts of public funding that were not marked as trade secret. All reports either indicated \$0 in public funding or marked their public funding as trade secret (or both).

Of the 71 product families we received Annual Price Increase Reports for, 20 of them (across 44 NDCs from four manufacturers) claimed their public funding data as trade secret.

These manufacturers marked their public funding data as trade secret in every Annual Price Increase Report they submitted this year:

B Braun Medical (35 NDCs)

Validus Pharmaceuticals (1 NDC)

Vanda Pharmaceuticals (7 NDCs)

In addition, Tersera Therapeutics submitted reports for four NDCs and claimed the public funding data as Trade Secret for one of them (Xermelo, NDC 70183012584).

Drug prices in other countries

When filing an Annual Price Increase Report, manufacturers are required to include the 10 highest prices paid for the drug in any country other than the United States converted to U.S. dollars. The prices should be reported as an average for the previous calendar year (this year, they should have reported the average prices over the calendar year 2020).

In the reports filed this year, manufacturers generally did not report any prices from other countries. Out of the 143 Annual Price Increase Reports we received, only three included non-U.S. prices that were not marked as trade secret. Another 39 reports marked their non-U.S. prices as trade secret, and the remaining 101 reports did not include any non-U.S. prices. When the program contacted manufacturers that did not report any non-U.S. prices to request clarification, responses generally confirmed that the drug was not sold by them in any other country besides the United States. The program will look into collecting data about different companies or legal entities selling the identical product in other countries.

Here is the data from the three reports that included non-U.S. prices and did not mark them as trade secret.

One report for Metopirone from HRA Pharma Rare Diseases (NDC 76336045518), a diagnostic drug for testing hypothalamic-pituitary ACTH function,⁷⁶ reported a WAC price of \$600 for the United Kingdom. According to the Medi-Span drug price history database, the average U.S. WAC for this NDC over the calendar year 2020 was \$470 and its WAC as of October 2021 is \$579.72.

⁷⁶ HRA Pharma Rare Diseases, Metopirone Patient Website, retrieved at: https://metopirone.com/ on Oct. 27, 2021.

One report for Addyi from Sprout Pharmaceuticals (NDC 58604021430), a drug used to treat hypoactive (low) sexual desire disorder,⁷⁷ reported a WAC price of \$240 for Canada. According to MediSpan, the average U.S. WAC for this NDC in 2020 was \$469 and its WAC as of October 2021 is \$522.50.

Finally, one report for Zerbaxa from Merck & Co. (NDC 67919003001), a cephalosporin indicated to treat certain kinds of pneumonia and other bacterial infections,⁷⁸ reported 10 different non-U.S. prices. According to Medi-Span, the average U.S. WAC for this NDC in 2020 was \$1,252 and its WAC as of October 2021 is \$1,252.20. The 10 non-U.S. prices reported for this NDC are:

1.	Mexico	\$1,389.10
2.	Singapore	\$1,313.40
3.	Peru	\$1,253.00
4.	Israel	\$1,197.10
5.	Korea	\$1,169.60
6.	Canada	\$1,110.00
7.	Slovenia	\$1,109.00
8.	Slovakia	\$1,100.20
9.	Austria	\$1,088.30
10.	Netherlands	\$1,088.00

These manufacturers marked their non-U.S. prices as trade secret in every Annual Price Increase Report they submitted this year:

B Braun Medical (35 NDCs) **Romark** (2 NDCs)

These manufacturers marked their non-U.S. prices as trade secret in some, but not all, of their reports:

HRA Pharma Rare Diseases – 1 NDC with trade secret non-U.S. prices (Lysodren, NDC 76336008060), 1 NDC without

Tersera Therapeutics – 1 NDC with trade secret non-U.S. prices (Xermelo, NDC 70183012584), 3 NDCs without

⁷⁷ Sprout Pharmaceuticals, Addyi Patient Website, retrieved at: https://addyi.com/ on Oct. 27, 2021.

⁷⁸ Merck & Co., Zerbaxa Patient Website, retrieved at: https://www.merckconnect.com/zerbaxa/dosing-administration/on Oct. 27, 2021.

Health insurance companies



Each year, health insurance companies in Oregon report the drugs most prescribed to their policyholders, the drugs with the highest total health plan spending, and the drugs contributing to the greatest increases in total health plan spending. This year, companies reported the top 25 generic drugs, brand-name drugs, and specialty drugs in each category. These reports vary in the type of plan being reported. They do not include self-insured plans. The types of plans reported by each company are listed in Appendix B.

The program received reports from these companies:

- BridgeSpan Health Company
- · Cigna Health and Life Insurance Company
- · Health Net Health Plan of Oregon, Inc.
- Kaiser Foundation Health Plan of the Northwest
- · Moda Health Plan, Inc.
- PacificSource Health Plans
- Providence Health Plan
- Regence BlueCross BlueShield of Oregon
- · Samaritan Health Plans, Inc.

 UnitedHealthcare Insurance Company / UnitedHealthcare of Oregon, Inc.

To create their lists, insurance companies first grouped together all drug products with the same name, including versions with modified-release dosages. For example, if a drug was sold in 50 mg tablets and 100 mg extended-release tablets, both of those would be grouped together. Then, they totaled the following:

- 1. The number of prescriptions for those drugs in 2020.
- 2. The money spent by them or their policyholders on those drugs in 2020.
- 3. The difference between the total amounts spent in 2019 and in 2020 (this is called the year-over-year increase).

They took the 25 drugs with the highest numbers of prescriptions, the 25 drugs with the most money spent, and the 25 drugs with the largest increases in spending in 2020 compared to 2019. They made separate lists for generic drugs, brand-name drugs, and specialty drugs, and submitted all of these top 25 lists to Oregon's Drug Price Transparency Program.

After receiving the lists from the health insurance companies, the Drug Price Transparency Program worked on combining the data to get a picture of prescriptions and spending across Oregon. The program took the lists submitted by all 10 companies and totaled the number of prescriptions, the amount of money spent, and the year-over-year spending differences for every drug. Our final lists show the top 10 drugs in each category.

The Drug Price Transparency Program curated the insurer information within the limits of its knowledge and database resources to combine drug entries and related information. We relied heavily on the Medi-Span drug database to assess the quality of the reported data and to improve it, if possible. The combined prescription counts and dollar amounts in our lists should be considered approximations since they represent only the data slices reported to us by the health insurance companies in their lists.

Most prescribed drugs

Health insurance companies reported the 25 generic drugs, the 25 brand-name drugs, and the

25 specialty drugs with the most pharmacy and medical prescription claims in 2020.

More prescriptions were reported for antidepressants than for any other class of drugs. Two of the top 10 most prescribed generic drugs were antidepressants: bupropion (often sold under the names Aplenzin, Forfivo, Wellbutrin, and Zyban) and sertraline (often sold under the name Zoloft). In total, health insurance companies reported 761,044 prescriptions for antidepressants in 2020.

Vaccines had the next-highest number of prescriptions, with 494,466 reported. Most of these were flu vaccines (383,665 prescriptions).

Other highly-prescribed drug classes were antihypertensives (459,962 prescriptions), antiasthmatic and bronchodilator agents (408,630 prescriptions), and antidiabetics (347,081 prescriptions).

The lists below show the generic, brand-name, and specialty drugs with the most prescription insurance claims in 2020.

Figure 19: Most Prescribed Generic Drugs

Drug	Class	Prescriptions
Levothyroxine	Thyroid Agents	251,442
Lisinopril	Antihypertensives	242,400
Atorvastatin	Antihyperlipidemics	237,489
Metformin	Antidiabetics	190,539
Hydrocodone-Acetaminophen	Analgesics - Opioid	161,417
Losartan	Antihypertensives	153,488
Bupropion	Antidepressants	147,694
Gabapentin	Anticonvulsants	139,568
Sertraline	Antidepressants	131,018
Amphetamine- Dextroamphetamine	ADHD/Anti-Narcolepsy/ Anti-Obesity/Anorexiants	129,473

Figure 20: Most Prescribed Brand-name Drugs

Drug	Class	Prescriptions
Influenza Virus Vaccine	Vaccines	383,665
Albuterol (multiple brands)	Antiasthmatic and Bronchodilator Agents	74,722
Basaglar/Lantus/Semglee/Toujeo	Antidiabetics	37,718
Shingrix	Vaccines	36,888
Adacel/Boostrix	Toxoids	32,198
Alvesco	Antiasthmatic and Bronchodilator Agents	31,379
Pentacel	Toxoids	30,645
Advair	Antiasthmatic and Bronchodilator Agents	28,509
Prevnar 13/Pneumovax 23	Vaccines	25,645
Humulin	Antidiabetics	24,816

Figure 21: Most Prescribed Specialty Drugs

Drug	Class	Prescriptions
Humira	Analgesics - Anti-Inflammatory	19,225
Trulicity	Antidiabetics	14,943
Enbrel	Analgesics - Anti-Inflammatory	8,601
Victoza	Antidiabetics	7,709
Kyleena/Liletta/Mirena/Skyla	Contraceptives	7,622
Ozempic/Rybelsus	Antidiabetics	7,093
Biktarvy	Antivirals	6,312
Truvada (or generic)	Antivirals	6,020
Botox	Neuromuscular Agents	4,938
Cosentyx	Dermatologicals	4,466

Most costly drugs

Health insurance companies reported the 25 generic drugs, the 25 brand-name drugs, and the 25 specialty drugs with the highest total payments made under the policy to health care providers on behalf of covered members, including payments made by issuers and member cost sharing, such as co-pays and co-insurance, in 2020.

More money was reported spent on anti-inflammatory analgesics than on any other drug class. Most of that was for Humira, a drug often used to treat arthritis, ankylosing spondylitis, Crohn's disease, ulcerative colitis, and plaque psoriasis. Humira has been the highest for all three years of Oregon's program. Health insurance companies reported spending \$93,544,597 on prescriptions for Humira. In total, companies reported spending \$153,753,608 on anti-inflammatory analgesics. Two drugs in this class, Humira and Enbrel, appear on our list of the 10 most costly specialty drugs.

Antineoplastics and adjunctive therapies had the next highest spent overall at \$123,815,822. One of these anti-cancer drugs (Keytruda) appears on our list of the 10 most costly specialty drugs.

Other high-cost drug classes were antivirals (\$81,778,043 spent), dermatologicals (\$75,691,256 spent), and antidiabetics (\$68,850,328 spent).

The lists below show the generic, brand-name, and specialty drugs with the most dollars spent on prescriptions in 2020.

Figure 22: Most Costly Generic Drugs

Drug	Class	Total Spent
Amphetamine- Dextroamphetamine	ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiants	\$7,789,739
Methylphenidate	ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiants	\$5,389,392
Albuterol	Antiasthmatic and Bronchodilator Agents	\$4,333,445
Levothyroxine	Thyroid Agents	\$4,128,038
Buprenorphine	Analgesics - Opioid	\$4,042,563
Bupropion	Antidepressants	\$3,829,827
Etonogestrel-Ethinyl Estradiol	Contraceptives	\$3,356,488
Estradiol	Estrogens	\$3,303,814
Fluticasone-Salmeterol	Antiasthmatic and Bronchodilator Agents	\$3,278,370
Atorvastatin	Antihyperlipidemics	\$2,624,513

Figure 23: Most Costly Brand-name Drugs

Drug	Class	Total Spent
Basaglar/Lantus/Semglee/Toujeo	Antidiabetics	\$12,127,873
Eliquis	Anticoagulants	\$10,964,955
Influenza Virus Vaccine	Vaccines	\$9,428,898
Vyvanse	ADHD/Anti-Narcolepsy/ Anti-Obesity/Anorexiants	\$7,373,427
Admelog/Chantix/Humalog/Xarelto	Antidiabetics	\$6,656,473
Pneumovax 23/Prevnar 13	Vaccines	\$6,383,198
Advair	Antiasthmatic and Bronchodilator Agents	\$6,329,550
Shingrix	Vaccines	\$6,218,227
Jardiance	Antidiabetics	\$6,197,655
Humulin	Antidiabetics	\$5,853,160

Figure 24: Most Costly Specialty Drugs

Drug	Class	Total Spent
Humira	Analgesics - Anti-Inflammatory	\$93,544,597
Enbrel	Analgesics - Anti-Inflammatory	\$38,306,710
Stelara	Dermatologicals	\$34,695,952
Biktarvy	Antivirals	\$27,977,637
Trikafta	Respiratory Agents	\$18,814,841
Truvada (or generic)	Antivirals	\$18,498,484
Cosentyx	Dermatologicals	\$18,098,487
Keytruda	Antineoplastics and Adjunctive Therapies	\$16,961,094
Entyvio	Gastrointestinal Agents	\$16,530,321
Tecfidera (or generic)	Psychotherapeutic and Neurological Agents	\$11,842,937

Drugs with the greatest increases in health plan spending

Health insurance carriers reported the 25 generic drugs, the 25 brand-name drugs, and the 25 specialty drugs with the greatest increases from total payments made in 2019 to total payments made in 2020. The difference from the 2019 total to the 2020 total is called the year-over-year increase.

This data on year-over-year increases is a new feature of this year's report. We did have greatest increase lists in our previous reports, but this is the first time we have been able to report the actual dollar amounts of these increases.

Overall, antineoplastics and adjunctive therapies (anti-cancer drugs) had the greatest reported year-over-year increases – they occupy four spots on our list of greatest increases for specialty drugs. The data we collected last year suggests that spending across all antineoplastics in 2020 is roughly the same as it was 2019, so the large increases reported for these specific antineoplastics indicates a shift of spending within the drug class.

We do not collect information on what causes increases in spending on individual antineoplastics, though there are some common reasons for reporting a large year-over-year increase. For example, spending would increase for a regularly-prescribed drug if the price of the drug increased. Spending could also increase if more patients needed to be prescribed the drug.

Spending increases could also be reported when a new drug is approved. The antineoplastic Kanjinti received FDA approval midway through 2019 and is 10th on our specialty drugs greatest increases list. Health insurance companies reported a total increase of \$3,535,044 in spending on it in 2020 compared to 2019. The respiratory agent Trikafta, topping the specialty drugs list, is in a similar situation – it received FDA approval in October 2019.

An existing drug may also gain FDA approval for use in a new patient population. Biktarvy, for example, is second on our specialty drugs greatest increases list with a total increase of \$10,114,820 in spending across all reporting insurance carriers. This drug was originally approved only for



treatment of HIV-1 infection in adults. In June 2019, it received approval to expand the eligible patient population to include HIV-1 infected pediatric patients. That said, the WAC price of this drug did also increase by 4.8 percent on Jan. 1, 2020, from \$3,089.99 to \$3,238.31.

Now, many drugs on our greatest increase lists have been on the market for a while and did not receive approval for new patient populations in 2019 or 2020. One such drug is the anticoagulant Eliquis, topping our brand-name drugs greatest increase list, for which companies reported a total increase of \$1,883,217 in spending. One thing that may have contributed to this spending increase is that the manufacturer of the drug, Bristol Myers Squibb, increased its WAC price by 6 percent on Jan. 1, 2020. Bristol Myers Squibb also increased the WAC price by 6 percent again on Jan. 1, 2021, so this drug may appear on our list again next year.

Another example is Humira, which is fourth on our specialty drug greatest increases list. Companies reported a

total increase of \$6,491,588 in spending on Humira in 2020, compared to 2019. This may relate to the fact that AbbVie, the manufacturer of Humira, increased the WAC price of the drug by 7.4 percent on Jan. 1, 2020. AbbVie increased the price by 7.4 percent again on Jan. 1, 2021, so Humira may also appear on our list again next year. Finally, note that several drugs on our greatest increases lists are also on our most costly lists.

Figure 25: Brand-name Drugs with the Greatest Increases in Plan Spending

Drug	Class	Year-Over-Year Increase
Eliquis	Anticoagulants	\$1,883,217
Influenza Virus Vaccine	Vaccines	\$1,531,858
Emgality	Migraine Products	\$1,421,842
Alvesco	Antiasthmatic and Bronchodilator Agents	\$1,332,253
Epogen/Procrit	Hematopoietic Agents	\$1,330,036
Jardiance	Antidiabetics	\$841,874
Pradaxa	Anticoagulants	\$777,159
Shingrix	Vaccines	\$727,727
Xarelto	Anticoagulants	\$716,506
Humulin	Antidiabetics	\$525,470

Figure 26: Specialty Drugs with the Greatest Increases in Plan Spending

Drug	Class	Year-Over-Year Increase
Trikafta	Respiratory Agents	\$15,826,660
Biktarvy	Antivirals	\$10,114,820
Ultomiris	Hematological Agents	\$8,223,291
Humira	Analgesics - Anti-Inflammatory	\$6,491,588
Skyrizi	Dermatologicals	\$5,304,568
Truxima	Antineoplastics and Adjunctive Therapies	\$5,291,097
Stelara	Dermatologicals	\$4,221,864
Keytruda	Antineoplastics and Adjunctive Therapies	\$4,002,162
Mvasi	Antineoplastics and Adjunctive Therapies	\$3,733,664
Kanjinti	Antineoplastics and Adjunctive Therapies	\$3,535,044

Drugs reported by insurers and manufacturers

Three drugs we received New High-Cost Drug Reports for also appear on our lists of top drugs reported by health insurers.

Emtricitabine-tenofovir disoproxil fumarate, sometimes sold under the brand name Truvada, appears on the list of the most prescribed specialty drugs and on the list of the most costly specialty drugs. We received New High-Cost Drug Reports for seven NDCs for generic versions of this drug.

Dimethyl fumarate, sometimes sold under the brand name Tecfidera, appears on the list of the most costly specialty drugs. We received New High-Cost Drug Reports for five NDCs for generic versions of this drug.

Ravulizumab-cwvz, sold under the brand name Ultomiris, appears on the list of the specialty drugs with the greatest increases in plan spending. We received New High-Cost Drug Reports for two NDCs for this drug from Alexion Pharmaceuticals. Two generic drugs we received Annual Price Increase Reports for also appear on our list of most costly drugs prescribed by insurers: methylphenidate and bupropion. All three Annual Price Increase Reports for these generic drugs were submitted by Amerisource Health Services.

None of the methylphenidate or bupropion NDCs we received Annual Price Increase Reports for were included in the lists of NDCs reported by insurers.



Compliance and enforcement efforts

While many states have passed transparency laws and begun implementation of drug price transparency programs since 2019, Oregon's law remains one of the most ambitious. Much of the information we collect from manufacturers is not mandated by any other state's reporting program, and no other state has the same authority to review and assess the validity of trade secret claims.

The program has the authority to impose civil penalties for failure to register with the program, file required reports, or respond to program correspondence. However, our compliance efforts to date have focused on outreach and education, rather than formal enforcement proceedings. This has led to a high rate of compliance overall, and program staff members have been diligently working with manufacturers to ensure the completeness and accuracy of information submitted.

In order to monitor compliance with the program's reporting requirements, the department has contracted with a private vendor, Medi-Span, for access to a database of WAC pricing data. We used algorithmic analysis of WAC data in Medi-Span to identify NDCs that met the new drug or price increase reporting requirements in which a report was not received from the manufacturer in the allowed time.

The resulting lists were reviewed to eliminate NDCs not subject to program requirements, such as medical devices and dietary supplements. We also removed NDCs that appeared to meet reporting

requirements, but did not actually qualify due to dosing recommendations and package size.⁷⁹ Program staff members may conduct outreach to the manufacturers of these NDCs, and further narrowed the list by identifying additional reasons a drug is not subject to reporting requirements or helping the manufacturer come into compliance.⁸⁰

If a manufacturer fails to provide required information, even after program staff members conduct this outreach, it may be necessary to refer an NDC to the division's enforcement team. The department is currently investigating several files that may lead to civil enforcement against a manufacturer; however, none have advanced to a stage where a civil penalty was imposed.

The program will continue to focus on outreach and education efforts to increase compliance with the reporting requirements of the Prescription Drug Price Transparency Act. The department continues to evaluate the best approaches to gaining compliance with all subject entities.



⁷⁹ For example, a drug might have a WAC of \$670 for a bottle containing 100 pills, in which a course of treatment is one pill. This would be pulled by our algorithm, since it meets the Medicare Part D specialty threshold on the basis of its WAC alone. However, since a typical patient takes only one pill in a course of treatment, the relevant cost for our purposes is only \$67, meaning a new drug report would not be required.

⁸⁰ Some drugs may not be subject to reporting despite showing up in our analysis of Medi-Span data even though they meet the WAC threshold. For example, we have identified specific drugs that are not sold in Oregon (manufacturer sells only to a single provider in a different state) or are listed in Medi-Span in anticipation of a market launch, but have not actually been offered for sale in the United States.

Policy recommendations



Prescription drug costs continue to be an issue for Oregonians. With the information reported, the program is learning several things about prescription drugs, such the factors contributing to high costs, the drugs that are the most costly for health insurers, and what drugs are of most concern to Oregonians. The data received over the three years of the program help identify areas for program improvements and a better understanding of drug pricing.

The Prescription Drug Price Transparency Act requires recommendations for legislative changes to contain the cost of prescription drugs and reduce the effect of price increases. Several of the recommendations offered are suggested improvements to the program to receive better quality data to inform policy recommendations.

Manufacturer reporting

<u>Recommendation 1: Expanded reporting</u> requirements for patient assistance programs

Patient assistance, such as manufacturer "coupons" for prescription drugs, and their interaction with cost-sharing requirements for health insurance have been a point of heavy discussion in the Oregon Legislature during recent sessions. The program currently receives information on patient assistance programs as part of our annual price increase reports.

However, since patient assistance program reporting is collected only for drugs with price increases of 10 percent or more, the program has been unable to collect related information for drugs such as

Humira, which has been the mostly costly drug for Oregon's health system for the entire duration of the program's existence (due to the manufacturer limiting price increases to 9.9 percent annually or less). During the 2021 legislative session, HB 2044 proposed adding the same patient assistance program reporting requirements applied to price increase reports to new high-cost drug reports. Several stakeholders pointed out that much of the information required for price increase reports is unavailable at the time a drug is launched, and the bill ultimately failed.

We recommend removing patient assistance program reports from annual price increase reports, and, instead, requiring all reporting manufacturers to report to the department annually on all patient assistance programs supported by each manufacturer. This will avoid the problems identified with HB 2044 (2021) requiring manufacturers to report information that is unavailable, and will allow us to collect information on high-cost drugs that have not experienced a price increase of 10 percent or more. This will allow us to get a better picture of the overall landscape of patient assistance and to better inform the Legislature and the public about the market impacts of patient assistance when the issue arises in future legislative debates.

Recommendation 2: Clarify the threshold for annual price increase reports

The statutory threshold for reporting an annual price increase report occurs when a drug is priced at \$100 or more for a course of treatment and "there was a net increase of 10 percent or more in the price of a prescription drug over the course of the previous calendar year." The program rules further clarify that the definition for "net yearly increase" is "an increase in the wholesale acquisition cost of a drug over the course of a calendar year, calculated by dividing the average wholesale acquisition cost of the drug over the course of a calendar year by the average wholesale acquisition cost over the course of the previous calendar year." We determined this definition to be the most appropriate and accurate

definition for the statutory threshold since it accounts for any increase or decreases in price that may occur throughout the year.

The advance notice requirement (HB 2685, 2019) contains different threshold price reporting terms.

We recommend changing the statutory language regarding the threshold for annual price increase reports to conform to HB 2658 terms:

A cumulative increase of 10 percent or more over the course of the previous year

or

When, at any point in the previous calendar year, an increase or series of increases in the price of the drug results in a price 10 percent higher than the price of the drug at any previous time during the calendar year.

Health insurer reporting

Recommendation 3: Expand reporting to additional insurers

Under the Prescription Drug Price Transparency Act, health insurance companies are required to submit specified information about prescription drug spending and use, including the top 25 most costly drugs and the top 25 most prescribed drugs, as part of the annual rate filing process. Since companies are required to submit rate filings only if they offer individual or small group health benefit plans, some health insurers that do not participate in these markets are not required to submit these reports. This may result in an incomplete picture of health plan spending on drugs in Oregon.

We recommend legislators consider separating the health insurance company reporting requirement from the rate review process and require it as a separate annual report from all health benefit plan issuers in Oregon.

Global recommendations

Recommendation 4: Transparency across the pharmaceutical supply chain

The price of a prescription drug is influenced by several factors. This includes the interactions and financial negotiations between pharmaceutical supply chain entities. The information the program receives from manufacturers on the wholesale acquisition cost of a drug is the starting point before the financial aspects of the drug price move to wholesaler distributors, pharmacy services administrative organizations, pharmacy benefit managers, health insurers, hospitals, medical providers, and pharmacies. Several of these entities can influence the price of the drug to consumers, either at the pharmacy counter, through consumers' health insurance premiums, or how drug costs contribute to overall health care system costs.

We recommend the Legislature consider transparency across the pharmaceutical supply chain entities to fully understand what influences and contributes to the price of the drug. This includes the recommendations and reporting on cost factors identified by the Task Force on Fair Pricing of Prescription Drugs – coupons, discounts, fees, incentive programs, insurance benefit design, list price, markups, pharmacist gag clause, and rebates. Cost factor information from pharmaceutical supply chain entities is important to the state's understanding of drug pricing and how to best identify policy recommendations to reduce the cost of prescription drugs.

Consumer notification reporting

Recommendation 5: Protection of consumerreported information

Consumer reports on the price increases of the prescription drugs they take is an essential component to the program. When consumers report to the program, they submit specific information about the drug they are reporting on, which the program uses to compare against the information

submitted by drug manufacturers and health insurers. Also, consumers report their ZIP code, health insurance information, and the reasons for the price increase.

This information is important for policymakers and stakeholders to know what is being reported to the department from the consumer perspective. However, collectively, the information could potentially identify a consumer. We recommend clarifying that the personally identifiable information collected will be protected from public disclosure.

This recommendation was included in HB 2044 (2021) which did not pass.

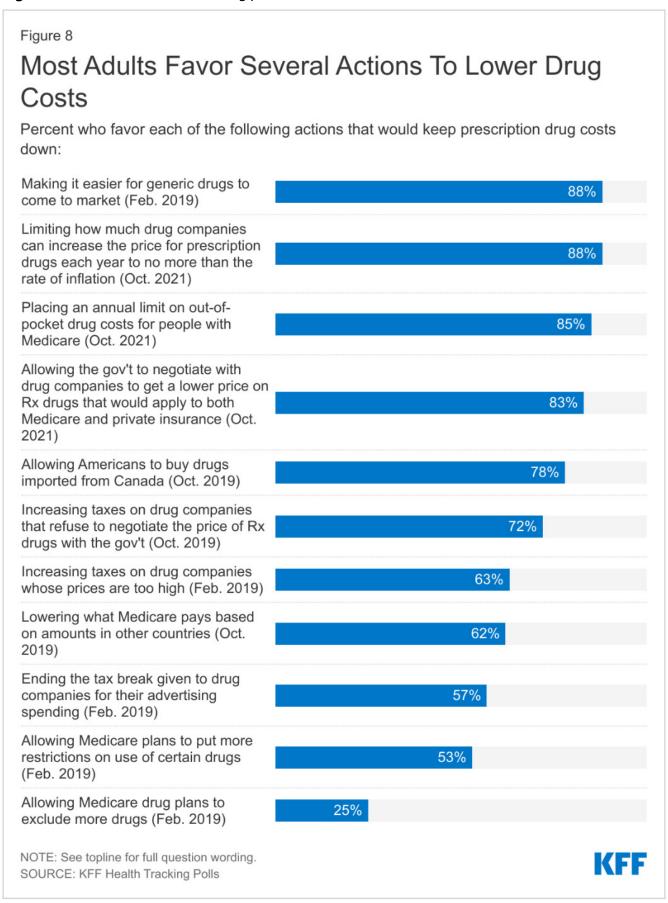
Program improvements

Oregon's program is unique and was one of the first prescription drug price transparency programs in the country. Since implementation in 2019, several areas have been identified in which changes would improve the goals and administration of the program.

Recommendation 6: Ongoing program evaluation

We will continue to evaluate the program and learn how to improve our processes. This may result in recommendations to the Legislature or changes the department can make to improve the overall program. Improvements may include changes to help manufacturers efficiently submit reports, internal changes to better administer the program and its deadlines, and any other changes that improve the program for the agency and its stakeholders. When evaluating any improvement to the program, the department will evaluate the time and resources needed to implement any change.

Figure 27: Public attitudes about drug price reforms



Drug policies in other states

The following section does not represent official recommendations from the department, but rather an overview of what drug policies other states have pursued to reduce the cost of prescription drugs on consumers, businesses, and the state. These items provide additional considerations for the Legislature in continuing to build and shape the program.

A 2019 Kaiser Family Foundation poll found that significant majorities of Americans support a wide variety of policies to keep prescription drug costs down, including making it easier for generic drugs to come to market, allowing Medicare to negotiate prices with drug companies, lowering what Medicare pays for drugs based on prices in other countries, and increasing taxes on drug companies with high prices.⁸¹

State legislatures across the country have continued to work on policies aiming to control the cost of prescription drugs in their state, even as the COVID-19 pandemic has disrupted legislative sessions around the country. In 2021, at least 305 bills related to the cost of prescription drugs have been introduced. The broad topics addressed by state legislation introduced in states this year includes:⁸²

- Drug affordability review board Establishing a regulatory body to review the affordability and cost of specific prescription drugs. Oregon, Colorado, and Virginia passed laws related to drug affordability review boards in 2021, and 16 similar bills were introduced across the states that year.
- Drug importation Directing the state to examine or establish a drug importation program from Canada.
 Florida and Maine enacted statutes establishing drug importation programs. Colorado and Vermont

- passed laws to design or provide findings on drug importation. The U.S. Department of Health and Human Services has promulgated regulations for implementation of these programs, but Canada recently outlawed the mass export of prescription drugs that are subject to a current shortage.⁸³
- Transparency Reporting on drug price information from specified pharmaceutical supply chain entities, such as pharmaceutical manufacturers, wholesale distributors, and pharmacy benefit managers, similar to this program. Forty-three bills related to prescription drug price transparency were introduced in other states in 2021, and 18 states have passed and are implementing drug price transparency programs.
- Coupons Regulating or prohibiting the use of discounts or coupons by specified pharmaceutical supply chain entities. Sixty-four bills relating to coupons or cost sharing were introduced in state legislatures in 2021.
- Pharmacy benefit managers Regulating or providing additional transparency on the actions of pharmacy benefit managers, such as preventing discrimination against certain protected entities, or preventing pharmacy benefit managers from being able to hold a pharmacy or pharmacist responsible for any fees related to certain processes. Addressing a wide range of issues, 111 bills related to pharmacy benefit managers were introduced by a majority of the states in 2021, making up more than one-third of the total bills introduced.

Ashley Kirzinger, et al, *KFF Health Tracking Poll – February 2019: Prescription Drugs*, March 1, 2019. Retrieved at: https://www.kff.org/health-costs/poll-finding/kff-health-tracking-poll-february-2019-prescription-drugs/ on Dec. 3, 2020.

⁸² Sarah Lanford, "2020 State Legislative Action to Lower Pharmaceutical Costs," National Academy for State Health Policy, Updated on Nov. 24, 2020, retrieved at: https://www.nashp.org/rx-legislative-tracker/ on Dec. 2, 2020. The bullets below are also largely derived from this list.

⁸³ Mathhew S. Schwartz, "Canada Blocks Export of Medications in Short Supply in Response to Trump Plan," *NPR*, Nov. 29, 2020. Retrieved at: https://www.npr.org/2020/11/29/939890111/canada-blocks-export-of-medications-in-short-supply-in-response-to-trump-plan on Dec. 2, 2020.

Conclusion

Oregon's Prescription Drug Price Transparency Program is one of the first in the nation to be fully implemented and has been collecting data for nearly three years. By analyzing the information received from drug manufacturers, health insurers, and consumers, the program is working to deepen the state's understanding of the factors that influence prescription prices, and how drug prices affect Oregonians.

Based on the information collected, the program has made the following key findings in this 2021 report:

- The program received more reports for new high-cost cancer drugs than for any other class of therapy. The two most expensive drugs introduced in 2021 – Abecma, with a list price of \$419,500, and Breyanzi, with a list price of \$410,300 – are both CAR-T (gene therapy) cancer treatments produced by Bristol Myers Squibb.
- Biogen's new drug report for its Alzheimer's
 disease treatment, Aduhelm, indicated that
 its \$56,000 list price was driven by the "overall
 value this treatment is expected to bring to
 patients, caregivers, and society, while reflecting
 key principles such as innovation, access, and
 sustainability." However, the price has been
 criticized by patient advocates and drug pricing
 experts as unjustified. If Medicare elects not to
 cover Aduhelm, the cost of providing the drug
 could fall to Medicaid, potentially increasing state
 spending on the Oregon Health Plan.
- For the third year in a row, the most costly drug for Oregon's insurance companies was Humira, with insurers reporting spending \$93,544,597 on Humira prescriptions. Overall, more was spent on anti-inflammatory analgesics, including Humira, than any other drug class, with companies reporting \$153,753,608 on prescriptions in this class. The next most costly class of drugs was cancer therapies, with insurers

- reporting \$123,815,822 spent on prescriptions for antineoplastics and adjunctive therapies.
- The number of price increase reports received by the program continued to fall this year, a trend that is consistent with wider data showing that the number and magnitude of price increases fell sharply from 2015 to 2017. However, in the same period, the average launch price of new brand-name drugs more than doubled, from less than \$4,000 to more than \$10,000. This may suggest that manufacturers are avoiding making controversial price increases while a drug is on the market by setting a drug's launch price higher.
- The largest price increase reported to the program in 2021 was a 778 percent increase from an average of \$10.99 in 2019 to \$96.48 in 2020. This increase was for generic promethazine hydrochloride syrup, used to treat the symptoms of allergic reactions and nausea. Four out of five of the largest price increases were for generic drugs. The median price increase reported for generic drugs was 27 percent and the median price increase reported for brand-name drugs was 13 percent. Half of the generic drugs reported indicated a profit margin of 32 percent or higher, with one generic reporting a 93 percent profit margin. Thirty-eight percent of brand-name drugs with price increases reported that they lost money on the product, with the worst performing drug recouping only 22 percent of costs.

Resources

For more information about the Drug Price Transparency Program, visit https://dfr.oregon.gov/ drugtransparency/.

Health insurance issues and access

If you have issues with your insurance company about prescription drug coverage, contact the Division of Financial Regulation Consumer Advocacy Team at 888-877-4894 (toll-free) or email DFR.InsuranceHelp@oregon.gov.

Anyone can enroll for free into the Oregon Prescription Drug Program, which may provide discounts on prescriptions drugs for those uninsured or for drugs not covered by the individual's insurance plan. For more information, call 800-913-4284 (toll-free).

If you are uninsured, contact the Oregon Health Insurance Marketplace or the Oregon Health Authority for more information on the health insurance plans that may be available to you.

For information on a specific drug

- U.S. Food and Drug Administration Drugs@FDA Database
- U.S. National Library of Medicine Drug Information Portal

For general information on prescription drugs

- U.S. Food and Drug Administration Resources for Consumers
- U.S. National Library of Medicine Drug Information for the Public



Appendix A - Average annual price increase formula

A net increase percentage compares the average price of a drug from one year to the average price the next year.

Suppose the list price of a brand-name prescription drug was \$500 for the first 100 days of 2019, then rose in price to \$600 on the 101st day and remained at that price for the remaining 265 days of the year. The drug's average list price in 2019 is the average of these list prices, \$500 and \$600, taking into account how much time the drug spent at each price.

So this drug's average list price in 2019 is

$$\frac{(100 \times \$500 + 265 \times \$600)}{365} = \$572.60$$

Suppose the drug had another price increase on Jan. 25, 2020, from \$600 to \$640, and then remained at that list price for the remaining 342 days of the year. The drug's average list price in 2020 is

$$\frac{(24 \times \$600 + 342 \times \$640)}{366} = \$637.38$$

Note: 2020 was a leap year with 366 days. We counted every one of those days, first 24 then another 342, so we divided by all 366 here instead of 365. Since 2019 was not a leap year, we divided by 365 when computing the drug's average list price in 2019.

To find the 2020 net increase percentage, we compare the average price in 2019 to the average price in 2020.

The drug's average list price in 2020, \$637.38, is 11.3 percent higher than its average list price in 2019, \$572.60:

So, the 2020 net increase percentage for this drug is 11.3 percent and the reporting manufacturer is required to file an annual price increase report for this prescription drug.

In general, the formula for computing a 2020 net increase percentage is

(\$(average 2020 list price)-\$(average 2019 list price)) (\$(average 2019 list price))

Appendix B – Types of plans for insurer reports received in 2021

The program received reports from these companies that included the types of plans listed for each:

- BridgeSpan Health Company
 - Individual
- Cigna Health and Life Insurance Company
 - Large group
- Health Net Health Plan of Oregon, Inc.
 - Individual
 - Large group
 - Small group
- Kaiser Foundation Health Plan of the Northwest
 - Individual
 - Large group
 - Small group
 - Medicaid (coordinated care organization)
 - OEBB
 - PEBB
- Moda Health Plan, Inc.
 - Individual
 - Large group
 - Small group
- PacificSource Health Plans
 - Individual
 - Large group
 - Small group

- Providence Health Plan
 - Individual
 - Large group
 - Small group
- Regence BlueCross BlueShield of Oregon
 - Individual
 - Small group
- Samaritan Health Plans, Inc.
 - Large group
 - Small group
 - Choice
 - Medicaid (coordinated care organization)
 - Medicare
- UnitedHealthcare Insurance Company / UnitedHealthcare of Oregon, Inc.
 - Large group
 - Small group