



Prescription Drug Price Transparency Results and Recommendations – 2019

In Accordance with 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 www.dCBS.oregon.gov.

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 www.dfr.oregon.gov.

All information reported and analyses provided in the report is based on information provided to the department that was not claimed as a trade secret and available publicly on the department's website.

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Executive Summary

Background

More than half of adults in the United States from 18 to 64 years old received a prescription drug in 2017. ¹ For older Americans, this number increases to approximately 86 percent. ² Prescription drugs provide therapeutic benefits to many of the diseases and conditions people face during their lifetime. However, affordability of the prices and costs of prescription drugs can be an issue. A recent Kaiser Family Foundation poll found that most adults believe prescription drugs have made lives better, but the cost is unreasonable. ³ In 2017, 22.2 percent of Oregonians made changes to their medications because of cost. ⁴

In 2018, the Oregon legislature passed the Prescription Drug Price Transparency Act to increase prescription drug transparency as the first step to understanding the pharmaceutical industry and the factors contributing to high drug prices.

Program Overview

The Prescription Drug Price Transparency Act directed the Oregon Department of Consumer and Business Services to establish a transparency program to accept reports and disclose certain information from prescription drug manufacturers, health insurance carriers, and consumers on drug prices.

The goal of the Prescription Drug Price Transparency Act is to provide accountability for prescription drug pricing through the notice

and disclosure of specific drug costs and price information from pharmaceutical manufacturers, health insurers, and consumers.

The program requires pharmaceutical manufacturers to report to the department on the following:

- New prescriptions drugs costing more than \$670 a month upon (or for a shorter course of treatment) introduction, which is the Medicare Part D threshold set by the Centers for Medicare and Medicaid Services.
- Annual price increases for drugs costing more than \$100 a month (or for a shorter course of treatment) and experiencing a 10 percent net increase over the course of the previous calendar year.

Health insurance companies in Oregon are required through the rate review process to provide information on the top 25 drugs for various categories – most frequently prescribed, most costly, and those causing the greatest increase in insurance spending.

Consumers report to the department price increases they experience when purchasing prescription drugs.

Results

Oregon's program is unique and one of the most comprehensive drug price transparency

¹ Centers for Disease Control and Prevention. Quick States: *Percentage of Adults Aged ≥18 Years Who Were Prescribed Medication in the Past 12 Months, by Sex and Age Group* — *National Health Interview Survey, 2017*. MMWR Morb Mortal Wkly Rep 2019; 68:97. <<http://dx.doi.org/10.15585/mmwr.mm6804a6external icon>>, visited Nov. 2019

² Ibid.

³ Kirzinger A, Muñana C, Fehr R, Rousseau D, for the Kaiser Family Foundation. US Public's Perspective on Prescription Drug Costs. *JAMA*. 2019; 322(15):1440. <<https://jamanetwork.com/journals/jama/fullarticle/2752910?>>, visited Nov. 2019.

⁴ SHADAC analysis of National Health Interview Survey and National Center for Health Statistics data, State Health Compare, SHADAC, University of Minnesota. <<http://statehealthcompare.shadac.org/map/73/percent-who-made-changes-to-medical-drugs-because-of-cost-in-the-past-year-by-age#13/24/110>>, visited Nov. 2019.



programs in the country. The program has successfully built a reporting infrastructure and program processes and received drug reports from pharmaceutical manufacturers, health insurers, and consumers in less than a year.

With the information reported to the program, the department has started learning several things about prescription drugs, such as how the U.S. list price compares to prices in other countries, drugs that are the most costly for health insurers, and what drugs are of most concern to Oregonians. This report is based on all data, not claimed to be a trade secret, submitted as of November 2019 and is available on the department's website. Highlights include:

- U.S. prices are typically five times more than the highest price globally for prescription drugs reported to the program. For example, the median price for cardiovascular drugs reported to the program was \$580, while the majority of prices in other countries ranged from \$5 to \$164.
- Most of the annual price increases reported to the program range from the reporting minimum of 10 percent to approximately 20 percent. Manufacturers attribute these increases to rebates, the use of co-pay assistance programs, obligations to shareholders, research and development costs, and other related factors.
- New brand-name drugs are significantly more expensive than new high-cost generics reported to the program. Manufacturers reported the high price is influenced by the number of competitors in the market, how well the drug works, how profitable it can be, and other factors.

- Most costly drugs reported to the program by health insurers tend to be brand-name and biologic drugs, such as Humira, which cost insurance companies approximately \$220 million to fill claims for about 6,000 Oregonians in 2018. Several of the most costly drugs also appeared on the list of drugs causing the greatest increase in insurance spending.
- Drugs costs have a profound effect on Oregonians. From one story reported to the program: "My father, 79, confessed that he is only doing one breathing treatment per day for his COPD rather than the two-a-day he is prescribed. He is trying to save money – a fixed income received from Social Security benefits. I also know that the reason he is trying to save money on HIS meds is because my mother has diabetes. He will sacrifice his medication to make sure she gets hers."

Recommendations

The Prescription Drug Price Transparency Act directs the department to provide the legislature with recommendations for legislative changes to contain the cost of prescription drugs and reduce the impact of price increases. Several of the recommendations offered are suggested improvements for the program to receive better quality data and help inform future policy recommendations. Not all recommendations require legislation.

General Program Recommendations

1. **Provide statutory access to the All Payer All Claims (APAC) Database** - Currently, DCBS does not have direct access to the database, but works closely with the Oregon

Health Authority when this data is needed. We recommend the legislature include DCBS within the APAC statutes to provide direct access to the data to further improve program analyses.

2. Evaluate the Program's Expenditure

Limitation - Several unanticipated factors underscore the need for the legislature to evaluate the current expenditure limitation for the drug price transparency program. We recommend the legislature work with the department to evaluate the program's expenditure limitation and determine how to properly adjust this based on the unanticipated factors contributing to higher expenses by Spring 2020.

3. **Ongoing program evaluation** - We will continue to evaluate the program. 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.

Manufacturer Reporting Recommendations

4. **Registration Requirement for Pharmaceutical Manufacturers** - There is no current requirement for pharmaceutical manufacturers to create an account with the program unless they are filing a report. We recommend that all drug manufacturers meeting the definition of a reporting manufacturer be required to register with the Prescription Drug Price Transparency Program to improve compliance with program regulations.
5. **Simplify the threshold for annual price increase reports** - A new reporting law, House Bill 2658, contains different threshold price reporting terms than those in the Prescription Drug Price Transparency Act. We recommend changing the Prescription Drug Price Transparency Act statutory language regarding

the threshold for annual price increase reports to similar terms in House Bill 2658.

6. **Patient Assistance Reporting for New Drug Reports** - New drug reports currently do not include any patient assistance information to the program despite several new drugs coming to market with patient assistance. We recommend the legislature consider including patient assistance reporting for new high cost drugs reported to the program to improve understanding on these programs.

Health Insurer Recommendations

7. **Expand Reporting to Additional Insurers** - Health insurance carriers are required to submit rate filings only if they offer individual or small group health benefit plans. Therefore, health insurers that do not participate in these markets are not required to submit these reports. We recommend legislators consider separating the health insurance carrier reporting requirement from the rate review process and require it as a separate annual report from all health benefit plan issuers in Oregon.
8. **Quantitative Information Reporting** - For the first year of health insurer reporting, the program received only a ranked list of drugs for the required reporting categories. We identified that receiving quantitative information about these drugs, such as the number of claims received and amount of money paid, would be useful to understand the scope and magnitude of the drugs ranked on these lists. We recommend the program receive quantitative information from the health insurers reporting top 25 drug lists to the program.

Consumer Notification Recommendation

9. **Protection of Consumer Reported Information** - When the program receives reports from consumers, 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. Additionally, the consumer reports ZIP code, health insurance information,



and the reasons for the price increase. We recommend clarifying that the personally identifiable information collected will be protected from public disclosure.

Other Recommendations

10. 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 the consumer at the pharmacy counter, through their health insurance premium, 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.

11. Program structure for current and future transparency requirements - In 2019, the

legislature passed House Bill 2658, which requires the department to receive advance notices for certain drug price increases. This new statute, while similar to the Prescription Drug Price Transparency Act, is completely separate. As the legislature considers additional prescription drug transparency requirements, we recommend integrating current and future transparency requirements to standardize the infrastructure and resources such as funding, rulemaking, and enforcement authorities.

The program will continue to build upon the information received in the first year to improve the program for future years and to continue understanding the effect of drug prices and costs. As more information is received, the program will engage in analyses to further inform policies to reduce the cost of prescription drugs to Oregonians.

Background

More than half of adults in the United States from 18 to 64 years old received a prescription drug in 2017.⁶ For older Americans, this number increases to approximately 86 percent.⁷ Prescription drugs provide therapeutic benefits to many of the diseases and conditions that people face in their lifetime. However, the prices and costs can be an issue for affording these medications. A recent Kaiser Family Foundation poll found that most adults believe that prescription drugs have made lives better, but the cost is unreasonable.⁸

This report focuses on analysis of the data the Oregon Department of Consumer and Business Services received from prescription drug manufacturers, health insurance companies, and consumers of prescription drugs. It begins with an overview of prescription drugs and spending in the U.S. and in Oregon. It includes a brief explanation of Oregon's Prescription Drug Price Transparency Program before highlighting what the program found during the first year of reporting. Data in this report is based on information submitted as of November 2019. The report concludes with recommendations to the legislature based on program implementation and the information received during the first year of implementation.

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 for someone to purchase them.⁹ Prescription drugs can be either a brand-name drug or generic drug. Brand-name prescription drugs are protected 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.¹⁰ Generic drugs typically cost less than brand-name drugs and are used more frequently due to the reduced cost when they are available.

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,

⁶ Centers for Disease Control and Prevention. *Quick States: Percentage of Adults Aged ≥18 Years Who Were Prescribed Medication in the Past 12 Months, by Sex and Age Group — National Health Interview Survey, 2017*. MMWR Morb Mortal Wkly Rep 2019; 68:97.

<<http://dx.doi.org/10.15585/mmwr.mm6804a6external icon>>, visited Nov. 2019.

⁷ Ibid.

⁸ Kirzinger A, Muñana C, Fehr R, Rousseau D, for the Kaiser Family Foundation. US Public's Perspective on Prescription Drug Costs. *JAMA*. 2019; 322(15):1440. <<https://jamanetwork.com/journals/jama/fullarticle/2752910?>>, visited Nov. 2019.

⁹ 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 Nov. 2019.

¹⁰ 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 Nov. 2019.

pharmacies, pharmacy benefit managers (PBM), health insurance companies, medical providers, and consumers make up the majority of the pharmaceutical supply chain participants.

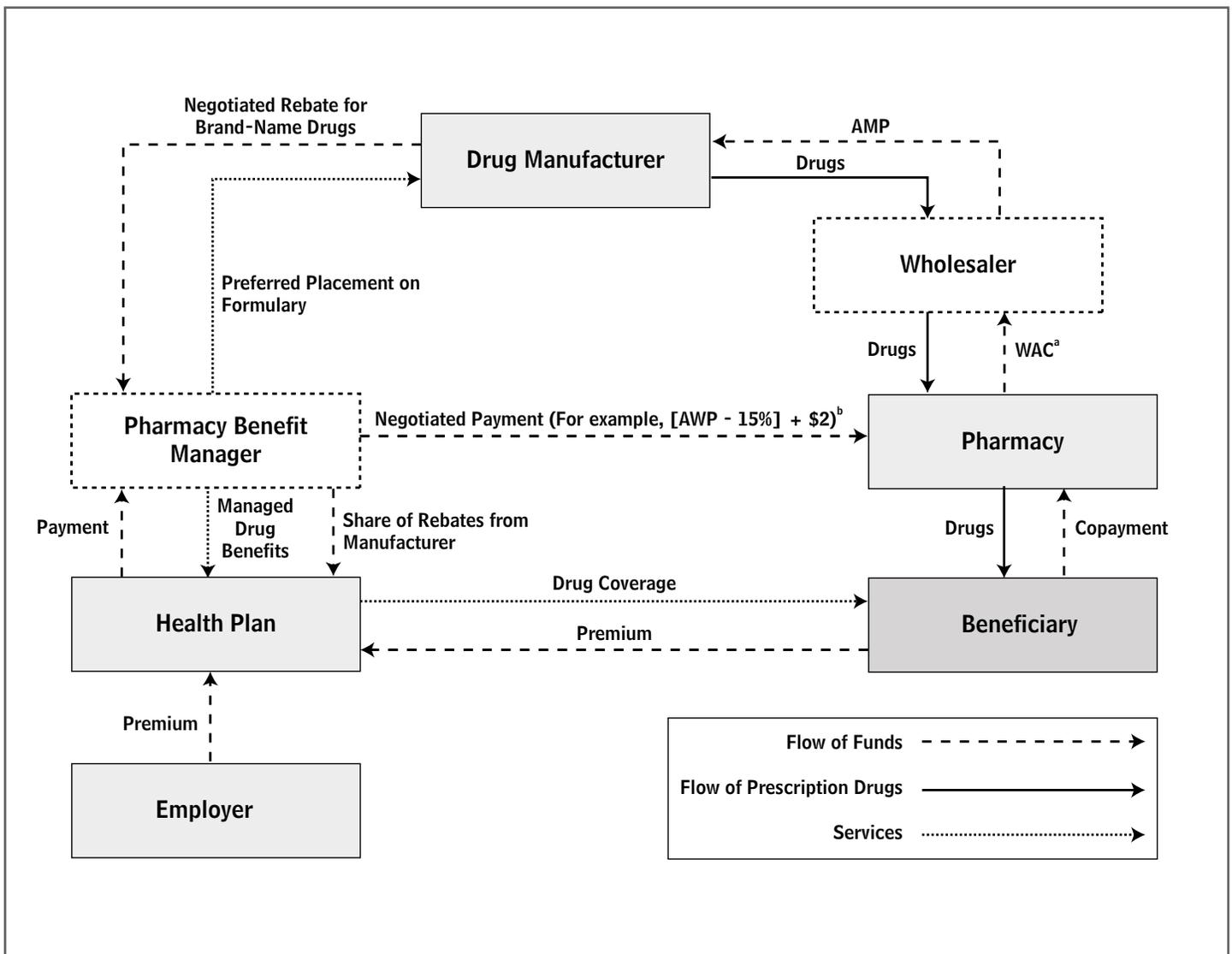
The price a consumer pays at the pharmacy can be influenced by the industry practices and financial negotiations between pharmaceutical supply chain

entities, as well as what type of health insurance coverage the consumer has obtained. 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

Figure 1: Pharmaceutical Supply Chain for Brand-Name Drug at Retail Pharmacy with Employer Health Insurance Plan

Source: Congressional Budget Office ¹¹



¹¹ Congressional Budget Office. [Prescription Drug Pricing in the Private Sector](#), 2007, visited Nov. 2019.

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.

Prescription Drug Spending in the United States and Oregon

In 2018, U.S. health care spending reached \$3.6 trillion, which is approximately \$11,000 per person.¹² It is estimated that prescription drug spending accounts for approximately 13 percent of health care spending – 9 percent retail and an estimated 4 percent nonretail.¹³ Between 2010 and 2014,

there was a significant increase in prescription drug spending for which the following factors contributed:¹⁴



10 percent
Population growth



30 percent
Increased prescriptions



30 percent
Inflation



30 percent
Higher priced drugs and price increases

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. Several new reports describe the effect of prescription drug costs, highlighting instances in which individuals have not taken the drugs they depend on to live, resulting in serious harm or death.^{15, 16} These reports have increased the attention on the effect prescription drug costs have on U.S. households.

¹² Centers for Medicare and Medicaid Services. *National Health Expenditure 2017 Highlights*. <<https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/highlights.pdf>>, visited Nov. 2019.

¹³ Alatum Institute. *Projections of the Prescription Drug Share of National Health Expenditures Including Non-Retail*. June 2019. <<https://altatum.org/publications/projections-prescription-drug-share-national-health-expenditures-including-non-retail-0>>, visited Nov. 2019.

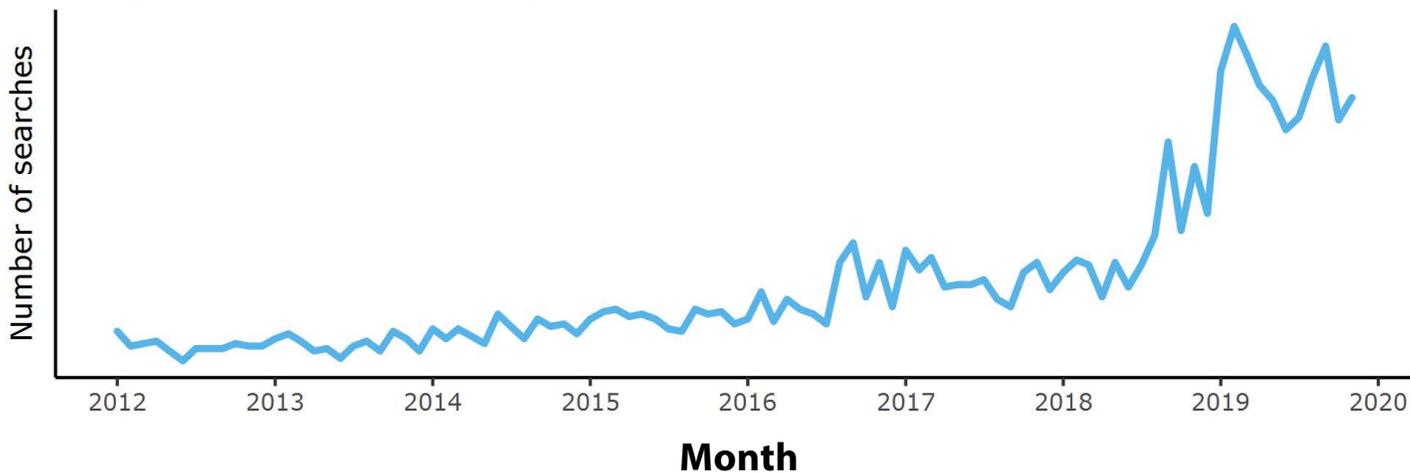
¹⁴ U.S. Department of Health & Human Services. *Observations on Trends in Prescription Drug Spending*. March 2016. <<https://aspe.hhs.gov/system/files/pdf/187586/Drugspending.pdf>>, visited Nov. 2019.

¹⁵ Sable-Smith, Bram. "Insulin's Steep Price Leads to Deadly Rationing". *Kaiser Health News*, Sept. 2018. <<https://khn.org/news/insulins-high-cost-leads-to-deadly-rationing/>>, visited Nov. 2019.

¹⁶ Carroll, Linda. "U.S. heart patients cut back on life-saving drugs due to cost.". *Reuters*, Nov. 2019. <<https://www.reuters.com/article/us-health-heart-expenses/us-heart-patients-cut-back-on-life-saving-drugs-due-to-cost-idUSKBN1XZ2HM>>, visited Nov. 2019.

Google search data provides further insight into Americans' rising interest about drug prices and the cost of specific types of drugs, such as insulin. To illustrate, the graph below displays some searches related to the cost of insulin.

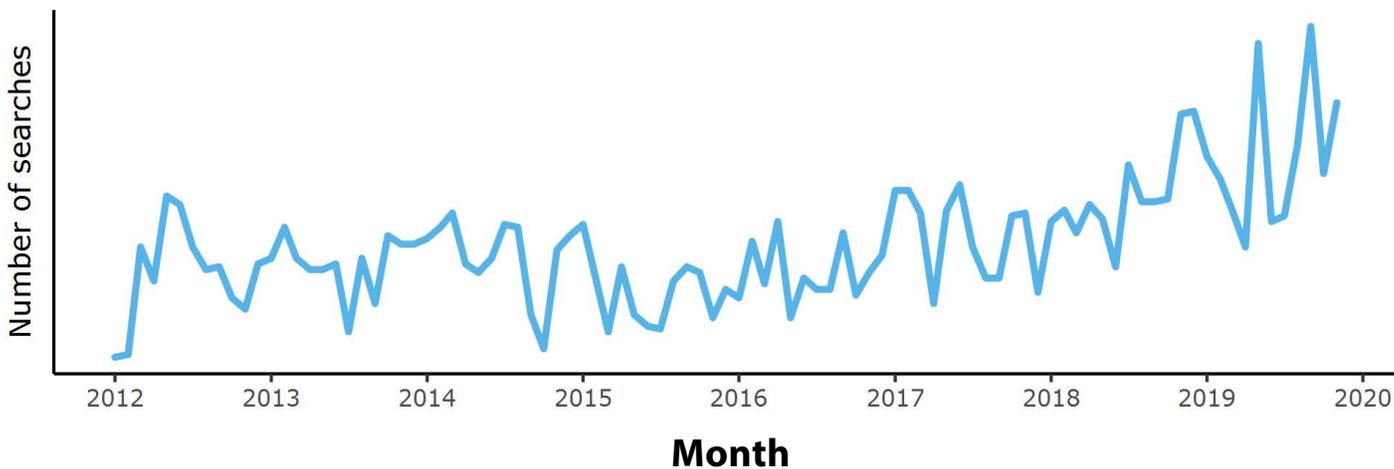
Google searches containing 'insulin' and 'expensive', 'cost', or 'price'



Source: Oregon Drug Price Transparency Program, 2019
Data: google trends

This Google search highlights that there has been a huge increase in interest about the cost of insulin in recent years. In fact, there is a massive spike in interest starting in January 2019, when Sanofi and Novo Nordisk increased the list prices of their insulin products by about 5 percent.

Google searches containing 'insulin' and 'without insurance'/'no insurance'



Source: Oregon Drug Price Transparency Program, 2019
Data: google trends

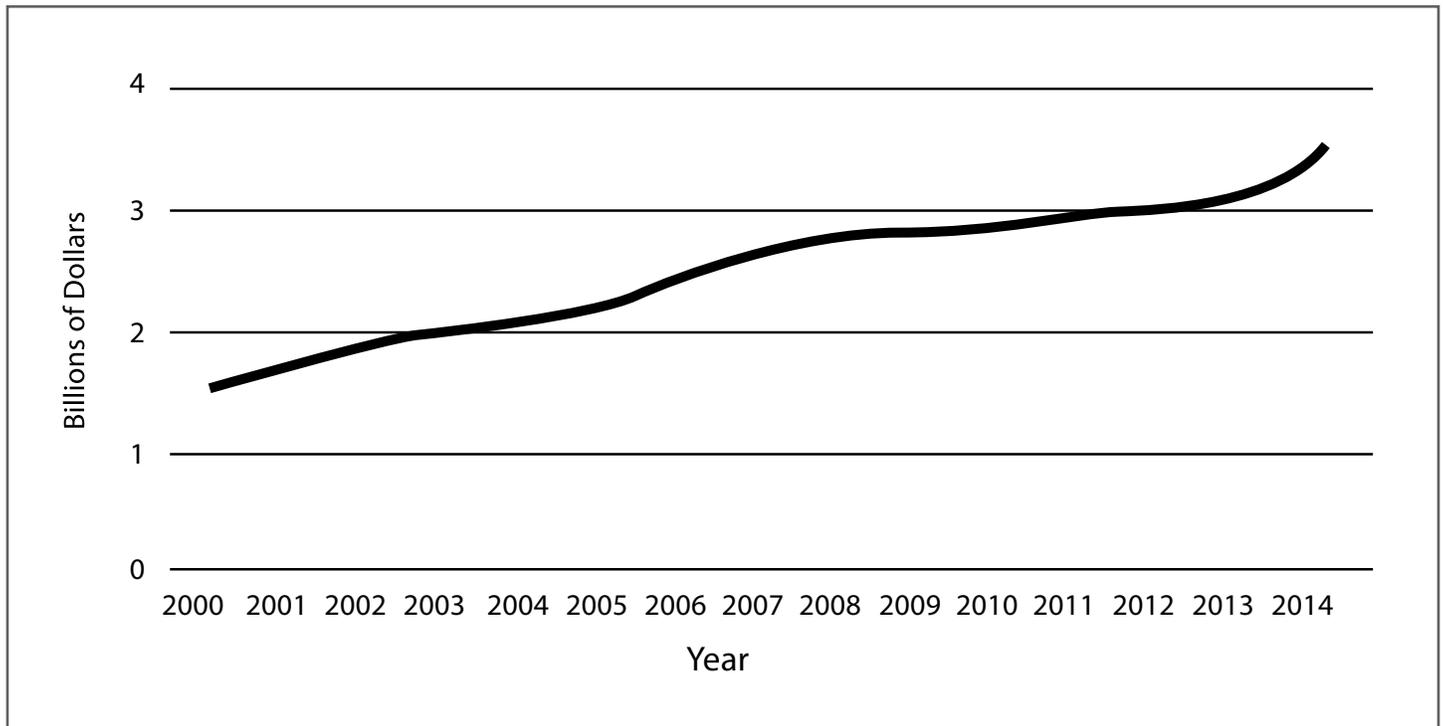
This graph shows that, since the start of 2016, Google searches containing "insulin," "insurance," and "without" or "no" have roughly doubled.

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. In Oregon, retail prescription drug spending accounts for approximately 11 percent of total health expenditures and has increased an average of 7.2 percent annually from 1991 to 2014.^{17, 18}

The increasing expenditure on retail and nonretail prescription drugs contributes to the overall health care costs people pay and their ability to pay those costs. Strategies generally used by Americans to reduce their prescription drug costs are asking for a lower cost medication, not taking the medication as prescribed, and using an alternative therapy.

Graph 3: Estimated expenditure on retail prescription drugs in Oregon (1991 to 2014)



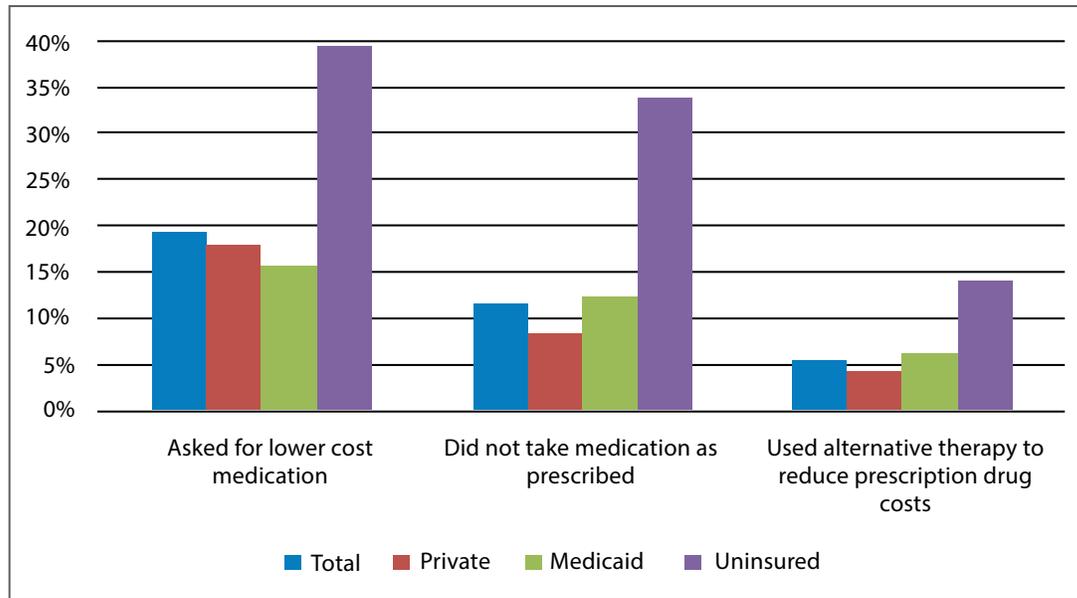
Source: Department of Consumer and Business Services, 2019.

Data: CMS National Health Expenditure Data – Accessed Nov. 2019.

¹⁷ Kaiser Family Foundation. *Distribution of Health Care Expenditures by Service by State of Residence in Millions*. <<https://www.kff.org/other/state-indicator/distribution-of-health-care-expenditures-by-service-by-state-of-residence-in-millions/?currentTimeframe=0&selectedRows=%7B%22states%22:%7B%22oregon%22:%7B%7D%7D%7D&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D>>, visited Nov. 2019.

¹⁸ Centers for Medicare & Medicaid Services. *National Health Expenditures by State of Residence, 1991-2014*. <<https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsStateHealthAccountsResidence>>, visited Nov. 2019.

Graph 4: Strategies Used by Adults to Reduce Their Prescription Drug Costs, 2017 ¹⁹



Source: Department of Consumer and Business Services, 2019.
Data: CDC, National Health Interview Survey – Accessed Nov. 2019.

Uninsured people use these strategies more frequently due to having no health insurance coverage for prescription drug costs. In 2017, 22.2 percent of Oregonians made changes to their medications because of cost.²⁰

The state is a major purchaser of prescription drugs through the administration of health benefit plans for Oregonians. From 2013 to 2015, it was estimated the Oregon Health Authority would spend \$1.2 billion on prescription drugs through the programs it administers, such as the Oregon Health Plan, Oregon Prescription Drug Program, Oregon Educators Benefit Board, Public Employees Benefit Board, and the Oregon AIDS Drug Assistance Program.²¹ The Oregon Health Plan, which provides Medicaid insurance coverage to Oregonians, accounted for approximately 62.5 percent of OHA’s estimated spending on

prescription drugs. Oregon Youth Authority, Oregon Department of Corrections, and the Oregon State Hospital also purchase prescription drugs for the people in their care.

Oregon’s Prescription Drug Price Transparency Act

In 2018, the Oregon legislature passed Oregon’s Prescription Drug Price Transparency Act to increase prescription drug price transparency.²² The statute established two components to address this:

1. Oregon’s Prescription Drug Price Transparency Program at the Department of Consumer and Business Services

¹⁹ Cohen RA, Boersma P, Vahratian A. Strategies used by adults aged 18–64 to reduce their prescription drug costs, 2017. NCHS Data Brief, no 333. Hyattsville, MD: National Center for Health Statistics. 2019. <<https://www.cdc.gov/nchs/products/databriefs/db333.htm>>, visited Nov. 2019.

²⁰ SHADAC analysis of National Health Interview Survey and National Center for Health Statistics data, State Health Compare, SHADAC, University of Minnesota. <<http://statehealthcompare.shadac.org/map/73/percent-who-made-changes-to-medical-drugs-because-of-cost-in-the-past-year-by-age#13/24/110>>, visited Nov. 2019.

²¹ Legislative Policy and Research Office. *Background Brief on Prescription Drugs*. 2014. <<https://www.oregonlegislature.gov/lpro/Publications/BB2014PrescriptionDrugs.pdf>>, visited Nov. 2019.

²² House Bill 4005 (2018), <https://olis.oregonlegislature.gov/liz/2018R1/Measures/Overview/HB4005>.

2. The Task Force on Fair Pricing of Prescription Drugs within the Oregon State Legislature.

The goal of the Prescription Drug Price Transparency Program is to provide accountability for prescription drug pricing through transparency of specific drug cost and price information from pharmaceutical manufacturers, health insurers, and consumers.

The Task Force on Fair Pricing of Prescription Drugs was charged with examining and developing transparency strategies for the entire pharmaceutical supply chain – from manufacturers to consumers

and all entities in between. Over six months, the task force identified key cost factors affecting the price of pharmaceutical drugs and developed a set of strategies to address them. These cost factors are coupons, discounts, fees, incentive programs/kickbacks, insurance benefit design, list price, markups, pharmacist gag clause, and rebates.²³

Legislators have described the Prescription Drug Price Transparency Act as being the first step to understanding prescription drug cost and pricing through increased transparency.

Oregon's Prescription Drug Price Transparency Program

After passage of the Act, the department convened a rulemaking advisory committee consisting of biologic drug manufacturers, consumer advocates, generic drug manufacturers, health care providers, insurance carriers, pharmacy benefit managers, pharmacies, brand-name prescription drug manufacturers, and wholesale drug distributors to provide input on program regulations and its estimated fiscal and economic impacts.²⁴

The program rules were finalized and the program became effective on March 1, 2019. Beginning March 15, 2019, the program accepted the first reports from manufacturers. Since then, the program has implemented all program components and has begun receiving reports from reporting entities on drug prices.

Next, the program will work with manufacturers to comply with the law, evaluate the trade secret claims received from manufacturers, and prepare for the second year of reporting.

The following sections detail the information the department has received from consumers, health insurance carriers, and pharmaceutical manufacturers as of November 2019.

Consumers

There are three ways consumers can contact the department: by phone, email, or online submission form. The department conducted significant outreach to provide Oregonians information about the option to report a price increase. Outreach was directed to where consumers would receive notice of a price change in their prescription drug – at the pharmacy counter. The department sent materials to more than 500 pharmacies in Oregon explaining the program, which included program rack cards with information on how to report a price increase.

The program will continue outreach to Oregonians using a variety of strategies, such as using census data to target outreach to communities who speak languages other than English. Program materials are also available in Russian, Spanish, and Vietnamese.

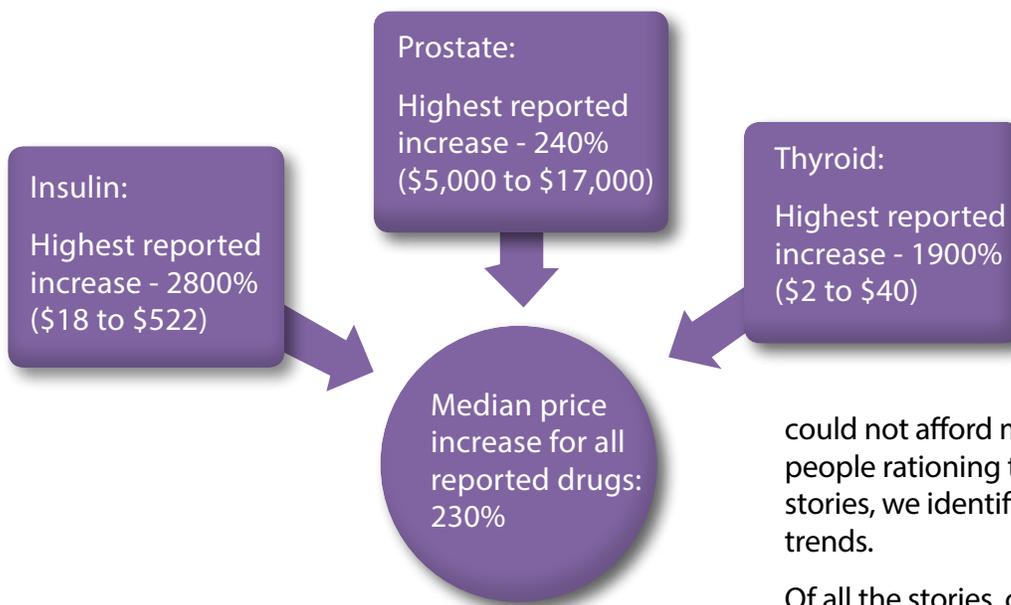
Price Increase Notices

The department has received numerous notifications from consumers on price increases. Of the price increases reported to the department, the most common types of medications that were reported on were insulin, prostate, and thyroid medications.

²³ For more information about the Task Force on Fair Pricing of Prescription Drugs, see the Task Force report: <https://olis.oregonlegislature.gov/liz/201711/Downloads/CommitteeMeetingDocument/152412>.

²⁴ Division of Financial Regulation. Prescription Drug Price Transparency Rulemaking Advisory Committee (HB 4005). < <https://dfr.oregon.gov/help/committees-workgroups/Pages/prescription-price-transparency-rac.aspx>>. Visited Dec. 2019.

Figure 2: Description of Price Increases Reported by Consumers to the Drug Price Transparency Program.



could not afford medication for their children, and people rationing their medications. From these stories, we identified some thought-provoking trends.

Of all the stories, comments, and questions received, there were 48 uses of the word insulin, and 20 mentions of the word diabetic/diabetes. Another top subject was 19 mentions each of asthma and inhaler, and six mentions of COPD – chronic obstructive pulmonary disease. There were also 27 different medications identified by name, with only a few overlapping references.

Several of the stories, comments, and questions were about the cost of these medications rising to the point of not being affordable or being high enough for there to be a financial strain on people.²⁵ One story came from an Oregonian who cannot retire because of the cost of prescriptions:

“My spouse takes needs to take Eliquis 5mg twice a day. A 90-day supply costs \$1343.00. Again why so much? My spouse has nine different prescriptions that has to be taken, another costs \$400 for a 30 day supply. My spouse is retired and SSI is only \$1200 a month, I continue to work to receive insurance benefits to cover those drug costs. I cannot retire until my spouse dies, I can't afford to.”

Another story was from a nurse who helps patients with diabetes:

“As a diabetic nurse I often found my patients would

Stories from Oregonians

In addition to a request to report price increases, the program asked Oregonians to submit their stories, comments, and questions. More than 100 stories, comments, and questions came in from the public. Submissions described friends and family struggle to make ends meet when drug costs rose, parents who

Figure 3: Word Cloud for the Stories, Comments, and Questions Submitted to the Drug Price Transparency Program.

Source: Stories, comments, and questions submitted to the Drug Transparency Program.



²⁵ For more information on the stories reported to the program, see the program website for all the stories reported to the program.

simply go without their diabetes medications because they could not afford them. We had a pharmacy at our safety-net clinic that could provide lower cost medications but even with our lower prices many patients could not afford insulin and other diabetes medications.”

Many people also cited insurance issues or had comments about their insurance coverage no longer covering the medications they needed. For example, the following stories were submitted regarding insurance coverage:

“I take a GLP-1 agonist called Bydureon. This helps to control my blood glucose levels in conjunction with diet, exercise, and insulin. At the start of the year is when I struggle the most to fill that prescription, because a one month supply without any discounts or special funding, is over \$700. It's a prescription that I often have to forego at the start of the year, until I've met my deductible.”

Another story describes the impact of lacking health insurance:

“My adult son had asthma his whole life and continued to suffer with it in his 50's. For an extended period he did not have health insurance...and could not afford the cost of the one inhaler medication that made it possible for him to keep working. The \$427 per month that I paid for this RX kept him alive until lack of health insurance coverage caused his death at 57.”

Several other Oregonians submitted stories about prescription drugs to the department. Many of the submitted stories are found in other sections. Look for these stories in call-out boxes throughout the report.

Health Insurance Companies

The program requires health insurance companies to report on prescription drugs in Oregon. Health insurance companies are required by state law to report the 25 most prescribed drugs, the 25 most costly drugs, and the 25 drugs that caused the biggest increases in yearly health plan spending in the 2018 calendar year.

Lists were received from all nine health insurance companies that file individual and small group health insurance rates with the department:

- BridgeSpan Health Company
- Health Net Health Plan of Oregon
- Kaiser Foundation Health Plan of the Northwest
- Moda Health Plan
- PacificSource Health Plans
- Providence Health Plan
- Regence BlueCross BlueShield of Oregon
- Samaritan Health Plans
- UnitedHealthcare Insurance Company

The Prescription Drug Price Transparency Program published a detailed report on the lists submitted by these companies on its website (dfr.oregon.gov/drugtransparency) and posted the individual lists as interactive webpages and as Excel documents. The combined list of Excel documents include specific information about the drugs' therapeutic classes, what the drugs are commonly prescribed for, their U.S. Food and Drug Administration approval dates, and whether generic versions of the drugs are available in the United States.

We include some highlights from that report below, along with some new data provided by the Oregon Health Authority from its All Payer All Claims Database.

Most Prescribed Drugs

Insurers reported the most prescribed drugs based on the number of claims they received for prescription drugs during the 2018 calendar year. This includes prescription drugs covered under both pharmacy and medical benefits.

Hydrocodone, a commonly prescribed opioid, ranked near the top of the most prescribed drugs list insurers submitted. More than 300,000 people received prescriptions for hydrocodone last year and the amount paid was approximately \$8.6 million. This amount includes what insurers paid and what patients paid out-of-pocket.

Another high-ranking drug was hydrochlorothiazide, which is used to treat high

blood pressure. More than 100,000 people received prescriptions for this drug, with more than \$1.2 million paid.²⁶

Atorvastatin Calcium is a drug used to lower cholesterol levels in the blood. There were more than 260,000 people who received prescriptions for this drug, with \$13.7 million paid.²⁶



Most Costly Drugs

Insurers reported prescription drugs that contributed the largest cost to total annual health plan spending during the 2018 calendar year. This takes into account total annual spending, including the net impact of any rebates or other price concessions.

Humira appeared at the top of many of the insurers' most costly lists. Humira is used to treat rheumatoid arthritis, Crohn's disease, and plaque psoriasis. This drug is prescribed much less often than the drugs listed above. In Oregon, just over 6,000 people got prescriptions for Humira in 2018. For this relatively small patient population, the total amount paid for Humira, counting both the amount paid by insurers and the amount paid out-of-pocket, was \$220.7 million.²⁶

Enbrel also ranked near the top of many of the most costly lists. This drug is also used to treat rheumatoid arthritis, Crohn's disease, and plaque psoriasis. In Oregon, just over 3,000 people got prescriptions for it, and a total of \$106.6 million was paid.²⁶



Stories from Oregonians
 "My son has Crohnes, he was first put on Humeria at \$9,xxx a month, that didn't work and they switched him to Stellara at a cost of \$20,500 every 8 weeks!!! Who can afford this? I'm very worried about my ability to retire when I need to pay his insurance as he also has some mental health issues and will likely never be employed."

Drugs That Caused the Biggest Increases in Plan Spending

Health insurers also reported the prescription drugs that caused the greatest increases in total plan spending in 2018 as compared to 2017. Just

²⁶ Preliminary 2018 information Received from Oregon All Payer All Claims Database, Oct. 2019. <https://www.oregon.gov/oha/HPA/ANALYTICS/Pages/All-Payer-All-Claims.aspx>.

as with the most costly drugs, this takes into account total annual spending, including the net impact of any rebates or price concessions. Humira and Enbrel, discussed above in the section on most costly drugs, were also reported as very large contributors to plan spending increases.

Stories from Oregonians

I work as an infusion nurse, infusing biologic medications that not only improve people's quality of life, but save lives as well. I have watched the price of the drugs I infuse increase every year over the last 4 years. I know of one long term biologic that had its patent run out in that time. This means other companies can now make a "generic" or "biosimilar" as they are called in this class of medications. Another company has created this. I have not seen any savings for my patients and in fact, the price of the trade brand and the biosimilar and have increased.

Another drug near the top of many of the lists was Mavyret, which is used for the treatment of hepatitis C. In Oregon, more than 1,500 people got prescriptions for Mavyret, amounting to \$46.7 million paid.²⁶



Ocrevus is used to treat multiple sclerosis. The All Payer All Claims Database contains information on fewer than 1,000 Oregonians who got prescriptions for this drug in 2018, with \$33.8 million paid.²⁶

Prescription Drug Manufacturers

Under the Prescription Drug Price Transparency Act, drug manufacturers are required to submit two types of reports to the program.

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

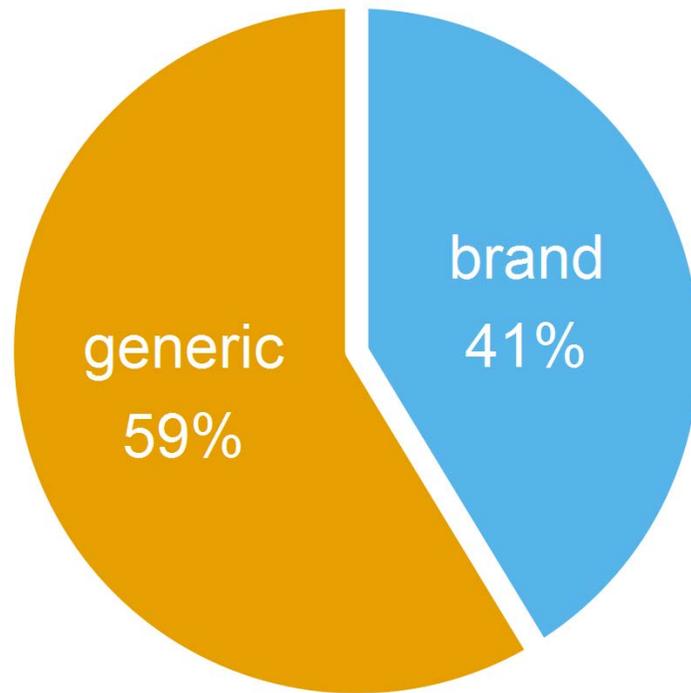
Second, manufacturers are required to annually submit a price increase report for any of their drugs with a list price of \$100 or more for a 30-day supply or for a course of treatment shorter than one month that experiences a net price increase of 10 percent or more from the previous year.

Under both types of reports, reporting is required for each qualifying NDC (National Drug Code) 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 multiple package sizes.

This report is based on all data, not claimed to be trade secret, submitted as of November 2019. This data is publicly available on the department's website.

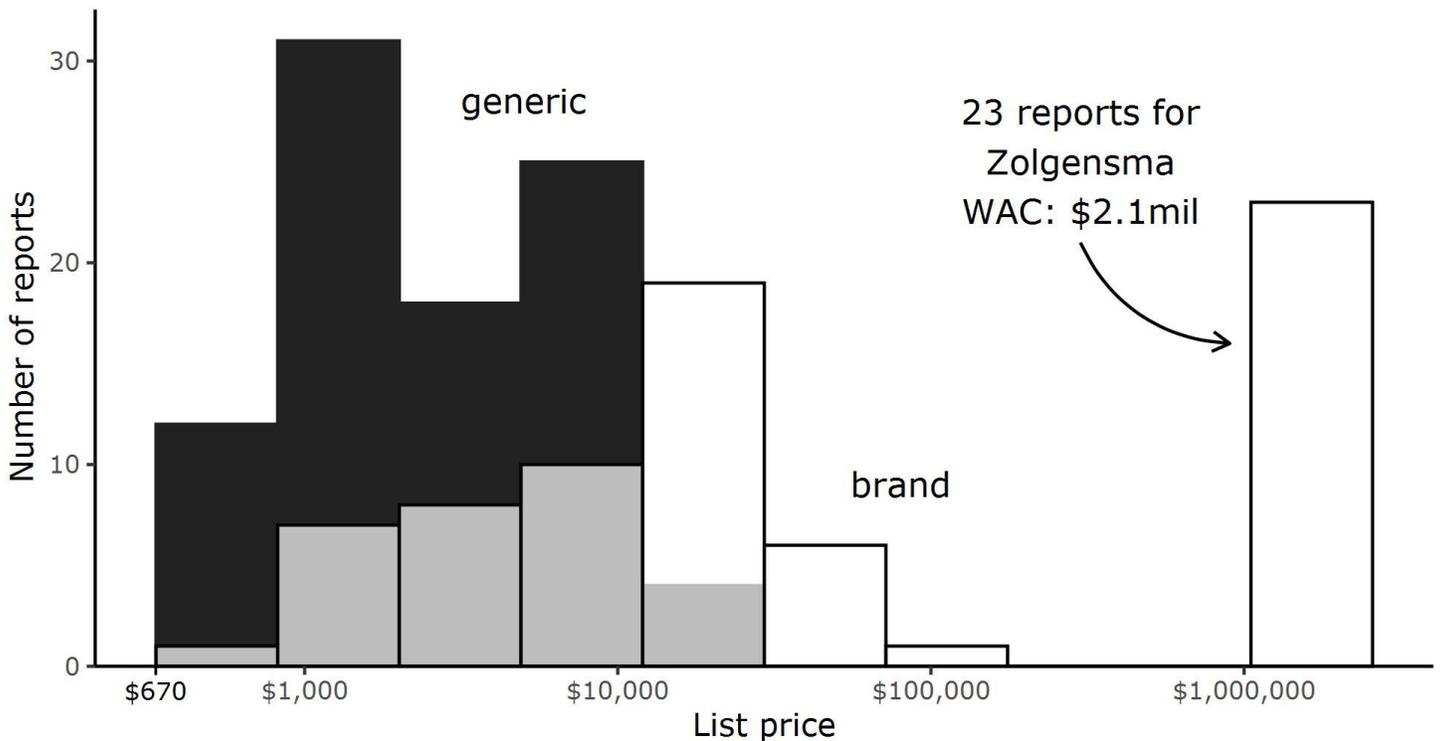
New High Cost Drug Reports

New high cost drugs are reported to the program when they are priced at or over \$670. This is the financial threshold set by the federal government to categorize a drug as a specialty drug under Medicare Part D. Reports for new drugs come in continuously, and there is a lot of variation in the volume of reports the program receives (anywhere from 10 to 60 reports per month). Most of the reports we receive are for generic drugs, though we do also receive a large number of reports for brand-name drugs. The generic-brand percent split is approximately 60-40.



The data in this report is based on the first 196 new drug reports received from March 2019 to November 2019. Reported data does not include information claimed to be a trade secret.

The graph below shows the distribution of list prices reported to the program for generic drugs and for brand-name drugs. The height of each bar represents the number of reports we received in that range.



Price Distribution for New Drugs

The graph on the previous page shows the distribution of list prices reported to the program for generic drugs and for brand-name drugs. The height of each bar represents the number of reports we received in that range.

The new brand drugs being reported are typically more expensive than the new generic drugs, though there is quite a bit of overlap between the prices in the two categories. Several of the reported generic drugs are priced more than \$10,000, including NDCs for:

- Teva Pharmaceutical Industries' generics of penicillamine and icatibant acetate
- Amerigen Pharmaceuticals' generic of penicillamine
- Zydus Pharmaceuticals' generic of trientine and bosentan
- Sandoz's generic of treprostinil

Stories from Oregonians

I was diagnosed with advanced ovarian cancer about 2 years ago. I underwent surgery and chemotherapy and entered a clinical trial sponsored by the Tesoro company, using the medication naraparib. I learned that this drug costs appx \$2500.00 a month and that any Medicare plan I chose would result in paying a minimum of \$6000.00 a year out of pocket for the med in addition to out of pocket expenses for other medical expenses. I don't have \$6000.00 a year available and it seems this drug is vitally important. So I will be looking for employment. I feel fortunate that I'm feeling well enough to work at something. However I'm concerned about overextending myself as I fight this disease.

Pricing Methodology

Finally, in the context of the new drug reports, it is worth considering the factors that go into setting the prices of the new drug. The information provided is based on reports by manufacturers who did not claim this information as a trade secret. These manufacturers report several factors that can be

grouped into three categories: market factors, patient population, and business factors.

Market factors include competitive factors a manufacturer considers, such as the number of generics being offered by competitors, discounts they are providing, and the supply and demand for a new drug. Patient population includes how well the drug works, how it compares to other treatments, and how available it is to patients who need it. Business factors include how innovative the drug is, how profitable it can be, and the overall costs to make and market the drug.

These three factors are depicted below:

Market Factors

- Number of generic competitors
- Discount off of reference drug
- Competition, supply, and demand
- Negotiations

Patient population

- How well the medicine works
- Compares to other available treatments
- Value and affordability for patient access
- Prevalence and incidence of condition

Business Factors

- Rewarding innovation
- Competitiveness determined by pricing committee
- Value-based methodology
- Profitability and costs

Marketing Strategies

Also, we requested that manufacturers share their marketing strategies for these new drugs. Many manufacturers noted they do not typically market generic products. However, for those that did share marketing information, media advertisements were a common method of marketing directly to consumers. This includes radio, TV, billboards, and social media. Again, this is based on data not claimed to be trade

secret. Manufacturers that reported this data also noted that they provide free samples, rebates, and coupons for consumers.

Some of the reported marketing was targeted at providers. This included advertisements in pharmaceutical trade magazines and group purchasing organization customer newsletters, as well as gifts and seminars for providers.

Drug Manufacturers – 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 for a course of treatment shorter than one month that experience a net price increase of 10 percent or more from the previous year.²⁷

The first annual price increase reports were due July 1, 2019, for drugs that experienced a net increase of 10 percent or more from 2017 to 2018. The program received 534 reports.

Price Increases Reported

The majority of the reports we received came from Pfizer subsidiaries. The table below shows the reported ranges of price increases and the

numbers of reports for several manufacturer parent companies.

Generally, there is quite a bit of variation in price increases even within the same company. There are a few exceptions, though. All reported price increases from Celgene and Lantheus fell in the 10 percent to 12 percent range.

We received 40 reports for net increases of 20 percent or more. Some of the highest increases reported to the program were:

Indocin (NDC: 42211010243)

- Reported increase: 218.85 percent
- Manufacturer: Zyla Life Sciences
- Commonly prescribed for relief of mild to moderate acute pain or symptoms of arthritis or gout.

Clindamycin Phosphate (NDC: 47781061969)

- Reported increase: 57 percent
- Manufacturer: Alvogen
- Commonly prescribed for the treatment of acne.

| Manufacturer | Price increase range | Number of reports received |
|---------------------|-----------------------------|-----------------------------------|
| Pfizer | 11% - 15% | 332 |
| Merck and Co. | 12% - 15% | 26 |
| Celgene | 10% - 12% | 22 |
| Endo | 10% - 20% | 17 |
| Eisai | 11% - 17% | 16 |
| Fresenius | 10% - 22% | 13 |
| Lantheus | 10% | 12 |
| Sawai | 12% - 21% | 10 |

²⁷ See the appendix “Calculating a Net Increase Percentage” for details on how a net price increase percent is calculated.

And eight NDCs manufactured by Hikma Pharmaceuticals:

| Drug | Increase % | Commonly prescribed for |
|--|-------------------|--------------------------------|
| Lithium NDC 000054352763 | 80.09% | Treatment of bipolar disorder |
| Propantheline Bromide NDC 000054472125 | 79.43% | Treatment of peptic ulcer |
| Meperidine Hydrochloride NDC 000641605425 | 75% | Pain relief |
| Digoxin NDC 000054005746 | 61.4% | Treatment of heart conditions |
| Prednisone NDC 000054372263 | 58.6% | Treatment of inflammation |
| Prednisone Intensol NDC 000054372144 | 58.04% | Treatment of inflammation |
| Codeine Sulfate NDC 000054024525 | 55.7% | Pain relief |
| Morphine Sulfate NDC 000054023624 | 55.7% | Pain relief |

Increase Factors

Pharmaceutical manufacturers reported to us the major reasons why the price of the drug increased. This reporting is not based on information claimed to be a trade secret



Increased Costs

- Operating expenses (logistics, labor, etc.)
- Cost of materials
- Amounts paid in rebates
- Use of co-pay assistance programs



Market and Economic Factors

- Obligations to shareholders
- Lack of competition
- Pricing among competitors and in other countries
- Increase in patient population



R&D Factors

- Investing in or recouping development costs
- New or expiring patents
- Costs associated with FDA requirements



Stories from Oregonians

I am insulin dependent. I have also been able to take some of the new class III drugs including Victoza, Trulicity and Ozempic. They work. But I've had to give Ozempic up so that I could eat and pay rent. I had to wait until I've reached the catastrophic level outside the Medicare donut hole to take up the medication again... temporarily. When the cycle starts over again, I will give up Ozempic and cut down on food so that I can take insulin, which is also Class III drugs. That will be more insulin than what I'm taking currently. I know I'm not alone.

A commonly reported factor contributing to price increases was an increase in costs. Costs included operating expenses and the cost of materials.

Increased costs also includes amounts paid in rebates and the use of co-pay assistance programs, both of which can affect the prices consumer pay.

Market and economic factors were also reported to contribute to price increases. These included obligations to shareholders, lack of competition,

pricing of the drug among competitors or in other countries, and growth of the patient population.

Factors relating to pharmaceutical research and development also contributed to price increases. Examples included investments in or recouping the development costs, new or expiring patents, and costs associated with FDA requirements.

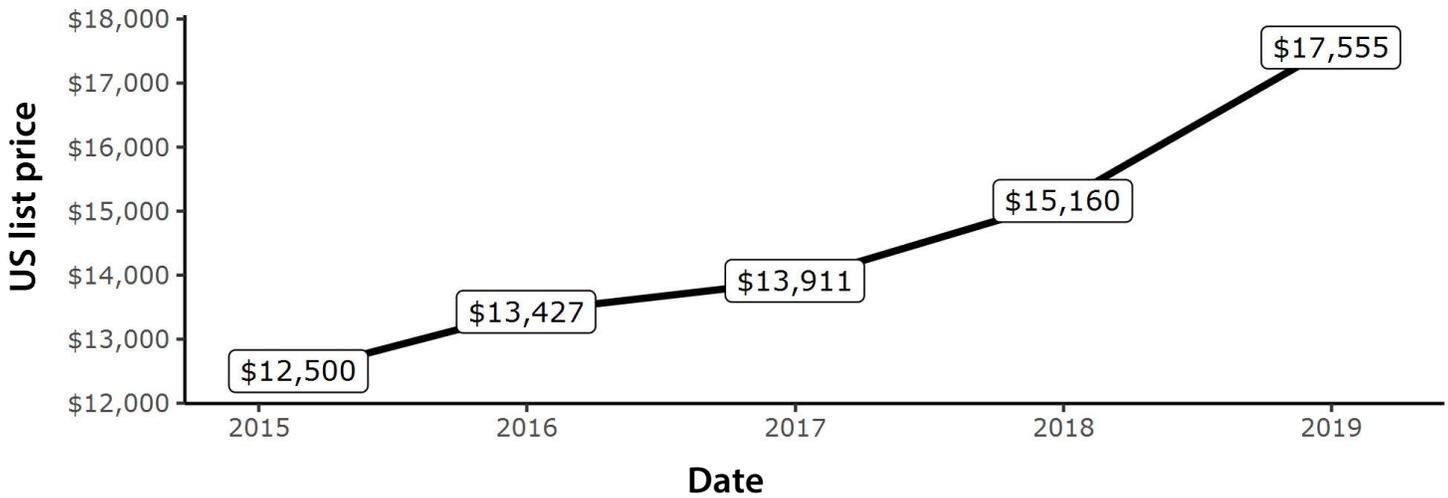
Price Increases Over Time

Lenvima is used to treat different types of thyroid, kidney, and liver cancer.

- In 2015, the drug was introduced at a price of \$12,500
- By the end of the year, the price rose to \$13,500
- At the end of 2016, its price had increased to close to \$14,000
- At the end of 2017, Lenvima was priced about \$15,000; by the end of 2018, the price increased by more than 15 percent to \$17,500

EISAI - Lenvima (NDC: 62856071030)

Source: Oregon Drug Price Transparency Program, 2019



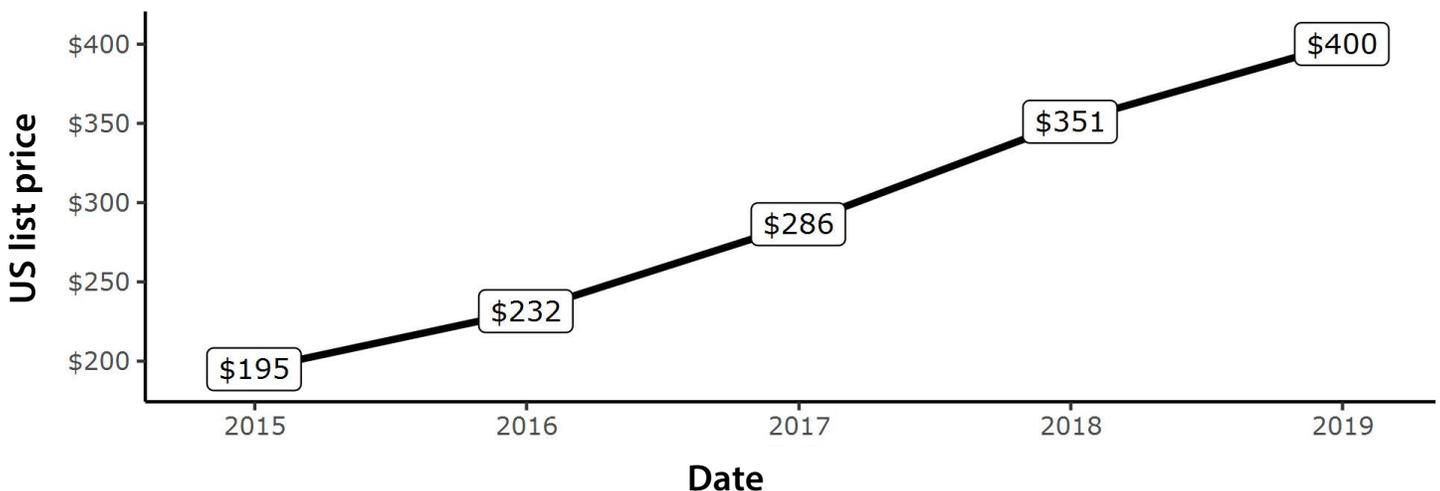
PFIZER - Xanax (NDC: 00009002901)

Source: Oregon Drug Price Transparency Program, 2019

The 10 highest international prices reported for the NDC for this drug range from \$2,400 to \$3,500. All reported NDCs for this drug have the same price in the U.S., but the non-U.S. prices vary by NDC; with some going as high as \$10,500 – all are still lower than the U.S. price.

Price increases like these are not unique. We received reports for many other drugs with large price increases.

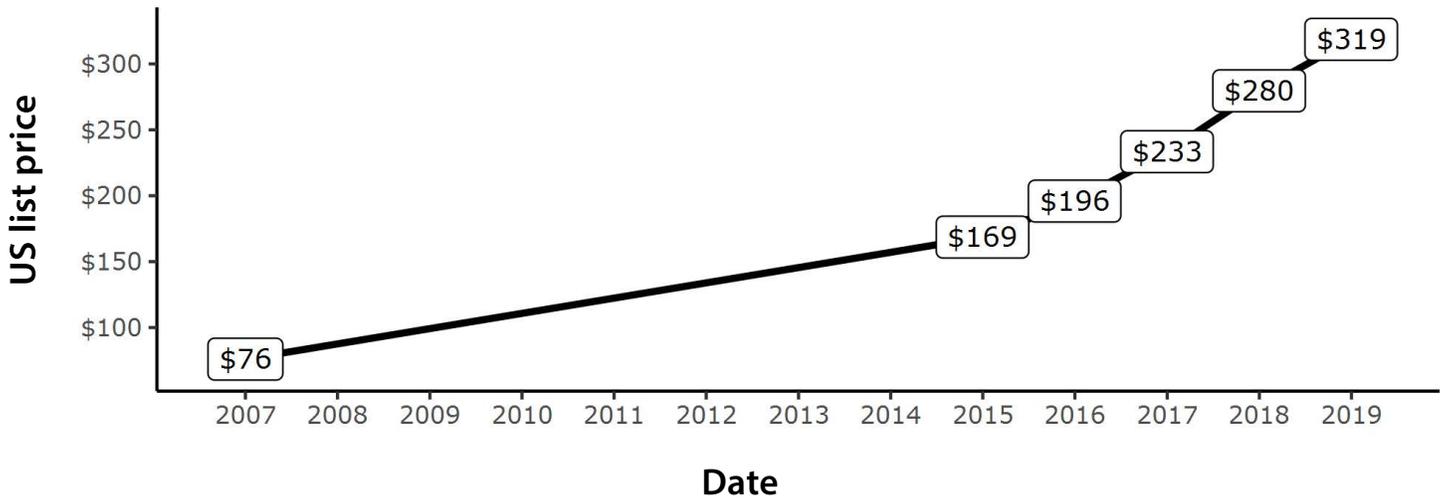
Xanax, manufactured by the Pfizer subsidiary Pharmacia & Upjohn, is used to treat anxiety and panic disorders. Over the past four years, its list price has doubled; the list price of its NDC 00009002901 rose from \$195 at the start of 2015 to \$400 at the end of 2018.



PFIZER - Zoloft (NDC: 00049490030)

Source: Oregon Drug Price Transparency Program, 2019

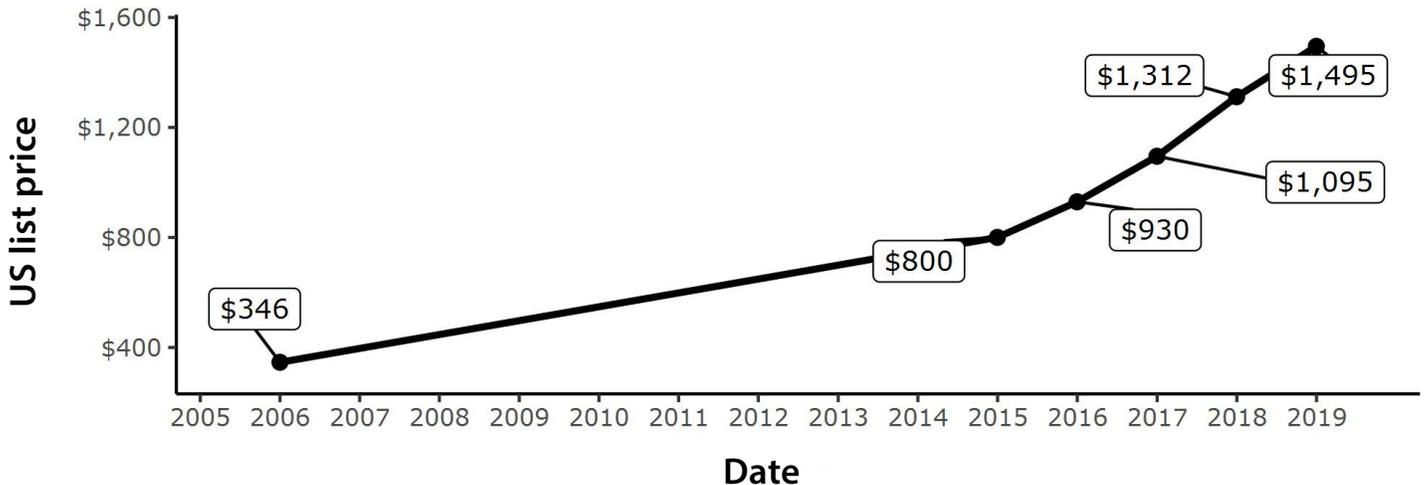
Zoloft, also manufactured by Pfizer, is used to treat depression, stress, and panic disorders, among other conditions. Its price has also nearly doubled in the past four years. The list price of its NDC 00049490030 rose from \$169 at the end of 2014 to \$319 at the end of 2018. In fact, the price doubled in half the time than it did before 2015.



PFIZER - Lipitor (NDC: 00071015640)

Source: Oregon Drug Price Transparency Program, 2019

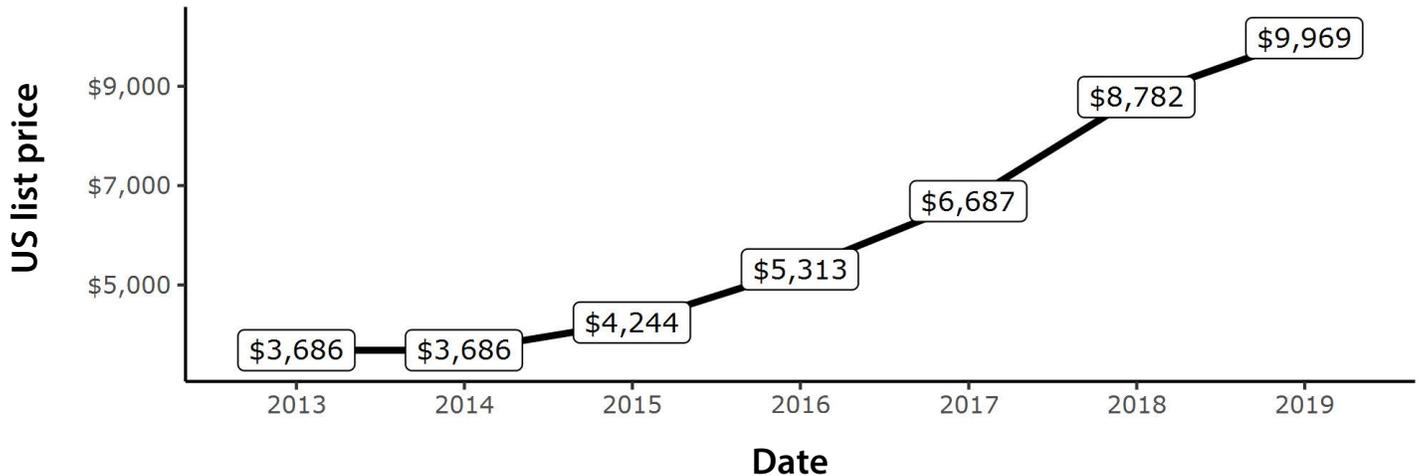
Lipitor, manufactured by the Pfizer subsidiary Parke-Davis, treats high cholesterol levels in the blood. Its price rose from \$800 at the end of 2014 to nearly \$1,500 at the end of 2018.



PFIZER - Atgam (NDC: 00009722402)

Source: Oregon Drug Price Transparency Program, 2019

Atgam – manufactured by the Pfizer subsidiary Pharmacia & Upjohn – is used to manage kidney transplant rejection and aplastic anemia. Its price rose from \$3,690 in 2013 to \$9,970 at the end of 2018.



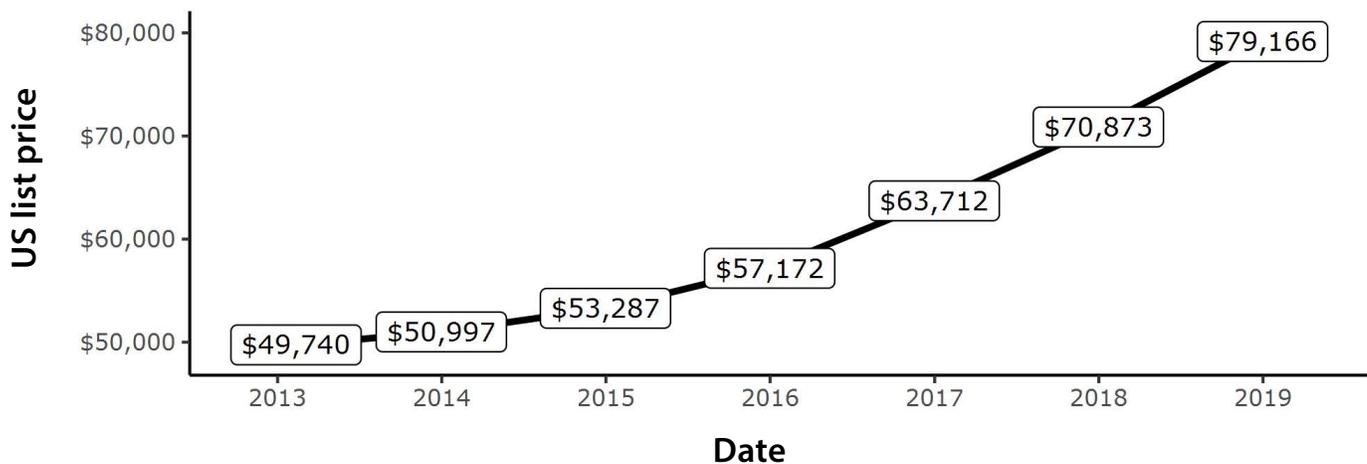
Pfizer submitted the following remarks to explain its price increases:

“When pricing its medicines, Pfizer Inc. strives to maintain a balance between value to patients and society and our ability to invest in future medicines, while ensuring the financial viability of our company and commitment to shareholders. There are a number of reasons that may contribute to a decision to increase the wholesale acquisition cost of a drug, including the following: (1) discovery of new uses and new patient populations through both trial data and real world evidence; (2) new or expiring patents; (3) improvements in the manufacturing and supply chain; (4) new product formulations; (4) market-based factors affecting product quality, supply, and the competitive landscape; (5) changes in local laws and mandates; and (6) continued investments in the development of the product. Further, Pfizer Inc. does not assign a specific percentage to any individual factor and considers a variety of factors holistically.”

CELGENE - Pomalyst (NDC: 59572050100)

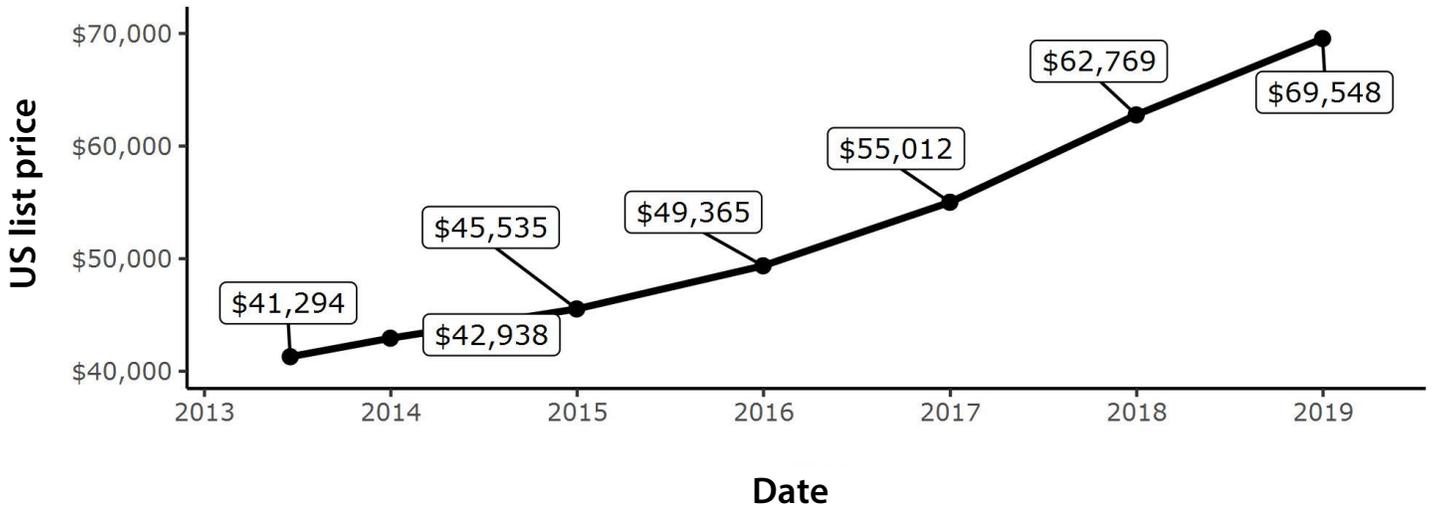
Source: Oregon Drug Price Transparency Program, 2019

The anti-cancer drugs Pomalyst and Revlimid, manufactured by Celgene, both increased in price by more than 55 percent since 2014. The list price of Pomalyst increased from \$51,000 to \$79,200, and the list price of Revlimid increased from \$42,900 to \$69,500.



CELGENE - Revlimid (NDC: 59572042000)

Source: Oregon Drug Price Transparency Program, 2019



Celgene submitted the following remarks to explain its price increases:

“The pricing of our innovative therapies – including the price increases during the designated time period for this report – is consistent with the following principles that are central to Celgene’s pricing decisions:

We believe that the value of innovative therapies should be assessed holistically to not only measure the direct benefit provided to patients, but also the benefits provided to the health system, the economy and society, and to future innovation. In addition to having the ability to reduce overall medical costs, we know that innovative therapies can have a meaningful impact for patients, caregivers, employers, and other elements of society. It is this multidimensional perspective on value that both guides the pricing of our medicines and inspires us to continue to bring transformative therapies to patients.

The success of our therapies is born of the belief that an enduring commitment to R&D is the

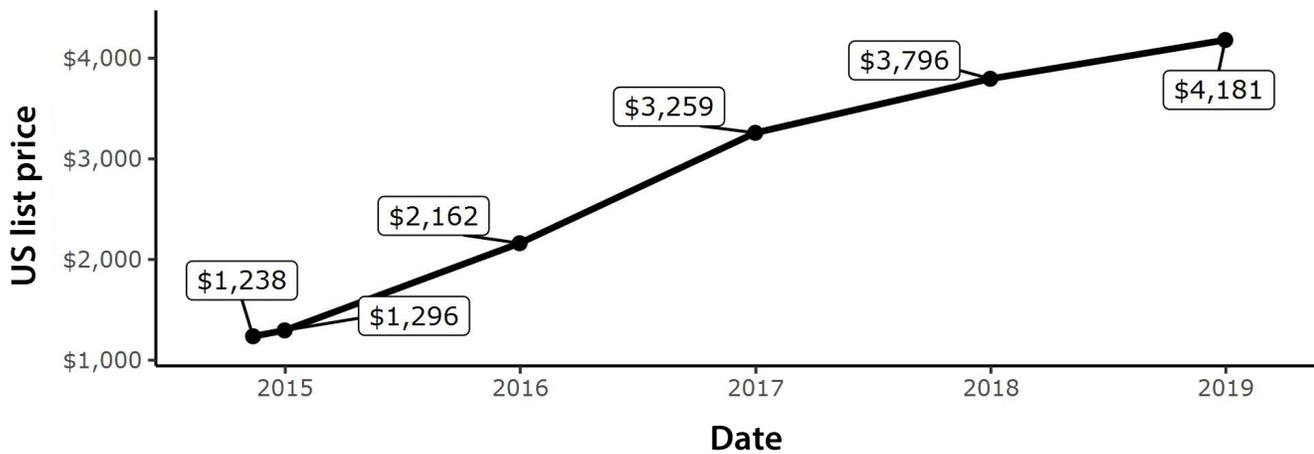
lifeblood of innovation. Indeed, we believe that R&D can be measured in a straightforward way: by dollars invested in research. Celgene is exceedingly proud that our share of revenue reinvested in research and development is among the highest of any large company in any industry anywhere in the world. Since 2015, Celgene has been among the top three globally, in percentage of revenue reinvested in research and development among companies that spend at least €1 billion on research and development in any industry anywhere. Over the last five years, we have reinvested an average of 39 percent of revenues back into R&D.

All of this investment is ultimately in the service of patients, and our goal is to ensure that patients see value from our research and our products.”

ENDO - Vasostriect (NDC: 42023016425)

Source: Oregon Drug Price Transparency Program, 2019

Vasostriect is an injection manufactured by the Endo subsidiary Par Pharmaceutical and is used to increase blood pressure in adults with vasodilatory shock. Its price has more than tripled in the past five years, rising from \$1,240 in 2014 to \$4,180 at the end of 2018.



Par Pharmaceutical submitted the following remarks to explain its price increases:

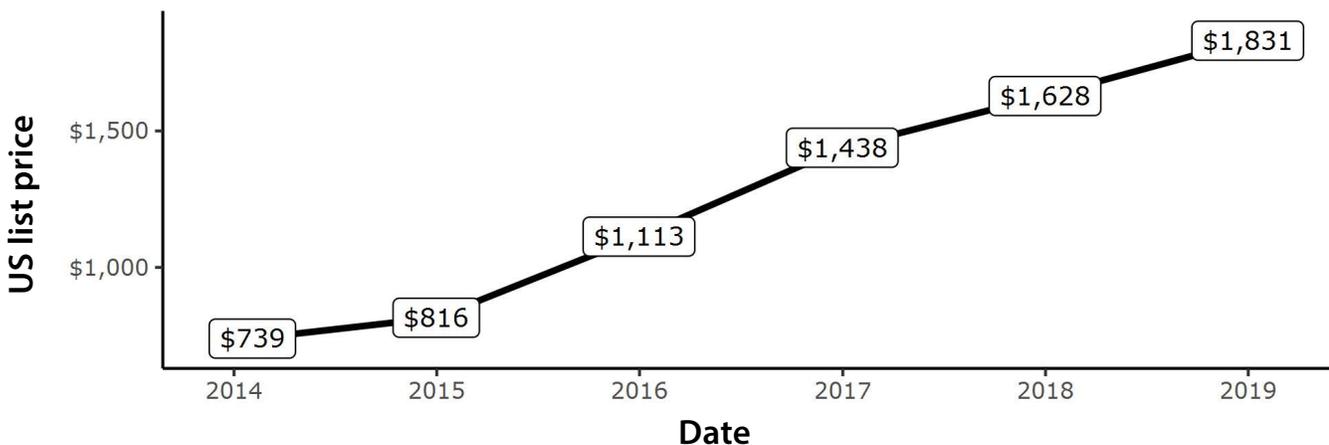
"Pricing considerations include market dynamics, an overall increase in cost of labor and goods and, most importantly, the funding of past, present and future product development initiatives across the Company's entire product portfolio – both those marketed and in development – designed to meet new and evolving patient and healthcare professional needs. The development funding includes the cost of product development successes and failures. The costs of failure include the costs of projects that the Company invested in but for various reasons was unable to successfully bring to market.

Additionally, significant investments have been made in Par's sterile injectables manufacturing facility to, amongst other things, ensure a reliable and sufficient supply of this and other critical sterile injectable products."

LUNDBECK - Onfi (NDC: 67386031401)

Source: Oregon Drug Price Transparency Program, 2019

Onfi, manufactured by Lundbeck, is used to treat seizures related to Lennox-Gastaut syndrome. Its price has more than doubled from \$740 in 2014 to \$1,830 at the end of 2018.



Lundbeck submitted the following remarks to explain its price increases:

“Our pricing adjustments for these therapies reflect the following financial and nonfinancial factors: the small number of patients with the rare diseases Lundbeck treats, further research and development work (such as efforts to develop new strengths or dosage forms sought by the patient community, or ongoing studies such as Phase IV clinical trial commitments), patient assistance programs, and efforts to maintain continuous, uninterrupted supply to patients who need our medicines. We also consider the value our therapies bring to patients and the healthcare system.”

Finally, here are three drugs that also had large price increases over short periods of time.

Cabometyx is manufactured by Exelixis and treats kidney and liver cancer. Its price rose from \$13,750 in 2016 to \$17,490 at the end of 2018. Exelixis submitted the following remarks to explain its price increases:

“Exelixis’ Mission: Exelixis strives to accelerate the discovery, development and commercialization of new medicines for difficult-to-treat cancers. That mission, however, entails tremendous risk of failure and research and development costs that total in the billions of dollars. At the present time, CABOMETYX and COMETRIQ are the only products that Exelixis sells and comprise the vast majority of Exelixis’ revenue. Exelixis is committed to spending the largest portion of this revenue on drug discovery research and clinical development, and to pricing CABOMETYX consistent with its value when compared to competitive products approved for similar conditions.

Drug Discovery Factors: Having recently constructed new laboratory facilities, Exelixis re-launched its drug discovery activities in 2018 and is working to discover the next generation of cancer therapies. Exelixis considered the investments necessary to undertake and support these drug discovery efforts when it contemplated changes to CABOMETYX’s wholesale acquisition cost.

CABOMETYX Development Factors: Since the initial commercial launch of CABOMETYX, Exelixis has received extensive additional data demonstrating that cabozantinib shows activity in an extremely broad and diverse collection of additional cancers. Alone and in combination with other therapies, it is currently

being studied in over 100 clinical trials for over 20 different forms of cancer. Exelixis considered the cost of this clinical development program, and the need to expand it to reach CABOMETYX’s full potential for treating the largest number of cancer patients, when it contemplated changes to the wholesale acquisition cost of CABOMETYX.

CABOMETYX Value Factors: CABOMETYX has been approved by the FDA to treat patients with liver and kidney cancer and has shown impressive efficacy relative to its competitors in treating patients with these life threatening diseases. It is the only drug of its kind to improve overall survival in a statistically significant manner in both kidney and liver cancer. When Exelixis contemplated a change to the wholesale acquisition cost for CABOMETYX, Exelixis considered the clinical value proposition of CABOMETYX relative to its competitor prescription drugs, as well as the competitive market generally and the existing price points of competitors.

CABOMETYX Cost Factors: At Exelixis, we are committed to ensuring that all patients in need can access our medicines. To ensure that the supply of CABOMETYX for our customers, and ultimately, patients is safe and uninterrupted, Exelixis has expanded its supply chain network, establishing redundancies to prevent supply disruption. In addition, Exelixis has and continues to incur increasing costs in manufacturing due to volatility in the cost of raw materials and other inputs. When Exelixis contemplated changes to the wholesale acquisition cost of CABOMETYX, Exelixis considered these investments in expanding and improving our manufacturing capabilities and supply chain, as well as rising manufacturing costs.”

Varizig is a post-exposure prophylaxis for varicella (chickenpox) for people at high risk and is manufactured by Saol Therapeutics. Over the course of 2015, its price rose more than 70 percent from \$700 to \$1,210. At the end of 2018, it was \$1,510. Saol Therapeutics submitted the following remarks to explain its price increases:

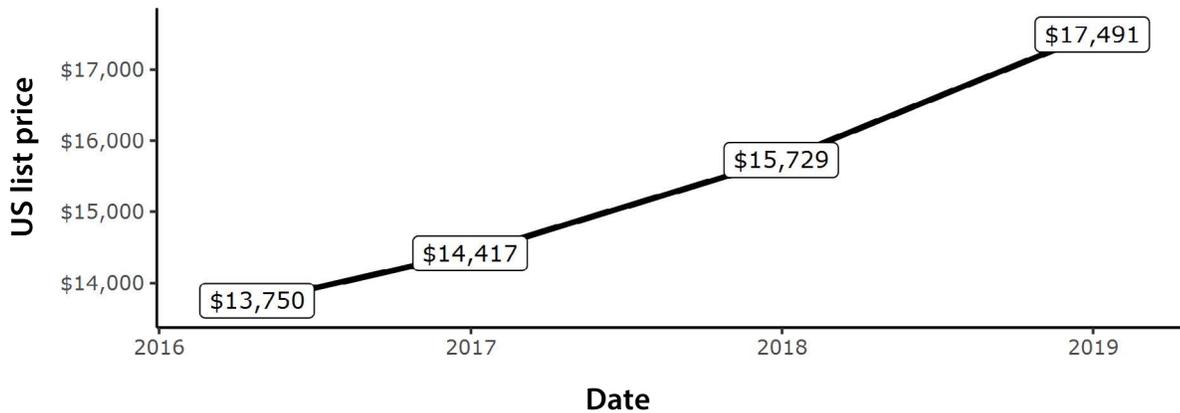
“Products were acquired in September 2017. Saol needed to expand its infrastructure to support the product acquisition and this further required Saol to scale the manufacturing process and supply chain capabilities to meet additional product overhead: shipping, stocking and distribution. Additionally, due

to increased contracted activities from our third-party logistics partner, financial costs increased for Saol. Market conditions did not influence our price increase decision.”

Topiramate is a generic drug that treats certain types of seizures. The Sawai Pharmaceutical Co. subsidiary Upsher-Smith Laboratories is one of the manufacturers that produces this drug. One of its NDCs rose in price by more than 60 percent in 2015, from \$98 to \$159. Its price continued to rise to \$254 at the end of 2018.

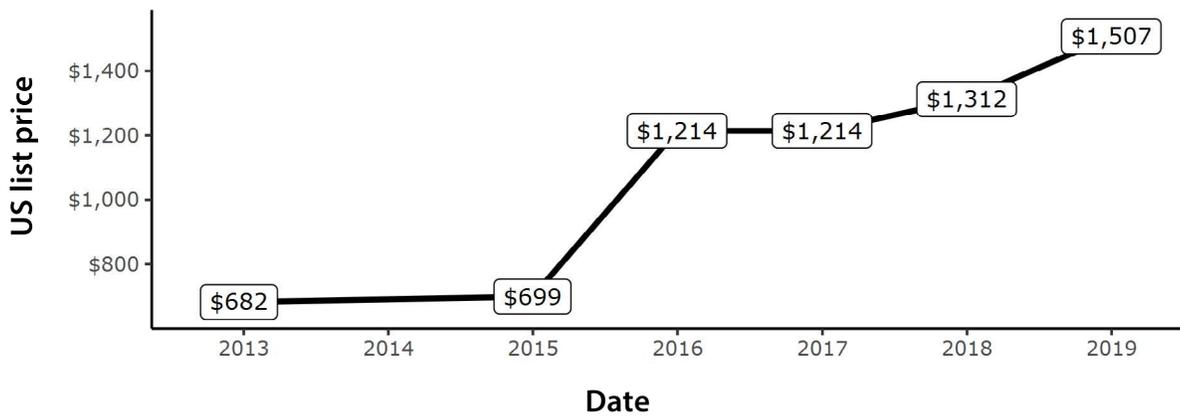
EXELIXIS- Cabometyx (NDC: 42388002326)

Source: Oregon Drug Price Transparency Program, 2019



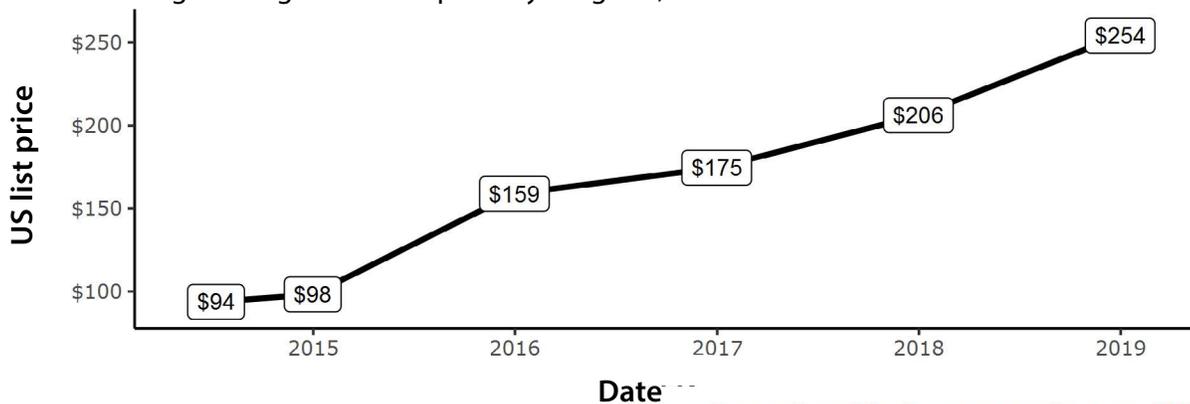
SAOL - VARIZIG (NDC: 70504012602)

Source: Oregon Drug Price Transparency Program, 2019



SAWAI- Topiramate (NDC: 00832107230)

Source: Oregon Drug Price Transparency Program, 2019



Note: Manufacturers did not directly include these past prices in their reports. See the appendix on “Calculating Past Prices” to see how they were calculated using the reported past percent increases.

Prices in other countries

The data reported to the program is helping us understand how much more the U.S. spends on prescription drugs than most other countries.

In each report, manufacturers are required to submit the 10 highest prices for their drug in other countries. This allows us to see how the U.S. price compares.

For each report that a manufacturer did not claim that foreign prices were a trade secret, we compared the U.S. price to the highest reported non-U.S. price, and found that the U.S. price is generally anywhere from half the highest non-U.S. price to 25 times more expensive than the highest non-U.S. price. On average, the U.S. price was five times higher than the highest non-U.S. price of the drug. This means that the average U.S. markup is about 400 percent over the next closest price in another country.

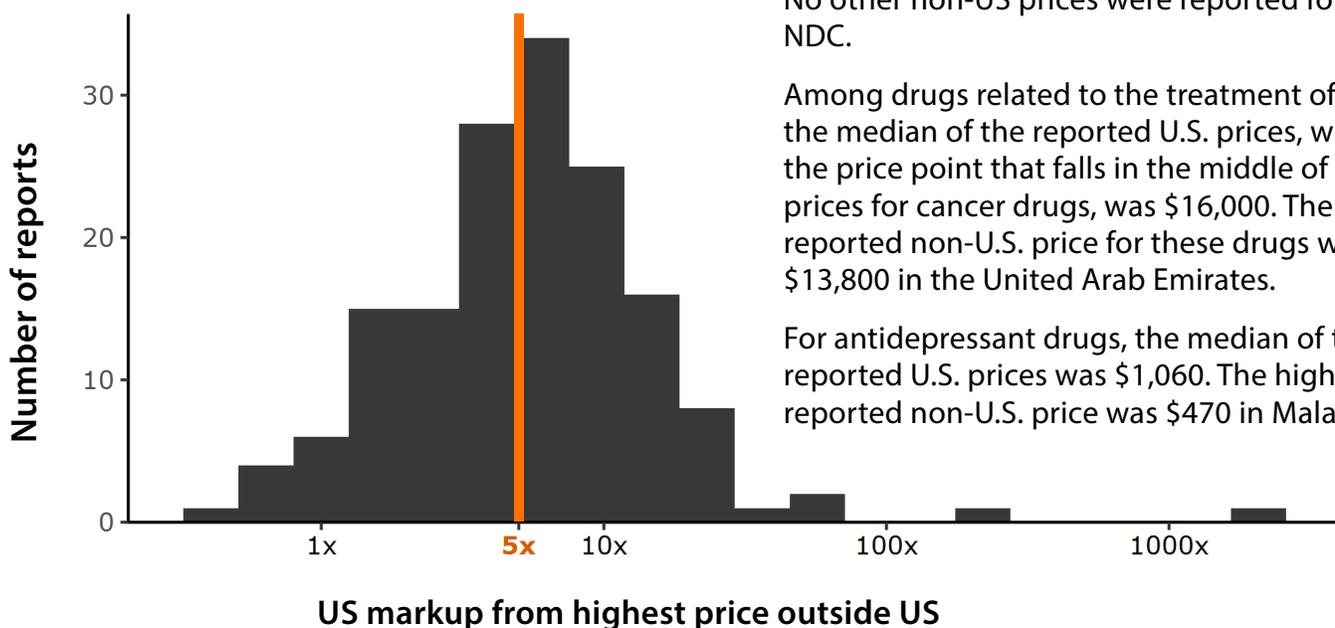
The graph below shows the distributions of U.S. markups for the reports submitted to the program. The height of each bar represents the number of reports with a markup in that range. The median five times markup is highlighted in orange.

Those two blips past a 100 times markup represent NDCs for the drugs Onfi and Medrol.

Drug: Onfi (NDC 67386-314-01)

Manufacturer: Lundbeck

Canada price: \$9.66



Stories from Oregonians

My son was diagnosed 4 years ago with HepC and has been unable to get the medicine he needs because it costs \$90,000 and his Oregon Health Care doctors won't prescribe. They say he does not have enough of the virus in his blood and yet the disease is damaging his liver and kidneys. He feels they are just waiting for him to die. We finally gave up and sent him to Chennai, India where the same drug cost him less than \$3000. This situation is just plain wrong! Makes me furious!!!!

Those two blips past a 100 times markup represent NDCs for the drugs Onfi and Medrol.

Drug: Onfi (NDC 67386-314-01)

Manufacturer: Lundbeck

Canada price: \$9.66

U.S. price: \$1831.52

The U.S. price is 190 times higher than the price in Canada.

No other non-US prices were reported for this NDC.

Drug: Medrol (NDC 0009-0020-01)

Manufacturer: Pfizer / Pharmacia & Upjohn

Japan price: 8 cents

U.S. price: \$161.70

The U.S. price is more than 2000 times higher than the price in Japan.

No other non-US prices were reported for this NDC.

Among drugs related to the treatment of cancer, the median of the reported U.S. prices, which is the price point that falls in the middle of the U.S. prices for cancer drugs, was \$16,000. The highest reported non-U.S. price for these drugs was \$13,800 in the United Arab Emirates.

For antidepressant drugs, the median of the reported U.S. prices was \$1,060. The highest reported non-U.S. price was \$470 in Malaysia.

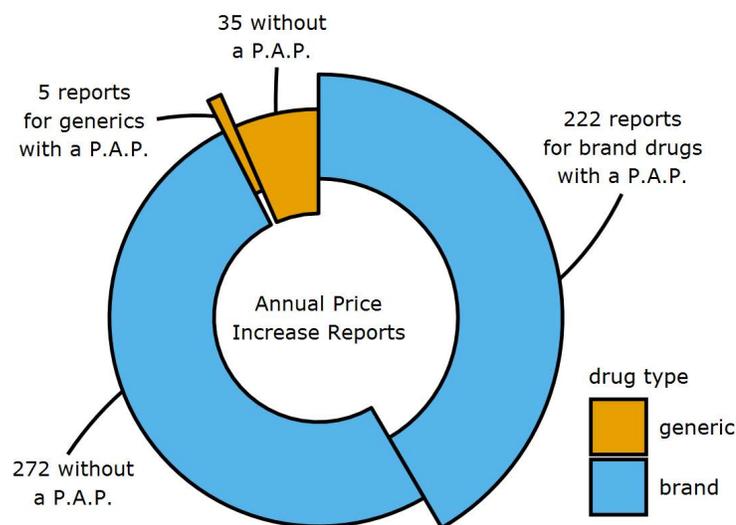
Zoloft, a common prescription to treat depression, panic attacks, and PTSD, is a good example of an anti-depressant drug. In the U.S. there are two price points: the first is \$318 and the other is \$1,051. Its price ranges anywhere from \$1 to \$470 in other countries.

For one more comparison, look at cardiovascular drugs. The median price point of the reported U.S. prices is \$580. The majority of prices reported for other countries ranged from \$5 to \$164. The highest non-U.S. price was actually higher than the U.S. price in this case: \$785 in Malaysia.

We have created an interactive graphic with other country data to help the public further understand how U.S. prices compare to other countries. The graph categorizes each drug according to its 2019 USP Drug Classification and allows for the comparison of prices for specific drugs or countries to the median reported U.S. price for drugs in each category. The interactive graphic can be accessed from the program website.

Patient Assistance Programs

Another important data element collected in the annual price increase reports is information on patient assistance programs provided by manufacturers to help consumers with the cost of prescription drugs.



In total, 43 percent of the annual price increase reports reported a patient assistance program. Most of these programs were for brand-name drugs. Of the 494 reports for brand-name drugs, 222 reported a patient assistance program. Of the 35 reports for generic drugs, five reported a patient assistance program.

Several of the patient assistance programs reported having income eligibility criteria. For example, many of the programs set their eligibility threshold for family income equal to or below 400 percent of the federal poverty level.

The assistance reported by manufacturers ranges from \$101 million to \$5 million in total assistance to Oregon consumers. The majority of Oregonians receiving assistance from manufacturers get between \$1,900 and \$152,000 in reported benefits. The total value provided to Oregonians in programs reported to DCBS is more than \$20 million.

Stories from Oregonians

Have experienced a minimum 300% mark-up in cost of insulin over the 20 plus years since diagnosed Type 1/Insulin DEPENDENT. Every time there is an improvement made to long or short acting insulin it goes in the most expensive tier in pharmacy insurance plans and is prohibitively expensive for anyone paying out of pocket. Also, companies are allowed to offer intrusive "coupons" to help drive the cost down to closer-to-general-consumer levels, but require that patients provide their personal health data in exchange. I am tired of being forced to give my personal health information in exchange for affordable life-saving medicine. I should not have to choose between managing my limited budget and managing my life-threatening disease to access the care that best treats my condition.

²⁸ USP Drug Classification: <https://www.usp.org/health-quality-safety/usp-drug-classification-system>.

Recommendations

Prescription drug costs continue to be an issue for Oregonians. With the information reported to the program, the department has begun to learn several things about prescription drugs such as how the U.S. list price compares to prices in other countries, drugs that are the most costly for health insurers, and what drugs are of most concern to Oregonians. The data received in the first year of the program helps guide the department to identify areas for program improvements, and better understand the topic of drug pricing.

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

Program Improvements

Oregon's program is unique and one of the first drug price transparency programs in the country. The program has built the reporting infrastructure and program processes, and received drug reports from pharmaceutical manufacturers, health insurers, and consumers in less than a year. Since the start of implementation in March 2019, several areas have been identified where changes would improve the goals and administration of the program.

General Program

Recommendation 1: Provide statutory access to the All Payer All Claims Database

DCBS worked with the Oregon Health Authority (OHA) to obtain and use data from the All Payer All Claims (APAC) database to provide context to the information received from health insurers. This information was useful to further understanding the effect drug prices have on Oregonians and health insurers.

Currently, DCBS does not have direct access to the APAC database, but does work closely with OHA

when this data is needed. This requires time and resources for both agencies. The statute establishing APAC provides direction for OHA to facilitate collaboration between DCBS to use the data. For the department to have direct access to the data, DCBS would need to be given explicit authority to do so in ORS 442.466. Several attempts to include DCBS into APAC statute have occurred in recent years as both DCBS and OHA recognize the shared interest in access to this data and improving health care data analyses.

We recommend the legislature consider adding DCBS to ORS 442.466 and provide authority to use APAC data for department analyses. This will enable more efficient administration of program analyses and streamline processes for using APAC data between OHA and DCBS.

Recommendation 2: Evaluate the program's expenditure limitation

The Prescription Drug Price Transparency Act provides the department with an expenditure limitation to administer the program. Several unanticipated factors require the need for the department to request an expenditure limitation increase for the drug price transparency program. These factors include the following:

- Higher than expected information technology costs related to the enhanced security measures the program is taking for information claimed to be trade secret
- Higher than expected legal and litigation costs as the program follows Oregon Department of Justice advice relating to establishing appropriate legal safeguards and due process for the program
- Unanticipated costs related to procuring access to a database with market wide information about drug prices to enable evaluation of manufacturer compliance with reporting requirements

We recommend the legislature work with the department to evaluate the program's expenditure limitation and determine how to properly adjust this based on the unanticipated factors contributing to higher expenses.

Recommendation 3: Ongoing program evaluation

We will continue to evaluate the program. 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.

Manufacturer Reporting

Recommendation 4: Registration requirement for pharmaceutical manufacturers

There is no current requirement for a pharmaceutical manufacturer to create an account with the program unless they are filing a report. Program regulations state that every pharmaceutical manufacturer is required to pay an annual assessment to the program if the entity meets the following requirements: (1) It is required to register with the Oregon Board of Pharmacy as a drug manufacturer, (2) It engages in the manufacture of prescription drugs, and (3) It sets or changes the wholesale acquisition cost of the drugs they manufacture. Some entities that meet the requirements did not create an account and, therefore, were not included in the initial billing for the \$400 annual assessment.

The program has engaged in compliance work for the first year to receive payment from all entities meeting the definition of a reporting manufacturer, as outlined above.

To improve compliance and the billing of future assessments, we recommend considering legislation to require all drug manufacturers that meet the definition of a reporting manufacturer to register with the Prescription Drug Price Transparency Program.

The registration requirement could help improve

compliance with Oregon's current drug price transparency law and help communicate relevant program information to the manufacturers.

Recommendation 5: 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." The program rules further clarify that the definition for "net yearly increase" is "means 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 new reporting law, HB 2658, 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.

Recommendation 6: Patient assistance reporting for new drug reports

The program currently receives information on patient assistance programs through the annual price increase reports. Several new high-cost drugs that come to market also have patient assistance programs to help consumers who are prescribed the drug with the cost. Unlike the annual price increase reports, the new drug reports do not

report any patient assistance program information to the program.

We recommend the legislature consider including patient assistance reporting for new high-cost drugs reported to the program to improve understanding of these programs, particularly when a new drug comes to market.

Health Insurer Reporting

Recommendation 7: Expand reporting to additional insurers

Under the Prescription Drug Price Transparency Act, health insurance carriers are required to submit specified information about prescription drug spending and utilization, including the top 25 most costly drugs and the top 25 most prescribed drugs, as part of the annual rate filing process. Since carriers 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 carrier reporting requirement from the rate review process and require it as a separate annual report from all health benefit plan issuers in Oregon.

Recommendation 8: Quantitative information reporting

For the first year of health insurer reporting, the program received only a ranked list of drugs for the required reporting categories. The program worked with OHA's All Payer All Claims (APAC) Database to provide quantitative information OHA received on the drugs reported in our lists to provide insight on the numbers of prescriptions made, the numbers of people who made insurance claims, and the dollar amounts of claims paid for the drugs on the list. This information was helpful for the first year, but has several limitations, including that the information submitted to APAC includes several other insurance companies than those reporting to the Prescription Drug Price Transparency Program.

We identified that receiving quantitative information about these drugs, such as the number of claims

received and amount of money paid, would be useful for understanding the scope and magnitude of the use and financial burden of the drugs ranked on these lists.

We recommend the program receive quantitative information from health insurers reporting top 25 drug lists to the program.

Consumer Notification Reporting

Recommendation 9: Protection of consumer-reported information

Consumer reports on the price increases of the prescription drugs they take is an essential component to the program. When the program receives reports from consumers, 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, the information collectively could potentially identify a consumer. We recommend clarifying that the personally identifiable information collected will be protected from public disclosure.

Other Recommendations

Recommendation 10: 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.

Recommendation 11: Integration of current and future transparency requirements

In 2019, the legislature passed House Bill 2658, which requires the department to receive advance notices for certain drug price increases. This new statute, while similar to the Prescription Drug Price Transparency Act, is not expressly integrated into the Oregon Drug Price Transparency Program.

As the legislature considers additional prescription drug transparency requirements, we recommend to consider integrating the Prescription Drug Price Transparency Act and House Bill 2658 as well as any future transparency requirements. Integration of transparency requirements will provide a standard infrastructure to stakeholders involved and the resources needed to implement this type of reporting to the department such as funding, rulemaking, and enforcement authority.

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.

Several states are examining ways to reduce the cost of prescription drugs. In 2019, more than 880 legislative bills were introduced and at least 130 new laws have been passed broadly related to prescription drugs.³⁰ About 280 legislative bills were introduced specifically to address the affordability of prescription drug costs.³¹ The broad topics addressed by legislation include:

- Bulk purchasing – Using state or multi-state leverage to volume purchase prescription drugs. Delaware and New Mexico enacted statutes establishing Interagency Pharmaceutical Purchasing Councils to review their states' prescription drug costs and purchasing across state agencies.
- Coupons – Regulating or prohibiting the use of discounts or coupons by specified pharmaceutical supply chain entities. Two bills were enacted in Arizona and Virginia to count payments made by the enrollee or on behalf of the enrollee towards the insured's cost-sharing contribution.
- Drug affordability review board – Establishing a regulatory body to review the affordability and cost of specific prescription drugs. Maine, Maryland, and Massachusetts passed laws related to drug affordability review boards in 2019.
- 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.
- Other topics – Other policies include, allowing

³⁰ National Conference of State Legislators. *Statewide Prescription Drug Database, 2015 to present*. <http://www.ncsl.org/research/health/prescription-drug-statenet-database.aspx#Topics_guide>, visited Dec. 2019.

³¹ National Academy for State Health Policy. *State Legislative Action to Lower Pharmaceutical Costs*. <<https://nashp.org/rx-legislative-tracker-2019/>>, visited Dec. 2019.



pharmacist substitutions for lower-cost drugs, capping the cost sharing for insulin medications, establishing a single preferred drug list, capping co-payments for specified drug thresholds, and establishing a prescription drug assistance program.

- Pharmacy benefit managers – Proposing or enacting several topics, including prohibiting pharmacy gag clauses, reporting or disclosing rebate information, prohibiting spread pricing and clawbacks, disclosing conflicts of interest, updating the maximum allowable cost lists in a timely manner, and obtaining a license with specified state agencies. Several states passed laws, including Oregon,³² regarding pharmacy benefit managers that addressed the topics outlined above.
- Studies – Conducting a study to review

prescription drug costs or other specified topics related to prescription drug prices such as pharmacy reimbursement, regulation of pharmacy benefit managers, prescription drug price transparency, effect of financial incentives from drug manufacturers on commercially insured members, and studying the effect of rebates.

- Transparency – Reporting on drug price information from specified pharmaceutical supply chain entities such as pharmaceutical manufacturers, wholesale distributors, and pharmacy benefit managers. Some states specified transparency requirements for specific types of drugs. For example, asthma medications in Nevada and Texas and Washington required reporting once a specified threshold was met.

³² 2019 House Bill 2185: <https://olis.oregonlegislature.gov/liz/2019R1/Downloads/MeasureDocument/HB2185/Enrolled>

Conclusion



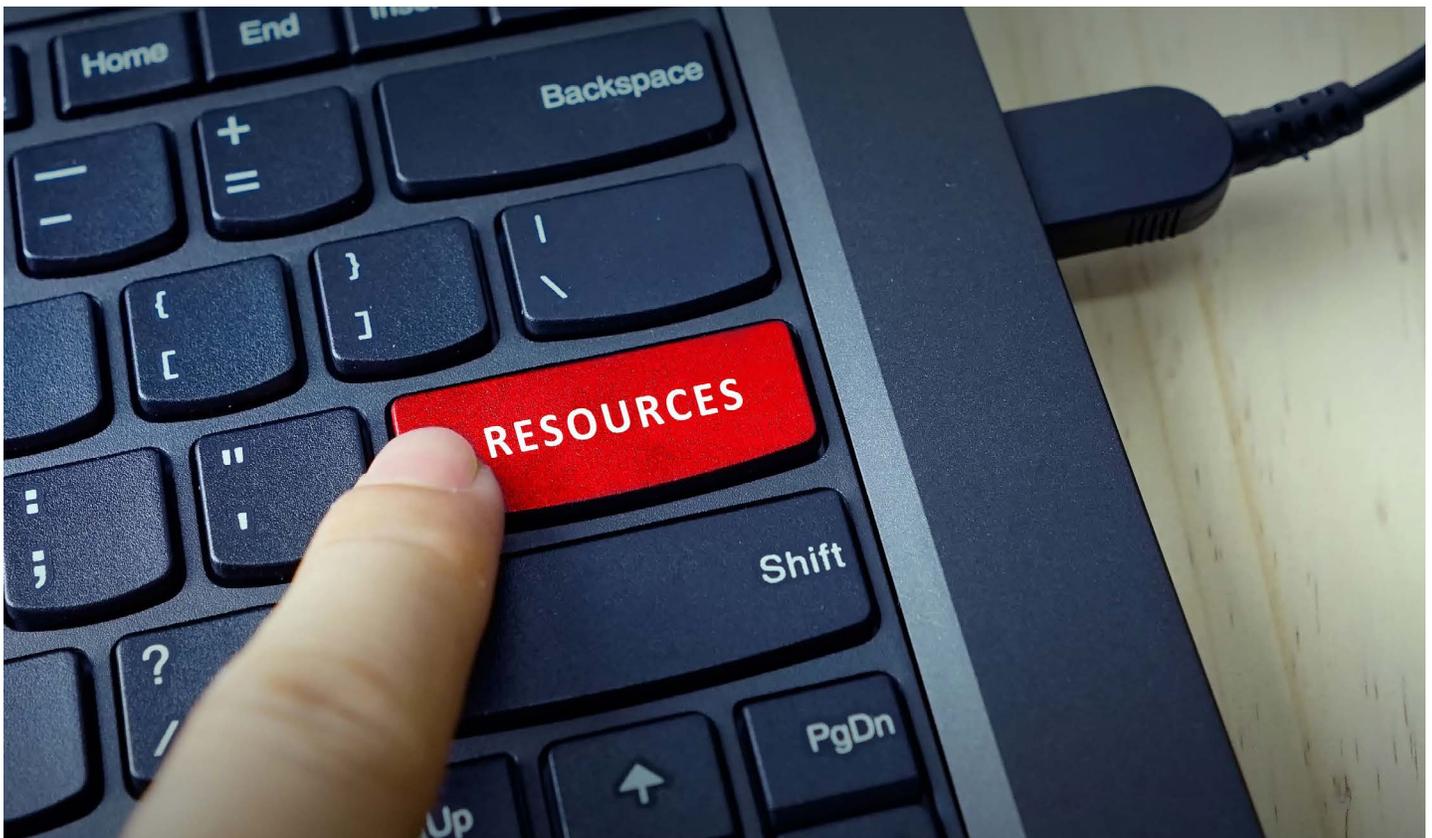
Oregonians pay significant costs towards the prescription drugs they need. Oregon's Prescription Drug Price Transparency Program is one of the first in the nation to be fully implemented and has gathered insightful information about drug prices. Through the information received from prescription drug manufacturers, health insurers, and consumers, the program is starting to understand the factors influencing drug prices and how this affects Oregonians. Highlights from the information received are:

- U.S. prices are typically five times more than the highest price globally for prescription drugs reported to the program. For example, the median price for cardiovascular drugs reported to the program was \$580, while the majority of prices in other countries ranged from \$5 to \$164.
- Most of the annual price increases reported to the program range from the reporting minimum of 10 percent to approximately 20 percent, and manufacturers attribute these increases to rebates, the use of co-pay assistance programs, obligations to shareholders, research and development costs, and other related factors.

- New brand-name drugs are significantly more expensive than new high-cost generics reported to the program. Manufacturers reported the high price is influenced by the number of competitors in the market, how well the drug works, how profitable it can be, and other factors.
- Most costly drugs reported to the program by health insurers tend to be brand-name and biologic drugs, such as Humira, which cost insurance companies approximately \$220 million to fill claims for about 6,000 Oregonians in 2018. Several of the most costly drugs also appeared on the list of drugs causing the greatest increase in insurance spending.
- Drugs costs have a profound effect on Oregonians. From one story reported to the program: "My father, 79, confessed that he is only doing one breathing treatment per day for his COPD rather than the two-a-day he is prescribed. He is trying to save money – a fixed income received from Social Security benefits. I also know that the reason he is trying to save money on HIS meds is because my mother has diabetes. He will sacrifice his medication to make sure she gets hers."

The program will continue to build upon the information received in the first year to improve the program for the future and to continue to understand the effect of drug prices and costs. As more information is received, the program will engage in analyses to inform policies to reduce the cost of prescription drugs to Oregonians.

Resources



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

Health Insurances Issues and Access

If you have issues with your insurance company about prescription drug coverage, contact the DCBS 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

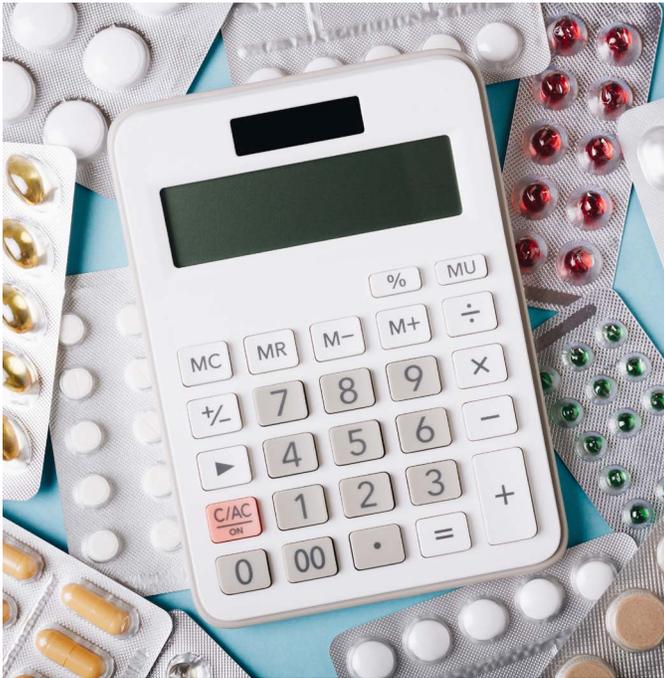
insurance plans that may be available to you.

General Information About Prescription Drugs

For general information on prescription drugs, visit the following pages:

- U.S. Food and Drug Administration – [Resources for Consumers](#)
- U.S. National Library of Medicine – [Drug Information for the Public](#)

Appendices



I. Calculating a Net Increase Percentage

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 drug was \$500 for the first 100 days of 2017, then rose in price to \$600 on the 101st day and remained at that price for the rest of the year. The drug's average list price in 2017 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 2017 is

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

Suppose the drug had another price increase on Jan. 25, 2018, from \$600 to \$640, and then remained at that list price for the rest of the year. The drug's average list price in 2018 is

$$\frac{25 \times \$600 + 340 \times \$640}{365} = \$637.26.$$

To find the 2018 net increase percentage, we compare the average price in 2017 to the average price in 2018.

The drug's average list price in 2018, \$637.26, is 11.3 percent higher than its average list price in 2017, \$572.60:

$$\frac{\$637.26 - \$572.60}{\$572.60} \times 100 = 11.3\%.$$

So, the 2018 net increase percentage for this drug is 11.3 percent.

In general, the formula for computing a 2018 net increase percentage is

$$\frac{\$(\text{average 2018 list price}) - \$(\text{average 2017 list price})}{\$(\text{average 2017 list price})} \times 100$$

II. Calculating Past Prices

The Price Increases Over Time section includes graphs showing how the list prices of various drugs have increased over time. However, manufacturers do not include past list prices in their reports to the program.

To calculate the past prices, we combined two other





pieces of information reported by manufacturers, namely the list price on Dec. 31, 2018, and price increase percentages for the past five years.

Let's use a specific example from the report: Lenvima (NDC 62856071030). The drug's manufacturer, Eisai, reported that the drug's list price was \$17,555 on Dec. 31, 2018. The company also reported these past list price increases:

2018: 15.8%

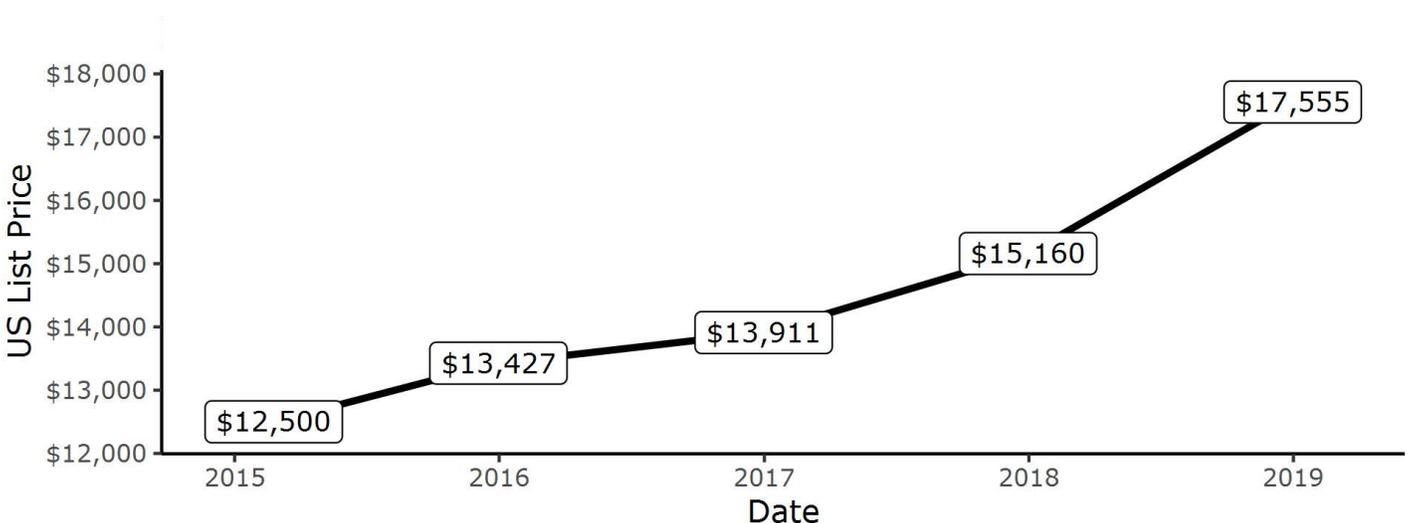
2017: 8.98%

2016: 3.6%

We use these percentages to calculate the past prices from the Dec. 31, 2018, price of \$17,555.

EISAI- Lenvima (NDC: 62856071030)

Source: Oregon Drug Price Transparency Program, 2019



The list price for Dec. 31, 2017 is calculated using the 2018 increase percent:

$$\frac{\$17,555}{1.158} = \$15,159.80.$$

Then, the list price for Dec. 31, 2016, is calculated using the 2017 increase percent and the Dec. 31, 2017 price:

$$\frac{\$15,159.80}{1.0898} = \$13,910.60.$$

This pattern continues: The list price for Dec. 31, 2015, is calculated using the 2016 increase and the Dec. 31, 2016, list price:

$$\frac{\$13,910.60}{1.036} = \$13,427.20.$$

The manufacturer reported that this national drug code went on the market on Feb. 24, 2015, with a list price of \$12,500. This is the first price shown on the graph.

Here is the full graph showing these computed list prices.