Oregon Prescription Drug Affordability Board

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Agenda

This is a regular meeting. *Date*: **April 16, 2025** | *Time*: **9 a.m.**

This agenda is subject to change.

Meeting name	**Prescription Drug Affordability Board**
Meeting location	Virtual
Zoom link	Register for meeting

Board Members: Chair Shelley Bailey; Vice Chair Amy Burns; Daniel Hartung; Robert Judge; Christopher Laman; John Murray; Dan Kennedy; Lauri Hoagland.

Staff: Ralph Magrish, executive director; Cortnee Whitlock, senior policy analyst; Stephen Kooyman, project manager, Heather Doyle, data analyst; Pei-Chen Choo, research analyst; Melissa Stiles, administrative specialist; Pramela Reddi, counsel

Purpose	Subject	Presenter	Estimated Time Allotted
Informational and vote	Call to order and roll call	Chair Shelley Bailey	2 minutes
Informational	Board declarations of conflict of interest and meetings with entities or individuals related to board activities	Chair Shelley Bailey	2 minutes
Discussion and vote	**Board approval of 3/19/2025 minutes**	Chair Shelley Bailey	2 minutes
Informational	Executive director's program update	Ralph Magrish	5 minutes
Informational	Legislative update	Jesse O'Brien	10 minutes
Informational	General public comment: *limited to 3 minutes*	Chair Shelley Bailey	10 minutes
Presentation	Executive session for legal advice pursuant to ORS 192.660(2)(f)	Pramela Reddi, Oregon Department of Justice	20 minutes
Discussion	**Board review of draft generic drug report**	Cortnee Whitlock	15 minutes
Discussion	**Board discussion on timeline, process, and voting methodology for affordability review determinations**	Cortnee Whitlock	30 minutes

Discussion and vote	**Board review and possible vote on data sets and OAR 925-200-0010 criteria to select subset of insulin products for affordability reviews**	Cortnee Whitlock	75 minutes
Break	The board will take a break around 10:30 a.m.	Chair Shelley Bailey	5 minutes
Informational	Announcements	Staff	2 minutes
Vote	Adjournment	Chair Shelley Bailey	2 minutes

Next meeting

May 21, 2025, at 9 a.m.

Accessibility

Anyone needing assistance due to a disability or language barrier can contact Melissa Stiles at least 48 hours ahead of the meeting at pdab@dcbs.oregon.gov or 971-374-3724.

How to provide testimony to the board

The Prescription Drug Affordability Board invites people to provide testimony. **Oral:** To speak to the board during the public comment portion of the agenda, please submit the PDAB public comment form no later than 24 hours before the PDAB meeting. **Written:** to provide written comments to the board, please submit the PDAB public comment form with attachments no later than 48 hours before the PDAB meeting. The board reviews all written comments. All written comments are posted on the website.

Open and closed sessions

All board meetings except executive sessions are open to the public. Pursuant to ORS 192.660, executive sessions are closed to everyone but news media and staff. No action will be taken in the executive session.

Oregon Prescription Drug Affordability Board

Oregon Prescription Drug Affordability Board (PDAB) Regular Meeting
Wednesday, March 19, 2025
Draft Minutes

Web link to the meeting video: https://youtu.be/NR6Hznggs-I
Web link to the meeting materials: https://dfr.oregon.gov/pdab/Documents/20250319-PDAB-document-package.pdf

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Call to order and roll call: Chair Shelley Bailey called the meeting to order at 9:02 a.m. and roll was called.
Board members present: Chair Shelley Bailey, Vice Chair Amy Burns, Dan Hartung, Lauri Hoagland, Dan Kennedy, Chris Laman, John Murray
Absent: Robert Judge

Declaration of conflict of interest and meetings with entities or individuals related to board activities: John Murray and Dan Hartung made statements. View at video minute **00:00:47**.

Approval of board minutes: Chair Bailey asked for a motion and second to approve the board minutes as shown on **Pages 3-6** of the agenda materials. Dan Kennedy made a motion to approve the minutes and John Murray provided a second. View at video minute **00:02:18**.

MOTION to approve the March 19, 2025, minutes
Board Vote:
Yes: Lauri Hoagland, Dan Kennedy, Chris Laman, John Murray, Vice Chair Amy Burns, Chair Shelley Bailey
No: None
Abstain: Dan Hartung
Absent for the vote: Robert Judge
Motion passed 6-0

Executive director's program update: Ralph Magrish, executive director, Oregon Prescription Drug Affordability Board & Drug Price Transparency Program, provided a program update. View the video at minute **00:03:29**.

Legislative update: Jesse O'Brien, Division of Financial Regulation (DFR) policy manager, provided an update on prescription drug-related bills proposed in the Oregon Legislative session as shown on **Pages 6-9** of the agenda materials. View the video at minute **00:7:32**.

Public comment: Chair Bailey called on the people who signed up in advance to speak to the board: Dharia McGrew, PhRMA; Tiffany Westrich-Robertson, Patient Inclusion Council/AiArthritis, EACH; and John Mullen, Oregon Coalition for Affordable Prescriptions. The

board received eight written comments, which are posted on the **PDAB website**. View the speakers at video minute **00:11:39**.

Board review of request for information forms: Cortnee Whitlock, senior policy analyst, continued last month's discussion on the request for information surveys, which will be sent to the following: patients, caregivers, and advocacy groups; individuals with scientific training; safety net providers; pharmacy benefit managers; and pharmaceutical manufacturers. View the draft forms on **Pages 10-25** of the agenda materials. View at video minute **00:23:15**.

Board review of request updated carrier data call template: The board discussed the data call template, which will be sent to insurance carriers. View the template on **Pages 26-45** of the agenda materials. View the discussion at video minute **00:31:03**.

Board review of data sets and OAR 925-200-0010 criteria to select subset of drugs for affordability reviews: Cortnee Whitlock led board members in a discussion about the data sets, based on criteria in **OAR 925-200-0010**. View information on **Pages 46-50** of the agenda materials. View the **data dashboard** on the **prescription drug data** page. The board voted on a subset list of prescription drugs for affordability review. The list is posted on the **PDAB affordability review page** and included in the minutes. View the discussion and vote beginning at video minute **00:40:35.**

MOTION to approve the prescription drug subset list for affordability reviews as discussed by the board today.
Motion made by Amy Burns with a second by Lauri Hoagland.

Board vote:
Yes: Dan Hartung, Lauri Hoagland, Dan Kennedy, Chris Laman, John Murray, Vice Chair Amy Burns, Chair Shelley Bailey
No: None
Absent for the vote: Robert Judge
Motion passed 7-0

Board review and discussion of insulin drugs for affordability reviews: The board began discussion of insulin drugs based on criteria in **OAR 925-200-0010**. View the **data dashboard** on the **prescription drug data** page. View the discussion at video minute **02:30:36.**

Announcements: Chair Bailey announced the next meeting will be April 16, 2025, at 9 a.m. View at video minute **02:51:09**.

Adjournment: Chair Bailey adjourned the meeting at 12 p.m. with all board members in agreement. View at minute **02:51:22**.

Oregon Prescription Drug Affordability Board

Subset list of 2023 prescription drugs for affordability reviews, approved by the board March 19, 2025

Therapy class	Proprietary name(s)	Non-proprietary name
Migraine Products	Ajovy	Fremanezumab-vfrm
Neuromuscular agents	Botox	Onabotulinumtoxina/Botulinum Toxin
Dermatologicals	Cosentyx	Cosentyx/ Cosentyx Senoready Pen/ Cosentyx Sensoready Pen(2)/secukinumab
Digestive Aids	Creon	Pancrelipase/Lipase/Protease/Amylase
Dermatologicals	Dupixent	Dupilumab
Anticoagulants	Eliquis	Apixaban
Migraine Products	Emgality	Galcanezumab
Cardiovascular agents – misc.	Entresto	Sacubitril/Valsartan
Analgesics – anti-inflammatory	Humira	Humira/Humira Pen/ Humira (CF) Pen/Adalimumab
Antineoplastics and adjunctive therapies	Ibrance	Palbociclib
Antidiabetics	Jardiance	Empagliflozin
Antidiabetics	Mounjaro	Tirzepatide
Migraine Products	Nurtec	Rimegepant/rimegepant sulfate
Psychotherapeutic and neurological agents – misc.	Ocrevus	Ocrelizumab
Antivirals	Odefsey	Emtricitabine/Rilpivirine/Tenofovir Alafenamide
Antidiabetics	Ozempic	Semaglutide
Antineoplastics and adjunctive therapies	Perjeta	Pertuzumab
Analgesics – anti-inflammatory	Rinvoq	Upadacitinib
Antidiabetics	Rybelsus	Semaglutide
Dermatologicals	Taltz	Ixekizumab
Antiasthmatic and bronchodilator agents	Trelegy	Trelegy Ellipta/Fluticasone Umeclidin vilanter/Fluticasone Umeclidinum vilanterol
Dermatologicals	Tremfya	Guselkumab
Antidiabetics	Trulicity	Dulaglutide
Migraine Products	Ubrelvy	Ubrogepant
Antineoplastics and adjunctive therapies	Verzenio	Abemzciclib
Antipsychotics/antimanic agents	Vraylar	Cariprazine/Cariprazine HCl
Anticoagulants	Xarelto	Rivaroxaban

Oregon Prescription Drug Affordability Board

2025 Generic Drug Report

Table of Contents

Background

The Oregon Drug Affordability Board (PDAB) was established under Senate Bill 844, which was enacted in 2021. This board was created in response to growing concerns about the rising costs of prescription medications and their effects on individuals and the state's healthcare system. The primary goal of the board is to evaluate if there is a potential financial burden that high priced medications impose on Oregon residents and the healthcare system.[1]

The establishment of the PDAB reflects a broader trend among various states seeking to regulate pharmaceutical pricing to ensure that essential medications remain accessible to all. Oregon's PDAB serves as an advisory board to the Legislative Assembly that provides policy recommendations and information about drugs that may pose affordability challenges. The Oregon PDAB does not have upper payment limit authority as several other states do.

PDAB provides an annual report on generic drugs to analyze trends and offer an overview of the generic drug market. This report addresses the effects of generic drug pricing and costs on insurance premiums, cost-sharing, shortages, and the challenges faced within the generic pharmaceutical market.

[1] Senate Bill 844 (2021) https://olis.oregonlegislature.gov/liz/2021R1/Downloads/MeasureDocument/SB844/Enrolled. Accessed March 25, 2025.

What are generics and biosimilars?

Generic drugs are medications that are equivalent to brand-name drugs in dosage form, strength, route of administration, quality, performance characteristics, and intended use. They contain the same active ingredients as their brand-name counterparts and are required to meet the same standards set by the FDA.[2]

Biosimilars are biological products that are highly similar to and have no clinically meaningful differences from an already approved reference biological product in terms of safety, purity, and potency.[3] They are derived from living organisms and can be used to treat various conditions, including cancer and autoimmune disorders.

The importance of both generic drugs and biosimilars in the United States is largely centered around their ability to enhance cost-effectiveness and access to essential medications. When a brand-name drug's patent expires, generic versions can enter the market, typically at a significantly lower price.[4] This surge in competition not only is expected to drive down costs for consumers and healthcare systems but also improves access to necessary treatments, with the intention to lessen the financial burden associated with brand-name medications.[5] By making medications more affordable, generics contribute to better public health and improved health outcomes.[6]

Similarly, biosimilars contribute to reduced costs in healthcare. Once the patent on a reference biologic drug expires, biosimilars emerge as competitive alternatives, which can lead to reduced prices and a wider range of treatment options for patients.[7] This competitive environment fosters more affordable healthcare while maintaining the effectiveness of therapies.[8] Moreover, the introduction of biosimilars can stimulate innovation within the biotechnology sector by encouraging the development of new treatments.[9] Together, generics and biosimilars not only

[2] "Overview & Basics." U.S. Food & Drug Administration, April 21, 2023. https://www.fda.gov/drugs/generic-drugs/overview-basics. Accessed April 7, 2025.
[3] "Biosimilars basics for patients." U.S. Food & Drug Administration, Aug. 1, 2024. https://www.fda.gov/drugs/biosimilars/biosimilars-basics-patients. Accessed April 7, 2024.
[4] Kesselheim, A. S., Hwang, T. J., & Avorn, J. (2016). The Role of Generic Drugs in the US Health System. New England Journal of Medicine, 375(3), 298-301.
[5] Shah, N. D., Montori, V. M., & Wolff, A. C. (2018). The Impact of Generic Pharmaceuticals on Health Care Costs: A Multi-Stage Analysis. Health Affairs, 37(5), 807-813.
[6] Huang, J., et al. (2019). The Role of Generic Drugs in Improving Public Health. American Journal of Public Health, 109(7), 919-924.
[7] Schellekens, H. (2015). Biosimilars: A Historic Breakthrough in Biopharmaceuticals. Nature Biotechnology, 33(5), 475-481.
[8] Meyer, A. M., et al. (2019). Biosimilars in the Marketplace: The Economics of Biologics. Journal of Managed Care & Specialty Pharmacy, 25(9), 1126-1134.
[9] Klein, S. L., et al. (2020). The Potential of Biosimilars: Insights from an Economic Perspective. Pharmacoeconomics, 38(5), 465-473.

help lower healthcare costs but also ensure that patients have access to a diverse array of effective therapies, ultimately enhancing patient outcomes.[10]

Generic drug pricing, market trends, and issues

Generic drugs are an alternative to branded drugs and account for approximately 90 percent of all prescription filled in the U.S.[11] However, they only represent 17.5 percent of total prescription drug spending due to their lower prices.[12] This discrepancy between volume and cost highlights the high expenses associated with branded drugs and the possible savings that could be achieved through more utilization of generic. In fact, the Food and Drug Administration (FDA) estimates that the projected savings from generic drug approved in 2022 alone were about $18.9 billion.[13] Overall, the annual savings from generics and biosimilars, including generics approved before 2021, is more than $408 billion in 2022.[14] These statistics emphasize the significant savings for the healthcare system and for patients through generics and biosimilars. Currently, there are more than 16,000 generic drugs available.[15]

Previous legislation, such as the Hatch-Waxman Act of 1994, allows the FDA to approve prescription medication through a guided process. However, the United States is still behind other countries in the field of biosimilars.[16] Compared to the European Commission (EC), the U.S. Congress is slower in passing biosimilars and related legislation. The European Union created the legal framework and regulatory approval pathways for biosimilars in 2005, while Congress passed the Biologics Price Competition and Innovations Act of 2009 (BPCIA).[17] Following the same trend, the EC approved the first biosimilar in 2006, just one year after the European legislation, whereas the FDA did not approve its first biosimilar until 2015, nearly six years after the legislation.[18]

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[10] Garrison, L. P., et al. (2018). Assessing the Value of Biosimilars: A Review of International Guidelines. Journal of Comparative Effectiveness Research, 7(2), 171-182.
[11] Association for Accessible Medicines. (2023, September). The U.S. Generic & Biosimilar Medicines Savings Report. https://accessiblemeds.org/sites/default/files/2023-09/AAM-2023-Generic-Biosimilar-Medicines-Savings-Report-web.pdf
[12] Ibid.
[13] Conrad, R., Nance, S., Tillman, Z., & Davis, K. (2024, September). Estimating Cost Savings from New Generic Drug Approvals in 2022. U.S. Food & Drug Administration. https://www.fda.gov/media/182435/download?attachment
[14] Association for Accessible Medicines. (2023, September). The U.S. Generic & Biosimilar Medicines Savings Report. https://accessiblemeds.org/sites/default/files/2023-09/AAM-2023-Generic-Biosimilar-Medicines-Savings-Report-web.pdf
[15] How Are Generics Affecting Drug Prices? | Cato Institute
[16] Drug Price Competition and Patent Term Restoration Act of 1984, S.2748, 98th Congress (1983-1984). http://www.congress.gob/bill/98th-congress/senate-bill/2784. Accessed on March 25, 2025.
[17] Gherghescu, I., & Delgado-Charro, M. B. (2020). The Biosimilar Landscape: An Overview of Regulatory Approvals by the EMA and FDA. Pharmaceutics, 13(1), 48. https://doi.org/10.3390/pharmaceutics13010048
[18] Ibid.

This slower progress in the United States hindered competition from entering the U.S. pharmaceutical market, contributing to the price difference of drugs between the two regions.[19, 20] With fewer biosimilars approved and developed, branded drugs in the U.S. maintain larger market shares for longer periods compared to Europe.[21]

In addition to timing delays, the U.S. also lacks a structured approach to biosimilar pathways. The European Medicines Agency (EMA) provides product-specific guidelines based on biological classifications, which speeds up the approval process. In contrast, the FDA evaluates biosimilars on a case-by-case basis.[22] The U.S. is actively working to enhance its review process to be similar to the foundation provided by BPCIA in an effort to reduce prescription drug prices.[23]

Limited competition also allows companies to raise prices when fewer generic manufacturers are in the marketplace. A lack of competition also contributes to drug shortages, as a limited number of suppliers make the supply chain more susceptible to disruptions. Drugs with few competitors are more prone to shortages. In these instances, demand for that generic drug can surge while supply remains low, driving prices higher.[24]

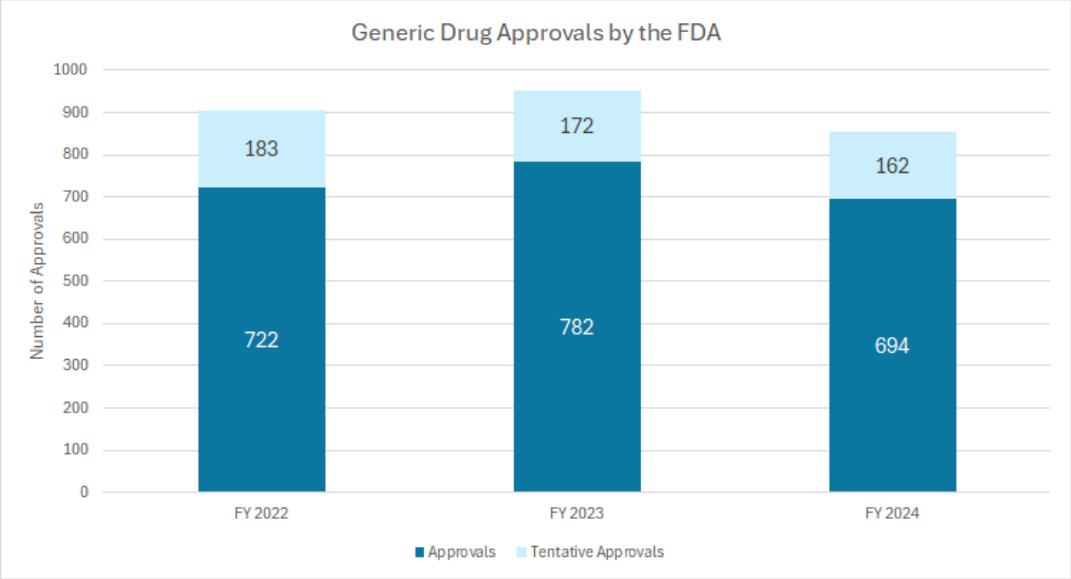
Trends and issues

The generic drug market is continually evolving, particularly with the expiration of patents on numerous branded drugs, such as Humira. According to the FDA 2022 annual report from the Office of Generic Drugs, there are nearly 32,000 generic drugs approved.[25] Table 1 shows the FDA approvals of generics from 2022 to 2024. Tentative approvals indicate a generic drug whose application is not allowed to market and the drug product was postponed until the patent or exclusivity issues are resolved.[26] The table shows an increase in approvals from 2022 to 2023 with a drop in 2024. Even with a decrease in approvals, by November 2024, the FDA approved

[19] Gherghescu, I., & Delgado-Charro, M. B. (2020). The Biosimilar Landscape: An Overview of Regulatory Approvals by the EMA and FDA. Pharmaceutics, 13(1), 48. https://doi.org/10.3390/pharmaceutics13010048
[20] Carl DL, Laube Y, Serra-Burriel M, Naci H, Ludwig W, Vokinger KN. Comparison of Uptake and Prices of Biosimilars in the US, Germany, and Switzerland. JAMA Netw Open. 2022;5(12):e2244670. doi:10.1001/jamanetworkopen.2022.44670
[21] Ibid.
[22] Daller J. Biosimilars: A consideration of the regulations in the United States and European union. Regul Toxicol Pharmacol. 2016 Apr;76:199-208. doi: 10.1016/j.yrtph.2015.12.013. Epub 2015 Dec 28. PMID: 26732800.
[23] Gherghescu, I., & Delgado-Charro, M. B. (2020). The Biosimilar Landscape: An Overview of Regulatory Approvals by the EMA and FDA. Pharmaceutics, 13(1), 48. https://doi.org/10.3390/pharmaceutics13010048
[24] Gupta, R., Shah, N. D., & Ross, J. S. (2019). Generic Drugs in the United States: Policies to Address Pricing and Competition. Clinical pharmacology and therapeutics, 105(2), 329–337. https://doi.org/10.1002/cpt.1314
[25] Office of Generic Drugs 2022 Annual Report Ensuring high-quality, affordable generic drugs are available to the American public." U.S. Food & Drug Administration, Office of Generic Drugs, January 2023. https://www.fda.gov/media/165435/download?attachment. Accessed April 8, 2025.
[26] "Office of Generic Drugs 2023 Annual Report: Ensuring high-quality, safe, and effective generic drugs are available to the American public." U.S. Food & Drug Administration, Office of Generic Drugs, February 2024. https://www.fda.gov/media/176440/download?attachment. Accessed April 8, 2025.

58 first-time generic drugs, fostering competition and potentially lowering prices.[27] Additionally, the expedited approval process for generics over the years provides more opportunities, although patent restrictions still pose challenges for many applications.[28]

Table 1: *Generic drug approvals by the FDA from 2022 to 2024* [29,30,31]



Health authorities, including insurers and government programs, are increasingly promoting generic prescriptions in an attempt to control healthcare costs, as brand-name drugs generally cost 30 to 60 percent more than their generic counterparts.[32] It is estimated that first-time

[27] Center for Drug Evaluation and Research. (n.d.). First generic drug approvals. U.S. Food and Drug Administration. https://www.fda.gov/drugs/drug-and-biologic-approval-and-ind-activity-reports/first-generic-drug-approvals

[28] Office of the Assistant Secretary for Planning and Evaluation. (n.d.). Number of US FDA ANDA approvals per Fiscal Year. ASPE. https://aspe.hhs.gov/number-us-fda-anda-approvals-fiscal-year

[29] "Generic Drugs Program Activities Report - FY 2022 Monthly Performance." U.S. Food & Drug Administration, 2022. https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/generic-drugs-program-activities-report-fy-2022-monthly-performance. Accessed April 8, 2025.

[30] "Generic Drugs Program Activities Report - FY 2023 Monthly Performance." U.S. Food & Drug Administration, 2023. https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/generic-drugs-program-activities-report-fy-2023-monthly-performance. Accessed April 8, 2025.

[31] "Generic Drugs Program Activities Report - FY 2024 Monthly Performance." U.S. Food & Drug Administration, 2024. https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/generic-drugs-program-activities-report-fy-2024-monthly-performance/. Accessed April 8, 2025.

[32] Straka, R. J., Keohane, D. J., & Liu, L. Z. (2017). Potential Clinical and Economic Impact of Switching Branded Medications to Generics. American Journal of Therapeutics, 24(3), e278–e289. https://doi.org/10.1097/MJT.0000000000000282.

generics can save the U.S. healthcare system roughly $5.2 billion dollars within a year of their approval.[33] This preference is reinforced as several states mandate pharmacists to substitute brand names with generics when available, easing financial burdens on consumers and the healthcare system.[34]

Lawmakers have also explored other pathways to increase competition against branded drugs. The FDA's Biosimilars Action Plan (BAP), implemented in 2018, aimed to enhance the development and approval process for biosimilars.[35] By clarifying regulatory requirements and providing application templates, the BAP seeks to facilitate market entry for more biosimilars.

Additionally, the 2019 Biologic Patent Transparency Act (BPTA) increased the details required in the FDA "Purple Book," a database of biologics.[36] The legislation mandates more transparency concerning patent and marketing information, which previously hindered biosimilar applicants. By imposing more requirements on brand companies, the BPTA ensures a more open market for biosimilar competition.[37]

The generic drug market faces significant challenges, primarily due to mergers and acquisitions that reduce competition and potentially inflate drug prices. The Federal Trade Commission has raised concern about "cross-market" acquisitions that enable manufacturers to dominate various therapeutic areas, allowing them to leverage their market share to raise prices.[38] The number of mergers in the generic market have increased in value, escalating from $1.86 billion in 2014 to $44 billion by 2016, indicating a trend in consolidation that limits consumer choices.[39]

Limited profitability for generics, can also reduce market entry. Small profit margins, coupled with fierce competition, deter new manufacturers and perpetuate a duopoly, restricting options for both the healthcare system and consumers. Consumer attitudes toward generic drugs further complicate the situation. Healthcare provider' prescribing patterns greatly influence

[33] "The U.S. Generic & Biosimilar Medicines Savings Report." Association for Accessible Medicines, September, 2023. https://accessiblemeds.org/sites/default/files/2023-09/AAM-2023-Generic-Biosimilar-Medicines-Savings-Report-web.pdf.
[34] Liu, M., & Yao, L. (2025). The effect of USA state generic substitution laws on the generic utilization and market competition. Pharmacoeconomics and Policy. https://doi.org/10.1016/j.pharp.2025.02.002.
[35] Center for Drug Evaluation and Research. (n.d.-a). Biosimilars Action Plan. U.S. Food and Drug Administration. https://www.fda.gov/drugs/biosimilars/biosimilars-action-plan.
[36] Purple Book Database of Licensed Biological Products. U.S. Food & Drug Administration. (n.d.). https://purplebooksearch.fda.gov/about.
[37] US SB659 | 2019-2020 | 116th congress. Congress.gov. (n.d.). https://www.congress.gov/bill/116th-congress/senate-bill/659/text.
[38] Nguyen, S. T. (2024, January 25). The future of pharmaceuticals: Examining the analysis of pharmaceutical mergers. Federal Trade Commission. https://www.ftc.gov/news-events/events/2022/06/future-pharmaceuticals-examining-analysis-pharmaceutical-mergers
[39] Gagnon, M. A., & Volesky, K. D. (2017). Merger mania: mergers and acquisitions in the generic drug sector from 1995 to 2016. Globalization and health, 13(1), 62. https://doi.org/10.1186/s12992-017-0285-x

drug utilization, which can be shaped by brand drug marketing and perceived efficacy concerns.[40] Although attitudes toward generics are improving, some healthcare professionals and patients remain hesitant to fully embrace them.[41,42]

Generic drug prices on a year-to-year basis

Annually Oregon insurance carriers report their top 25 drugs of the most costly, most prescribed, and greatest increase in spending to the Drug Price Transparency (DPT) Program. For the 2023 data provided by DPT, the PDAB staff identified nine generic drugs that contributed to healthcare system costs in Oregon. This means they were the top contributors for cost of generics. This section and Figure 1 discuss the history of the carrier reporting and supplemental data for these drugs. Staff analysts used Medi-Span database to compile the median Wholesale Acquisition Cost (WAC) of each drug over a three-year period for analysis and comparison. The data collected indicated that generic drug prices are generally consistent, with two identified trends.

The first trend, shown in Figure 1, indicates an increase in WAC from 2021 to 2022, followed by a decrease in 2023. For example, albuterol, used to treat bronchospasm, had a minor rise from $17.23 in 2021 to $20.94 in 2022, but then dropped back to $17.23 in 2023. Other drugs, such as testosterone, lisinopril, and atorvastatin, followed similar trends with slight price increases from 2021 to 2022, but decreased in cost from 2022 to 2023.

The second trend involves estradiol and gabapentin showing the same WAC was maintained from 2021 to 2022 but increased in 2023. . Both experienced shortages in 2023, which may have contributed to the price hikes. Estradiol cypionate injections were reported to be in a shortage by the American Society of Health-System Pharmacists (ASHP) in May of 2022, with the shortage resolved in October 2023.[43] Similarly, gabapentin oral solution was declared to be

[40] Howard, J. N., Harris, I., Frank, G., Kiptanui, Z., Qian, J., & Hansen, R. (2018). Influencers of generic drug utilization: A systematic review. Research in social & administrative pharmacy: RSAP, 14(7), 619–627. https://doi.org/10.1016/j.sapharm.2017.08.001

[41] Kesselheim, A. S., Eddings, W., Raj, T., Campbell, E. G., Franklin, J. M., Ross, K. M., Fulchino, L. A., Avorn, J., & Gagne, J. J. (2016). Physicians' Trust in the FDA's Use of Product-Specific Pathways for Generic Drug Approval. PloS one, 11(10), e0163339. https://doi.org/10.1371/journal.pone.0163339

[42] Shrank, W. H., Cadarette, S. M., Cox, E., Fischer, M. A., Mehta, J., Brookhart, A. M., Avorn, J., & Choudhry, N. K. (2009). Is there a relationship between patient beliefs or communication about generic drugs and medication utilization? Medical care, 47(3), 319–325. https://doi.org/10.1097/MLR.0b013e31818af850

[43] American Society of Health-System Pharmacists. (2022, May). Drug shortage detail: Estradiol cypionate injection. ASHP. https://www.ashp.org/drug-shortages/current-shortages/drug-shortage-detail.aspx?id=838

in a shortage in May 2023, which is expected to continue until July 2024.[44] Figure 1 illustrates that the timing of these generic drugs shortages aligns with the WAC increases. .

The rest of the generic drugs shown in Figure 1 did not follow the WAC trends described above. For example, epinephrine maintained a WAC of $150 in 2021 and 2022 before experiencing a slight decrease to $149.60 in 2023. Five states have passed legislation in 2023 to curb the price of epinephrine and three states have implemented caps in 2024 and 2025.[45, 46, 47, 48, 49, 50]

Levothyroxine, another generic drug analyzed, started at a WAC of $60.34 in 2021, dropped to $58.41 in 2022, and then increased slightly to $60.23 in 2023. The ASHP reported that a shortage resulted from one manufacturer, Piramal Critical Care, discontinuing levothyroxine injection in late 2022.[51] In contrast, progesterone had a higher WAC at $99.51 in 2021 but decreased to $84.91 in 2022 and 2023.

Overall, the PDAB analysis showed generic drug pricing trends remains relatively stable barring influences from drug shortages or legislative actions. Note, these are pre-rebate prices. Actual costs may be varied and be impacted by rebates and volume discounts.

[44] American Society of Health-System Pharmacists. (2023). Drug shortage detail: Gabapentin oral solution. ASHP. https://www.ashp.org/drug-shortages/current-shortages/drug-shortage-detail.aspx?id=943&loginreturnUrl=SSOCheckOnly

[45] NJ Legislature

[46] Price caps on insulin, inhalers, EpiPens take effect • New Jersey Monitor

[47] *Release: Rep. Howard highlights new co-pay cap on life-saving medications taking effect in January*. Rep. Michael Howard - Release: Rep. Howard highlights new Co-Pay Cap on Life-Saving Medications taking effect in January. (2024). https://www.house.mn.gov/members/profile/news/15518/39829

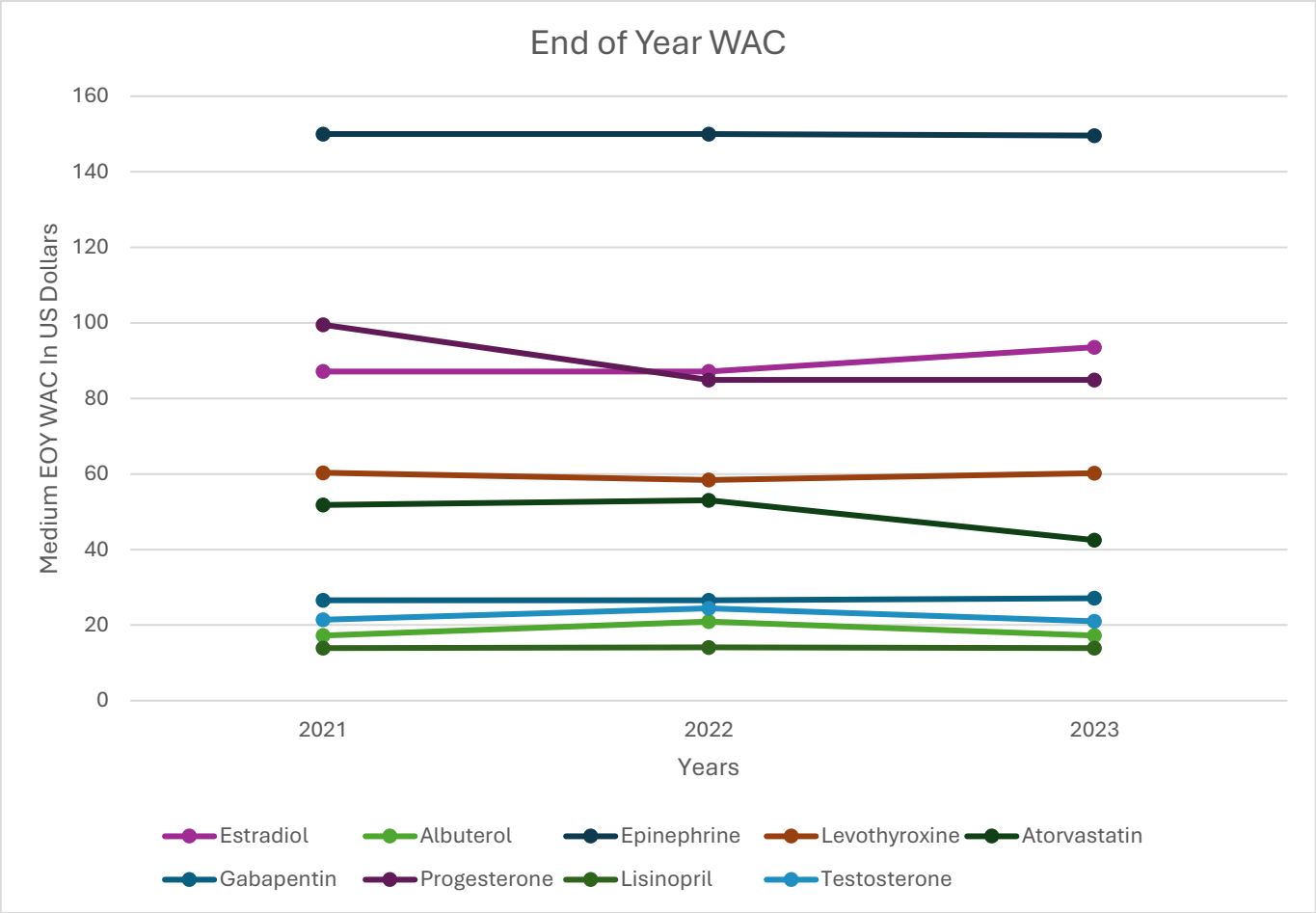
[48] Keith, S. (2023, May 9). *House passes Williams bill to require insurance companies to cover epipens for Delawareans of all ages*. Delaware House Democrats. https://housedems.delaware.gov/2023/03/14/house-passes-williams-bill-to-require-insurance-companies-to-cover-epipens-for-delawareans-of-all-ages/

[49] State Of Colorado. (2023). HOUSE BILL 23-1002. State of Colorado. https://leg.colorado.gov/sites/default/files/2023a_1002_signed.pdf

[50] *State of Rhode Island General Assembly*. RI State Seal. (2023). https://www.rilegislature.gov/pressrelease/_layouts/RIL.PressRelease.ListStructure/Forms/DisplayForm.aspx?List=c8baae31-3c10-431c-8dcd-9dbbe21ce3e9&ID=373770

[51] American Society of Health-System Pharmacists. (2023). Drug shortage detail: Levothyroxine Sodium Injection. ASHP. https://www.ashp.org/drug-shortages/current-shortages/drug-shortage-detail.aspx?id=804&loginreturnUrl=SSOCheckOnly

Figure 1: *Medium end of year WAC for top reported generic drugs*



Generic drug pricing impacts on health insurance premiums and cost-sharing

The influence of generic drug costs in medical insurance premiums is important yet often misunderstood, primarily due to the private nature of pharmacy benefit managers (PBMs). PBMs are middlemen between pharmacies, drug manufacturers, and insurers, negotiate rebates and manage drug formularies.[52] Often discrepancies occur between the invoices sent to insurers and the reimbursements provided to pharmacies, a situation compounded by the private nature

[52] "Pharmacy Benefit Managers." National Association of Insurance Commissioners, April 11, 2022. https://content.naic.org/cipr-topics/pharmacy-benefit-managers. Accessed Mar. 27, 2025.

of PBM practices and pricing strategies according to a 2023 Journal of the American Medical Association Health Forum article.[53]

The Association for Accessible Medicines (AAM), the generic trade association reports use of generics and biosimilars resulted in savings of approximately $4.2 billion for Oregon in 2023.[54] Beginning in 2025, enrollees in Medicare Part D began realizing cost-sharing opportunities related to both brand and generic drugs. Cost-sharing charges refer to a patient's financial responsibility and out-of-pocket costs for a range of medical services or items included in their health insurance plans. Such expenses may include costs related to hospital admissions, physician visits, or prescription medications. Health insurance plans typically consist of three primary categories of cost-sharing charges:

- **Deductibles**: the fixed amount that a policyholder must pay for healthcare services before their insurance coverage commences.
- **Copayments (co-pays)**: a predetermined fee that individuals are required to pay each time they access a specific service or item, such as a medical consultation or a prescription refill, even after fulfilling their deductible.
- **Coinsurance**: a percentage of the cost of a covered service that individuals are obliged to pay after attaining their deductible, thus signifying a shared cost arrangement between the insurance provider and the insured.

Not all health insurance plans incorporate all three types of cost-sharing, and the specific terms and conditions may vary among different plans.

In recent years, health insurers have shifted toward tiered cost-sharing models that place prescription drugs on a formulary or preferred drug list that determines prescription drug coverage. Under these models, generic medications are positioned within the best tier placement, while brand-name drugs are categorized into higher-cost tiers. This arrangement is designed to motivate consumers to select generics, which frequently provide comparable therapeutic benefits to their brand-name equivalents while being considerably more cost effective.

It is important generics are on the best tiered placements for coverage so patients have more access to generic options, contributing to reduced out-of-pocket expenditures. The decision to promote generics not only results in substantial savings for individual patients but also contributes to overall cost reductions for insurance providers. By advancing the use of generics,

[53] Mattingly TJ, Hyman DA, Bai G. Pharmacy Benefit Managers: History, Business Practices, Economics, and Policy. *JAMA Health Forum.* 2023;4(11):e233804. doi:10.1001/jamahealthforum.2023.3804

[54] "The U.S. Generic & Biosimilar Medicines Savings Report." Association for Accessible Medicines, September, 2023. AAM-2024-Generic-Biosimilar-Medicines-Savings-Report.pdf.

the healthcare system can mitigate some of the financial pressures associated with prescription drug expenditures, ultimately benefiting both consumers and insurers.

Generic drug shortages and impact on the health care system

This past year, two notable prescription drug shortages disrupted access to necessary medications and affected patients: IV fluids and stimulants used to treat ADHD.

The 2024 IV solution shortage

On September 26, 2024, Hurricane Helene damaged a manufacturing plant in Marion, North Carolina, which produced 60 percent of the sterile IV solutions used daily in the United States.[55] In a letter dated Oct. 7, 2024, to former President Joe Biden, the American Hospital Association (AHA) reported substantial shortages of these solutions and highlighted the impact on patients. The AHA requested the FDA declare a shortage of sterile IV solutions to provide health care providers with the flexibility in addressing the issue.[56]

"If you turn off a hospital supply of IV fluids, it's like turning off the water supply to your house," according to Chris DeRienzo, AHA chief physician executive, who was quoted in The Washington Post on Oct. 14, 2024. "We need to have a continuous, consistent flow to the hospitals, especially as we are walking into the winter respiratory virus season."[57]

The FDA announced a shortage on October 11, 2024, and the Centers for Disease Control and Prevention (CDC) issued a health advisory to healthcare providers regarding the supply disruption and its potential impact on patients.[58] In an update on Nov. 25, 2024, the ASHP and University of Utah Health, which monitors drug shortages, provided 76 suggestions for

[55]Pollack, Richard J. "Letter to President Joseph R. Biden." American Hospital Association, Oct. 7, 2024. https://www.aha.org/2024-10-07-aha-president-urging-administration-take-immediate-action-address-iv-solution-supply-shortage-result-helene. Accessed Feb. 28, 2025.

[56] Ibid.

[57] Nirappil, Fenit and Roubein, Rachel. "IV fluid shortage due to hurricane prompts hospitals to postpone surgeries." Washington Post, Oct. 14, 2024. https://www.washingtonpost.com/health/2024/10/14/iv-fluid-shortage-baxter/. Accessed Feb. 28, 2025.

[58] "Disruptions in availability of peritoneal dialysis and intravenous solutions from Baxter International facility in North Carolina." Centers for Disease Control Health Alert Network, Oct. 12, 2024. https://www.cdc.gov/han/2024/han00518.html. See also "Hurricane Helene: Baxter's manufacturing recovery in North Carolina." U.S. Food & Drug Administration, Information and updates on CDER-regulated drug and biologic products, Feb. 21, 2015. https://www.fda.gov/drugs/updates-2024-hurricane-season/hurricane-helene-baxters-manufacturing-recovery-north-carolina. Accessed Feb. 28, 2025.

conserving and managing the limited supply. One of the recommendations was to use oral electrolyte solution, such as Gatorade, instead of IV fluids when possible.[59]

About one month after the hurricane, a survey of hospitals representing 101,143 patient beds found nearly 17 percent had cancelled elective surgeries and other procedures. Additionally, 58 percent were contemplating further cancellations. This information was reported by Premier, a health technology and supply chain company. The survey also indicated that 86 percent of healthcare providers were experiencing shortages of IV fluids following Hurricane Helen.[60]

ADHD medication supply

There has also been a recent shortage of attention-deficit/hyperactivity disorder (ADHD) medication, including Adderall. The CDC issued a health alert regarding this shortage, which is linked to a federal healthcare fraud indictment against a large telehealth company that provided ADHD treatment to patients ages 18 years and older.[61] The CDC estimated this shortage could affect between 30,000 to 50,000 patients.[62] CDC has also warned that the shortage may lead to adverse outcomes for those with untreated ADHD and raise concerns about the use of illegally obtained stimulant medications.[63]

In addition to the recent shortage, there has been a shortage of ADHD medications, which can be attributed in part to a rise in prescriptions during the pandemic. Dr. Susan Trachman, writing for Psychology Today, notes that the CDC reported a more than 10 percent increase in stimulant

[59] "Small- and large-volume fluid shortages – suggestions for management and conversation." American Society of Health-System Pharmacists (ASHP), Nov. 25, 2024. https://www.ashp.org/drug-shortages/shortage-resources/publications/fluid-shortages-suggestions-for-management-and-conservation?loginreturnUrl=SSOCheckOnly. Accessed Feb. 28, 2025.
[60] "Premier, Inc. Data: More than 86 percent of providers experiencing shortages of IV fluids in aftermath of October Hurricanes." Premier, Inc., Oct. 10, 2024. https://premierinc.com/newsroom/blog/premier-inc-data-more-than-86-percent-of-providers-experiencing-shortages-of-iv-fluids-in-aftermath-of-october-hurricanes. Accessed Feb. 28, 2025.
[61] "Disrupted access to prescription stimulant medications could increase risk of injury and overdose." Centers for Disease Control Health Alert Network, June 13, 2024. https://www.cdc.gov/han/2024/han00510.html#print. Accessed Feb. 28, 2025.
[62] "Disrupted access to prescription stimulant medications could increase risk of injury and overdose." Centers for Disease Control Health Alert Network, June 13, 2024. https://www.cdc.gov/han/2024/han00510.html#print. Accessed Feb. 28, 2025.
[63] Ibid.

prescriptions used primarily for ADHD among females aged 15-44 and males aged 25-44 during the years of 2020-2021.[64,65]

Senator Ron Wyden, D-Oregon, described the impact of the ADHD medication shortage on patients in rural areas. Many of these patients are forced to drive for hours to find a pharmacy which has their medication in stock. Others have had to switch to different medications or dosages due to the shortages. Additionally, some patients who previously paid a $10 copay for a generic drug are facing copays of $75 for brand-name alternatives. “When trying to feed a family, a patient might make their own health the lowest priority. Right now, too many Americans are suffering, particularly those who need medicines for ADHD,” said Sen. Wyden. He called for improved communication and transparency between federal agencies and manufacturers to find solutions to these shortages.[66] Inexpensive, low-cost generic drugs that have been available for a long time are more likely to have shortages. According to Eric Fox, an adjunct professor of pharmacy and the associate chief pharmacy officer at University of Utah Health, this issue has been monitored since 2001. When manufacturers encounter a problem—often related to quality issues at the manufacturing facilities—it can weaken the supply chain. For example, “Drug companies aren’t making any money on these drugs and so they don’t have that incentive to really make any extra. They almost have an incentive to make just enough and if there’s a shortage, they don’t lose any money, but patients pay the price and that’s what’s so frustrating about this issue.”[67]

Generic drug pricing impact on Medicare and Medicaid spending

The pricing of generic drugs is a factor influencing the annual expenditures of state medical assistance programs, as highlighted by Hernández et al.[68] Generally, generic medications are

[64] Trachman, Susan B., MD. “ADHD Medication: The shortage is getting worse.” Psychology Today, July 2, 2024. https://www.psychologytoday.com/intl/blog/its-not-just-in-your-head/202406/adhd-medication-the-shortage-is-getting-worse?msockid=253f8de194d46adb0a7c9e0795506bab. Accessed Feb. 28, 2025.
[65] Danielson, Melissa L., et al. “Trends in stimulant prescription fills among commercially-insured children and adults – United States, 2016-2021.” CDC Morbidity and Mortality Weekly Report, March 31, 2023. https://www.cdc.gov/mmwr/volumes/72/wr/mm7213a1.htm?s_cid=mm7213a1_w. Accessed Feb. 28, 2025.
[66] Sen. Ron Wyden. “Wyden sounds the alarm on ADHD drug storage.” YouTube, June 8, 2023. https://www.youtube.com/watch?v=XCRipHwXKdY. See also “Wyden sounds the alarm on ADHD drug shortage.” Ron Wyden United States Senator for Oregon Press Release, June 8, 2023. https://www.wyden.senate.gov/news/press-releases/wyden-sounds-the-alarm-on-adhd-drug-shortage. Accessed Feb. 28, 2025.
[67] Nelson, Chris and Fox, Erin. “U of U Health has a national role in tracking prescription drug shortages.” The University of Utah, U Rising. https://attheu.utah.edu/u-rising/u-of-u-health-has-a-national-role-in-tracking-prescription-drug-shortages/. Accessed Feb. 28, 2025.
[68] Hernández, I., Smith, A., & Johnson, R. (2020). Health care spending in the states: An overview of the impact of generic drugs. State Health Policy Review, 15(3), 233-245.

significantly less expensive than their brand-name counterparts, facilitating substantial savings for state budgets. Studies indicate that generics can cost approximately 80 to 85 percent less than branded drugs, underscoring the potential for cost reduction.[69]

However, the impact of generic drug prices can vary widely depending on factors such as market competition and the availability of specific generics.[70] In areas with limited competition, generic drug prices may remain higher than expected, leading to increased spending for state programs.[71] Furthermore, if states fail to negotiate effectively or implement strategies to prioritize the use of generics, the potential savings may not be fully realized.[72] Overall, while generic drug pricing promises to reduce annual spending in state medical assistance programs, the effectiveness of these savings is contingent upon market dynamics and strategic management initiatives.[73]

**Additional information will be provided based on OHP utilization data provided by OSU Drug Use Research and Management (DURM) group.

https://www.orpdl.org/durm/reports/utilization/2024/DUR_Utilization_2024_Q1.pdf
https://pharmacy.oregonstate.edu/research/drug-use-research-management/dur-reports

Generic multisource drugs and Medicaid

Generic multiple source (aka multisource) drugs in Medicaid are important as they provide a pathway for cost savings, and enhance patient access to necessary medications. These drugs, which are chemically identical to their brand-name counterparts, offer similar therapeutic effects at a reduced cost, making them an essential component of the healthcare system.[74]

The Medicaid program ensures access to essential medications to low-income individuals and families. Among the range of medications covered under Medicaid, generic multisource drugs are particularly significant. Generic multisource drugs help to alleviate the financial burden on both the Medicaid program and its recipients. By increasing the availability of affordable medications, these generics contribute to better health outcomes and adherence to treatment regimens, especially for chronic conditions that require long-term medication management.[75]

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[69] Kesselheim, A. S., Misono, A. S., Lee, J. K., & Stedman, M. (2016). The role of generic drugs in prescription medication spending: A review. The New England Journal of Medicine, 375(13), 1283-1290.
[70] Sheingold S and Nguyen NX. Impacts of Generic Competition and Benefit Management Practices on Spending for Prescription Drugs: Evidence from Medicare's Part D Benefit. *Medicare Medicaid Res Rev*. 2014;4:E1–E13.
[71] Wiske CP, Ogbechie OA, Schulman KA. Options to Promote Competitive Generics Markets in the United States. *JAMA.* 2015;314(20):2129–2130. doi:10.1001/jama.2015.13498.
[72] Challenges and Potential Improvements to Patient Access to Pharmaceuticals | Circulation
[73] Shen, X., Li, Q., & Zheng, Y. (2019). Strategic management of generic drug pricing: A pathway for state Medicaid programs. Journal of Health Economics, 65, 1-14.
[74] Federal Register :: Medicaid Program; Multiple Source Drug Definition
[75] "Medicaid and the Children's Health Insurance Program (CHIP) Coverage." Centers for Medicare & Medicaid Services, 2021. https://www.cms.gov.

The use of generic drugs can lead to substantial savings for state Medicaid programs, thereby allowing for the allocation of resources to other critical healthcare services.[76]

Moreover, the promotion of generic drugs aligns with the broader healthcare initiative aimed at curbing prescription drug costs nationwide. The Food and Drug Administration (FDA) supports the production and use of generics to enhance market competition and ultimately drive down prices.[77] This is particularly beneficial for Medicaid patients who may have limited options.

Generic drug market concerns with importation and tariffs

Federal Tariffs on Drug Imports

The Trump Administration has announced tariffs but exempted pharmaceutical imports for now.[78,79] If pharmaceutical tariffs were implemented, they could have unintended consequences by cutting off key ingredients of critical generic medicines people rely on daily. Tariffs could disturb the already fragile supply chains and create generic drug shortages, leading to higher prices.[80] To consider the implications of tariffs, it is helpful to know that there are three types of prescription drug importation and to know the differences between the operation of the brand-name and generic markets.

Three types of prescription drug importation

Individuals and employers administering employee benefits consider importing drugs as a means to lower the costs of medications for consumers and employers, given that pharmaceutical prices in the U.S. are the highest in the world.

[76] "Generic Drug Prices and Market Dynamics." United States Government Accountability Office, 2019. https://www.gao.gov.
[77] "Generic Drugs." Food and Drug Administration, March 13, 2025. https://www.fda.gov/drugs/buying-using-medicine-safely/generic-drugs.
[78] Wosinska, Marta. "Will Pharmaceutical Tariffs Achieve Their Goals?" Brookings, Washington D.C. March 27, 2025. https://www.brookings.edu/articles/pharmaceutical-tariffs-how-they-play-out/. Accessed April 4, 2025.
[79] Philpott, Jenna, "Pharma industry dodges tariff blow but still braces for disruption." Pharmaceutical Technology, April 3, 2025. https://www.pharmaceutical-technology.com/news/pharma-industry-dodges-tariff-blow-but-still-braces-for-disruption/?cf-view. Accessed April 4, 2025.
[80] Roades, Thomas, Colvill, Stephen McClellan, Mark B. "Pharmaceutical Tariffs: Potential Impacts And The Need For Vulnerability Assessments." HealthAffairs, March 26, 2025. https://www.healthaffairs.org/content/forefront/pharmaceutical-tariffs-potential-impacts-and-need-vulnerability-assessments. Accessed on March 27, 2025.

Federal law addresses three types of importation of finished prescription drugs that are ready for use: [81]

- **Reimportation**: Manufacturer brings in a drug produced outside the U.S. (known as 'ex-US') from countries such as Ireland, England, France, India, among other sites.
- **Wholesale importation**: States or wholesalers can import drugs from Canada, but this process requires approval by the FDA.
- **Personal importation**: Individuals bring into the U.S. a quantity of prescription drugs for personal use, which cannot exceed a 90-day supply for treatment.

Manufacturer reimportation

Reimportation (Ex-U.S.) drug product manufacturing is fully licensed and approved by the FDA. Information regarding this ex-U.S. manufacturing is completely disclosed as part of a company's FDA drug approval and licensure application. The industry has shifted manufacturing operations out of the U.S. (offshoring) to achieve of cost-efficient distribution to locations outside North America, as well as to take advantage of lower corporate tax rates in some other countries.[82]

Wholesale prescription drug importation from Canada by states

Currently, eight states have laws directing the executive branch to pursue wholesale importation, as permitted under current federal law. However, federal approval is necessary for any state importation program to proceed.[83] During the first Trump Administration, five of these states submitted wholesale importation plans. To date, no state has received full federal approval. Any importation under a state program would be restricted to finished products that are licensed for the Canadian market.

Personal importation

According to federal law, large-scale personal importation of prescription drugs is not allowed without a specific program administered by the FDA, which has not been established. However, the FDA exercises "enforcement discretion," permitting individuals to import prescription drugs for personal use. These drugs can be sourced from any country, and there are US-based online services that evaluate pharmacies in various countries to facilitate these transactions. A valid prescription is required for this process. It was estimated about ten years ago that around 500

[81] Wosinska, Marta. "Will Pharmaceutical Tariffs Achieve Their Goals?" Brookings, Washington D.C. March 27, 2025. https://www.brookings.edu/articles/pharmaceutical-tariffs-how-they-play-out/. Accessed April 4, 2025.
[82] The tax changes of 2017 allowed corporations to bring revenues back to the US with very preferable tax treatment rules with the expectation that companies would invest in US operations. Research has shown that most of the tax windfall went to stock buy backs that boosted corporate stock price and thus executive compensation based on stock price. After the early opportunity of re-shoring profits, the bill did not encourage a return of manufacturing to the U.S.
[83] ME, VT, NH, CO, VA, NM, FL, ME.

U.S. employers had designed their employee pharmacy benefits to encourage personal importation from Canada.[84]

Tariffs on Imports of Prescription Drugs

Generally, it is believed that tariffs will increase the cost of medicines, which are already expensive in the U.S. Additionally, tariffs could affect the potential savings from U.S. wholesale importation. Federal law requires that any state wholesale importation must demonstrate significant savings for consumers.

These tariffs will impact state wholesale importation programs that are limited to Canadian products. Some states that submitted wholesale importation proposals to the first Trump administration estimated that the cost associated with the program could consume up to 40 percent of the expected savings. With the addition of proposed tariffs, these administrative costs could rise to as much as 65 percent of the savings. Consequently, the range of products eligible for importation may be much smaller than it would be without tariffs, particularly if states decide that only the most expensive products are worth importing.[85] It is challenging to predict how individual consumers will respond when the cost of their imported product increases.

Currently, the effect of tariffs on state importations is nearly irrelevant due to the rising tensions between Canada and the U.S., largely stemming from trade issues between the two countries. Several years ago, before this escalation, Florida implemented a wholesale importation law, prompting Canadian officials to declare that they would prohibit the export of pharmaceuticals approved for the Canadian market. They pointed out that Florida's population, which is approximately 23.5 million, is less than half the population of Canada, which is around 41.5million.

As of Spring 2025, the deteriorating relationship between the U.S. and Canada make the likelihood of wholesale importation increasingly unlikely. Despite this growing improbability, as many as nine states are pursuing wholesale importation bills during their 2025 legislative sessions. [86]

Impact on generic drugs

The United States relies heavily on manufacturing sites in India and China that make active pharmaceutical ingredients (API) used in medications. These crucial ingredients are produced in

[84] Wosinska, Marta. "Will Pharmaceutical Tariffs Achieve Their Goals?" Brookings, Washington D.C. March 27, 2025. https://www.brookings.edu/articles/pharmaceutical-tariffs-how-they-play-out/. Accessed April 4, 2025.
[85] Wosinska, Marta. "Will Pharmaceutical Tariffs Achieve Their Goals?" Brookings, Washington D.C. March 27, 2025. https://www.brookings.edu/articles/pharmaceutical-tariffs-how-they-play-out/. Accessed April 4, 2025.
[86] CT, IL, MS, NY, RI, TN, TX, WV, and WI

other countries because of mass production, lower labor costs and lighter environmental rules. Consider these numbers from a 2021 Washington University study:

- 80 percent of all active pharmaceutical ingredients (API) for essential medicines used in the U.S. have no domestic manufacturing source.
- Less than 5 percent of large-scale API manufacturing sites are in the U.S.
- Four of the 103 sites worldwide that manufacture and sell more than 30 API products are in the U.S. The U.S. has 15 of the 350 global companies that make more than 10 API products.
- In comparison, India has 60 API sites and China has 10 API sites with more than 30 products. [87]

The U.S. generic market is highly competitive, with profit margins being very small. This competitive landscape can lead to drug shortages when one manufacturer decides to end production or sales into the U.S., and the remaining manufacturers do not have capacity to meet the full market demand.

The generic market economics suggest that it may not be feasible for a generic manufacturer to build facilities in the U.S. This is largely due to the revenue that a plant could generate in comparison to the construction costs, which have increased due to a 25 percent tariffs on aluminum and steel.[88] Additionally, if imported raw material are also taxed at 25 percent, it further raises production costs. It takes five to 10 years to build and qualify a new site. Setting up a new plant may also involve retrofitting facilities, relocating equipment, and sourcing APIs. Some manufacturers may respond by discontinuing the product. In the short term, drug companies may struggle to find specialized manufacturing capacity and capabilities for drugs such as antibiotics outside of India and China.[89] Furthermore, tariffs could be lifted by a future administration, making it difficult for manufacturers to decide about relocation.

Impact of Medicaid and Medicare price increase penalties

There are several ways a company manages the impact of the tariffs: by absorbing the costs; passing costs along to the consumer through higher prices; or reducing purchaser discounts and

[87] Sardella, Anthony, "The US active pharmaceutical ingredient infrastructure: The current state and considerations to increase US Healthcare Security." Center for Analytics and Business Insights, Olin Business School at Washington University, Aug. 1, 2021. The US Active Pharmaceutical Ingredient Infrastructure: The current state and considerations to increase US Healthcare Security .pdf | Powered by Box. Accessed on April 8. 2025.
[88] O'Neil, Shannon K., and Huesa, Julia, "What Trump's aluminum and steel tariffs will mean, in six charts." Council on Foreign Relations, Feb. 14, 2025. https://www.cfr.org/article/what-trumps-aluminum-and-steel-tariffs-will-mean-six-charts. Accessed April 4, 2025.
[89] Roades, Thomas, Colvill, Stephen McClellan, Mark B. "Pharmaceutical Tariffs: Potential Impacts And The Need For Vulnerability Assessments." HealthAffairs, March 26, 2025. https://www.healthaffairs.org/content/forefront/pharmaceutical-tariffs-potential-impacts-and-need-vulnerability-assessments. Accessed on March 27, 2025.

payor rebates while keeping prices steady. The decisions will be influenced by the federal laws that impose financial penalties on manufacturers who increase drug prices beyond the rate of inflation in any calendar quarter. These penalties are based on the volume of sales to Medicare or Medicaid enrollees and are paid as rebates to the federal government for Medicare and to both the state and federal governments for Medicaid for each unit of the drug sold during that quarter.[90] The approach a company takes depends on various factors, including whether the product is a brand-name or generic drug, its market position, competition, remaining patent life, and its ability to absorb or pass along the tariff costs. This leads to considerable market uncertainty and could potentially contribute to drug shortages.

A recent change to the Medicaid price inflation rebate formula has increased penalties for older products. This increase in penalties appears to be associated with the removal of some older products from the market, while others have been relabeled and reintroduced at much higher prices than those of the product they replaced.

Anticipating how companies will respond to tariffs, when and if they are imposed, and the manner of their implementation, can be challenging. Industry reactions are likely to vary significantly and will often be specific to individual products rather than reflective of a uniform corporate strategy.

Group purchasing organization and pharmacy benefit manager practices

Understanding the Role of GPOs in the Oregon Generic Drug Market

Disclaimer: The GPOs mentioned—Zinc, Ascent, ClarusOne, and Red Oak Sourcing—are cited as major players, but do not represent an exhaustive list of all GPOs operating in the generic pharmaceutical space.

Group Purchasing Organizations (GPOs) negotiate drug prices on behalf of pharmacies, payors, and other healthcare stakeholders.[91] By pooling purchasing power, GPOs can often secure bulk discounts and more favorable contract terms from manufacturers. GPOs and their impact on Oregon payors, pharmacies, and patients GPO-negotiated contracts can yield cost savings for large chain, mail order, or PBMs, potentially leading to lower copays for some patients.

[90] The formula and its administration is more complex than described here but this simplified approach makes the general point about the impact of the price inflation penalty in the context of managing a 25 percent tariff.
[91] Ferguson, Andrew N., Chairman, "Concurring Statement of Commissioner Andrew N. Ferguson Regarding the Pharmacy Benefit Managers Interim Staff Report." Federal Trade Commission, July 9, 2024. https://www.ftc.gov/terms/general-purchasing-organizations-gpos. Accessed April 4, 2025.

However, smaller independent pharmacies in Oregon may struggle to access similar discounts if not aligned with a powerful GPO or if GPO-negotiated pricing structures favor large-scale distribution networks.

As GPOs like Zinc, Ascent, ClarusOne, and Red Oak Sourcing continue to shape the generic market, Oregon stakeholders—including payors, pharmacies, and policymakers—must watch for both cost-saving benefits and potential downsides. Although GPOs can streamline procurement and reduce prices through bulk purchasing, the consolidation of negotiating power may raise questions about transparency and equitable distribution of savings.

International GPOs

Zinc is an international GPO that collaborates with global drug manufacturers to provide generics medications to healthcare organizations, including PBMs and wholesalers. Proponents argue that international GPOs can exploit broader supply networks, potentially lowering costs through larger-scale negotiations.[92] However, skeptics warn that these structures might reduce transparency if the terms of global contracts are not clearly disclosed. For pharmacies in Oregon, the impact of these arrangements depends on which GPO-driven discounts are passed on or leveraged to benefit vertically integrated PBMs.

Beyond Zinc, there are several well-known GPOs that compete in this space. Ascent Health Services, which is affiliated with Express Scripts under the Cigna umbrella, operates globally and negotiates prices and supply deals for generics.[93] ClarusOne is a joint venture involving Walgreens Boots Alliance and other major entities, similarly, focused on consolidated purchasing for generics.[94,95] Each GPO holds significant influence over drug pricing and availability because large payors and PBMs rely on their negotiating power to secure cost-effective supplies.

[92] Abrams Kaplan, Deborah, "PBMs are creating GPOs, and stirring debate as to why." Managed Healthcare Executive, July 12, 2022. https://www.managedhealthcareexecutive.com/view/pbms-are-creating-gpos-and-stirring-debate-as-to-why. Accessed April 4, 2025.
[93] "Common misconceptions about PBMs." Evernorth Health Services, 2025. https://www.evernorth.com/esfacts/myths-facts. Accessed April 4, 2025.
[94] "Walgreens Boots Alliance enters into definitive agreement to be acquired by Sycamore Partners." Walgreens Boots Alliance, March 6, 2025. https://investor.walgreensbootsalliance.com/news-releases/news-release-details/walgreens-boots-alliance-enters-definitive-agreement-be-acquired. Accessed April 4, 2025.
[95] Fein, Adam J., "Five or maybe six reasons the largest PBMs operate group purchasing organizations." Drug Channels, May 24, 2023. https://www.drugchannels.net/2023/05/five-or-maybe-six-reasons-that-largest.html.

Domestic GPOs and their competitors

Domestically, Red Oak Sourcing—a joint venture equally owned by CVS Health and Cardinal Health—is one of the largest GPOs in the country.[96,97] It primarily consolidates generic procurement for CVS Caremark's PBM clients, which could influence the supply chain in Oregon by determining which medications are purchased in bulk and at what price.[98] Other GPOs, like ClarusOne and Ascent, compete with Red Oak by negotiating volume and supplier relationships. Although these competitors may foster some degree of market balance, critics maintain that large, consolidated GPOs like Red Oak still limit transparency and could undermine competition at the pharmacy level.

Overview of PBM-owned generic and biosimilar manufacturing

In recent years, some PBMs have established or acquired subsidiaries that produce or distribute biosimilars, which are high-cost alternatives to complex biologic drugs. This vertical integration can influence how certain medications are covered, dispensed, and reimbursed throughout the Oregon pharmaceutical ecosystem through plan design. Here are examples:

- Cordavis, a CVS Health subsidiary, collaborates with Sandoz to offer the drug Hyrimoz (adalimumab-adaz), which integrates with CVS Caremark's formularies.[99] This partnership streamlines supply chains but centralizes pricing and distribution under one corporate umbrella.
- Quallent Pharmaceuticals, under Cigna's Evernorth, provides multiple Humira biosimilars, including adalimumab-adbm (with Boehringer Ingelheim) and adalimumab-ryvk (Simlandi) with Alvotech/Teva, along with a ustekinumab biosimilar referencing Stelara.[100, 101] Being linked to Express Scripts allows for aligned formulary placement and

Accessed April 4, 2025.

[96] "Cardinal Health Annual Report." Cardinal Health 2024. https://www.cardinalhealth.com/content/dam/corp/web/documents/Report/cardinal-health-FY24-annual-report.pdf. Accessed April 4, 2025.

[97] Fein, Adam J., "Five or maybe six reasons the largest PBMs operate group purchasing organizations." Drug Channels, May 24, 2023. https://www.drugchannels.net/2023/05/five-or-maybe-six-reasons-that-largest.html. Accessed April 4, 2025.

[98] Pifer, Rebecca, "CVS reportedly creating group purchasing organization for PBM business." HealthCareDive, July 1, 2020. https://www.healthcaredive.com/news/cvs-reportedly-creating-group-purchasing-organization-for-pbm-business/580889/#:~:text=Dive%20Brief:,%2D%20and%20Walgreens%2Daffiliated%20PBM. Accessed April 4, 2025.

[99] "CVS Health launches Cordavis." CVS Health, Aug. 23, 2023. https://www.cvshealth.com/news/pbm/cvs-health-launches-cordavis.html. Accessed April 4, 2025.

[100] "Boehringer Ingelheim expands access to adalimumab-adbm injection, the company's biosimilar to Humira." Boehringer Ingelheim, May 13, 2024. https://www.boehringer-ingelheim.com/us/new-agreement-quallent-expands-biosimilar-access. Accessed April 4, 2025.

[101] Ibid.

reimbursements. For Oregon payors, patients, and pharmacies, this may affect which biosimilars are most readily dispensed in clinical settings.

- Nuvaila, a subsidiary of OptumRx (UnitedHealth Group), distributes Amjevita (adalimumab-atto) and Wezlana (ustekinumab-auub), in partnership with Amgen.[102] While this can simplify access to biosimilars for patients, it may also reduce competition if formulary decisions favor these in-house products over other available biosimilars in the state.

Potential impact for Oregon payors and patients with PBM-owned generic and biosimilar manufacturing

When PBMs own or partner directly with biosimilar manufacturers, Oregon payors may find their ability to negotiate competitive rates diminished. This is because the PBM has a financial interest in promoting its own products. Since PBMs negotiate reimbursement rates and manage the distribution of biosimilars, healthcare providers might experience reduced profit margins if reimbursement does not keep pace with procuring these products.[103]

As a result, formulary designs may prioritize in-house biosimilars, which can limit broader market competition and choice for providers and patients. Consequently, patients might encounter a narrower range of covered treatments, as alternative biosimilars may be deprioritized or excluded based on cost-sharing and contractual arrangements. Over time, this decreased flexibility could affect both the affordability and the availability of essential therapies for Oregonians.

Conclusion

In conclusion, generic drugs play a crucial role in shaping the economics of the healthcare system. While generics typically provide a more affordable alternative to brand-name medications, their pricing dynamics can significantly influence insurance premiums and the out-of-pocket expenses consumers face through cost-sharing. Despite the advantages, the generic pharmaceutical market faces persistent increased costs and accessibility issues. Additionally, regulatory and manufacturing hurdles can stifle competition, further complicating this sector's pricing structure. To enhance patient access and affordability, it is important that stakeholders—including manufacturers, pharmacy benefit managers, health insurance payors, and

[102] "Optum subsidiary Nuvaila will offer biosimilars of Stelara, Humira." AISHealth, Sept. 12, 2024. https://aishealth.mmitnetwork.com/blogs/radar-on-specialty-pharmacy/optum-subsidiary-nuvaila-will-offer-biosimilars-of-stelara-humira. Accessed April 4, 2025.

[103] Fein, Adam J., "Five or maybe six reasons the largest PBMs operate group purchasing organizations." Drug Channels, May 24, 2023. https://www.drugchannels.net/2023/05/five-or-maybe-six-reasons-that-largest.html. Accessed April 4, 2025.

policymakers—collaborate to address these challenges, ensuring that people and our healthcare system can realize the benefits of generics and biosimilars. As the complex market becomes better understood, a balanced approach will be essential in promoting the value of generic medications while safeguarding the interest of patients and the healthcare system.

DRAFT

Oregon Prescription Drug
Affordability Board

Prescription Drug Affordability Board

2025 Affordability Review Roadmap

April 16, 2025

2025 Affordability Review (AR) Calendar

Rx Subset list

Board approval

AR reviews 1 | AR reviews 2 | AR reviews 3 | AR reviews 4 | AR reviews 5

Stakeholder RFI
(Request for Information)

Survey distribution → Analysis write-up → Shared w/ Board

Insulin Subset list

Board approval

AR reviews 1 | AR reviews 2 | AR reviews 3 | AR reviews 4

Data call

Rx → Analysis write-up

Insulin → Analysis write-up

Shared w/ Board

Annual Report

Draft Rx Report → **Final Rx Report**

Review Timeline

April

Set-up for Affordability Reviews

- Board consideration of a second review of the subset list in June to determine if any additional drugs should be removed from AR
  - How to review information to remove additional drugs?
    - Can consider sending out survey to board members on what top 10 drugs they want to review and compile list of most requested Rxs to review
- Board discussion on when public comments should be provided for each drug under review
- Board discussion on timing of vote to identify the nine drugs and at least one insulin product

Review Timeline

April

- Discussion for options to vote to identify 9 drugs and at least one insulin product
- When should the Board vote to identify a drug or insulin product that may cause an affordability challenge?
  - Vote on each drug at the meeting it is presented
  - Vote on each drug at the end of all the reviews
- What should be the order of the drug review? Most costly, most costly by utilization, alphabetic, or other?
- Does that board want to select the Rx independently and then discuss the top-rated ones?

Review Timeline

May

- Board meeting dedicated to consumer and supply chain feedback

June

- Review information about each drug on the AR subset list and determine if any drugs can be removed from the list

If no drugs are removed from the current list, the addition of the selected insulin products may lead to a review of approximately eight drugs each month

Review Timeline

July to October

- Review of possibly eight drugs or fewer each month
- Material packets for drugs selected will be discussed
- There will be public comment time for each Rx being reviewed

*(**Board to initially determine if comments will be for each drug or have one public comment time for all drugs and if that time should be at a different time than the public comment time**)*

Review Timeline

November

- Identify nine drugs and a least one insulin product that may create affordability challenges to the Oregon's healthcare system or patient out of pocket costs

December

- Final drug report approved

Oregon Prescription Drug
Affordability Board

Agenda item: Board review and possible vote on data sets and OAR 925-200-0010 criteria to select subset of insulin products for affordability reviews

Click on the **Prescription Drug Affordability Board data web page** to access the data in Excel format. Here are the file names:

- **OREGON PDAB DATA DASHBOARD**
- **Carrier_2023_Preliminary_aggregated_information_v03**
- **Insulin_2023_Preliminary_aggregated_information_based_on_APAC_pharmacy_data_v01**
- **mfr-2023-annual-increase-v01.xlsx**
- **mfr-2023-new-specialty-v01.xlsx**

Location on the PDAB website: **https://dfr.oregon.gov/pdab/Pages/data.aspx**

Help PDAB determine drug affordability!

PDAB would love to hear from Oregonians, including:

- ☑ Patients, caregivers, and advocacy groups
- ☑ Individuals with scientific or medical training (medical providers, professors, scientists)
- ☑ Safety net providers (340B entities)
- ☑ Pharmaceutical manufacturers
- ☑ Pharmacy benefit managers

The Prescription Drug Affordability Board (PDAB) is seeking input from individuals and organizations affected by the prescription drugs selected by the board to review. The surveys aim to collect insight to assess drug affordability.

Go to the PDAB affordability review page or scan the QR code and select the relevant group to fill out and submit a form. Example questions include:

How much did you pay out-of-pocket each month for the prescription drug?

What is the dosage and frequency of the prescription drug you take?

440-5659 (3/25/COM)

On May 21, 2025, at 9 a.m., PDAB will host an online hearing for Oregon consumers about the impact of prescription drug costs under review. You are invited to **sign up and share your experience**.

Oregon Prescription Drug Affordability Board

¡Ayude a PDAB a determinar la asequibilidad de los medicamentos!

A PDAB le encantaría escuchar a los habitantes de Oregon:

- ☑ Pacientes que toman medicamentos recetados
- ☑ Cuidadores de pacientes
- ☑ Grupos de representación

La Junta de Asequibilidad de Medicamentos Recetados (PDAB, por sus siglas en inglés) está buscando la opinión de personas y organizaciones afectadas por los medicamentos recetados seleccionados por la junta para revisión.

Haga clic aquí para completar y enviar la encuesta o escanear el código QR. Algunos ejemplos de preguntas son:

¿Cuánto pagó de su bolsillo cada mes por el medicamento recetado?

¿Cuál es la dosis y la frecuencia del medicamento recetado que toma?

440-5659s (3/25/COM)

El 21 de mayo de 2025, a las 9 a.m., PDAB llevará a cabo una audiencia virtual para consumidores de Oregon acerca del impacto de los costos de los medicamentos recetados que se están revisando. Le invitamos a participar y compartir su historia **pdab@dcbs.oregon.gov**. Se ofrecerá interpretación en español para la audiencia.

Oregon Prescription Drug **Affordability Board**