Oregon Prescription Drug Affordability Board

350 Winter Street NE, Salem, OR 97309-0405 | 971-374-3724 | pdab@dcbs.oregon.gov | dfr.oregon.gov/pdab

Agenda

This is a regular meeting. *Date*: **May 21, 2025** | *Time*: **9 a.m.**
This is a draft agenda and 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 4/16/2025 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
Discussion	**Board discussion on timeline, process, and voting methodology for affordability review determinations**	Cortnee Whitlock	30 minutes
Discussion and vote	**Board review and vote on final generic drug report**	Cortnee Whitlock	20 minutes
Break	The board will take a break	Chair Shelley Bailey	5 minutes

Informational	Public comment period for the list of prescription drugs and insulin products selected for affordability review per ORS 646A.694. The board has designated the main portion of this board meeting to hearing from people impacted by or benefiting from these drugs. Board members may have follow-up questions for the speakers. Each speaker will have 3 minutes. The board chair has the discretion to extend a speaker's time. The board will hear from: • Patients and caregivers • Individuals with scientific or medical background • Pharmaceutical manufacturers • Advocacy groups • Safety net providers • Pharmacy benefit managers.	Chair Shelley Bailey	90 minutes
Informational	Announcements	Chair Shelley Bailey	2 minutes
Vote	Adjournment	Chair Shelley Bailey	2 minutes

Next meeting
June 18, 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. American sign language and Spanish interpretation will be available during the May 21 board meeting.

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.

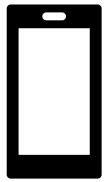
Open and closed sessions
All board meetings except executive sessions are open to the public. Pursuant to ORS 192.660, executive sessions are closed to everyone but news media and staff. No action will be taken in the executive session.

How to listen to Spanish language interpretation

Windows | macOS | Web client

1. In your meeting/webinar controls, click **Interpretation**
2. Click Spanish language.
3. (Optional) To hear the interpreted language only, click Mute Original Audio.

Note: You must join the meeting audio through your computer audio/VoIP. You cannot listen to language interpretation if you use the dial-in or call me phone audio features.



Android | iOS

1. In your meeting controls, tap the ellipses ....
2. Tap Language **Interpretation**.
3. Tap Spanish language.
4. (Optional) Tap the toggle to Mute Original Audio.
5. Click Done.

Note: You cannot listen to language interpretation if you use the dial-in or call me phone audio features.

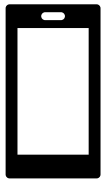
For help, please email pdab@dcbs.oregon.gov or call 971-374-3724.

Cómo escuchar la interpretación del idioma español

Windows | macOS | Cliente web

1. En los controles de la reunión/seminario web, haga clic en Interpretación.
2. Haga clic en idioma español.
3. (Opcional) Para escuchar solo el idioma interpretado, haga clic en silenciar audio original.

Nota: Debe unirse al audio de la reunión a través de su computadora audio/VolP. No puede escuchar la interpretación de idiomas si utiliza las funciones de audio de marcación o de llamada telefónica.



Android | iOS

1. En los controles de la reunión, toque los puntos suspensivos ....
2. Toca Interpretación de idiomas.
3. Toca idioma español.
4. (Opcional) Toca el interruptor para silenciar el audio original.
5. Haga clic en Listo.

Nota: No puede escuchar la interpretación de idiomas si utiliza las funciones de audio de marcación o de llamada telefónica.

Para obtener ayuda, envíe un correo electrónico a pdab@dcbs.oregon.gov o llame al 971-374-3724.

Oregon Prescription Drug Affordability Board

Oregon Prescription Drug Affordability Board (PDAB) Regular Meeting
Wednesday, April 16, 2025
Draft Minutes

Web link to the meeting video: https://youtu.be/nuhImgNKmOg
Web link to the meeting materials: https://dfr.oregon.gov/pdab/Documents/20250416-PDAB-document-package.pdf

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Call to order and roll call: Chair Shelley Bailey called the meeting to order at 9:03 a.m. and roll was called.
Board members present: Chair Shelley Bailey, Vice Chair Amy Burns, Dan Hartung, Lauri Hoagland (arrived shortly after roll call), Robert Judge, Dan Kennedy, John Murray
Absent: Chris Laman

Declaration of conflict of interest and meetings with entities or individuals related to board activities: John Murray, Robert Judge, and Dan Hartung made statements. Chair Bailey announced the board has an updated the conflict of interest form that will be sent to board members. It is also posted on the **PDAB website**. View at video minute **00:00:43**.

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 **00:03:50**.

MOTION to approve the March 19, 2025, minutes
Board Vote:
Yes: Dan Hartung, Lauri Hoagland, Dan Kennedy, John Murray, Vice Chair Amy Burns, Chair Shelley Bailey
No: None
Abstain: Robert Judge
Absent: Chris Laman
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. He announced the resignation of board member Robert Judge. A **vacancy announcement** is posted on the PDAB website and candidates may **apply** through June 6, 2025. View the video at minute **00:05:27**.

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 40-42** of the agenda materials. View the video at minute **00:10:35**.

Public comment: Chair Bailey called on the people who signed up in advance to speak to the board: Nathan Sauser, patient; Lorren Sandt, Caring Ambassadors Program; Michiel Peters, Global Coalition on Aging; Liisa Bozinovic, Oregon Bioscience Association; and Dharia McGrew, PhRMA. The board received 12 written comments, which are posted on the **PDAB website**. View the speakers at video minute **00:17:49**.

Executive session for legal advice pursuant to ORS 192.660(2)(f): The board adjourned to executive session. Due to technical difficulties, the session ended early and the board returned to open session. Chair Bailey said the board would return to executive session later in the meeting. View the announcement at video minute **00:32:31**. Note: The recording was off briefly during roll call when a quorum was established but the recording came back on before the first agenda item after the executive session.

Board review of draft generic drug report: Cortnee Whitlock, senior policy analyst, led the board in a discussion about the generic drug report. View the draft report on **Pages 26-45** of the agenda materials. View at video minute **00:33:41**.

Return to executive session for legal advice pursuant to ORS 192.660(2)(f): The board adjourned to executive session. No decisions were made in executive session. The board returned to open session, took a five-minute break, returned and took a roll call to confirm a quorum. Chair Bailey announced the meeting will be extended by 15 minutes to 12:15 p.m. View the announcements at **01:03:47**.

Board discussion on timeline, process, and voting methodology for affordability review determinations: Cortnee Whitlock led the board members in a discussion about the affordability review process, including the PDAB surveys seeking feedback from individuals and groups. The discussion about voting methodology will continue in next month's meeting. View the slides on **Pages 30-36** of the agenda materials. View the discussion at video minute **01:07:19**.

Board review of data sets and OAR 925-200-0010 criteria to select subset of insulin for affordability reviews: Cortnee Whitlock led board members in a discussion about the insulin data sets, based on criteria in **OAR 925-200-0010**. View the **data dashboard** on the **prescription drug data** page. The board voted on a subset list of insulin products for affordability review. The list is included in the minutes and posted on the **PDAB affordability review page**. View the discussion and vote beginning at video minute **01:31:58.**

MOTION to approve the insulin subset list for affordability reviews as discussed by the board today.
Motion made by Dan Hartung with a second by John Murray.
Board vote:
Yes: Dan Hartung, Lauri Hoagland, Robert Judge, Dan Kennedy, John Murray, Vice Chair Amy Burns, Chair Shelley Bailey

No: None
Absent for the vote: Chris Laman
Motion passed 7-0

Announcements: Chair Bailey announced the next meeting will be May 21, 2025, at 9 a.m. Chair Bailey also invited patients, caregivers and others to participate in the PDAB surveys. These surveys are intended to collect information from people and organizations affected by the cost of prescription drugs. The surveys are posted on the **PDAB website** and is offered in English and Spanish. Please have feedback submitted by April 30.

Additionally, Chair Bailey encouraged patients, caregivers, and individuals with scientific and medical training to sign up to provide testimony at the May 21 board meeting about the **prescription drugs** and **insulin products** selected for review. The May meeting will provide the board with the opportunity to hear from people impacted by, or benefiting from, these drugs. Regular board business will still occur, but will be limited. **Sign up to speak** at the May meeting. View the announcement at video minute **02:11:06**.

Adjournment: Chair Bailey adjourned the meeting at 12:11 p.m. with all board members in agreement. View at minute **02:12:13**.

Subset list of 2023 insulin products for affordability reviews, approved by the board April 16, 2025

NDC	Proprietary Name	Non-Proprietary Name*	Insulin Subclass	Brand and Generic
00002771559	Basaglar KwikPen	Insulin Glargine	Long Acting Insulin	Brand
00002821405	Basaglar Tempo Pen	Insulin Glargine	Long Acting Insulin	Brand
49502039380	Insulin Glargine-yfgn	Insulin Glargine	Long Acting Insulin	Generic
49502039475	Insulin Glargine-yfgn	Insulin Glargine	Long Acting Insulin	Generic
00088222033	Lantus	Insulin Glargine	Long Acting Insulin	Brand
00088221905	Lantus SoloStar	Insulin Glargine	Long Acting Insulin	Brand
00002898005	Rezvoglar KwikPen	Insulin Glargine	Long Acting Insulin	Brand
49502025080	Semglee (yfgn)	Insulin Glargine	Long Acting Insulin	Brand
49502025175	Semglee (yfgn)	Insulin Glargine	Long Acting Insulin	Brand
00024587102	Toujeo Max SoloStar	Insulin Glargine	Long Acting Insulin	Brand
00024586903	Toujeo SoloStar	Insulin Glargine	Long Acting Insulin	Brand

DRAFT

Oregon Prescription Drug Affordability Board

Prescription Drug Affordability Board

2025 Affordability Review Roadmap

May 21, 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 → Share with board → Survey open for drugs under review

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

Share with board

Annual Report

Draft Rx Report → **Final Rx Report**

Review Timeline

May

Set-up for cost 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?
- Board discussion on when public comments should be provided for each drug under review
- What should be the order of the drug review? Most costly, most costly by utilization, alphabetic, or other?

Review Timeline

May

- When does the board want to review insulin products?
- 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

Review Timeline

May

- Board meeting will provide opportunity to hear from consumers and industry

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 regular public comment time on the agenda.**)*

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

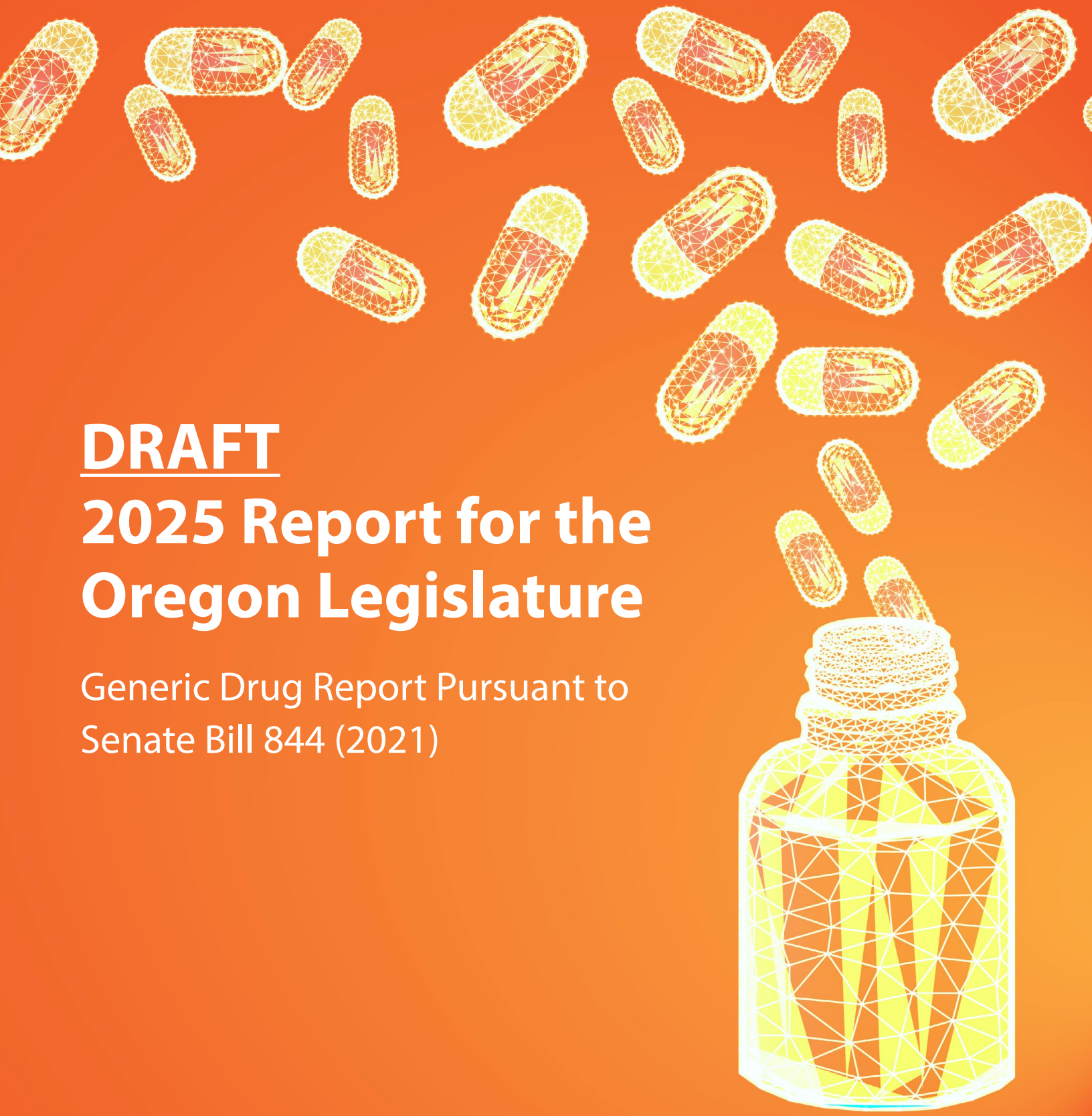
December

- Final drug report approved

DRAFT

2025 Report for the Oregon Legislature

Generic Drug Report Pursuant to Senate Bill 844 (2021)



Oregon Prescription Drug
Affordability Board

Acknowledgments

This report is a work product of the Oregon Prescription Drug Affordability Board.

Board members

Shelley Bailey, chair

Dr. Amy Burns, vice chair

Dr. Dan Hartung

Lauri Hoagland

Robert Judge

Dan Kennedy

Dr. Christopher Laman

John Murray

Prescription Drug Affordability Board staff:

Ralph Magrish, executive director

Cortnee Whitlock, program and policy analyst

Stephen Kooyman, project manager

Melissa Stiles, administrative specialist

Heather Doyle, data analyst

Pei Choo, data researcher

Other contributors who supported the development of this report

Jane Horvath, Horvath Health Policy

Jason Horton, public information officer, DCBS

Michael Plett, communications officer/editor, DCBS

Jessica Knecht, lead designer, DCBS

For more information:

Prescription Drug Affordability Board
350 Winter St. NE
Salem, OR 97309-0405
971-374-3724
pdab@dcbs.oregon.gov
dfr.oregon.gov/pdab

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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 health care 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 health care 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 Oregon Legislature 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.

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 U.S. Food and Drug Administration (FDA).[2]

Biosimilars are biological products that are highly similar to and have no clinically meaningful differences from an already approved reference

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

2 "Overview & Basics." U.S. Food and Drug Administration, April 21, 2023. https://www.fda.gov/drugs/generic-drugs/overview-basics. Accessed April 7, 2025.

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

3 "Biosimilars basics for patients." U.S. Food and 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.

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.

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 drugs. In fact, the FDA estimates that the projected savings from generic drugs approved in 2022 alone were about $18.9 billion.[13] Overall, the annual savings from generics and biosimilars, including generics approved before 2021, was more than $408 billion in 2022.[14] These statistics emphasize the significant savings for the health care system and for patients through generics and biosimilars. Currently, there are more than 16,000 generic drugs available.[15]

The flourishing generic market in the U.S. is largely a result of the Hatch-Waxman Act of 1984 which allowed for the approval of generic formulations on the basis of pharmacokinetic equivalence studies (abbreviated new drug application) rather than additional phase 3 clinical trials for each new generic product. This regulatory change markedly reduced the evidentiary burden and development costs for generic manufacturers and ushered in a large increase in generic products into the U.S. market. An analogous regulatory framework for biosimilars was passed as part of the Affordable Care Act titled the Biologics Price Competition and Innovations Act of 2009 (BPCIA).[16] However, the development and penetration of biosimilars in the U.S. still lags other countries for a variety of reasons.[17] The European Union created the legal framework and regulatory approval pathways for biosimilars in 2005, with the first biosimilar approved in 2006; whereas the FDA did not approve its first biosimilar until 2015, nearly six years after the legislation.[18]

This slower progress in the U.S. 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 biologics in the U.S. maintain larger market shares for longer periods compared to Europe.[21]

In addition to longer times for drugs to get approved, 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

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 and Drug Administration. https://www.fda.gov/media/182435/download?attachment

14 "The U.S. Generic & Biosimilar Medicines Savings Report." Association for Accessible Medicines, September 2024. https://accessiblemeds.org/wp-content/uploads/2025/01/AAM-2024-Generic-Biosimilar-Medicines-Savings-Report.pdf. Accessed May 8, 2025.

15 How Are Generics Affecting Drug Prices? | Cato Institute

16 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://www.mdpi.com/1999-4923/13/1/48

17 Drug Price Competition and Patent Term Restoration Act of 1984, S.2748, 98th Congress (1983-1984). http://www.congress.gov/bill/98th-congress/senate-bill/2784. Accessed on March 25, 2025.

18 Ibid.

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.

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] Finally, substitution of biosimilars when available is not as straightforward as small molecule generic products. In most states, pharmacists can substitute an FDA-approved generic for a branded drug prescription without obtaining permission from the prescriber. However, state laws are not as permissive for biosimilars and has led to slower penetration for applicable biologics.

Trends and issues

The generic and biosimilar 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.[24] 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.[25] 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 58 first-time generic drugs, fostering competition and potentially lowering prices.[26] Additionally, the expedited approval process for generics over the years provides more opportunities, although patent restrictions still pose challenges for many applications.[27]

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

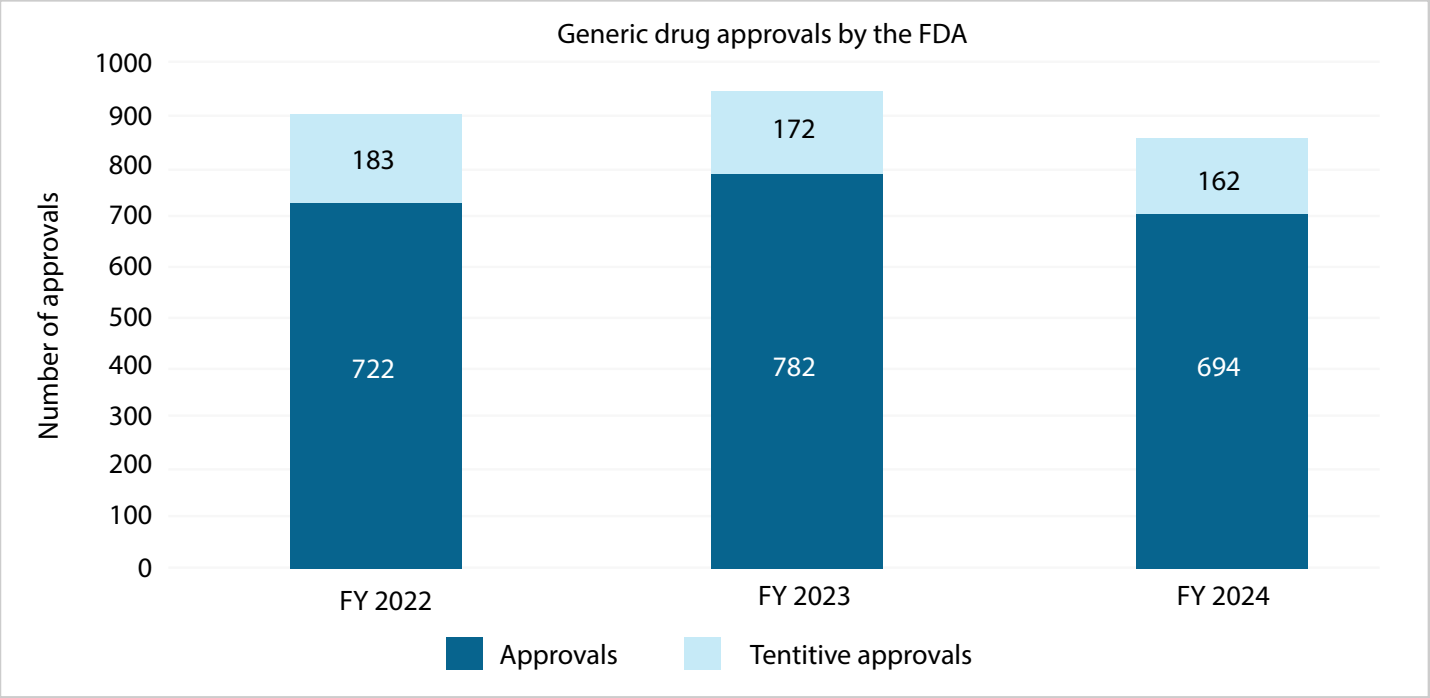
24 Office of Generic Drugs 2022 Annual Report Ensuring high-quality, affordable generic drugs are available to the American public." U.S. Food & Drug Administration, Office of Generic Drugs, January 2023. https://www.fda.gov/media/165435/download?attachment. Accessed April 8, 2025.

25 "Office of Generic Drugs 2023 Annual Report: Ensuring high-quality, safe, and effective generic drugs are available to the American public." U.S. Food and Drug Administration, Office of Generic Drugs, February 2024. https://www.fda.gov/media/176440/download?attachment. Accessed April 8, 2025.

26 "First generic drug approvals." U.S. Food and Drug Administration, Center for Drug Evaluation and Research, Nov. 25, 2024. https://www.fda.gov/drugs/drug-and-biologic-approval-and-ind-activity-reports/first-generic-drug-approvals.

27 "Number of US FDA ANDA approvals per Fiscal Year." ASPE Office of the Assistant Secretary for Planning and Evaluation. https://aspe.hhs.gov/number-us-fda-anda-approvals-fiscal-year.

Table 1: Generic drug approvals by the FDA from 2022 to 2024[28,29,30]



Health authorities, including insurers and government programs, are increasingly

promoting generic prescriptions in an attempt to control health care costs, as brand-name drugs generally cost 30 percent to 60 percent more than their generic counterparts.[31] It is estimated that first-time generics can save the U.S. health care system roughly $5.2 billion within a year of their approval.[32] This preference is reinforced as several states mandate pharmacists to substitute brand names with generics when available, easing financial burdens on consumers and the health care system.[33]

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.[34] By clarifying regulatory requirements and providing application

28 "Generic Drugs Program Activities Report - FY 2022 Monthly Performance." U.S. Food and 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.

29 "Generic Drugs Program Activities Report - FY 2023 Monthly Performance." U.S. Food and 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.

30 "Generic Drugs Program Activities Report - FY 2024 Monthly Performance." U.S. Food and 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.

31 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.

32 The U.S. Generic & Biosimilar Medicines Savings Report." Association for Accessible Medicines, September 2024. https://accessiblemeds.org/wp-content/uploads/2025/01/AAM-2024-Generic-Biosimilar-Medicines-Savings-Report.pdf. Accessed May 8, 2025.

33 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.

34 Biosimilars Action Plan. U.S. Food and Drug Administration, Center for Drug Evaluation and Research. https://www.fda.gov/drugs/biosimilars/biosimilars-action-plan.

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.[35] 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.[36]

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 (FTC) 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.[37] 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.[38]

Limited profitability for generics, can also reduce market entry. Lower profit margins, coupled with fierce competition, deter new manufacturers and perpetuate a duopoly, restricting options for both the health care system and consumers. Consumer attitudes toward generic drugs further complicate the situation. Health care provider prescribing patterns greatly influence drug utilization, which can be shaped by brand drug marketing and perceived efficacy concerns.[39]

In addition to prescribing habits of providers, generic and biosimilar usage is also shaped by insurance plan design, controlling whether brand-name biologics or biosimilar alternatives are placed on preferred tiers, which can affect out-of-pocket costs for Oregonians. As insurance coverage rules influence provider prescribing patterns and patient expenses, Oregonians are directly affected by insurance plan design.[40] Although attitudes toward generics are improving, some health care professionals and patients remain hesitant to fully embrace them.[41,42]

Generic drug prices on a year-to-year basis

Annually, Oregon insurance companies 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, PDAB staff identified nine generic drugs that contributed to health care system

35 Purple Book Database of Licensed Biological Products. U.S. Food and Drug Administration. (n.d.). https://purplebooksearch.fda.gov/about.

36 US SB659 | 2019-2020 | 116th congress. Congress.gov. (n.d.). https://www.congress.gov/bill/116th-congress/senate-bill/659/text.

37 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.

38 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.

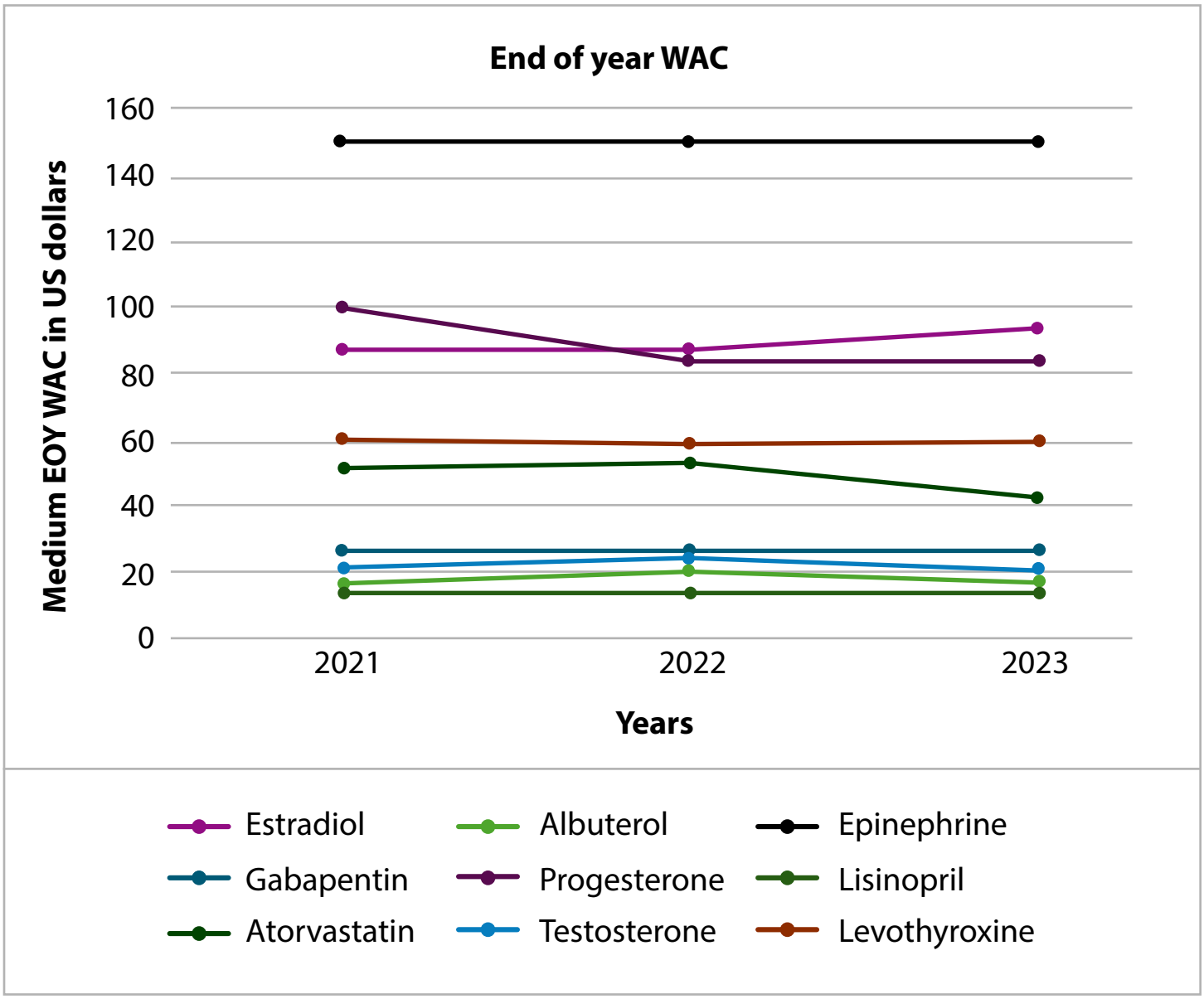
39 Howard, J. N., Harris, I., Frank, G., Kiptanui, Z., Qian, J., & Hansen, R. (2018). Influencers of generic drug utilization: A systematic review. Research in social & administrative pharmacy: RSAP, 14(7), 619–627. https://doi.org/10.1016/j.sapharm.2017.08.001.

40 Allen, Arthur. "The Market for Biosimilars Is Funky. The Industry Thinks PBMs Are To Blame." KFF Health News, Dec. 19, 2023. https://kffhealthnews.org/news/article/health-202-biosimilar-drugs-market-humira/.

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

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



costs in Oregon. The drugs were identified from the preliminary list that contained drugs on five or more most-costly, most-prescribed, and greatest-increase lists across all health plans in Oregon. The selection was further narrowed to include only generics and drugs that have therapeutic equivalents or biosimilars, resulting in the nine generic drugs examined. This means they were the top contributors for cost of generics. This section and Figure 1 discuss the history of the insurance company reporting and supplemental data for these drugs. Staff analysts used the 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 in a shortage in May 2023, which was expected to continue until July 2024.[44] Figure 1 illustrates that the timing of these generic drug 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 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 injections 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, despite noted drug shortages and legislative actions, the PDAB analysis showed generic drug pricing trends remained relatively stable. Note, these are pre-rebate prices. Actual costs may be varied and be affected by rebates and volume discounts.

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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

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

45 Bill S1614 ScaAca(2R) Session 2022-2023. New Jersey Legislature. https://www.njleg.state.nj.us/bill-search/2022/S1614.

46 Biryukov, Nikita. "Price caps on insulin, inhalers, EpiPens take effect." New Jersey Monitor, Jan. 1, 2025. https://newjerseymonitor.com/briefs/price-caps-on-insulin-inhalers-epipens-take-effect/.

47 "Release: Rep. Howard highlights new co-pay cap on life-saving medications taking effect in January." Rep. Michael Howard, Minnesota Legislature, Dec. 27, 2024. https://www.house.mn.gov/members/profile/news/15518/39829.

48 "House passes Williams bill to require insurance companies to cover EpiPens for Delawareans of all ages." Delaware House Democrats, March 14, 2023. https://housedems.delaware.gov/2023/03/14/house-passes-williams-bill-to-require-insurance-companies-to-cover-epipens-for-delawareans-of-all-ages/.

49 House Bill 23-1002. State Of Colorado, June 7, 2023. https://leg.colorado.gov/sites/default/files/2023a_1002_signed.pdf.

50 "Assembly Oks bill requiring no EpiPen coverage." State of Rhode Island General Assembly, Press Releases, June 16, 2023. https://www.rilegislature.gov/pressrelease/_layouts/RIL.PressRelease.ListStructure/Forms/DisplayForm.aspx?List=c8baae31-3c10-431c-8dcd-9dbbe21ce3e9&ID=373770.

51 "Levothyroxine Sodium Injection." Current Drug Shortages, American Society of Health-System Pharmacists, Feb. 6, 2025. https://www.ashp.org/drug-shortages/current-shortages/drug-shortage-detail.aspx?id=804&loginreturnUrl=SSOCheckOnly.

Generic drug pricing effects 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 who 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 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: "Pharmacy Benefit Managers." National Association of Insurance Commissioners, April 11, 2022. https://content.naic.org/cipr-topics/pharmacy-benefit-managers.

- **Deductibles**: The fixed amount that a policyholder must pay for health care services before their insurance coverage commences.
- **Copayments (copays)**: 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, the health care system can mitigate some of the financial pressures associated with prescription drug expenditures, ultimately benefiting both consumers and insurers.

52 "Pharmacy Benefit Managers." National Association of Insurance Commissioners, April 11, 2022. https://content.naic.org/insurance-topics/pharmacy-benefit-managers.

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.

Generic drug shortages and effects 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 attention-deficit/hyperactivity disorder (ADHD).

The 2024 IV solution shortage

On Sept. 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 U.S.[55] In a letter dated Oct. 7, 2024, to President Joe Biden, the American Hospital Association (AHA) reported substantial shortages of these solutions and highlighted the effect 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," said 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 Oct. 11, 2024, and the Centers for Disease Control and Prevention (CDC) issued a health advisory to health care providers regarding the supply disruption and its potential effect 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 conserving and managing the limited supply. One of the recommendations was to use an 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 canceled 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 health care providers were experiencing shortages of IV fluids following Hurricane Helen.[60]

ADHD medication supply

Since at least 2022, an ongoing shortage of stimulant drugs, which includes generic and branded versions of amphetamine/dextroamphetamine (Adderall),

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.

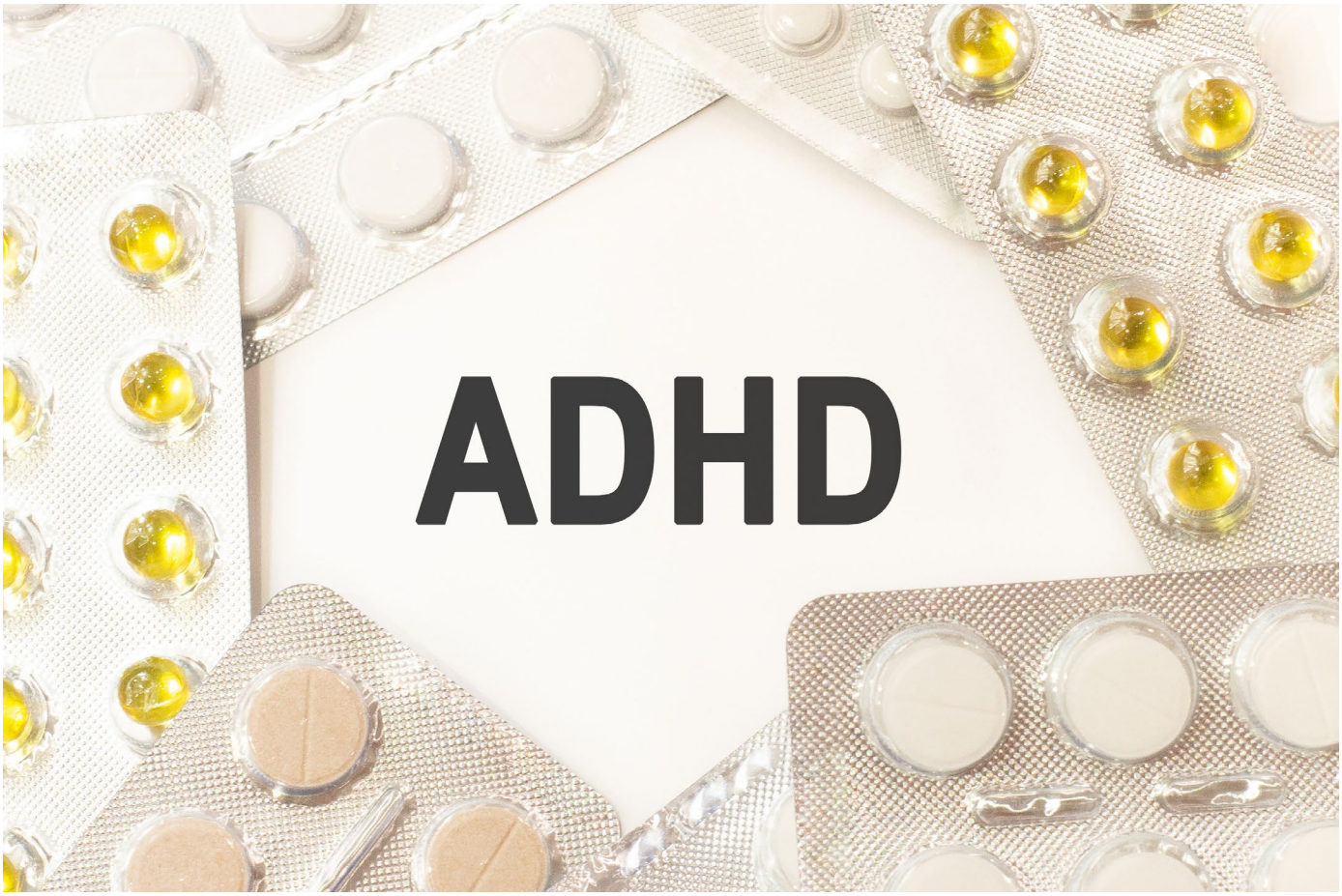
56 Ibid.

57 irappil, 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 isruptions 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, 2025.4

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.



methylphenidate (Ritalin), and lisdexampfetamine (Vyvanse), has seriously affected access for patients with ADHD. Shortages of stimulant medications are likely attributable to several factors related to an imbalance between growing demand and inadequate supply.

Although stimulants are not the only treatment for ADHD, they are widely considered the most consistently effective of available therapies. While rising demand for stimulants predates the COVID-19 pandemic, the expansion of telemedicine that occurred during the public health emergency greatly increased ADHD treatment, especially among adults.[61] Between 2016 and 2020, the percentage of individuals aged 5-64 receiving a stimulant medication increased by 1.4 percent per year, jumping to 7.9 percent per year after 2020.

The inability of supply chains to respond to this surging demand is likely multifactorial but exacerbated by production constraints imposed by the Drug Enforcement Agency (DEA), which heavily regulates distribution of these drugs at all points in the supply chain. Stimulants such as amphetamine and methylphenidate are Schedule II controlled substances and subject to significant regulatory oversight by manufacturers, distributors, and pharmacies. In particular, the DEA sets production quotas of stimulants and some have argued that the agency has been slow to modify quotas to meet increased demand. However, the DEA has asserted that manufacturers have not increased production sufficiently.[62] Additionally, some manufacturers have

61 Danielson ML, Bohm MK, Newsome K, et al. Trends in Stimulant Prescription Fills Among Commercially Insured Children and Adults — United States, 2016–2021. MMWR Morbidity Mortal Weekly Rep 2023;72:327–332. DOI: http://dx.doi.org/10.15585/mmwr.mm7213a1.

62 Milgram, Anne. Letter about stimulant medication shortages. U.S. Department of Justice, Drug Enforcement Administration. https://www.dea.gov/sites/default/files/2023-11/Quota-Shortages%20Letter.pdf.

cited challenges in sourcing raw materials needed for production.[63]

Another contributing factor to challenges related to accessing generic ADHD medications is the intensified regulatory focus arising from the opioid crisis – most notably following lawsuits and settlements involving Purdue Pharma and wholesalers. Because ADHD drugs are Schedule II controlled substances, they fall under suspicious order monitoring requirements outlined in 21 CFR § 1301.74(b), prompting wholesalers to adopt conservative thresholds – sometimes known as "controlled-substance chargeback programs" – that limit how much medication pharmacies can acquire at one time. While the chargeback mechanism originally served as a billing practice to reconcile discounted pricing between wholesalers and manufacturers), it now functions as a stringent control tool in response to tighter scrutiny from the DEA. These measures mitigate legal risks but often mean pharmacies cannot maintain sufficient stocks on controlled substances, including ADHD medications.[64]

Apart from the major inconvenience for patients trying to identify pharmacies with these medications in stock, stimulant shortages might lead to other more serious adverse health effects. The U.S. Centers for Disease Control and Prevention has 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.[65]

Sen. Ron Wyden, D-Oregon, described the effect 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," Wyden said. 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]

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63 Ault, Alicia. "No end in sight for national ADHD drug shortage." Medscape, March 12, 2024. https://www.medscape.com/viewarticle/no-end-sight-national-adhd-drug-shortage-2024a10004me?form=fpf.

64 Statement of the National Association of Chain Drug Stores for United States Senate Caucus on International Narcotics Control." Hearing on Improving Management of the Controlled Substances Quota Process, May 5, 2025. https://www.nacds.org/pdfs/Narcotics_Control_Statement_GAO_Report_DEA.pdf.

65 Ibid.

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.

Generic drug pricing effect on Medicare and Medicaid spending

President Donald Trump's 2025 executive order on health care released April 15, 2025, intends to promote a more market-driven approach to health care, focusing on increasing market-driven reforms, price transparency, and efforts to shift pharmaceutical manufacturing back to the U.S. Key goals including regulatory rollbacks, promotion of generic drug competition, and introduction of international reference pricing models to reduce Medicare spending.

The executive order outlined that within 60 days of the order, the secretary of Health and Human Services will propose guidance on the Medicare Drug Price Negotiation Program for 2028, focusing on transparency, selecting high-cost drugs for negotiation, and minimizing adverse effects on pharmaceutical innovation.[68] Within 180 days, the assistant to the president for domestic policy, in coordination with relevant officials, will provide recommendations to stabilize and reduce Medicare Part D premiums.[69] Furthermore, the secretary will work with Congress to modify the Medicare Drug Price Negotiation Program to ensure that small molecule drugs are treated equitably with biologics, this ending the distortion that hinders investment into vital medications.

The pricing of generic drugs is a factor influencing the annual expenditures of state Medicaid programs.[70] Generally, generic medications are considered 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.[71]

However, the effect of generic drug prices can vary widely depending on factors such as market competition and the availability of specific generics.[72] In areas with limited competition, generic drug prices may remain higher than expected, leading to increased spending for state programs.[73] Furthermore, if states are unable to negotiate effectively or implement strategies to prioritize the

68 "Lowering drug prices by once again putting Americans first." Executive Orders, The White House, President Donald J. Trump, April 15, 2025. https://www.whitehouse.gov/presidential-actions/2025/04/lowering-drug-prices-by-once-again-putting-americans-first/.

69 Ibid

70 "Factors Influencing Affordability." Making Medicines Affordable, National Library of Medicine Bookshelf. https://www.ncbi.nlm.nih.gov/books/NBK493090/.

71 Straka, Robert J. "Potential Clinical and Economic Impact of Switching Branded Medications to Generics." National Library of Medicine, PubMed, May 24, 2017. https://pubmed.ncbi.nlm.nih.gov/26099048/.

72 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.

73 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.

use of generics, the potential savings may not be fully realized.[74]

Generic drug prices affecting Oregon annual spend in Medicaid

Oregon State University College of Pharmacy Drug Use Research and Management (DURM) Program collaborates with the Oregon Health Authority (OHA) to compile and publish quarterly comprehensive Medicaid drug utilization data. The partnership aims to analyze and report on medication use patterns across the state's Medicaid programs and provide insights into pharmaceutical expenditures.

The quarterly reports provide monthly rolling averages of pharmacy-paid claims, allowing for monitoring of drug utilization trends. In the fourth quarter of the 2024 Federal Fiscal Year - specifically from July 2023 through June of 2024 – the utilization report provided finding regarding generic drug costs and their utilization percentage.

According to Table 2, which uses information from the fourth quarter report, the average gross amount paid per claim for generic multisource drugs with rebates not subtracted was $24.73.[75]

In contrast, mental health carve-out drugs had a lower average gross amount of $17.47. In comparison, fee-for-service (FFS) physical health drugs had a higher average payment of $111.87 per claim, which is a result of inclusion of claims for tribal members at the all-inclusive rebate that was $719 per claim during the reporting period.[76]

Furthermore, the report provided statistics regarding drug utilization rates, also shown in Table 2. The monthly average for generic drug prescriptions reached 91.1 percent, with the utilization rate for mental health carve-out medications at 97.5 percent. Conversely, the utilization rate for FFS physical health drugs was lower at 85.3 percent, which reflects the handful of drugs where the FFS program required pharmacies to dispense the brand version of select drugs, instead of the generic alternative.[77] As a result of the significant rebates with brand versions, it resulted in the net cost of them to be substantially less than the generic alternative.

Table 2: 2024 fourth-quarter DUR information on generic drugs gross amount paid per claim and percent utilizations[78]

	Gross amount paid per claim	Generic drug use percentage
Generic drugs	$24.73	91.1%
Mental health carve-out drugs	$17.41	97.5%
FFS Physical Health drugs	$111.87*	85.3%**
Encounter physical health drugs	$23.19	89.9%

74 Psotka, Mitchell A., PhD, et al. "Challenges and Potential Improvements to Patient Access to Pharmaceuticals: Examples from cardiology." Circulation, AHA ASA Jounrals, Aug. 24, 2020. https://www.ahajournals.org/doi/10.1161/CIRCULATIONAHA.119.044976.

75 "Pharmacy utilization summary report: July 2023-June 2024. "Oregon State University, Drug Use Research & Management Program." https://www.orpdl.org/durm/reports/utilization/2024/DUR_Utilization_2024_Q4.pdf.

76 Ibid.

77 Ibid.

78 Ibid.

Generic multisource drugs and Medicaid

A generic multisource drug is a prescription medication that is produced by at least two different manufacturers, each making the same active ingredient(s) in the same dosage form and strength as the original brand-name product. By definition, these manufacturers' products have been deemed therapeutically equivalent (i.e., substitutable) by the FDA.[79] In other words, they must meet the same quality, purity, and efficacy standards as the brand drug, but do not carry a patent or exclusivity preventing competition. Because numerous manufacturers can produce the same medication once patents and exclusivities expire, multisource drugs typically face market competition that helps lower prices. 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 health care system.[80]

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.[81] The use of generic drugs can lead to substantial savings for state Medicaid programs, thereby allowing for the allocation of resources to other critical health care services.[82]

Moreover, the promotion of generic drugs aligns with the broader health care initiative aimed at curbing prescription drug costs nationwide. The FDA supports the production and use of generics to enhance market competition and ultimately drive down prices.[83] This is particularly beneficial for Medicaid patients who may have limited options.

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79 eCFR : 42 CFR 447.502. Code of Federal Regulations, Definitions. https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-C/part-447/subpart-I/section-447.502.

80 "Medicaid Program; Multiple Source Drug Definition: A Rule by the Centers for Medicare & Medicaid Services on March 14, 2008." Federal Register. https://www.federalregister.gov/documents/2008/03/14/08-1022/medicaid-program-multiple-source-drug-definition.

81 "Medicaid and the Children's Health Insurance Program (CHIP) Coverage." Centers for Medicare & Medicaid Services, 2021. https://www.cms.gov.

82 "Generic Drug Prices and Market Dynamics." United States Government Accountability Office, 2019. https://www.gao.gov.

83 "Generic Drugs." Food and Drug Administration, March 13, 2025. https://www.fda.gov/drugs/buying-using-medicine-safely/generic-drugs.

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.[84,85] 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.[86] 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.

Federal law addresses three types of importation of finished prescription drugs that are ready for use:[87]

- Reimportation: Manufacturer brings in a drug produced outside the U.S. (known as "ex-U.S.") 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.[88]

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

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 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.

86 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.

87 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.

88 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. See also Popken, Ben. "What did corporate America do with that tax break? Buy record amounts of its own stock." NBC News, June 26, 2018. https://www.nbcnews.com/business/economy/what-did-corporate-america-do-tax-break-buy-record-amounts-n886621.

importation program to proceed.[89] 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 U.S.-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 10 years ago that around 500 U.S. employers had designed their employee pharmacy benefits to encourage personal importation from Canada.[90]

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 affect 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.[91] It is challenging to predict how individual consumers will respond when the cost of their imported product increases.

Currently, there are 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 41.5 million.

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.[92]

The effect on generic drugs

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

89 ME, VT, NH, CO, VA, NM, FL, ME.

90 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.

91 Ibid.

92 CT, IL, MS, NY, RI, TN, TX, WV, and WI

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.[93]

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.

If there is limited competition that allows manufacturers to raise prices when fewer generics are in the marketplace, that could contribute to drug shortages, as a limited number of suppliers make the supply chain more susceptible to disruptions. Drugs with few competitors are considered to be more prone to shortages. In these instances, the demand for that generic drug can surge while supply remains low, driving prices higher.[94]

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.[95] 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.[96] Furthermore, tariffs could be lifted by a future administration, making it difficult for manufacturers to decide about relocation.

Potential effect on pharmacies and medication access

Tariffs on imported pharmaceutical products and APIs may have an impact on Oregon pharmacies and, by extension, Oregon patients. When wholesalers incur additional tariff-related costs, it is anticipated that higher acquisition costs will be passed on to pharmacies, thereby increasing pharmacies' acquisition prices for medications However, PBMs are not legally required to update reimbursement rates at the same pace. This market force may leave Oregon pharmacies to absorb the mismatch between rapidly increasing purchase costs and static reimbursement amounts.[97] As a result, many pharmacies – particularly smaller or independent ones – may face increased losses on certain medications,

which can threaten their ability to dispense drugs and maintain necessary services in their communities.

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93 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.

94 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

95 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.

96 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.

97 Cheema, Muhammad, Pharm D. "PBM Price Negotiations Have Unintended Consequences for Independent Pharmacies." Pharmacy Times, Nov. 27, 2024. https://www.pharmacytimes.com/view/pbm-price-negotiations-have-unintended-consequences-for-independent-pharmacies.

The effect of Medicaid and Medicare price increase penalties

There are several ways a company manages the effect of the tariffs: by absorbing the costs; passing costs along to the consumer through higher prices; or reducing purchaser discounts and 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.[98] 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.

98 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.

Understanding the role of GPOs in the Oregon generic drug market

Disclaimer: The group purchasing organizations (GPOs) mentioned – Zinc, Ascent, Walgreens Boots Alliance Development, 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.

GPOs negotiate drug prices on behalf of health care providers, such as hospitals and pharmacies. By combining the buying power of various health care providers, GPOs negotiate better prices and terms with pharmaceutical manufacturers and distributors on their behalf.[99] This involves aggregating purchases from different provider types to secure favorable prices and terms. GPOs and their effect 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. However, smaller independent pharmacies in Oregon may struggle to access similar discounts if not aligned with a powerful GPO and their wholesaler relationships, or if GPO-negotiated pricing structures favor large-scale distribution networks.

Domestic GPOs and their competitors

The largest generic drug GPOs in the U.S. are Red Oak Sourcing (a joint venture equally owned by CVS Health and Cardinal Health), ClarusOne (a joint venture involving Walgreens Boots Alliance and other major entities), Ascent Health (affiliated with Express Scripts under the Cigna umbrella) and Zinc (owned by CVS Health) and McKesson OneStop (a purchasing group that includes McKesson, Rite Aid, and Walmart). These GPOs aggregate the purchasing power of large buyers like wholesalers, pharmacy chains, health care systems, and PBMs to negotiate prices and terms with drug manufacturers, significantly influencing the pricing and availability of generic drugs in the U.S. By consolidating demand and shaping procurement decisions, these GPOs play a crucial role in directing the flow of generic medications through the supply chain and determining which drugs are purchased in bulk and at what price. 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. Because of their size and influence on the supply chain, 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, their consolidation of negotiating power and the resulting downward pressure on generic drug prices can destabilize the generic drug supply chain by squeezing wholesale prices and eroding manufacturer profits.

International GPOs

Zinc is an international GPO that collaborates with global drug manufacturers to provide generics medications to health care organizations, including PBMs and wholesalers. Proponents argue that international GPOs can exploit broader supply networks, potentially lowering costs through larger-scale negotiations.[100] However, skeptics warn that these structures might reduce transparency if the terms of global contracts are not clearly disclosed. For pharmacies in Oregon, the effect 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 operates globally and negotiates prices and supply deals for generics.[101]

99 "At a Glance: Key Differences Between Healthcare Group Purchasing Organizations (GPOs) & Pharmacy Benefit Managers (PBMs)", Healthcare Supply Chain Association, 2018. https://www.supplychainassociation.org/wp-content/uploads/2019/01/HSCA-GPO-and-PBM-Comparison.pdf. Accessed April 18, 2025.

100 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.

101 "Common misconceptions about PBMs." Evernorth Health Services, 2025. https://www.evernorth.com/esfacts/myths-facts. Accessed April 4, 2025.

Conclusion

In conclusion, generic drugs play a crucial role in shaping the economics of the health care 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 and biosimilar market faces several challenges to maintain itself as a critical cost counterweight to escalating branded and biologic drug prices. 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 policymakers – collaborate to address these challenges, ensuring that people and our health care 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 health care system.