

2024 Report for the Oregon Legislature

Generic Drug Report Pursuant to
Senate Bill 844 (2021)



Oregon Prescription Drug
Affordability Board

Board members

Shelley Bailey, chair
Dr. Amy Burns, vice chair
Dr. Dan Hartung
Robert Judge
Dr. Christopher Laman
John Murray
Akil Patterson

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

Acknowledgements

This report was prepared by the following Prescription Drug Affordability Board staff:

Ralph Magrish, executive director
Cortnee Whitlock, program and policy analyst
Stephen Kooyman, project manager
Melissa Stiles, administrative specialist

Other contributors who supported the development of this report:

Program On Regulation, Therapeutics, And Law (PORTAL),
Harvard Medical School and Brigham & Women's Hospital
Jason Horton, public information officer, DCBS
Michael Plett, communications officer/editor, DCBS
Jessica Knecht, lead designer, DCBS

Table of contents

| | |
|--|-----------|
| Background | 4 |
| Authorized generics | 5 |
| Manufacturer strategies to prevent/delay generic or biosimilar competition .. | 6 |
| Pay-for-delay settlements | 6 |
| Citizen petitions | 7 |
| Product hopping | 7 |
| Limited supply agreements | 8 |
| Drug tier placement..... | 8 |
| Generic- and biosimilar-related litigation and legislation | 9 |
| Generic and biosimilar drug pricing | 10 |
| Generics in other countries | 12 |
| Generic formulary placement | 13 |
| Generic drug shortages | 14 |
| Generic and biosimilar substitution | 16 |
| Conclusion | 17 |

Background



What are prescription drugs and what role do generics play? Prescription drugs are intended for the diagnosis, cure, mitigation, treatment, or prevention of disease.¹ Generics are created to be the same as already-marketed, brand-name prescription drugs in dosage, safety, strength, performance, and use, working the same way and providing the same clinical benefit.² However, generic drugs usually cost less for patients and the Oregon health care system. In 2021, the use of generics and biosimilars in Oregon brought about a savings of \$951 million in the Medicare program.³

The work of the Prescription Drug Affordability Board (PDAB) is to consider prescription drugs that may create affordability challenges for Oregonians and the state's health care system. If medications

are not affordable, Oregonians may be unable to take them as prescribed, resulting in poor health outcomes. When the Oregon Legislature created PDAB in 2021 through Senate Bill 844, it asked the board to study generic drugs and their affordability for patients. The board has prepared two generic drug reports for the Legislature so far. In 2022, the board's report focused on the supply chain, drug shortages, and the need to reform patent laws to encourage the use of generics. The 2023 report looked at the cost savings from biosimilars, which work the same as biologic drugs. This 2024 generic drug report evaluates the use of generic drugs to lower the cost of medications for consumers and the health care system.

¹ Prescription Drugs and Over-the-Counter (ORC) Drugs: Questions and Answers. *U.S. Food & Drug Administration*. Nov. 13, 2017. <https://www.fda.gov/drugs/frequently-asked-questions-popular-topics/prescription-drugs-and-over-counter-otc-drugs-questions-and-answers>.

² Generic Drugs: Questions & Answers. *U.S. Food & Drug Administration*. March 16, 2021. <https://www.fda.gov/drugs/frequently-asked-questions-popular-topics/generic-drugs-questions-answers#q1>.

³ Generic and Biosimilar Medicines Save Oregon Patients Billions. *Biosimilars Council*, a division of *Association for Accessible Medicines*. <https://accessiblemeds.org/sites/default/files/2023-01/AAM-2022-generic-biosimilar-savings-Oregon.pdf>.

Authorized generics

Authorized generics refer to drugs sold by brand-name drug manufacturers or their licensees under generic labels. Although authorized generics constitute a small portion of filled prescriptions, brand manufacturers often use authorized generics to maintain high drug prices that can undermine generic competition.⁴ There are three primary reasons why brand manufacturers use authorized generics:

1. To maintain market share after generic drugs have entered the market.
2. As a bargaining chip in pay-for-delay settlement deals with generic manufacturers before the entry of independent generic drugs, thereby delaying generic competition.
3. To allay public concern and criticisms concerning the high prices of brand-name drugs.⁵

A recent study of entacapone, a medication used for Parkinson's disease, showed that the presence of multiple authorized generics can lead to increased spending when there is limited independent generic competition. Almatica Pharma, the manufacturer of brand-name entacapone (Comtan) successfully delayed effective competition by signing settlement agreements with several generic manufacturers. These generic manufacturers produced and sold authorized generics instead of independent generics, which undermined the ability of generic competition to lower the drug's price.⁶



⁴ Rome BN, Gunter SJ, Kesselheim AS. Market dynamics of authorized generics in Medicaid from 2014 to 2020. *Health Services Research*. 2023;58(4):953-959. doi:[10/gs3g4m](https://doi.org/10/gs3g4m)

⁵ Dusetzina SB, Keating NL, Huskamp HA. Authorized Generics and Their Evolving Role in Prescription Drug Pricing and Access. *JAMA Internal Medicine*. 2021;181(4):423-424. doi:[10.1001/jamainternmed.2020.8450](https://doi.org/10.1001/jamainternmed.2020.8450)

⁶ Rome BN, Egilman AC, Patel NG, Kesselheim AS. Using Multiple Authorized Generics to Maintain High Prices: The Example of Entacapone. *Value Health*. 2023;26(3):370-377. doi:[10.1016/j.jval.2022.08.013](https://doi.org/10.1016/j.jval.2022.08.013)

Manufacturer strategies to prevent/delay generic or biosimilar competition

Manufacturers use various tactics to prevent generics from entering the market and delay competition. These tactics include “pay-for-delay” settlements, misuse of citizen petitions, product hopping, secondary patenting, limited supply agreements, and patenting Food and Drug Administration (FDA)-mandated risk evaluation and mitigation strategies (REMS).⁷

Pay-for-delay settlements

Delaying the introduction of new generics to the market can significantly influence health care costs, particularly for Medicaid programs. According to a study published in *Health Affairs*, the cost of delays in generic drug entry, primarily due to patent litigation, resulted in around \$761 million in excess spending by state programs.⁸ From 2010 to 2016, 69 brand-name drugs were expected to lose market exclusivity. Of these, 45 percent either did not face competition from generics by the end of the study period or had the

introduction of generics delayed by more than a quarter.⁹

Pay-for-delay agreements occur when brand-name pharmaceutical companies pay generic competitors to delay the entry of lower-cost generic drugs into the market. These agreements arise during patent litigation settlements between brand-name and generic drug manufacturers.¹⁰

This works by brand-name pharmaceutical companies delaying generic competition by paying a generic competitor to hold its competing product off the market for a certain period of time. These agreements are often considered a win-win for the companies involved: brand-name pharmaceutical prices remain high, and both the brand and generic drug share the benefits of the brand’s monopoly profit. However, consumers lose because they miss out on the significant cost savings that generic drugs offer. Generic medications can be as much as 90 percent less expensive than their brand-name counterparts. For example, a brand-name drug costing \$300 per month might have a generic version available for as little as \$30 per month.¹¹

The influence on consumer affordability is substantial. Pay-for-delay agreements are estimated to cost American consumers \$3.5 billion per year, which adds up to \$35 billion over the next 10 years.¹² These anticompetitive deals effectively block other generic drug competition, preventing consumers from accessing more affordable alternatives. The Federal Trade Commission (FTC)



⁷ Vokinger KN, Kesselheim AS, Avorn J, Sarpatwari A. Strategies That Delay Market Entry of Generic Drugs. *JAMA Internal Medicine*. 2017;177(11):1665-1669. doi:10.1001/jamainternmed.2017.4650

⁸ Dave CV, Sinha MS, Beall RF, Kesselheim AS. Estimating the Cost of Delayed Generic Drug Entry to Medicaid. *Health Affairs (Millwood)*. 2020;39(6):1011-1017. doi:10.1377/hlthaff.2019.00673

⁹ Ibid.

¹⁰ Pay-for-delay: When Drug Companies Agree Not to Compete. *Federal Trade Commission*. June 20, 2023. <https://www.ftc.gov/news-events/topics/competition-enforcement/pay-delay>

¹¹ Ibid.

¹² Ibid.

has been actively investigating and taking enforcement actions against pay-for-delay agreements to deter their use. The FTC recommends that the U.S. Congress pass legislation to protect consumers from such anticompetitive practices as these agreements significantly postpone consumer savings from lower generic drug prices, ultimately affecting affordability and access to essential medications.

Citizen petitions

A 2020 study revealed that misuse of the FDA's citizen petition process by brand-name manufacturers resulted in a financial burden of \$1.9 billion to the government and American taxpayers.¹³ This process is intended to provide individuals and advocates an avenue to shape FDA decision-making. Yet, it has been observed that pharmaceutical companies sometimes misuse citizen petitions to delay the entry of generic drugs into the market. Even a delay of 90 days can generate hundreds of millions of dollars in revenue for brand-name drug companies, making the filing of these petitions worthwhile despite their spurious nature.¹⁴

Product hopping

Manufacturers also have been known to engage in product hopping, a tactic in which a newer, ostensibly improved version of a drug is released as the original product nears generic competition. Patients are then encouraged to switch to the newer version, often



generating increased profits for the manufacturer. An analysis found that product hopping for just five drugs prevented generic competition and cost the U.S. health care system \$4.7 billion annually for the past 20 years.¹⁵

For example, in the early 2000s, as generic competition for the drug TriCor was close to coming to market, the manufacturer slightly reformulated the drug preventing the launch of any generic options. The manufacturer engaged in multiple reformulations between 2000 and 2008 resulting in nearly \$1.4 billion in annual U.S. sales.¹⁶ Other drugs observed engaging in product hopping include Prilosec, Suboxone, Doryx, and Namenda.

Regulatory reforms and policies should be implemented so manufacturers are prevented from product hopping and generics can enter markets in a timely manner.¹⁷

¹³ Feldman R. The Burden on Society from Eleventh-Hour “Citizen Petitions” Filed to Slow Generic Drugs. *Maryland Law Review Online*. 2020; 79:1. <https://digitalcommons.law.umaryland.edu/cgi/viewcontent.cgi?article=1061&context=endnotes>

¹⁴ Ibid.

¹⁵ Brand Drug Product Hopping Costs US \$4.6B Annually. *PharmaNews Intelligence*. Sept. 17, 2020; <https://pharmanewsintel.com/news/brand-drug-product-hopping-costs-us-4.7b-annually>

¹⁶ Downing N, Ross J, Jackevicius C, Krumholz H. Avoidance of generic competition by Abbott Laboratories’ fenofibrate franchise. *NIH Archives of Internal Medicine*. 2021; 172 (9): 724–30. <https://pubmed.ncbi.nlm.nih.gov/22493409/>.

¹⁷ Wouters OJ, Feldman WB, Tu SS. Product Hopping in the Drug Industry - Lessons from Albuterol. *New England Journal of Medicine*. 2022;387(13):1153-1156. doi:10.1056/NEJMp2208613

Limited supply agreements

Like generic drugs, biosimilars face challenges upon entering the market, including various delay tactics from manufacturers. From 2016 to 2019, the FDA approved five biosimilars for the popular drug adalimumab (Humira); however, patent litigation delayed the market entry of these biosimilars until 2023. It is estimated that if adalimumab biosimilars had been launched upon approval, biosimilar competition would have saved Medicare \$2.19 billion between 2016 and 2019, highlighting the importance of timely biosimilar entry.¹⁸

Despite biosimilars entering the market in 2023, Humira, manufactured by AbbVie, continues to dominate the market due to the release of an updated version in 2018. This has complicated biosimilar competition because biosimilar versions of adalimumab need to mimic changes made by the brand-name manufacturer to be considered interchangeable with Humira.

Drug tier placement

When prescription drug formularies place biologics and biosimilars on the same tier, it can create market issues. In a recent example, one biosimilar manufacturer attempted a two-price strategy to improve formulary coverage. This led to pharmacy benefit managers preferring the higher priced biosimilar for payer coverage formularies, which potentially negatively effects the ability of Humira biosimilars to generate savings through competition.¹⁹ Indeed, recent analyses suggest that biosimilar competition has yet to translate into lower out-of-pocket costs for patients using biologics.²⁰

One obstacle to timely biosimilar competition is the results of litigation. The Biologics Price Competition

and Innovation Act (BPCIA), established in 2010 as part of the Affordable Care Act, aimed to create an abbreviated approval pathway for biosimilars. However, according to an article published in Health Affairs, the BPCIA has faced two main challenges that limit biosimilar competition: (1) noncompliance from biosimilar manufacturers with the litigation process outlined in the BPCIA biosimilar approval pathway; and (2) the enforcement of a large number of patents by biologic manufacturers.²¹ As a result, patent infringement litigation often delays biosimilar entry for years after biosimilars receive FDA approval. Although there are differences between the biosimilar approval pathway and their reference product, generally biosimilars are priced lower. Lowered drug prices can lead to significant cost savings for the health care system through better drug tier placement and potentially reduce patient costs. Additional information on cost savings from biosimilars can be found in the 2023 generic drug report for the Oregon Legislature.²²



¹⁸ Lee CC, Najafzadeh M, Kesselheim AS, Sarpatwari A. Cost to Medicare of Delayed Adalimumab Biosimilar Availability. *Clinical Pharmacology & Therapeutics*. 2021;110(4):1050-1056. doi:10.1002/cpt.2322

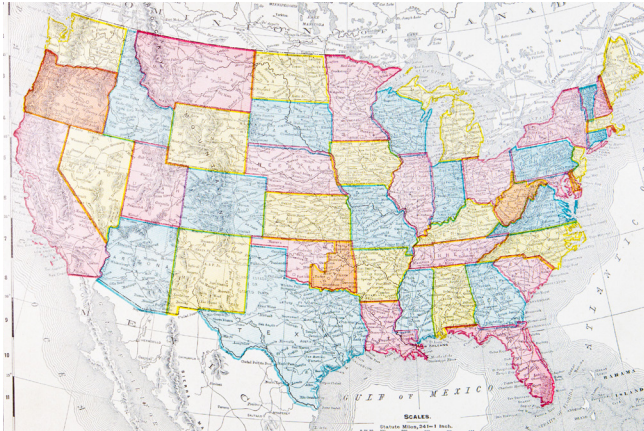
¹⁹ Rome BN, Kesselheim AS. Biosimilar Competition for Humira Is Here: Signs of Hope Despite Early Hiccups. *Arthritis Rheumatol*. 2023;75(8):1325-1327. doi:10/gs3g33

²⁰ Feng K, Russo M, Maini L, Kesselheim AS, Rome BN. Patient Out-of-Pocket Costs for Biologic Drugs After Biosimilar Competition. *JAMA Health Forum*. 2024;5(3):e235429. doi:10.1001/jamahealthforum.2023.5429

²¹ Van de Wiele VL, Kesselheim AS, Sarpatwari A. Barriers to US Biosimilar Market Growth: Lessons from Biosimilar Patent Litigation. *Health Affairs (Millwood)*. 2021;40(8):1198-1205. doi:10.1377/hlthaff.2020.02484

²² 2023 Report for the Oregon Legislature. *Oregon Prescription Drug Affordability Board*. June 2023. <https://dfr.oregon.gov/pdab/Documents/reports/PDAB-Generic-Drug-Report-2023.pdf>

Generic- and biosimilar-related litigation and legislation



The Hatch-Waxman Act of 1984 is the primary federal law in the U.S. that governs how generic drugs are brought to the market. It provides some significant provisions, such as enticing generics to challenge a brand-name drug patent with a lucrative 180-day exclusivity for being the first to come to market. Additionally, it allows generics to show bioequivalence to a reference brand drug without undergoing expensive and duplicative clinical trials. It also enables patent infringement litigation as soon as generics file for approval from the FDA. This helps determine whether the brand manufacturer's patents prevent generic entry and whether the generic does not have to enter "at risk."²³ Despite federal laws supporting prompt generic market entry, litigation concerning trade agreements and limiting "skinny labeling," in which generic manufacturers can enter the market only for drug indications that no longer have market exclusivity, have further delayed generic entry and

produced excess costs in the U.S. health care system.²⁴ This same issue affects biosimilar drugs. An assessment was performed on the frequency of biosimilars marketed with skinny labels from 2015 to 2021, finding that the use of skinny labels led to a median of 2.5 years of earlier biosimilar competition through 2021. The investigators estimate this saved Medicare \$1.5 billion through 2020, emphasizing the importance of skinny labels to ensure timely biosimilar competition for high-cost biologics.²⁵

Recently, a U.S. judge of the Eastern District of Pennsylvania approved a settlement in an antitrust class action brought by direct pharmaceutical purchasers. The plaintiffs alleged that Sun Pharmaceutical Industries Ltd., Taro Pharmaceutical Industries Ltd., and others participated in a scheme to fix generic drug prices. The approved settlement amounted to \$85 million.²⁶ However, it is important to note that on another front, a federal district court judge in Pennsylvania ruled that states were not entitled to a share of the profits that generic manufacturers allegedly made from their price-fixing scheme.²⁷ The case encompasses potential class action lawsuits related to price fixing of generic drugs in violation of the Sherman Act and state antitrust laws. Currently, there are claims concerning 18 drugs against several pharmaceutical manufacturers, and the scope has been expanded to include claims brought by 40 states through their attorneys general.²⁸

²³ The Kesselheim AS, Darrow JJ. Hatch-Waxman Turns 30: Do We Need a Re-Designed Approach for the Modern Era? *Yale Journal of Health Policy, Law, and Ethics*. 2015;15(2):293-347. <http://hdl.handle.net/20.500.13051/5929>

²⁴ Walsh BS, Bloomfield D, Kesselheim AS. A Court Decision on "Skinny Labeling": Another Challenge for Less Expensive Drugs. *JAMA*. 2021;326(14):1371-1372. doi:10.1001/jama.2021.0006

²⁵ Egilman AC, Van de Wiele VL, Rome BN, et al. Frequency of Approval and Marketing of Biosimilars with a Skinny Label and Associated Medicare Savings. *JAMA Internal Medicine*. 2023;183(1):82-84. doi:10.1001/jamainternmed.2022.5419

²⁶ Generic pharmaceutical drugs direct purchasers \$85M class action settlement. *Top Class Actions*. Feb. 16, 2024. <https://topclassactions.com/lawsuit-settlements/prescription/generic-pharmaceutical-drugs-direct-purchasers-85m-class-action-settlement/>.

²⁷ Dunleavy K. Generic drugmakers win one, lose one in sweeping price-fixing case involving 49 states, 20 companies. *Fierce Pharmacy*. June 9, 2022. <https://www.fiercepharma.com/pharma/generic-drugmakers-win-one-lose-one-price-fixing-sweeping-case-involving-49-states-20>.

²⁸ MDL 2724 In Re: Generic Pharmaceuticals Pricing Antitrust Litigation. *United States District Court Eastern District of Pennsylvania*. 2016. <https://www.paed.uscourts.gov/mdl/mdl-2724-re-generic-pharmaceuticals-pricing-antitrust-litigation>

Generic and biosimilar drug pricing



Although generic drug prices are meant to offset the high initial prices of brand-name drugs, rising prices of generic products are a cause for concern. A study using Medicaid State Drug Utilization Data (2012-2018) found that price spikes for generic drugs are associated with injectable products, fewer manufacturers, and shortages.³¹ While fewer price spikes seem to be occurring over time, the costs can still be substantial.

The high prices of some off-patent drugs are influenced by various market dynamics and manufacturer behaviors, including market consolidation, drug shortages, and anticompetitive practices among generic drug manufacturers. Articles reviewed highlight recent trends in the regulatory approval, manufacturing, and pricing of generic drugs in the U.S. This includes the influence of competition on generic drug prices, strategies that manufacturers use to delay generic entry, such as pay-for-delay or reverse-payment settlements, and the role of the FDA in prioritizing review of generic drug applications for markets with few manufacturers.²⁹ Suggested potential policy solutions to address these issues include greater antitrust enforcement, reducing barriers to generic drug entry, and novel solutions to minimize drug shortages, such as drug importation and nonprofit drug manufacturing.³⁰

A study assessed whether generic competition will be an effective mechanism for high-priced specialty drugs, using commercial claims data to investigate treatments for chronic myeloid leukemia. The analysis found that, between 2001 and 2016, the list price of imatinib, a lifesaving anticancer drug, more than doubled. Generic imatinib was highly anticipated to provide more cost savings compared to the high price of the brand. Imatinib, an effective cancer drug, was first approved in 2003, but it had low patient adherence due to its costs. The first generic imatinib entered the market in 2016, but the launch price was only 8 percent lower than that of the brand-name drug.³² Using data from Medicare Part D, a study was done to estimate spending on imatinib to see if this changed upon generic entry. While the acquisition cost for imatinib fell, the markup cost increased substantially, and Medicare

²⁹ Gupta R, Shah ND, Ross JS. Generic Drugs in the United States: Policies to Address Pricing and Competition. *Clinical Pharmacology & Therapeutics*. 2018;105(2):329-337. doi:[10.1002/cpt.1314](https://doi.org/10.1002/cpt.1314)

³⁰ Tessema FA, Kesselheim AS, Sinha MS. Generic but Expensive: Why Prices Can Remain High for Off-Patent Drugs. *Hastings Law Journal*. 2020;71:1019

³¹ Patel AN, Kesselheim AS, Rome BN. Frequency of Generic Drug Price Spikes and Impact on Medicaid Spending. *Health Affairs (Millwood)*. 2021;40(5):779-785. doi:[10.1377/hlthaff.2020.02020](https://doi.org/10.1377/hlthaff.2020.02020)

³² Cole AL, Dusetzina SB. Generic Price Competition for Specialty Drugs: Too Little, Too Late? *Health Affairs*. 2018;37(5):738-742. doi:[10.1377/hlthaff.2017.1684](https://doi.org/10.1377/hlthaff.2017.1684)

beneficiaries faced out-of-pocket costs of \$80 to \$400 per fill.³³ This indicates that barriers to entry may be significant, and few firms entered the generic market to sell the drug, leading to minimal price reduction.

Despite the expected post-Hatch-Waxman trends, high point-of-sale prices have led to more costs for Medicare Part D patients. Another article highlighted the complex financial dynamics of the drug supply chain, including rebates offered by drug manufacturers to incentivize expensive drugs and the spread pricing method adopted by pharmacy benefit managers to generate profits and benefit from higher drug prices. However, implementing the Inflation Reduction Act of 2022 should lead to annual out-of-pocket costs of \$2,000 for Part D beneficiaries starting in 2025. Furthermore, the Pharmacy Benefit Manager Transparency Act of 2023 will require pharmacy benefit managers to report their fees, leading to more transparency and accountability.³⁴

Lastly, a study examining the association between generic drug prices and market competition showed nearly half of the 1,120 generic drugs examined exist in a baseline duopoly-like state. Generic drugs with low competition were associated with greater price increases (63.8 percent) than drugs with high competition (9.7 percent).³⁵ Reviews showed several potential reasons for this trend, including the lack of a financial incentive in smaller markets and consolidation among generic drug manufacturers. Those with low competition were associated with greater price increases than those with high competition.

Overall, studies show the complexities of the U.S. drug market, highlighting the need for greater competition and policy solutions to ensure affordable access to necessary medications.

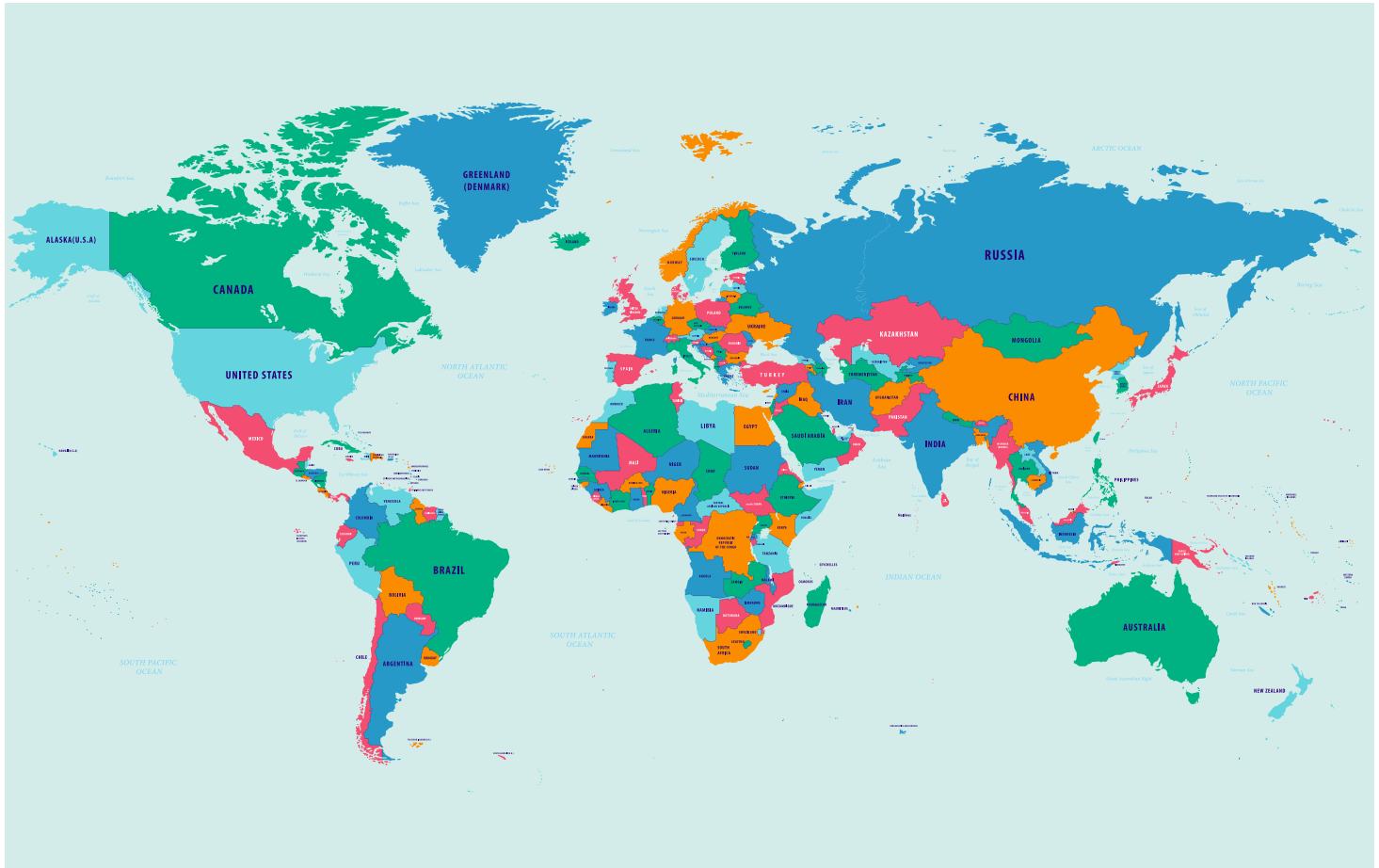


³³ Dusetzina SB. Medicare Part D Payments for Generic Imatinib From 2017 to 2023. *JAMA Internal Medicine*. 2024;184(1):104-105. doi:[10.1001/jamainternmed.2023.3932](https://doi.org/10.1001/jamainternmed.2023.3932)

³⁴ Crosson FJ, Kesselheim AS. Why Some Patients Overpay for Specialty Generic Drugs. *JAMA Internal Medicine*. Published online November 20, 2023. doi:[10.1001/jamainternmed.2023.6071](https://doi.org/10.1001/jamainternmed.2023.6071)

³⁵ Dave CV, Kesselheim AS, Fox ER, Qiu P, Hartzema A. High Generic Drug Prices and Market Competition: A Retrospective Cohort Study. *Annual Internal Medicine*. 2017;167(3):145-151. doi:[10.7326/M16-1432](https://doi.org/10.7326/M16-1432)

Generics in other countries



It is widely known that Americans pay more for prescription drugs than people in other developed countries. A 2017 study compared the prices of generic drugs in the U.S. with 13 European countries. The study found that generic drug prices varied significantly among European countries and were generally higher than in the U.S. However, the U.S. has recently seen sharp price increases for some generic products. The study also noted that uptake of generic prescriptions is slower in Europe than in the U.S. The report highlights differences between U.S. regulatory and pricing strategies and those used in Europe, where internal reference pricing and

tendering (when payers buy generic drugs in bulk from the manufacturers that offer the best prices) for generic drugs are more common.³⁶

Another report compared U.S. drug prices to those of 32 comparable Organization of Economic Cooperation and Development (OECD) countries. The report found that while U.S. prices for brand-name drugs were more than four times higher than in other countries, average prices for unbranded generics were 33 percent lower in the U.S. than in peer countries.³⁷ This finding emphasizes the effect of robust competition on price.

³⁶ Wouters OJ, Kanavos PG, McKee M. Comparing Generic Drug Markets in Europe and the United States: Prices, Volumes, and Spending. *The Milbank Quarterly*. 2017;95(3):554-601. doi:10.1111/1468-0009.12279

³⁷ Mulcahy AW, Schwam D, Lovejoy SL. International Prescription Drug Price Comparisons: Estimates Using 2022 Data. *RAND Corporation*; 2024. https://www.rand.org/pubs/research_reports/RRA788-3.html

Generic formulary placement

Formulary decisions for generic drugs can vary across health plans and pharmacy benefit managers, particularly between commercial and government plans (e.g., Medicare and Medicaid). A formulary outlines which drugs are covered and any restrictions such as prior authorization requirements, quantity limits, or step therapy prerequisites. Typically, health plans only pay for drugs listed on their formulary, and most plans require copays. Most drug formularies are organized into tiers, with Tier 1 usually covering generics and having the lowest copay cost. The higher the tier number, the higher the out-of-pocket costs for patients with the goal of directing the patient to the lowest cost. Concerns have been raised that some generic drugs may be providing less favorable formulary placement over their branded counterparts, as brand-name manufacturers offer more substantial rebates or discounts on their products to payers.

A study conducted in 2021 analyzed the plan coverage of brand-name drugs and their associated generics across Medicare Part D plans (2013-2019). The results indicated that shifting from a lower to a high-cost-sharing tier could increase out-of-pocket patient costs.³⁸ Even if generic drugs have favorable formulary placement, branded drugs may be placed on a better coverage tier due to rebates or other price concessions manufacturers offer. Findings from a study done on Medicare Part D found that 72 percent of Part D formularies placed at least one branded drug on a lower cost-sharing tier than its generic.³⁹ In comparison, 30 percent of formularies had at least one branded drug with fewer utilization management controls than its associated generic.⁴⁰

The study's author highlighted rebates' role in this brand-over-generic placement and how such practices can increase patient out-of-pocket costs and overall health care spending.



³⁸ Dusetzina S, Juliette Cubanski P, Andrew W. Roberts P, et al. Trends in Medicare Part D Coverage of Generics With Equivalent Brand-Name Drugs. *The American Journal of Managed Care*. 2021;27. doi:[10.37765/ajmc.2021.88701](https://doi.org/10.37765/ajmc.2021.88701)

³⁹ Socal MP, Bai G, Anderson GF. Favorable Formulary Placement of Branded Drugs in Medicare Prescription Drug Plans When Generics Are Available. *JAMA Internal Medicine*. 2019;179(6):832-833. doi:[10.1001/jamainternmed.2018.7824](https://doi.org/10.1001/jamainternmed.2018.7824)

⁴⁰ Ibid.

Generic drug shortages

Drug shortages are a widespread problem that affects certain medications more frequently than others. Multiple causes of these shortages exist, with significant economic and clinical implications. An article addressing the causes and effects of drug shortages proposes several strategies countries can implement to manage present and prevent future shortages. These strategies include addressing the current shortage, making operational improvements to identify possible shortages in advance, making policy changes, and enhancing education and training for health care professionals on managing these shortages.⁴¹



A literature review of more than 400 papers conducted between 2001 and 2019 studied drug shortages. Most of the documents described the shortages and their negative effects, while fewer papers discussed strategies to prevent or respond to the shortages. The review recommends that more attention be given to working toward long-term policy solutions to address this issue.⁴²

Policy solutions aimed at addressing drug shortages must target the root cause of the shortage. Policymakers have three levers at their disposal to tackle the issue:

- Reducing the likelihood of a shortage
- Minimizing the size or scope of a shortage
- Mitigating the effect of a shortage⁴³

An effective policy solution should incorporate all three levers and create a framework for existing

legislative proposals on drug shortages. This framework should assess the strengths and weaknesses of each proposal, such as hospital billing changes, transparency, and domestic manufacturing.

Several factors have been shown to increase the risk of generic drug shortages. A study assessed the association between generic shortages, price, market competition, and market size, finding that only the price was associated with a risk of shortage.⁴⁴ Low-priced generic drugs were found to be more likely to experience shortages, while shortages were associated with a modest increase in drug prices.

Another research letter examined the influence of shortages on generic drug prices, finding that prices for generic drugs in shortage between

⁴¹ Shukar S, Zahoor F, Hayat K, et al. Drug Shortage: Causes, Impact, and Mitigation Strategies. *Frontiers in Pharmacology*. 2021;12. doi:10.3389/fphar.2021.693426

⁴² Tucker EL, Cao Y, Fox ER, Sweet BV. The Drug Shortage Era: A Scoping Review of the Literature 2001–2019. *Clinical Pharmacology & Therapeutics*. 2020;108(6):1150-1155. doi:10.1002/cpt.1934

⁴³ Wosińska ME. Drug Shortages: A Guide to Policy Solutions. *Brookings Institution*. Published March 14, 2024. <https://www.brookings.edu/articles/drug-shortages-a-guide-to-policy-solutions/>

⁴⁴ Dave CV, Pawar A, Fox ER, Brill G, Kesselheim AS. Predictors of Drug Shortages and Association with Generic Drug Prices: A Retrospective Cohort Study. *Value Health*. 2018;21(11):1286-1290. doi:10.1016/j.jval.2018.04.1826



2015 and 2016 increased more than twice as quickly (7.3 percent before the shortage, 16.0 percent after the shortage) in the absence of a shortage.⁴⁵ This phenomenon was more pronounced among drugs with three or fewer manufacturers.

Drug shortages particularly influence generic drugs. A study published in *Value in Health* in 2018 found that generic low-priced medicines were more likely to experience shortages, while shortages were associated with a modest increase in drug prices. Another analysis of a cohort of 77 drugs losing market exclusivity between 2010 and 2013 found that oral small-molecule drugs and drugs with large markets tended to have more stable prices and competition.⁴⁶ On the other hand, smaller markets and injectable drugs had fewer market entrants, higher exit rates, greater price instability, and an increased risk of shortages.⁴⁷

Potential drivers of generic drug shortages include weak market incentives, supply chain complexities, and inadequate incentives for high-

quality manufacturing practices, which are considered primary issues that lead to shortages.⁴⁸ Increased consolidation among group purchasing organizations and offshoring of supply chain entities can create further market imbalances. Researchers propose involving the FDA and payers in strategies to incentivize high-quality generic drug production to remedy these dynamics.⁴⁹



⁴⁵ Hernandez I, Sampathkumar S, Good CB, Kesselheim AS, Shrank WH. Changes in Drug Pricing After Drug Shortages in the United States. *Annals of Internal Medicine*. 2019;170(1):74-76. doi:[10.7326/M18-1137](https://doi.org/10.7326/M18-1137)

⁴⁶ Frank RG, McGuire TG, Nason I. The Evolution of Supply and Demand in Markets for Generic Drugs. *The Milbank Quarterly*. 2021;99(3):828-852. doi:[10.1111/1468-0009.12517](https://doi.org/10.1111/1468-0009.12517)

⁴⁷ Ibid.

⁴⁸ Hernandez I, Hershey TB, Donohue JM. Drug Shortages in the United States: Are Some Prices Too Low? *JAMA*. 2020;323(9):819-820. doi:[10.1001/jama.2019.20504](https://doi.org/10.1001/jama.2019.20504)

⁴⁹ Ibid.

Generic and biosimilar substitution

State laws surrounding generic substitution can significantly affect the adoption and use of generic drugs. According to a 2022 Value in Health report, patients in states that require consent or pharmacist notification to substitute with generics tend to use generics less, while mandating versus permitting generic substitution and protecting pharmacists from liability had no significant effects.⁵⁰

In Oregon, pharmacists may substitute a drug product with a generic that is the same in strength, quantity, dose, dosage form, and therapeutic equivalency. State law requires pharmacists to post a sign at the counter that reads, “This pharmacy may be able to substitute a less expensive drug which is therapeutically equivalent to the one prescribed by your doctor unless you do not approve.” Doctors may also specify that no substitutions be allowed.⁵¹

Another study surveyed state-level generic drug substitution regulations that dictate how pharmacists can substitute prescriptions for

brand-name drugs with lower-cost generics or biosimilars. The survey found that there is significant variation in these laws across states, with only one-third of states requiring that pharmacists automatically substitute branded prescriptions with an FDA-approved generic. Additionally, 15 percent of states require patient consent for substitution.⁵² When examining substitution of biologics with an interchangeable biosimilar, 45 states had more stringent requirements, such as mandatory physician notification. This highlights the potential barriers to biosimilar uptake in the U.S. In Oregon, pharmacies can substitute a biologic for an FDA-approved biosimilar under the following conditions: (1) it must be designated as “interchangeable” by the FDA; (2) the prescriber must not have explicitly prohibited substitution; (3) the pharmacy must notify the patient of the substitution; and (4) the pharmacy must maintain records of the substitution.⁵³



⁵⁰ Rome BN, Sarpatwari A, Kesselheim AS. State Laws and Generic Substitution in the Year After New Generic Competition. *Value Health*. 2022;25(10):1736-1742. doi:10.1016/j.jval.2022.03.012

⁵¹ Oregon Revised Statutes 689.515. https://www.oregonlegislature.gov/bills_laws/ors/ors689.html

⁵² Sacks CA, Van De Wiele VL, Fulchino LA, Patel L, Kesselheim AS, Sarpatwari A. Assessment of Variation in State Regulation of Generic Drug and Interchangeable Biologic Substitutions. *JAMA Internal Medicine*. 2021;181(1):16. doi:10/gjjdfn

⁵³ Oregon Revised Statutes 689.522. https://www.oregonlegislature.gov/bills_laws/ors/ors689.html

Conclusion



Generic drugs are an essential component in the process of making prescription drugs more affordable for patients and the health care systems in Oregon. However, brand manufacturers often use strategies to prevent or delay generic drug competition, such as creating authorized generics and pay-for-delay or biosimilar competition agreements, which can increase health care costs by keeping drug prices inflated. The Prescription Drug Affordability Board's focus on studying generic drugs' affordability for patients, as well as opportunities for supply chain reform, can help address these challenges to encourage generic use and prevent brand manufacturers from undermining generic competition. Policymakers should continue exploring strategies to promote generic competition and lower drug prices to ensure affordable and high-quality health care for all Oregonians.

