DRAFT

2023 Report for the Oregon Legislature

Generic Drug Report Pursuant to Senate Bill 844 (2021)

Oregon Prescription Drug
Affordability Board

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Executive summary

Background

The Oregon Legislature created the Prescription Drug Affordability Board in 2021 to find ways to make prescription drugs more affordable for Oregonians. Legislators were concerned about rising prescription drugs costs and their negative effect on patients and the health system in the state. The board met for the first time on June 23, 2022. Board members started immediately working on the road map provided in its founding legislation, Senate Bill 844 (2021). An early task was to study the generic drug market. The board presented its first report to the Legislature in December 2022, with recommendations that were later proposed as part of Senate Bill 404 in the 2023 legislative session. Now, in June 2023, the board is presenting to the Legislature an updated report that reviews generic spending, drug shortages, price fixing, pay for delay, spread pricing, market disrupters, and cost savings from biosimilars. This report is available on the PDAB website at https://dfr.oregon.gov/pdab/Pages/index.aspx.

What are generics?

Generics are small-molecule drugs synthesized through a chemical process and marketed once the patent has expired on the original, innovator branded product. The Food and Drug Administration (FDA) approved more than 900 generic products in 2022. Generics represent 91 percent of all prescriptions filled in the U.S., but only 18.2 percent of total drug spending. Generics and biosimilars saved the U.S. health care system $373 billion in 2021. Generics play a significant role in cost savings for Oregon Medicaid. There were 10,190 Medicaid prescriptions filled in 2021, 87 percent filled with generics. Total Medicare savings in Oregon due to generics and biosimilars was $951 million, saving the average Oregon Medicare enrollee $1,742 in 2021.

This report looks at:

- Drug shortages: Shortages typically occur with low-cost generics used by hospitals. In response, a consortium of hospital systems created an organization to secure, distribute, and eventually manufacture generic drugs. Using lower-cost generics helps the health system control costs.
- Price fixing: The U.S. Department of Justice has charged seven generic companies with collusion and price fixing. Each case involves a different

number of drugs, up to 1,200 generic products.

- Pay for delay: This occurs when generic manufacturers are offered a financial incentive not to enter a market.
- Spread pricing: Commonly used with generics, this practice occurs when the pharmacy benefit manager (PBM), which is a third-party administrator of prescription drug programs, reimburses a pharmacy the cost of the dispensed drug and then bills the health plan at a much higher price.
- Market disrupters: This can happen when nonprofits or state governments contract for the manufacturing of generic drugs and offer them at a low cost to patients. There is more opportunity for market disrupters to operate in the generic market because generic drugs are not patent protected and one manufacturer does not control the price or supply.
- Cost savings from biosimilars: A biosimilar is a biologic drug that is highly similar to, and has no clinically meaningful differences from, the FDA-approved reference biologic. They are taken the same way, have the same strength and dosage, and have the same potential side effects. Biologic products are more expensive to manufacture than biosimilars. Oregonians saved $3.6 billion on generics and biosimilars in 2021. Nationally, biosimilars saved $7 billion in 2021 and $13 billion since the first biosimilar was approved in 2015. One approach to improving biosimilar use is through reimbursement.

The federal Inflation Reduction Act of 2022 reinforces the importance of affordable, accessible health care, and promotes a more sustainable and effective system for the future. It also changes the way Medicare Part B will reimburse for biosimilars, which could increase biosimilar use and improve affordability for prescription drugs. This is significant because biosimilars are an important tool for promoting competition in the pharmaceutical industry. By reducing costs and making alternative treatments more accessible, they can help to broaden access to medicines for many patients. Additionally, these changes to Medicare Part B reimbursement create an incentive for health care providers to choose the most cost-effective treatment option for their patients, which can improve overall costs and make health care more affordable.

Conclusion

The study of generic drugs in the U.S. is important in today's health care landscape. By examining the safety and efficacy of generic drugs, we can ensure Oregon residents, state and local governments, commercial health plans, health care providers, licensed pharmacies and other stakeholders have access to affordable medications. Furthermore, understanding the regulatory processes surrounding generic drug approval can help streamline drug development and promote greater access to new and innovative therapies. Continued research and development of generic drugs are critical to improving health care outcomes and promote a more effective, efficient, and sustainable health care system for all.

Introduction

The Oregon Legislature created the Prescription Drug Affordability Board (PDAB) in 2021. One of the board's tasks is to conduct a study on the operation of the U.S. generic and biosimilar drug markets that includes drugs dispensed by pharmacists and drugs administered by physicians. The board presented its original report in December 2022. The 2022 report provided background on both generic and biosimilar products, markets, and licensing processes.[1] This 2023 report updates the initial work with more detail on generic and biosimilar market trends, and builds on the foundational information provided in 2022.

Generic drug products

Quick statistics

- Generics represent 91 percent of all prescriptions in the U.S., but just 18.2 percent of total drug spending.[2]
- Generics account for only 3 percent of total U.S. health care spending.[3]
- Generics and biosimilars saved the health care system $373 billion in 2021 in the U.S.[4]

Generics are small-molecule drugs synthesized through a chemical process and marketed once the patent has expired on the original, innovator branded product. These are tablets, capsules, oral liquids, and other self-administered formulations. As a group, they are referred to as multisource generics or multisource products if there is more than one manufacturer of the generic product. The Maryland PDAB published a report of the small-molecule generic market in June 2020.[5] Its key findings were:

- Generic drug prices are generally stable year to year despite large increases for certain products.
- Generic drug prices have a minimal effect on insurance premiums.
- Cost sharing for generic drugs is stable.
- Generic drug shortages of essential drugs present significant challenges for providers and patients.

The available data did not allow a determination of the effect of generics on Medicaid spending.

In general, the innovator product does not engage in price competition with multisource products. Innovator sales drop dramatically once the patent expires and generic equivalents enter the market.

2022 generic approvals

The Food and Drug Administration approved or tentatively approved more than 900 generic products in 2022. About 106 of these were first generics – the first generic on the market after the innovator patent expiration. First generics are allowed 180 days of exclusive market access.

[1] "2022 Report for the Oregon Legislature: Prescription Drug Distribution System and Generic Drug Reports Pursuant to Senate Bill 844 (2021)." Prescription Drug Affordability Board, Dec. 19, 2022. https://dfr.oregon.gov/pdab/Documents/reports/PDAB-Report-2022.pdf. Accessed April 10, 2023.

[2] "U.S. Generic and Biosimilar Medicines Savings Report: Generics and biosimilar medicines deliver more savings every year." Association for Accessible Medicines, September 2022. https://accessiblemeds.org/resources/blog/2022-savings-report. Accessed April 10, 2023.

[3] Ibid.

[4] Ibid.

[5] "Study of the Operation of the Generics Drug Market." Maryland Prescription Drug Affordability Board, June 1, 2022. https://pdab.maryland.gov/documents/pdab_study_of_Operation_of_the_Generic_Drug_Market.pdf. Accessed April 11, 2023.

"substitution allowed" box is checked. In other words, lack of a "dispense as written" indication is not sufficient for biosimilar substitution in some states.[40]

Some states require the pharmacist to proactively offer information about lower cost biosimilars without requiring a substitution. Mandatory substitution of a biosimilar for the reference product seems to be almost always subject to the permission of the patient in addition to any other requirements that limit dispensing.

Another approach to improving biosimilar uptake is reimbursement. Included in the federal Inflation Reduction Act of 2022 was a change in how Medicare Part B will reimburse for biosimilars.[41] Before the Inflation Reduction Act change, providers were reimbursed for the administered biosimilar at the average sales price (ASP) of the reference product plus 6 percent. Per the new law, providers will be reimbursed the ASP plus 8 percent for the biosimilar, if the biosimilar manufacturer's ASP is less than the ASP of the reference product. This incentivizes the provider to use the biosimilar and requires the manufacturer to keep the biosimilar price below the original reference product. This counters the possibility that biosimilars come to market priced close to the reference product in order to offer rebates, for instance. The Medicare change to plus 8 percent means the Medicare patient will pay a bit more out of pocket for the biosimilar relative to ASP plus 6 percent.[42]

As more biosimilars come to market, the threats to reference products market dominance become more acute, which is why all these reference product market strategies have been developed. Biosimilar companies are responding by bringing their biosimilar to market at two different list prices, a high price with rebates to PBMs and health plans, and a lower price for health plans and PBMs willing to pay less to reimburse providers and forego rebates.

This phenomenon affects drugs other than biosimilars. Amgen started this two-price market strategy when it launched its very expensive biologic treatment for familial hyperlipidemia, Repthatha. Amgen has reprised the strategy for its biosimilar, Amjevita, which will compete with Humira and other Humira biosimilars.

The effects of generics and biosimilars on health care spending and insurance premiums

The Association for Accessible Medicines found that Oregon, in total, saved $3.6 billion in drug costs due to generics and biosimilars in 2021.[43] Nationally, generics saved the U.S. health system $366 billion and biosimilars saved $7 billion in 2021.[44]

Data is not currently available for determining the effects of generics and biosimilars on Oregon insurance premiums. There is little national data available about generic and biosimilar effects on insurance premiums specifically. The impact on premiums of small molecule generics in any one year would depend on the number of brands losing expiration, the amount that a plan spent on the brand(s) in the prior years before expiration, the percentage of plan spending dedicated to the patented products before expiration, and the speed with which multiple generics enter the market.

Determining the effect of biosimilars on Oregon health insurance premiums will require similar information to what is required to understand their effect on national insurance premiums. Because biologics are so expensive, the effect of biosimilars may be more readily apparent than the impact of generics.

[40] Horvath, Jane. Horvath Health Policy, April 2023.

[41] Cohen, Joshua. "Inflation Reduction Act Provision Aims To Further Spur Biosimilar Uptake With Temporary Add-On Payment In Medicare Part B." Forbes, Oct. 5, 2023. https://www.forbes.com/sites/joshuacohen/2022/10/05/inflation-reduction-act-provision-aims-to-further-spur-biosimilar-uptake-with-temporary-add-on-payment-in-medicare-part-b/?sh=42c2a0c77bcd. Accessed April 12, 2023.

[42] Horvath, Jane. Horvath Health Policy, April 2023.

[43] "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. Accessed April 11, 2023.

[44] Ibid.