

# 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

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## 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

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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.<sup>1</sup> 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

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### Quick statistics

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

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.<sup>5</sup> 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.

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<sup>1</sup> "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.

<sup>2</sup> "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.

<sup>3</sup> Ibid.

<sup>4</sup> Ibid.

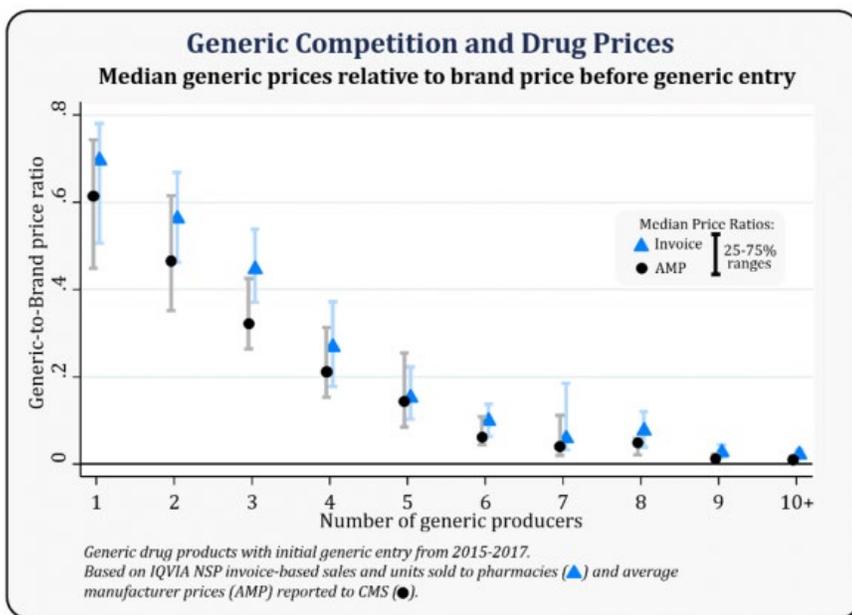
<sup>5</sup> "Study of the Operation of the Generics Drug Market." Maryland Prescription Drug Affordability Board, June 1, 2022. [https://pdab.maryland.gov/documents/pdab\\_study\\_of\\_operation\\_of\\_the\\_generic\\_drug\\_market.pdf](https://pdab.maryland.gov/documents/pdab_study_of_operation_of_the_generic_drug_market.pdf). Accessed April 11, 2023.

No other generic can enter the market during this market exclusivity period. The FDA initiative to encourage more generic products and market competition seems to be bearing fruit. The initiative encourages manufacturers to apply for licenses for products without generic competition. Along with streamlining initiatives, FDA also works more closely with applicants during the licensing process to minimize the extent to which applications have to be returned to the applicant for corrections.

## Generic drug market trends and issues

The first generic generally does not provide much price relief because it can shadow the price of the innovator. Studies have shown that first generics might provide up to 30 percent price reduction relative to the brand – which is some price relief for consumers, but not the full potential. If there is a fifth manufacturer of the product, the savings can reach 85 percent of the innovator price.

**Figure 1:** How Generic Competition Helps Bring Down Drug Prices.<sup>6</sup>



## Drug shortages

The products on the FDA national shortage list are typically 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.

Even though the nation relies on generics for the majority of medication needs, it is not always a stable market for consumers or providers. The downside to multisource competition is that prices can go so low that some manufacturers may decide to exit the market for the product. At a minimum, this allows manufacturers who remain in the market to raise prices and stabilize the market. At worst, stiff price competition and manufacturer exits can lead to drug shortages because there is not enough remaining production capacity to meet demand, at least in the short term until remaining manufacturers can increase production. Drugs shortages have become such a significant issue that the FDA now tracks drug shortages and asks manufacturers for advance warning of material changes to their market participation that could produce a shortage.<sup>7</sup>

Other than a manufacturer exiting the product market, there are other circumstances that could produce a shortage. There could be a supply shortage if a factory goes offline to update manufacturing processes or resolve quality problems. Environmental disasters can force a manufacturing stoppage due to facility damage, loss of power, or lack of staffing. Environmental disasters could affect wholesaler storage facilities. Active pharmaceutical ingredients (API) shortages could occur for a number of different reasons that could affect all manufacturers of a product.

<sup>6</sup>“How Generic Competition Helps Bring Down Drug Prices.” U.S. Food and Drug Administration, Sept. 12, 2022. <https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/generic-competition-and-drug-prices>. Accessed April 10, 2023.

<sup>7</sup>“Drug Shortages.” U.S. Food and Drug Administration, April 5, 2023. <https://www.fda.gov/drugs/drug-safety-and-availability/drug-shortages>. Accessed April 10, 2023.



## Price fixing litigation

The opposite of stiff market price competition is price fixing. A lawsuit by the majority of states was filed in 2016.<sup>8</sup> Another lawsuit was filed in 2020 on behalf of 46 states and territories against 26 manufacturers.<sup>9</sup> States made the case that 1,200 drugs had increased in price an average of 450 percent in one year while some of the products increased up to 1,000 percent. 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.<sup>10</sup> Some of the companies have also faced shareholder

lawsuits based on the price fixing charges. A few of the companies have made financial settlements in one or more of the lawsuits.<sup>11</sup>

## Pay for delay

Generic manufacturers sometimes have a financial incentive not to enter a market. Pay-for-delay agreements between generic and patent-holding pharmaceutical manufacturers prevent lower-priced generics from entering the market. These agreements tend to eliminate the 180-day period of exclusive market access for the first generic to market. According to the Federal Trade Commission (FTC), prescription drug pay-for-delay agreements cost consumers \$3.5 billion every year.<sup>12</sup>

In 2013, the U.S. Supreme Court found these agreements to be legal within reason. The deals cannot be large and unjustified. The FTC monitors these agreements and has reported that the number of agreements has declined slightly since the Supreme Court decision.<sup>13</sup>

Only California has enacted a law penalizing prescription drug pay-for-delay agreements. An industry legal challenge succeeded in rolling back the scope and application of the state law, but state authority to pursue certain pay-for-delay deals was maintained.<sup>14</sup>

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<sup>8</sup> "Current Cases: Generic Drugs Price Fixing Litigation (filed 2016)." Washington State Office of the Attorney General. <https://www.atg.wa.gov/antitrust-cases#generic%20drugs>. Accessed April 12, 2023.

<sup>9</sup> Bartz, Diane and Stempel, Jonathan. "U.S. states accuse 26 drugmakers of generic drug price fixing in sweeping lawsuit." Reuters, June 10, 2020. <https://www.reuters.com/article/us-usa-drugs-antitrust-lawsuit-idUSKBN23H2TR>. Accessed April 12, 2023.

<sup>10</sup> "Generic Drugs Investigation Targets Anticompetitive Schemes. Division update Spring 2021." The United States Department of Justice, March 24, 2021. <https://www.justice.gov/atr/division-operations/division-update-spring-2021/generic-drugs-investigation-targets-anticompetitive-schemes>. Accessed April 12, 2023.

<sup>11</sup> "Pharmaceutical Companies Pay Over \$400 Million to Resolve Alleged False Claims Act Liability for Price-Fixing of Generic Drugs." The United States Department of Justice, Oct. 1, 2021. <https://www.justice.gov/opa/pr/pharmaceutical-companies-pay-over-400-million-resolve-alleged-false-claims-act-liability>. Accessed April 12, 2023.

<sup>12</sup> "Pay-for-Delay: When Drug Companies Agree Not to Compete. Federal Trade Commission." <https://www.ftc.gov/news-events/topics/competition-enforcement/pay-delay>. Accessed April 10, 2023.

<sup>13</sup> Paradise, Jordan. "The Status of California's Pay-for-Delay Legislation & Litigation." Food and Drug Law Institute. Fall 2022. <https://www.fdli.org/2022/08/the-status-of-californias-pay-for-delay-legislation-litigation/>. Accessed April 10, 2023.

<sup>14</sup> Ibid.

## Pharmacy benefit managers generic spread pricing

The concerning practice of spread pricing by pharmacy benefit managers (PBM) typically involves generic drugs. The practice occurs when the PBM reimburses a pharmacy the cost of the dispensed drug, typically using a national average price to set the reimbursement. The PBM then bills the health plan for the drug at a much higher price, possibly even the brand product price. The Centene Corporation, the predominant PBM for Medicaid programs, has become known for its use of spread pricing in unwitting Medicaid programs.<sup>15</sup> It has been or is being investigated in 20 states and has already settled with 14, including Oregon in December 2022. As a general matter, the FTC decided in 2022 to study PBM business practices because of a concern for anti-competitive and other unfair trade practices.

## Generic coverage and PBMs

Generic drug availability on health plan formularies can be impeded by brand drug patient assistance programs and rebates. Manufacturers of high-cost brand drugs may offer significant patient cost sharing assistance to greatly reduce the cost of otherwise costly patient coinsurance. Doctors may prescribe the high-cost patented product rather than an alternative generic treatment because the patient cost sharing is less. Similarly, branded manufacturers may offer substantial rebates that bring the PBM net cost of the brand to less than the cost of the generic, incentively the PBM to delay or block coverage of the generic. Consumers, however,

pay cost sharing based on the market price of the drug, not the insurer/PBM net cost. This phenomenon can be taken to extremes, as in the 2022 CVS Caremark scheme.<sup>16</sup>

## Generic market disrupters

Drug price increases have affected the generic market to extents similar to the patented market. But unlike the patent-protected brand market, there is more opportunity for market disrupters to operate in the generic market. This is because generic drugs are not patent protected; one manufacturer does not control the price or supply.

### Civica and CivicaRx:

Civica began in 2018 as a consortium of hospital systems that provided capital for the manufacture of generics important to inpatient hospital care – drugs that are often in short supply and subject to price hikes. The organization has contracted for the manufacture of generic drugs but is now close to opening its own manufacturing plant in Virginia.



<sup>15</sup> “Centene Gives Big as It Courts Contracts and Settles Accusations of Overbilling.” California Healthline, Dec. 15, 2022. <https://californiahealthline.org/multimedia/centene-gives-big-as-it-courts-contracts-and-settles-accusations-of-overbilling/>. Accessed April 12, 2023.

<sup>16</sup> Silverman, Ed. “A veritable playground: CVS whistleblower details how patients were charged higher drug prices.” Stat, June 16, 2022. <https://www.statnews.com/pharmalot/2022/06/16/cvs-whistleblower-silverscript-medicare-generics/>. Accessed April 11, 2023.

Two years ago, Civica – through its operating unit CivicaRx – partnered with the Blue Cross Blue Shield Association and 18 of its health plans to supply generics at low cost to participating pharmacies and funding members.<sup>17</sup> Other health plans have subsequently joined. The first product of the initiative was a prostate cancer product. Civica recently announced it will begin manufacturing off-patent, long-acting insulins.<sup>18</sup> The products will be available to anyone. Civica will distribute the insulins through every distribution channel, but dispensing pharmacies must agree to limit charges to \$30 per vial or \$55 per pen. Health plans will direct their enrollees to participating pharmacies. Since Civica made this announcement, the three big brand insulin makers announced steep reductions in the price of their insulins.<sup>19</sup>

### **Cost Plus Drugs:**

This company started in early 2022 as an online generic pharmacy with 350 generic drugs available. It began as a cash-only business that did not interact with health plans or PBMs. It charges product cost, delivery, and a 15 percent mark-up. It has moved quickly to expand its business model. In late 2022, Cost Plus announced it will work with a coalition of public and private employers who will connect their enrollees to Cost Plus generics.<sup>20</sup> To do this, the coalition created its own PBM based on a straight fee for a paid claim, which was \$3 at the time

of the announcement. This in itself is a market disruption. In March 2023, Cost Plus announced a contract with brand manufacturer Janssen to sell their patented anti-diabetic product Invokana for \$294 per month, less than half the average retail price of \$676 per month. The company now carries 1,100 drugs and will add a brand from IBSA Pharma.<sup>21</sup> Cost Plus is also working with independent and chain pharmacies across the country to expand access.

### **State drug manufacturing initiatives:**

California and Washington have enacted laws that require the state to either manufacture or contract for distribution of affordable generic drugs. California recently signed a contract with Civica to manufacture insulins that will be available to cash-paying customers.<sup>22</sup> The manufacturing facility is expected to be located in California. Arizona, Illinois, Massachusetts, and New York all have proposed legislation that would follow the lead of California and Washington.

### **Generic multisource drugs and Medicaid**

The Medicaid Drug Rebate Program (MDRP) began in 1990 and applies to branded drugs and generics. A generic manufacturer must provide to each state a 13 percent rebate for each of its products used in the state's Medicaid program, which is calculated for each calendar quarter. If the product price rose faster than the rate of

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<sup>17</sup> Silverman, Ed. "Civica Rx teams with Blue Cross Blue Shield to widen its alternative market for generics." Stat, Jan. 23, 2020. <https://www.statnews.com/pharmalot/2020/01/23/civica-blue-cross-shield-generics-drug-prices/>. Accessed April 11, 2023.

<sup>18</sup> Civica, 2023. <https://civicarx.org/>. Accessed April 12, 2023.

<sup>19</sup> Smith, Bram Sable and Young, Samantha. "Eli Lilly Slashed Insulin Prices. This Starts a Race to the Bottom." Kaiser Health News, March 2, 2023. <https://kffhealthnews.org/news/article/eli-lilly-slashed-insulin-prices-this-starts-a-race-to-the-bottom/>. Accessed April 12, 2023.

<sup>20</sup> Silverman, Ed. "True disruption: Mark Cuban's company will sell brand-name diabetes medicines from J&J." Stat, April 4, 2023. <https://www.statnews.com/pharmalot/2023/04/04/janssen-diabetes-invokana-cuban-cost/>. Accessed April 12, 2023.

<sup>21</sup> Emerson, Jakob and Twenter, Paige. "Leadership & Management: 10 exclusives Mark Cuban told Becker's in April." Becker's Hospital Review, April 11, 2023. <https://www.beckershospitalreview.com/hospital-management-administration/10-exclusives-mark-cuban-told-beckers-in-april.html>. Accessed April 12, 2023.

<sup>22</sup> "Governor Newsom announces \$30 insulin through CalRX." Office of Governor Gavin Newsom, March 18, 2023. <https://www.gov.ca.gov/2023/03/18/governor-newsom-announces-30-insulin-through-calrx/>. Accessed April 12, 2023.

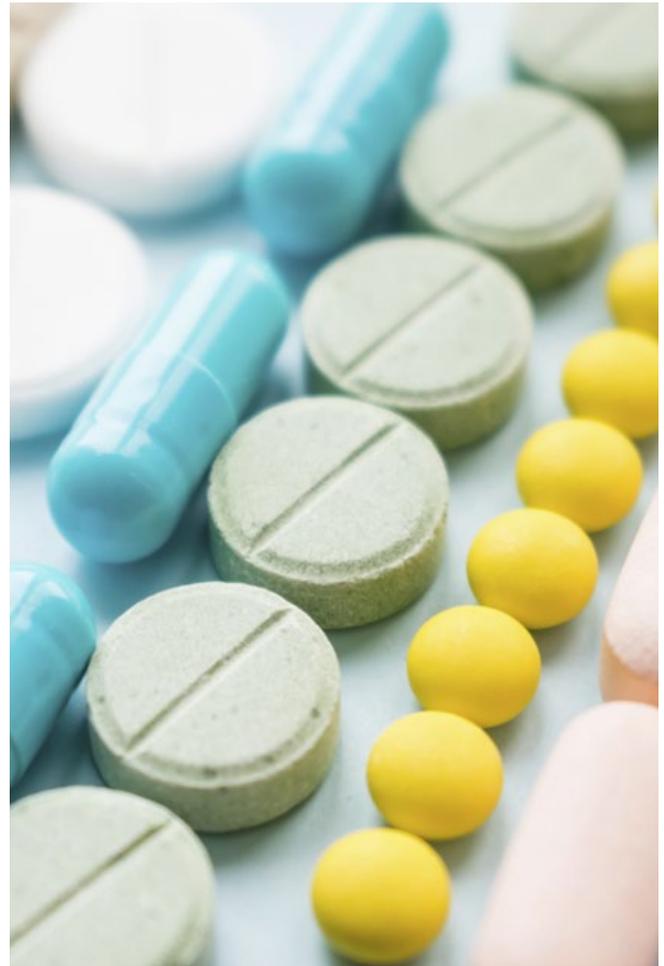
inflation, a manufacturer must pay an additional inflation penalty rebate for each unit of product dispensed in a state's Medicaid program. For years it has been suggested that Medicaid fee-for-service pharmacy benefit programs favored the use of more expensive innovator brands rather than the generic versions because of the larger rebates of the brand products. New York specifically requires coverage of the brand if the net is less costly than the generic.<sup>23</sup>

## Oregon and generics

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- Oregonians saved \$3.6 billion in 2021 on generics and biosimilars according to the generic and biosimilar trade association, Association for Accessible Medicines (AAM).<sup>24</sup>
- The AAM also finds that the average Oregon Medicare enrollee saved \$1,742 in 2021, and total Medicare savings in Oregon due to generics and biosimilars was \$951 million in 2021. This is a savings for employer retiree health benefits programs, including state and local government retirees.<sup>25</sup>
- In 2021, Oregon Medicaid spent \$778 million on prescription drugs, 81 percent was spent on brands, and 18.6 percent on generics, excluding biosimilars, which are technically patented brands. The fee-for-service program spent \$135.5 million total and the Medicaid coordinated care organizations (CCO) spent \$642.5 million.<sup>26</sup>

- There were 10,190 Medicaid prescriptions filled in 2021. Thirteen percent were filled with brands and 87 percent were filled with generics. Interestingly, 6 percent of prescriptions were for brands in fee-for-service programs, while 15 percent were for brands in the CCO programs. Without looking at the claims, it is impossible to tell what this means.<sup>27</sup>



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<sup>23</sup> "NYRx, the Medicaid Pharmacy Program." Magellan Medicaid Administration. [https://newyork.fhsc.com/providers/bltgp\\_about.asp](https://newyork.fhsc.com/providers/bltgp_about.asp). Accessed April 11, 2023.

<sup>24</sup> "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.

<sup>25</sup> "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.

<sup>26</sup> "MACStats: Medicaid and CHIP Data Book." The Medicaid and CHIP Payment and Access Commission (MACPAC), December 2022. [https://www.macpac.gov/wp-content/uploads/2022/12/MACSTATS\\_Dec2022\\_WEB-508.pdf](https://www.macpac.gov/wp-content/uploads/2022/12/MACSTATS_Dec2022_WEB-508.pdf). Accessed April 25, 2023.

<sup>27</sup> Ibid.

## Biologic and biosimilars

The original/first innovator biologic is called a reference product in the context of a discussion of biosimilars. Biosimilars are a category of biologics. Like all biologics, they can have patent-protected, branded products.

- FDA defines a biosimilar as a biologic that is highly similar to, and has no clinically meaningful differences from, the FDA approved reference biologic. This means biosimilars:<sup>28</sup>
  - Are given the same way (same route of administration).
  - Have the same strength and dosage form.
  - Have the same potential side effects.

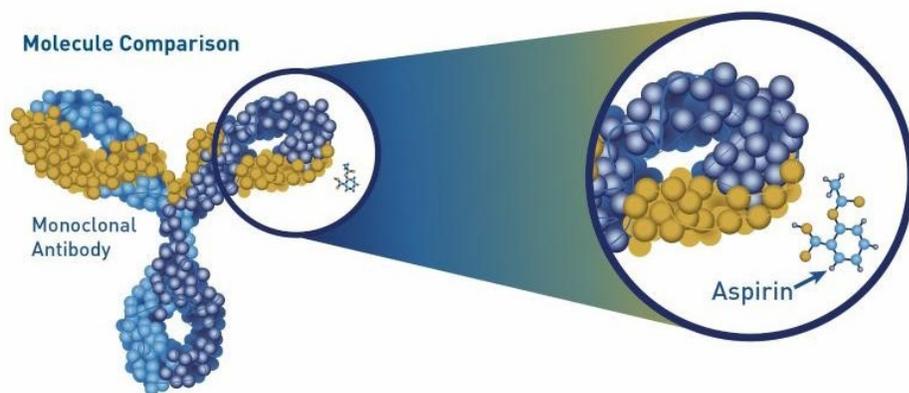
Small molecule generics must be chemically identical within a tight range specified by the FDA. This tight standard is not possible with biologics because biologics are derived from living systems, such as bacteria, yeasts, and other cells. Living cells are not identical, unlike the chemical components of small molecule products. A biosimilar cannot be identical to the reference product, but is similar and can be expected to produce the same clinical results.

Biologics are made of large molecules, as opposed to small molecule drugs and their generics. The manufacturing

process is complex. Some biologics such as insulin can be self-administered, but many biologic treatments are administered in outpatient clinic or inpatient settings. Congress created a new, separate approval pathway for biologic/biosimilars in the 2009 Biologics Price Competition and Innovation Act with processes for the first biologic and for biosimilar approval. Prior to a dedicated approval pathway, biologics such as insulins, were approved through the existing pathway that is now only for small molecule drugs.<sup>29</sup>

There were 40 biosimilar products on the U.S. market as of December 2022.<sup>30</sup> The first U.S. biosimilar was approved in 2015. The first biosimilar in the EU was approved in 2006. There are 69 on the market in Europe.<sup>31</sup>

**Figure 2:** A molecule comparison of monoclonal antibody and aspirin shows the difference in large and small molecule drugs.<sup>32</sup>



<sup>28</sup> "Biosimilar and Interchangeable Biologics: More Treatment Choices." U.S. Food & Drug Administration, Oct. 12, 2021. <https://www.fda.gov/consumers/consumer-updates/biosimilar-and-interchangeable-biologics-more-treatment-choices>. Accessed April 11, 2023.

<sup>29</sup> "Review and Approval." U.S. Food & Drug Administration, Dec. 13, 2022. <https://www.fda.gov/drugs/biosimilars/review-and-approval>. Accessed April 11, 2023.

<sup>30</sup> "Biosimilar Product Information." U.S. Food & Drug Administration. Dec. 19, 2022. <https://www.fda.gov/drugs/biosimilars/biosimilar-product-information>. Accessed April 11, 2023.

<sup>31</sup> Figg, Anthony E., et al. "How the U.S. Compares to Europe on Biosimilar Approvals and Products In the Pipeline." *Biosimilars Law Bulletin*, March 14, 2022. <https://www.biosimilarsip.com/2022/03/14/how-the-u-s-compares-to-europe-on-biosimilar-approvals-and-products-in-the-pipeline-updated-march-14-2022/>. Accessed April 11, 2023.

<sup>32</sup> "Overview for Health Care Professionals." U.S. Food & Drug Administration, Dec. 13, 2022. <https://www.fda.gov/drugs/biosimilars/overview-health-care-professionals>. Accessed April 11, 2023.

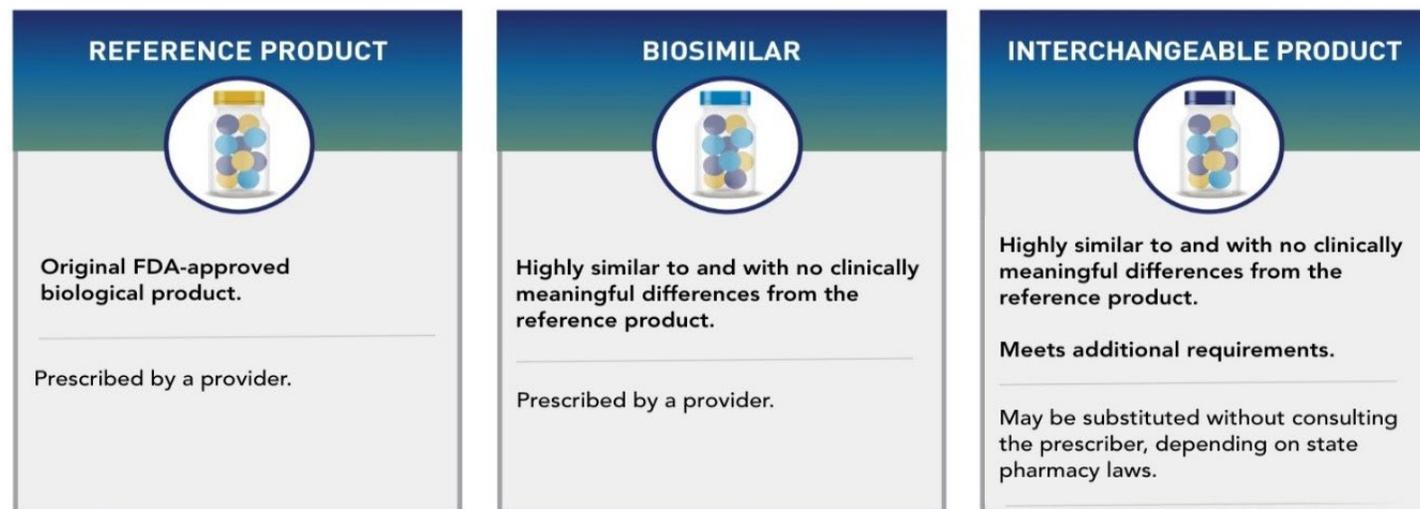
## Interchangeable biosimilars

FDA defines an interchangeable biosimilar product as a biosimilar that meets additional requirements to demonstrate that there is no additional risk when substituted for the reference product at the pharmacy.<sup>33</sup> It is not an indication of superior quality relative to a biosimilar without the designation.

An interchangeable biosimilar product may be substituted at the pharmacy counter without the intervention of the health care professional who prescribed the reference product, much like how generic drugs are routinely substituted for brand name drugs at the pharmacy. This is commonly called pharmacy-level substitution and is subject to state pharmacy laws.

New proposed state laws would limit plan ability to cover biosimilars, when launched, by requiring step therapy (use reference product first) or requiring delayed biosimilar coverage until the new calendar year. This is very different than laws to facilitate biosimilar substitution at the pharmacy counter, which has been the trend of the last few years.<sup>34</sup>

**Figure 3:** A comparison of reference products, biosimilars, and interchangeable products.<sup>37</sup>



<sup>33</sup> "Biosimilar and Interchangeable Biologics: More Treatment Choices." Consumer Updates, U.S. Food & Drug Administration, Oct. 12, 2021. <https://www.fda.gov/consumers/consumer-updates/biosimilar-and-interchangeable-biologics-more-treatment-choices>. Accessed April 12, 2023.

<sup>34</sup> "Eliminate Threats to Coverage of Lower-Cost Biosimilar Medicines." Association for Accessible Medicines, January 2023. <https://accessiblemeds.org/sites/default/files/2023-01/AAM-BC-Eliminate-Threats-Coverage-Lower-Cost-Biosimilar-Medicines-2023.pdf>. Accessed May 2, 2023.

<sup>35</sup> "Approved Cellular and Gene Therapy Products." U.S. Food & Drug Administration. Dec. 16, 2022. <https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/approved-cellular-and-gene-therapy-products>. Accessed April 11, 2023.

<sup>36</sup> Ibid.

<sup>37</sup> "Overview for Health Care Professionals." U.S. Food & Drug Administration, Dec. 13, 2022. <https://www.fda.gov/drugs/biosimilars/overview-health-care-professionals>. Accessed April 11, 2023.

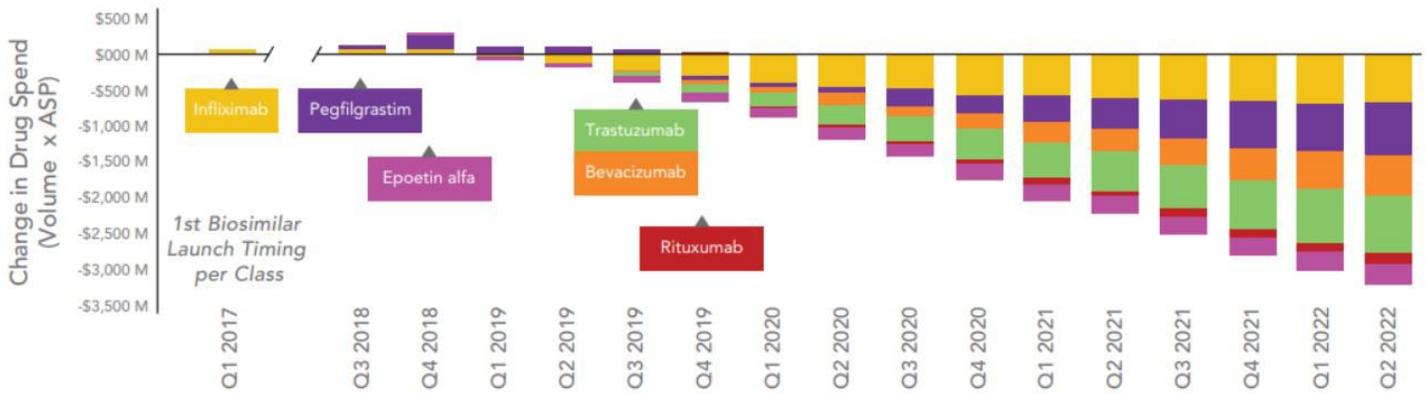
## Cell and gene therapy biologics

The FDA defines cell and gene therapies as therapy that modifies or manipulates the expression of a gene or to alter the biological properties of living cells for therapeutic use.<sup>35</sup> The FDA has approved both cellular and gene therapy products that are regulated by the FDA Center for Biologics. Gene and cell therapies can use a patient's own cells that are modified and returned to the patient. Treatments can mitigate or cure a person's inherited disease. There are 27 approved cell and gene therapies. These one-time therapies can and do cost millions of dollars for a one-time treatment.<sup>36</sup>

## Biosimilar costs and savings

Biologic products are much more costly to manufacture than small molecule chemical products. Biologics do not achieve the same manufacturing efficiencies as small molecules because the process is complex and remains complex for each batch of product. Biosimilars saved \$7 billion nationally in 2021 and \$13 billion

**Figure 4:** Estimated Change in Total Drug Spend for Amgen Biologics After Biosimilar Competition.<sup>38</sup>



since the first biosimilar was approved in 2015.<sup>39</sup> This graphic shows the impact of biosimilar competition on reference biologics using Amgen reference products.

### Biosimilar market uptake

The adoption of biosimilar has been slower than hoped. There are several reasons for this. One is clinician reticence to use a biosimilar without full knowledge or trust that the treatment will have the same clinical outcome as the reference product. This is where the designation as interchangeable is important to improve uptake of biosimilars.

In addition to prescriber reticence, reference product makers encourage use of reference products over biosimilar competitors, similar to branded efforts to thwart generic uptake. Reference product sponsors provide tens of thousands of dollars to individual patients to buy down the patient’s out-of-pocket costs for the reference product. Biosimilars often do not have the financial ability to compete on patient assistance without raising their market price. In the face of biosimilar competition, reference product sponsors will also offer very high rebates as incentive for the PBM to keep the biosimilar off the formulary in favor of the reference product. In this instance, the PBM and insurer reduce the net cost of the reference product below the cost of the biosimilar. Here again,

the biosimilar company may not have the ability to compete on rebates without raising their list prices.

In addition to FDA efforts to designate interchangeable products, states have been creating laws for biosimilars substitution patterned after mandatory/voluntary generic substitution at the pharmacy. Oregon has had a biosimilar substitution law since 2016. It was updated in 2019. Most states have generic substitution laws and have for years. As of June 2019, the majority of states have enacted laws concerning the substitution of a lower cost, interchangeable, biosimilar product for the reference biologic. About 35 states have enacted biosimilar substitution laws as of 2019.

Most of the state’s biosimilar substitution bills and laws are permissive. The pharmacist may offer to substitute a biosimilar if “dispense as written” is not on the prescription. There may be other requirements that precede the substitution. There may be requirements that apply after the substitution has been made, such as notifying the prescriber within a set period of days about the substitution. A few states require the specific affirmation from a prescriber that substitution is permitted before substitution can occur. Some of the laws require prescription pads to have a checkbox for “dispense as written” and a checkbox for “substitution allowed.” In some states that require a substitute biosimilar, pharmacists can only do so if the

<sup>38</sup> “2022 Biosimilar Trends Report.” Amgen Biosimilars, 2022. <https://www.amgenbiosimilars.com/commitment/-/media/Themes/Amgen/amgenbiosimilars-com/Amgenbiosimilars-com/pdf/USA-CBU-81397-2022-Amgen-Biosimilars-Trend-Report-Oct-2022.pdf>. Accessed April 11, 2023.

<sup>39</sup> “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. <sup>39</sup> Horvath, Jane. Horvath Health Policy, April 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.<sup>40</sup>

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.<sup>41</sup> 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.<sup>42</sup>

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**

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

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.

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<sup>40</sup> Horvath, Jane. Horvath Health Policy, April 2023.

<sup>41</sup> 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.

<sup>42</sup> Horvath, Jane. Horvath Health Policy, April 2023.

<sup>43</sup> “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.

<sup>44</sup> Ibid.