Oregon Prescription Drug Prices Annual Public Hearing

1:30 to 4 p.m., Thursday, Dec. 4, 2025

Sign up in the chat to provide public testimony.

Send written comments to rx.prices@dcbs.oregon.gov.

DFR | Division of Financial Regulation

Department of Consumer and Business Services

Welcome

Welcome and introductions

- TK Keen (he/him), insurance commissioner, DFR, DCBS
- Sarah Young (she/her), Prescription Drug Affordability Board executive director, DFR, DCBS

Moderators

- Sen. Deb Patterson
- Sen. Diane Linthicum
- Rep. Emerson Levy
- Rep. Rob Nosse

Drug Price Transparency Program

Program presenters:

- Sofia Parra (she/her), program coordinator, Drug Price Transparency Program, DFR, DCBS
- Taran Heins (he/him), research analyst, Drug Price Transparency Program, DFR, DCBS
- Numi Rehfield-Griffith (she/her), senior policy advisor, DFR, DCBS

Drug Price Transparency Program

- Operates under ORS 646A.680 to 646A.692 and administrative rules OAR 836-200-0500 to 836-200-0560.

- Reporting manufacturers are required to register, file certain reports, and pay an annual fee to cover program costs.

- Reporting manufacturers are those who meet all the following criteria:
  - ✓ Registered with the Oregon Board of Pharmacy.
  - ✓ Manufactures prescription drugs for sale in Oregon.
  - ✓ Sets the drug's price (wholesale acquisition cost – WAC).

https://dfr.oregon.gov/laws-rules/Pages/index.aspx

Pharmaceutical supply chain diagram

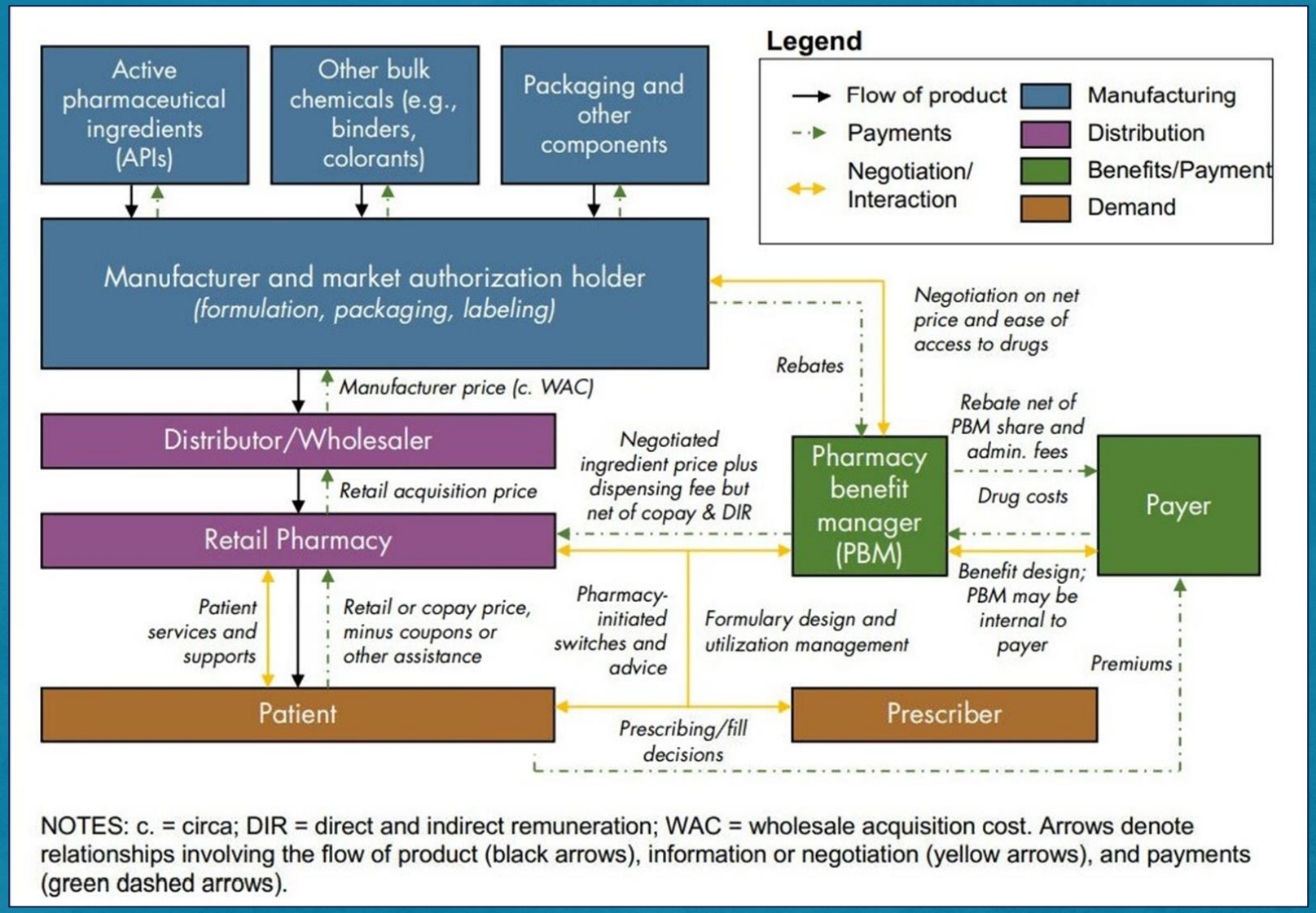


Figure 2 on Page 12 of the 2025 DPT legislative report. Source: Mulcahy, Andrew W. and Kareddy, Vishnupriya. "Typical Supply Chain for Brand-Name Drugs Dispensed Through Retail Pharmacies." Rand Health Q, June 30, 2022; 9(3):7. 2021. https://pmc.ncbi.nlm.nih.gov/articles/PMC9242571/figure/figure-1/

Drug price transparency reporting

Wholesale Acquisition Cost (WAC) is a price set by the manufacturer.

Program is directed by statute to receive these reports:

- *New drug*: Enters market at WAC of $670 or more for one-month supply.
- *Annual price increase*: WAC of $100 or more for a one-month supply with a 10 percent price increase and a patient assistance program.

- *60-day price increase notice*: 10 percent or $10,000 increase for brand name, 25 percent and $300 increase for generic.
- *Insurers*: Top 25 most costly and most prescribed drugs, and the effect of drug costs on premium rates.

- *Pharmacy benefit managers (PBMs)*: Payments from manufacturers and their distribution.
- *Consumers*: Personal increases in prescription drug prices.

Program compliance and trade secret reviews

Manufacturer compliance

- Identifying manufacturer noncompliance and sending letters of noncompliance.
- Goal is compliance. Primary areas of potential noncompliance:
  - ✓Failure to respond to the request for additional information.
  - ✓Failure to provide accurate and complete information for the required data elements.

Manufacturer trade secret claims

- Research and analysis of trade secret claims conducted for various data elements.
- Process to review and address trade secret claims from manufacturers is lengthy and complex.
- Information determined not to be trade secret is published to our website.

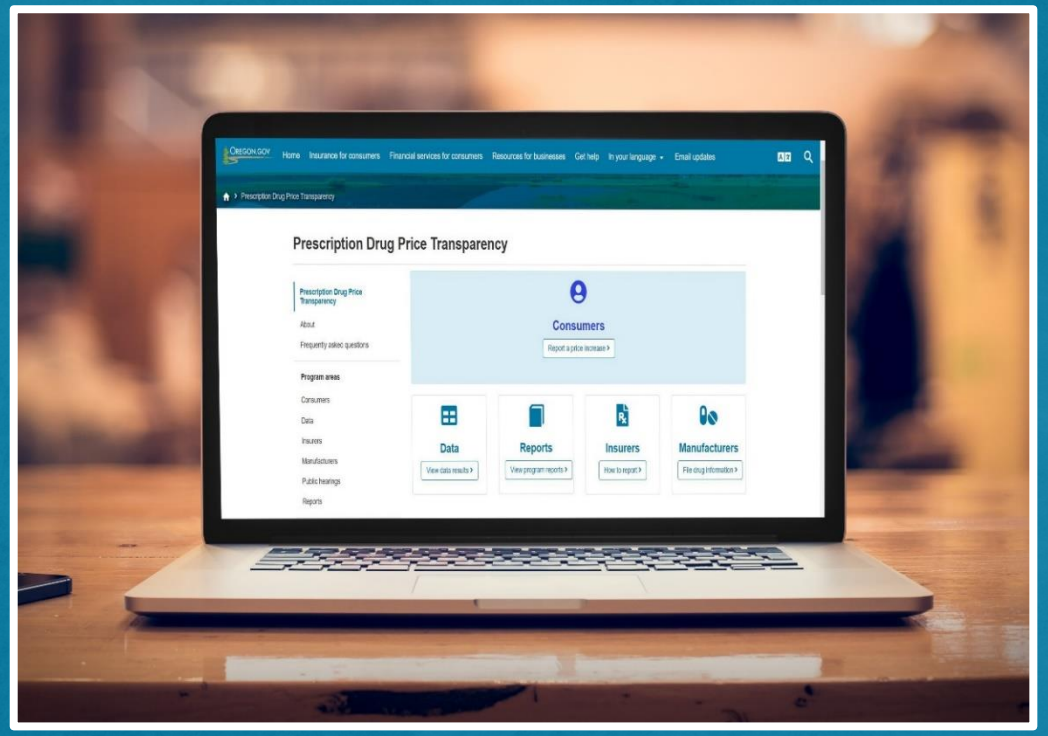
Consumers and transparency

Consumer reporting:

- Price increase reporting
- Stories and questions
- Outreach

Transparency website:

- Reported data from manufacturers (determined not to be trade secret)
- Information from insurers
- Consumer reports submitted



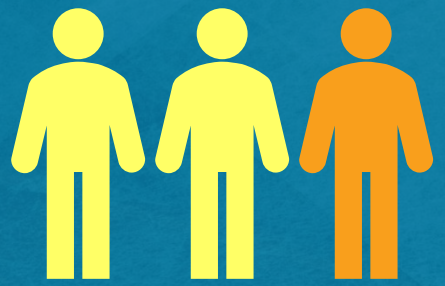
https://dfr.oregon.gov/drugtransparency/Pages/consumers.aspx and https://dfr.oregon.gov/drugtransparency/data/Pages/new-drug-reports.aspx#drug

Highlights from 2025 data

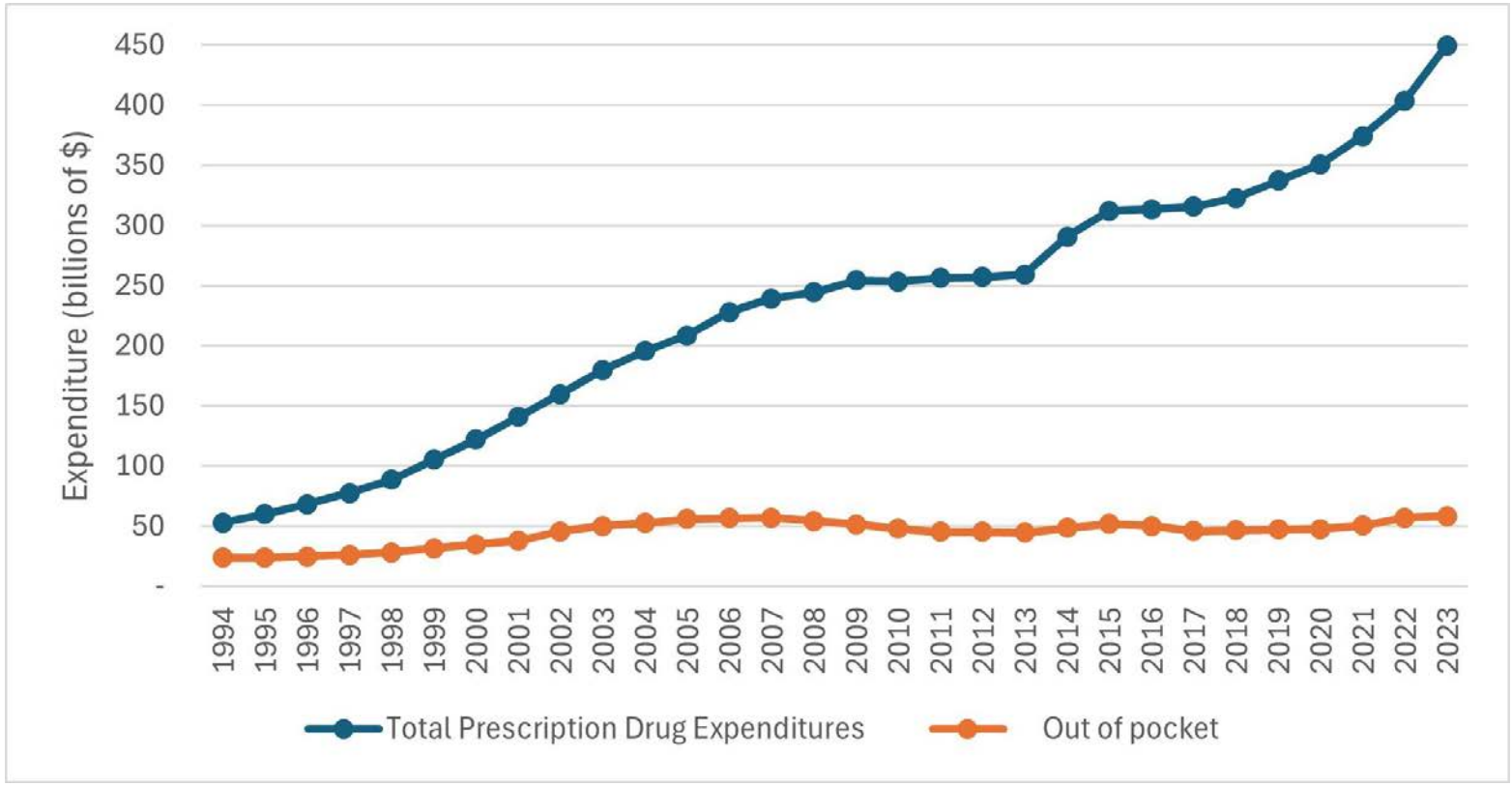
- Highest new drug prices reported by manufacturers:
  - ✓ $3.5 million for Beqvez™, a treatment for hemophilia B, manufactured by Pfizer.
  - ✓ $3.1 million for Lyfgenia™, a treatment for sickle cell disease, manufactured by bluebird bio Inc.
  - ✓ $2.3 million for Zolgensma™, a treatment for spinal muscular atrophy, manufactured by Novartis Gene Therapies Inc.
- PBMs reported collecting $377 million in payments from manufacturers and reported passing on 97.8 percent to insurers.
- With only one exception (Kaiser), health insurers reported receiving rebates ranging from 15.4 percent to 30.1 percent of their total pharmaceutical spending.

Health spending information

- In 2023, U.S. national health expenditures reached $4.9 trillion.
- Oregon spent more than $1.3 billion on prescription drugs in 2024.
- About 72.2 million (1 in 3) American adults did not seek needed health care due to the cost.
- Some 49% of Americans report struggle to cover medical bills.



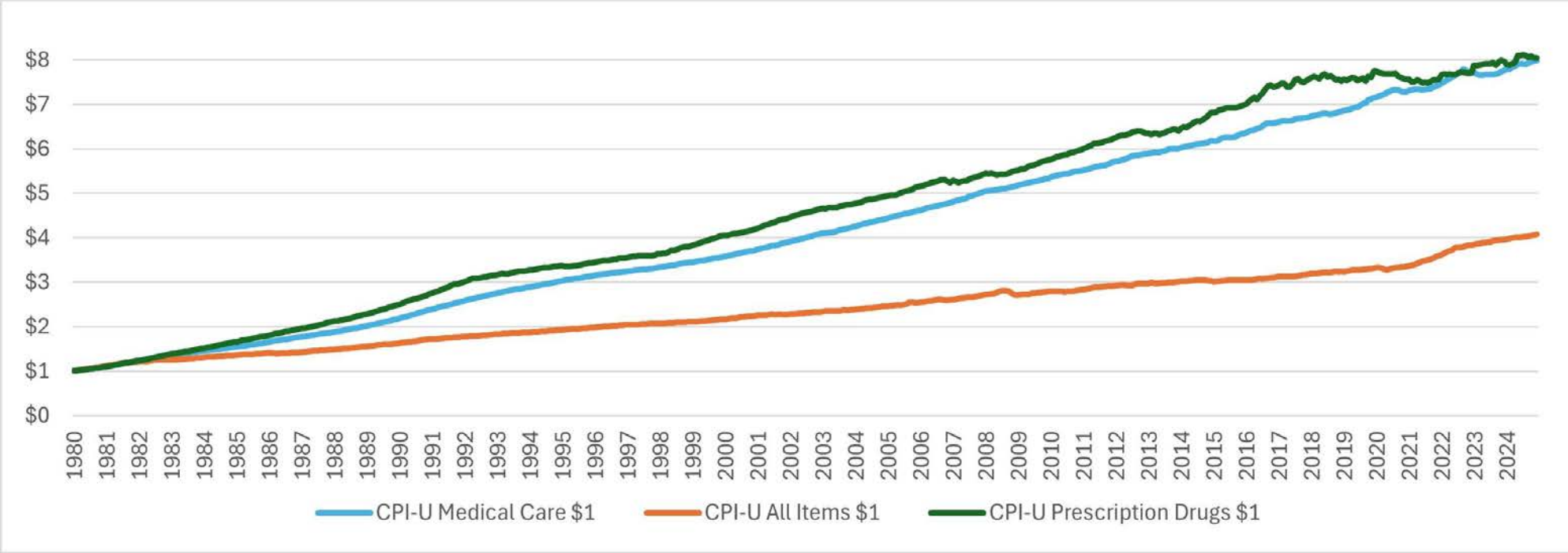
Estimated total expenditures and consumer out-of-pocket costs on prescription drugs in the U.S. from 1994 to 2023



- For 2023, U.S. prescription drug expenditures grew by 11.4 percent.
- National prescription drug expenditures have increased 748.2 percent from 1994 to 2023.

Figure 4 on Page 14 of the 2025 DPT legislative report. Source: ”Historical.” Centers for Medicare and Medicaid, National health expenditure data, Dec. 18, 2024. https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/historical. Accessed Sept. 24, 2025.

Overall inflation compared to the increases for prescription drugs and medical expenses from 1980 through 2024



- Medical care prices increased 96.0 percent more than inflation (CPI-U All) since 1980.
- Prescription drug prices increased 97.7 percent more than inflation.

Figure 5 on Page 15 of the 2025 DPT legislative report. Sources: “Consumer price index for all urban consumers: Medical care in U.S. city average.” Federal Reserve Bank of St. Louis Fred Economic Data. https://fred.stlouisfed.org/series/CPIMEDSL. Also refer to “Consumer price index for all urban consumers: All items in U.S. city average.” Federal Reserve Bank of St. Louis Fred Economic Data. https://fred.stlouisfed.org/series/CPIAUCSL. Also refer to “BLS Data View.” U.S. Bureau of Labor Statistics. https://data.bls.gov/dataViewer/view/timeseries/CUSR0000SEMF01;jsessionid=95E7085FC504B86A4B4ED23DFB016957.

Consumer-reported financial difficulty ratings prescription drugs

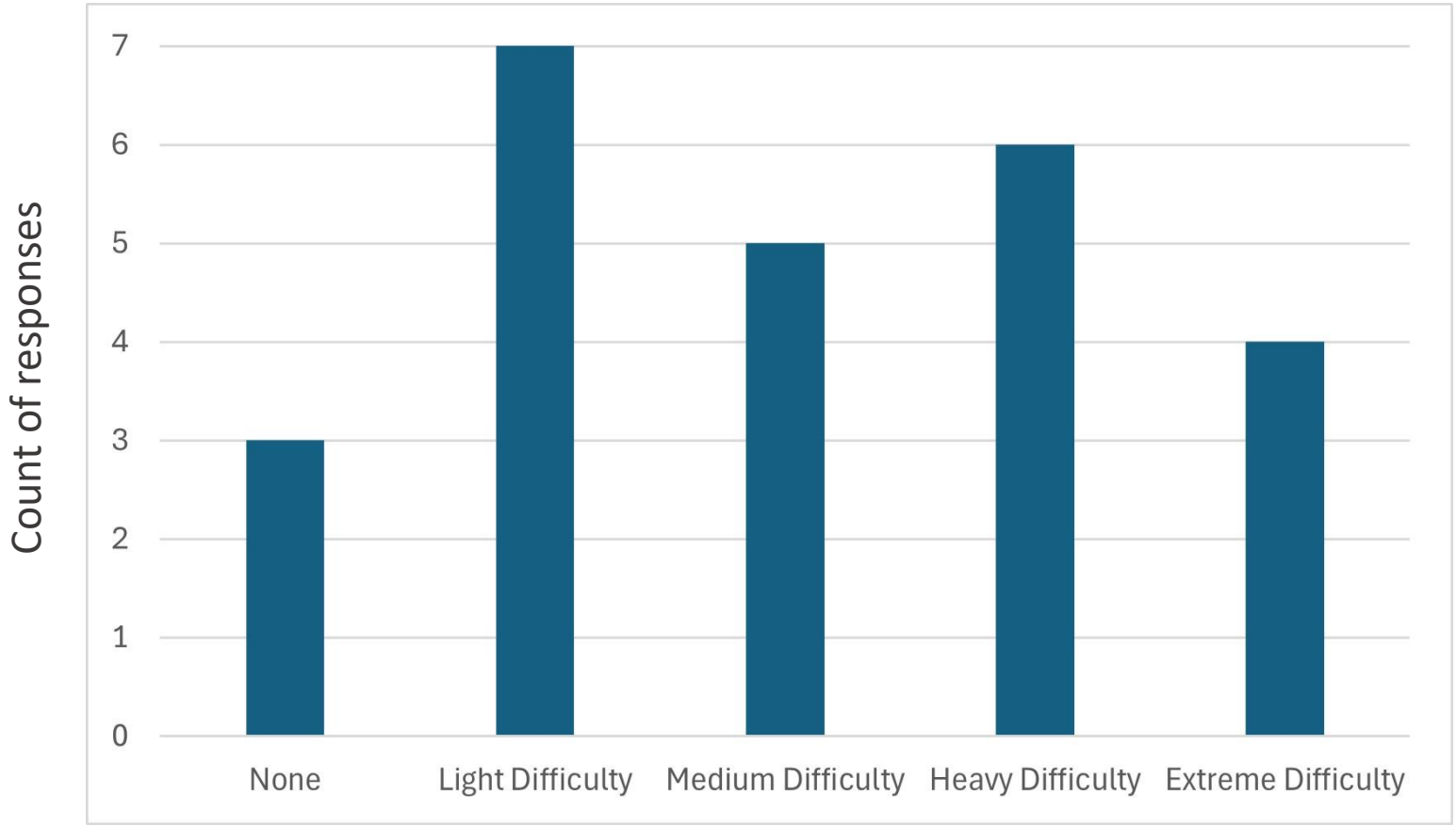
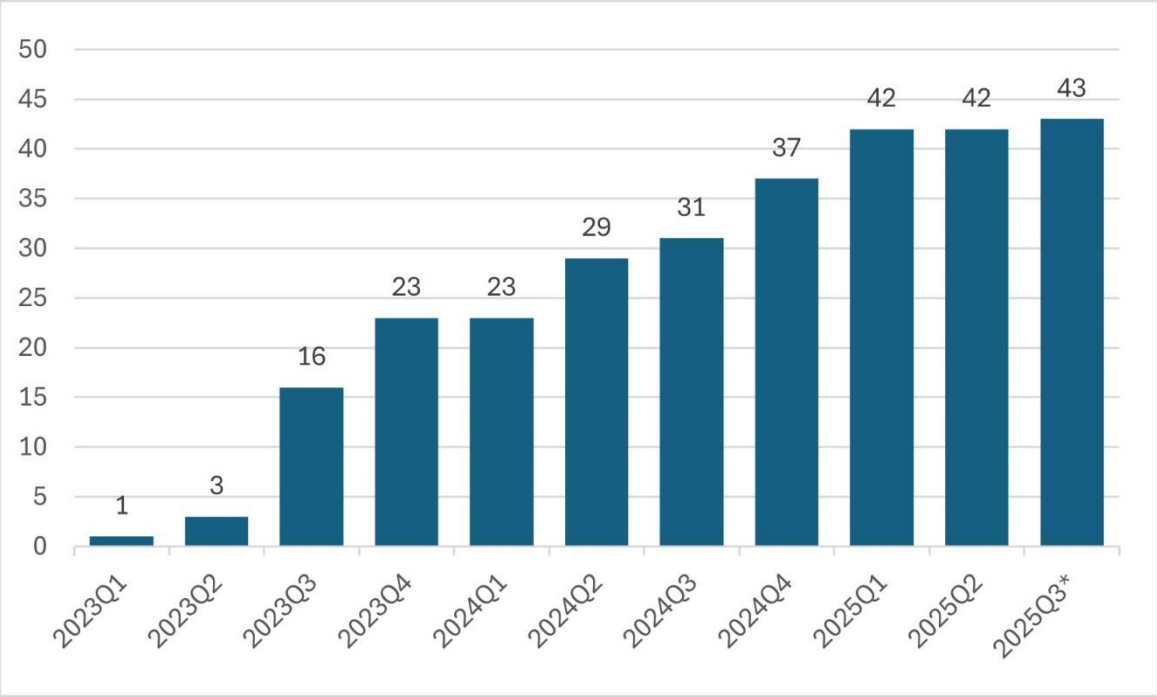


Figure 6 on Page 18 of the 2025 DPT legislative report. Information is from the 25 people who responded to this question in the Qualtrics survey from June 2024 through September 2025.

Humira and biosimilars

Count of Humira biosimilars on the market



Oregon insurer-reported spending on Humira as reported to DPT starting in 2019

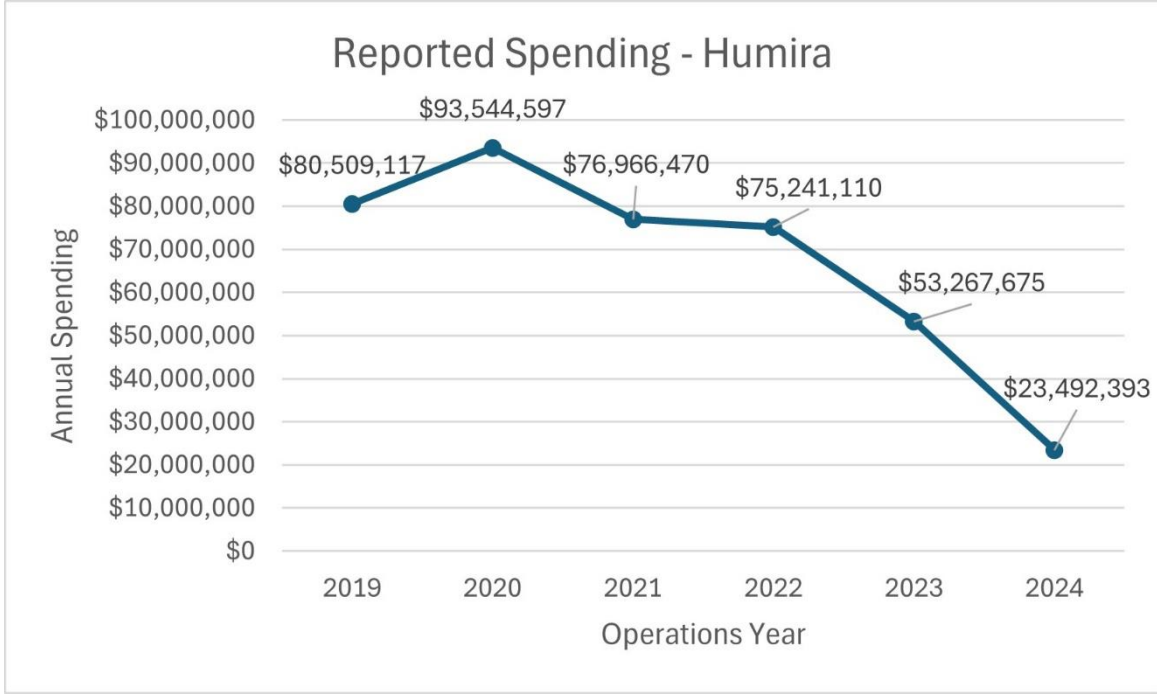
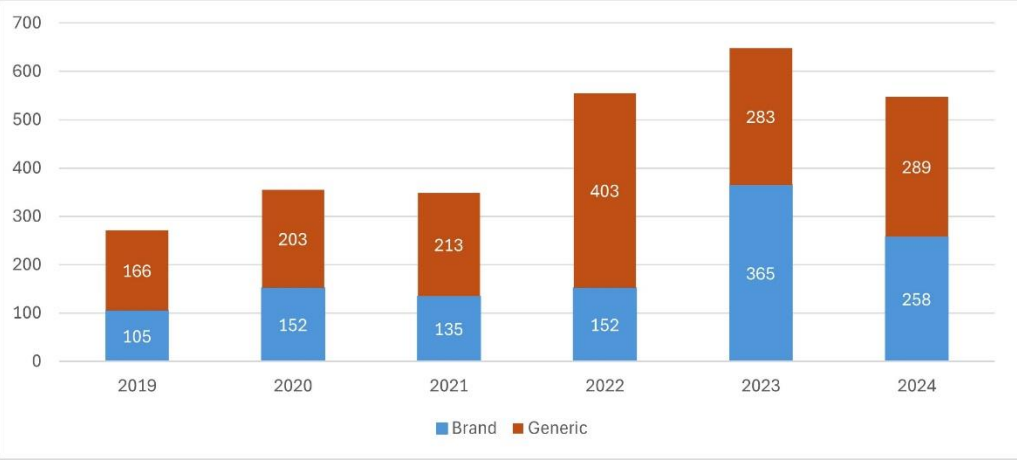


Figure 7 on Page 21 and Figure 9 on Page 22 of the 2025 DPT legislative report.

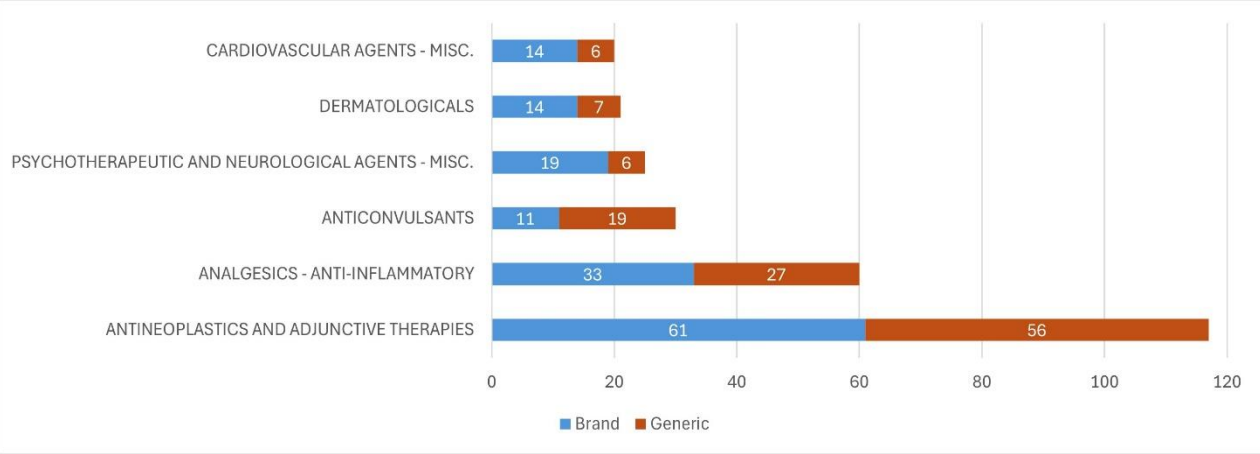
New prescription drug manufacturer reports 2019-24

Report counts for generic and brand-name new prescription drugs for each calendar year from 2019 to 2024



- January 2024 through December 2024, DPT received 547 new prescription drug reports.
- Generics counted for 289 reports; brand-name drugs counted for 258.

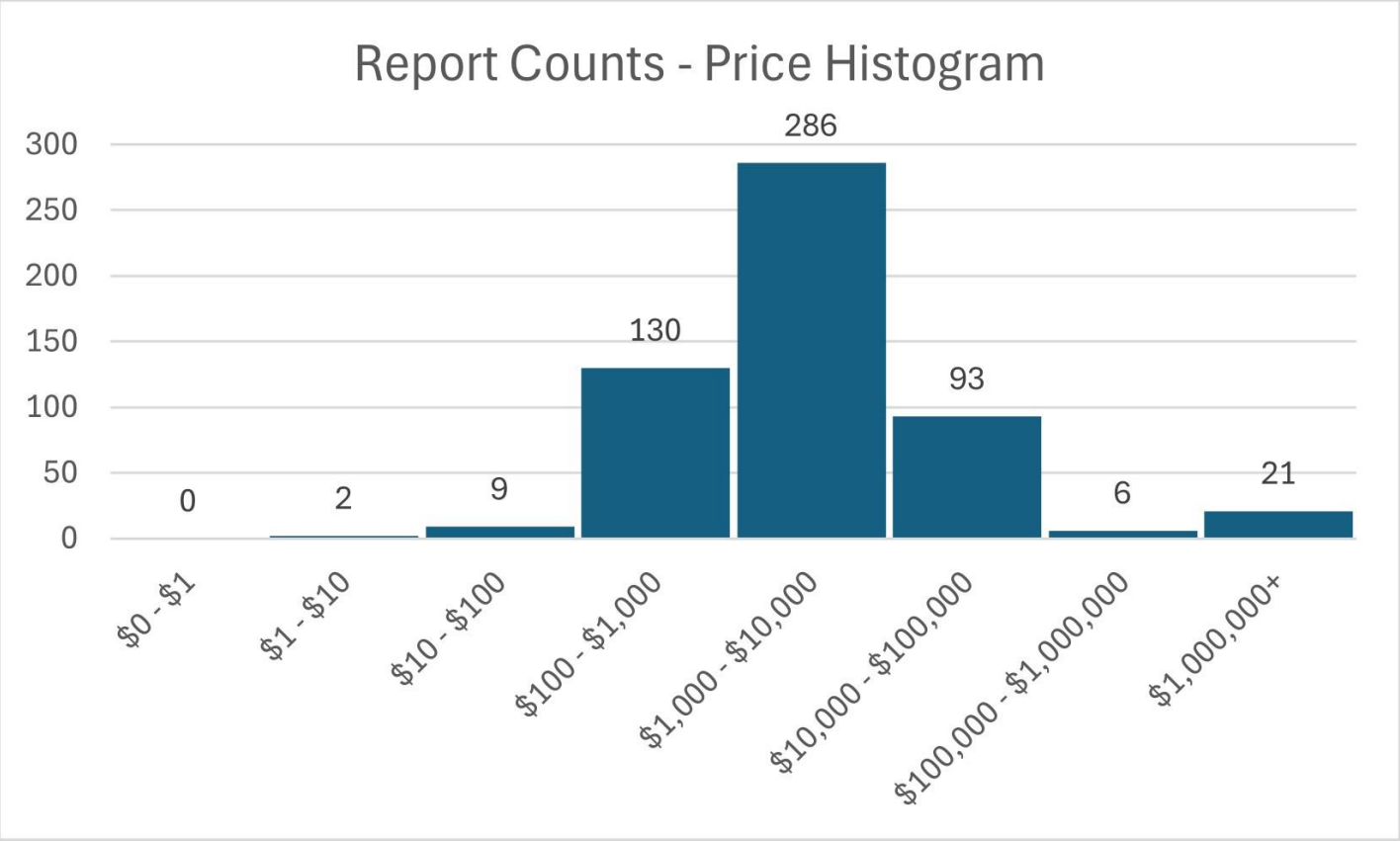
Distribution of brand-name and generic new prescription drugs by most common therapeutic classes



- Antineoplastic and adjunctive therapies were 21 percent.
- Analgesics – anti-inflammatory drugs were 11 percent.
- Anticonvulsants were 5.5 percent.

Figures 13 and 14 on Page 27 of the 2025 DPT legislative report.

WAC price ranges for new prescription drug reports received in 2024



Wholesale acquisition cost (WAC) is a price set by the manufacturer.

To make the histogram easier to read we grouped the reports in categories by price using a base 10 logarithmic scale.

Figure 15 on Page 28 of the 2025 DPT legislative report.

Highest-reported WACs for new drugs – brand name

Drug	WAC	Therapeutic class	Manufacturer
Beqvez™	$3.5 million	Hematological agents – miscellaneous	Pfizer
Lyfgenia™	$3.1 million	Hematopoietic agents	bluebird bio Inc.
Zolgensma	$2.3 million	Neuromuscular agents	Novartis Gene Therapies Inc.
Casgevy®	$2.2 million	Hematopoietic agents	Vertex Pharmaceuticals
Tecelra®	$727,000	Antineoplastics and adjunctive therapies	Adaptimmune LLC
Aucatzyl	$525,000	Antineoplastics and adjunctive therapies	Autolus Inc.
Amtagvi™	$515,000	Antineoplastics and adjunctive therapies	Iovance Biotherapeutics Inc.
Livmarli	$106,800	Gastrointestinal agents – miscellaneous	Mirum Pharmaceuticals
Miplyffa	$106,020 – 79,515	Psychotherapeutic and neurological agents – miscellaneous	Acer Therapeutics Inc.
Rivfloza™	$62,880	Genitourinary agents – miscellaneous	Novo Nordisk Inc.

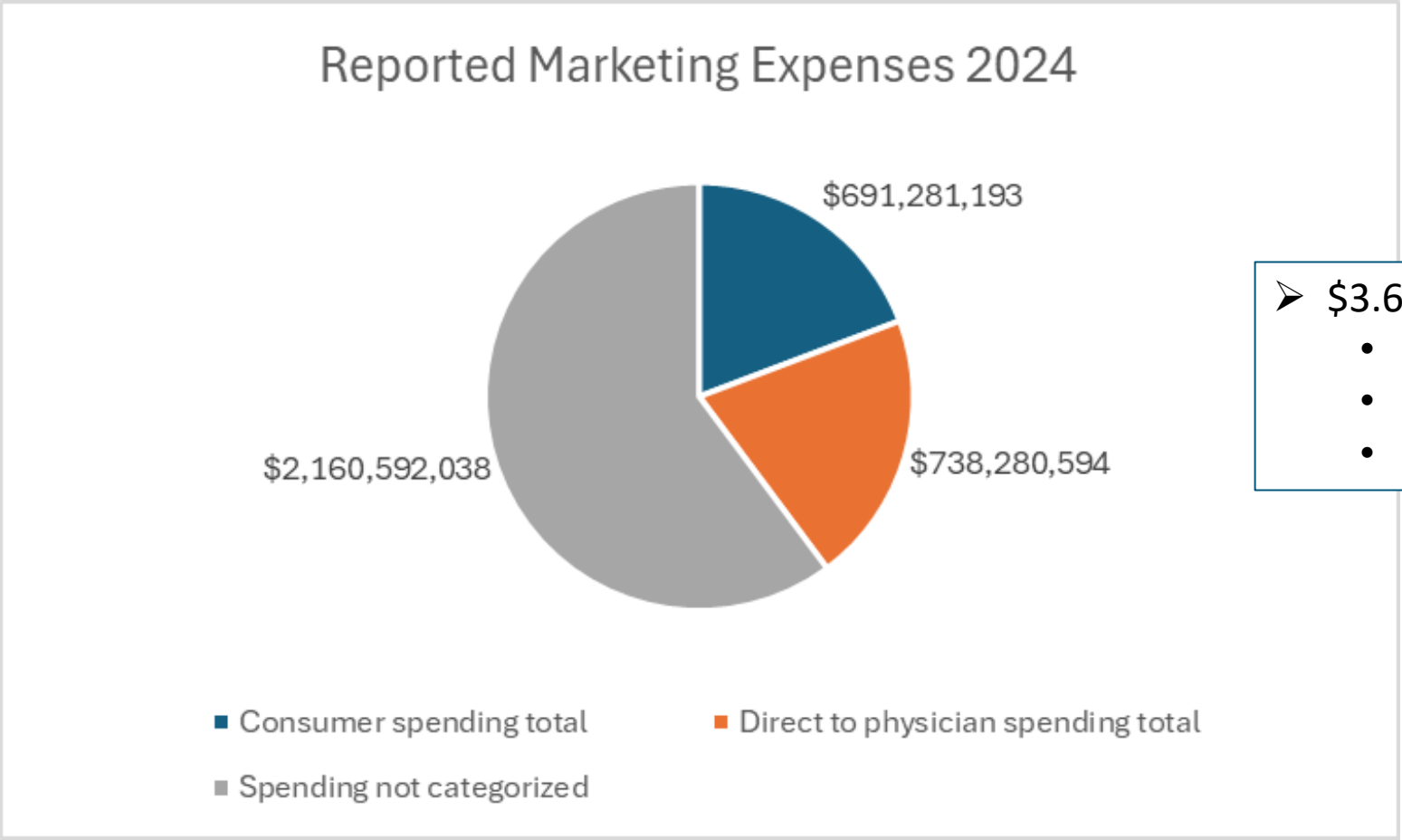
Figure 16 on Page 29 of the 2025 DPT legislative report.

Highest-reported WACs for new drugs – generic

Drug	WAC (package)	WAC per unit	Therapeutic class	Manufacturer
Mifepristone (280 tablets at 300 mg)	$170,435	$609 / tablet	Endocrine and metabolic agents - miscellaneous; progesterone receptor antagonists (abortifacient)	Corcept Therapeutics Inc.
Nitisinone (60 capsules from 20 to 2 mg)	$38,580 – $3,858	$643 - $64 / capsule ($32 / mg)	Endocrine and metabolic agents – miscellaneous	Eton Pharmaceuticals Inc.
Mifepristone (28 tablets at 300 mg)	$16,734	$598 / tablet	Endocrine and metabolic agents – miscellaneous; progesterone receptor antagonists (abortifacient)	Teva Pharmaceuticals
Lenalidomide (28 capsules from 2.5 to 10 mg; 21 capsules from 15 to 25 mg)	$15,172 – $10,908	$541 – $519 / capsule	Miscellaneous therapeutic classes (Immunomodulators)	Exelan Pharmaceuticals Inc.
Dasatinib (60 tablets from 50 to 70 mg)	$14,173 – $13,849	$236 – $231 / tablet	Antineoplastics and adjunctive therapies	Prasco LLC and Apotex Corp
Dasatinib (30 tablets from 80 to 140 mg)	$12,772 – $12,480	$426 – $416 / tablet	Antineoplastics and adjunctive therapies	Prasco LLC and Apotex Corp
Pazopanib (120 tablets at 200 mg)	$11,349	$95 / tablet	Antineoplastics and adjunctive therapies	Avkare Inc.
Indomethacin (30 suppositories at 50 mg)	$10,314	$344 / suppository	Analgesics/anti-inflammatories	Zydus Pharmaceuticals USA Inc.
Pazopanib (120 tablets at 200 mg)	$8,900	$74 / tablet	Antineoplastics and adjunctive therapies	Novugen Pharma USA LLC
Tiopronin delayed release (DR) (300 tablets at 100 mg)	$8,463	$28 / tablet	Genitourinary agents – miscellaneous	Torrent Pharma Inc.

Figure 17 on Page 30 of the 2025 DPT legislative report.

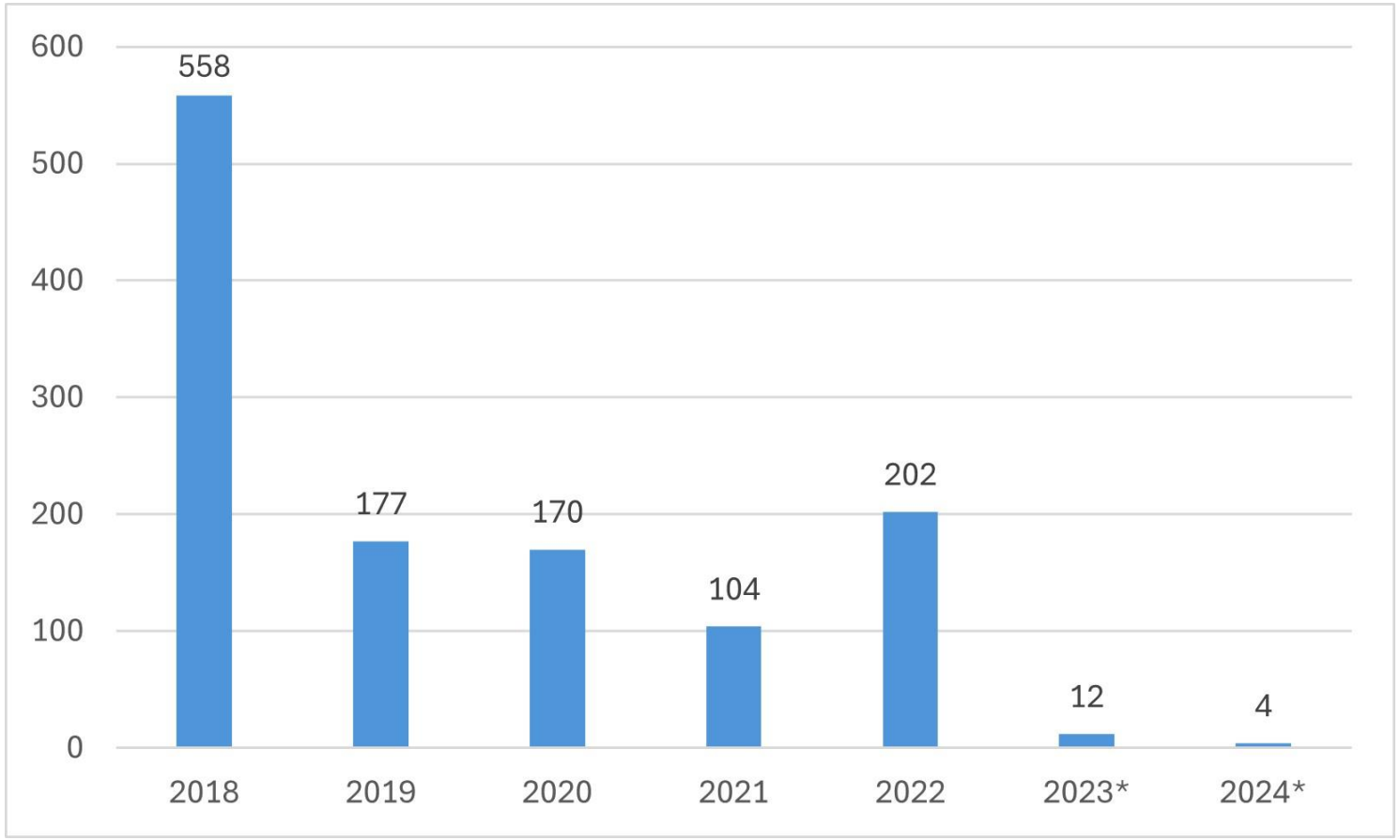
New prescription drug reported marketing expenses



- $3.6 billion in total marketing reported:
  - 20.6 percent direct to physician
  - 19.3 percent consumer
  - 60.2 percent unspecified

Figure 18 on Page 32 of the 2025 DPT legislative report.

Counts for annual price increase reports based on the year of the data being reported for 2018 to 2024



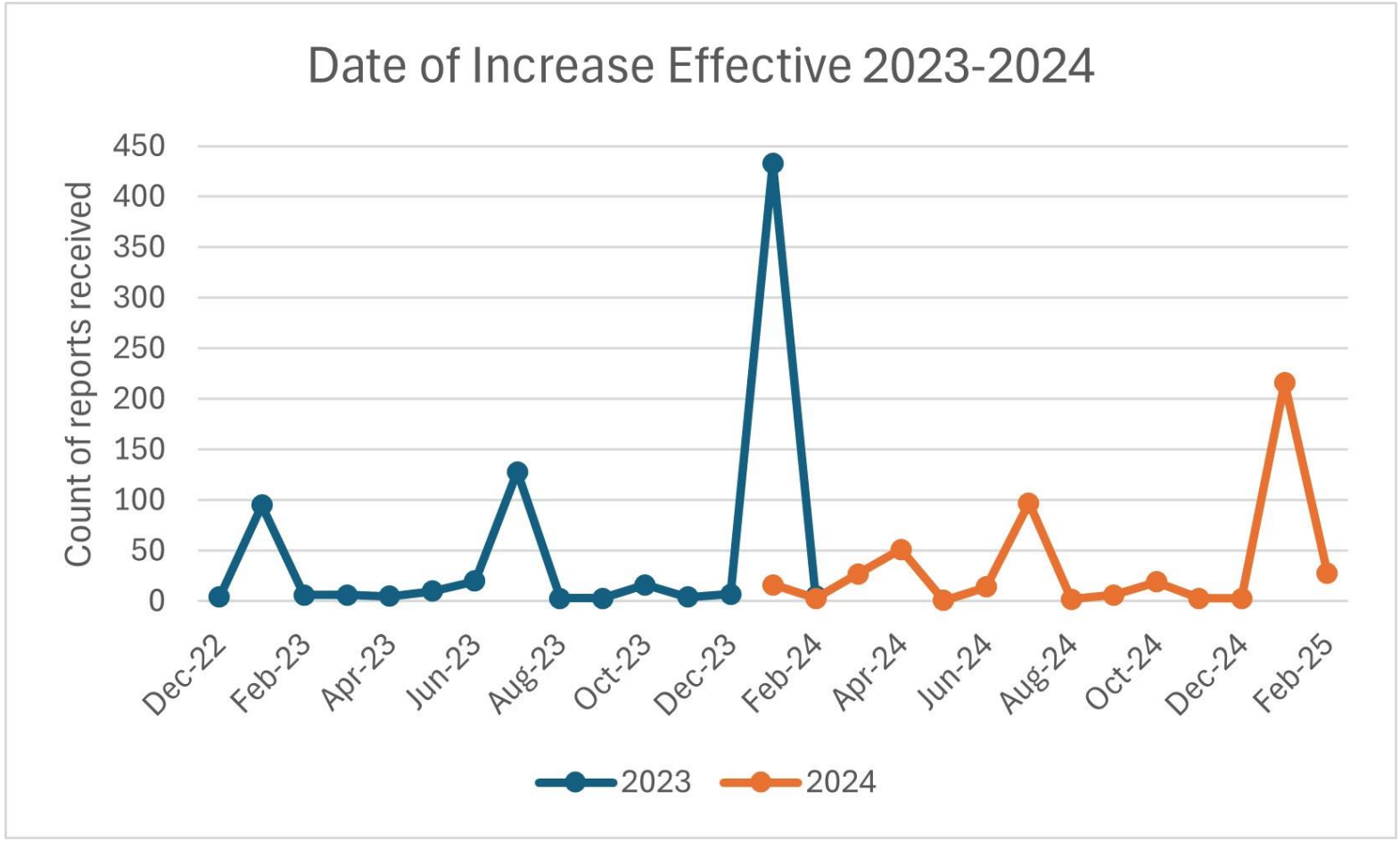
Reporting is required for drugs with a patient assistance program that are also $100 or more for a 30-day supply and have a 10 percent net yearly increase.

With the reporting window switch, data received in 2024 was about operations in year 2023, and data received in 2025 was for operations in 2024.

*Note: Operation years 2023 and 2024 only include those with voluntary data.

Figure 19 on Page 35 of the 2025 DPT legislative report.

Number of 60-day price increase notices received based on the month of the planned increase



Through 2023 and 2024, 52.7% of reports received had an effective increase at the beginning of the calendar year (January).

Reporting is required for brand-name drugs with a 10 percent or $10,000 increase or generic drugs with a 25 percent and $300 increase.

Figure 21 on Page 37 of the 2025 DPT legislative report.

Aggregated data from reported PBM information

Reporting element	Aggregated data	Number of PBMs
(1) Total rebates, fees, price protection payments, and any other payments received from manufacturers related to managing pharmacy benefits for carriers issuing health benefit plans in Oregon:	$377,273,218	12
Amount of (1) passed to carriers issuing health benefit plans in Oregon:	$369,134,168	11
Amount of (1) passed to enrollees of health benefit plans in Oregon:	$432,204	3
Amount of (1) retained by the PBM as revenue:	$7,706,846	6
The total dispensing fees paid to the PBM in this state from carriers, coordinated care organizations, and the Oregon Prescription Drug Program:	$15,599,279	10

Reporting element	Aggregated data	Number of PBMs
The total dispensing fees paid to pharmacies in this state by the PBM:	$17,765,746	14
The total administrative fees received from carriers:	$33,919,368	6
The total administrative fees from carriers that were retained by the PBM:	$33,919,368	6
The total amount of revenue received by the PBM through spread pricing, pay-for-performance arrangements, or similar means:	$11,654,515	7

Figure 25 on Page 42 of the 2025 DPT legislative report. Chart and details are from 2025 PBM report published here: https://dfr.oregon.gov/drugtransparency/Pages/DPT-pharmacy-benefit-managers.aspx

PBM rebate comparisons of data years 2023 and 2024

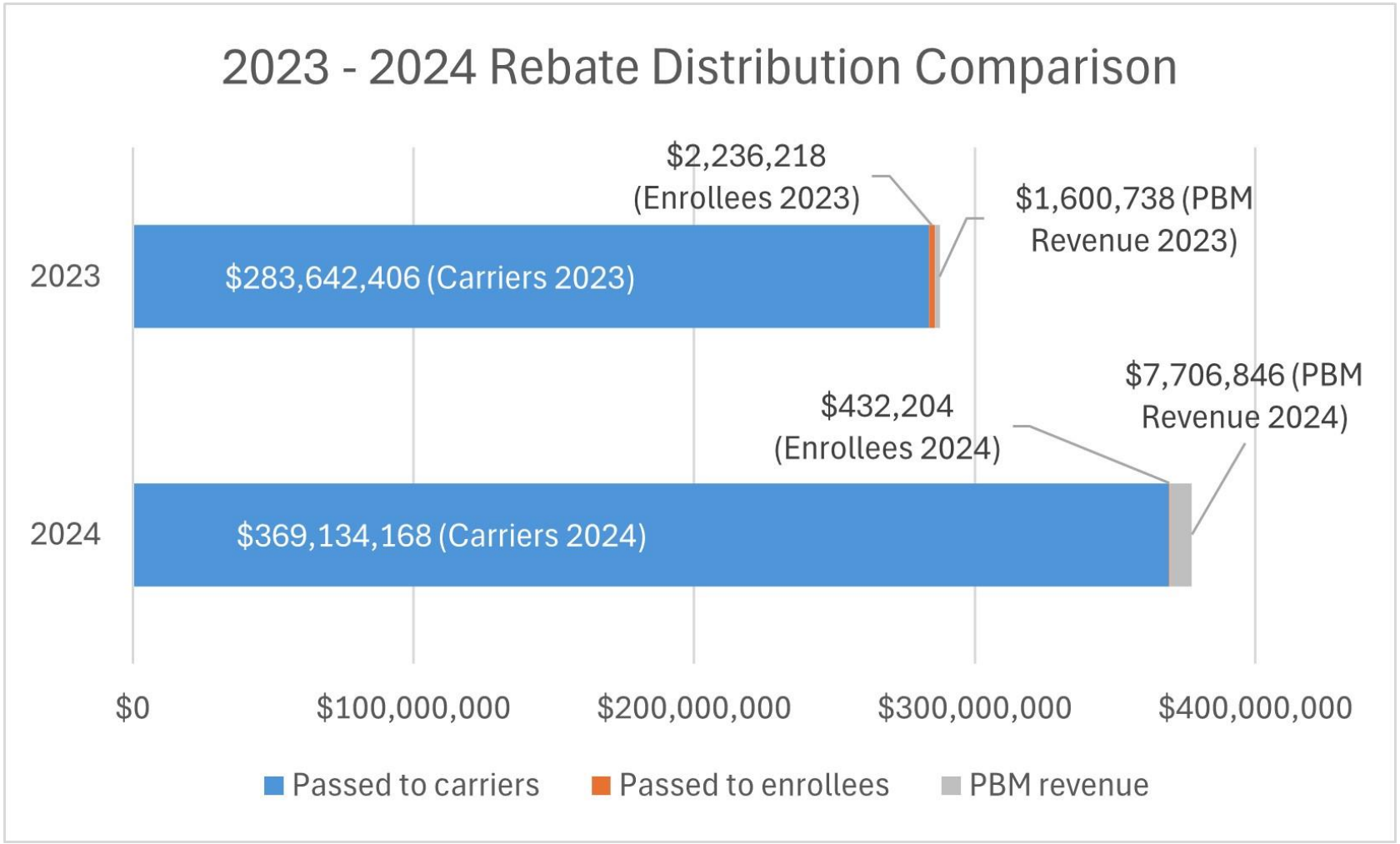
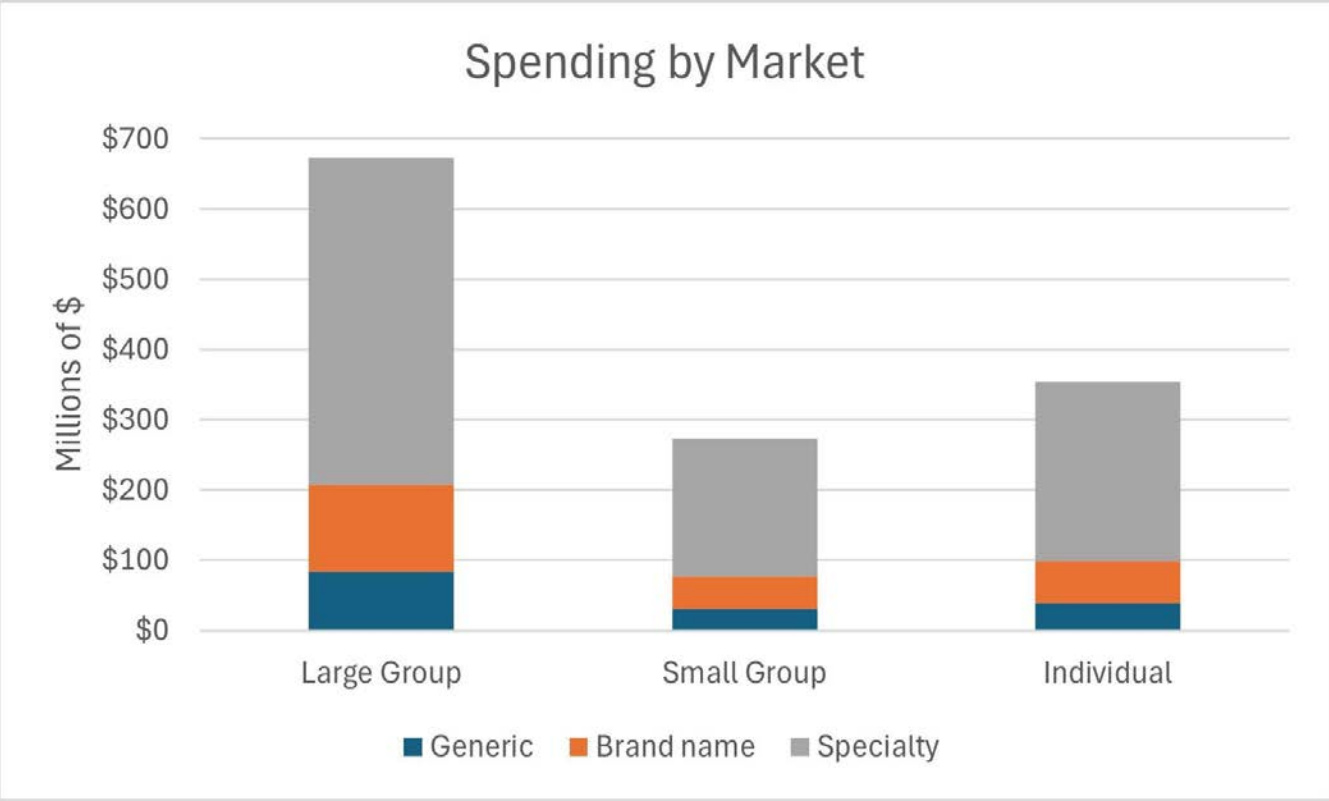


Figure 27 on Page 44 of the 2025 DPT legislative report. Chart and details are from 2025 PBM report published here: https://dfr.oregon.gov/drugtransparency/Pages/DPT-pharmacy-benefit-managers.aspx

Insurer spending by markets and drug category



- Drug type spending:
  - ✓ Generic – $154,156,566
  - ✓ Brand Name – $228,781,648
  - ✓ Specialty – $917,587,270
- Market type spending:
  - ✓ Large Group – $673,048,355
  - ✓ Small Group – $273,823,088
  - ✓ Individual – $353,654,040

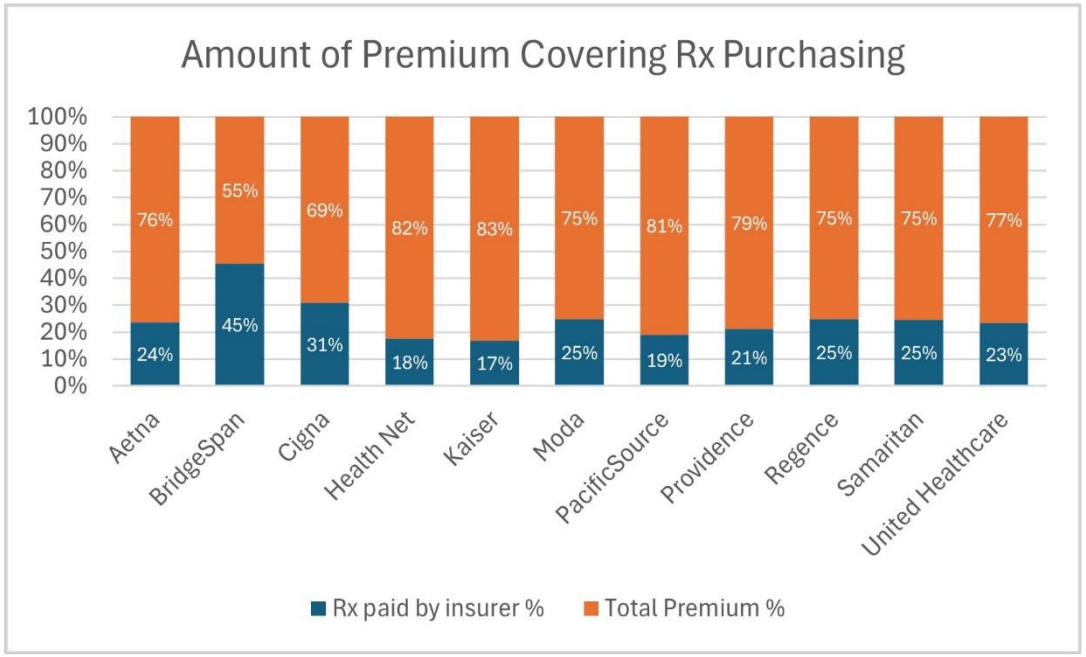
- **Total spending – $ 1,300,525,483**

Large group are employers with 50 or more employees. Specialty drugs for this reporting are those that cost $670 or more for a one-month supply.

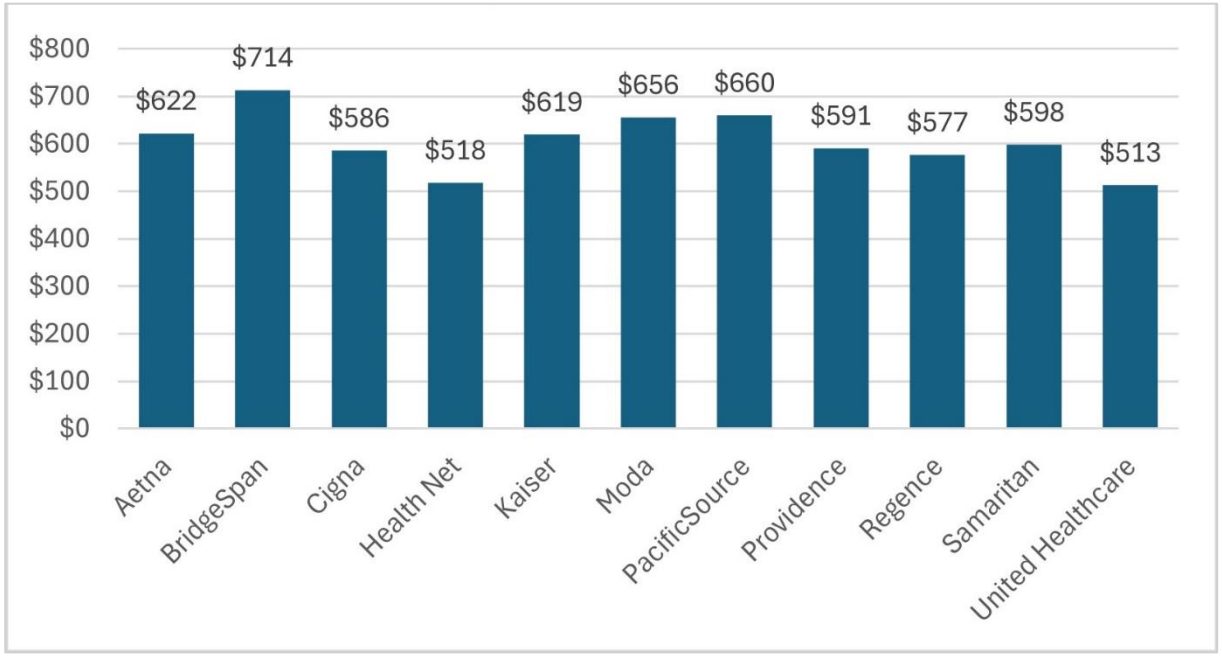
Figure 29 on Page 47 of the 2025 DPT legislative report.

Insurer spending on drugs based on premiums collected

Plan spending on prescription drugs as a percentage of premiums collected



Average premium per member per month

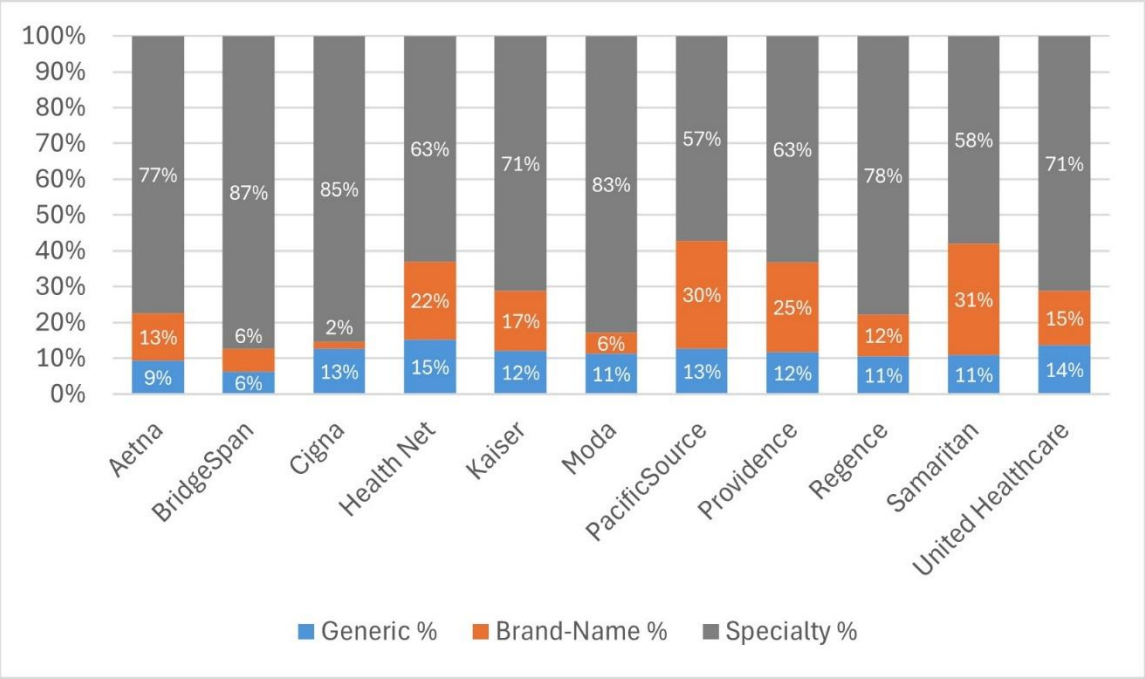


The average premium per member per month is the total of premiums collected by the insurer during 2024 divided by how many members were covered each month.

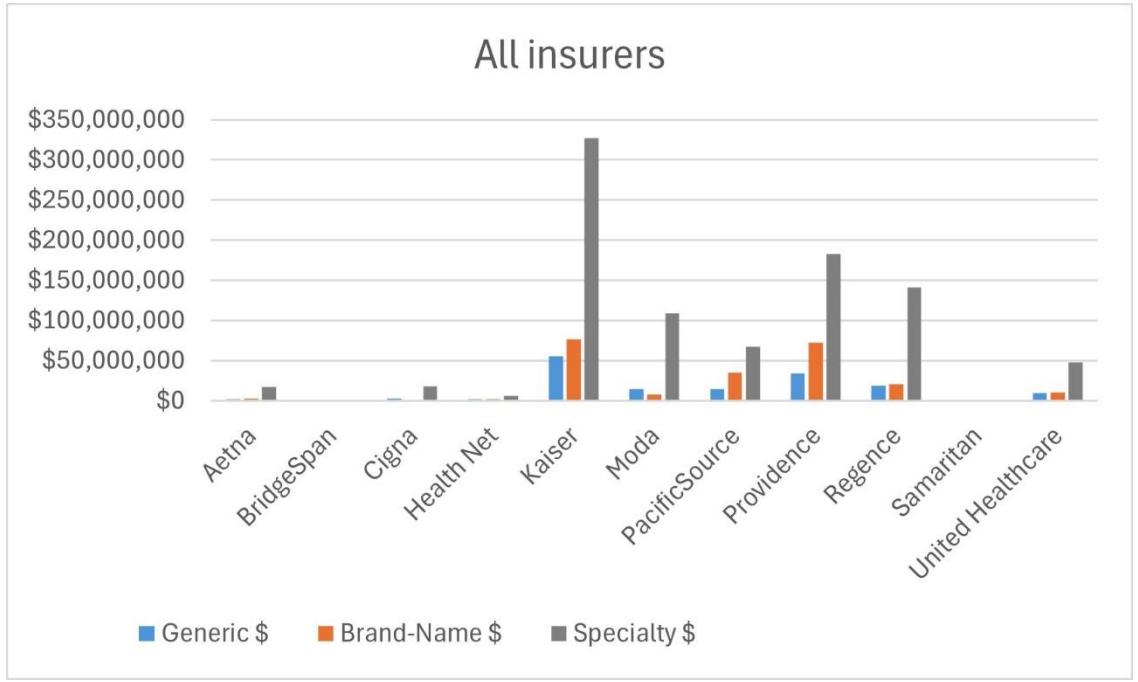
Figures 31 and 32 on Page 49 of the 2025 DPT legislative report.

Insurer spending on prescription drugs by drug category

Prescription drug spending by percentage (%)



Prescription drug spending by dollar amount ($)



Figures 33 and 34 on pages 50 and 51 of the 2025 DPT legislative report.

Total prescription drug spending by insurers, 2019-2024

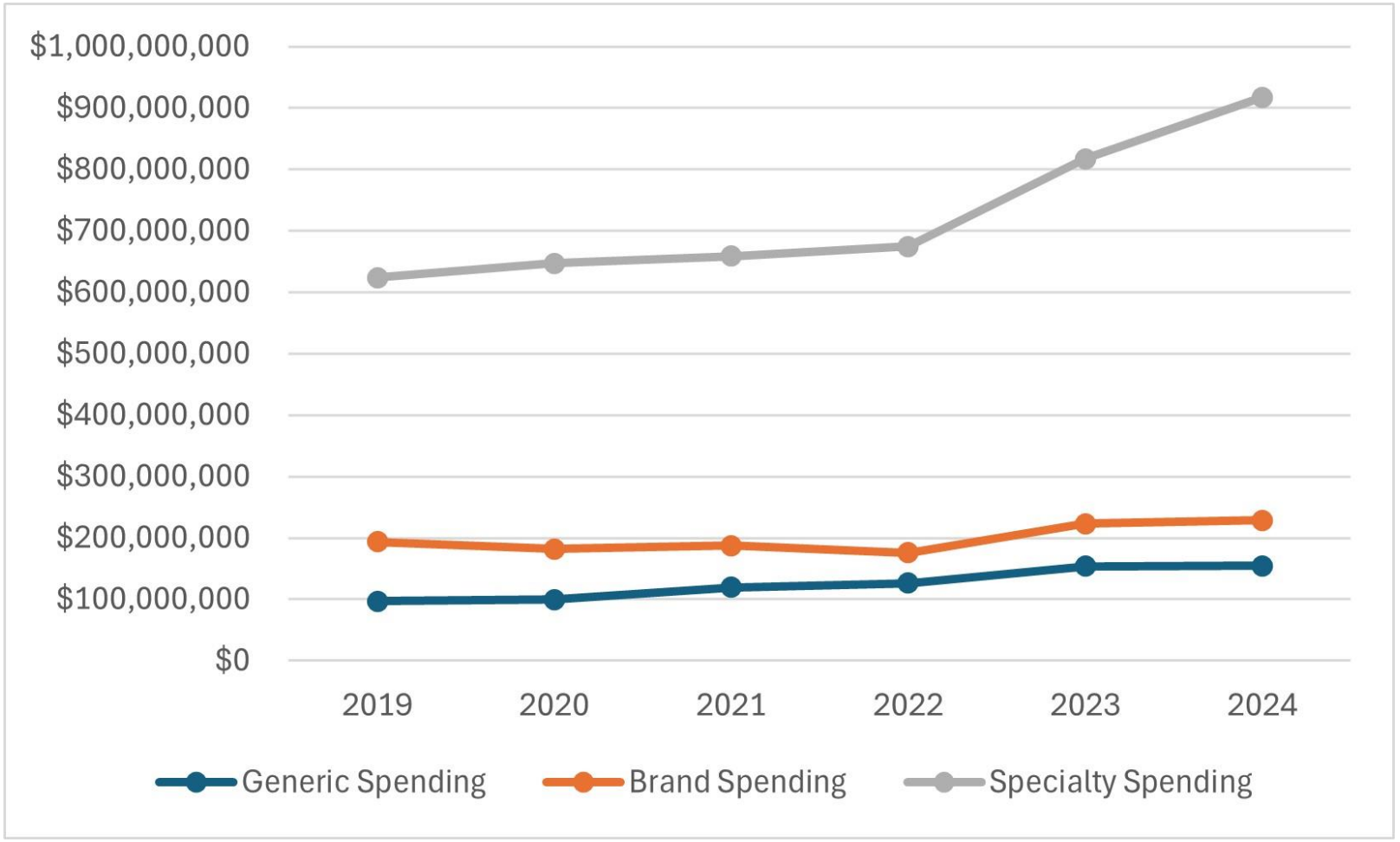
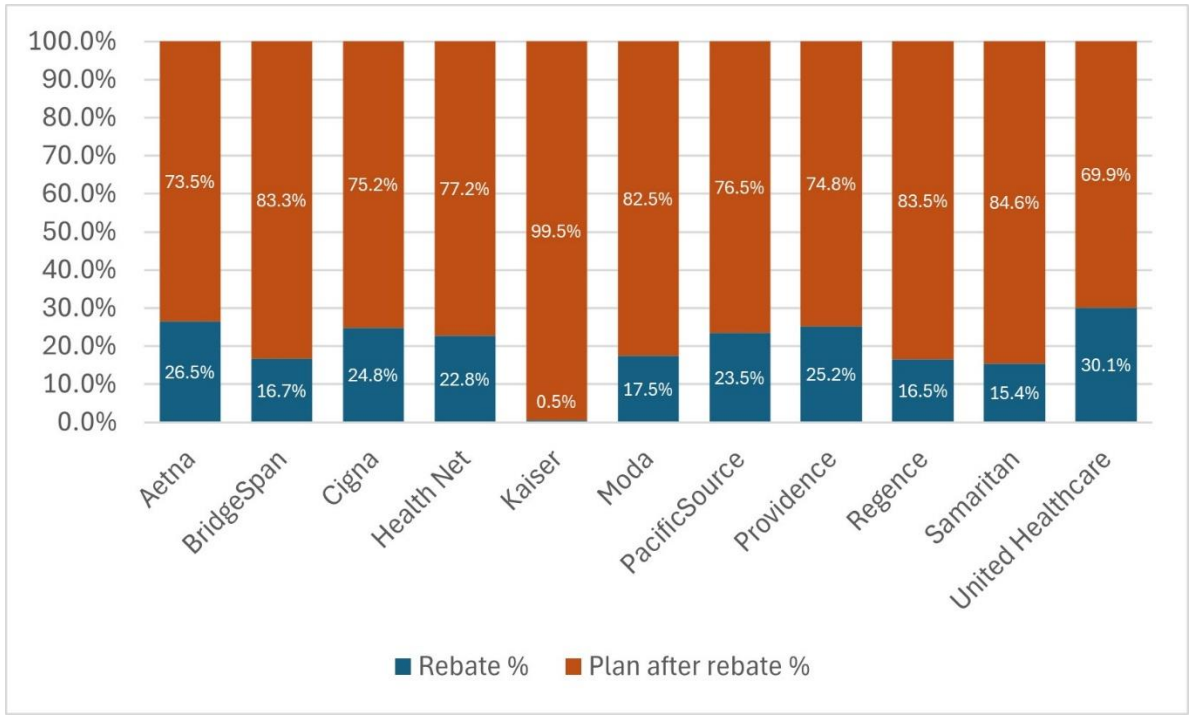


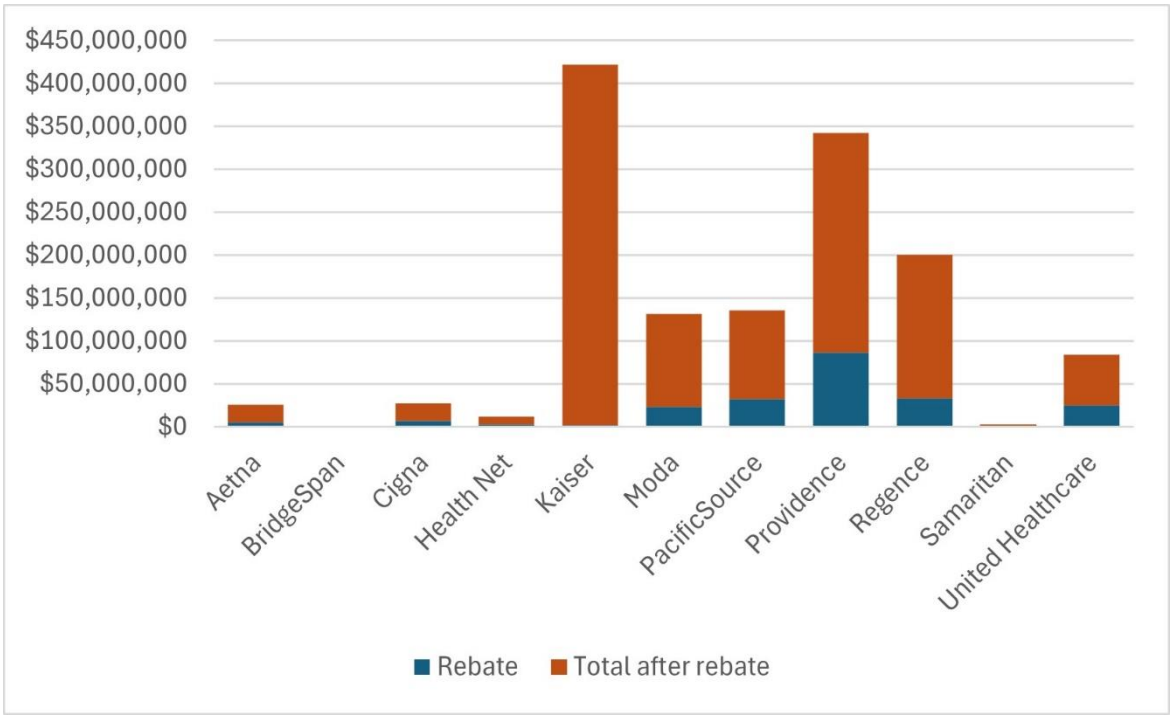
Figure 36 on Page 53 of the 2025 DPT legislative report.

Insurer drug rebates received versus total drug spending

Rebate versus plan spending by percentage (%)



Rebate versus plan spending by dollar ($)



- United Healthcare reported highest percentage of rebates to total spending at 30.1 percent.
- Kaiser reported the lowest percentage of rebates at 0.5 percent.

- Providence reported the highest amount of rebates, about $86.3 million.
- BridgeSpan reported the lowest amount of rebates, $199,072.

Figures 39 and 40 on Page 56 of the 2025 DPT legislative report.

Insurer most prescribed prescription drugs in 2024

Drug name	Therapeutic class	Prescriptions
Amphetamine	ADHD/anti-narcolepsy/anti-obesity/anorexiants	213,586
Atorvastatin	Antihyperlipidemics	185,523
Levothyroxine	Thyroid agents	171,105
Bupropion	Antidepressants	166,146
Metformin	Antidiabetics	161,716
Lisinopril	Antihypertensives	159,183
Albuterol	Antiasthmatic and bronchodilator agents	157,926
Losartan	Antihypertensives	134,219
Sertraline	Antidepressants	132,611
Escitalopram	Antidepressants	121,840

Nine of the drugs on this year's most-prescribed table were also on last year's table. These are amphetamine, atorvastatin, levothyroxine, bupropion, metformin, lisinopril, albuterol, losartan, and sertraline.

Figure 43 on Page 61 of the 2025 DPT legislative report.

Insurer most costly prescription drugs in 2024

Drug name	Therapeutic class	Total annual plan spending
Skyrizi	Dermatologicals	$37,536,013
Keytruda	Antineoplastics and adjunctive therapies	$36,481,289
Stelara	Dermatologicals/gastrointestinal agents – misc.	$35,685,330
Ozempic	Antidiabetics	$27,326,718
Trikafta	Respiratory agents – misc.	$25,747,283
Biktarvy	Antivirals	$24,080,914
Humira	Analgesics – anti-inflammatory	$23,492,393
Entyvio	Gastrointestinal agents – misc.	$23,070,291
Cosentyx	Dermatologicals	$20,562,420
Dupixent	Dermatologicals	$20,274,398

Nine of the drugs on this year's most costly table were also on last year's table. These are Skyrizi, Keytruda, Stelara, Ozempic, Biktarvy, Humira, Entyvio, Cosentyx, and Dupixent.

Figure 44 on Page 62 of the 2025 DPT legislative report.

Insurer prescription drugs with greatest increases in plan spending from 2023 to 2024

Drug name	Therapeutic class	Year-over-year increase in total spending
Skyrizi	Dermatologicals	$15,701,487
Ozempic	Antidiabetics	$8,934,850
Paxlovid	Antivirals	$7,566,764
Nexviazyme	Endocrine and metabolic agents – misc.	$5,674,528
Stelara	Dermatologicals/gastrointestinal agents – misc.	$5,370,053
Keytruda	Antineoplastics and adjunctive therapies	$5,332,555
Lisdexamfetamine	ADHD/anti-narcolepsy/anti-obesity/anorexiants	$5,121,695
Trikafta	Respiratory agents – misc.	$4,942,366
Mounjaro	Antidiabetics	$4,564,057
Dupixent	Dermatologicals	$4,463,941

Five of the drugs on this year's greatest increase in plan spending table were also on last year's table. These are Skyrizi, Ozempic, Stelara, Keytruda, and Dupixent.

Figure 45 on Page 63 of the 2025 DPT legislative report.

Policy recommendations

1) Expand patient assistance program reporting
   - Continue to recommend manufacturers be required to report annually on all patient assistance
2) Require insurers and PBMs to report on copay accumulator programs
   - Continue to recommend they be required to report annually on copay accumulators in Oregon
3) Expand and strengthen Oregon's bulk purchasing authority
   - Recommend establishing multistate purchasing authority on behalf of state, **and**
   - Recommend state entities be required to purchase drugs through Oregon Prescription Drug Program (OPDP) and require OPDP to report annually to Oregon Legislature

Refer to pages 64 through 66 and appendixes A through E on pages 71 through 78 of the 2025 DPT legislative report: https://dfr.oregon.gov/drugtransparency/Pages/annual-reports.aspx

Policy recommendations (continued)

4) Centralize state Medicaid drug purchasing
    - To create administrative efficiencies, adequate oversight, cost savings, and equitable consumer experiences
5) Centralize pharmacy purchasing and analytics
    - To provide coordination and oversight for all state prescription drug purchasing to ensure Oregon is leveraging its position in the marketplace

Refer to pages 64 through 66 and appendixes A through E on pages 71 through 78 of the 2025 DPT legislative report: https://dfr.oregon.gov/drugtransparency/Pages/annual-reports.aspx

Questions?

Members of the public:

Use the chat window to sign up to give public testimony.

Program presenters:
Sofia Parra, program coordinator
Taran Heins, research analyst
Numi Rehfield-Griffith, senior policy advisor

First public comment period

Send written testimony to rx.prices@dcbs.oregon.gov

First panel – biosimilars

Presenters:

- Benjamin N. Rome (he/him), M.D., MPH, assistant professor of medicine, Harvard Medical School and Brigham and Women's Hospital
- Alex Keeton (he/him), executive director, Biosimilars Council, Association of Accessible Medicines
- Michael Reilly, Esq. (he/him), executive director, Alliance for Safe Biologic Medicines

First panel – biosimilars

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- Benjamin N. Rome, M.D., MPH, assistant professor of medicine, Harvard Medical School and Brigham and Women's Hospital

PORTAL
Program on Regulation, Therapeutics, And Law

DoPE BWH

Oregon Annual Hearing on Prescription Drug Prices | December 4, 2025

Challenges with Biosimilar Competition in the US

Benjamin N. Rome, MD, MPH

Assistant Professor of Medicine, Harvard Medical School

Program on Regulation, Therapeutics, and Law (PORTAL)
Division of Pharmacoepidemiology and Pharmacoeconomics
Department of Medicine
Brigham and Women's Hospital

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HARVARD MEDICAL SCHOOL

Brigham and Women's Hospital
Founding Member, Mass General Brigham

Disclosures

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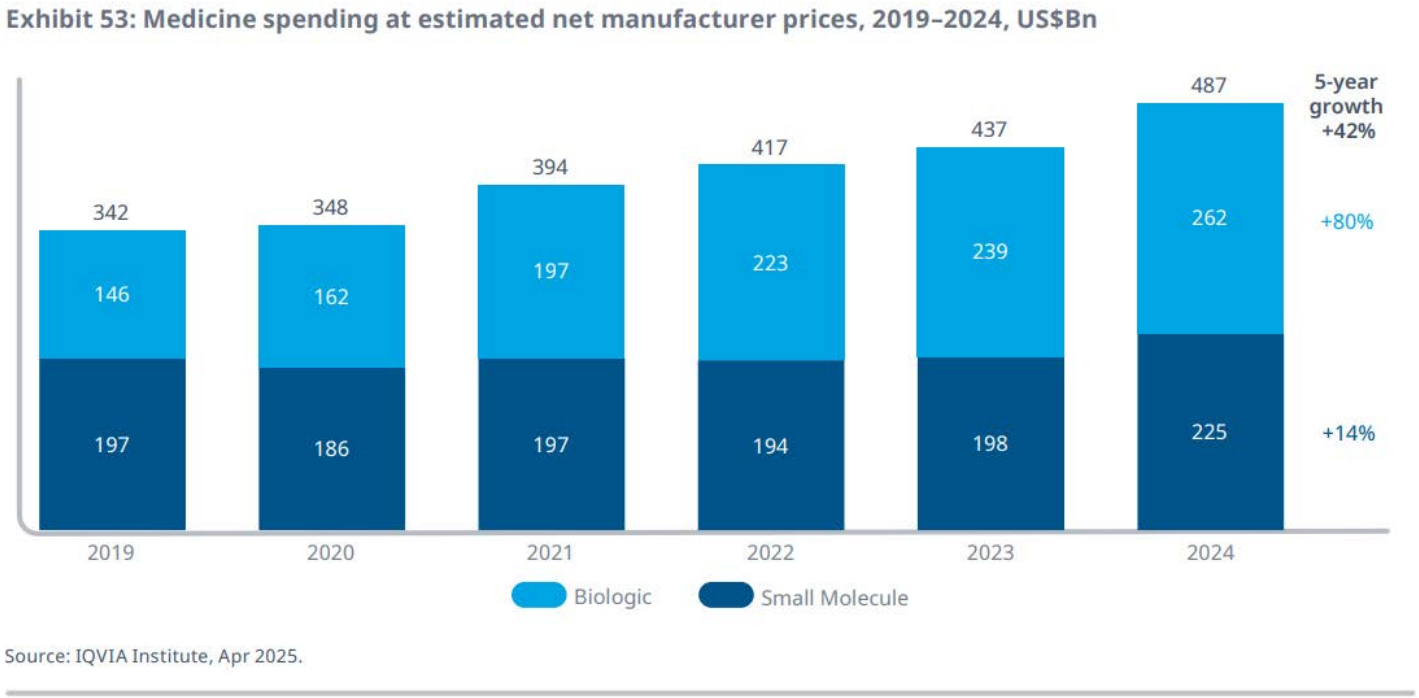
  - Arnold Ventures
  - The Commonwealth Fund
  - The Elevance Public Policy Institute
  - Humana
  - PCMA Foundation
  - The Greenwall Foundation
  - The National Academy for State Health Policy
  - Colorado Division of Insurance

- Consulting for the non-profit Alosa Health (academic detailing)

Biologics are a growing source of prescription drug spending in the US

- Biologics represent only about **2% of retail prescriptions** dispensed in the US but account for more than **half of prescription drug spending**.

- From 2019-2024, spending on biologics **increased by 80%**



https://jamanetwork.com/journals/jamaoncology/fullarticle/2788563
https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/understanding-the-use-of-medicines-in-the-us-2025

A regulatory pathway for biosimilars was designed to increase competition and lower costs

- To address rising spending on biologics, Congress passed the **Biologics Price Competition and Innovation Act** (BCPIA) as part of the Affordable Care Act in 2009.
- The BCPIA established an **expedited FDA pathway for biosimilars**, more affordable versions of biologic medications.

Signing of the Affordable Care Act, March 23, 2010

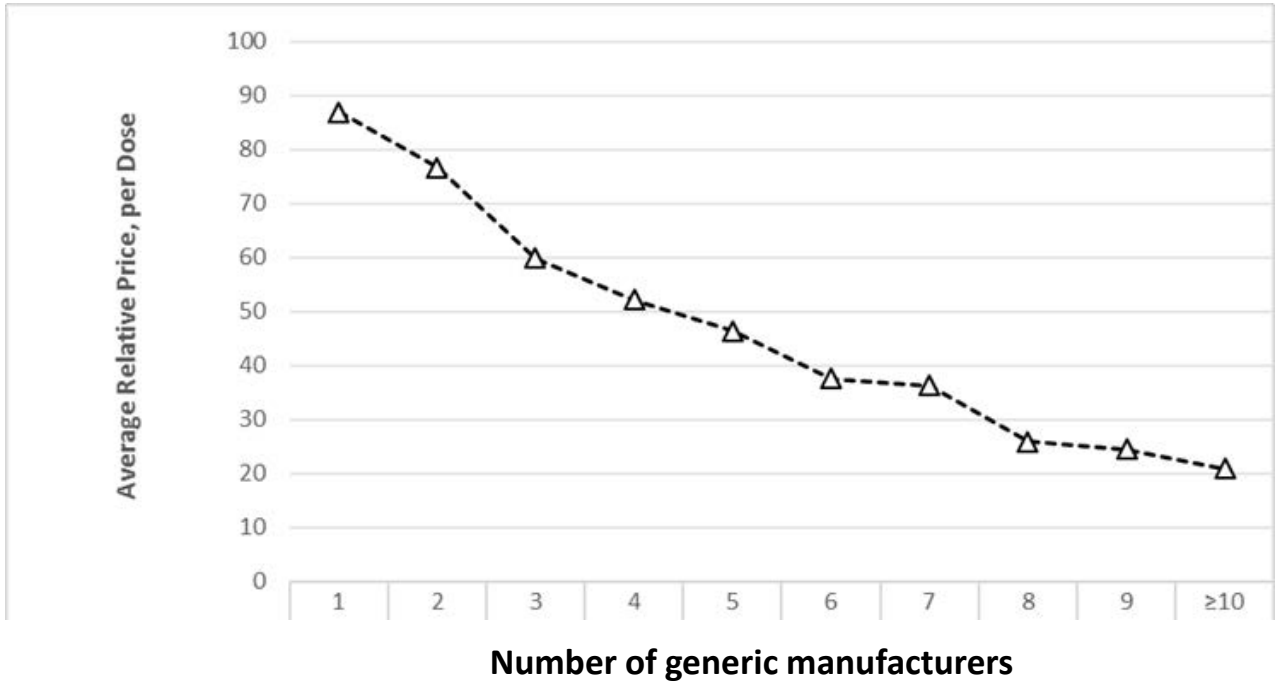
Photo: https://www.nytimes.com/2010/03/24/health/policy/24health.html

The hope was to replicate the success of generic drug competition

- Sufficient generic competition can lower prices by 80% or more

- Generic drugs account for **9 out of 10 prescriptions** in the US, but **less than 20% of prescription drug spending**.

Prices fall as the number of generic competitors increases

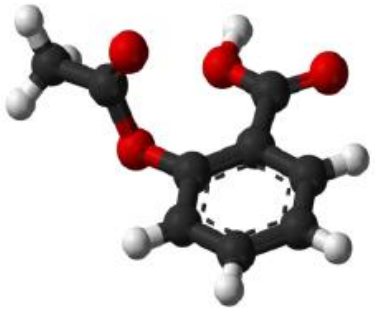


Dave, Hartzema, Kesselheim. *NEJM* 2017.
https://accessiblemeds.org/resources/reports/2022-savings-report/

Because biologics are more complex, biosimilar regulation differed from generics

Small molecule drug

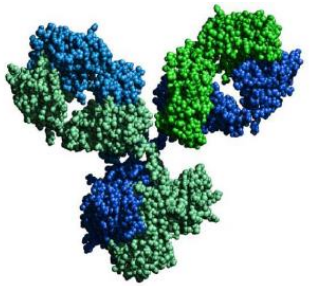
- Well-defined chemical structure could be relatively easily replicated
- Generic drugs must be "**bioequivalent**" to the original



Aspirin
21 atoms

Biologic drug

- Complex structure that varies from batch to batch because they are made from living cells
- Biosimilars must be "**highly similar**" with "**no clinically meaningful differences**" from the original



Trastuzumab (Herceptin)
~25,000 atoms

Images: https://www.edisongroup.com/thematic/the-a-b-t-of-biosimilars-explaining-contemporary-life-science-issues/
FDA Guidance Document FDA-2011-D-0605. April 2015.
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/scientific-considerations-demonstrating-biosimilarity-reference-product

Biosimilars, unlike generics, are not automatically interchangeable with the original biologic

- Nearly all FDA-approved **generic drugs** are deemed "**therapeutically equivalent**" to the original brand-name drug, which means that pharmacists can automatically substitute them unless a prescriber specifies "dispense as written."
- By contrast, Congress set separate standards were for biosimilars to be deemed **interchangeable** with the reference biologic (i.e., substitutable by pharmacist).
  - Because of this separate requirement, the FDA originally required **"switching studies"** to study the impact of patients switching between the biosimilar and the reference biologic.

FDA Guidance Document FDA-2017-D-0154. May 2019.
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/considerations-demonstrating-interchangeability-reference-product-guidance-industry

Current status of biosimilars in the US

- Since the first biosimilar was approved in 2015, the FDA has approved **75 biosimilars for 19 reference biologics**, as of June 2025.
  - 21 were deemed interchangeable.
  - Some not yet marketed due to patents.
- **14 biologic drugs** had 1 or more biosimilar versions marketed in the US, as of August 2025.
  - For 5 drugs (marked with *), biosimilar competition began in 2024 or 2025

Immunology

- Adalimumab (Humira)
- Eculizumab (Soliris)*
- Infliximab (Remicade)
- Tocilizumab (Actemra)*
- Ustekinumab (Stelara)*

Oncology

- Bevacizumab (Avastin)
- Filgrastim (Neupogen)
- Pegfilgrastim (Neulasta)
- Rituximab (Rituxan)
- Trastuzumab (Herceptin)

Ophthalmology

- Aflibercept (Eylea)*
- Ranibizumab (Lucentis)

Other

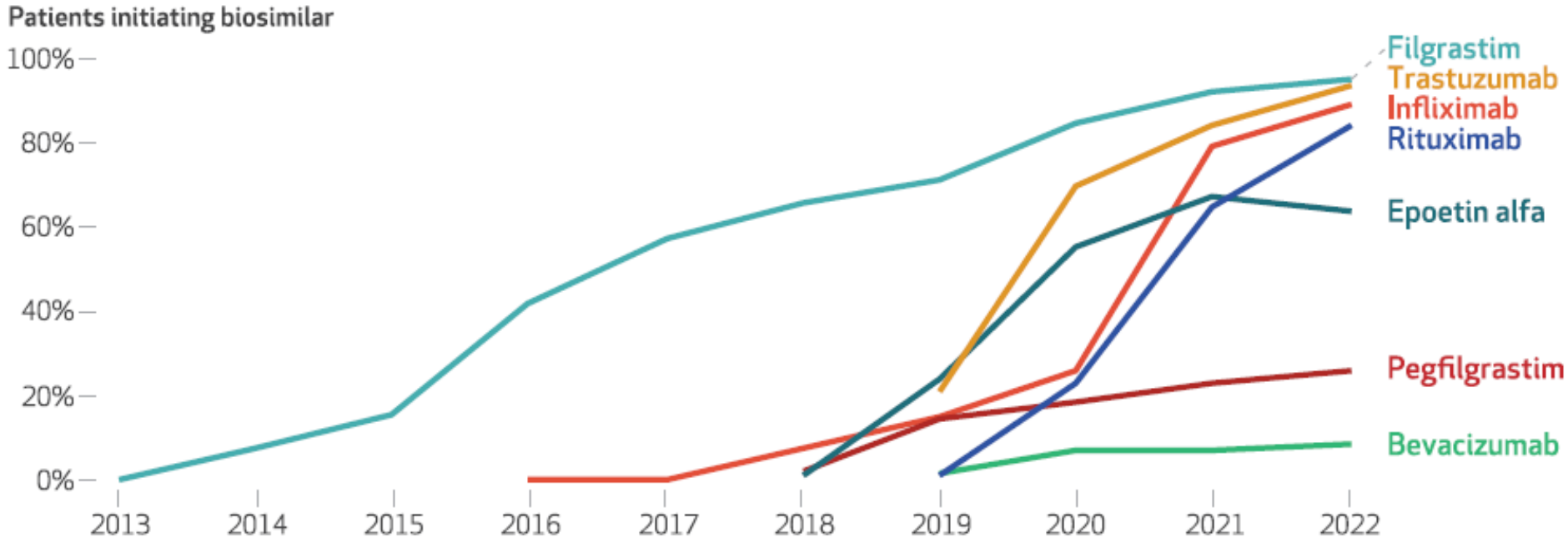
- Epoetin alfa (Epogen)
- Denosumab (Prolia)*
- Insulin glargine (Lantus)

https://www.fda.gov/drugs/biosimilars/biosimilar-product-information
https://www.gabionline.net/biosimilars/general/biosimilars-approved-in-the-us

Uptake of biosimilars is variable across biologic drugs

EXHIBIT 1

Percent of patients initiating biosimilars among 7 biologic drugs facing competition, 2013–22



Hong D, Kesselheim AS, Sarpatwari A, Rome BN. *Health Affairs.* 2024. Doi: 10.1377/hlthaff.2023.01215

Biosimilars still represent a small proportion of the use of biologics in the US

- About **two-thirds** of biologics used in the US don't have a biosimilar version available.

- Even for biologics with 1 or more biosimilar versions available, biosimilars are only used **24% of the time**.

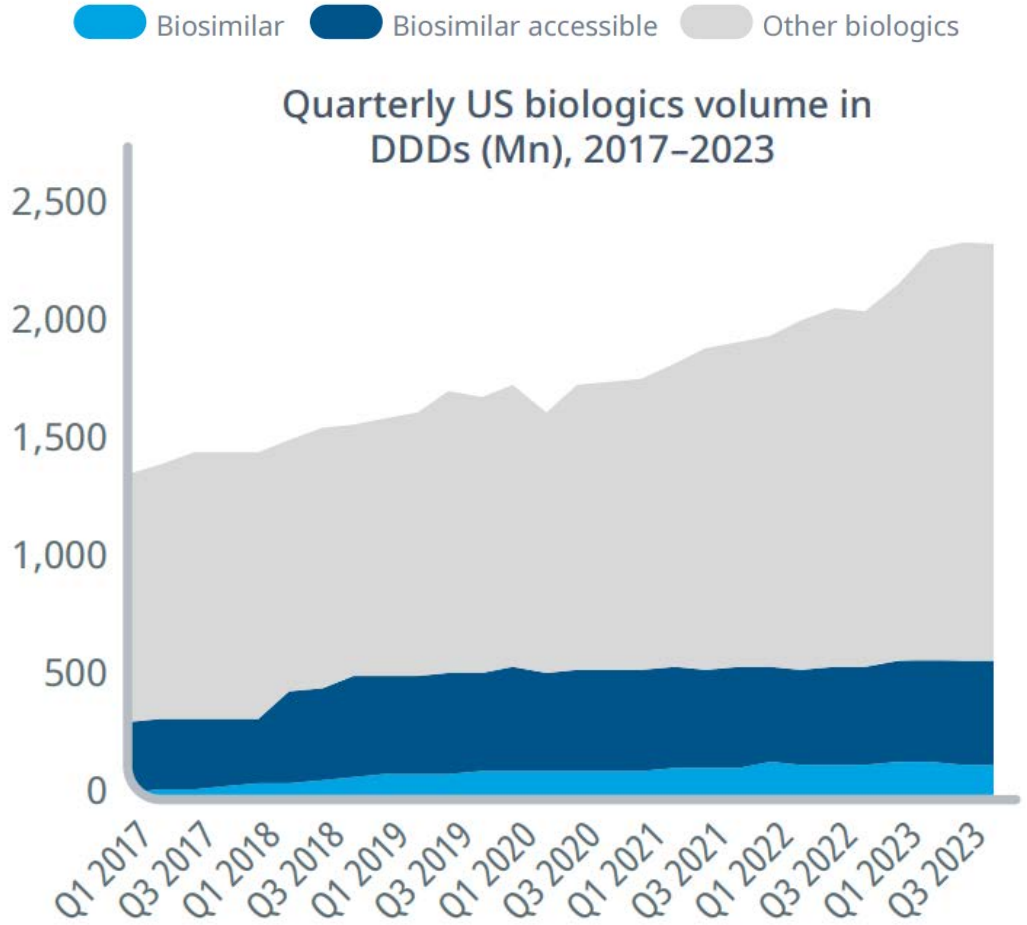
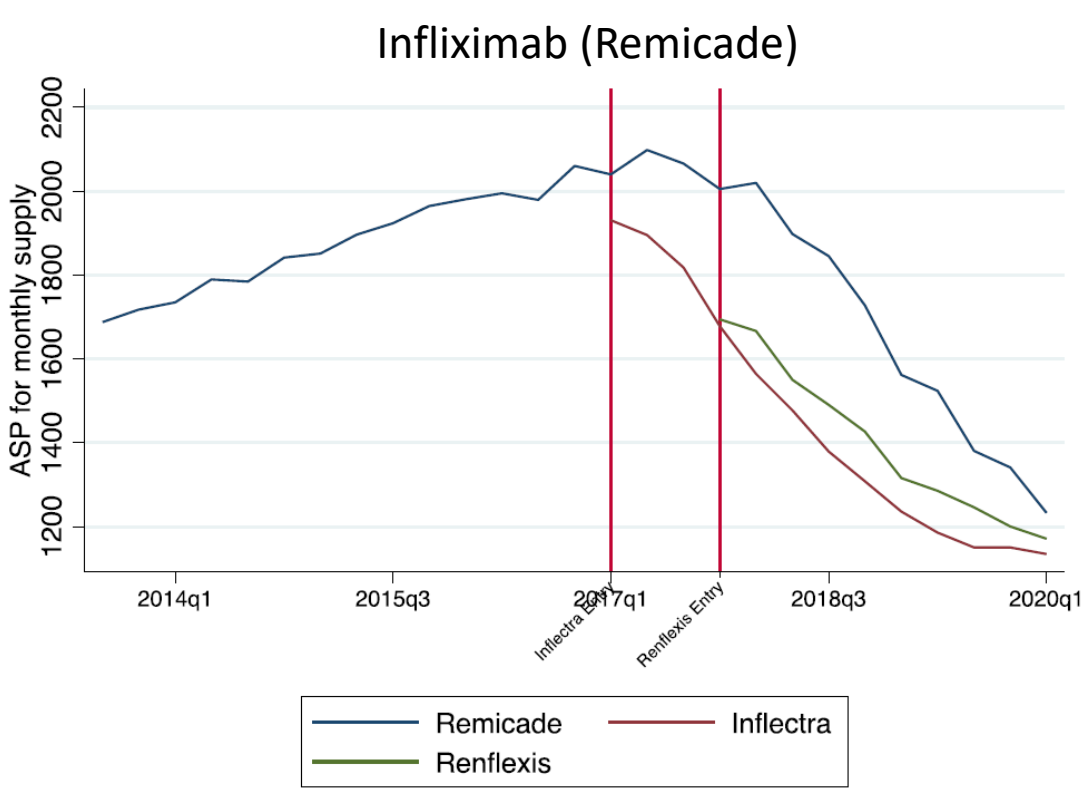
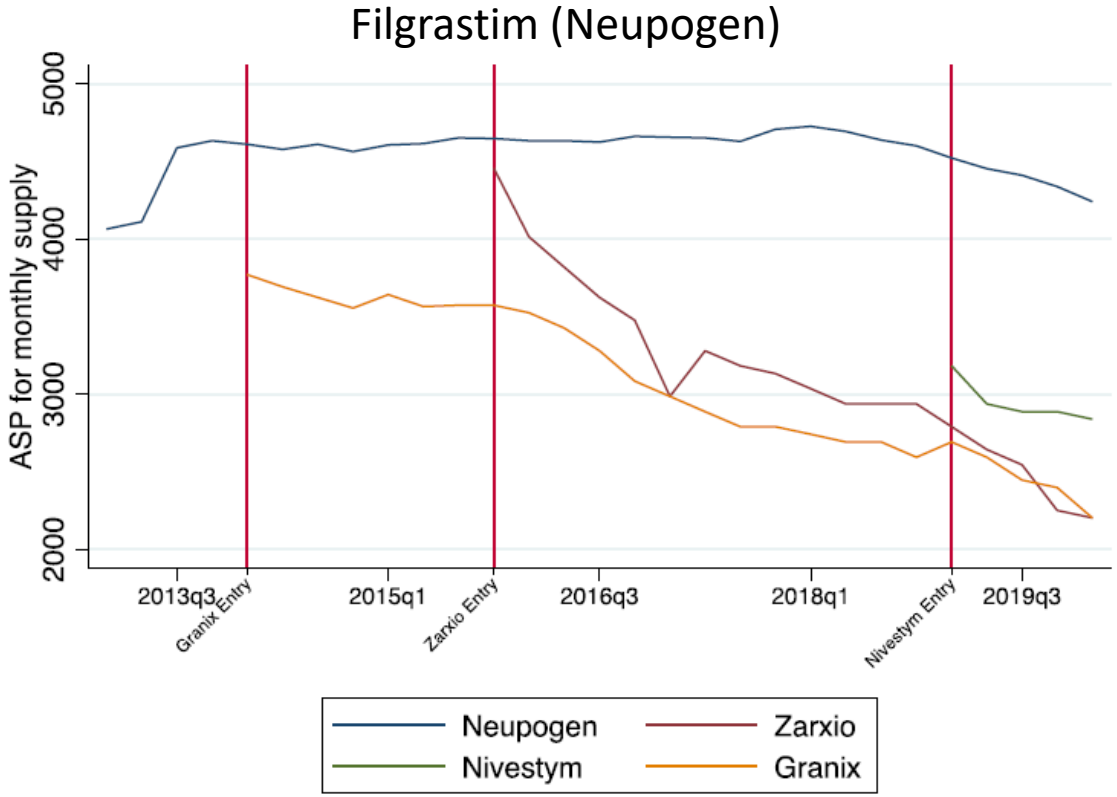


Figure: https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/the-use-of-medicines-in-the-us-2024
Statistics: https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/understanding-the-use-of-medicines-in-the-us-2025

Biosimilars cost substantially less than brand-name biologics, and prices decrease over time

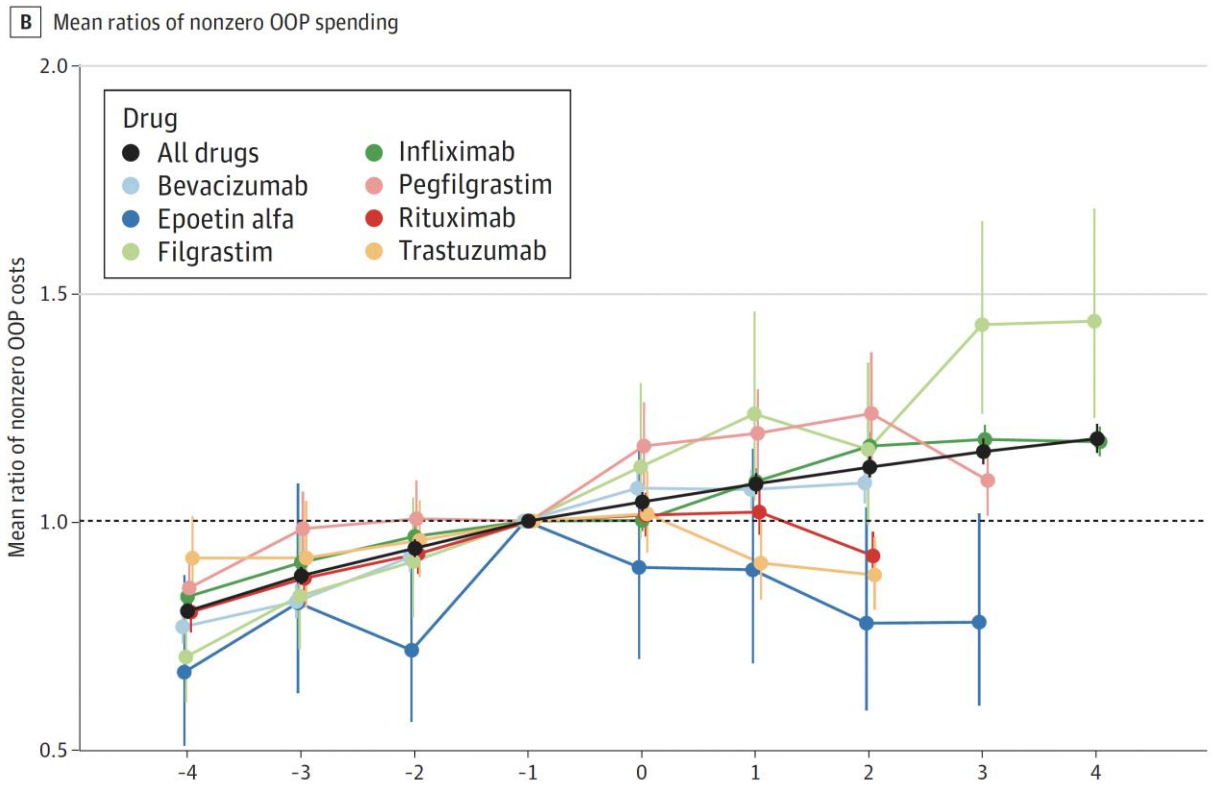




Frank RG, et al. *Health Econ.* 2022. 10.1002/hec.4471

Biosimilars competition has not consistently lowered out-of-pocket costs for patients

- Study of over 190,000 patients with commercial insurance who used 1 of 7 biologics facing biosimilar competition.
  - All clinician-administered drugs.
- Average annual out-of-pocket costs continued to increase after biosimilar competition began



Feng K…Rome BN. *JAMA Health Forum.* 2023. Doi: 10.1001/jamahealthforum.2023.5429

Recent FDA changes designed to streamline biosimilar regulation

- **June 2024:** FDA issued draft guidance eliminating need for switching studies for biosimilars to be deemed interchangeable
  - Based on an FDA meta analysis of 5,252 patients from 31 switching studies that found zero differences in safety and efficacy when patients switched from biologics to biosimilars.
  - There have also been proposals for Congress to eliminate the separate designation for interchangeable biosimilars.
- **October 2025:** FDA issued draft guidance that not all biosimilars would require head-to-head comparative effectiveness trials with reference biologic
  - Would make it much less expensive to develop biosimilars.

FDA Draft Guidance Document FDA-2017-D-0154. June 2024.
Herndon TM, et al. *PLOS One.* 2023. Doi: 10.1371/journal.pone.0292231.
FDA Draft Guidance Document. FDA-2011-D-0605. October 2025.

Remaining challenges that may hinder the success of biosimilar competition

Patent thickets that delay biosimilars from reaching the market.

State pharmacist substitution laws that are stricter in most states for interchangeable biosimilars than generics, such as extra notification requirements to prescribers and patients.

Pharmacy benefit manager rebates from brand-name biologic manufacturers being used as leverage to prevent biosimilars from being covered for patients.

Patient and clinician confidence that biosimilars are just as safe and effective as brand-name biologics

Rome BN, Bhaskar A, Kesselheim AS. *Am J Manag Care.* 2025. Published early.
Sacks CA, et al. JAMA Intern Med. 2021. doi:10.1001/jamainternmed.2020.3588

Thank you, and I look forward to questions and discussion.

First panel – biosimilars

Presenter:

- Alex Keeton, executive director, Biosimilars Council, Association of Accessible Medicines

Biosimilars in the United States

Navigating Barriers, Unlocking Savings

Alex Keeton
Executive Director, Biosimilars Council
Senior Vice President, Policy, Association for Accessible Medicines

Savings Report Introduction

- Annual publication in partnership with IQVIA Institute (September)
- Includes:
  - Overall savings generated by generics and biosimilars
  - Deflation
  - Drug shortages
  - Savings by category, state, method of payment
  - Generic uptake and delays
  - Inflation Reduction Act
  - Value of User Fee Programs
  - 10 years of biosimilars
  - AAM Priorities and Advocacy Plan
  - Savings by Individual State (January)
  - Savings by Patient Condition (~20 conditions; January)

U.S. Biosimilar Market Overview

84
APPROVED

67
MARKETED

21
REFERENCE PRODUCTS

90% of the 118 biologics losing exclusivity in the next decade—valued at $234 billion overall—currently have no biosimilars in development.

Biosimilar savings since 2015
$56.2 BILLION

Biosimilars have been used in almost **3.3 BILLION DAYS** of patient therapy and have resulted in more than **460 MILLION INCREMENTAL DAYS** of therapy

As of July 11, 2025
Source: US FDA and AAM Commercial Assessment. Includes 9 unbranded products. Savings and patient day data developed by the Biosimilars Council with IQVIA.

Biosimilars Deliver Safe Therapy

- Since 2015, biosimilars have been used globally in more than 3 billion days of patient therapy with no unique clinical challenges
- Overall use of molecules with biosimilar competition has increased – more patients use medicines when a biosimilar is available
- Biosimilar competition has now supported 460 million additional patient-days of therapy, care that patients would not have received otherwise

3.3 billion
total days of therapy for patients on biosimilars

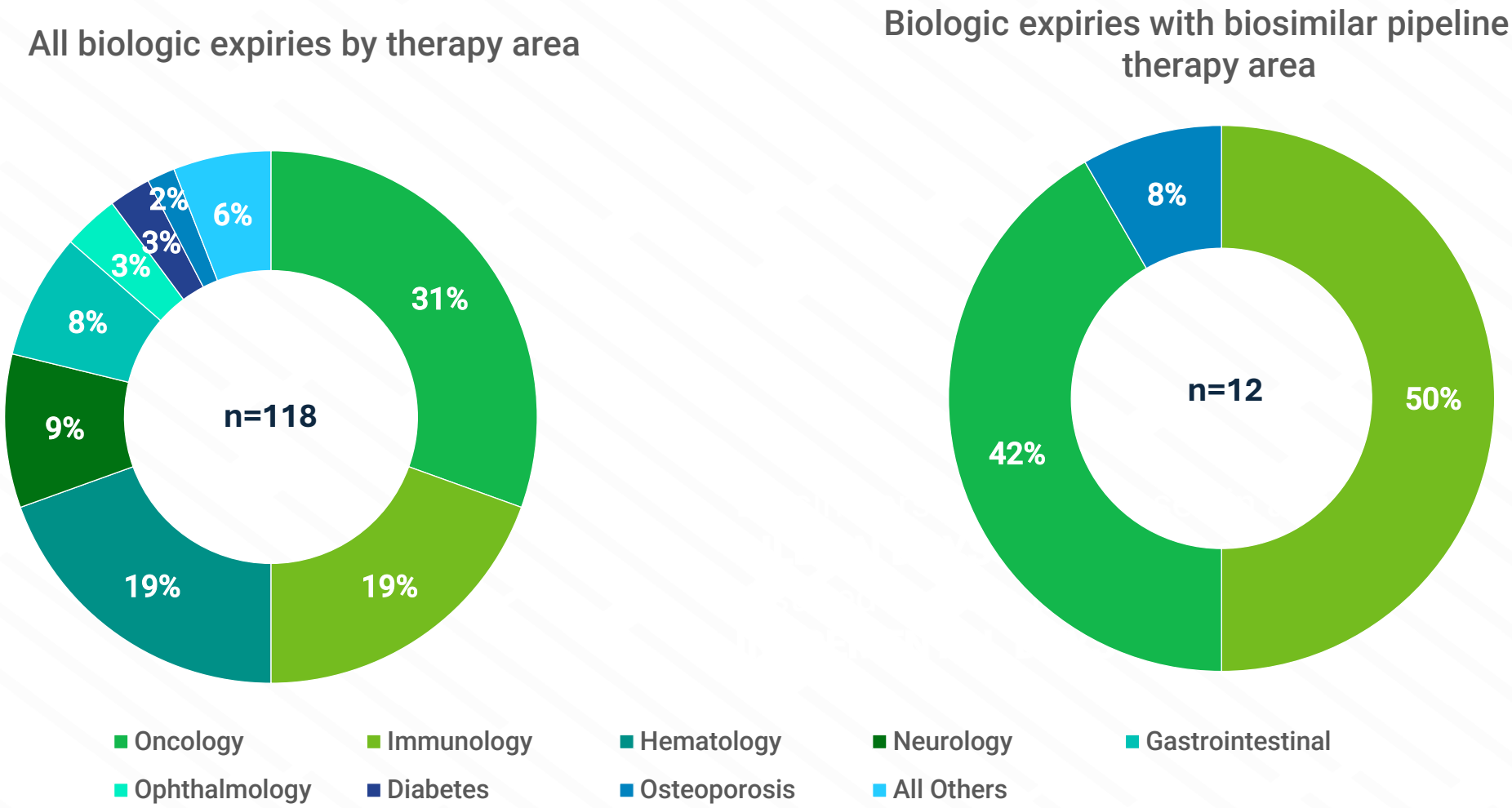
460 million
additional patient-days of therapy arising from the availability of biosimilars

Biosimilar introduction often results in overall greater patient access to therapy

The U.S. Generic & Biosimilar Medicines Savings Report SEPTEMBER 2025. Available at: https://accessiblemeds.org/resources/blog/2025-savings-report/ (accessed September 2025).

Biologic Expiries 2025–2034 and Biosimilar Pipeline by Therapy Area

The Image Below Shows That Biosimilar Pipeline Development Is Limited to a Few Specific Therapy Areas — With the Rest Stuck in the Void



Source: IQVIA Institute for Human Data Science. February 2025. Assessing the Biosimilar Void in in the U.S.: Achieving Sustainable Levels of Biosimilar Competition. Available from iqviainstitute.org.

Key barriers to biosimilars' market penetration in the U.S. remain

- Misaligned Incentives
- Originator Behavior
- Regulatory Hurdles
- IP Landscape
- Pricing & Reimbursement

Recent FDA Announcements

Draft guidance reducing the need for CES

- **Significantly reduces the time and money needed to bring a biosimilar to market**

Future final guidance eliminating switching studies

- **Eliminates an unnecessary hurdle to demonstrate interchangeability**

Association for Accessible Medicines

Your Generics & Biosimilars Industry

Thank You!

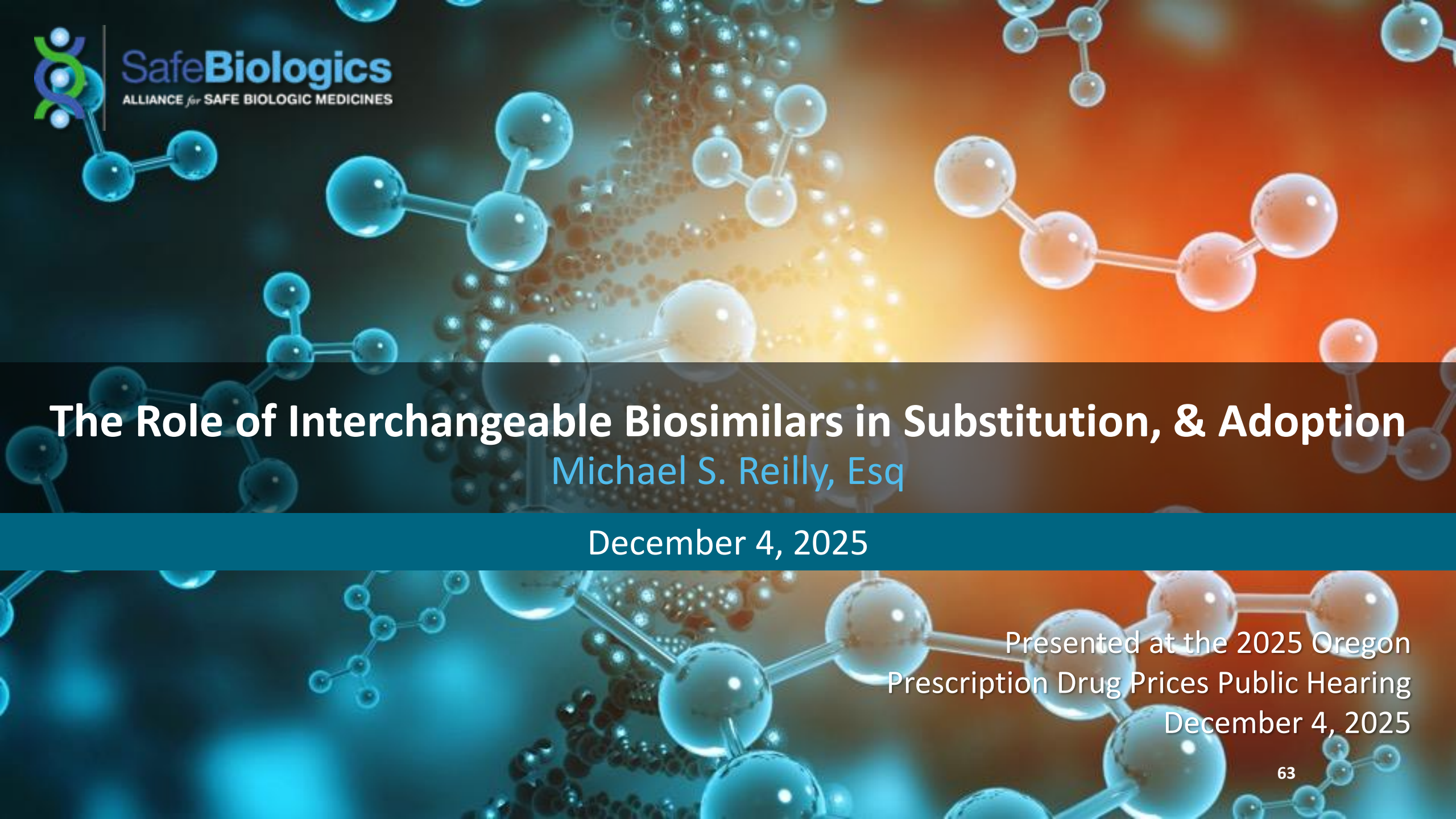
accessiblemeds.org

biosimilarscouncil.org

First panel – biosimilars

Presenter:

- Michael Reilly, Esq., executive director, Alliance for Safe Biologic Medicines



The Role of Interchangeable Biosimilars in Substitution, & Adoption

Michael S. Reilly, Esq

December 4, 2025

Presented at the 2025 Oregon
Prescription Drug Prices Public Hearing
December 4, 2025

Michael S, Reilly, Esq.

- **Executive Director, Alliance for Safe Biologic Medicines,** 2010-Present
- Associate Deputy Secretary at the U.S. Department of Health and Human Services (HHS) from 2005-2008
- Responsible for policy development and implementation, regulatory oversight for issues involving CMS and the FDA.
- Senior Advisor to the Assistant Secretary for Public Affairs and the Assistant Secretary for Planning and Evaluation at HHS from 2002-2005

About ASBM

SafeBiologics
ALLIANCE for SAFE BIOLOGIC MEDICINES

Formed in 2010 with the passage of the Affordable Care Act (ACA) and Biosimilar Price Competition and Innovation Act (BPCIA); with the goal of keeping patient safety at the forefront of biosimilar policy discussions.

<u>ASBM's Steering Committee is composed entirely of patient and physician member organizations.</u>

- PATIENT ADVOCATES
- PHYSICIANS
- PHARMACISTS
- RESEARCHERS
- MANUFACTURERS (INNOVATOR & BIOSIMILAR)

LYMPHOMA COALITION
Worldwide Network of Lymphoma Patient Groups

American Gastroenterological Association

CSRO
Coalition of State Rheumatology Organizations

More than 130 organizations spread across six continents; the majority of these are patient groups, including several patient coalitions.

Partnering With Regulators Worldwide

Since 2010, ASBM has worked closely with national and international regulatory authorities to craft biosimilar policy.

- **2011-Present: Conducted physician surveys in 16 countries and presented these results to their health ministries, including FDA, Health Canada, Australia's TGA, the WHO and European Commission.**
- **Since 2013, regularly participate in WHO's International Nonproprietary Name (INN) Expert Group Consultations on biologic nomenclature policy and international harmonization efforts.**
- **2015-2016 Organized a series of meetings between FDA, Health Canada and WHO to discuss biologic nomenclature issues and harmonization.**

This Morning: December 4, 2025 European Commission Meeting: 9th Biosimilar Multi-Stakeholder Meeting

European biosimilar regulatory process is marked by:

- **Gradual, methodical changes rooted in science – not rash or implusive reversals of long-standing policies**
- **Highly collaborative and inclusive of a wide variety of stakeholder perspectives- particularly physician and patient**
- **Respect for physician and patient control of individual treatment decisions**

9TH BIOSIMILAR MULTISTAKEHOLDER EVENT
4 DECEMBER 2025, ONLINE
08H30 – 13H00 CET

DRAFT AGENDA

08.30 – 08.40	**Introductory note** ➢ DG SANTE, European Commission
08.40 – 08.50	**Patient keynote speech** ➢ Speaker to be confirmed
08.50 – 09.35	**Impact of advertising and promotion regulations on biosimilar uptake** ➢ OECD
09.35 – 10.50	**AUGMENT: an EU4Health biosimilar capacity-building project** ➢ AUGMENT Consortium
10.50 – 11.05	***Coffee break***
11.05 – 12.05	**AUGMENT: an EU4Health biosimilar capacity-building project (ctd.)** ➢ AUGMENT Consortium
12.05 – 12.45	**IQVIA biosimilar competition report** ➢ IQVIA
12.45 - 13.00	**Closing words** ➢ DG SANTE

Example: September 22, 2025 EMA Meeting: "Workshop on a Tailored Clinical Approach to Biosimilar Development"

Key messages:

- the draft reflection paper outlines a **proportionate approach** to biosimilar development;
- **in certain cases**, robust analytical and pharmacokinetic data **may replace the need for extensive confirmatory clinical trials**;
- the aim is to **accelerate patient access to biosimilars without compromising quality, safety or efficacy;**
- **stakeholder input is essential** to ensure the final reflection paper is **scientifically sound**, fit for purpose, and internationally relevant.

September 19, 2025 FDA Meeting: "The Genericization of Biosimilars"

For the first time, we hear the word "genericization" used in reference to biosimilars, by CDER Director George Tidmarsh (since resigned).

"Landscape of Stakeholder Perspectives" Panel:

- **Only industry trade group representatives were included.**
- **Patient and clinician testimony was excluded.**

October 29, 2025: Breaking with 20 years of International Regulatory Norms and Consensus: Trump HHS/FDA "Genericization" of Biosimilars

Treating Biosimilars as Generics:

"[the pharmaceutical industry] claimed that biologics were too delicate, that they were too mystical to allow true generics. … It was **all clever marketing. None of it was based on science."**

"**Think of biosimilars as the generic version** of the expensive biologics."

"…we're going to implement the **same procedure that is used for small-molecule drugs,** which is if the active ingredient works, if it's been proven safe, if it's been proven efficacious, then you ought to be able to get it on the market right away, **the same as small molecule."**

Promoting Third-Party Automatic Substitution of Biosimilars:

"The lobby **invented a fake distinction** between biosimilars and interchangeable biosimilars."

"We're saying basically we think **all biosimilars should be interchangeable** … we're not going to wait for [Congress]"

"These changes will also help ensure that more biosimilars are considered interchangeable, **allowing pharmacists to substitute them just like they do with traditional generic drugs.**"

HHS Secretary Robert F Kennedy, Jr and FDA Commissioner Marty Makary, MD

FDA in 2025: A Pattern of Instability and Chaos… Undermining Confidence

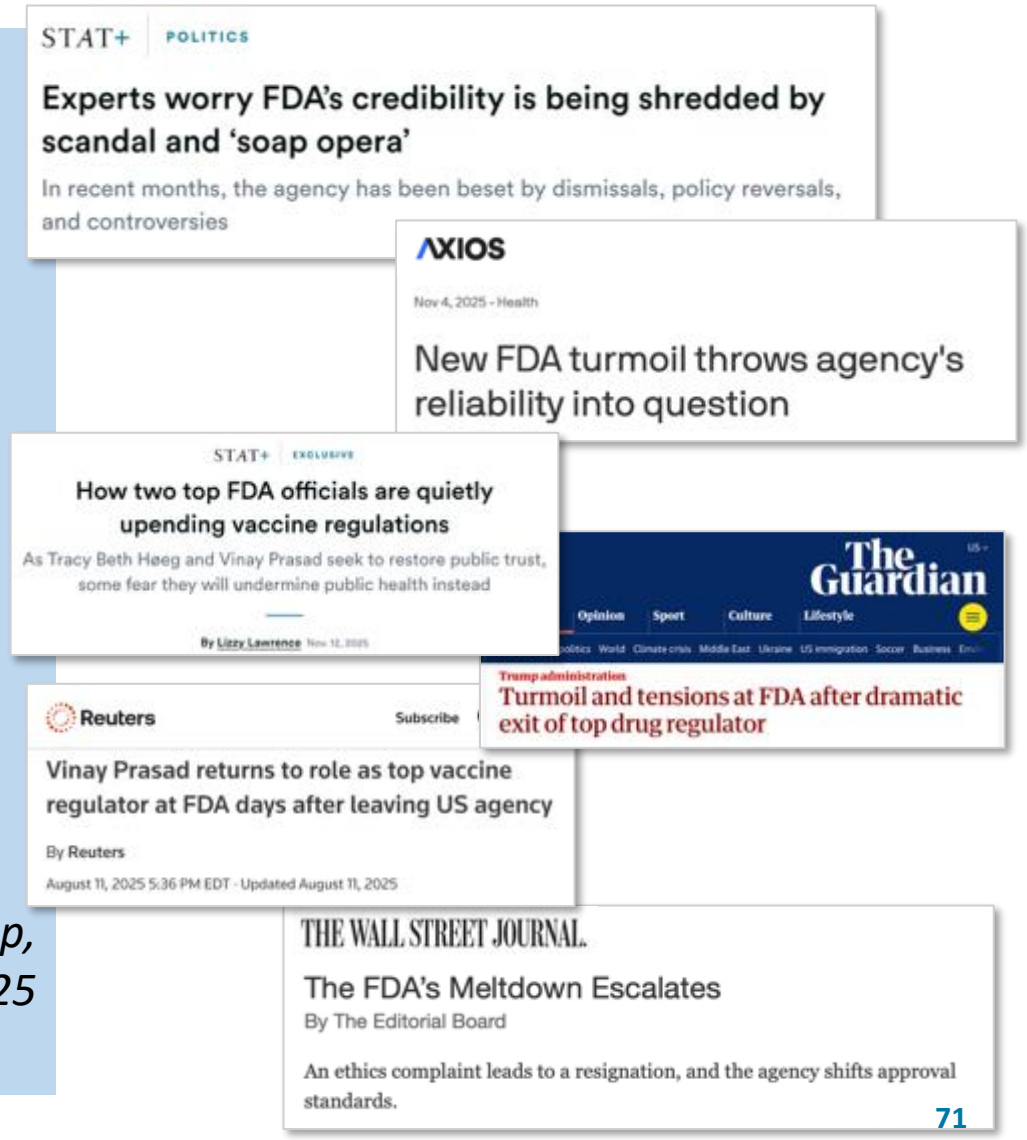
"There seems to be an interest in trying to **get things done through the least amount of process,"** said one former FDA official. "All of those things lead to a **public perception that the agency is making things up as it goes along**."

"**nearly all of the actions have been criticized by experts**, watchdog groups or even more traditional conservative allies as **deviating from established regulatory or scientific processes**, possibly at the risk of **undermining public trust in the agency**.

"The general approach of **rushing things**, of going first through media and op-eds and television before announcements are made, and to not start with the medical, the specific **... that just does not inspire confidence,"**

-Axios, The FDA's self-fulfilling prophecy trap, November 14, 2025

AXIOS



What Congress Might Do: The "Biosimilar Red Tape Elimination Act" (S. 1954)

Would Deem ALL BIOSIMILARS "interchangeable"
Under state law, insurers/PBMs would be newly empowered to switch patients to whichever product is most profitable.

Sen. Mike Lee (R-UT)
Bill Sponsor

Removes Physician & Patient Safeguards Congress Built into the BPCIA

Removes the legal need to show:

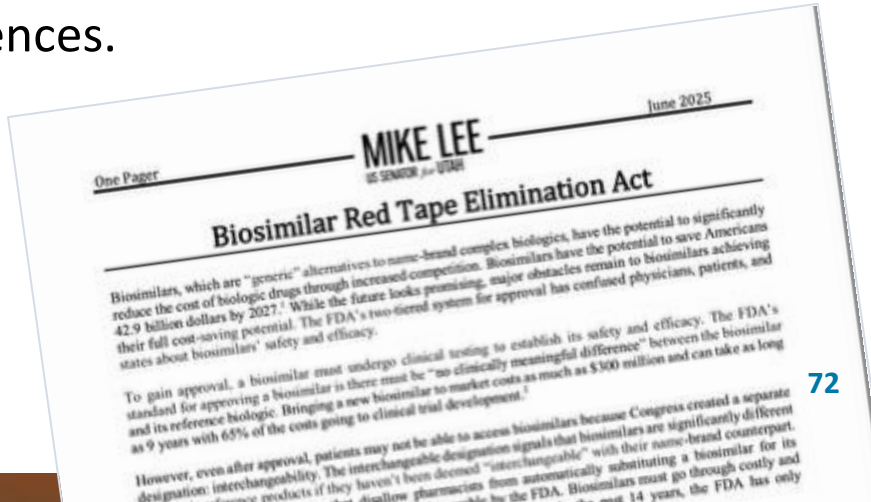
- no extra risk from alternating/switching
- same clinical result in any patient
- additional evidence for third-party (insurer/PBM) automatic substitution

Codifies the MAHA "Genericization" of Biologics

Regulates biologics like small-molecule generics, despite scientific differences.

Other Potential Consequences

Lower Approval Standards -> Lower Patient Confidence in Biosimilars
PBMs Gain Even More Power Over Treatment Decisions
Safety Risks Not Evaluated = Some Patients Switched Inappropriately



One Pager — MIKE LEE, US SENATOR for UTAH — June 2025

Biosimilar Red Tape Elimination Act

Biosimilars, which are "generic" alternatives to name-brand complex biologics, have the potential to significantly reduce the cost of biologic drugs through increased competition. Biosimilars have the potential to save Americans 42.9 billion dollars by 2027.[1] While the future looks promising, major obstacles remain to biosimilars achieving their full cost-saving potential. The FDA's two-tiered system for approval has confused physicians, patients, and states about biosimilars' safety and efficacy.

To gain approval, a biosimilar must undergo clinical testing to establish its safety and efficacy. The FDA's standard for approving a biosimilar is there must be "no clinically meaningful difference" between the biosimilar and its reference biologic. Bringing a new biosimilar to market costs as much as $300 million and can take as long as 9 years with 65% of the costs going to clinical trial development.[2]

However, even after approval, patients may not be able to access biosimilars because Congress created a separate designation: interchangeability. The interchangeable designation signals that biosimilars are significantly different products if they haven't been deemed "interchangeable" with their name-brand counterpart. This allows pharmacists from automatically substituting a biosimilar for its

The World's Medicines Regulators Have Long Agreed: Biosimilars are NOT Generic Biologics

FDA (United States)
Biosimilars are not generics—and important differences exist between them."

WHO (World Health Organization)
"The **generic approach is not suitable** for the licensing of biosimilars."

EMA (European Medicines Agency)
"[A] biosimilar is **not regarded as a generic of a biological medicine**."

Health Canada
"**Unlike generic drugs,** biosimilars can never be identical to their reference biologic drug."

TGA (Australia)
"A biosimilar is **not a generic biological medicine.**"

PMDA (Japan)
"**The approach used for generic chemical drugs is not applicable** because the active ingredient of a biosimilar cannot be completely identical to that of the reference product."

ANVISA (Brazil)
"A biosimilar is not an exact replica of the reference—and, hence, **cannot be considered as generic.**"

While Safe and Effective, Biosimilars are NOT Generics- and Should NOT Be Treated as Such. They Must be Regulated Differently.

GENERIC (Chemical) DRUG:

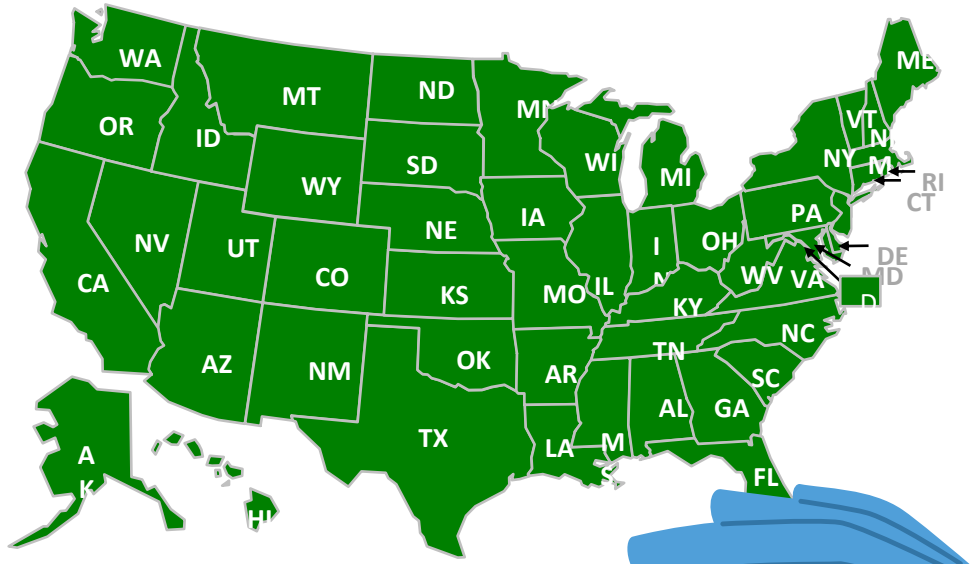
- **"small molecule"**
- **EXACT COPY of Reference Medicine**
- **80%-90% discount** over the originator.
- **"AUTOMATIC" SUBSTITUTION** (substitution without prior physician authorization) at the pharmacy is **widely accepted and uncontroversial.**

BIOSIMILAR:

- **Larger, more complex molecule**
- **HIGHLY SIMILAR to Reference Medicine**
- **Discounts vary** depending on country and product. **Can be low (5% lower than list price) or higher (70-80%) in competitive classes. Usually launch 15-35% lower.**
- **"AUTOMATIC" SUBSTITUTION** (substitution without prior physician authorization) at the pharmacy is **controversial and opposed by most physicians. The practice is banned throughout much of Europe.**

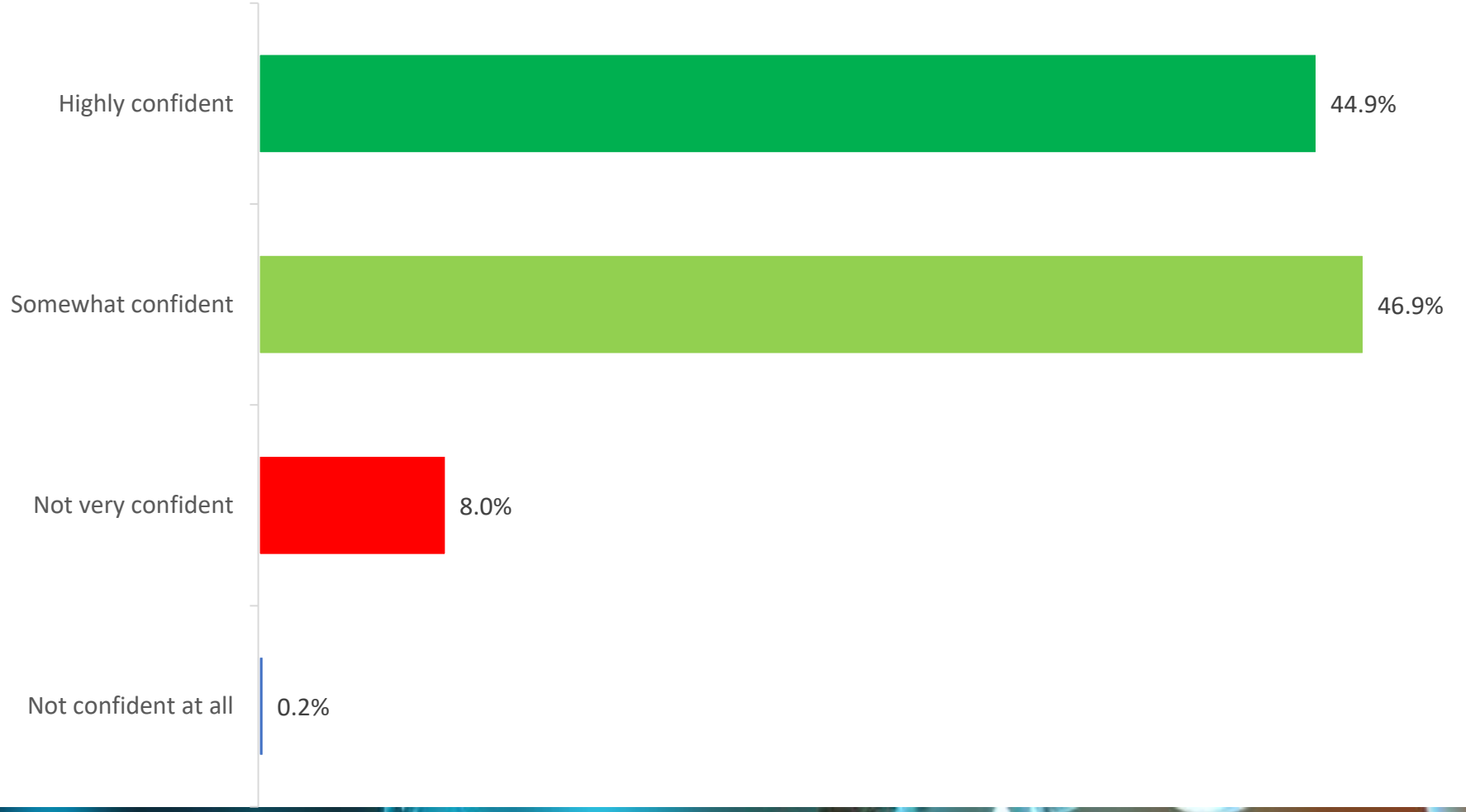
"Interchangeable Biosimilars" More Data; More Confidence that Treatment Stability Won't Be Disrupted

- Provided **additional data** to demonstrating a patient can **switch back and forth** multiple times with no change in safety or effectiveness.
- This data provides **clinical confirmation, not just analytic similarity**, helping preserve patient stability.
- Under state laws, **only interchangeables may be substituted at the pharmacy level without prior prescriber approval**.
- State medical societies and patient groups nationwide supported legislation permitting ANY automatic substitution **conditional on these limits.**



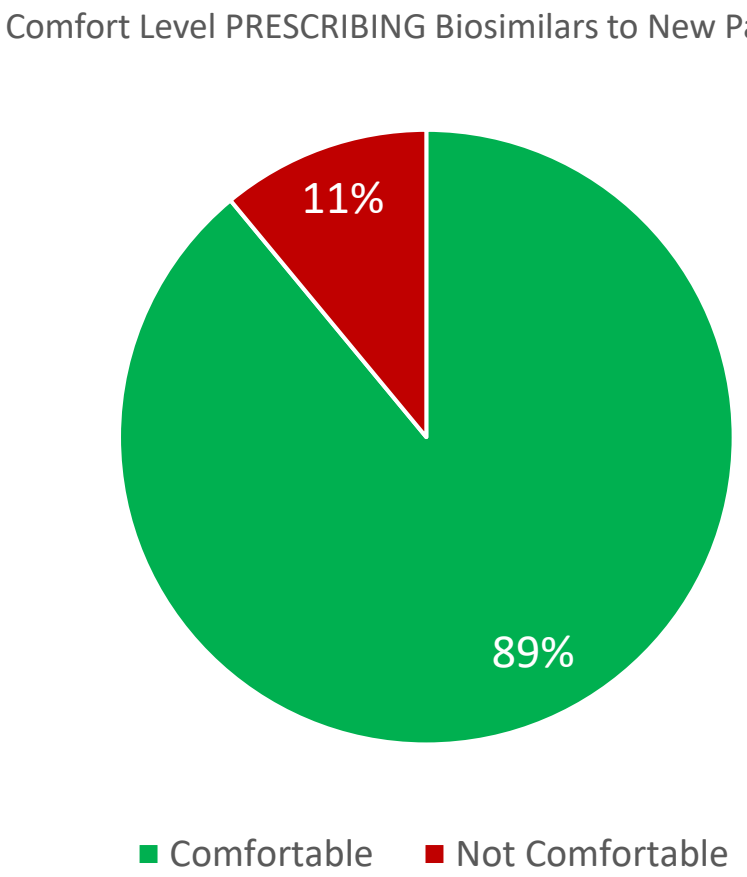
2021 Survey (n=401) U.S. Physicians Are Very Confident in Biosimilars

- Q1. How would you describe your personal confidence level in the safety and efficacy of biosimilars? (n=401)



92% expressed confidence in the safety and efficacy of biosimilars.

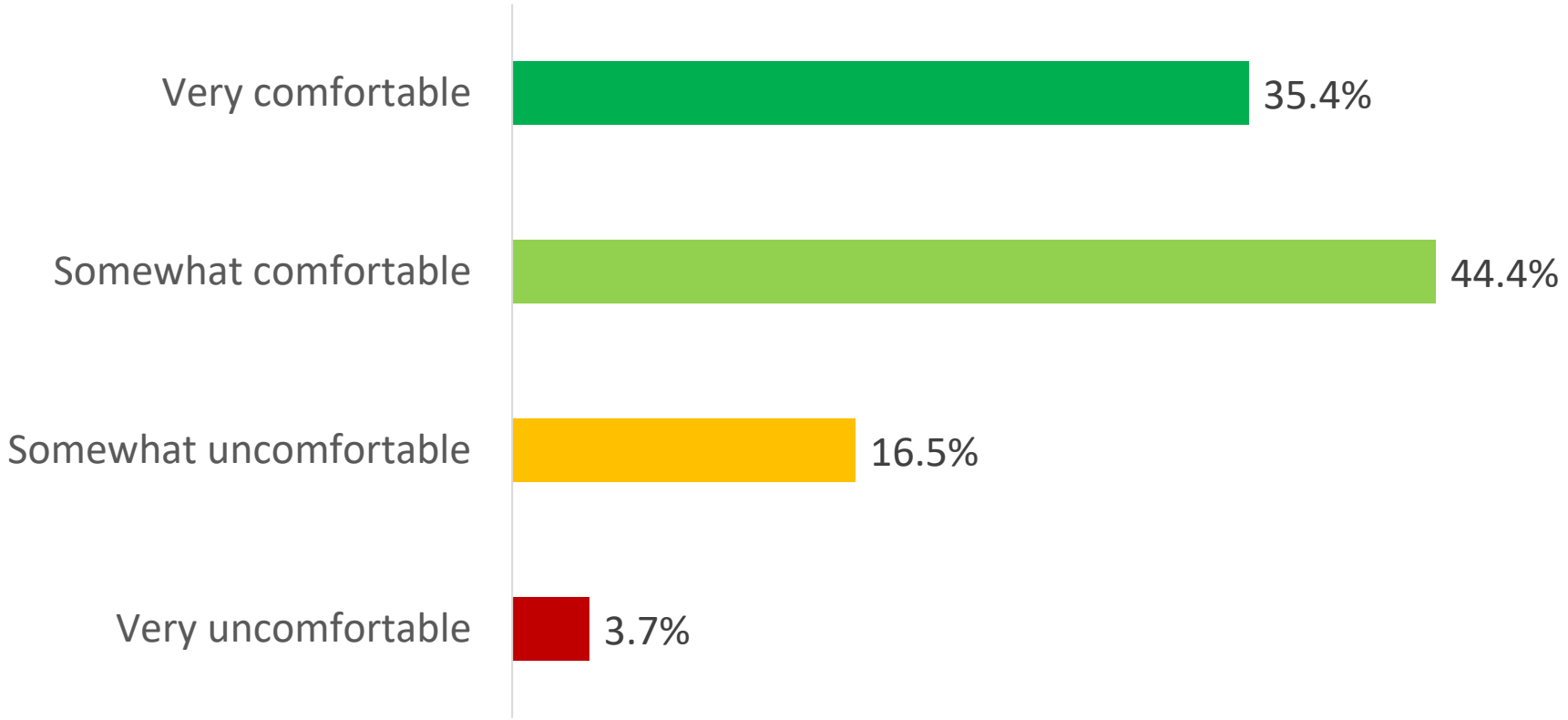
U.S. Physicians Are Very Comfortable Prescribing Biosimilars to New Patients (n=401)



Physician confidence in and comfort with biosimilars is high- the vast majorities of physicians have no concerns with prescribing biosimilars- to new patients.

US Physicians Are Generally Comfortable Switching A Patient to a Biosimilar…
…if they are leading the switch:

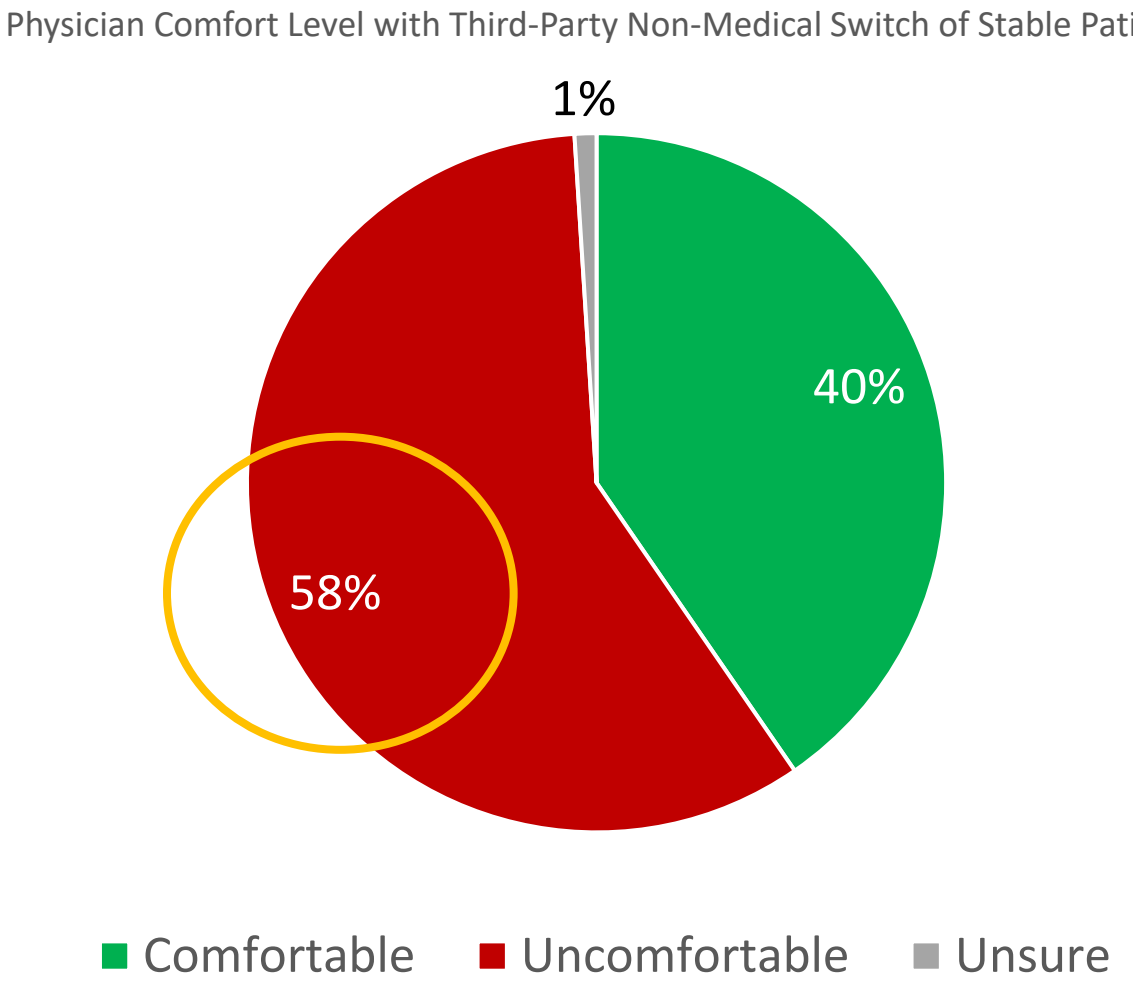
- Q4. How comfortable are you with **switching a stable patient from an originator medicine to a biosimilar?** (n=401)



80% of respondents are comfortable, to some degree, with switching a patient to a biosimilar.

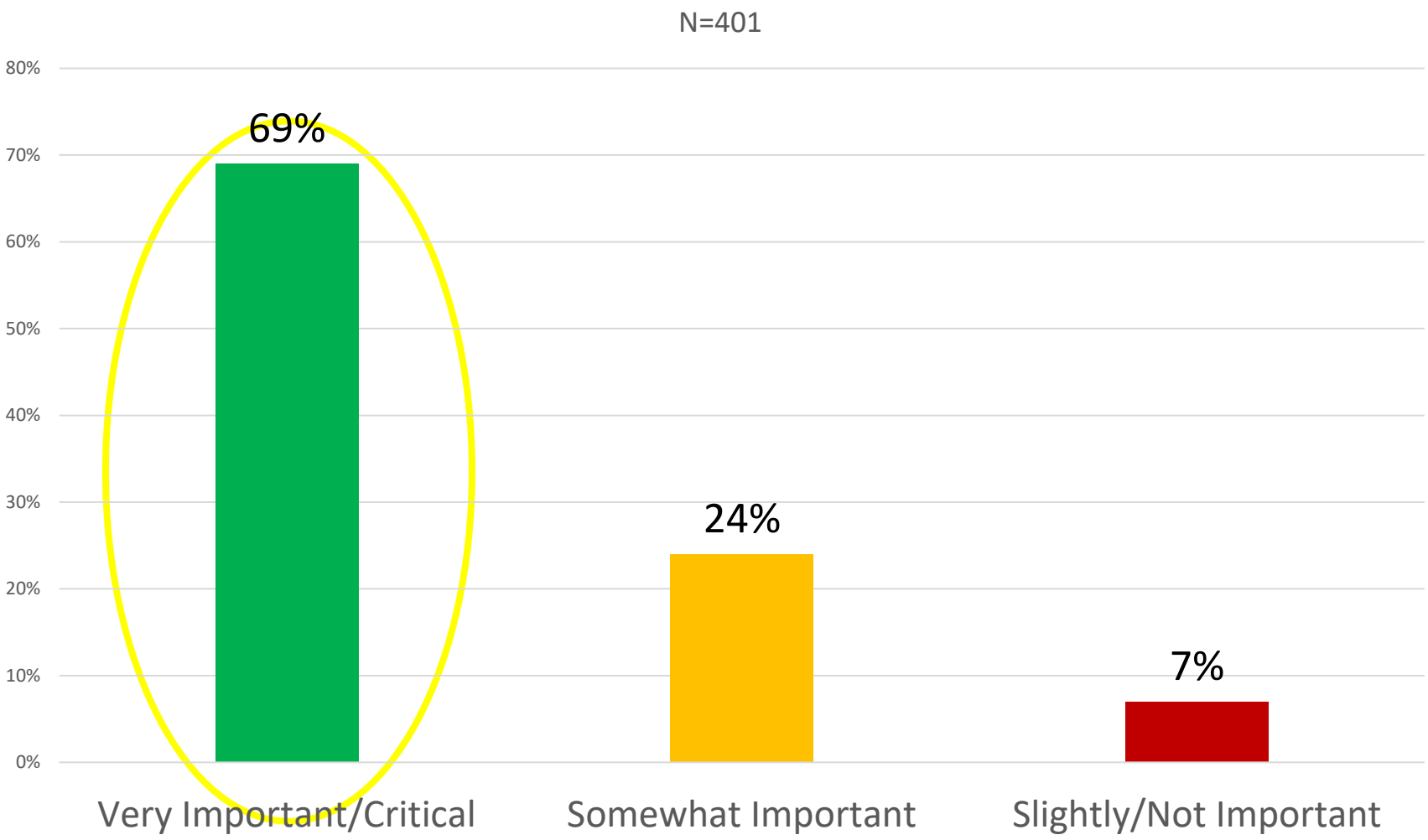
However, 20% are not comfortable doing so.

Majority of U.S. Physicians Are Not Comfortable with Third Party Non-Medical Switching of a Stable Patient



The majority of U.S. physicians, 58% are NOT comfortable with Third Party Non-Medical Switching for a patient who is stable on their current treatment.

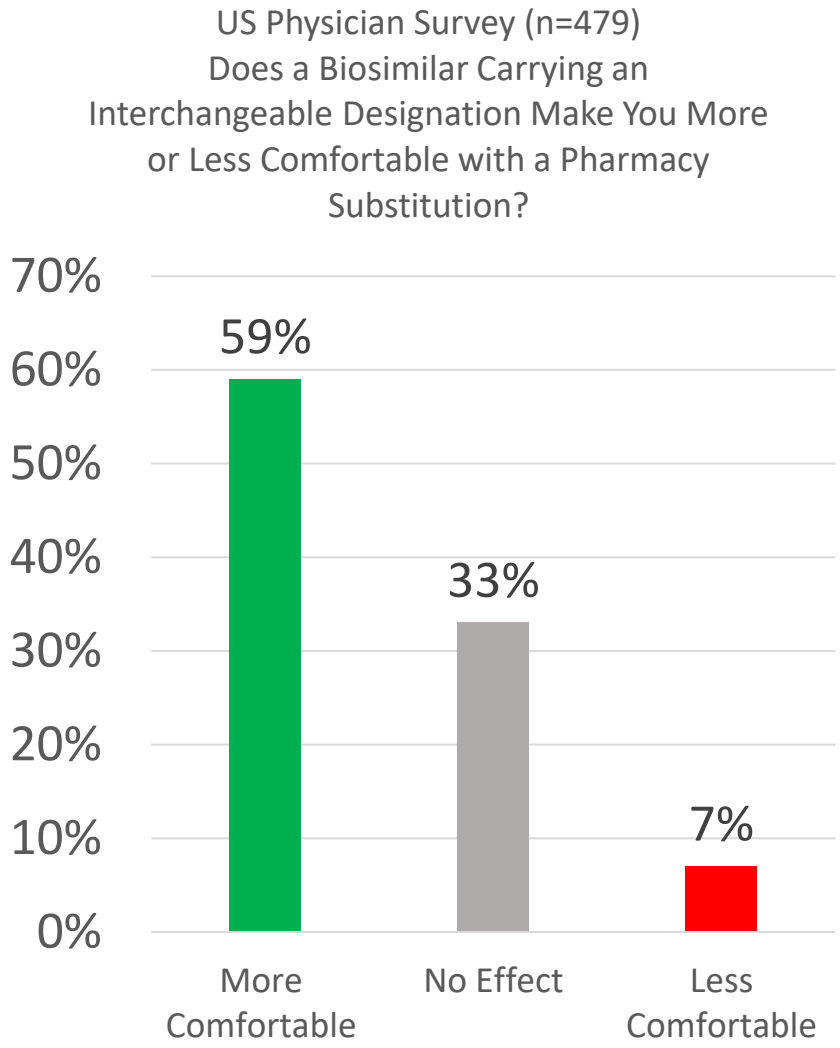
Importance of Physician/Patient Control of Treatment Decisions



A strong majority of U.S. physicians agree it is **very important- or CRITICAL** – that the **physician, with the patient, decides which treatment option to use -** rather than a third party.

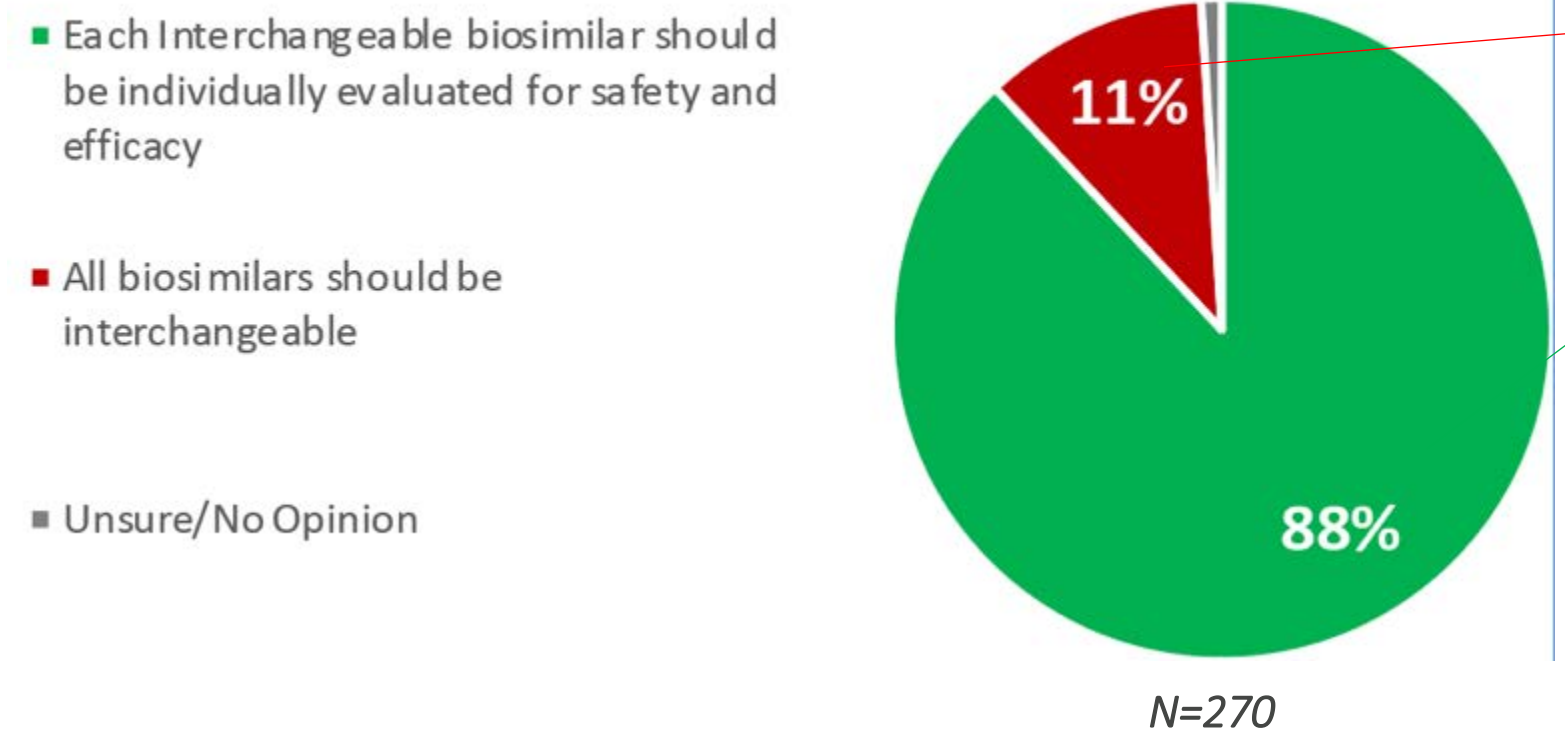
Data Shows the Interchangeability Designation Creates Confidence for Physicians, Not Confusion.

- **As a result of the FDA's data requirements, physicians can be 100% sure that a switch to an interchangeable biosimilar will not negatively impact a patient- either in safety or in reduced efficacy.**
- **This is especially useful for complex patients (i.e. those with multiple autoimmune conditions) where maintaining stability is critical.**
- **59% of U.S. physicians surveyed were more comfortable with an interchangeable being substituted in place of the prescribed originator product.**



U.S. Physicians STRONGLY OPPOSE the Genericization of Biosimilars

Vast Majority Want to Preserve Individual Evaluation of Switching and Efficacy



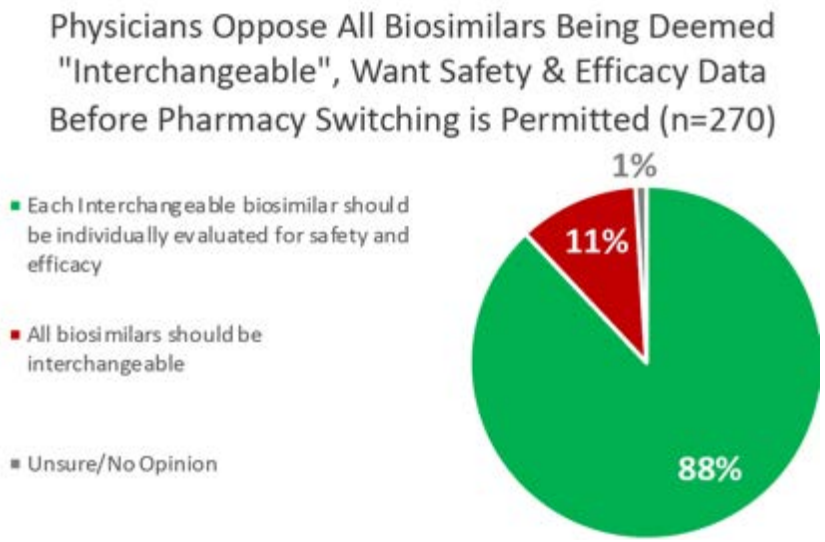
N=270

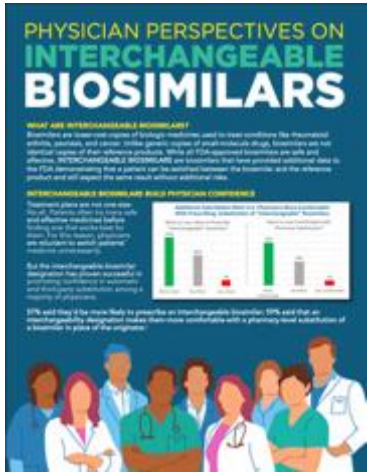
- **Only 11% believe <u>all</u> biosimilars should be deemed interchangeable.**
- 88% of respondents believe <u>each</u> interchangeable biosimilar should be individually evaluated specifically for the impact of switching on safety and efficacy.

Note: The words <u>each</u> and <u>all</u> were underlined in the response options when respondents took the survey.

Key Takeaways from U.S. Physician Surveys 2021-2024

- **92% are confident in safety and efficacy of biosimilars.**
- **Still 69% believe physician/patient control over treatment choice/switching is "very important or critical"**
- **58% are NOT comfortable with third-party (non-medical) switching.**
- **Only 11% believe all biosimilars should be deemed interchangeable (which would allow them to be substituted by third parties like generics).**





Learn More:

2025/2026 U.S. Physician Survey (in Progress)

- N= ~400 participants
- **All participants practice medicine in the United States and prescribe biologic medicines.**
- Drawn in roughly equal proportion from Dermatology, Endocrinology, Gastroenterology, Immunology, Nephrology, Neurology, Oncology, Ophthalmology, and Rheumatology

Physicians will be asked their views on:

- **FDA shift to treating biosimilars as generics**
- Effect of lowered biosimilar approval standards on **physician confidence**
- Mass third-party substitution of biosimilars unsupported by individual evaluations of the impact of switching patients
- Effect of radical policy shifts and reversals on **overall confidence in FDA**

U.S. Biosimilar Uptake Comparable to Europe

- **U.S. biosimilar market shares have now caught up to European uptake rates (which range 20-80% varying by product and country):**
- 80% for filgrastim trastuzumab and bevacizumab biosimilars
- 60% for rituximab biosimilars
- 40% for infliximab, pegfilgrastim, and erythropoietin-stimulating agent (ESA) biosimilars
- 20-25% for adalimumab biosimilars
- US approval pace comparable to Europe: 7 or 8 per year.

Biosimilar APPROVALS are NOT the Obstacle to Uptake.

HUMIRA $6,900/mo LIST PRICE (WAC)

- 10 FDA-Approved biosimilars
- **8 interchangeable (already substitutable by insurer/pharmacy) – shown to not disrupt stable patients if switched.**
- **Sold at 22 different list prices** (high-WAC, low-WAC) some at 80-85% discount.
- **One interchangeable version offered at 92% discount $550/mo cash pay (GoodRx)**
- **Humira market share likely <80% and falling as contracts expire.**

FDA has already delivered **many, deeply discounted, interchangeable options**. FDA science/approval standards are **NOT** holding biosimilar uptake back.

DRUG CHANNELS
Expert Insights on Pharmaceutical Economics and the Drug Distribution System

"For 2025, the Big Three PBMs shifted national formularies **to favor their private-label biosimilars over Humira and its many biosimilar competitors.** In fact, **nearly all marketed Humira biosimilars are excluded** from the larger PBMs' 2025 formularies."

– DrugChannels.net, 1/22/25

The Real Obstacle to Biosimilar Adoption: PBM Formulary Economics… NOT FDA Scientific Standards.

THE WALL STREET JOURNAL.

PBMs "can move entire markets with a single formulary decision," often **choosing products that deliver "the highest net revenue**." –6/3/25

AXIOS

PBMs "**prefer their own co-branded or affiliated biosimilars**," steering prescriptions **regardless of interchangeability.** – 7/23/25

FTC & Senate Finance reports: **PBMs use "rebate walls" and "formulary blockades" that prevent lower-cost competitors, including biosimilars, from gaining share**.

The top three PBMs control 80% of the U.S. prescription drug market.

Bipartisan PBM reform efforts underway in Congress represent **a more appropriate and productive avenue for those seeking to further increase biosimilar adoption.**

Summary

- Biosimilars are safe, effective medicines - but **the world's medicines regulators agree they are NOT GENERICS and should not be substituted like generics** (i.e., allowing third party-substitution by people other than the prescribing physician)
- **Physicians are confident in biosimilars but OPPOSE their third-party substitution and OVERWHELMINGLY OPPOSE treating all biosimilars like generics.**
- **Biosimilars are an important tool to increase access and lower costs through price competition** – but we must do this in a way that (as the EMA says): **"accelerate[s] patient access to biosimilars without compromising quality, safety or efficacy" -** not simply ignore 20 years of science and regulation.
- Permitting mass, generic-style third-party substitution of biosimilars would **place the U.S. far outside international norms**—especially in Europe, where such practices are **rare and often explicitly prohibited**.
- Lowering scientific standards, treating biosimilars like generics will **jeopardize patient treatment stability - and hard-won physician and public confidence in biosimilars.**
- **PBM formulary and rebate economics are the chief determinant of biosimilar adoption** and will not be addressed by lowering FDA standards.

Additional Resources About Interchangeable Biosimilars

STOP the "Genericization" of Biosimilars

Under pressure from insurers, PBMs, and manufacturer trade groups, FDA is moving to strip away the evidence required to ensure that patients will remain stable after switching to a biosimilar—and opening the door to mass, profit-driven switching of stable patients.

BIOSIMILARS: SAFE, EFFECTIVE — BUT NOT GENERICS

Biosimilars are lower-cost versions of biologic medicines used to treat conditions such as rheumatoid arthritis, psoriasis, and cancer. **Unlike generic copies of traditional chemical drugs (typically pills), biosimilars are not identical to the medicines they reference.** For this reason, an insurance company or pharmacy benefit manager (PBM) may not automatically substitute a biosimilar without prior physician approval, which is commonly accepted with generics.

Treatment plans are not one-size-fits-all. Patients often try many safe and effective medicines before finding one that works best for them. For this reason, physicians are reluctant to switch a stable patient unnecessarily.

Under state law, only biosimilars that provide additional data to FDA—proving a patient can switch back and forth with no change in safety or efficacy—may be substituted at the pharmacy level. These are called **interchangeable biosimilars.**

State medical societies and patient groups agreed to permit biosimilar substitution in their states only with these limits. Weakening or eliminating these patient protections would betray the commitments policymakers made to physicians and patients.

THE WORLD'S REGULATORS AGREE: BIOSIMILARS ≠ GENERICS

- FDA: **"Biosimilars are not generics—and important differences exist between them."**
- WHO: **"The generic approach is not suitable for the licensing of biosimilars."**
- EMA: **"a biosimilar is not regarded as a generic of a biological medicine."**
- Health Canada: **"unlike generic drugs, biosimilars can never be identical to their reference biologic drug."**
- TGA: **"a biosimilar is not a generic biological medicine."**
- PMDA: **"the approach used for generic chemical drugs is not applicable because the active ingredient of a biosimilar- cannot be completely identical to that of the reference product"**
- ANVISA: **"a biosimilar is not an exact replica of the reference-and, hence, cannot be considered as generic."**

GENERICIZING BIOSIMILARS?

In a keynote address at a September 19, 2025 FDA workshop, George Tidmarsh, Director of the FDA's Center for Drug Evaluation and Research (CDER), announced: **"We are ready for the 'genericization' of biosimilars."** As the *Pink Sheet* reported: "In my mind, [the] analytical revolution brings biosimilars very, very close to generic drugs. And in the generic drug world, of course, we just characterize the molecule."

Tidmarsh calls the current biosimilar testing framework "quite burdensome." But the comparison to generics contradicts decades of FDA and EMA statements affirming that biologics, including biosimilars, are not small-molecule drugs and cannot be "fully characterized".

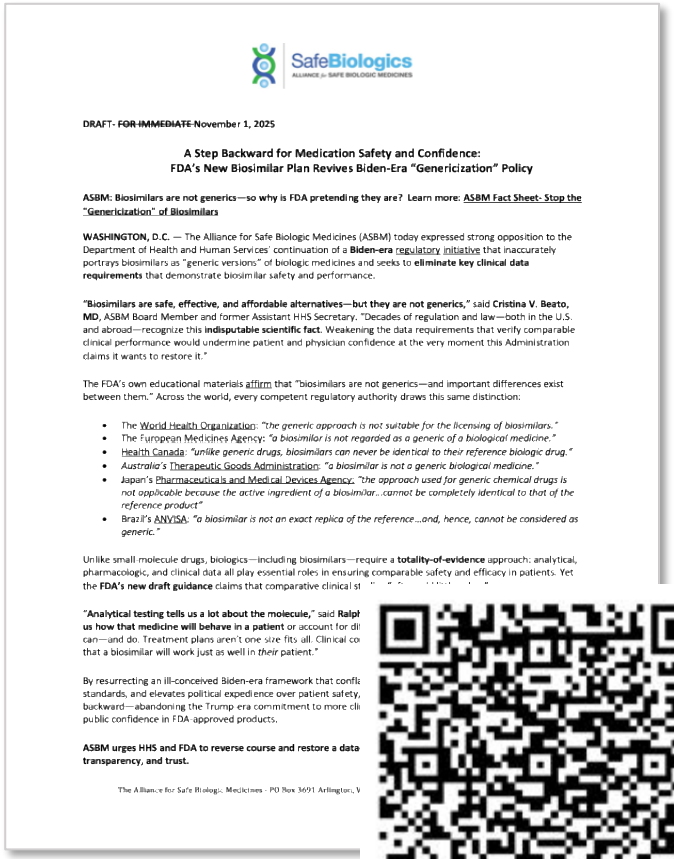
LOWER STANDARDS = HIGH

While physicians choose medic
insurers and **PBMs choose bas**
the product that offers the larg
other discounts.

If FDA lowers approval standard
declares all biosimilars intercha
even greater power to switch s
now unconstrained by current

But it would not address financial

Fact Sheet:
Stop the Genericization of Biosimilars



SafeBiologics
ALLIANCE for SAFE BIOLOGIC MEDICINES

DRAFT- ~~FOR IMMEDIATE~~ November 1, 2025

A Step Backward for Medication Safety and Confidence:
FDA's New Biosimilar Plan Revives Biden-Era "Genericization" Policy

ASBM: Biosimilars are not generics—so why is FDA pretending they are? Learn more: ASBM Fact Sheet- Stop the "Genericization" of Biosimilars

WASHINGTON, D.C. — The Alliance for Safe Biologic Medicines (ASBM) today expressed strong opposition to the Department of Health and Human Services' continuation of a **Biden-era** regulatory initiative that inaccurately portrays biosimilars as "generic versions" of biologic medicines and seeks to **eliminate key clinical data requirements** that demonstrate biosimilar safety and performance.

"Biosimilars are safe, effective, and affordable alternatives—but they are not generics," said **Cristina V. Beato, MD**, ASBM Board Member and former Assistant HHS Secretary. "Decades of regulation and law—both in the U.S. and abroad—recognize this **indisputable scientific fact**. Weakening the data requirements that verify comparable clinical performance would undermine patient and physician confidence at the very moment this Administration claims it wants to restore it."

The FDA's own educational materials affirm that "biosimilars are not generics—and important differences exist between them." Across the world, every competent regulatory authority draws this same distinction:

- The World Health Organization: *"the generic approach is not suitable for the licensing of biosimilars."*
- The European Medicines Agency: *"a biosimilar is not regarded as a generic of a biological medicine."*
- Health Canada: *"unlike generic drugs, biosimilars can never be identical to their reference biologic drug."*
- Australia's Therapeutic Goods Administration: *"a biosimilar is not a generic biological medicine."*
- Japan's Pharmaceuticals and Medical Devices Agency: *"the approach used for generic chemical drugs is not applicable because the active ingredient of a biosimilar…cannot be completely identical to that of the reference product"*
- Brazil's ANVISA: *"a biosimilar is not an exact replica of the reference…and, hence, cannot be considered as generic."*

Unlike small molecule drugs, biologics—including biosimilars—require a **totality-of-evidence** approach: analytical, pharmacologic, and clinical data all play essential roles in ensuring comparable safety and efficacy in patients. Yet the **FDA's new draft guidance** claims that comparative clinical st

"Analytical testing tells us a lot about the molecule," said **Ralph**
us how that medicine will behave in a patient or account for dl
can—and do. Treatment plans aren't one size fits all. Clinical co
that a biosimilar will work just as well in *their* patient."

By resurrecting an ill-conceived Biden-era framework that confla
standards, and elevates political expedience over patient safety,
backward—abandoning the Trump era commitment to more cli
public confidence in FDA-approved products.

ASBM urges HHS and FDA to reverse course and restore a data
transparency, and trust.

The Alliance for Safe Biologic Medicines · PO Box 3691 Arlington, V

ASBM Statement on FDA's Proposed Genericization of Biosimilars

ISR

ASBM Study: US Physician Perspectives on Interchangeable Biosimilars

ISR Market Research

August 2024

ASBM Physician Survey (2024)


SafeBiologics
ALLIANCE for SAFE BIOLOGIC MEDICINES
Thank You for Your Attention

Questions for presenters on biosimilars?

- Benjamin N. Rome, M.D., MPH, assistant professor of medicine, Harvard Medical School and Brigham and Women's Hospital
- Alex Keeton, executive director, Biosimilars Council, Association of Accessible Medicines
- Michael Reilly, Esq., executive director, Alliance for Safe Biologic Medicines

Second panel – alternative financing

Presenters:

- Daniel Ollendorf (he/him), Ph.D., MPH, chief scientific officer and director of health technology assessment methods and engagement, Institute for Clinical and Economic Review (ICER)
- Deborah “Dee” Weston (she/her), J.D., pharmacy program policy advisor, Oregon Health Authority
- Sharon Lamberton (she/her), M.S., R.N., deputy vice president state policy and external outreach, PhRMA

Second panel – alternative financing

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- Daniel Ollendorf, Ph.D., MPH, chief scientific officer and director of health technology assessment methods and engagement, Institute for Clinical and Economic Review (ICER)

Paying for Innovations that Pose Health-System Affordability Challenges

Testimony for Oregon Prescription Drug Transparency Program

Dan Ollendorf, PhD
Chief Scientific Officer and Director of HTA Methods & Engagement
Institute for Clinical and Economic Review
December 4, 2025

ICER
INSTITUTE FOR CLINICAL AND ECONOMIC REVIEW

Disclosures

- Employee of ICER, which produces publicly-accessible reports on comparative effectiveness and value of new and established interventions

ICER and Therapeutic Innovations

- ICER integrates assessments of the (a) lifetime cost-effectiveness and (b) potential 5-year budget impact for each new technology evaluated
- Cell/gene therapies evaluated to date: 14
  - *Found to be cost-effective at current or expected discounted prices: 10*
  - *Health system challenges borne of "budget shocks" from high upfront costs for single administration*
- GLP-1 drugs for obesity found to be *highly* cost-effective
  - *At current net prices, and even more so at recently negotiated prices*
  - *But <1% of patients could be treated without exceeding annual budget target tied to growth in health spending*

ICER Policy Summit

- Annual convening of life sciences executives and payer/PBM leaders to discuss policy topics of shared interest
- Focus: understanding of the key issues and recommendations for moving the field forward
- Conducted under Chatham House rule
- Public white paper produced after deliberations

2024 Paper: Managing the Challenges of Paying for Gene Therapy

- ~50,000 patients in US may be eligible for gene therapies annually by 2030, at prices from $1-$4 million per administration
- Fair pricing, budget impact, and clinical uncertainty all must be managed for successful health system implementation
- Market reforms and policy actions targeted to each, along with combination strategies across them

https://icer.org/wp-content/uploads/2024/04/Managing-the-Challenges-of-Paying-for-Gene-Therapy-_-ICER-NEWDIGS-White-Paper-2024_final.pdf

2024 Paper: Managing the Challenges of Paying for Gene Therapy

Issue	Tool	Pros	Cons
Fair Pricing	Reduced pricing for uncertainty	Shared risk, adjustment	Disincentivize gene Rx?
	Weight pricing by severity	Int'l experience	What is "severe"?
Budget Impact	Stop loss / reinsurance	Catastrophic protection	"Lasering", high premiums
	Subscription models	Predictable costs	Limits on gene Rx, high premiums
	Federal risk pool	Universal access	Inefficiency, reduced care continuity
Clinical Uncertainty	Milestone-based rebates	Relatively simple design	How much $$$ at risk?
	Warranty models	Lower admin burden	Warranty-price mismatch
	Performance-based payment	Shared risk	Higher admin burden

2024 Paper: Managing the Challenges of Paying for Gene Therapy

- Combination strategies
  - “Stacking” – e.g., general stop loss for any gene therapy + standard price negotiation and milestone- or performance-based agreements for specific therapies
  - “Layering” – e.g., integrating multiple tools for each gene therapy
- Conclusions
  - No single strategy likely to be effective on its own
  - Combination strategies may require additional policy or market reforms to be feasible (e.g., funding Federally-supported databases, amending MDRP and other programs to facilitate subscription models)

2025 Paper: Affordable Access to GLP-1 Obesity Medications

- GLP-1s are highly effective and cost-effective obesity solutions
- The sheer size of the obesity problem in the US (~100 million Americans) makes affordability the major concern
- Market strategies and Federal policy actions discussed

2025 Paper: Affordable Access to GLP-1 Obesity Medications

Strategy	Tool	Pros	Cons
Formulary Management	BMI/comorbidity restrictions	Prioritize patients at greatest need	Add'l indications for GLP-1s may increase budget
	Limit duration of coverage	Reduces financial risk	No supporting evidence
	Step through older drugs	Some patients may benefit	Side effects a cause for clinical concern
Network Management	Curated expert network with open prescribing	Maximizes potential for comprehensive care	Greatly reduced access for patients
	Carve-out program	Potential for tailored and individual care	Likely to delay or limit GLP-1 access
Payment	Performance agreements	Risk sharing	Difficult to enforce
	Subscription models	Predictable costs	Feasible for chronic meds?
	Volume-based rebates	Payer financial protection	Manufacturer incentive?

2025 Paper: Affordable Access to GLP-1 Obesity Medications

- Possible Federal policy actions
  - Offer coverage in Medicare in return for lower price ☑
  - USPSTF recommendation for mandated coverage in private plans
  - Special private insurance subsidies for obesity medications
  - License GLP-1s for development of generic alternatives
- Conclusions
  - Questions remain on targeted vs. broad access approaches
  - Broader use is inevitable, so some “middle ground” is necessary
  - Federal action is possible (and helpful), but…
  - Budget challenges remain

Thank you!

dollendorf@icer.org

Second panel – alternative financing

Presenter:

- Deborah “Dee” Weston, J.D., pharmacy program policy advisor, Oregon Health Authority

2025 Annual Public Hearing on Prescription Drug Prices

Thursday, December 4, 2025

Deborah “Dee” Weston, Pharmacy Program and Policy Advisor

Medicaid-Specific Impacts

- **Medicaid Drug Rebate Program (MDRP)**
  - Discounts for all non-340B drugs
  - Net prices must be at least as good best commercial rates
  - Protection against inflation-driven price hikes
- **Pricing Leverage**
  - Better deals for favorable drug placement
  - Ability to negotiate aggressive rebate agreements (?)
- **Trade-offs**
  - Limited utilization management tools
- **Vulnerabilities**
  - High-priced drugs (e.g., cell & gene therapies) pose major risk

Additional Access Challenges for Cell & Gene Therapy in Oregon Health Plan

- **Bundled inpatient reimbursement** often falls short of therapy cost
- **Single case agreements**: solution but add administrative burden
- **Medicaid rebate issue:** bundles rates not rebate-eligible
- **CMS Access Model**: lowers prices, links cost to outcomes

Oregon's Participation in CGT Access Model

- **Multi-year CMS initiative**: 33 states + D.C. + Puerto Rico
- **Initial focus**: CGT for sickle cell disease
- **Agreements**: guaranteed supplemental rebates + outcome-based discounts with 2 manufacturers
- **Requirements**: unbundled inpatient reimbursement + uniform coverage + data reporting and other terms
- **Additional benefit**: fertility preservation services included
- **Oregon launch**: January 1, 2026
  - OHSU as single contracted provider
  - Drug cost carved out from CCO capitation

Possible Expansion

- **Potential expansion**: CMS could add treatments for other rare diseases
- **Oregon options**: negotiate additional outcomes-based rebate agreements independently or with other states
- **Uncertainty**: unclear if real savings will result
- **Challenges**: added cost & complexity from
  - Agreement development & negotiation
  - Rebate invoicing
  - Outcomes monitoring & reporting
  - Meeting manufacturer demands for uniformity and coverage criteria

Thank You!

Second panel – alternative financing

Presenter:

- Sharon Lamberton, M.S., R.N., deputy vice president state policy and external outreach, PhRMA

Enormous Promise: The Path Ahead

Innovative Payment Approaches

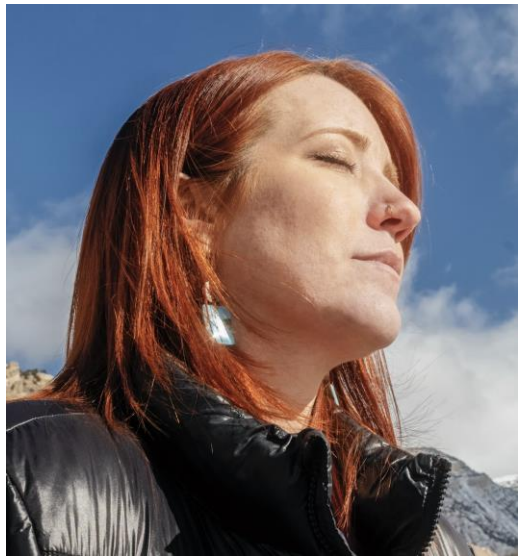
Sharon Lamberton, MS, RN
PhRMA

Oregon Public Hearing (2:50-4:05 p PST)
December 4, 2025


Alkermes
AMGEN
astellas
AstraZeneca
Boehringer Ingelheim
BAYER
Biogen
BIOMARIN
Bristol Myers Squibb
CSL
Daiichi-Sankyo
Eisai
EMD SERONO
Genmab
GILEAD
Creating Possible
GSK
Genentech
A Member of the Roche Group
Incyte
IPSEN
Innovation for patient care
Johnson&Johnson
KYOWA KIRIN
Lilly
Lundbeck
MERCK
Be well
NEUROCRINE BIOSCIENCES
NOVARTIS
novo nordisk
Otsuka
Pfizer
sanofi
Sumitomo Pharma
Takeda
ucb
Inspired by patients.
Driven by science.

The Atlantic

THE CYSTIC-FIBROSIS BREAKTHROUGH THAT CHANGED EVERYTHING

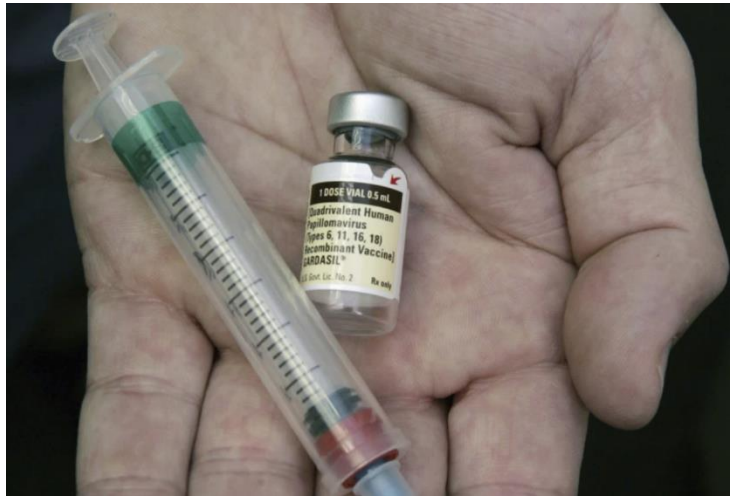


The New York Times

Life Without Sickle Cell Beckons Boy Who Completed Gene Therapy

abc NEWS

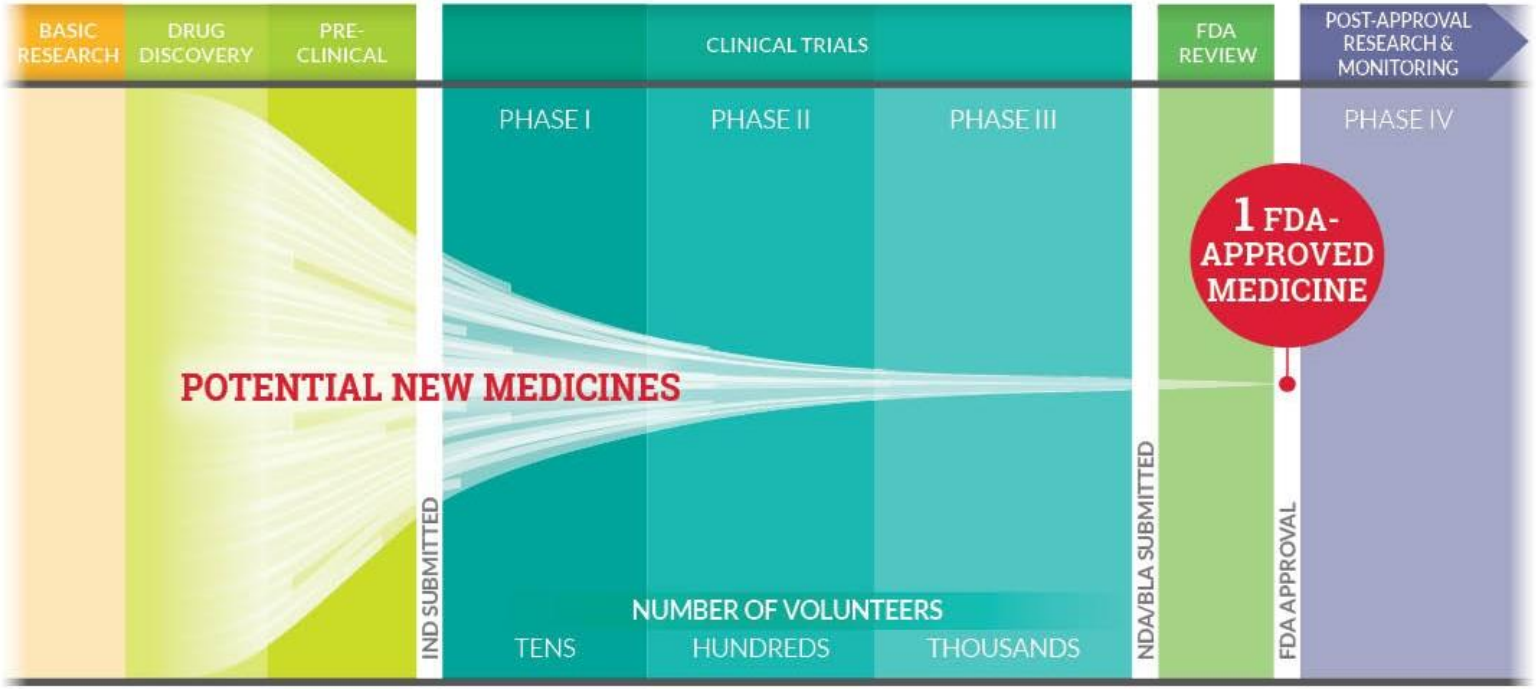
CDC report adds to evidence that HPV vaccine is preventing cervical cancer



PhRMA
RESEARCH + PROGRESS + HOPE

R&D: A Risky, Long and Expensive Process

- From drug discovery through FDA approval, developing a new medicine takes, on average, 10 to 15 years and costs $2.6 billion. Less than 12% of the candidate medicines that make it into Phase I clinical trials are approved by the FDA.



Key: IND=Investigational new drug application, NDA=New drug application, BLA=Biologics license application

*The average R&D cost required to bring a new FDA-approved medicine to patients is estimated to be $2.6 billion over the past decade (in 2013 dollars), including the cost of the many potential medicines that do not make it through to FDA approval.

Sources: PhRMA adaptation of DiMasi JA et al[12]; Tufts CSDD[13]; FDA[14]

How do we develop these breakthroughs?

- An IP system that promotes long term risk taking and fosters collaboration

- A reimbursement system that rewards innovation

- A delivery system that empowers physicians and healthcare providers, placing the patient needs first

Cell and Gene Therapies (C&GTs) Represent a New Treatment Paradigm

Treat the Root Cause of Disease

Potentially Curative, Durable Effects

One-Time Administration

C&GTs Are Revolutionizing Treatments for Patients Today and Tomorrow

Cell Therapy

In cell therapy, cells are modified outside the body before being returned to the patient to treat a condition in which the patient's cells are damaged or diseased.

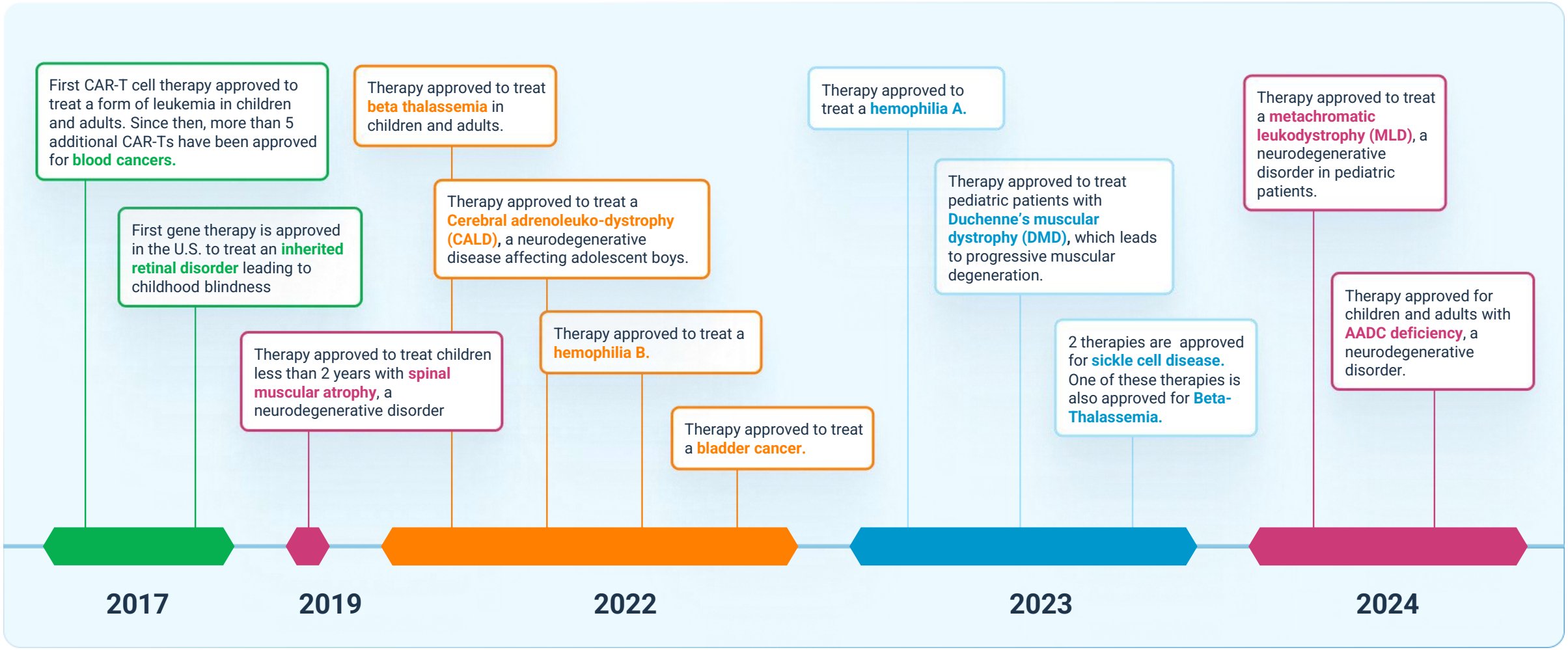
Gene Therapy

In gene therapy, a patient's disease-causing genes are modified, replaced or deleted to treat, cure, or even prevent a disease.

Gene-Modified Cell Therapy

In gene-modified cell therapy (e.g. CAR T-cell), cells are genetically modified outside the body before being (re)introduced into the patient to treat disease.

A Decade of C&GT Approvals Focus on Rare Diseases and Cancer



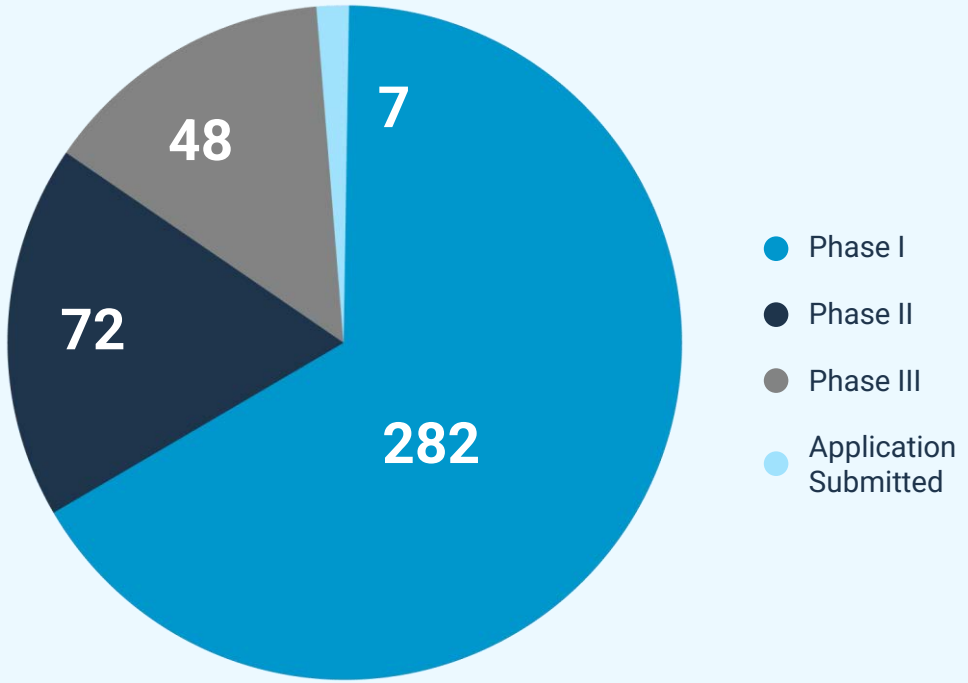
C&GT Landscape Holds Tremendous Promise

US C&GT Pipeline Overview

255 Cell Therapies

154 Gene Therapies

C&GT Pipeline, by Phase



Source: Public, government and industry sources, and the Springer “Adis Insight” database based on the latest information. Daa current as of **May 30, 2025.**

C&GTs Provide Enormous Healthcare System Value, But Pose Payer Challenges Due to Upfront Payments

Small and Stable Share of Healthcare Spending

Projected to represent just 0.1% of healthcare spending and 1.3% of prescription drug spending by 2030.

Curative, durable long-term effects

Potential for significant avoided cost, but that value is realized over the lifetime of the patient.

Payers Moving Towards Paying for Value

Coverage and reimbursement system is evolving to ensure patients can access these treatments through innovative contracting.

Innovative Contracting Help Reduce Payer Risk by Tying Payment to Value/Patient Outcomes

Voluntary arrangements between manufacturers and other entities

Allows manufacturers and payers to share risk of certain medications

Directly link the amount paid to previously agreed upon outcomes or performance measures

Potential to lower costs and increase patient access

Various Innovative Contracting Arrangements Address Different Challenges

	Value Based/Outcomes-Based Contracts			Alternative Financing	
Challenge Addressed	**Milestone**	**Warranty**	**Pay-Over-Time (Annuity)**	**Stop-loss and Reinsurance**	**Enhanced Risk Pool/Subscription Model**
Clinical Uncertainty	✓	✓	✓		
Budgetary Constraints of upfront payment			✓	✓	✓
Actuarial Risk				✓	✓
Multi-year contracting restrictions	✓	✓			

Policy and Administrative Barriers Must Be Addressed to Advance Innovative Contracting Approaches

Outcomes and Data

Data infrastructures may lack sufficient capacity, efficiency, interoperability and timeliness.

Time Horizon

Tracking longer-term outcomes can be burdensome and hindered by patients switching among payers over time.

Administrative Infrastructure

Payers and providers may not have the capacity or incentives in place to carry out complex payment arrangements.

Legal Barriers

Federal laws including the Anti-Kickback Statue and Medicaid Rules can impede the implementation of innovative contracts.

PhRMA Created the Medicine Assistance Tool, or MAT, A Search Engine To Help Patients Navigate Affordability

MAT makes it easier for those struggling to afford their medicines to find and learn more about various programs that can make prescription medicines more affordable.

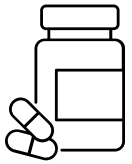
www.mat.org (Medicine Assistance Tool) Includes:

A search engine to connect patients with

900+

assistance programs offered by biopharmaceutical companies, including some free or nearly free options

Resources to help patients navigate their insurance coverage



Links to biopharmaceutical company websites where information about the cost of a prescription medicine is available

PhRMA
RESEARCH • PROGRESS • HOPE

Questions for presenters on alternative financing?

- Daniel Ollendorf, Ph.D., MPH, chief scientific officer and director of health technology assessment methods and engagement, Institute for Clinical and Economic Review (ICER)
- Deborah “Dee” Weston, J.D., pharmacy program policy advisor, Oregon Health Authority
- Sharon Lamberton, M.S., R.N., deputy vice president state policy and external outreach, PhRMA

Second public comment period

Send written testimony to rx.prices@dcbs.oregon.gov

Thank you for attending

Send written comments to rx.prices@dcbs.oregon.gov

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Department of Consumer and Business Services