Oregon Prescription Drug Prices Annual Public Hearing

1:30 p.m. to 4 p.m., Thursday, Dec. 7, 2023

Sign up in the chat to provide public testimony.

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

Department of Consumer and Business Services

Welcome

Welcome and introductions

- Andrew Stolfi (he/him), insurance commissioner and agency director, DCBS.
- Ralph Magrish (he/him), Prescription Drug Affordability Board executive director, DFR, DCBS.

Moderators

- Sen. Deb Patterson (she/her).
- Rep. Christine Goodwin.
- Rep. Cyrus Javadi.
- Rep. Rob Nosse (he/him).

Drug Price Transparency Program

Program presenters:

- Sofia Parra (she/her), program coordinator, Drug Price Transparency Program, DFR, DCBS.
- Numi Rehfield-Griffith (she/her), senior policy advisor, DFR, DCBS.

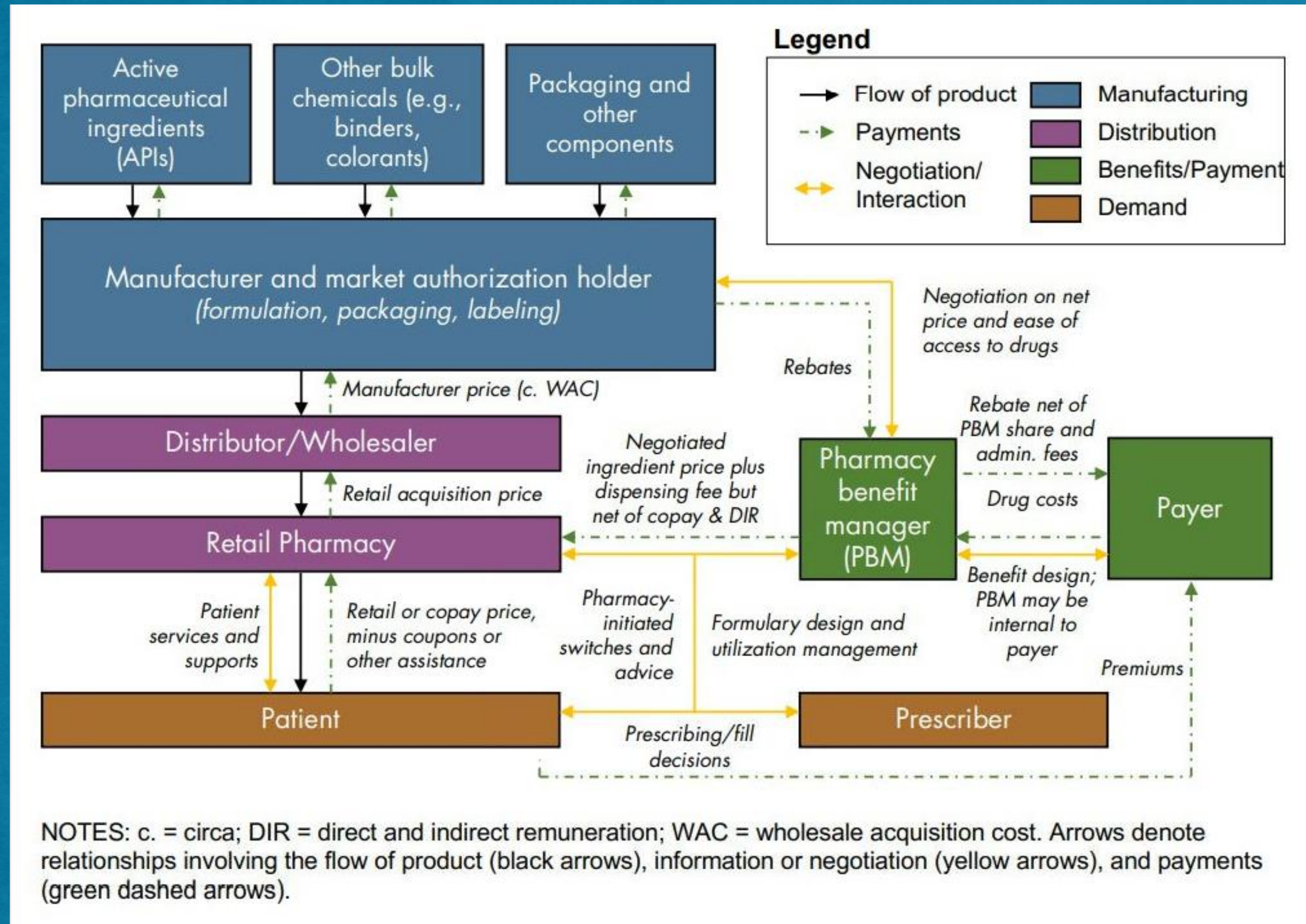
Drug Price Transparency Program

- Operates under ORS 646A.680 to 646A.692 and OAR 836-200-0500 to 836-200-0560. ORS 743.025 requires insurers to file annual reports with the program.

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

- Reporting manufacturers are those who meet all the following:
  - ➢ Registered with the Oregon Board of Pharmacy.
  - ➢ Manufacture prescription drugs for sale in Oregon.
  - ➢ Set the drug’s price (wholesale acquisition cost (WAC)).

Pharmaceutical supply chain diagram



Drug price transparency reporting

Program is directed by statute to receive:

- Manufacturer reports:
  - ➢ New specialty drug reports: More than $670 for 30-day supply.
  - ➢ Annual price increase reports: $100 or more and 10 percent net yearly increase.
  - ➢ 60-day price increase notices: 10 percent or $10,000 increase for brand name, 25 percent and $300 increase for generic.
- Insurer reports: Top 25 most costly and most prescribed drugs, and the effect of drug costs on premium rates.
- Pharmacy benefit manager (PBM) reports: Amounts received from manufacturers and how they were distributed.
  - ➢ New reporting starting in 2024.
- Consumer reports: Personal price increase in Rx purchased.

Program compliance and trade secret reviews

DPT compliance

- A letter of noncompliance is sent when staff members identify a manufacturer report that is not in compliance. This allows 30 days to become compliant before file is referred to enforcement unit and manufacturer potentially accrues civil penalties.
- Primary areas of noncompliance have been:
  - ➢ Failure to respond to the request for additional information.
  - ➢ Failure to provide accurate and complete information in the required data elements.
- The goal is compliance for each report.
  - ➢ Almost all manufacturers come into compliance after receiving a noncompliance letter.

Program compliance and trade secret reviews

Manufacturer trade secret claims

- When filing reports, manufacturers can claim individual data elements (such as profit data and pricing factors) as a trade secret.
- Reviewing trade secret claims for various data elements is a lengthy and complex process, even when in agreement with the claim.
- There are additional steps when the program disagrees with a trade secret claim before it can publish the information. A trade secret determination letter is issued for the parts of the claim where the program does not agree. The manufacturer has 15 days to appeal the decision.

Program compliance and trade secret reviews

Manufacturer trade secret claims continued

- Since the program began, DPT has received more than 1,900 reports with trade secret claims. In the past year, 475 reports with claims have been received.
  - Since the program started working on trade secret reviews in 2022, it has processed trade secret claims on 140 reports.
  - Compliance staff members have also addressed manufacturers' inappropriate claims, and many manufacturers decided to remove their claims allowing the information to be published in full without having to issue trade secret determinations.

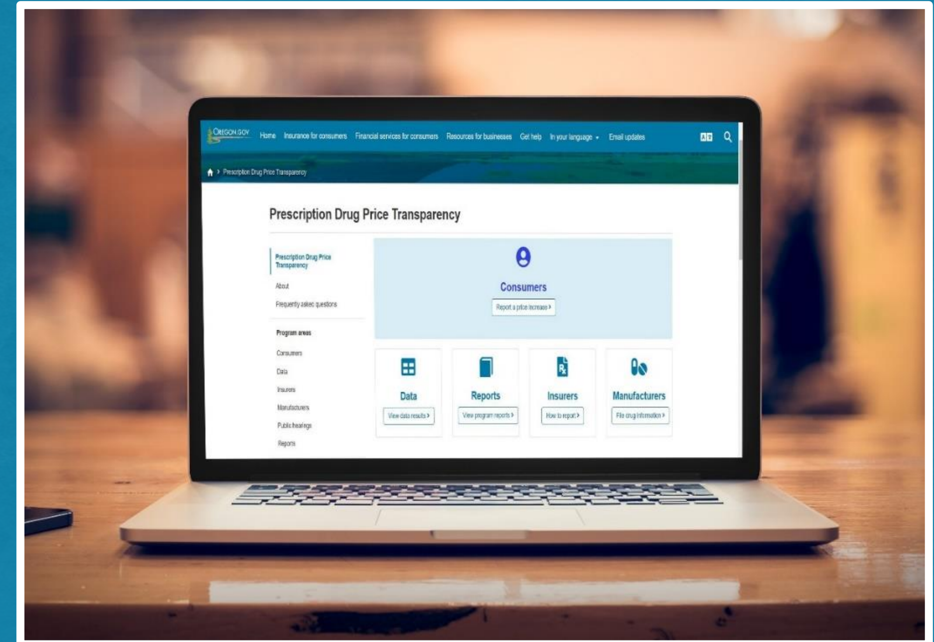
Consumers and transparency

Consumers

- Price increase reporting.
- Stories about high drug prices.

Transparency website

- Reported data from manufacturers (non-trade secret).
- Information from insurers.
- Consumer price increase reports.



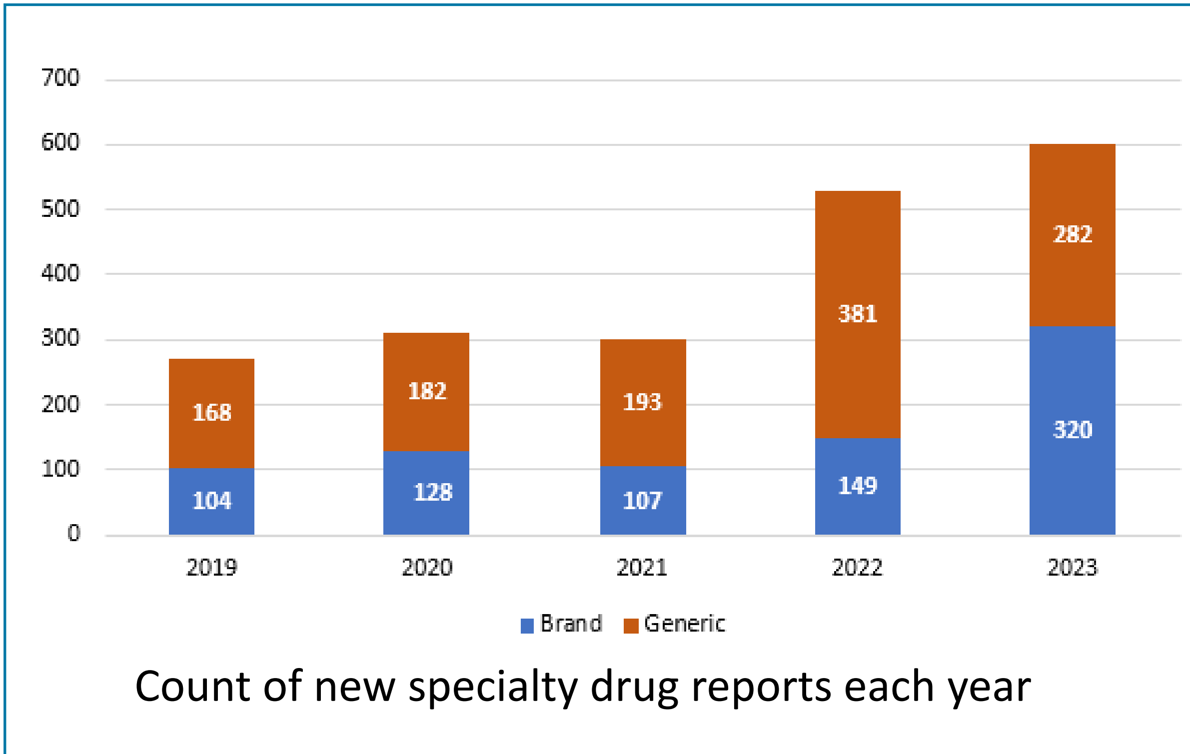
Key findings for 2023

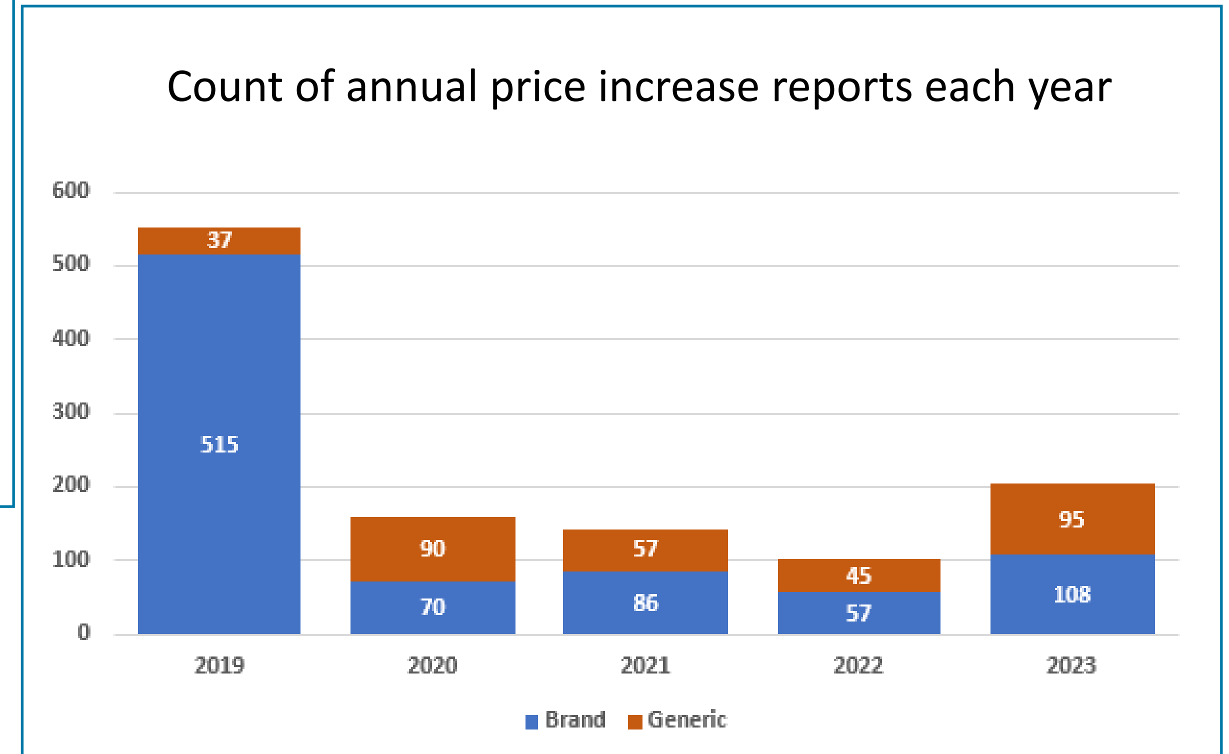
- New specialty drug report highlight: Antineoplastics and adjunctive therapies, used to treat cancer, were the most frequent category of new specialty drugs reported to the program. The highest WAC for a brand name drug was $3.5 million for **Hemgenix**, a treatment for hemophilia B, manufactured by **CSL Behring LLC**.

- Annual increase report highlight: The largest price increase reported to the program in 2022 was a 25 percent increase from $575 to $718.75. This price increase was for a generic drug, **Aquasol A**, a generic vitamin A solution, manufactured by **Casper Pharma**.

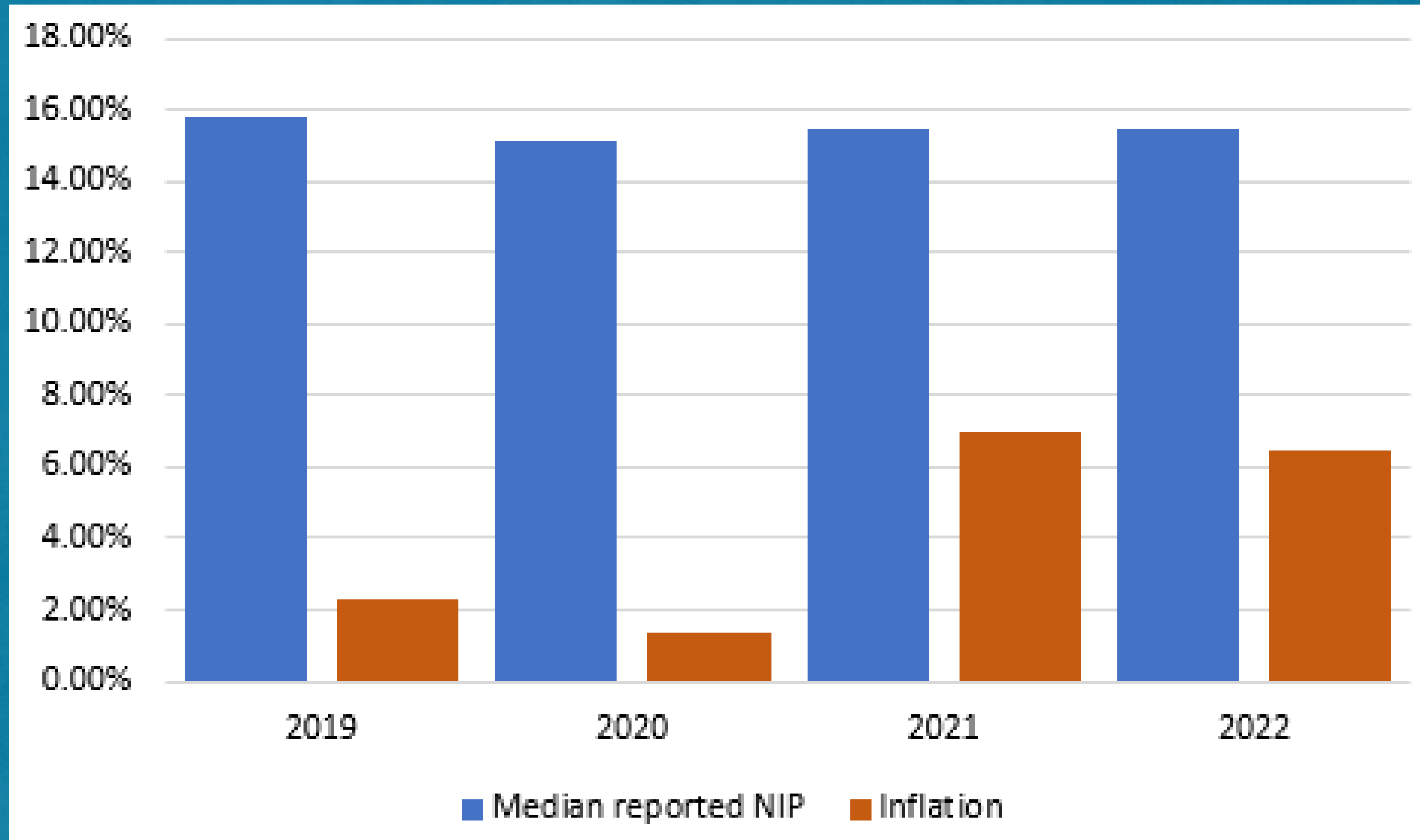
- Insurer report highlight: **Humira,** manufactured by **AbbVie Inc**, continues to be the most costly drug contributing to more plan spending than any other drug for five years running. In 2022, health insurance companies in Oregon reported $75.24 million in spending on **Humira**.

Manufacturer report filings

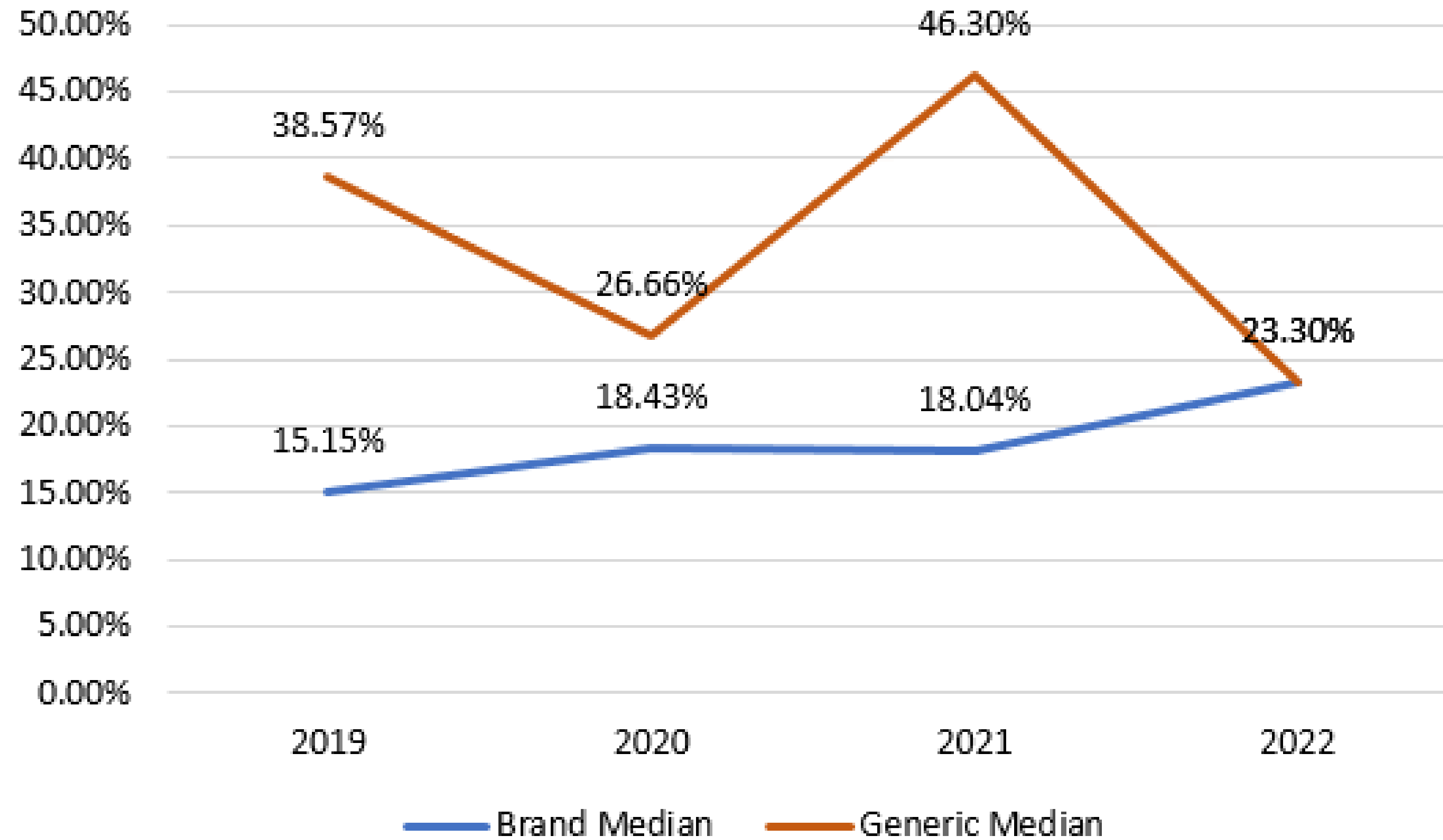




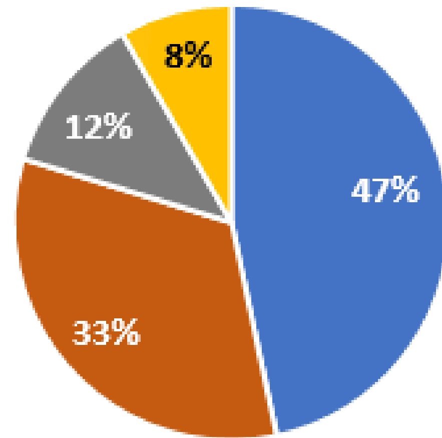
Net increase percentages



Profit margins



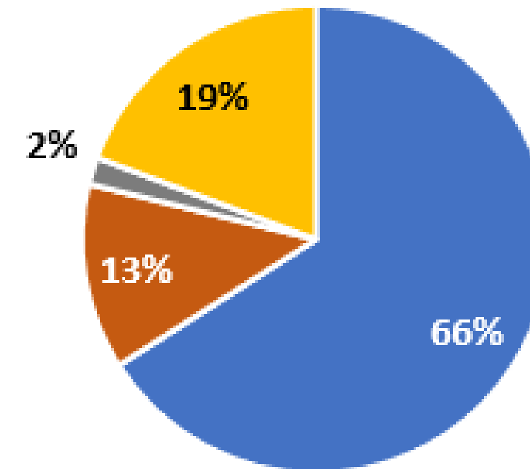
Manufacturer direct cost breakdown



■ Manufacturing % ■ Marketing % ■ Distribution % ■ Safety & Effectiveness %

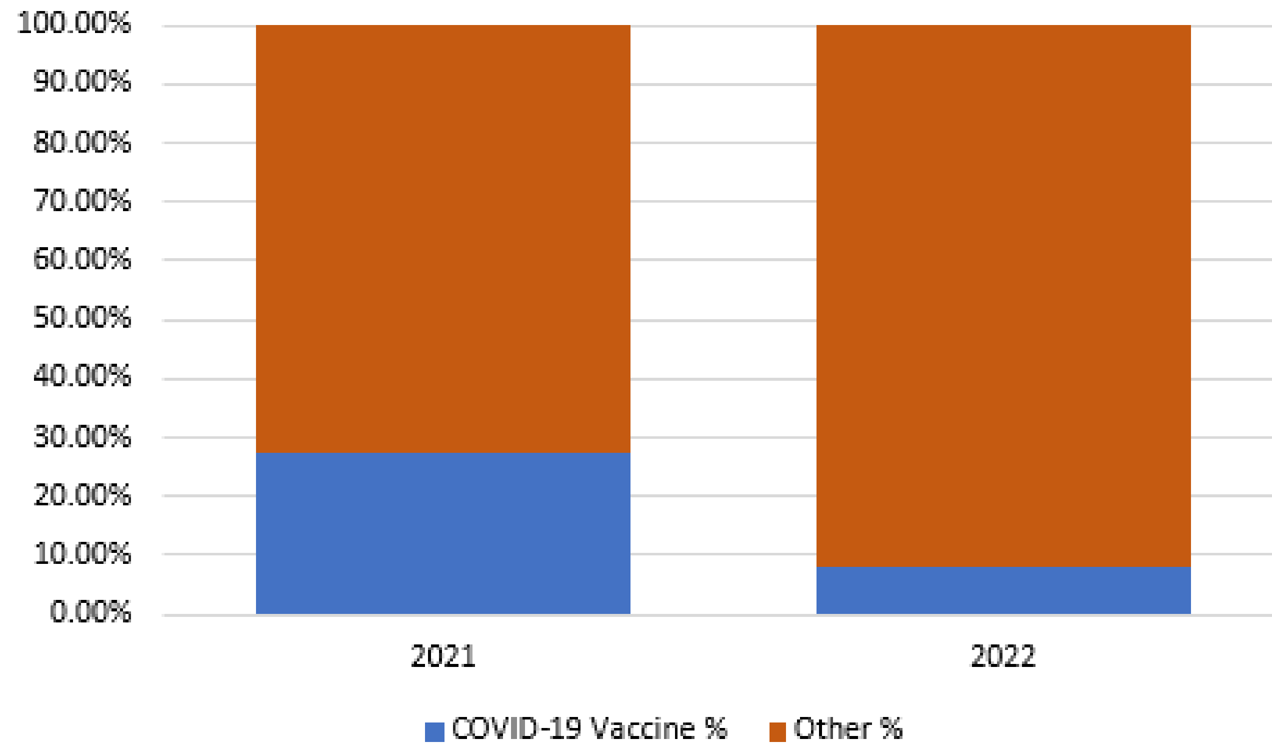
Brand Name Direct Costs

Generic Direct Costs



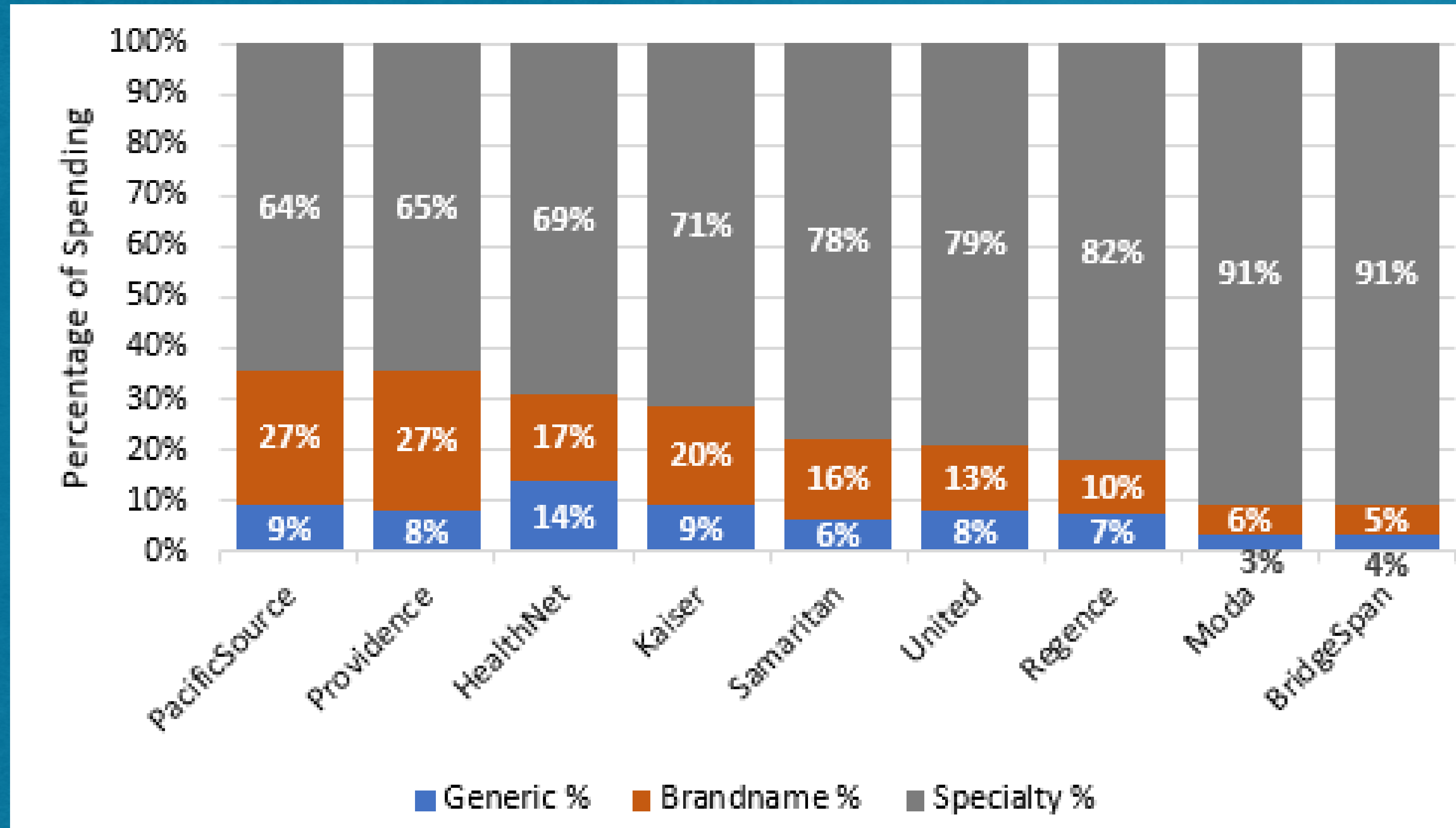
■ Manufacturing % ■ Marketing % ■ Distribution % ■ Safety & Effectiveness %

COVID-19 prescription volumes

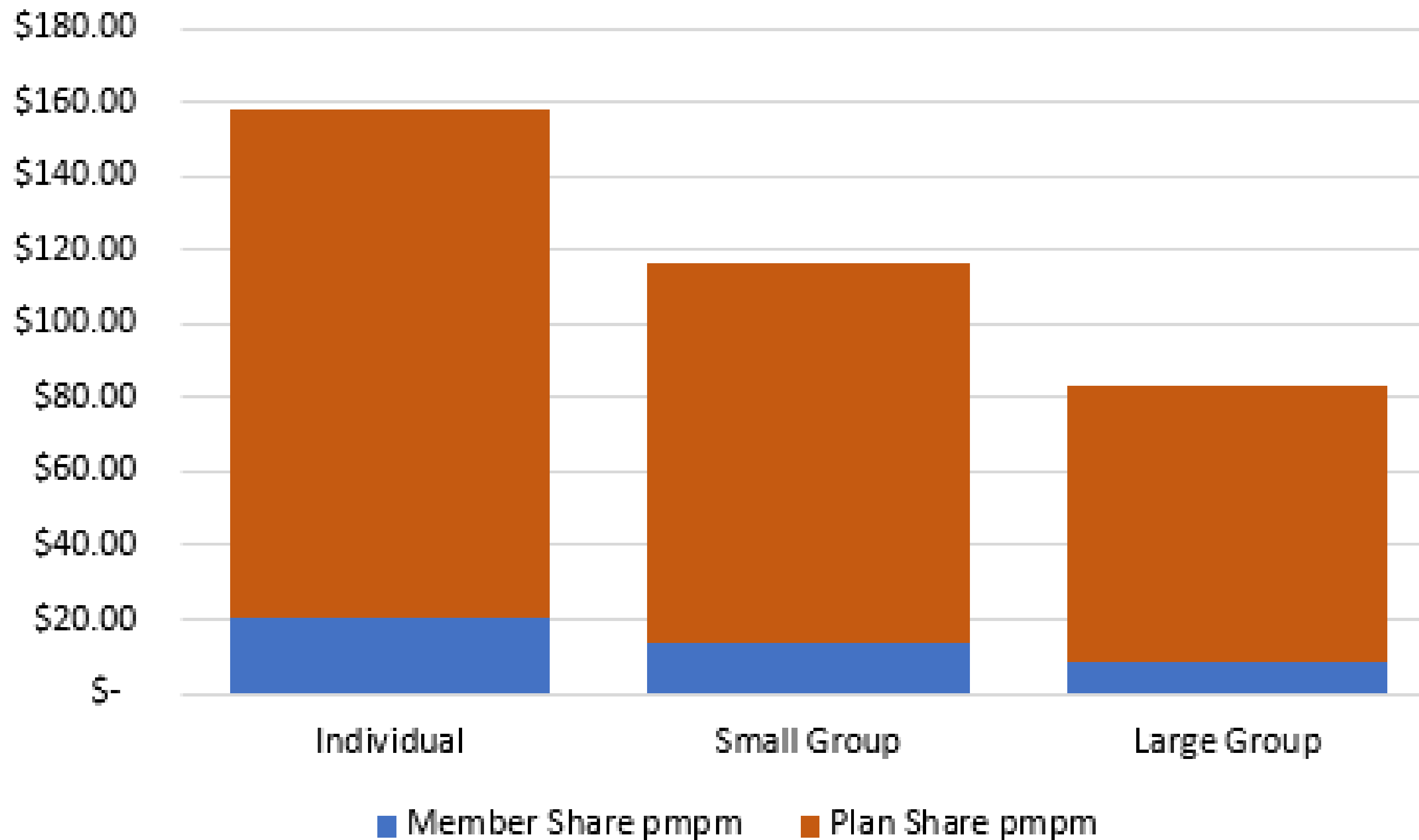


2021 Prescription Volume – 537,155
2022 Prescription Volume – 124,948

Plan spending on prescription drugs

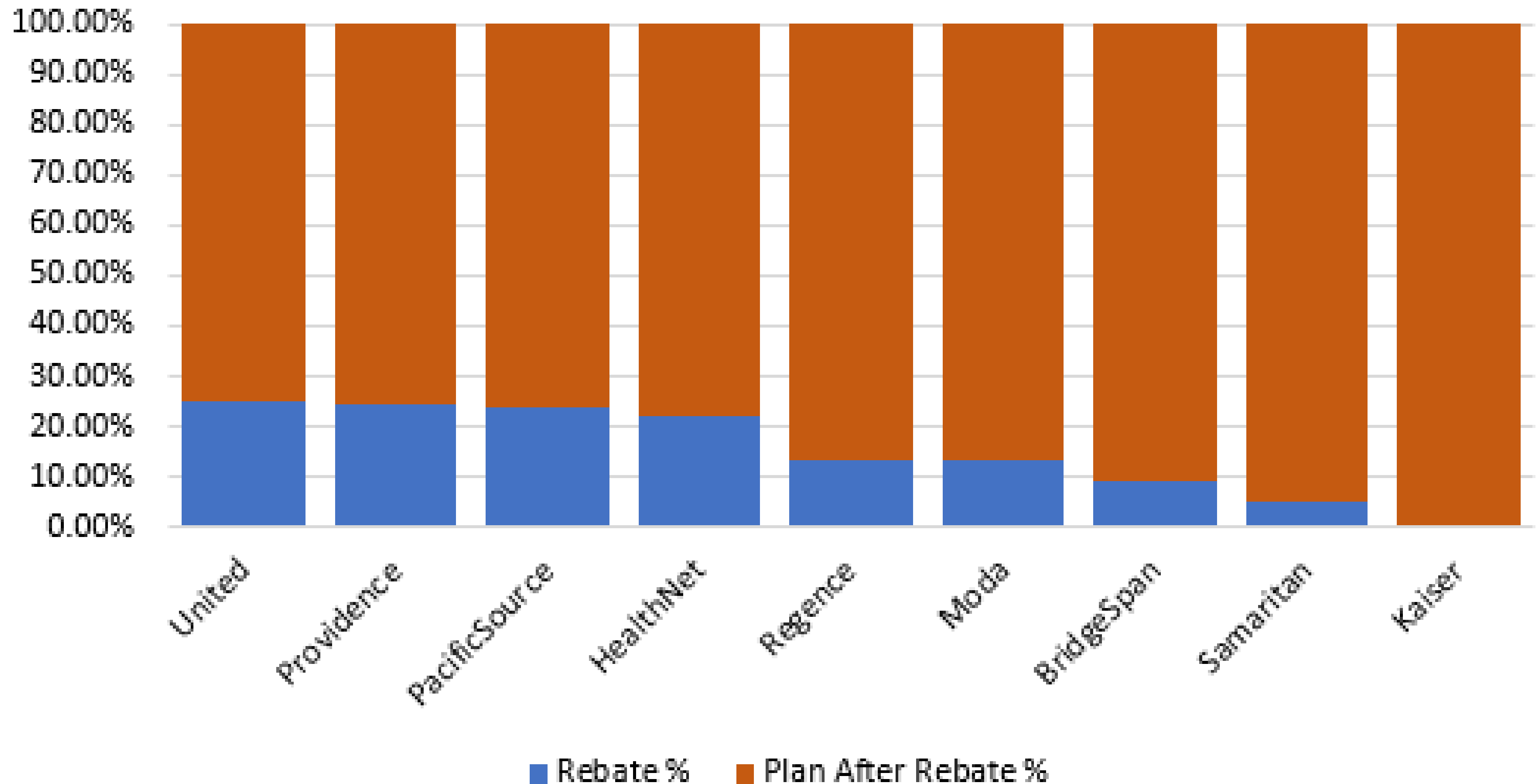


Plan prescription spending per member per month



- Individual Market:
  - Member Share - $20.79
  - Plan Share – 136.93
- Small Group Market:
  - Member Share – $13.86
  - Plan Share - $102.34
- Large Group Market:
  - Member Share - $8.38
  - Plan Share - $75.10

Insurer rebates



Most prescribed prescription drugs

Drug	Class	Prescriptions
Brand names: **Afluria, Fluarix, Flulaval, Fluzone** Influenza Virus Vaccine	Vaccines	221,220
Brand names: **Euthyrox, Levoxyl, Synthroid, Tirosint** Levothyroxine Sodium	Thyroid Agents	169,336
Brand names: **Atorvaliq, Lipitor** Atorvastatin Calcium	Antihyperlipidemics	166,505
Brand names: **Prinivil, Qbrelis, Zestril** Lisinopril	Antihypertensives	161,174
Brand names: **Adderall, Mydaysis** Amphetamine-Dextroamphetamine	ADHD/Antinarcolepsy/Anti obesity/Anorexiants	156,001
Brand names: **ProAir, Proventil, Ventolin** Albuterol Sulfate	Anti-Asthmatic/Broncodilator Agents	141,372
Metformin HCl	Antidiabetics	137,692
Bupropion HCl	Antidepressants	126,612
Brand name: **Moderna and Pfizer-BioNTech** COVID-19 (SARS-CoV-2) mRNA Virus Vaccine	Vaccines	124,948
Includes Brand name: **Zoloft** Sertraline HCl	Antidepressants	119,432

Most costly prescription drugs

Drug	Class	Total Annual Plan Spending
Brand name: **Humira** Adalimumab	Analgesics – AntiInflamatory	$75,241,110
Brand name: **Stelara** Ustekinumab	Dermatologicals	$28,957,943
Brand name: **Keytruda** Pembrolizumab	Antineoplastics & Adjunctive Therapies	$28,248,898
Brand name: **Biktarvy** Bictegravir-Emtricitabine-Tenofovir Alafenamide Fumarate	Antivirals	$26,988,465
Brand name: **Enbrel** Etanercept	Analgesics – AntiInflamatory	$22,017,823
Brand name: **Trikafta** Elexacaftor-Tezacaftor-Ivacaftor	Respiratory Agents	$21,559,651
Brand name: **Cosentyx** Secukinumab	Dermatologicals	$18,723,855
Brand name: **Entyvio** Vedolizumab	Gastrointestinal Agent	$17,655,131
Brand name: **Inflectra** Infliximab-dyyb	Gastrointestinal Agent	$16,516,923
Brand name: **Skyrizi** Risankizumab-rzaa	Dermatologicals	$15,517,811

Prescription drugs with increased plan spending

Drug	Class	Year-over-Year Increase
Brand name: **Keytruda** Pembrolizumab	Antineoplastics & Adjunctive Therapies	$11,840,653
Brand name: **Skyrizi** Risankizumab-rzaa	Dermatologicals	$8,385,287
Brand name: **Inflectra** Infliximab-dyyb	Gastrointestinal Agents	$5,489,239
Brand name: **Trikafta** Elexacaftor-Tezacaftor-Ivacaftor	Respiratory Agents	$4,417,699
Brand name: **Gammagard** Immune Globulin (Human) IV	Passive Immunizing & Treatment Agents	$4,312,556
Brand name: **Humira** Adalimumab	Analgesics - AntiInflammatory	$3,682,844
Brand name: **Dupixent** Dupilumab	Dermatologicals	$3,333,668
Brand name: **Rybelsus/Ozempic** Semaglutide	Antidiabetics	$3,238,534
Brand name: **Stelara** Ustekinumab	Dermatologicals	$3,077,394
Brand name: **Adcetris** Brentuximab Vedotin	Antineoplastics & Adjunctive Therapies	$3,020,976

Policy recommendations

- Increase transparency of patient assistance programs:
  - Only 18 patient assistance programs were reported this year (more than 200 estimated).
  - Require annual reporting on all patient assistance programs, instead of just those with price increases.

- Require insurers and PBMs to report on their use of “copay accumulator” programs:
  - These programs may increase costs for certain consumers.

- Transparency across the pharmaceutical supply chain:
  - Add more of the layers in the supply chain.

Policy recommendations continued

- Study feasibility of state generic manufacturing and expanded bulk purchasing:
  - ➢ Allow state to leverage bulk purchasing power.
  - ➢ Explore uniform drug lists for all state programs and PBM services.
  - ➢ Establish centralized office of pharmacy purchasing for coordination and oversight of all state purchasing.

- Update reporting thresholds to align 60-day notice and annual increase reporting:
  - ➢ Match the reporting thresholds for these reports to reduce administration issues and increase compliance.

Questions?

Members of the public:

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

Program presenters:

Sofia Parra, program coordinator

Numi Rehfield-Griffith, senior policy advisor

First public comment period

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

First panel – Diabetic drugs approved for weight loss

Presenters:

- David Rind, MD (he/him), chief medical officer, Institute for Clinical and Economic Review.
- Irvin M. Brown, Ed.D. (Black/African American, he/him), vice president Salem-Keizer NAACP, political action chair NAACP Alaska, Oregon, Washington.
- Mihir Patel (he/him), PharmD, chief pharmacy officer, Regence Blue Cross Blue Shield of Oregon.
- Charlie Fisher, OSPIRG state director.

Presenter:

- David Rind, MD, chief medical officer, Institute for Clinical and Economic Review.

Diabetic Drugs Approved for Weight Loss

David Rind, MD
Chief Medical Officer, ICER
December 7, 2023

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Institute for Clinical and Economic Review (ICER)

- Started as an ethics and evidence policy research program
- Since 2013, independent HTA group
- Develops publicly available value assessment reports
- Uses cost-effectiveness analysis to determine value-based price benchmarks
- Tries to time reviews to complete around FDA approval to influence price negotiations

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Epidemiology of Obesity

- Obesity is a common chronic disease that increases one's risk for diabetes, high blood pressure, arthritis, cancer, heart disease, and death
- More than 40% of adults in the US have obesity; projected to reach 50% by 2030
- Obesity is even more common among certain racial and ethnic groups, including Hispanic adults and non-Hispanic Black women
- US medical costs attributable to obesity estimated to be $260 billion annually

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The Medications

Medication	Brand Name	Route/Freq	Mechanism	Approved?	Works?
Liraglutide	Victoza	SQ/Daily	GLP-1 RA	No	+/-
	Saxenda	SQ/Daily		Yes	+/-
Dulaglutide	Trulicity	SQ/Weekly	GLP-1 RA	No	+
Semaglutide	Ozempic	SQ/Weekly	GLP-1 RA	No	++
	Rybelsus	Oral/Daily		No	++
	Wegovyy	SQ/Weekly		Yes	+++
Tirzepatide	Mounjaro	SQ/Weekly	GLP-1/GIP RA	No	++++
	Zepbound	SQ/Weekly		Yes	++++

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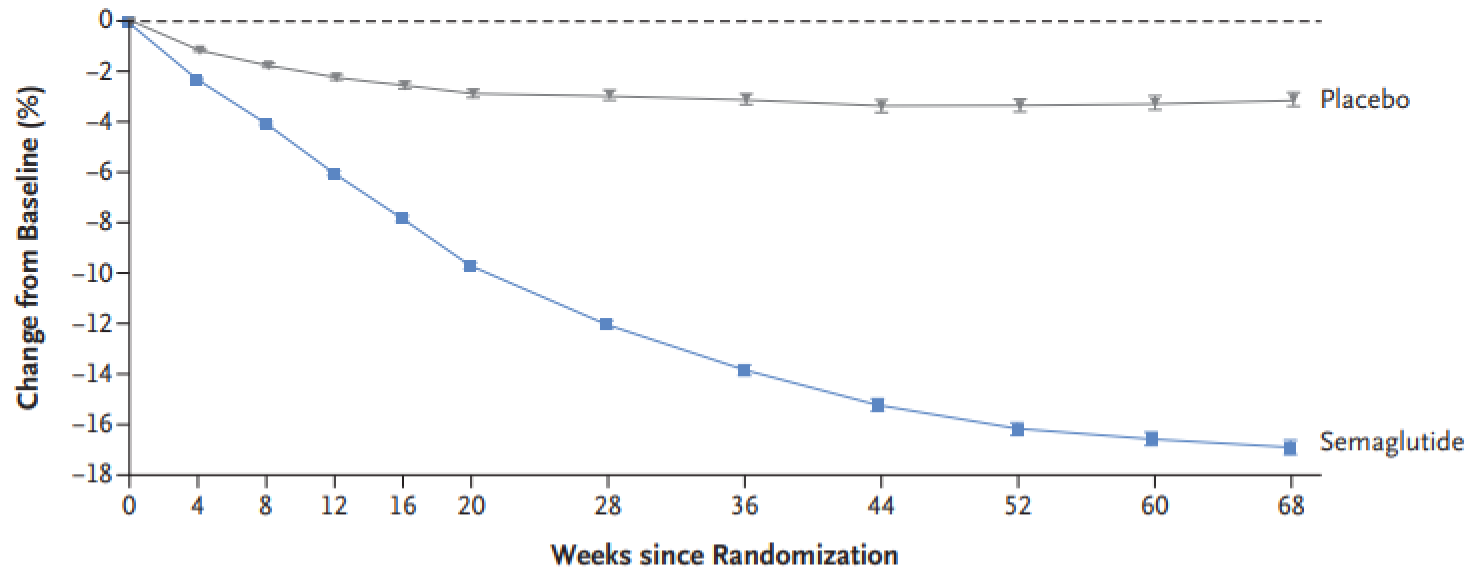
Semaglutide: Weight Loss Over Time



From: Wilding JPH, et al. N Engl J Med 2021; 384:989-1002

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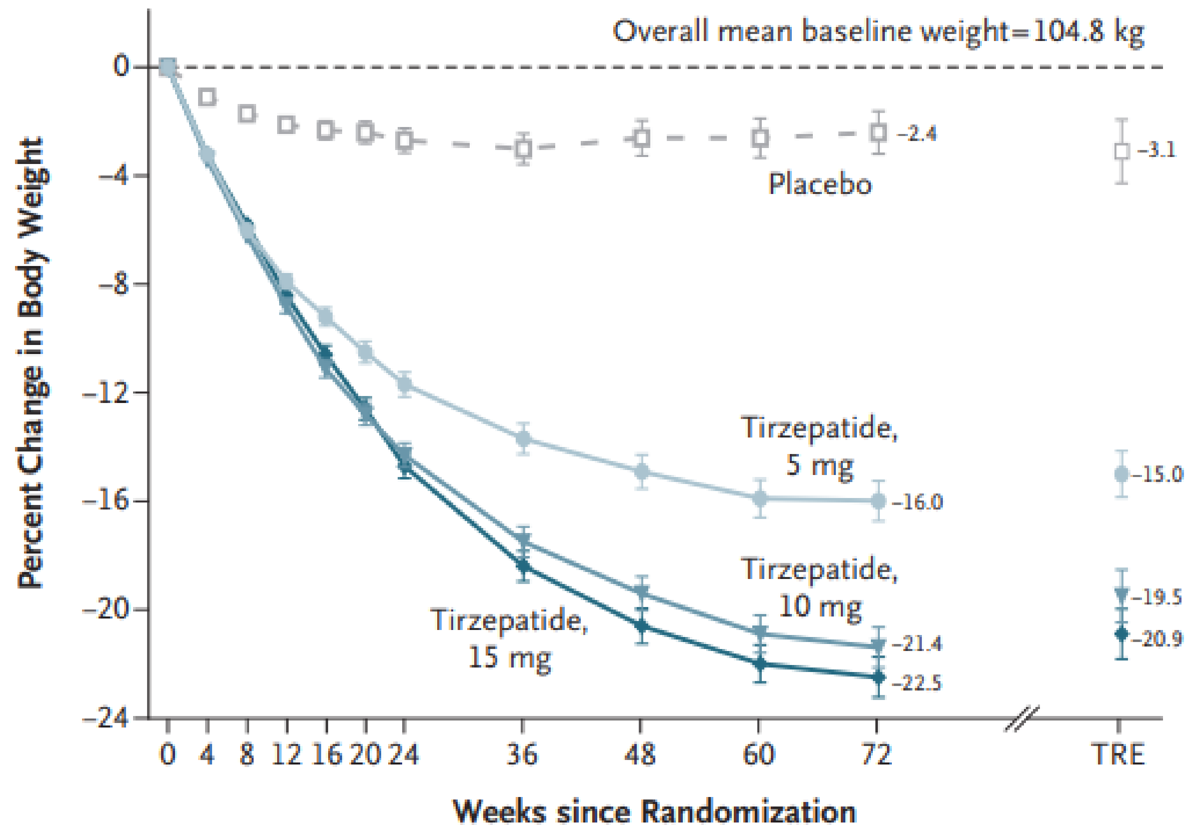
Tirzepatide: Weight Loss Over Time



From: Sims JR, et al. JAMA 2023; 330: 512-527

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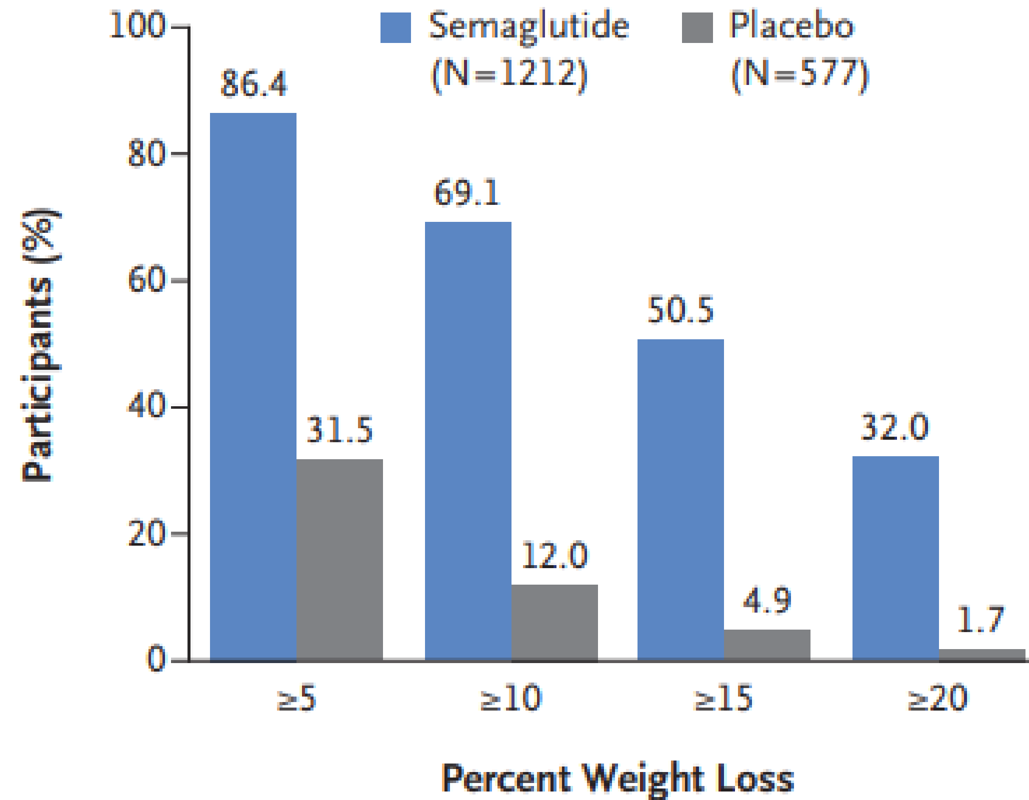
Semaglutide: Achieving Percentage Targets



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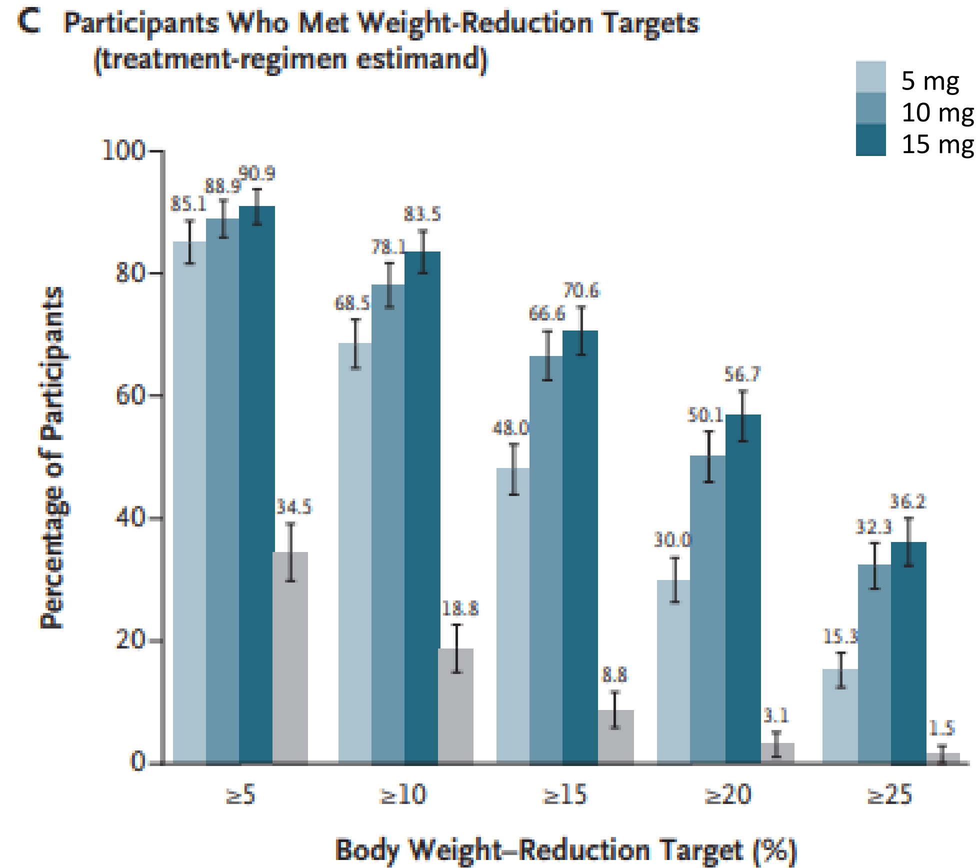
Tirzepatide: Achieving Percentage Targets



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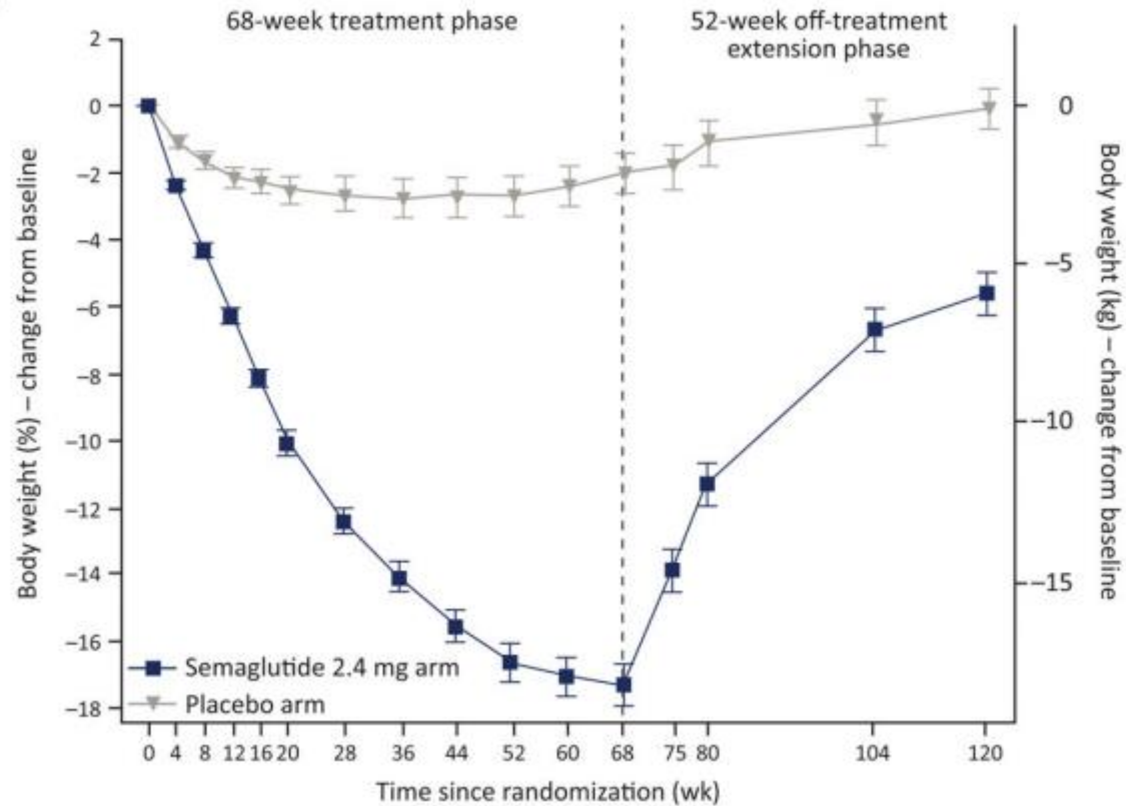
Weight Loss Only Maintained While on Therapy



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Cardiovascular Benefits

- GLP-1 RAs reduce CV risk in T2 diabetes
  - We have years of data on this
- Semaglutide in patients with with CAD and obesity
  - 20% reduction in MACE
  - 19% reduction in all-cause mortality
- Tirzepatide does not have CVOT data yet even in diabetes
  - Early data looked similar to semaglutide

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Shortages

- Semaglutide has been difficult for many patients to obtain
- Same could occur now with tirzepatide
- In my experience, dulaglutide has been widely available and there are other GLP-1 options

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Fair Price

- ICER analyses suggest that at their net prices, both tirzepatide and semaglutide are cost-effective

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Budget Impact of Semaglutide

- At WAC ($17,600), could treat 0.1% of eligible patients within five years

- At lower end of ICER price range ($7500), could treat 0.26% within five years

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Strategies to Control Budget Impact

- Restrict to High BMI (e.g., >40)
  - Missing benefit in many patients
- Require Lifestyle Management
  - Little evidence this is really needed, so potentially wasted spending to lower budget impact
- Netflix Model

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Conclusions

- The vast majority of patients cannot achieve long-term weight loss with diet and exercise
- These new medications work
- Semaglutide reduces CV events; if tirzepatide has the same benefit, it will likely take over from semaglutide
- Even at fair prices, the budget impact will be enormous
  - May want to consider other payment models

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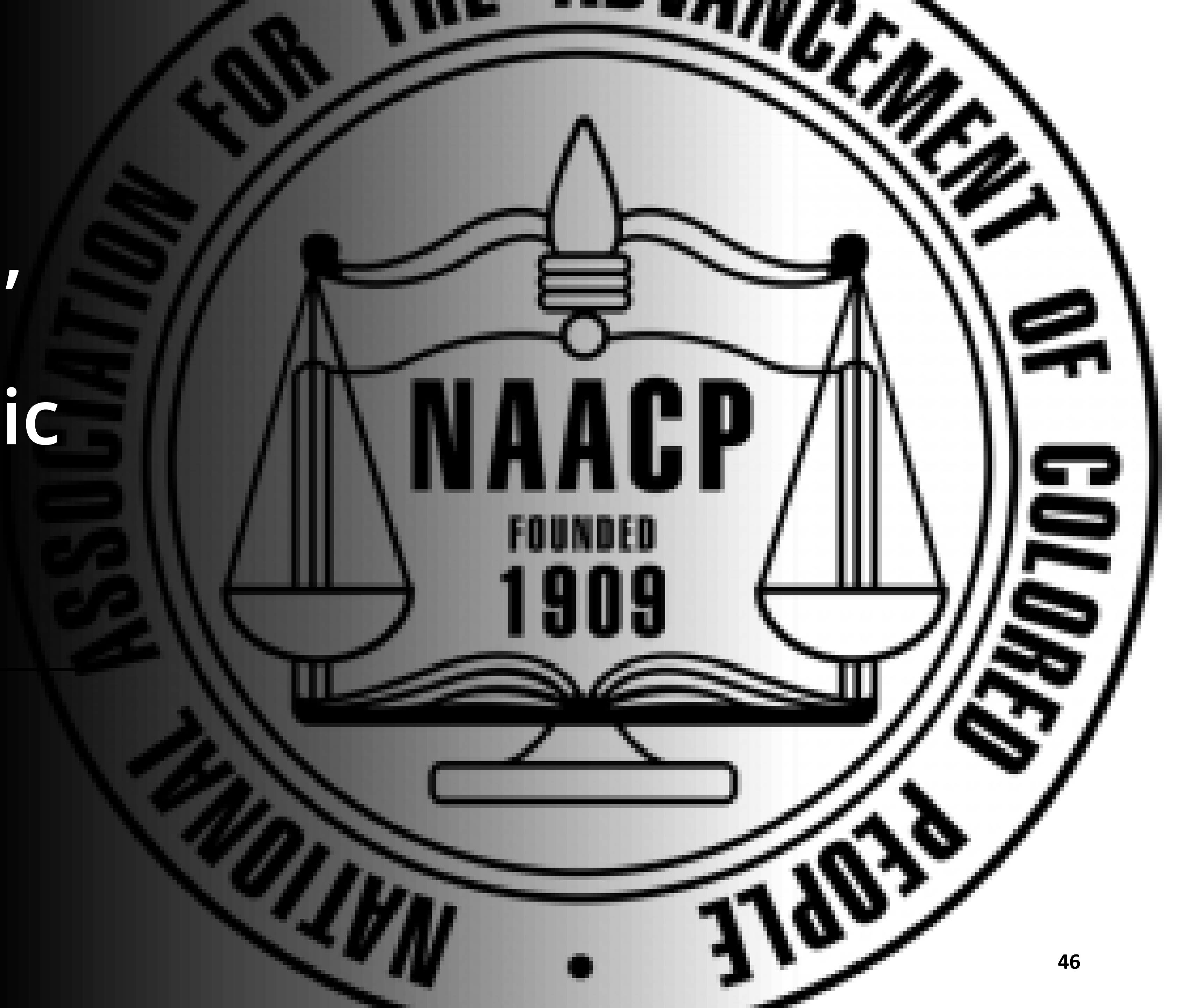
Thank you!

Presenter:

- Irvin M. Brown, Ed.D., vice president Salem-Keizer NAACP, political action chair NAACP Alaska, Oregon, Washington.

Obesity, Race, and Socioeconomic Status

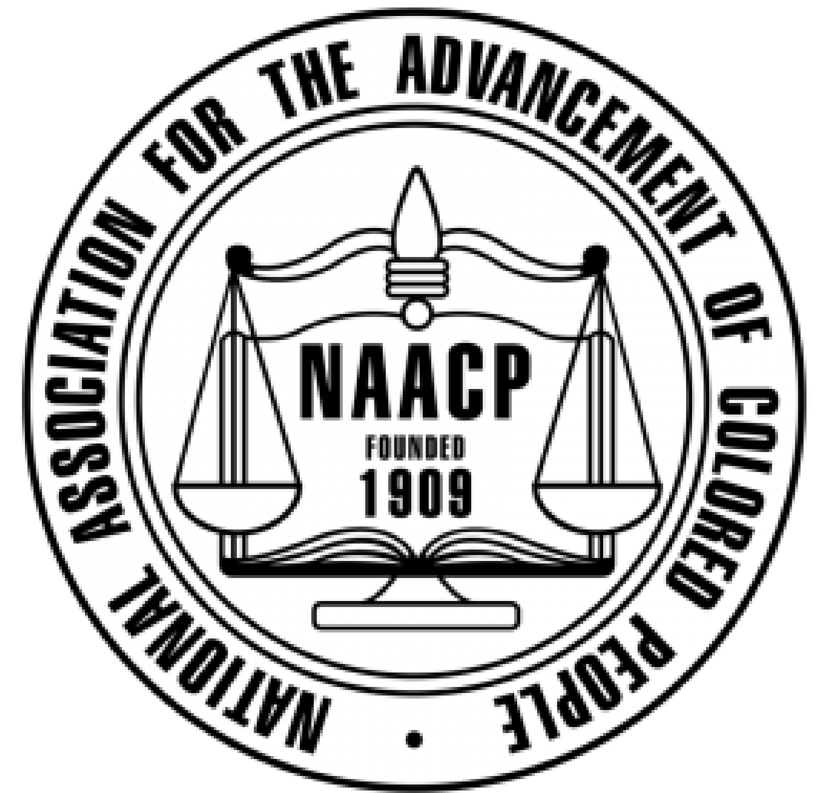
Let's Talk About It.



Be Courageous and Inclusive

"Let's talk about what's killing us every day… when I treat [my patient's] obesity, I treat their heart disease. I treat the 14 cancers caused by obesity. I treat their diabetes. I treat their apnea."

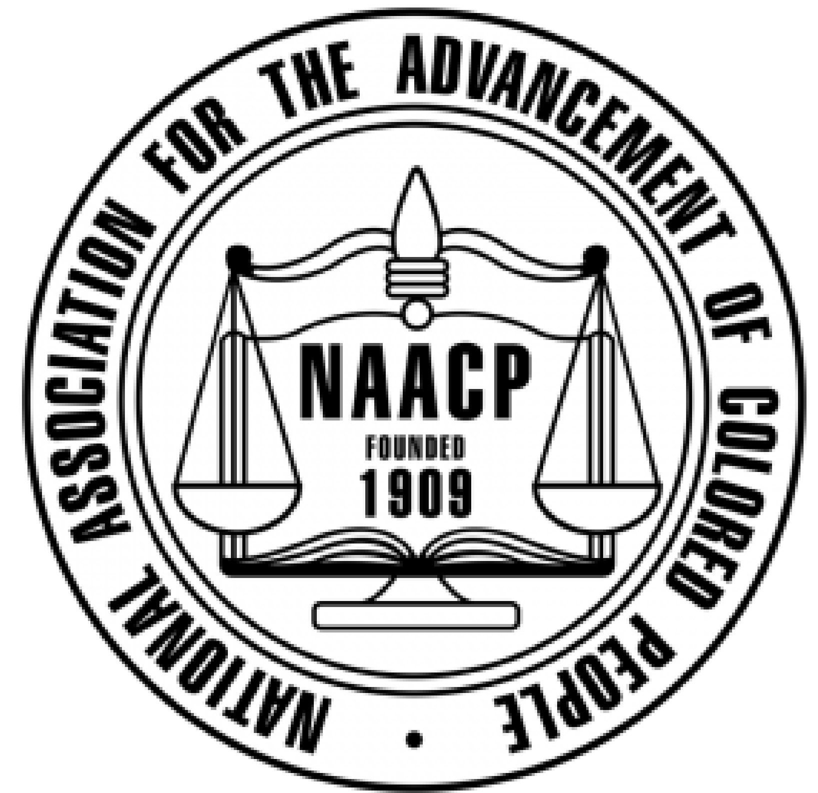
- **Dr. Fatima Cody Stanford | Leading Obesity Science Physician**
  Health Equity Coalition for Chronic Disease/HECCD



Data Speaks for Itself

- Over 42% of Americans are living with obesity | 60 and older
- 34.2% of rural Americans live with obesity compared to 28.7% of those living in metropolitan cities
- 78% of people hospitalized, placed on a ventilator or died from the pandemic were overweight or live with obesity
- 25% reduction would have = 120k fewer hospitalizations; 45k fewer ICU admissions, and 65k deaths

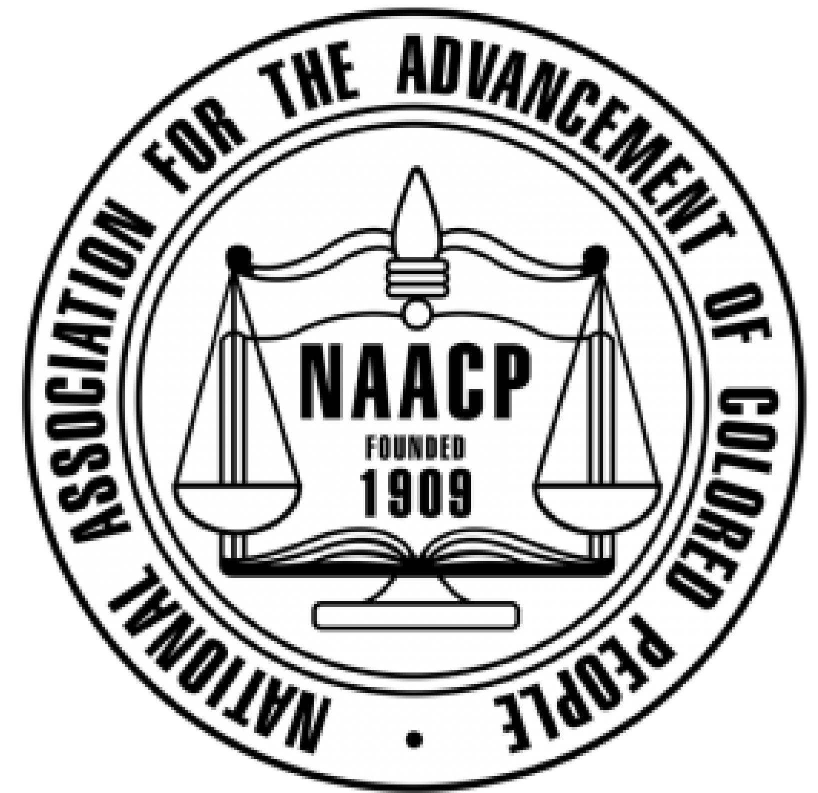
➢ Health Equity Coalition for Chronic Disease/HECCD



Race Still Matters

- 60% of African American/Black women and nearly half of all African American/Black and Hispanic Americans are now living with obesity
- The obesity prevalence was 39.8% among adults aged 20 to 39 years
- 44.3% among adults aged 40 to 59 years

➢ CDC National Center for Health Statistics



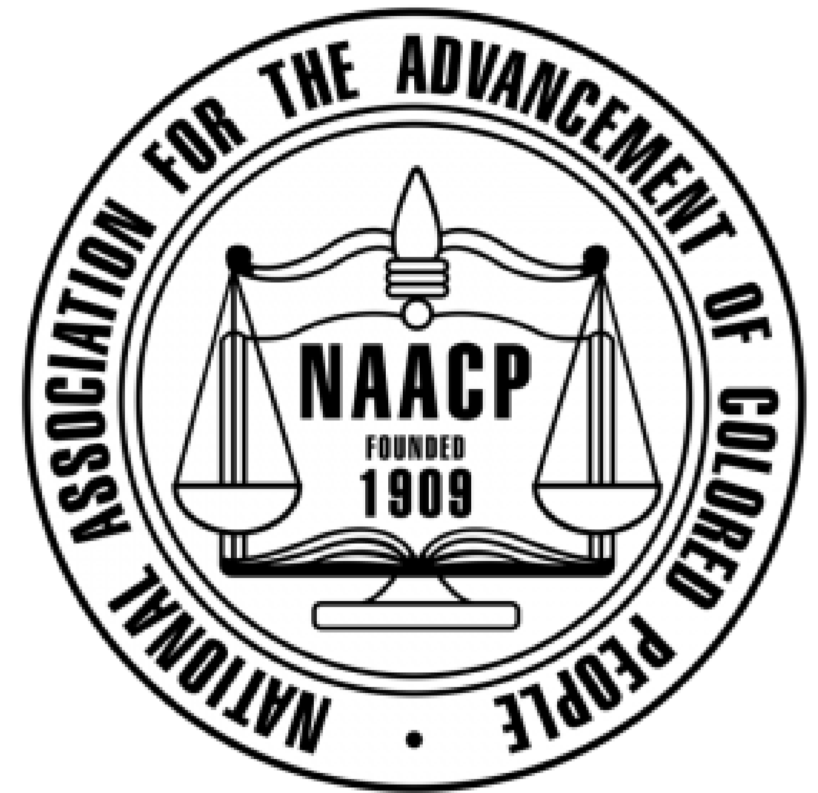
Obesity + income or educational level + sex/gender + race/ethnicity = a complexity of concerns

- men and women with college degrees had lower obesity prevalence compared with those with less education

- About 1 in 3 adult community members in Marion and Polk Counties | compared to 27% in the State

- AA/B, American Indian/Alaska Native, Hispanic, Pacific Islander had higher prevalence than their peers

➢ 2019 Marion-Polk Community Health Assessment

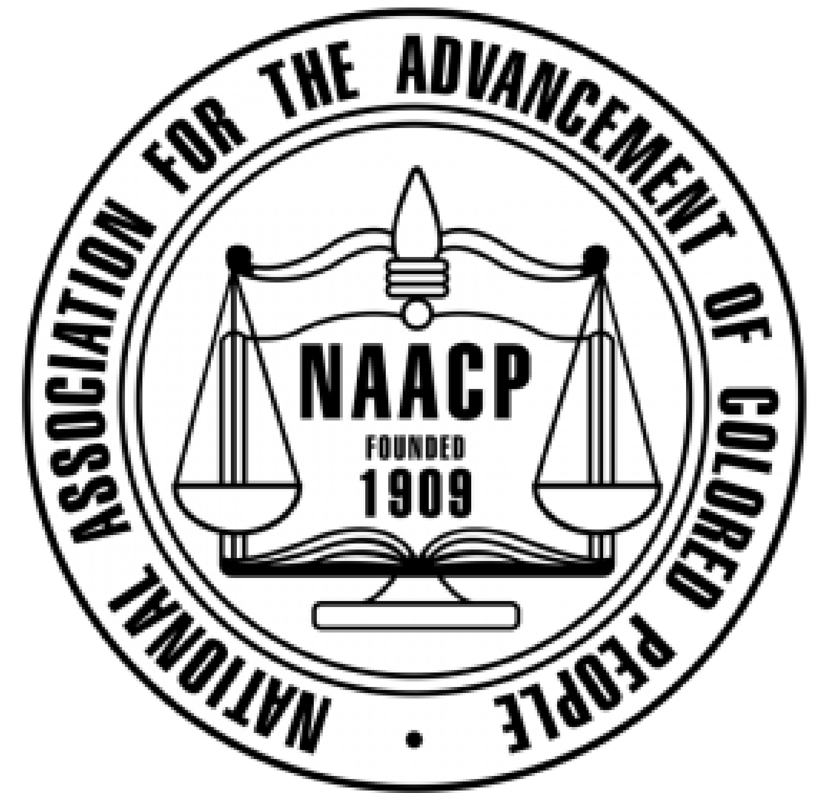


Obesity + income or educational level + sex/gender + race/ethnicity = a complexity of concerns

- Diseases associated with obesity, such as heart disease, stroke, type 2 diabetes and certain types of cancer, are the leading causes preventable death in the U.S.

- *"Our most challenging hurdle is access to affordable, quality, comprehensive obesity care."*
  Kristal Hartman, OAC Board Chair

➢ 2023 Obesity Action Coalition



Multi-Billion Dollar Question

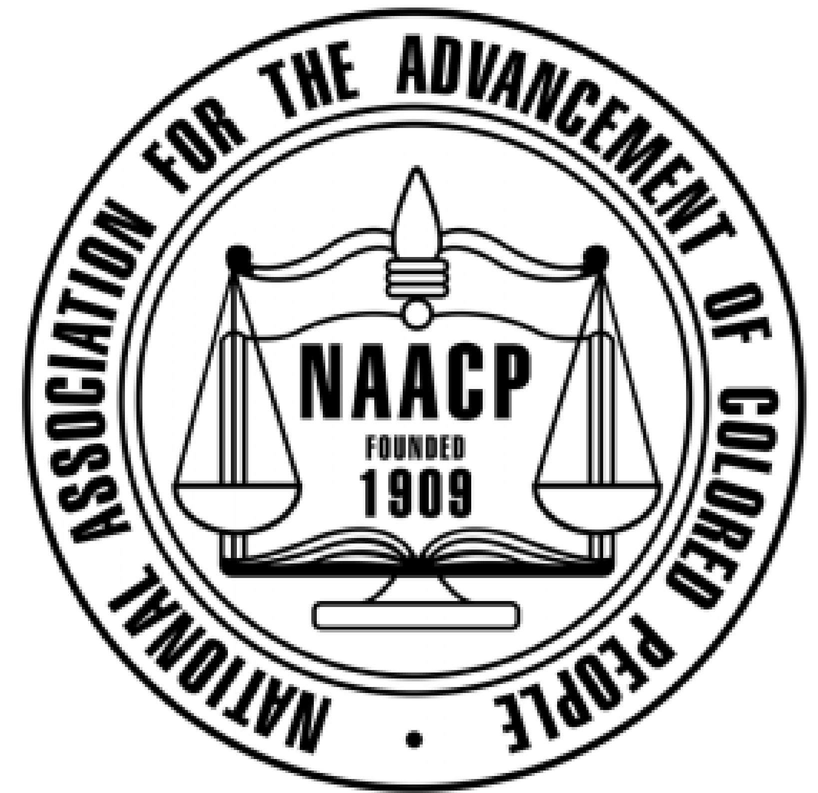
- Does Medicare include FDA-approved anti-obesity medications (AOMS) in Medicare Part D coverage?

- Obesity = over $170 billion in excess medical costs per year |highest costs for adults 60-70

➢ National Health and Nutrition Examination Survey (NHANES, 2021)

➢ CDC National Center for Health Statistics

➢ Health Equity Coalition for Chronic Disease/HECCD



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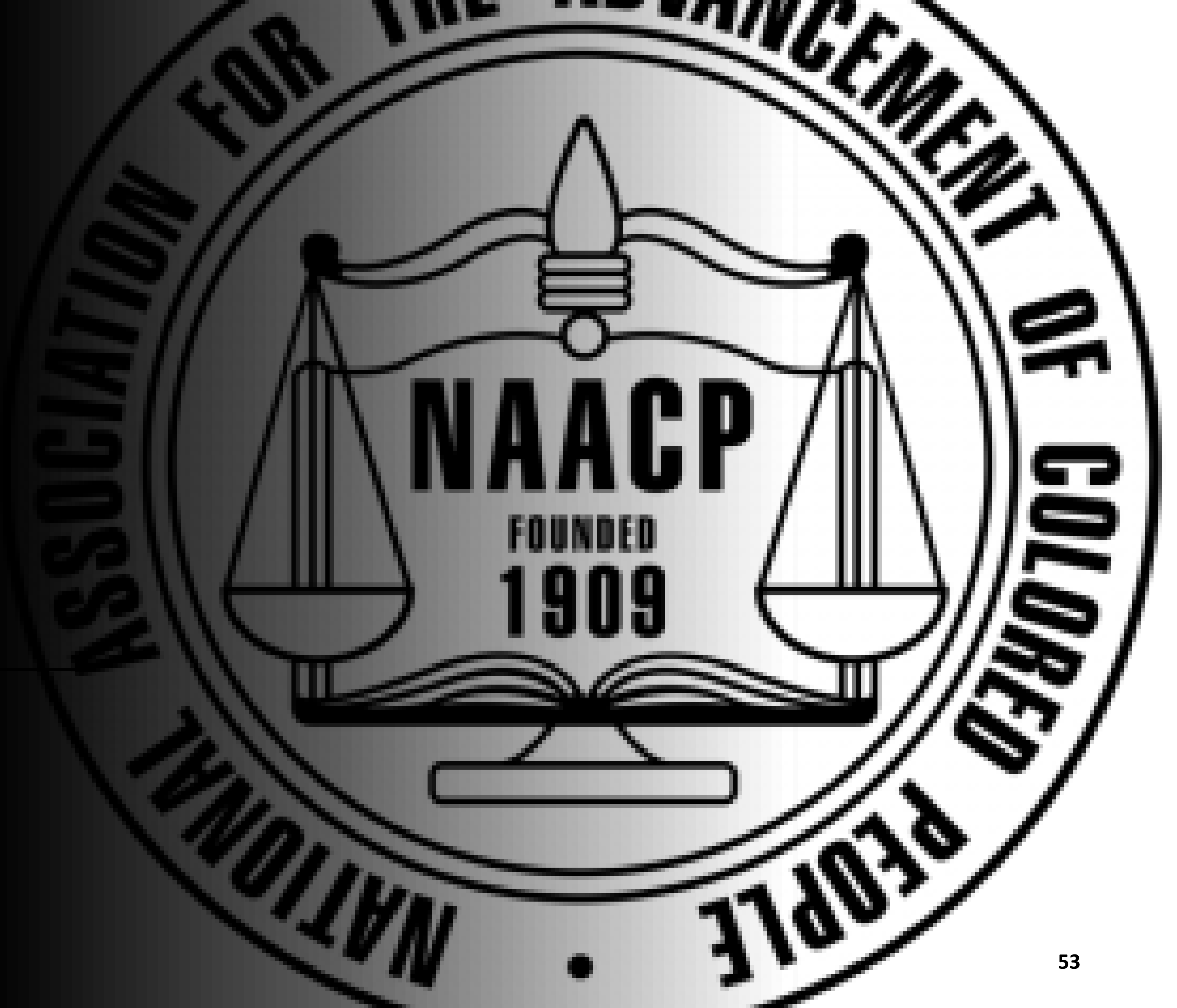
Keep the
Conversation
Going…



Presenter:

- Mihir Patel, PharmD, chief pharmacy officer, Regence Blue Cross Blue Shield of Oregon.

Regence

Regence GLP-1 Agonist Experience

Mihir Patel, PharmD, RPh
Chief Pharmacy Officer

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GLP-1 Landscape

INGREDIENT	BRAND NAME	FDA APPROVED INDICATION	FDA APPROVAL DATE	WEIGHT LOSS	A1C REDUCTION	ANNUAL COST (WAC)
dulaglutide	Trulicity	1) Diabetes, 2) Reduce CV risk	12/2014	~ 5%	0.8%	$12,090
exenatide	Byetta	Diabetes	04/2005	~ 5%	1%	$10,725
	Bydureon	Diabetes	01/2012	<5%	1.5%	$10,439
liraglutide	Victoza	Diabetes	01/2010	~ 4%	0.8-1.1%	$14,508
	Saxenda	Weight management	12/2014	~ 5-7%	0.8-1%	$17,537
semaglutide	Ozempic	1) Diabetes, 2) Reduce CV risk	12/2017	~ 5-10%	1.4-1.6%	$12,155
	Rybelsus	Diabetes	01/2023	~ 2%	1.2-1.4%	$11,220
	Wegovy	1) Weight management, 2) Reduce CV risk (pending)	12/2022	~ 15%	1.6%	$17,537
tirzepatide	Mounjaro	Diabetes	05/2022	~ 21%	2-2.5%	$13,299
	Zepbound	Weight management	11/2023	~ 21%	2-2.5%	$13,767

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Regence health plans are Independent Licensees of the Blue Cross and Blue Shield Association serving members in Idaho, Oregon, Utah and select counties of Washington

Regence Current State

- GLP-1 drugs for diabetes are subject to preauthorization consistent with our benefit plans.
- GLP-1 drugs for weight management are benefit excluded for most plans.
- Self-funded groups have the option to cover or adopt the benefit exclusion for weight management medications based on their own business needs.
- Side effects associated with GLP-1 drugs may limit long term efficacy. In one study, only 27% of patients remained adherent on therapy after one year[1].
- We continue to assess for sustainable opportunities for coverage in the weight management space. To date, the differential pricing of these agents specifically for obesity remain the primary barrier to coverage.
- As stewards of our clients’ finances, we recognize the need to address cost trends.

1. https://www.primetherapeutics.com/wp-content/uploads/2023/07/GLP-1a-obesity-treatment-1st-year-cost-effectiveness-study-abstract-FINAL-7-11.pdf

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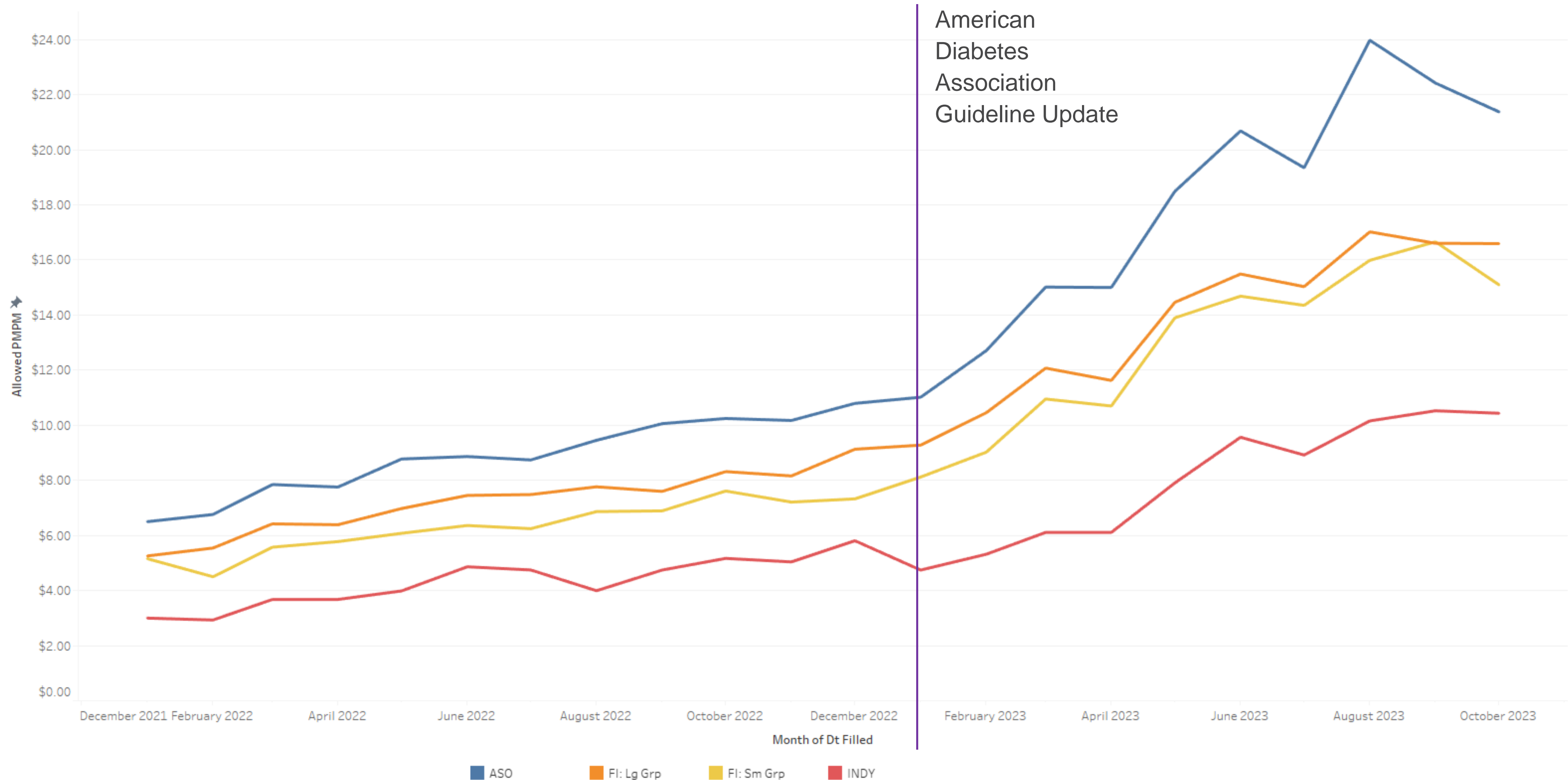
Regence Oregon Utilization Trend



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Value and Affordability

- Institute for Clinical and Economic Review (ICER) released an analysis in October 2022 on obesity medications.
- Concluded GLP-1 agonists should be discounted 45%+ to be considered cost-effective based on health-benefit price benchmarking.
- Current pricing stifles coverage opportunities and impacts accessibility.

	Annual Price (WAC)	ICER Threshold
Wegovy	$17,537	$7,500 to $9,800
Saxenda	$17,537	$3,800 to $4,800
Zepbound	$13,767	Not Evaluated

Atlas SJ, Kim K, Beinfeld M, et al. Medications for Obesity Management: Effectiveness and Value; Final Evidence Report. Institute for Clinical and Economic Review, October 20, 2022. https://icer.org/assessment/obesity-management-2022/

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Presenter:

- Charlie Fisher, OSPIRG state director.

Questions for presenters?

- David Rind, MD, chief medical officer, Institute for Clinical and Economic Review.
- Irvin M. Brown, Ed.D., vice president Salem-Keizer NAACP, political action chair NAACP Alaska, Oregon, Washington.
- Mihir Patel, PharmD, chief pharmacy officer, Regence Blue Cross Blue Shield of Oregon.
- Charlie Fisher, OSPIRG state director.

Second panel – What determines the cost of a generic and why are many so expensive?

Presenters:

- Michael Sargent, MPA, senior director, policy, Association for Accessible Medicines.
- Dharia McGrew (she/her), Ph.D.; director, state policy, PhRMA.
- Tonia Sorrell-Neal (she/her), senior director state affairs for Oregon, Taft-Hartley plan employer trustee, Pharmaceutical Care Management Association.
- Kevin Russell, RPh, MBA, BCACP, director, Prescryptive Pharmacy, Redmond, Oregon.

Presenter:

- Michael Sargent, MPA, senior director, policy, Association for Accessible Medicines.

Oregon Division of Financial Regulation

Prescription Drug Prices

December 7, 2023

Topline Findings

Total Savings from Generics and Biosimilars

- Total generic and biosimilar savings in 2022: $408 billion
- Total generic and biosimilar savings for the past ten years: $2.9 trillion
- Total generic and biosimilar savings in Medicare in 2022: $130 billion ($2,563 per beneficiary)
- Total generic and biosimilar savings in the commercial market in 2022: $194 billion
- Share of total U.S. prescriptions filled: 90 percent
- Share of total U.S. prescription drug spending: 17.5 percent
- Share of total U.S. health care spending: 1.5 percent

Generic Savings

- Average generic copay: $6.16
- Average brand-name copay: $56.12
- 92 percent of generics have a copay less than $20; 53 percent of brands have a copay less than $20

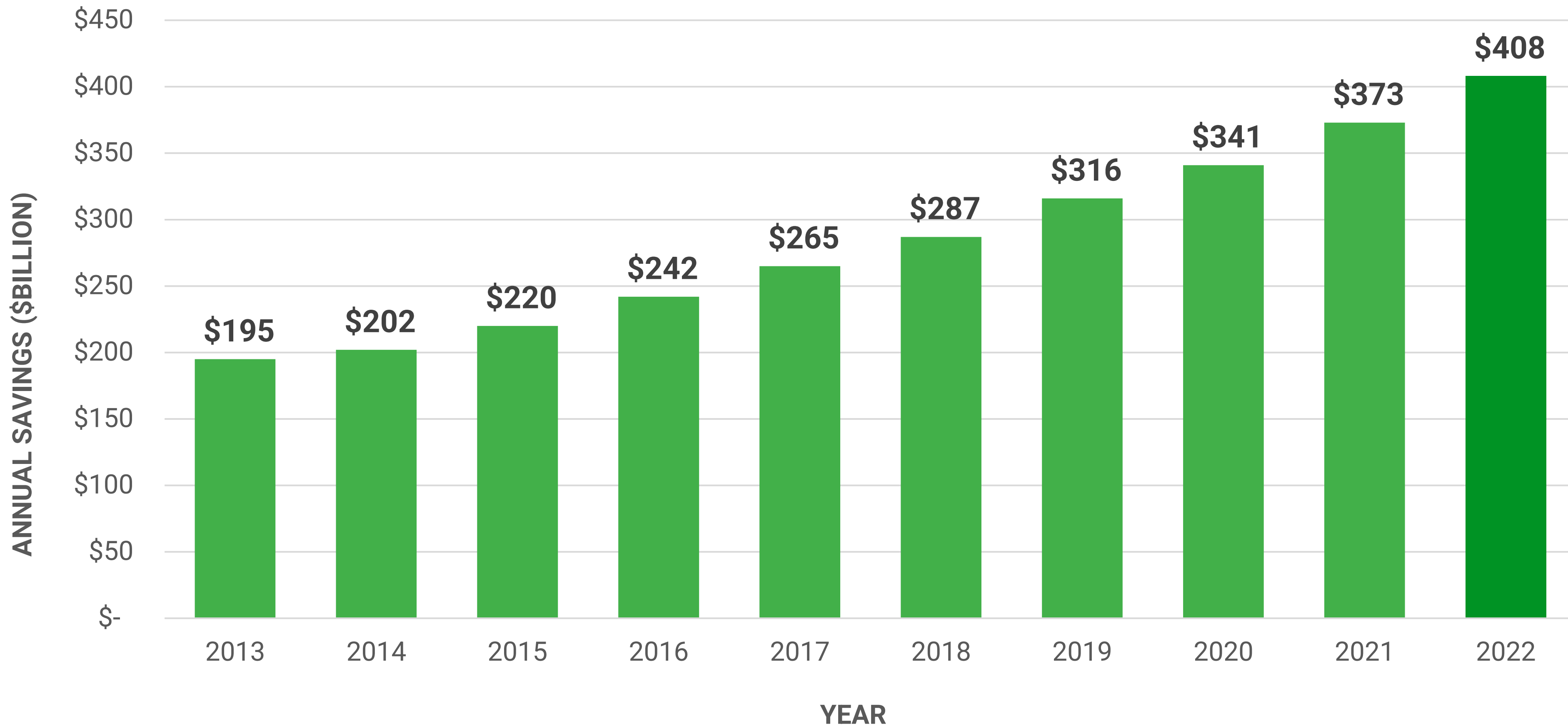
Biosimilar Savings

- Savings in 2022: $9.4 billion
- Total savings since first biosimilar entry in 2015: $23.6 billion
- Total days of patient therapy since 2015: 694 million
- Incremental days of patient therapy that would not have occurred without biosimilar competition: 344 million

Source: IQVIA National Sales Perspective, December 2022.

aam
Association for Accessible Medicines

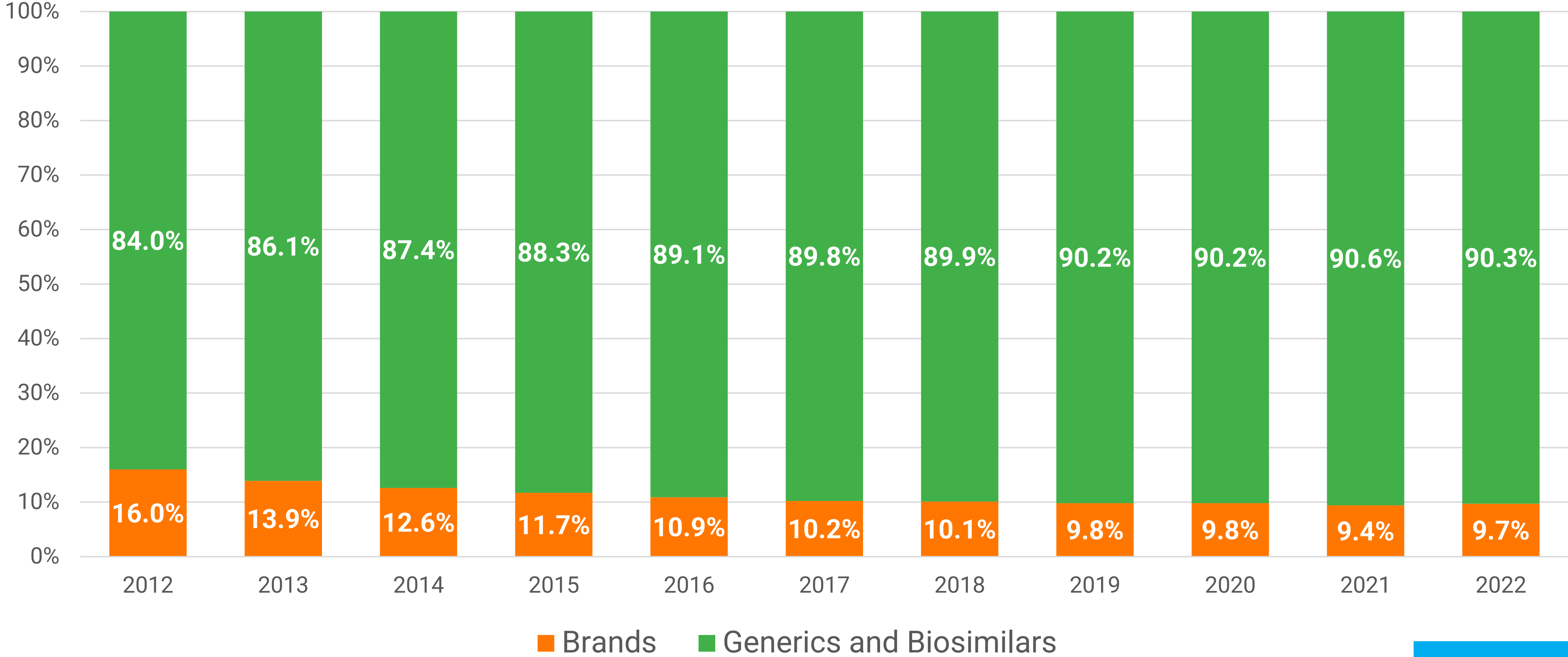
Annual Savings From Generic and Biosimilar Medicines



Source: IQVIA National Sales Perspective, December 2022.

aam Association for Accessible Medicines

Generics and Biosimilars Are More Than 90% of Prescriptions but Less Than 18% of Spending



Source: IQVIA National Sales Perspective, June 2022.

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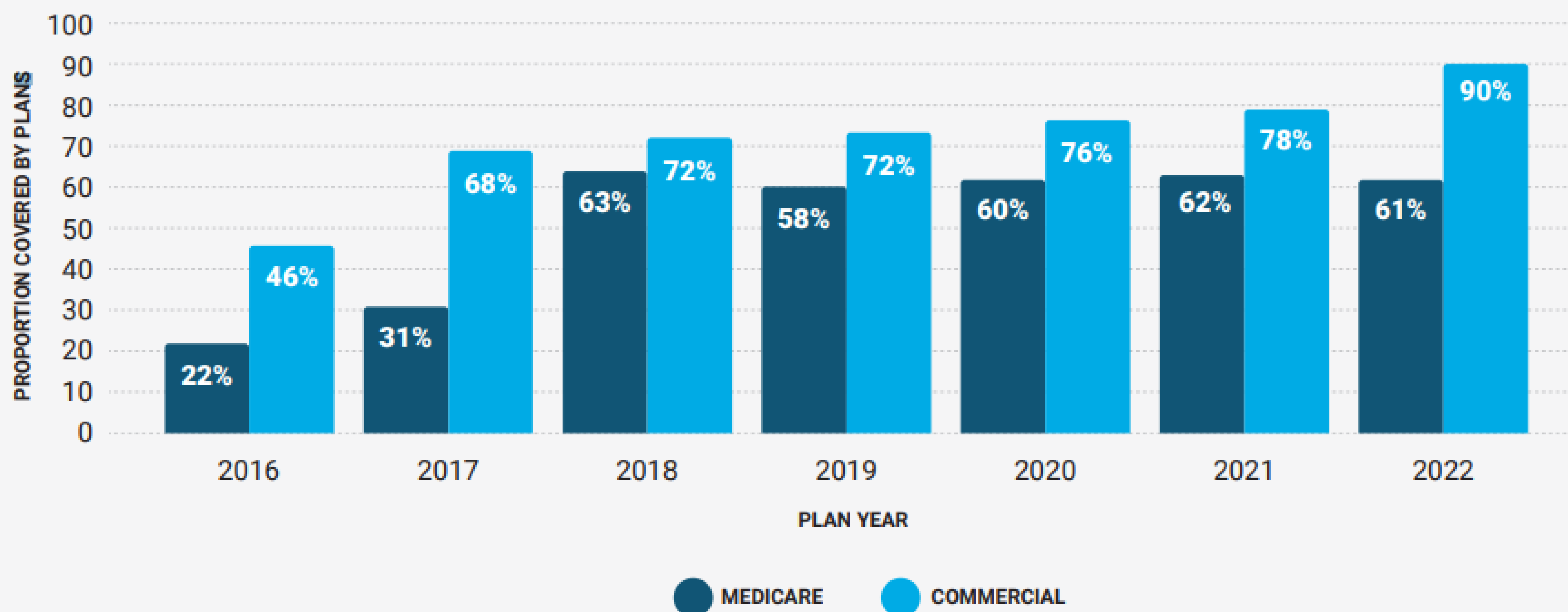
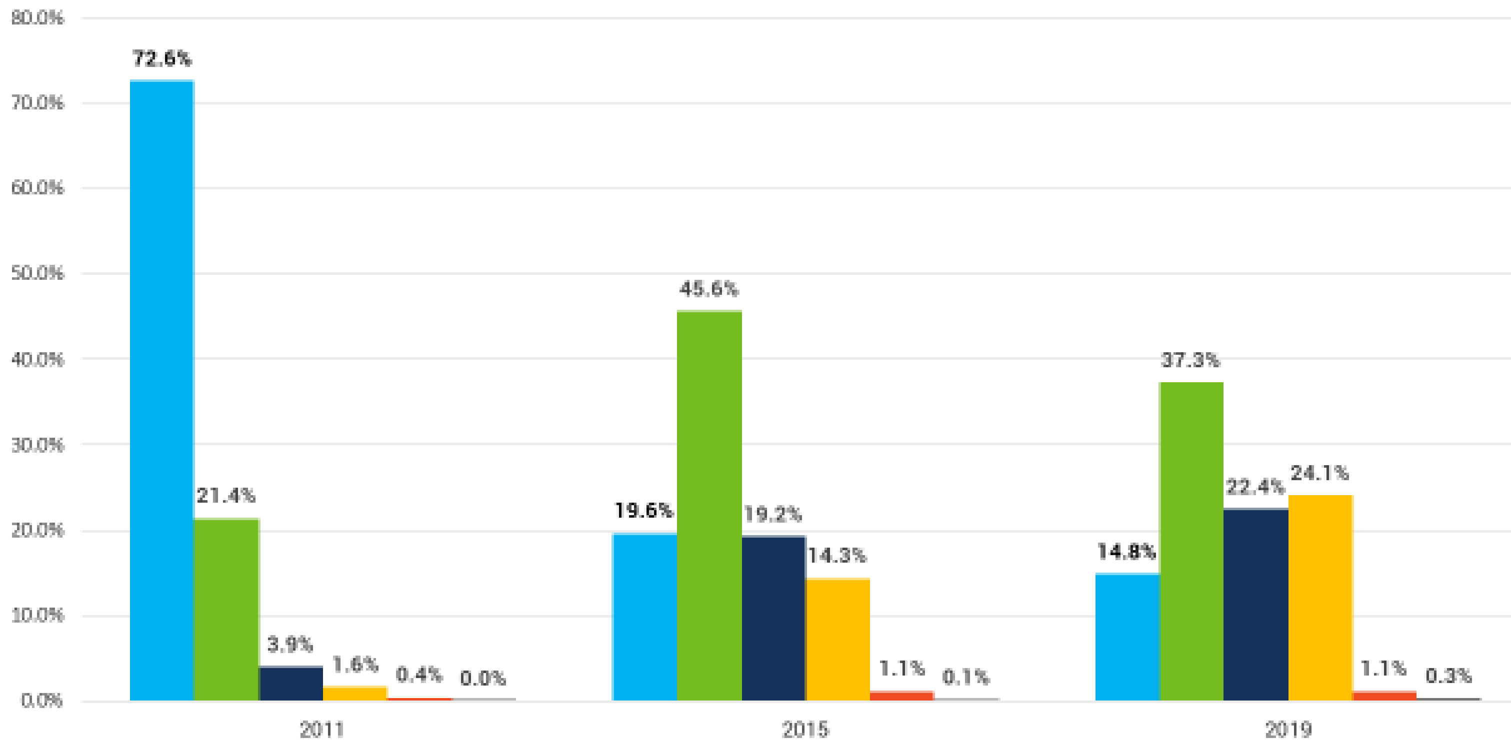


Source: IQVIA. (December 2022). National Sales Perspective

Although generic drug prices fell, PBMs and plans increased patient cost sharing requirements for them.



PATIENT SPENDING FOR GENERICS IN MEDICARE 2011 VS 2019

135% Increased Patient Out-of-Pocket Costs

21% Increase in Volume

-38% Average change in generic drug prices

Presenter:

- Dharia McGrew, Ph.D.; director, state policy, PhRMA.

PhRMA
RESEARCH • PROGRESS • HOPE

Oregon Annual Hearing on Prescription Drug Prices

December 7, 2023

Dharia McGrew, PhD
Director, State Policy

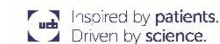
Who is PhRMA?

Representing the country's leading innovative biopharmaceutical research companies

Since 2000, PhRMA member companies have invested

+$1.1 trillion

in the search for new treatments and cures



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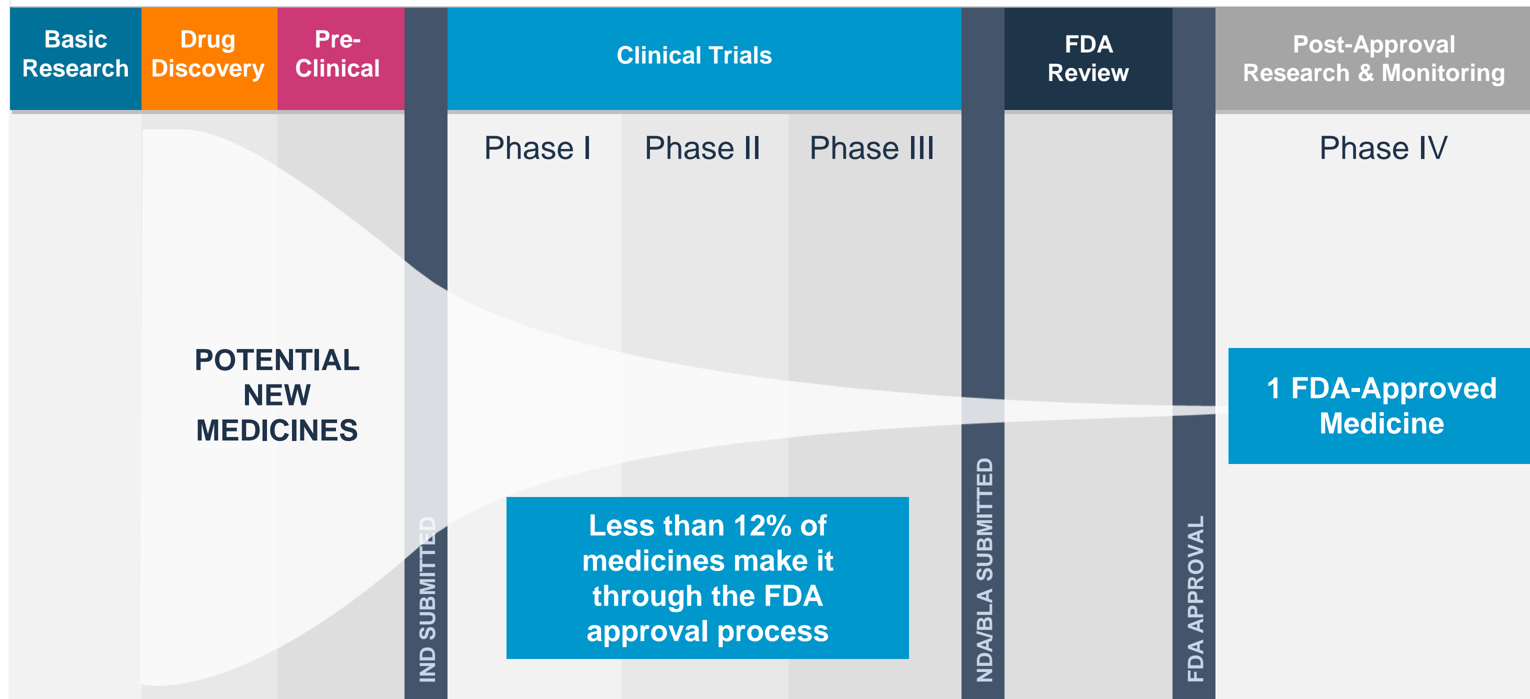
The Biopharmaceutical Research and Development Process Continues to be Lengthy, Costly, and Uncertain

From drug discovery through FDA approval, developing a new medicine takes 10 to 15 years and costs an average of $2.6 billion, more than double the cost just a decade ago.[1]



Key: IND= Investigational New Drug Application, NDA= New Drug Application, BLA= Biologics License Application

The typical science-based business startup is not unlike a long-range multistage rocket mission: Each stage must fire perfectly for the next step of the mission to begin. If any stage fails to execute, the entire mission fails. Even investors with a high tolerance for risk are deterred by the uncertainty of the risk.

MIT PROFESSOR ANDREW W. LO and **HARVARD PROFESSOR GARY P. PISANO**[2]

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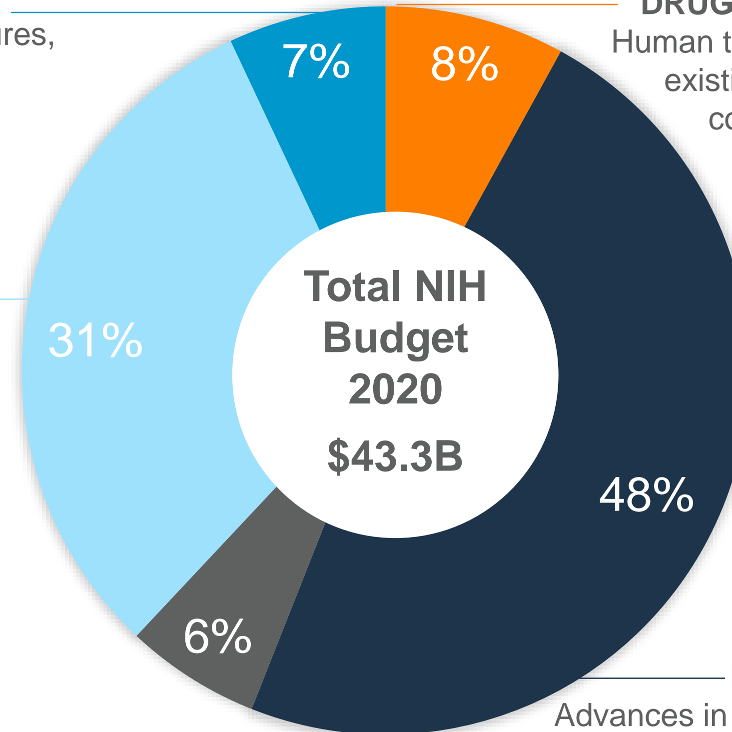
Sources: PhRMA adaptation of DiMasi J. et al[1], Lo A. et al[2]

Biopharmaceutical Industry Does the Majority of Research to Advance Basic Science Into New Medicines

The biopharma industry invested **$122 billion** in R&D in 2020, **100%** of which was focused on drug development.

The **entire** NIH budget in FY 2020 was **$43.3 billion,** only **8%** of which was focused directly on research related to drug development.

The NIH Does Research in a Variety of Important Areas Complementary to Drug Development



OTHER CLINICAL TRIALS: For example, devices, procedures, other interventions

DRUG CLINICAL TRIALS: Human trials involving new or existing drugs, alone or in combination with other interventions

RESEARCH SUPPORT AND OTHER APPLIED RESEARCH: Wide ranging - from efforts to optimize cell line techniques to clinical research other than clinical trials, such as health

BASIC RESEARCH: Advances in the understanding of fundamental mechanisms affecting human health and disease

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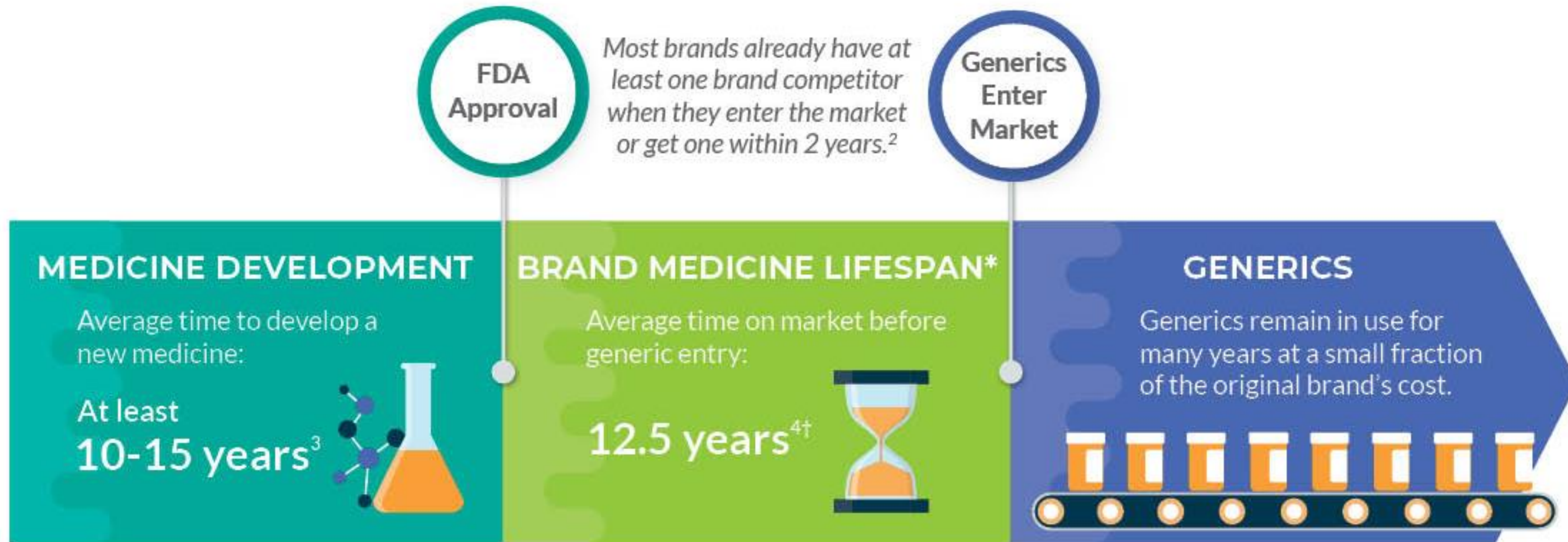
Illustrative Pharmaceutical Lifecycle

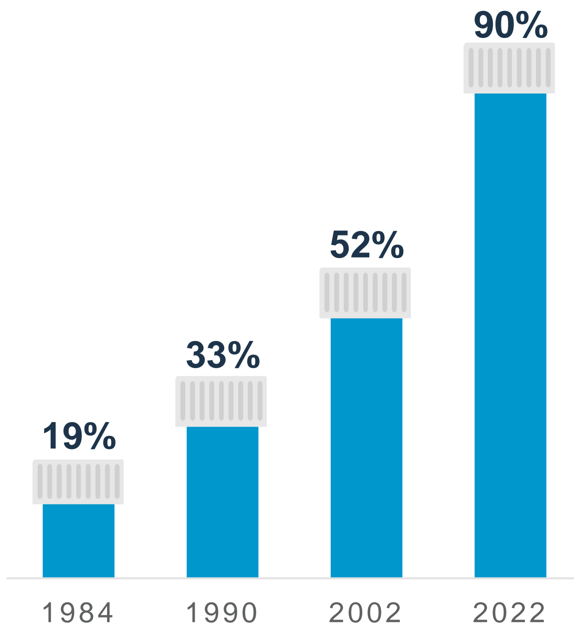
New pharmaceutical medicines typically face competition after a relatively short time on the market, first from brand competitors, and eventually from generics.



Sources: PhRMA[1]; DiMasi JA et al[2,3]; Grabowski H et al[4]

Generic and biosimilar medicines drive significant savings in the health care system.

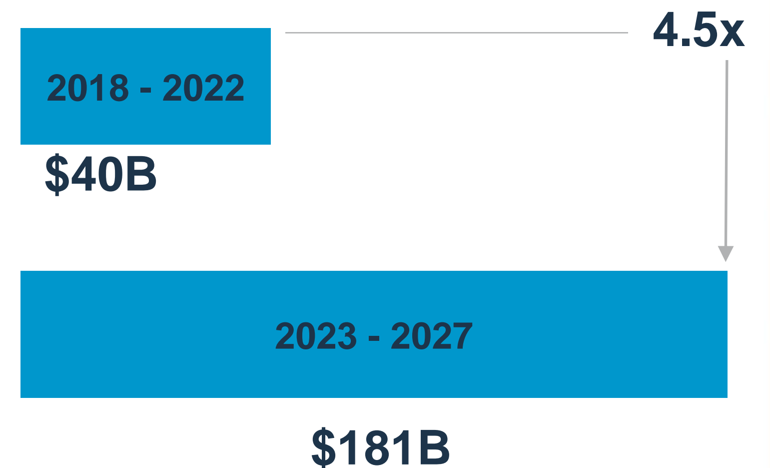
91% of All Drugs Dispensed in the United States are Generics



Nearly $2.6 trillion

10-year savings from use of generic and **biosimilars** (2013 - 2022)

Looking Ahead, Biosimilar Savings Projected to Grow More than 4x



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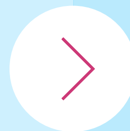
Sources: Drug Channels, AAM, IQVIA.

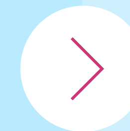
Current System Can Lead Middlemen to Favor Medicines with High List Prices and Large Rebates

While follow-on, authorized generic and biosimilar insulins drive competition across the market, misaligned incentives mean PBMs may block patient access to these lower list-priced products in favor of products with large rebates.

Follow-on insulins launched in 2016 and 2018 have been found to capture just 2-17% of the market share in Medicare by 2019.



In 2022, two of the three largest PBMs excluded insulin authorized generics from nation commercial formularies



None of the nation's 3 largest PBMs included the low-list priced interchangeable biosimilar insulin on 2022 and 2023 national commercial formularies.

* Following the transition date, authorized generics are regarded as unbranded biologics.

SOURCES: MedPAC Report to Congress, March 2022; Fein, A. "A World Without Rebates: Predictions for How the Channel Will Evolve and Why Drug Prices Will Go Down," March 20, 2019; Xcenda. "Skyrocketing growth in PBM formulary exclusions continues to raise concerns about patient access." May 24, 2022; Drug Channels, Five Takeaways from the Big Three PBMs' 2022 Formulary Exclusions January 2022. Drug Channels. The Big Three PBMs' 2023 Formulary Exclusions: Observations on Insulin, Humira, and Biosimilars, January 2023.

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

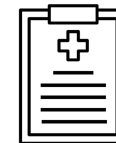
MAT makes it easier for those struggling to afford their medicines to find and learn more about various programs that can make prescription medicines more affordable.

The Medicine Assistance Tool Includes:

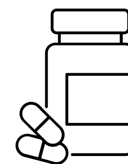
A search engine to connect patients with

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

MAT.org

PhRMA
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Presenter:

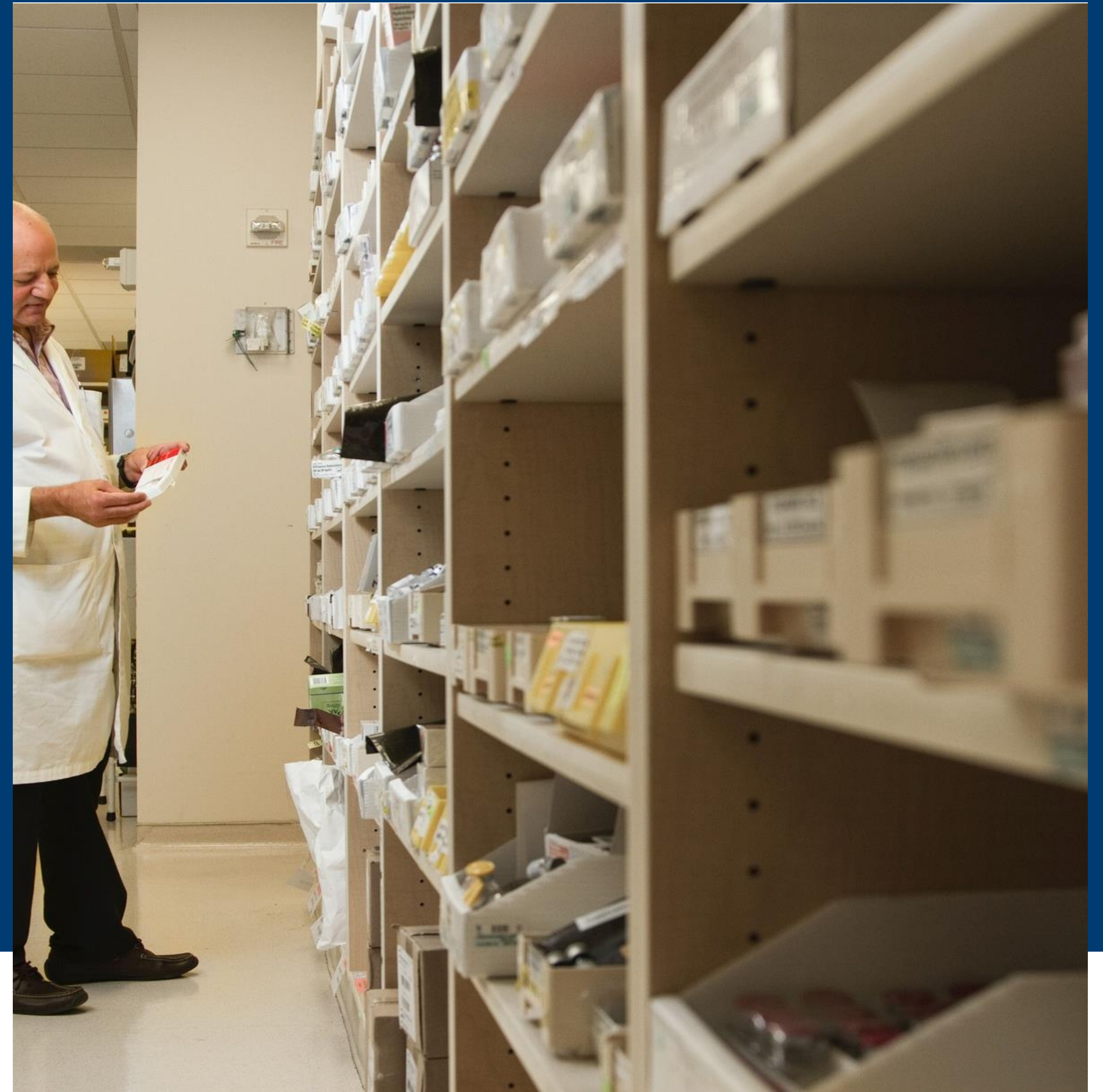
- Tonia Sorrell-Neal, senior director state affairs for Oregon, Taft-Hartley plan employer trustee, Pharmaceutical Care Management Association.

Determinants of Generic Drug Prices

This presentation will examine factors that influence the prices of generic drugs.

Tonia Sorrell-Neal
PCMA Sr. Director of State Affairs

Generic drugs provide significant cost savings compared to brand-name drugs. However, some generic drugs still have high costs due to lack of competition after initial exclusivity periods. Looking at the entire supply chain helps to understand the underlying factors driving costs for certain generic drugs.



The drug supply chain

- **Drug manufacturers**

  Research, develop, and produce brand name and generic drugs

- **Wholesalers & PSAOs**

  Purchase drugs from manufacturers and distribute them to pharmacies and hospitals.

- **Pharmacies**

  Dispense prescription drugs to patients

- **Insurers**

  Provide prescription drug coverage to beneficiaries and reimburse pharmacies

- **Pharmacy benefit managers (PBMs)**

  Negotiate prices and reimbursement rates for drugs on behalf of health plans

- **Hospitals**

  Purchase and administer drugs to inpatients

Why Hire A PBM?

*Pharmacy benefit companies are working every day to **secure savings**, **enable better health outcomes**, and **support access to quality prescription drug coverage** for patients, families, employers, and taxpayers*

PBMs negotiate rebates for some brand and generic drugs

PBMs enable patient access

PBMs play a unique and central role in **driving adherence, holding down costs,** and **increasing quality**

PBMs drive better health outcomes

PBM tools **deliver savings** for plan sponsors and patients

PBMs deliver savings

Who influences drug pricing?

Drug Manufacturers

Lack of Competition

Not enough generic competitors entering the market allows manufacturers to keep prices high.

Pay-for-Delay Agreements

Brand name manufacturers pay generics to delay entering the market and keep prices high.

Patent Thickets

Manufacturers get multiple patents to prevent generics and biosimilars from entering.

PBM

Formulary Placement

Formulary placement encourages cost-effective prescribing practices, promoting the use of generic drugs over more expensive brand-name alternatives.

Rebates

Rebates incentivize the use of generic drugs over brand-name drugs, leading to increased competition and lower prices.

What Tools Do PBMs Use to Keep Costs Down?

FORMULARY

- List of prescription drugs approved for usage by a plan sponsor.
- Plan sponsors customize the drug list to meet their plan-specific needs.
- Tier structures create preferred groups of drugs and incent lower cost choices.
- Formularies can change when new drugs are approved, changed, or recalled by the FDA.

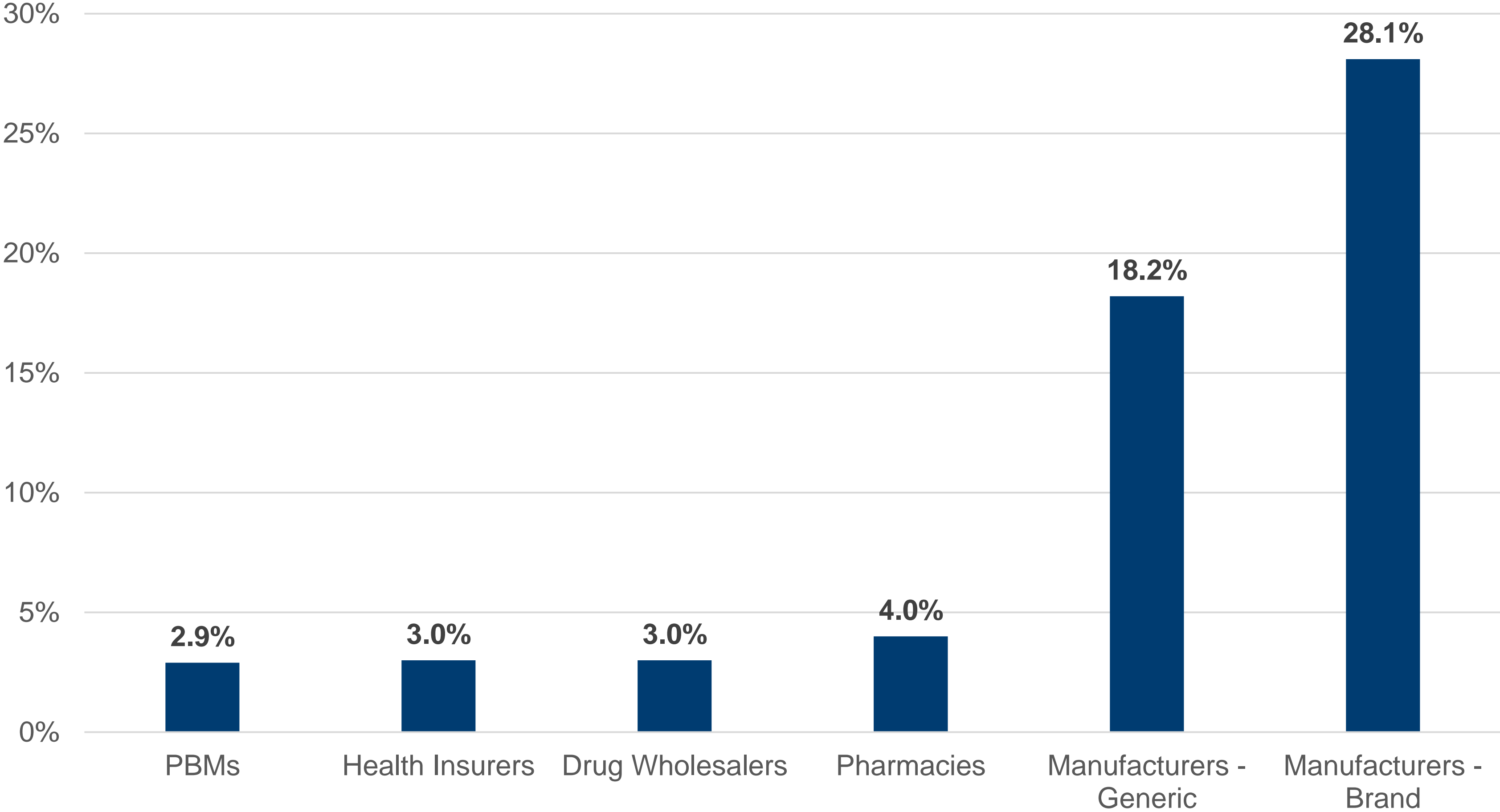
REBATES

- Drug manufacturers compete against each other for formulary coverage by negotiating rebates with PBMs.
- Rebates get passed through to health plans who can use savings to lower premiums and other patient costs.
- Negotiating rebates or discounts on prescription drugs with drug companies lowers patient prescription drug costs by nearly $1,000 each year.

UTILIZATION MANAGEMENT

- Utilization management not only helps reduce medication errors and improve patient safety, it encourages use of lower-cost, clinically effective drugs.
- PBMs are working to leverage technology to improve patient experience, including through electronic prior authorization and real-time benefits tools.

Pharmaceutical Supply Chain Profit Margins



Source: *The Flow of Money Through the Pharmaceutical Distribution System.* Schaeffer Center for Health Policy & Economics, University of Southern California. June 2017.

PCMA

The Importance of Competition

- Pharmacy benefit companies support competition in the prescription drug marketplace, which is the best way to lower prescription drug costs for patients and families
- Enabling a robust private prescription drug marketplace that promotes competition is the best way to drive down prescription drug costs and make more affordable alternatives available for patients

88

Who controls drug pricing?

Daraprim Price Hike

Turing Pharmaceuticals raised the price of the parasite and malaria drug Daraprim from $13.50 to $750 per tablet **overnight** in 2015. This dramatic price hike sparked outrage and prompted questions about generic drug pricing.

Turing's overnight 5,000% price increase of the generic Daraprim drew outrage and exemplifies extreme generic drug price inflation.

What can states do to help generic drug pricing?

- Examine PSAO and Wholesale pricing models
- Ensure pharmacists can substitute biosimilars and brand name products for cost effective alternatives
- Preserve formulary design
- Preserve PBM tools to negotiate pricing
- Focus on actionable transparency for the entire drug supply chain
- Encourage the FDA to update patent practices to promote faster competition

Questions.

Presenter:

- Kevin Russell, RPh, MBA, BCACP, director, Prescryptive Pharmacy, Redmond, Oregon.

A Community Pharmacy Perspective of Generic Drug Pricing

Kevin Russell R.Ph, MBA, BCACP
Director of Pharmacy, Prescryptive Pharmacy in Redmond, OR
Kevinr@prescryptive.com

Good news! Generics are still affordable.

Example Prescryptive Pharmacy November 2023:

- 81% of generic prescriptions sold for < $30 (patient + insurer)
- 98% of generic prescriptions sold for < $100 (patient + insurer)
- 93% of patients paid <$30

- Of 2% generics > $100, 29% of generics were new to market and 71% were long established generics with recent price hikes likely due to decreased competition (shortages or competitors left the market).

What happens when a PBM mandates a brand name drug?

The tale of two PBMs:

	Drug	Pharmacy Cost	PBM+Copay	Patient Copay	Pharmacy Loss
PBM 1	Advair 250/50	$378.57	$310.58	$10	$67.99
PBM 2	Advair 250/50	$378.57	$360.68	$104.41	$17.89

The pharmacy loss in the PBM 1 example was due to something called brand effective rate where the PBM can pay one pharmacy at a loss and make it up by paying another pharmacy in the network more. This cannot be tracked or audited and is an example of an unconscionable PBM contract.

In the PBM 2 example $104.41 is approximately equal to the full price of the generic. This patient has either a 25% or $0 copay for all her other generic drugs. She should have paid less than $30 for this prescription.

Specialty generics and biosimilars

Almost all specialty drugs and high-priced generics are required to be filled at a PBM affiliated specialty pharmacy. But at what cost for patients and payors?

The report referenced below found that in 2021 the generic drug dimethyl fumarate cost approximately $350 and PBM affiliated pharmacies billed Oregon Medicaid an average of $2,928.

This is still going on today in the commercial space. I just sold a prescription of dimethyl fumarate to a patient for $94 cash. She said that her copay through her insurance (PBM) specialty pharmacy was about $300, and she is supposed to have a 20% copay!

Let's get these prescriptions back in community pharmacies where there is accountability and caring pharmacists!

Understanding Pharmacy Reimbursement Trends in Oregon can be accessed at Oregon State Pharmacy Association (oregonpharmacy.org

How can Oregon help?

1) Pass PBM reform
2) Require negotiated savings be passed on to patients
3) Support national efforts to reduce drug shortages

Questions for presenters?

- Michael Sargent, MPA, senior director, policy, Association for Accessible Medicines.
- Dharia McGrew, Ph.D.; director, state policy, PhRMA.
- Tonia Sorrell-Neal, senior director state affairs for Oregon, Taft-Hartley plan employer trustee, Pharmaceutical Care Management Association.
- Kevin Russell, RPh, MBA, BCACP, director, Prescryptive Pharmacy, Redmond, Oregon.

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.