Oregon Prescription Drug Prices Annual Public Hearing

10 a.m. to 12:30 p.m., Wednesday, Dec. 4, 2024

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

- 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. Emerson Levy (she/her)
- Rep. Rob Nosse (he/him)

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
- Lily Sobolik (she/her), senior policy advisor, DFR, DCBS

Drug Price Transparency Program

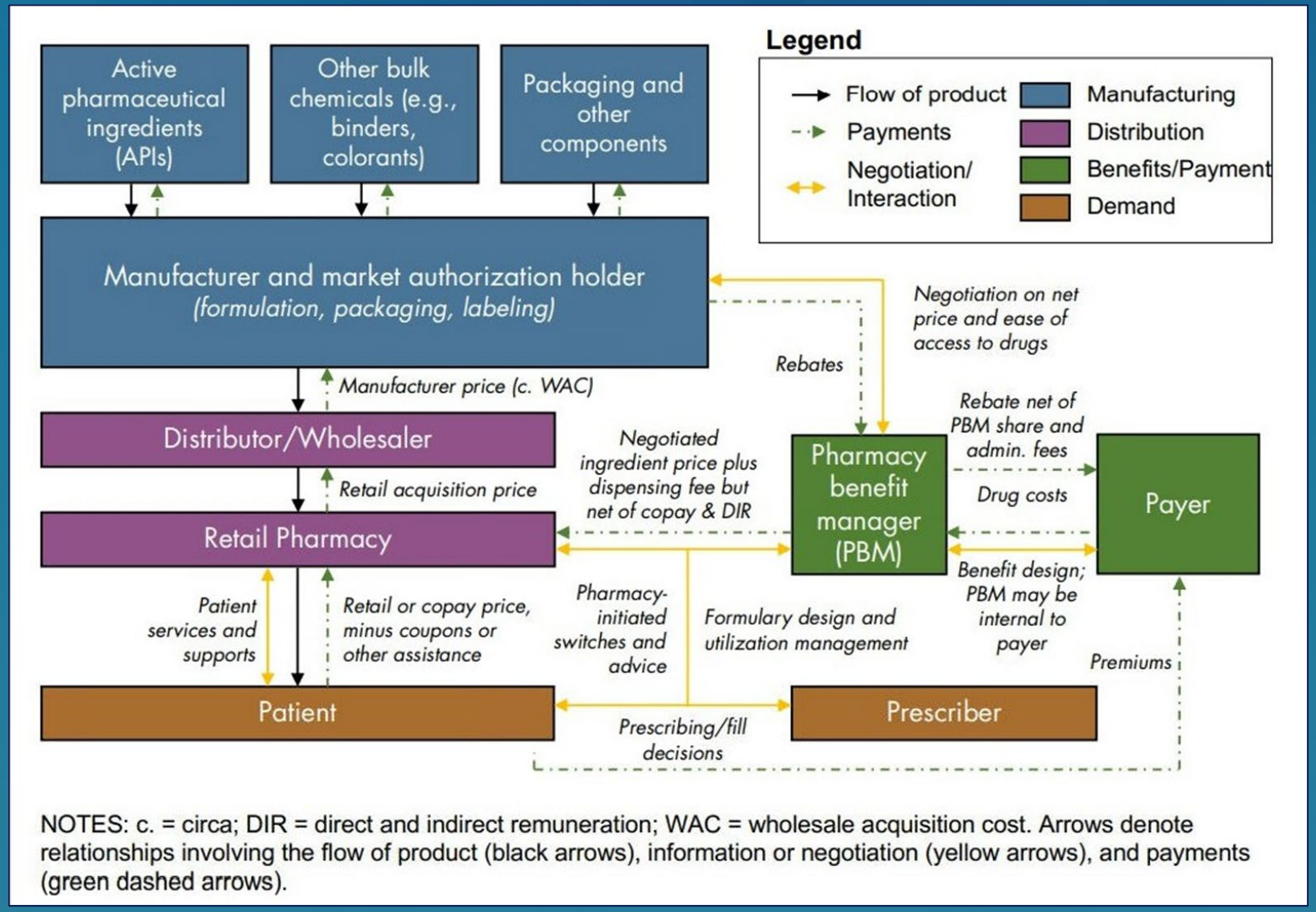
- Operates under ORS 646A.680 to 646A.692 and administrative rules OAR 836-200-0500 to 836-200-0560.

- 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 of 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).

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

Pharmaceutical supply chain diagram



NOTES: c. = circa; DIR = direct and indirect remuneration; WAC = wholesale acquisition cost. Arrows denote relationships involving the flow of product (black arrows), information or negotiation (yellow arrows), and payments (green dashed arrows).

Figure 2 on Page 13 of the 2024 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.
- The department issued its first civil penalties totaling $75,000 in 2024.

Manufacturer trade secret claims

- Research and analysis of trade secret claims for various data elements.
- Lengthy and complex process to review and address trade secret claims from manufacturers.
- Publish to our website information determined not to be trade secret.

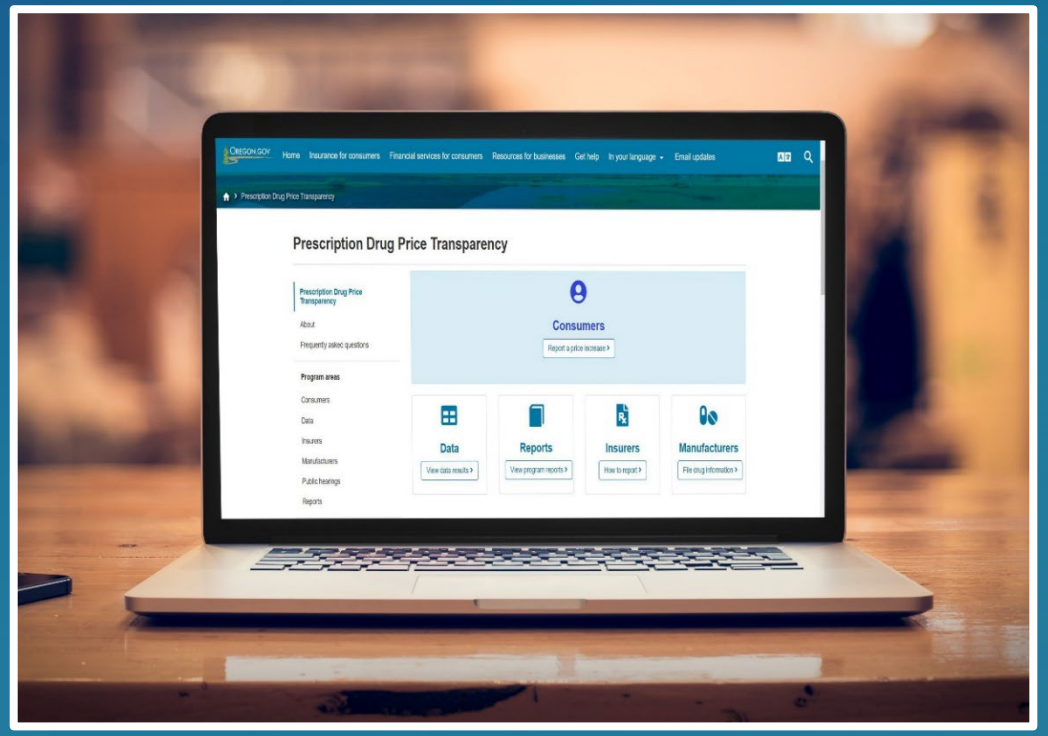
Consumers and transparency

Consumer reporting:

- Price increase reporting
- Stories and questions
- Outreach

Transparency website:

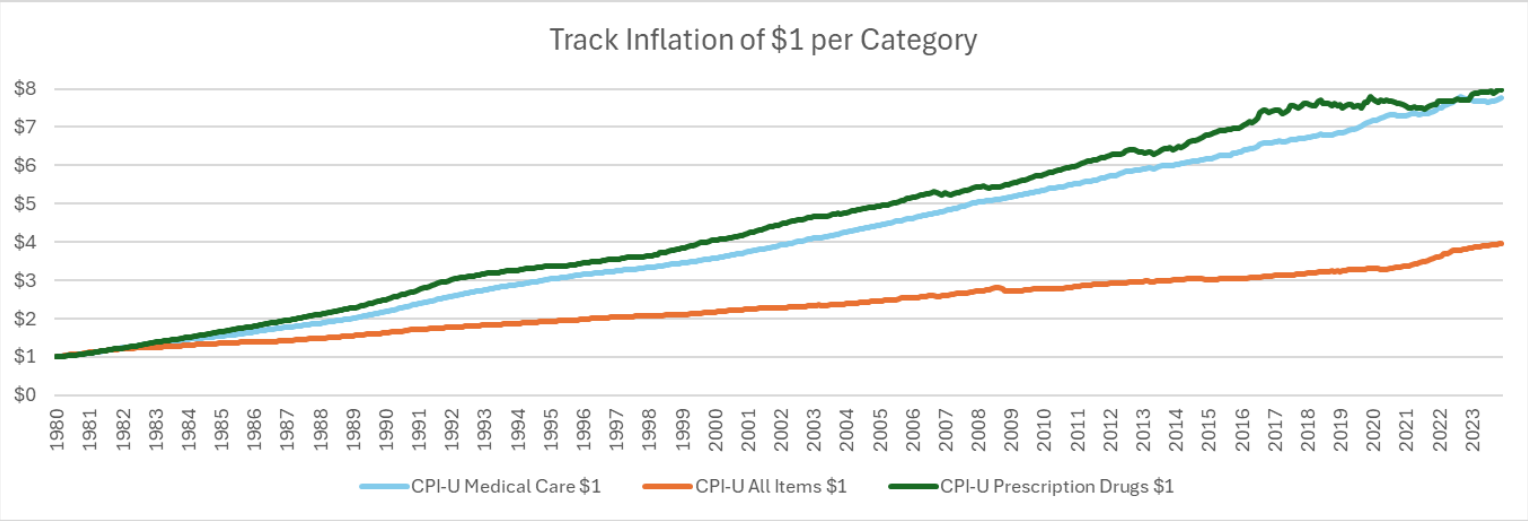
- Reported data from manufacturers (determined not to be trade secret)
- Information from insurers
- Consumer reports submitted

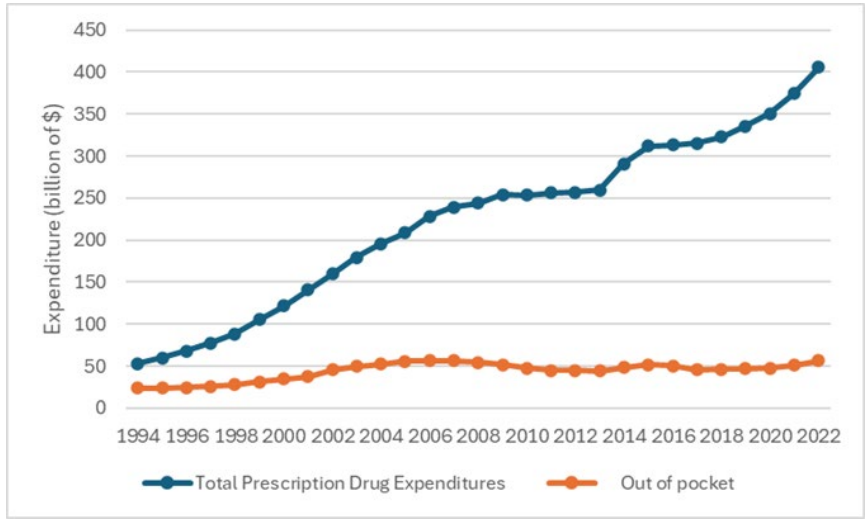


Highlights from 2024 data

- 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.
  - ✓ $2.2 million for Casgevy™, a treatment for sickle cell disease, manufactured by Vertex Pharmaceuticals Inc.
- PBMs reported collecting $287 million in payments from manufacturers and reported passing on 98.7 percent to insurers.
- Most health insurers reported receiving rebates ranging from 9.9 percent and 27.3 percent of their total pharmaceutical spending.
- Humira continues to be the most-costly drug. Even with a $22 million cost reduction, insurers reported payments of more than $53 million in 2023.

Inflation compared to prescription drug price increases through 2023





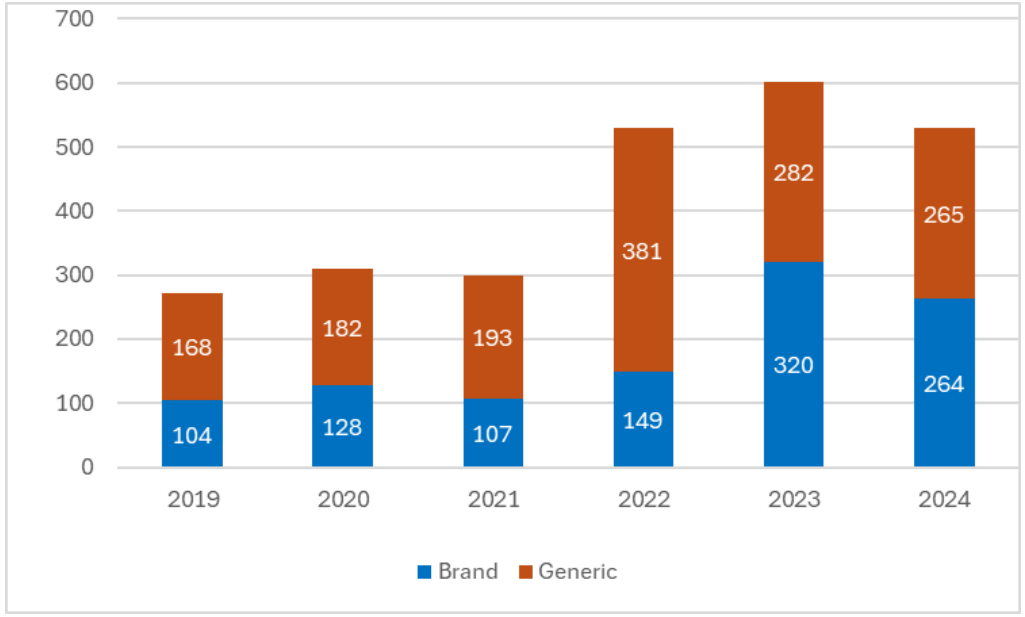
- Medical care prices increased 96.1 percent more than inflation (CPI-U all) since 1980
- Prescription drug prices increased 101 percent more than inflation

- For 2022, prescription drug expenditures grew by 8.4 percent, increasing at a rate double the rate increase for all other health care expenditures.
- Prescription drug expenditures have increased 665.6 percent from 1994 to 2022

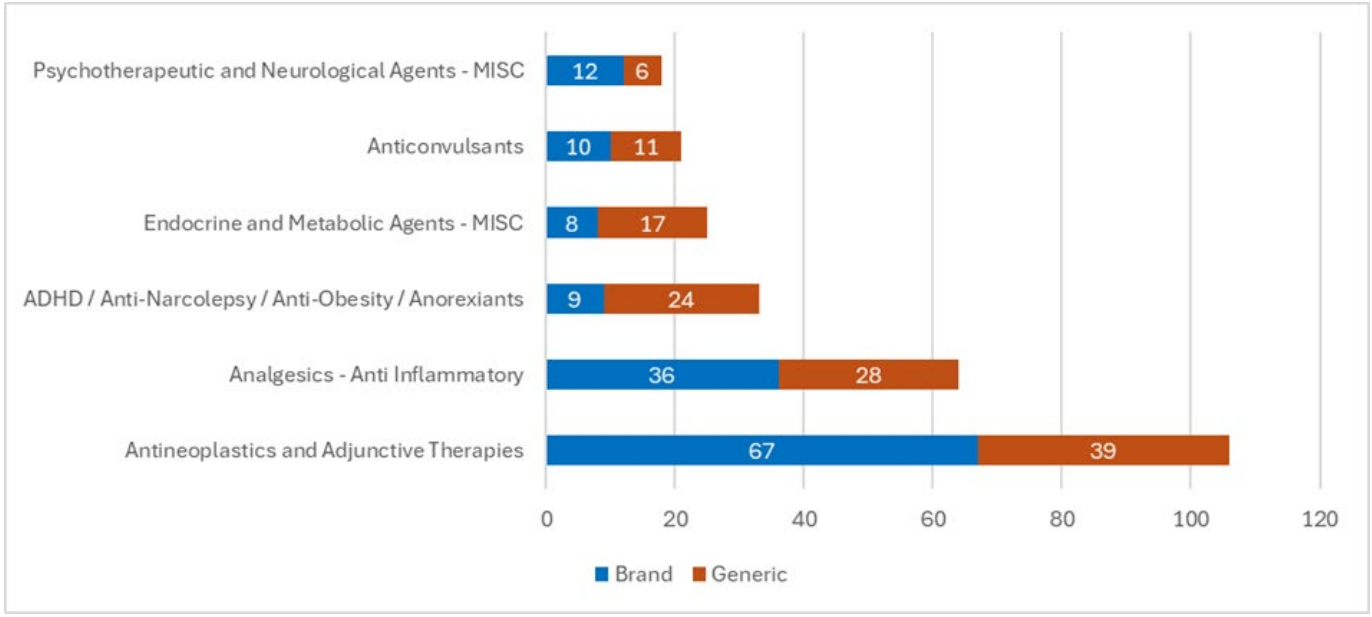
Figures 4 and 5 on Pages 15 and 16 of the 2024 DPT legislative report. Sources: “Consumer price index for all urban consumers: Medical care in U.S. city average.” Federal Reserve Bank of St. Louis Fred Economic Data. https://fred.stlouisfed.org/series/CPIMEDSL. “Consumer price index for all urban consumers: All items in U.S. city average.” Federal Reserve Bank of St. Louis Fred Economic Data. “https://fred.stlouisfed.org/series/CPIAUCSL. “BLS Data View.” U.S. Bureau of Labor Statistics. https://data.bls.gov/dataViewer/view/timeseries/CUSR0000SEMF01;jsessionid=95E7085FC504B86A4B4ED23DFB016957.

New prescription drug manufacturer reports 2019-24

Count of reports received



Drug Type of reports received



- September 2023 through August 2024, DPT received 529 new prescription drug reports
- 264 were for generics; 265 were for brand name prescription drug

Figures 6 and 7 on Pages 22 and 23 of the 2024 DPT legislative report.

- 20 percent were for antineoplastic and adjunctive therapies
- 12 percent were for analgesics – anti-inflammatory
- 6.2 percent were for ADHD/anti-narcolepsy/anti-obesity/anorexiants

Highest priced new drugs reported – brand name

Drug	WAC	Therapeutic class	Manufacturer
Beqvez™	$ 3,500,000	Hematological agents – miscellaneous	Pfizer
Lyfgenia™	$ 3,100,000	Hematopoietic agents	bluebird bio Inc.
Casgevy®	$ 2,200,000	Hematopoietic agents	Vertex Pharmaceuticals
Tecelra®	$ 727,000	Antineoplastics and adjunctive therapies	Adaptimmune LLC
Amtagvi™	$ 515,000	Antineoplastics and adjunctive therapies	Iovance Biotherapeutics Inc.
Rivfloza™	$ 62,880 – 50,304	Genitourinary agents – miscellaneous	Novo Nordisk Inc.
Adstiladrin ®	$60,000	Antineoplastics and adjunctive therapies	Ferring Pharmaceuticals Inc.
Sohonos®	$47,880	Musculoskeletal therapy agents	Ipsen Biopharmaceuticals Inc.
Fabhalta®	$ 45,205	Hematological agents – miscellaneous	Novartis Pharmaceuticals
Wainua™	$ 41,583	Psychotherapeutic and neurological agents – miscellaneous	AstraZeneca Pharmaceuticals LP

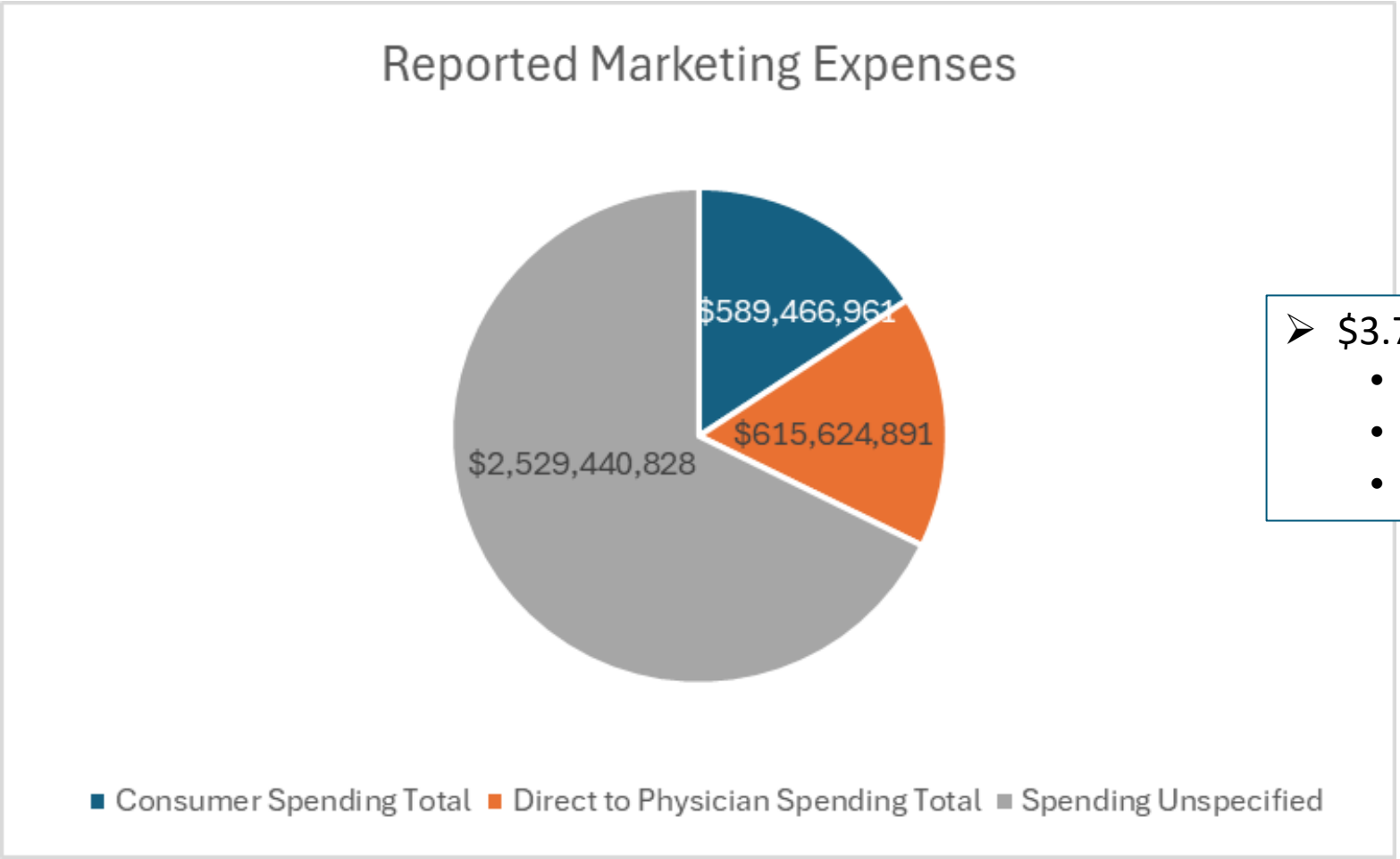
Figure 9 on Page 25 of the 2024 DPT legislative report.

Highest priced new drugs reported – generic

Drug	WAC per unit	WAC	Therapeutic class	Manufacturer
Lanreotide acetate	$13,387 / ML	$6,693	Endocrine and metabolic agents – miscellaneous	Cipla USA Inc.
Tasimelteon	$686 / capsule	$20,571	Hypnotics / sedatives / sleep disorder agents	Apotex Corp.
Nitisinone	$643 / 20 g capsule	$38,580 - $9,645	Endocrine and metabolic agents – miscellaneous	Eton Pharmaceuticals Inc.
Mifepristone	$608.70 / tablet	$170,435	Endocrine and metabolic agents - miscellaneous; progesterone receptor antagonists (abortifacient)	Corcept Therapeutics Inc.
Mifepristone	$598 / tablet	$16,734	Endocrine and metabolic agents - miscellaneous; progesterone receptor antagonists (abortifacient)	Teva Pharmaceuticals
Indomethacin suppositories 50mg N+	$344 / suppository	$10,314	Analgesics/ anti-inflammatories	Zydus Pharmaceuticals USA Inc.
Gefitinib	$237 / tablet	$7,103	Antineoplastics and adjunctive therapies	Apotex Corp.
Deferiprone	$140 / tablet	$6,976	Antidotes and specific antagonists	Taro Pharmaceutical USA Inc.
Pazopanib	$128 - $74 / tablet	$15,392 - $8,900	Antineoplastics and adjunctive therapies	Multiple
Tiopronin delayed release (DR) tablets	$85 / 300 mg pill	$8,463 - $7,616	Genitourinary agents – miscellaneous	Torrent Pharma Inc.

Figure 10 on Page 26 of the 2024 DPT legislative report.

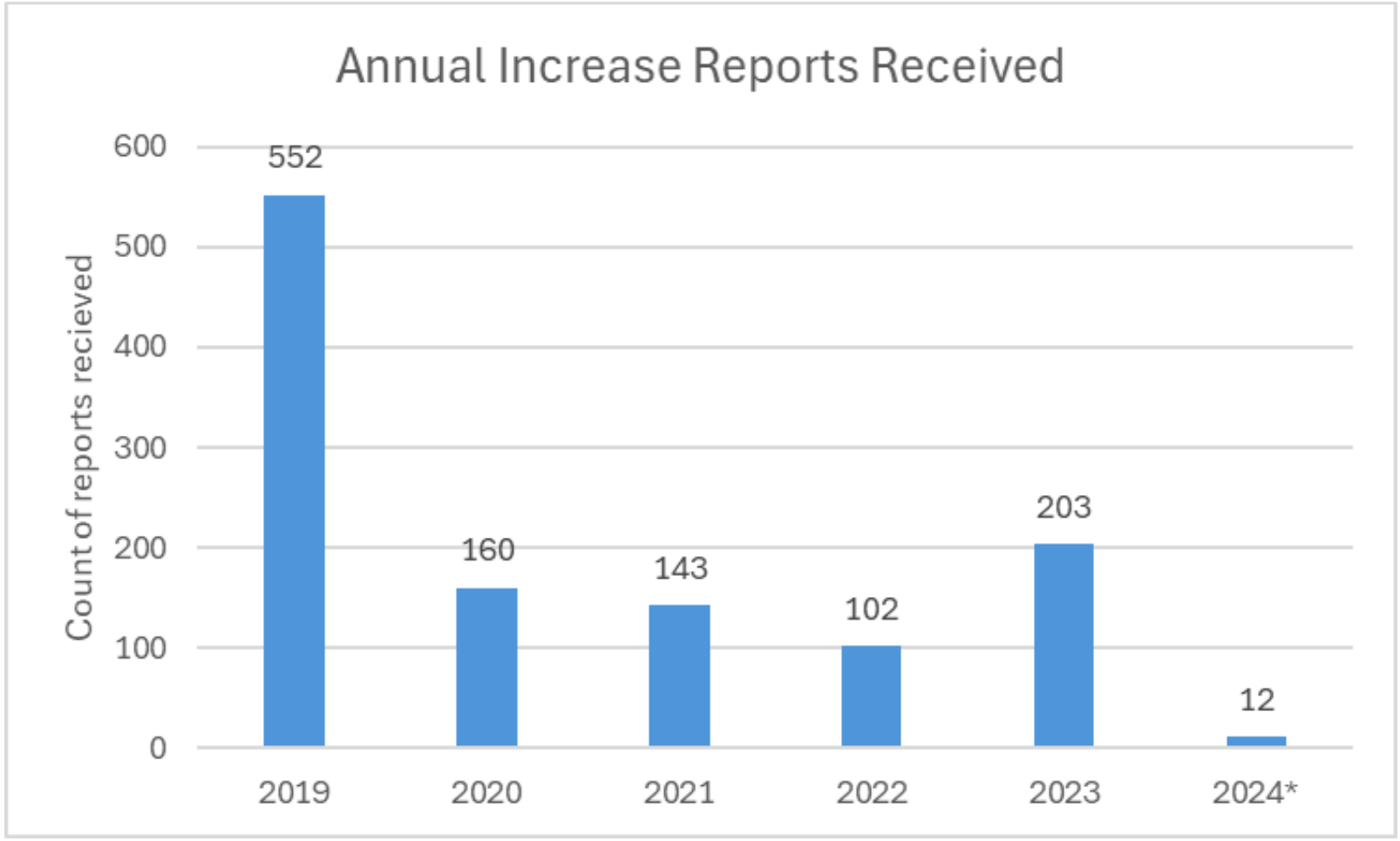
Marketing expenses included in new drug reports



- $3.7 billion in total marketing reported
  - 16.5 percent direct to physician
  - 15.8 percent consumer
  - 67.7 percent unspecified

Figure 11 on Page 27 of the 2024 DPT legislative report.

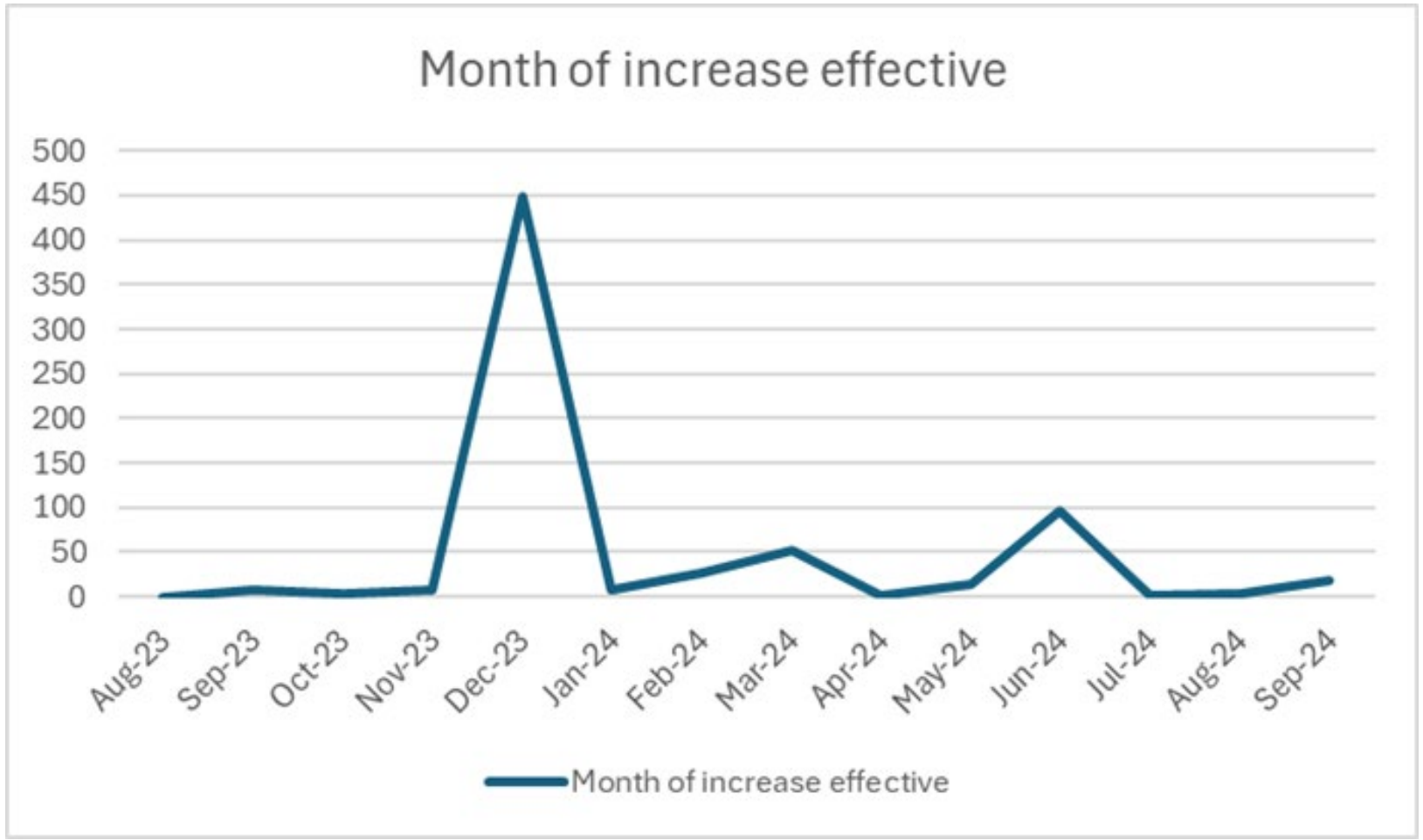
Reduction in annual price increase reports



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.

Figure 12 on Page 31 of the 2024 DPT legislative report.

60-day price increase notices



65 percent of reports have an effective price increase at the beginning of the calendar year.

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 14 on Page 33 of the 2024 DPT legislative report.

2023 pharmacy benefit manager (PBM) data reported

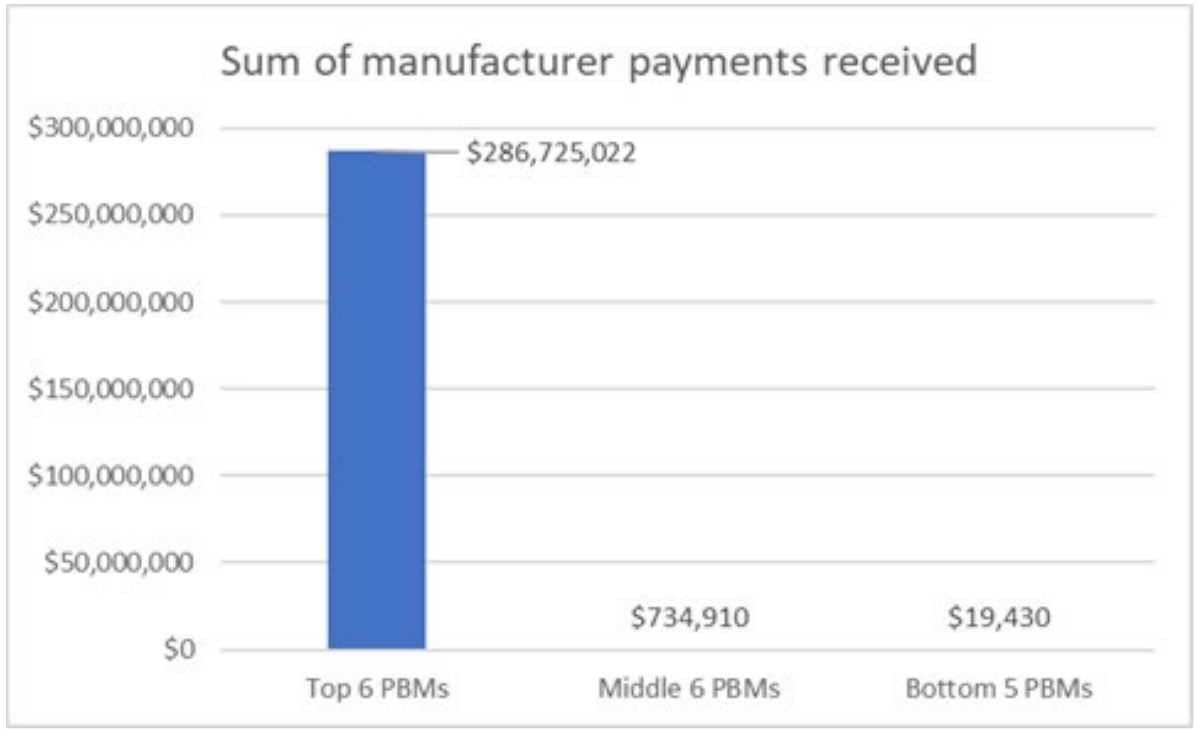
According to ORS 735.537, the DPT program has published the aggregate sum for all 17 PBMs for each of these four data points:

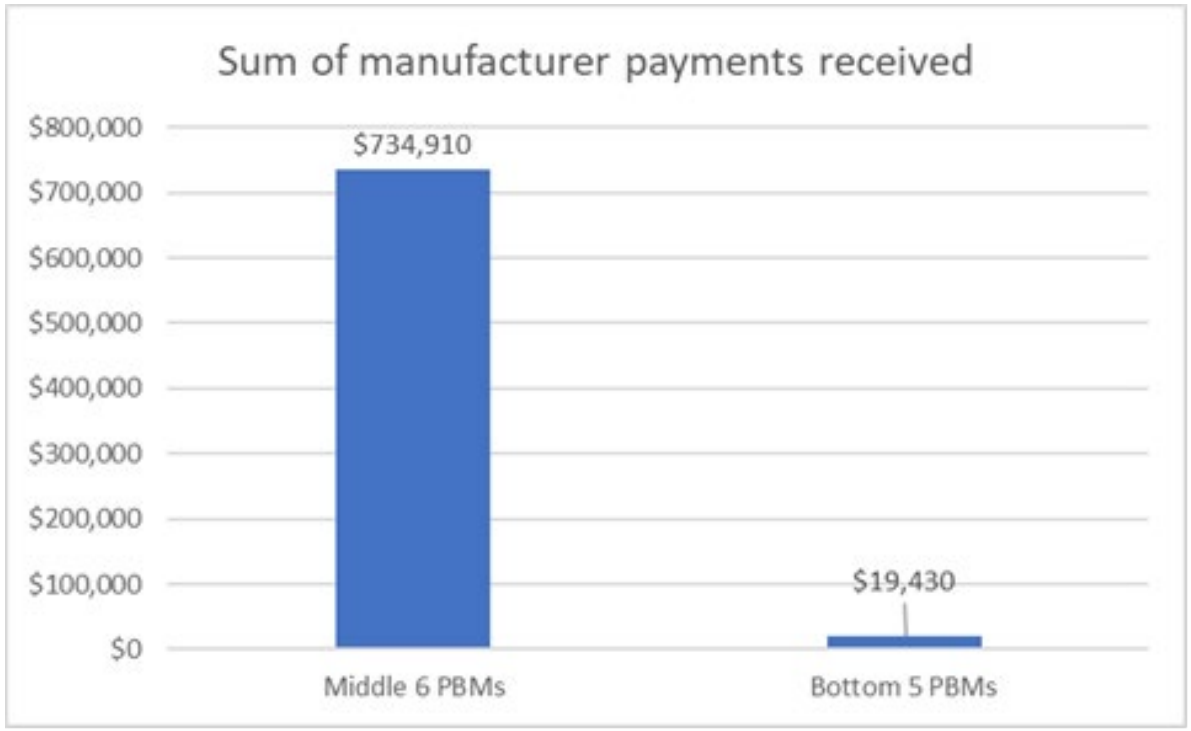
Rebates and payments from manufacturer	Amount passed to insurers	Amount passed to enrollees	Amount retained as revenue
$287,479,362	$283,642,406	$2,236,218	$1,600,738
- - -	98.67%	0.78%	0.56%

Note that the PBM information reported to Oregon does not include information related to federal and military health plans, Medicare, Public Employees' Benefit Board (PEBB), Oregon Educators Benefit Board (OEBB), self-insured health plans, Medicaid coordinated care organizations, and other plans not considered “health benefit plans."

Figures 20 and 22 on Page 41 of the 2024 DPT legislative report. See full PBM data here: https://dfr.oregon.gov/drugtransparency/Pages/DPT-pharmacy-benefit-managers.aspx

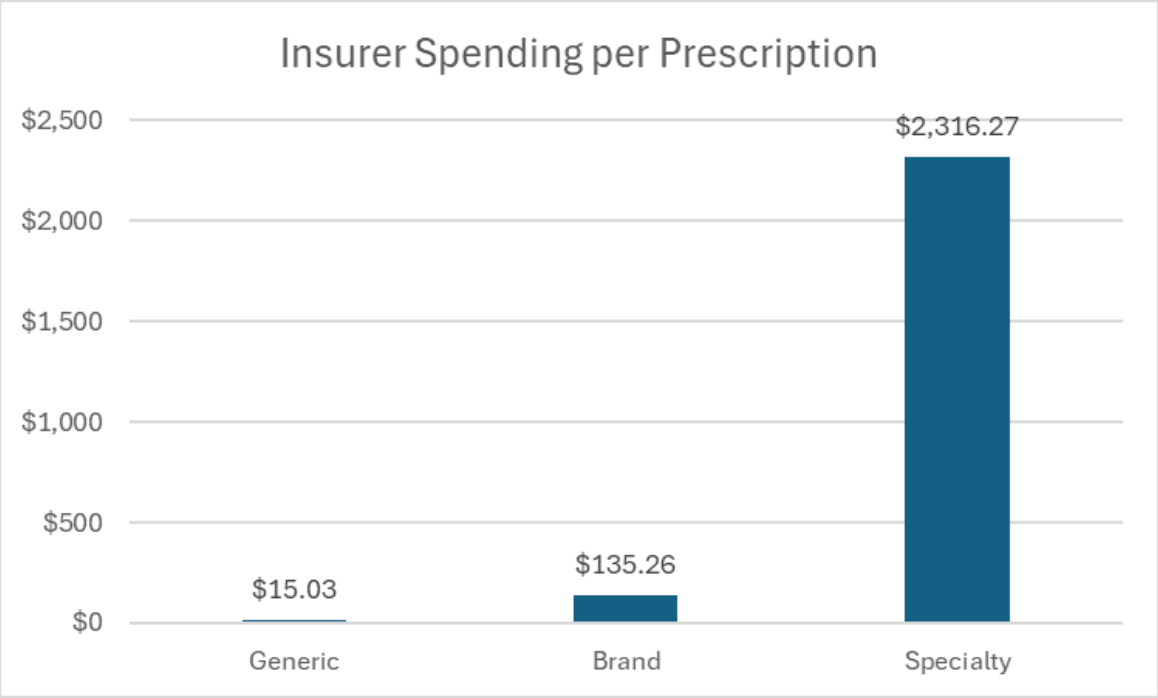
2023 pharmacy benefit manager (PBM) data reported

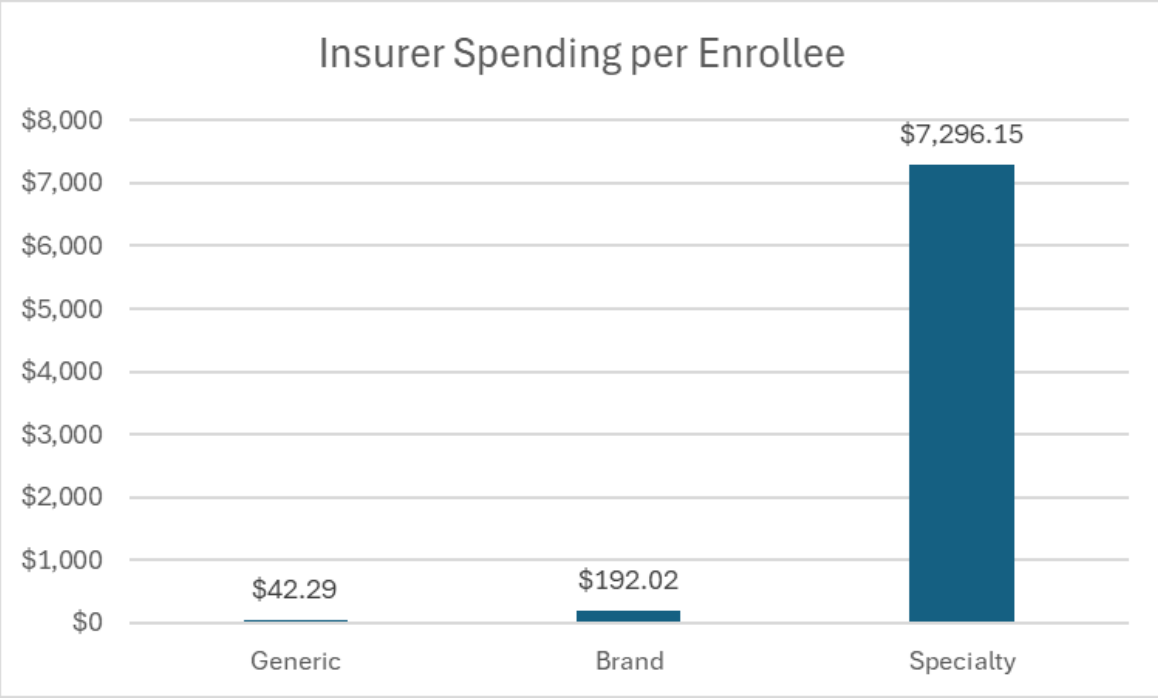




Figures 23 and 24 on Page 42 of the 2024 DPT legislative report.

Insurer spending on the top 25 most prescribed

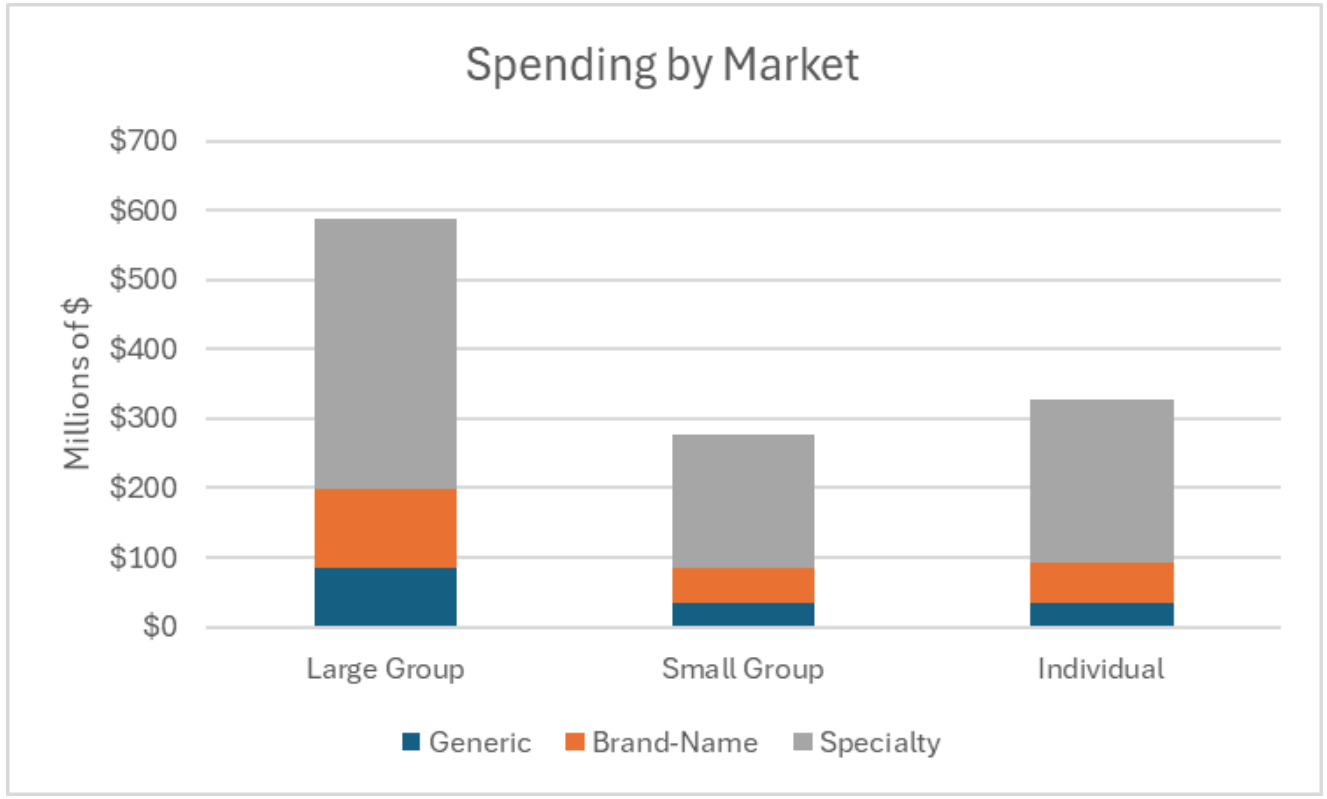




Specialty drugs are those more than $670 for a 30-day supply or course of treatment lasting less than one month and may include both brand and generic designated drugs. This is the amount set in 2019 by the Centers for Medicare and Medicaid Services (CMS) for specialty drugs in the Medicare Part D program.

Figures 27 and 28 on Page 45 of the 2024 DPT legislative report.

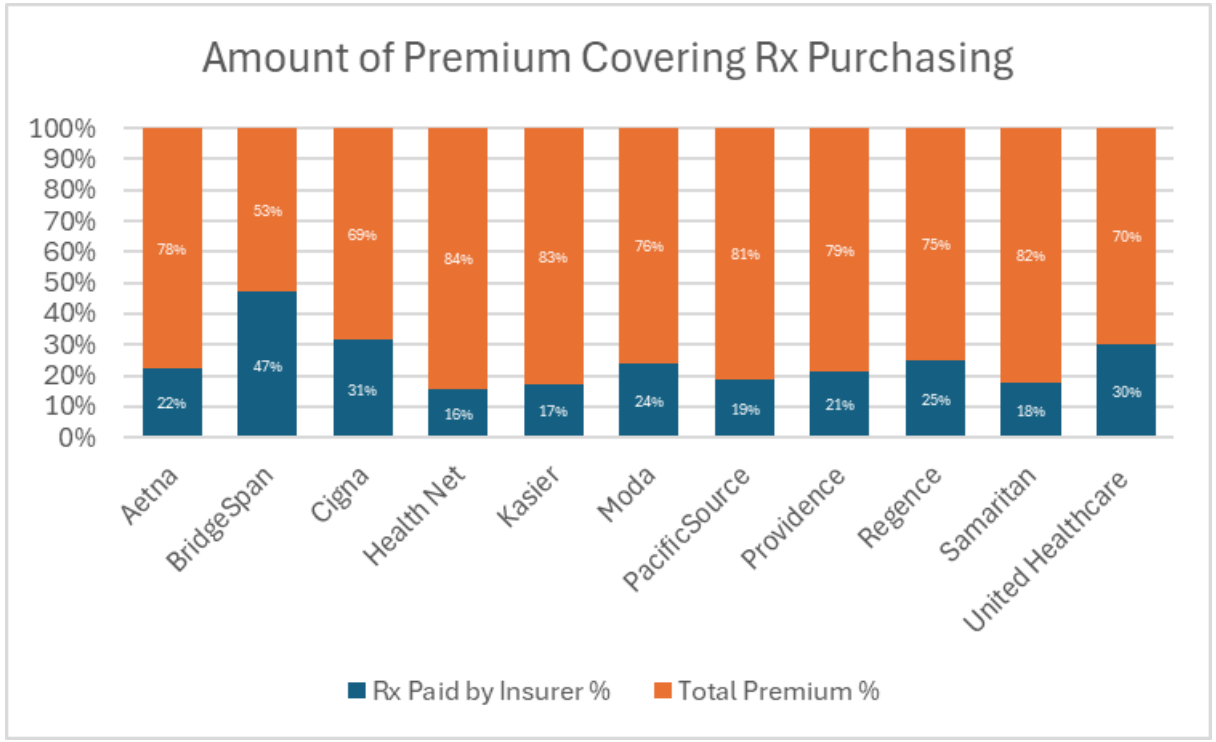
Insurer spending by type and market

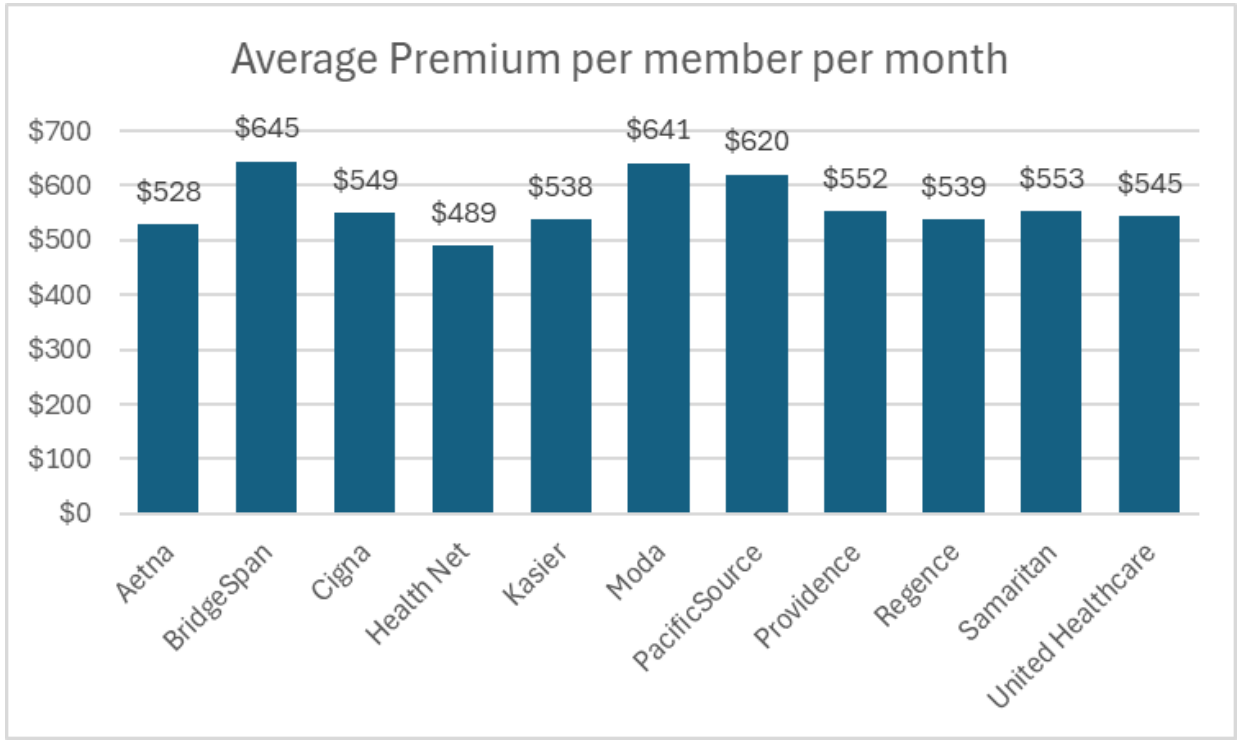


- Drug type spending:
  - ✓ Generic - $153,704,575
  - ✓ Brand Name - $223,403,845
  - ✓ Specialty - $817,138,452
- Market type spending:
  - ✓ Large Group – $588,378,129
  - ✓ Small Group – $277,426,099
  - ✓ Individual – $328,442,644
- **Total spending – $1,194,246,872**

Figure 26 on Page 44 of the 2024 DPT legislative report.

Insurer spending on prescription drugs: Percentage of premium



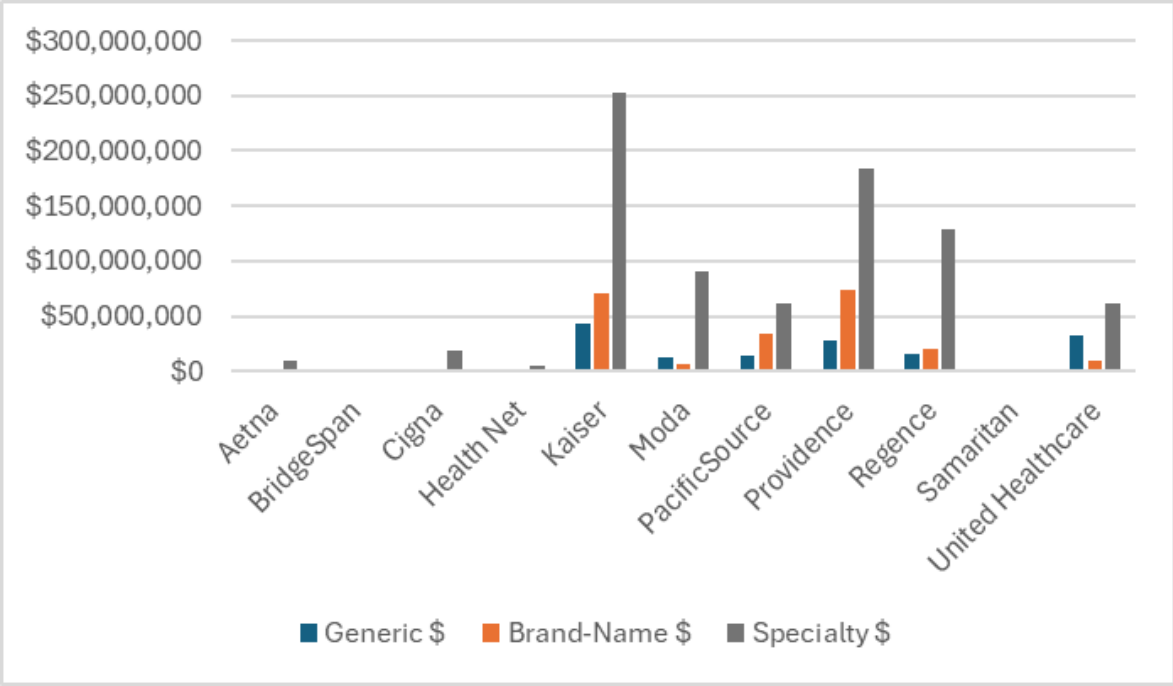


The average premium per member per month is the total of premiums collected by the insurer during 2023 divided by how many members were covered each month.

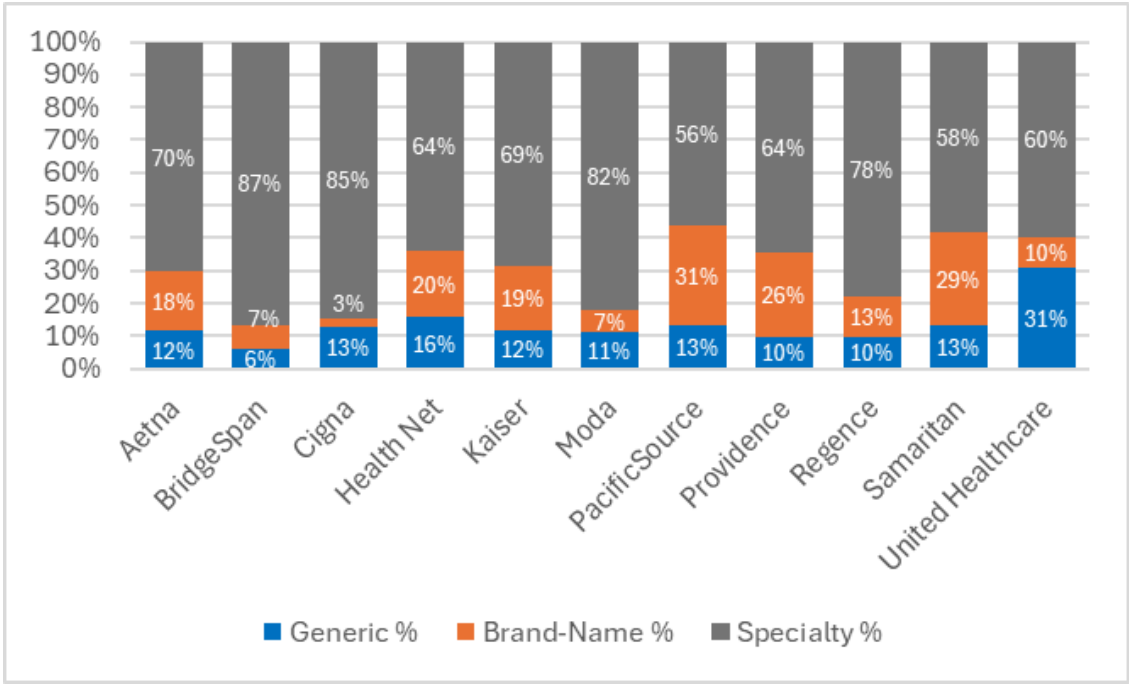
Figures 29 and 30 on Page 46 of the 2024 DPT legislative report.

Insurer spending on prescription drugs by drug category

Prescription spending by dollar ($)

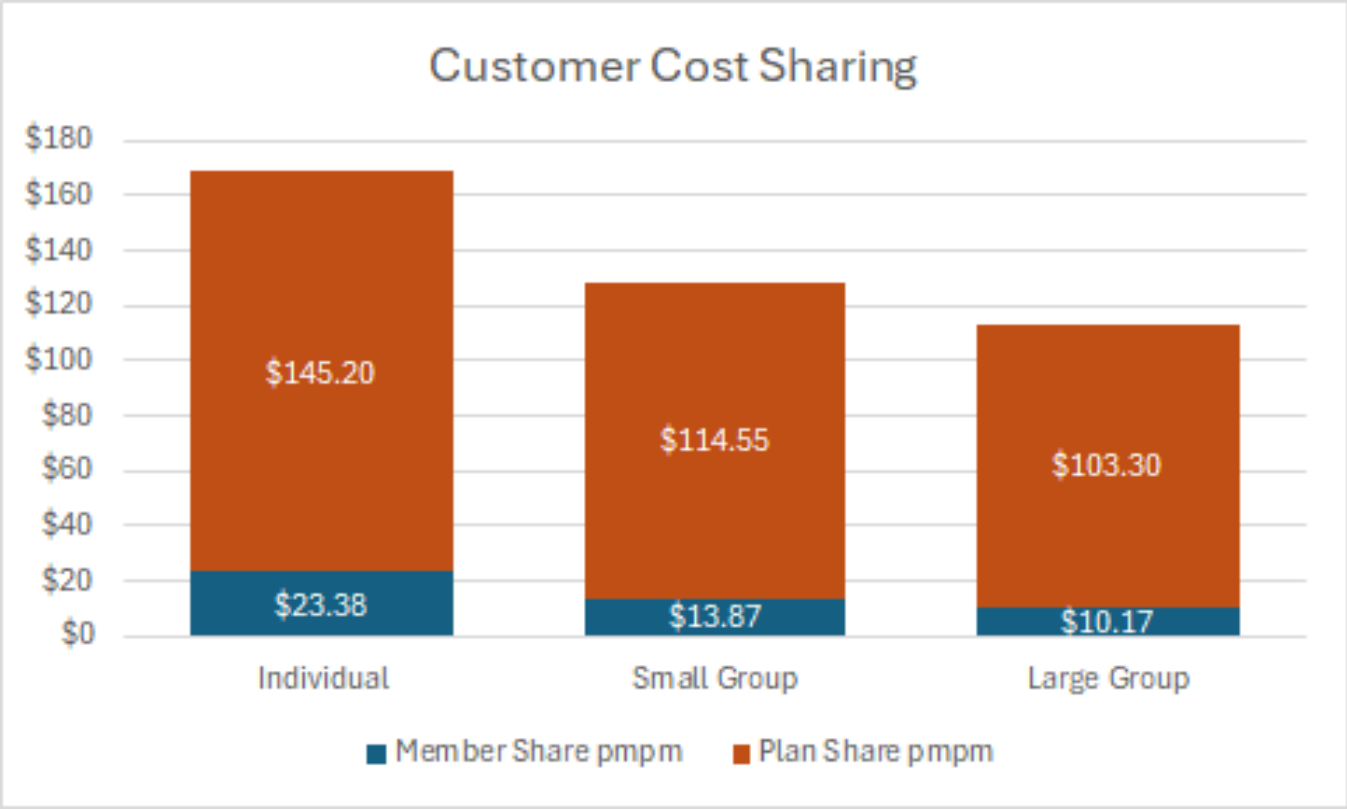


Prescription spending by percentage (%)



Figures 31 and 32 on Pages 47 and 48 of the 2024 DPT legislative report.

Insurer reporting on consumer cost sharing



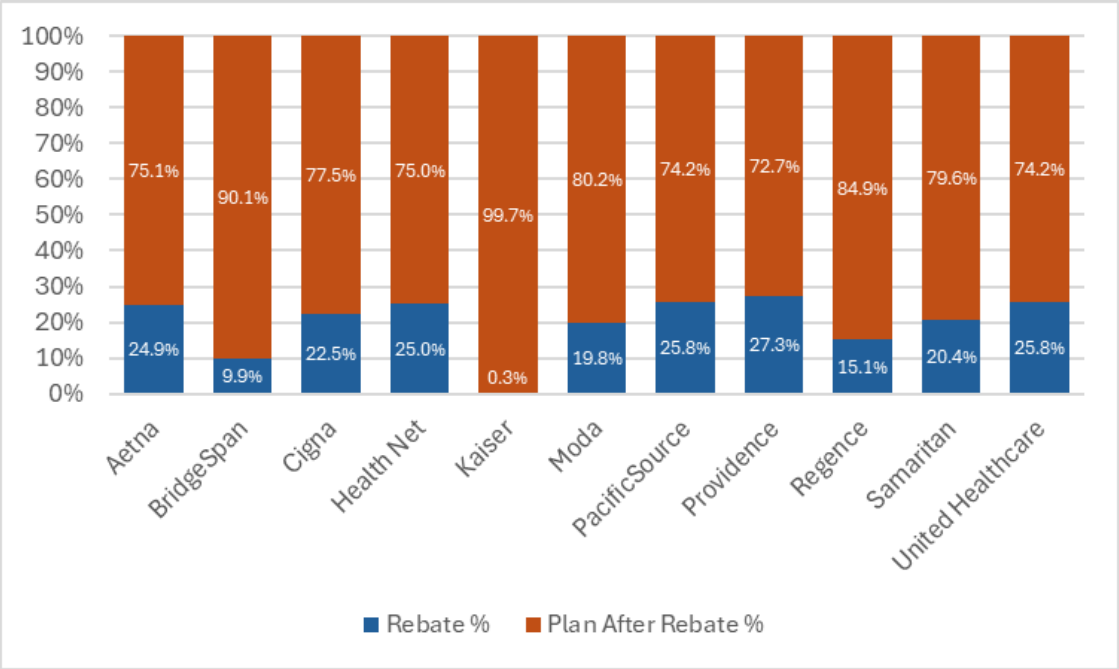
Average amount spent on prescription drugs:

- Individual – $168.58 per member per month
- Small Group – $128.42 per member per month
- Large Group – $113.47 per member per month

Figure 35 on Page 50 of the 2024 DPT legislative report.

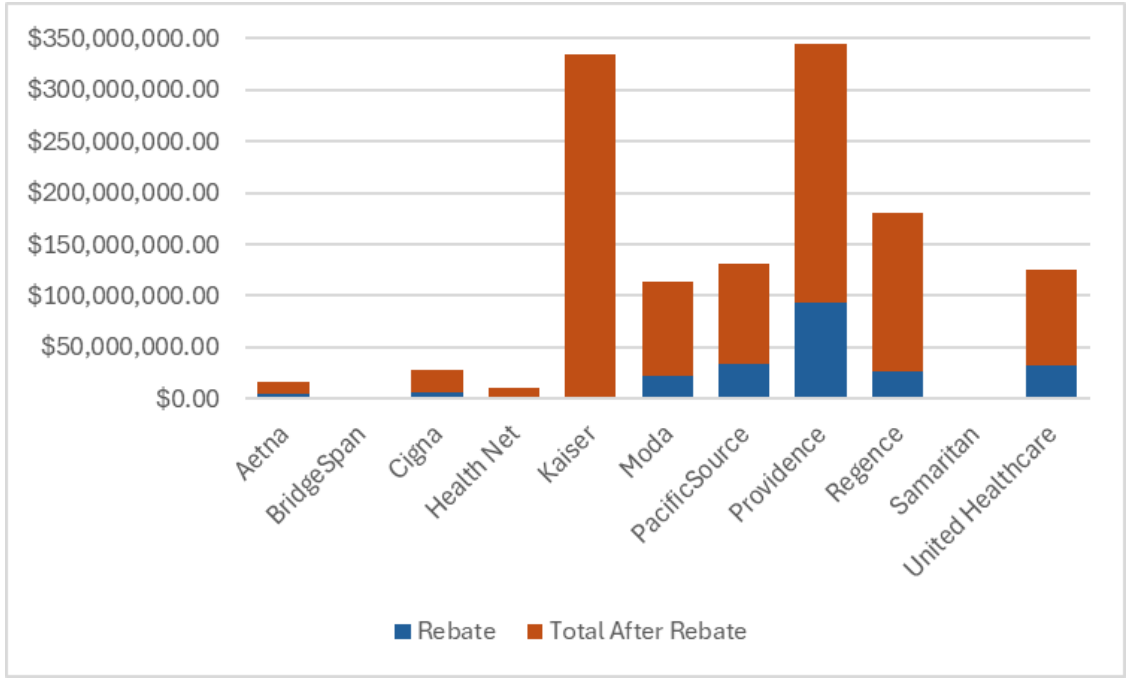
Insurer drug rebates received versus total drug spending

Rebate versus plan spending by percentage (%)



- Providence reported highest percentage of rebates to total spending at 27.3 percent.
- Kaiser reported the lowest percentage of rebates at 0.3 percent.

Rebate versus plan spending by dollar ($)



- Providence reported the highest amount of rebates, about $94.1 million.
- Bridgespan reported the lowest amount of rebates, $163,000.

Figures 37 and 38 on Pages 52 and 53 of the 2024 DPT legislative report.

Insurer most prescribed prescription drugs

Drug	Class	Prescriptions
Atorvastatin calcium	Antihyperlipidemics	185,385
Levothyroxine sodium	Thyroid agents	168,754
Lisinopril	Antihypertensives	164,576
Amphetamine-dextroamphetamine	ADHD/anti-narcolepsy/anti-obesity/anorexiants	151,018
Metformin HCl	Antidiabetics	146,749
Bupropion HCl	Antidepressants	145,453
Fluzone	Vaccines	131,030
Sertraline HCl	Antidepressants	125,994
Losartan	Angiotensin receptor blockers	125,620
Albuterol sulfate	Anti-asthmatic/bronchodilator agents	119,330

Drugs also on last year's list: atorvastatin calcium, levothyroxine sodium, lisinopril, amphetamine-dextroamphetamine, metformin HCl, bupropion HCl, Fluzone, sertraline HCl, and albuterol sulfate.

Figure 40 on Page 55 of the 2024 DPT legislative report.

Insurer most costly prescription drugs

Drug	Class	Total Allowed
Humira	Analgesics/anti-inflammatory	$53,267,675
Keytruda	Antineoplastics and adjunctive therapies	$37,816,382
Stelara	Dermatologicals	$31,156,649
Biktarvy	Antivirals	$26,933,839
Skyrizi	Dermatologicals	$25,622,754
Entyvio	Gastrointestinal agent	$21,299,837
Enbrel	Analgesics/anti-inflammatory	$21,147,861
Cosentyx	Dermatologicals	$20,464,979
Ozempic	Antihyperglycemic	$18,232,971
Dupixent	Dermatologicals	$17,124,535

Drugs also on last year's list: Humira, Keytruda, Stelara, Biktarvy, Skyrizi, Entyvio, Enbrel, and Cosentyx.

Figure 41 on Page 56 of the 2024 DPT legislative report.

Insurer reported drugs with increased plan spending

Drug	Class	Year over year increase
Keytruda	Antineoplastics and adjunctive therapies	$13,569,234
Skyrizi	Dermatologicals	$10,452,298
Ozempic	Antidiabetics	$8,708,006
Comirnaty	Vaccine	$5,964,667
Prevnar	Vaccine	$4,735,807
Dupixent	Dermatologicals	$4,510,445
Stelara	Dermatologicals	$4,315,271
Verzenio	Antineoplastic and Adjunctive Therapies	$3,716,818
Jardiance	Antidiabetic	$2,666,754
Entyvio	Gastrointestinal Agents – Misc.	$2,327,492

Drugs also on last year's list: Keytruda, Skyrizi, Ozempic, Dupixent, and Stelara.

Figure 42 on Page 57 of the 2024 DPT legislative report.

Policy recommendations

1) Expand patient assistance programs reporting
    - Continue to recommend manufacturers be required to report annually on all patient assistance
2) Require insurers and PBMs to report on copay accumulators
    - 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

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

See Pages 58 through 60 and Appendixes A through E on Pages 65 through 72 of the 2024 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
Lily Sobolik, senior policy advisor

First public comment period

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

First panel – drug advertising

Presenters:

- Michael DiStefano, Ph.D., assistant professor, Center for Pharmaceutical Outcomes Research, University of Colorado Skaggs School of Pharmacy and Pharmaceutical Sciences
- Sneha Dave (she/her), founder and executive director, Generation Patient
- Dharia McGrew (she/her), Ph.D., director, state policy, PhRMA
- Gray Brokaw, high value health care campaign associate, OSPIRG

First panel – drug advertising

Presenter:

- Michael DiStefano, Ph.D., assistant professor, Center for Pharmaceutical Outcomes Research, University of Colorado Skaggs School of Pharmacy and Pharmaceutical Sciences

Skaggs School of Pharmacy and Pharmaceutical Sciences
UNIVERSITY OF COLORADO
ANSCHUTZ MEDICAL CAMPUS

Consumer Advertising and Drug Benefit

Michael J. DiStefano, PhD
December 4, 2024

Background

- US & New Zealand are the only countries that allow direct-to-consumer advertising (DTCA) for prescription drugs

- From 1997 to 2016, spending on DTCA in the US grew from $1.3 to $6 billion[1]
  - The component of medical marketing that increased most rapidly
  - No. of ads increased from 79k to 4.6 million (~660k TV commercials)

1. Schwartz LM, Woloshin S. Medical marketing in the United States, 1997-2016. *JAMA*. 2019;321(1): 80-96. doi:10.1001/jama.2018.19320

DTCA and Spending

- DTCA is associated with increased patient requests and increased clinician prescribing for advertised products[2,3]

- Concerning if this increases use of cost-ineffective drugs, *e.g.*:
  1. Branded product vs. cheaper generic/biosimilar
  2. Branded reformulation vs. cheaper generic (*i.e.* product hopping)
  3. Branded product vs. branded competitor that might work better for the individual patient
  4. Branded product not priced in accordance with value

2. Khokar B, Weathers S, Mattingly TJ II. Direct-to-consumer advertising and the advancement of the quadruple aim: a narrative review. *Clin Pharm Forum.* 2022;5(4):459-466. doi: 10.1002/jac5.1599
3. Franquiz MJ, McGuire AL. Direct-to-consumer drug advertisement and prescribing practices: evidence review and practical guidance for clinicians. *J Gen Intern Med*. 2021;36(5):1390-1394. doi:10.1007/s11606-020-06218-x

Existing Literature

- Previous research examined the relationship between clinician-targeted promotion and drug innovativeness
  - From 2013-2014, top-promoted drugs were significantly less likely to be innovative than top-selling drugs[4]
  - From 2013-2015, 92-96% of promotional spending on top-promoted drugs was for drugs with little to no therapeutic gain[5]
- From 2015-2021, fewer than 1/3 of the most common drugs featured in television ads were rated as having moderate or greater added benefit[6]

4. Greenway T, Ross J. US drug marketing: How does promotion correspond with health value? BMJ 2017;357:j1855.
5. Lexchin J. The relation between promotional spending on drugs and their therapeutic gain: a cohort analysis. *CMAJ Open*. 2017;5(3):E724-E728. doi:10.9778/cmajo.20170089
6. Patel NG, Hwang TJ, Woloshin S, Kesselheim AS. Therapeutic Value of Drugs Frequently Marketed Using Direct-to-Consumer Television Advertising, 2015 to 2021. *JAMA Netw Open.* 2023;6(1):e2250991. doi:10.1001/jamanetworkopen.2022.50991

Motivation for Further Research

- Small samples
- Existing research does not always control for confounders like molecule type, generic/biosimilar availability, etc.
- More research needed into DTCA (incl. beyond TV ads) vs. clinician-targeted ads

Study Objective and Methods

- What drug characteristics are associated with larger proportions of promotional spending allocated to DTCA vs. clinician-targeted ads?

- Top 150 drugs with highest US sales in 2020
- Promotional spending data from IQVIA ChannelDynamics
  - Product sampling, clinician contacts, meetings/events, journals, mail, DTCA
- Collected data on several covariates including added benefit

Results

Table 3. Absolute Change in the Proportion of Total Promotional Spending Allocated to Direct-to-Consumer Advertising

Variable	Unadjusted mean marginal effect (95% CI)[a]	*P* value	Adjusted mean marginal effect (95% CI)[a]	*P* value
Total product sales (per 10% increase)	0.92 (0.16 to 1.68)	.02	1.50 (0.44 to 2.56)	.005
Added clinical benefit (low vs high)[b]	1.58 (-8.75 to 11.9)	.77	14.3 (1.43 to 27.2)	.03
Approval year (since 2012 vs earlier)	13.0 (3.40 to 22.7)	.008	10.7 (-0.61 to 21.9)	.06
Molecular type (biologic or biosimilar vs small molecule)	13.9 (3.32 to 24.5)	.01	15.5 (-1.27 to 32.3)	.07
Single indication (yes vs no)	-2.53 (-11.7 to 6.60)	.59	12.2 (-2.07 to 26.4)	.09
Anatomical group				
Alimentary tract and metabolism	[Reference]		[Reference]	
Anti-infectives for systemic use	36.8 (8.84 to 64.7)	.01	38.6 (8.42 to 68.9)	.01
Antineoplastic and immunomodulating agents	24.2 (12.9 to 35.4)	<.001	22.6 (7.84 to 37.3)	.003
Nervous system	7.84 (-3.14 to 18.8)	.16	21.6 (0.96 to 42.2)	.04
Respiratory system	9.59 (-1.99 to 21.2)	.11	21.9 (1.33 to 42.4)	.04
Other[c]	7.90 (-0.80 to 16.6)	.08	19.4 (4.95 to 33.9)	.009
Condition targeted				
Chronic	[Reference]		[Reference]	
Chronic or acute	0.91 (-8.73 to 10.6)	.85	10.4 (-4.46 to 25.2)	.17
Acute	10.6 (-4.15 to 25.3)	.16	16.4 (-4.20 to 37.0)	.12
Medicare spending per beneficiary (per 10% increase)	0.72 (0.32 to 1.12)	<.001	0.31 (-0.30 to 0.92)	.32
Administration (clinician administered vs self-administered)	16.4 (3.38 to 29.5)	.01	6.25 (-13.3 to 25.8)	.53

- On average, drugs with low added benefit have 14.3% more promotional spending allocated to DTCA (vs. drugs with high added benefit)
- This result was robust in 4 sensitivity analyses using different model specifications

DiStefano MJ, Markell JM, Doherty CC, Alexander GC, Anderson GF. Association Between Drug Characteristics and Manufacturer Spending on Direct-to-Consumer Advertising. *JAMA*. 2023;329(5):386–392. doi:10.1001/jama.2022.23968

Limitations

- Added benefit ratings are widely used in published research, but have limitations:
  - Assessments by international agencies may incorporate value judgments misaligned with the US public
  - May not always incorporate most recent clinical evidence
- Primary finding is statistically significant, but substantial variation

Significance

- Allocating a greater share of promotional spending to DTCA (vs. clinician-targeted ads) may reflect strategy to drive patient demand for drugs clinicians would be less likely to prescribe, because:
  - There are similarly/more effective Tx available, possibly at a lower cost
  - They face burdensome utilization controls like prior authorization (intended to direct demand toward cheaper/more effective available Tx)

- Overall effect could be to raise costs through inefficient utilization

Looking Ahead

- The DTCA landscape is rapidly evolving with increasing reliance on digital ads (*e.g.* targeted social media ads)

- Future research should focus on this unique element of DTCA

First panel – drug advertising

Presenter:

- Sneha Dave, founder and executive director, Generation Patient

Pharmaceutical direct-to-consumer advertising on social media

Generation Patient is a nonprofit created and led by young adults with chronic medical conditions (such as lupus, Crohn's disease, hemophilia, Lyme disease, and more). We drive meaningful change for young adult patients by building community and creating systems-level change.

Generation patient

Direct Support

- Six virtual peer support meetings per month
- International Virtual Health Advocacy Summit
- Peer-led resources in higher education and advanced planning

Research and policy

- Patent reform
- Pharmaceutical direct-to-consumer advertising on social media
- Representation of adolescents and young adults in clinical trials

Leadership Programming

- Health Policy Scholars Program
- Crohn's and Colitis Young Adults Network Fellowship Program
- Inflammatory Bowel Disease Medical Student Scholars Program

Roundtables

- Higher Education and Medical Disabilities
- Young Adults with Inflammatory Bowel Diseases
- Peer Support Interventions
- Social Media Direct-to-Consumer Advertising

Our Health Policy Work

Generation Patient's (Health) Policy Lab spearheads our organization's work in health policy, aiming not only to drive significant change in areas that have the most impact on young adult patients but also to empower young adult patients with policy education and advocacy opportunities to ensure that their voices are heard. Read more about these issues (and learn about the advocacy work we've done!) on our website!

Patent Reform

Problem: There is an over-patenting of prescription drugs, reducing timely biosimilar availability and disincentivizing novel therapeutics.

Clinical Trials

Problem: Lack of representation of adolescents/young adults in clinical trials and there is a need to disaggregate data to account for young adults.

Pharma DTC advertising on Social Media

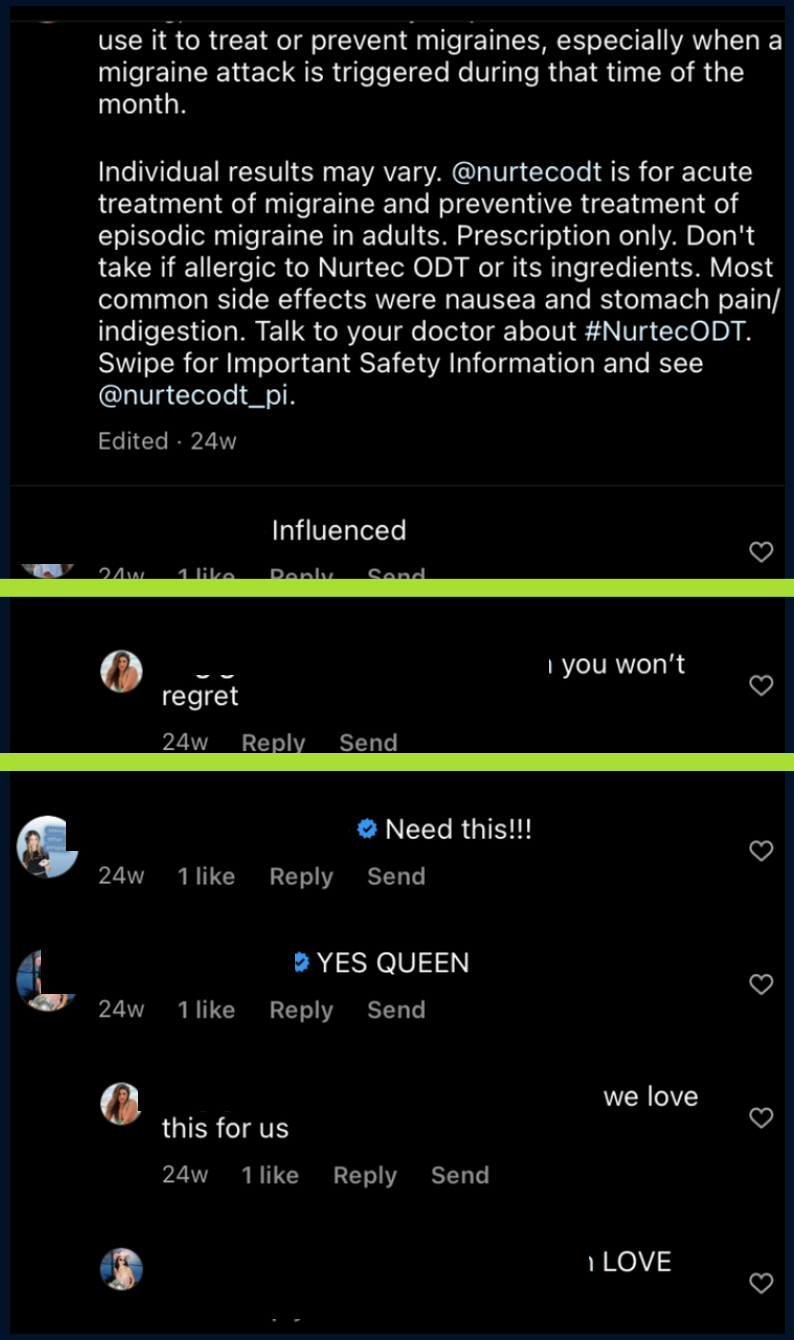
Problem: Increase of pharma-sponsored influencer prescription drug advertisements. We are working to increase regulation with FDA and to enable an FDA/FTC collaboration.

At a 2021 workshop at the Duke Margolis Center for Health Policy, vulnerable populations on social media as it pertains to pharma direct-to-consumer advertising were defined as including **adolescents** and those with **chronic health conditions**.

Impact of social media

- Majority of COVID-19 misinformation came from **12 people** who have combined **59 million followers** across multiple social media platforms.
- Virality and viewership, especially on TikTok and Instagram reels.
- Influencers are not just marketing tools, but rather have the potential to develop relationships with their followers.
- Accounts with around 1,000-100,000 followers, or less. (1) Leveraged as a more “authentic” avenue to appeal to consumers Stronger parasocial relationships due to smaller following making the micro influencer seem more like a friend or peer.

While the FDA Office of Prescription Drug Promotion (OPDP) has discretion over the advertisement of prescription medications, they updated their guidance a couple of months ago, **TEN** years after their first guidance. They have not held a public workshop since **2009**.

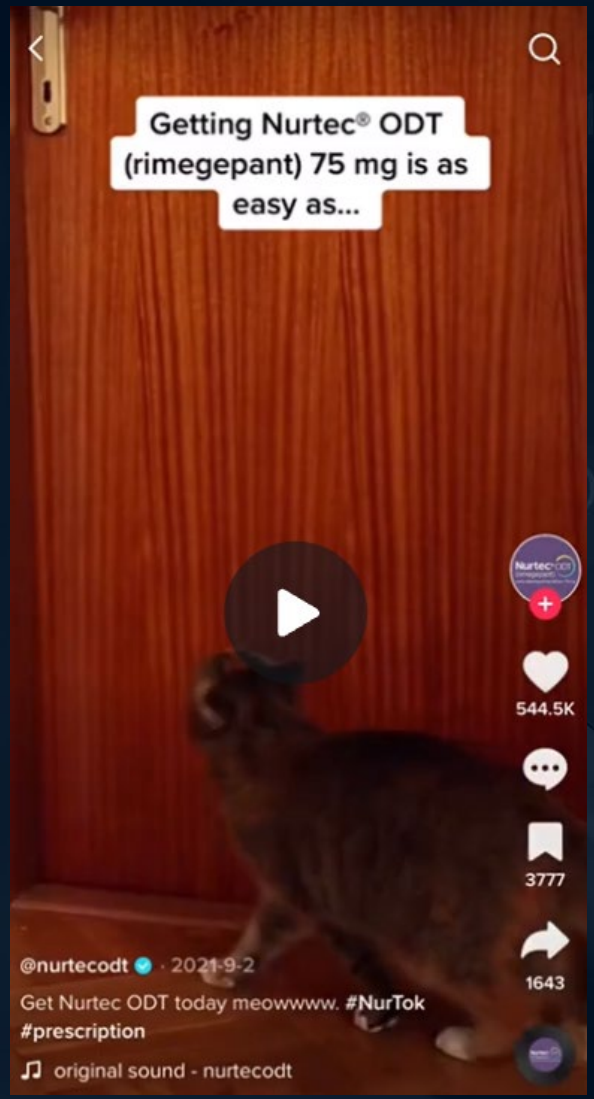


- Lack of regulation of comment sections
- Lack of regulation of direct messaging

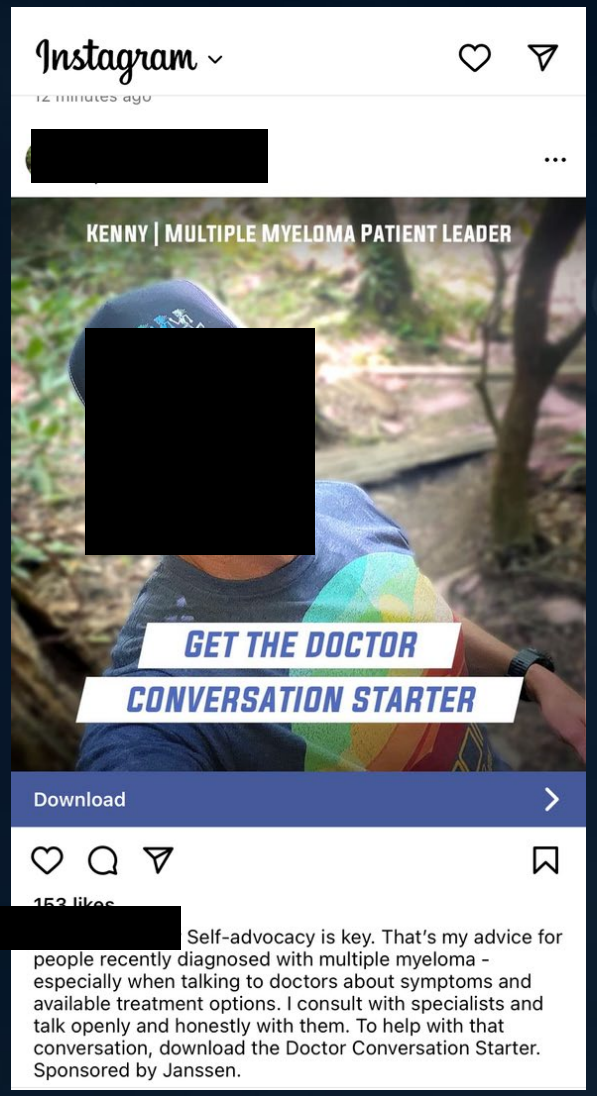
- Biohaven collaborated to design a jacket for New York Fashion Week. They partnered with an influencer who modeled the jacket.
- Instagram stories versus posts
  - One influencer's Instagram stories all tag NurtecODT but there is no apparent safety information in any of these stories.

Glamour.com; Image from Hardware LDN

Advertisement on TikTok



Advertisement on Instagram



Taking action!

Federal Trade Commission

Generation Patient is a nonprofit focused on empowering the next generation of patients, led *entirely* by young adults with chronic and rare conditions. Our work has touched regions across the country. Through our nonpartisan and focused initiatives—the **Health Policy Lab** and the **Crohn's and Colitis Young Adults Network**—we work to increase the health literacy, confidence, self-management skills, public policy knowledge, and advocacy strategies of young adult patients. We have developed programming related to navigating the higher education landscape as well as educating people about health policy with independent research and analysis. Additionally, we have facilitated more than 250 virtual meetings during the past two years focused on connecting young adult patients around the world and providing them with critical peer support.

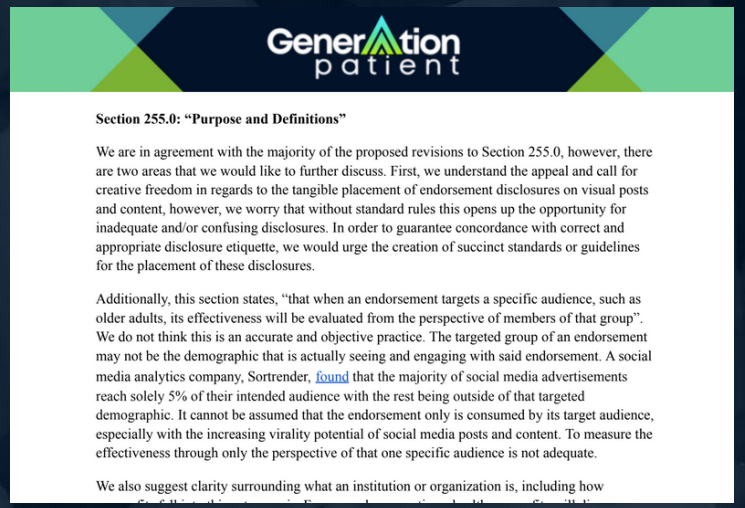
We thank you for the opportunity to comment on the Federal Trade Commission's upcoming virtual event on *Protecting Kids from Stealth Advertising in Digital Media*.

As an organization, we uphold the urgent necessity for clear regulations on stealth advertising that specifically targets children, adolescents, and young adults. We commend the Federal Trade Commission for taking a step toward addressing this problem. With younger and younger demographics engaging with social media each year, and increasing numbers of advertisements being seen on these platforms, this is an emerging and pressing issue.

We suggest and urge pharmaceutical advertising to be one of the specific topics addressed at this event. It is important to note that a recent workshop between the Duke Margolis Center for Health Policy and the Food and Drug Administration identified that vulnerable consumers include adolescents and those with existing health conditions. While we recognize that FDA has discretion over prescription medication advertisements, we note that it is imperative for interagency discussions about the rise of micro-influencers and influencers advertising prescription medications.

Direct-to-consumer advertising (DTCA) of any product can be misleading to a child, especially with a lack of clear and apparent disclosure, however, DTCA of pharmaceutical medications is arguably extensively more misleading and deceptive. Even as an adult it can be near impossible to identify an advertisement disclosure, or locate safety information, on a pharmaceutical advertisement. For a child, who likely has a lower level of health understanding and literacy, these advertisements are further manipulative.

Our comment on the FTC event on "Protecting Kids from Stealth Advertising in Digital Media"



Section 255.0: "Purpose and Definitions"

We are in agreement with the majority of the proposed revisions to Section 255.0, however, there are two areas that we would like to further discuss. First, we understand the appeal and call for creative freedom in regards to the tangible placement of endorsement disclosures on visual posts and content, however, we worry that without standard rules this opens up the opportunity for inadequate and/or confusing disclosures. In order to guarantee concordance with correct and appropriate disclosure etiquette, we would urge the creation of succinct standards or guidelines for the placement of these disclosures.

Additionally, this section states, "that when an endorsement targets a specific audience, such as older adults, its effectiveness will be evaluated from the perspective of members of that group". We do not think this is an accurate and objective practice. The targeted group of an endorsement may not be the demographic that is actually seeing and engaging with said endorsement. A social media analytics company, Sortrender, found that the majority of social media advertisements reach solely 5% of their intended audience with the rest being outside of that targeted demographic. It cannot be assumed that the endorsement only is consumed by its target audience, especially with the increasing virality potential of social media posts and content. To measure the effectiveness through only the perspective of that one specific audience is not adequate.

We also suggest clarity surrounding what an institution or organization is, including how

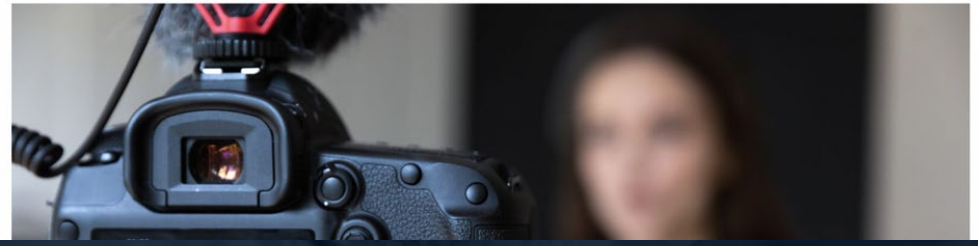
Our comment on the FTC endorsement guidelines

Opinion Editorials → Oversight letter

FIRST OPINION

The FDA and FTC need to crack down on TikTok and Instagram influencers pitching prescription drugs

By Sneha Dave, Sydney Reed, and Steven Woloshin Jan. 22, 2024 Reprints



United States Senate

WASHINGTON, DC 20510

February 14, 2024

Robert M. Califf, MD
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

Dear Commissioner Califf:

With the dramatic rise in social media use—especially among youth—there has been an alarming proliferation of dangerous and misleading content promoting prescription drugs. We write to urge the Food and Drug Administration (FDA) to take swift action to update its enforcement tools to reflect the current platforms and methods used to promote prescription drugs and biologics, and to prioritize the protection of children from harmful and inaccurate medical advice.

Studies show that patients are more likely to ask their provider for a particular medication and to receive a prescription if the patient has seen a direct-to-consumer (DTC) advertisement for the drug. This can inflate demand for medications that may not be clinically appropriate, or for which alternative interventions may be available. DTC ads making product claims for disease treatment are only permitted in the United States and New Zealand, and the appeal and potency of DTC ads demand adequate FDA oversight. Unfortunately, it appears there are gaping holes in FDA's oversight of DTC promotions that are being exploited on social media at the expense of children and patients.

First, FDA has not updated its draft guidance on prescription drug promotion for social media since 2014. The social media landscape has evolved dramatically with the skyrocketing amount of time that users—particularly children—spend scrolling on platforms, and the emergence of platforms such as Instagram, Snapchat, X, and TikTok. While we recognize FDA has conducted initial research in this space and supported a one-day workshop, the agency's decade-old guidance must be modernized. FDA's guidance needs to clarify that these platforms are subject to its jurisdiction and should reflect the way that advertisements on these platforms must comply with federal requirements—such as conspicuousness and duration of statements, and size/contrast of imagery, including accounting for character counts and other limitations.

Second, new entrants appear to be exploiting a perceived gap in FDA's jurisdiction. According to reporting from the *Wall Street Journal* (WSJ), telehealth companies have engaged in extensive social media promotion for prescription drugs—without adhering to traditional requirements on accuracy, side effect disclosures, and fair balance of risk information. During a four-week period in 2022, the WSJ found more than 1,800 social media ads promoting prescription drugs without warnings or risks, and 500 ads for product uses that FDA did not approve. The Washington Journal of Law, Technology, and Arts article "*TikTok Told Me I Have ADHD*" examined instances where social media advertisements "simplify complex…symptoms and lead consumers to believe they have the condition," then provide immediate access to a tele-

Legislative Opportunities

"Young adult patients have been exposed to misleading prescription medicine advertisements for far too long, putting their health at risk. This legislation marks a crucial step in protecting all patients, especially young adults who are more vulnerable to such advertisements, by empowering the FDA with increased capacity and clearer enforcement guidelines. It creates a safer online environment where young patients can more confidently navigate health-related posts. We at Generation Patient proudly endorse this legislation, recognizing its potential to impact both current and future generations of patients positively. Thanks to Senators Durbin and Braun for listening and working with patients to develop this critical legislation." – Sneha Dave, Executive Director, Generation Patient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EXCLUSIVE HEALTHCARE

Senators Target Influencers, Telehealth Firms for Misleading Weight-Loss and Other Drug Promotion

Bill would allow the FDA to fine individuals, companies up to $500,000 for posting false information online about Ozempic, Wegovy


Generation patient

HOME ABOUT PEER SUPPORT ROUNDTABLES PROGRAMS RESOURCES NEWS STORE DONATE

STOPPING MISLEADING RX DRUG ADS ON SOCIAL MEDIA

The Protecting Patients from Deceptive Drug Ads Online Act

Nearly 90% of teens and young adults who use social media say they use it to find information about their healthcare. But when young people open our feeds, we are often faced with a barrage of dangerous misinformation and misleading content about the prescription drugs we desperately need to live full, healthy lives.

Whether it's in viral content paid for by a telehealth company pushing an expensive service, comments and DMs from an influencer paid by a drug manufacturer, or targeted ads that follow us around the internet, young people have been left on our own to sort through information that's designed to take advantage of our vulnerabilities.

A variety of ways to combat false/misleading pharmaceutical advertisements

- The bill will take on the misinformation polluting our feeds by:
  - Enforcing the same accurate information requirement on social media advertising that the FDA has for ads on TV, in newspapers, etc. That means making sure all drug communications on social media must include clear and accurate information about side effects, contraindications, and effectiveness.
  - Creating penalties for influencers, healthcare providers, and telehealth companies who benefit financially from sharing misleading information about prescription drugs on social media.
  - Directing the FDA to monitor communications that are specific to social media, like comment sections and viral trend hopping.
  - Making the FDA keep a payment disclosure database where payments made to influencers or healthcare providers to promote drugs must be reported and made public.
  - Establishing a task force in coordination with the Federal Trade Commission to enhance monitoring and enforcement with respect to prescription drug advertisements.

Takeaways:

- Important to expand regulations to address emerging social media pharma DTC
- Involve young patients who are the most impacted by these advertisements
- Work on improving state consumer protection laws and state-specific restrictions for pharma advertisements

Connect with us!

- Email: sneha@generationpatient.org
- Visit **www.generationpatient.org**
- **@generationpatient** on Instagram and **@genpatient** on Twitter
- Sign up for our newsletter!

First panel – drug advertising

Presenter:

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

PhRMA
RESEARCH • PROGRESS • HOPE

Annual Hearing on Drug Prices

Dharia McGrew, PhD
Director, State Policy
PhRMA

Who is PhRMA?

30 leading, innovative biopharmaceutical research companies in the U.S.

Since 2000, PhRMA member companies have invested

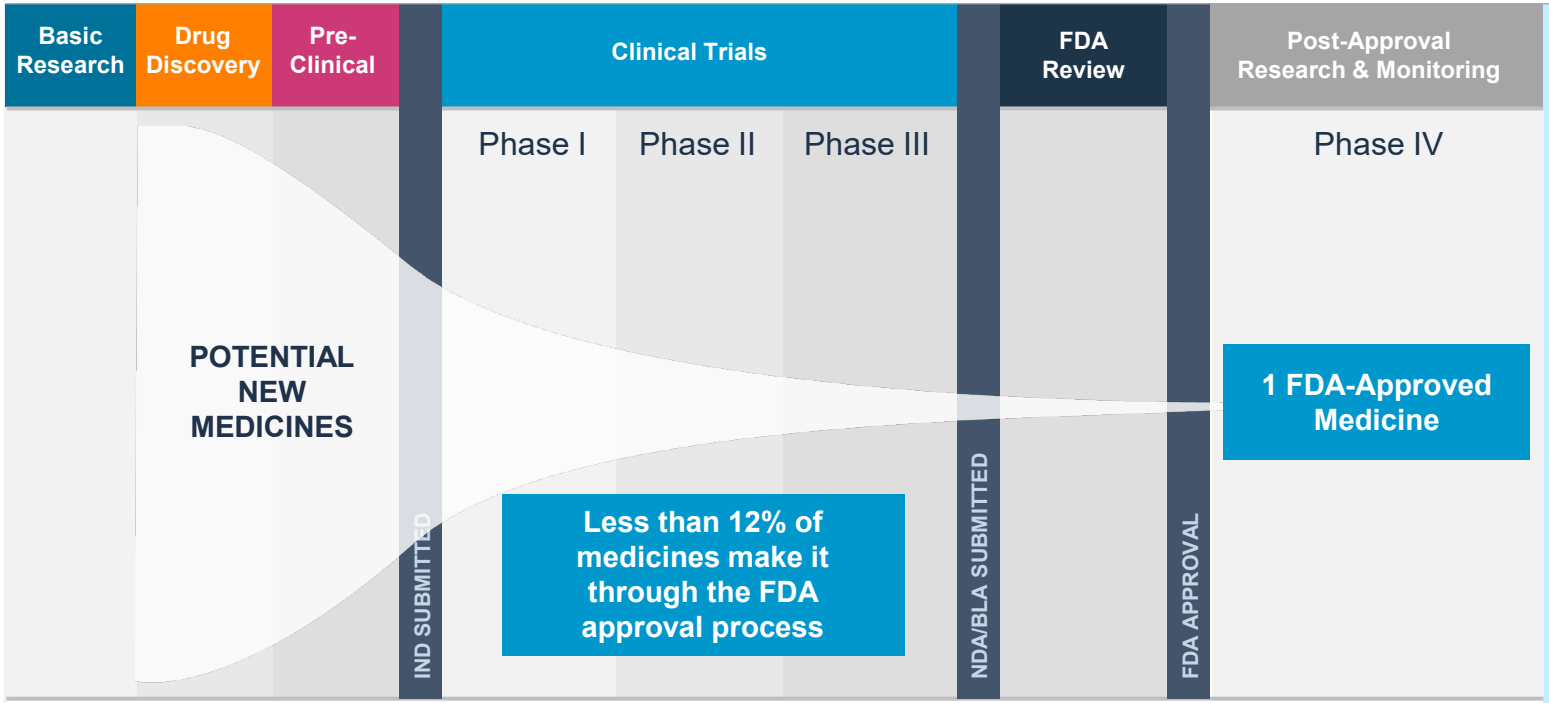
+$1.1 trillion

in the search for new treatments and cures

PhRMA
RESEARCH • PROGRESS • HOPE

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]

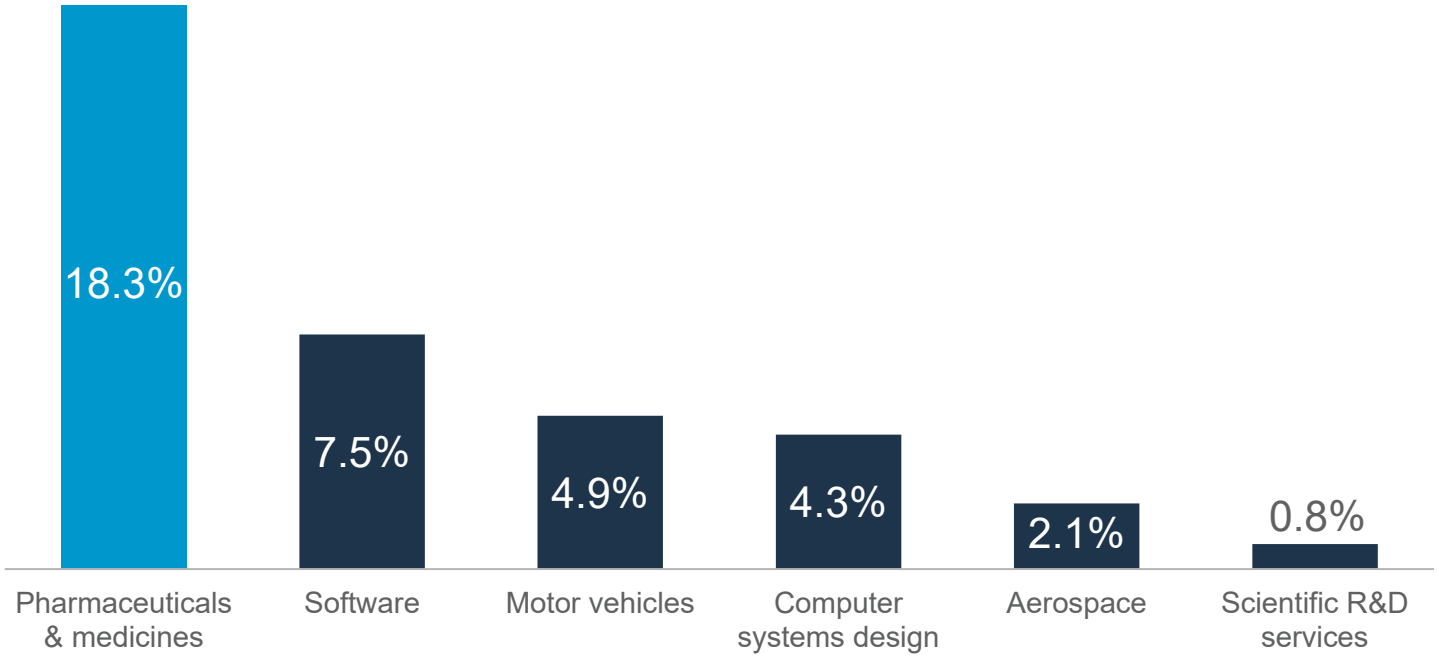
PhRMA RESEARCH • PROGRESS • HOPE

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

The Biopharmaceutical Industry Is the Single Largest Funder of Business R&D in the United States

The biopharmaceutical industry accounts for the single largest share of all self-funded R&D, representing 1 out of every 6 dollars (18%) spent on domestic R&D by U.S. businesses. Furthermore, U.S. industry is also the largest global funder of biopharmaceutical R&D, accounting for about half of all R&D investments worldwide.

Share of Total U.S. Business R&D Paid for by Industry, 2019*



*The remaining 62.1% share of business R&D spending is conducted by other industries, including subsectors of the machinery sector; computer and electronic products sector; and electrical equipment, appliance, and components sector.

Source: National Science Foundation. Adapted from Science & engineering indicators. Table RD-9. April 2022. Accessed January 2023. https://ncses.nsf.gov/pubs/nsb20225/u-s-business-r-d. Research!America. U.S. Investments in Medical and Health Research and Development, 2016-2020. 2022.

Comparisons of spending on R&D versus marketing and promotion are often misleading and grossly overstate marketing and promotion spending.

Reported sales, general and administrative (SG&A) expenses required in companies' U.S. Securities and Exchange Commission (SEC) filings include many activities unrelated to marketing and promotion.

Marketing & Promotion:

- Consumer directed advertising and promotion
- Product-specific advertising to health care professionals (HCPs)
- Direct promotional communications with HCPs

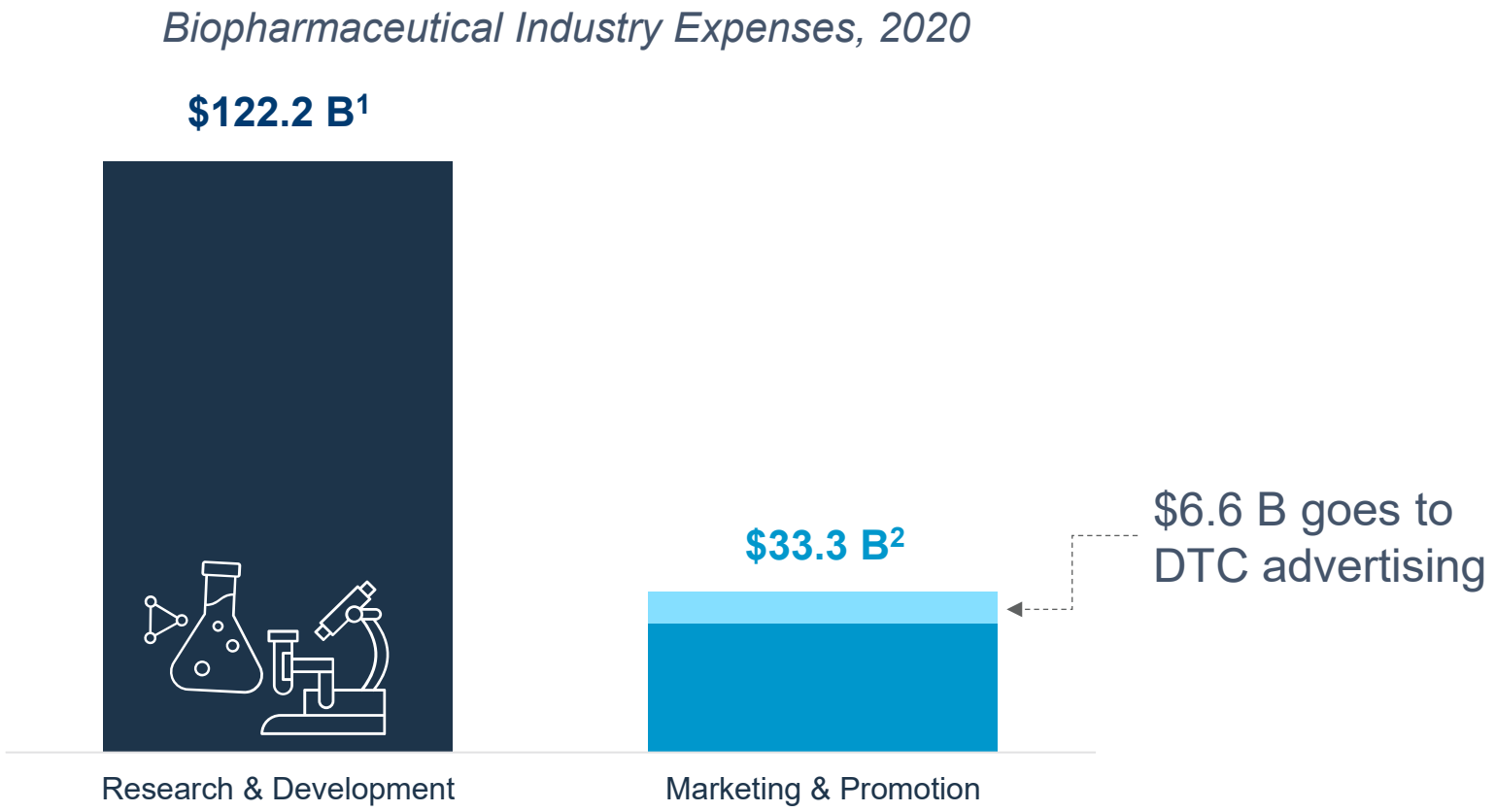
Unrelated Activities:

- Shipping and distribution
- Rent
- Office furniture and supplies
- Utilities
- Repairs of equipment
- Postage, printing, overhead and other overly broad expenses.

1. Source: https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/P-R/PhRMA_Marketing_IssueBrief.pdf

The Biopharmaceutical Industry Spends Significantly More On R&D Than On Marketing And Promotion

Comparisons of R&D versus marketing and promotion (M&P) spending often grossly overstate M&P by including unrelated expenses.



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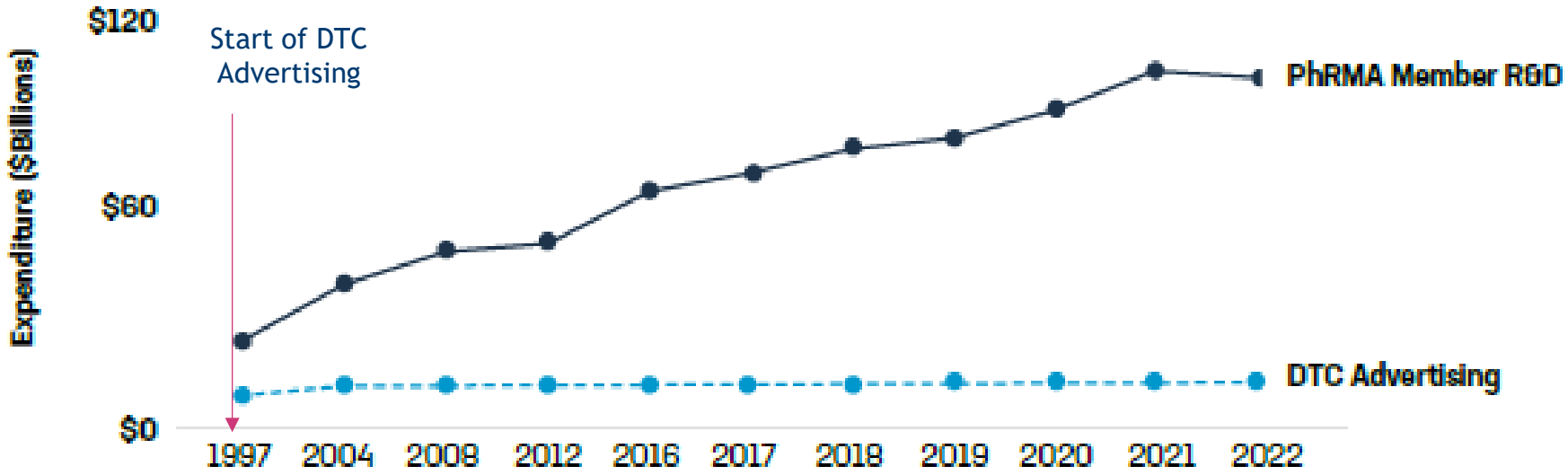
1. Research!America. U.S. Investments in Medical and Health Research and Development, 2016-2020, January 2022.
2. NDP Analytics analysis of data from Kantar Media, IQVIA, and CMS Open Payments (analysis for PhRMA applying approach from Schwartz LM, Woloshin S. Medical marketing in the United States, 1997-2016. JAMA. 2019;321(1):80-96).

R&D Spending Has Increased Significantly as DTC Advertising Investment Grew Gradually

R&D and marketing are not a zero-sum game. Biopharmaceutical R&D investment is far greater and has significantly increased over DTC advertising.



Source: PhRMA. 2023 PhRMA Annual Membership Survey (for R&D figures); Kantar Media (for DTC advertising figures). Note that DTCA includes spending on prescription drugs and disease awareness.

PhRMA
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Thank you

Questions?

First panel – drug advertising

Presenter:

- Gray Brokaw, high value health care campaign associate, OSPIRG

Questions for presenters on drug advertising?

- Michael DiStefano, Ph.D., assistant professor, Center for Pharmaceutical Outcomes Research, University of Colorado Skaggs School of Pharmacy and Pharmaceutical Sciences
- Sneha Dave, founder and executive director, Generation Patient
- Dharia McGrew, Ph.D., director, state policy, PhRMA
- Gray Brokaw, high value health care campaign associate, OSPIRG

Second panel – drug rebates

Presenters:

- Mihir Patel (he/him), PharmD, chief pharmacy officer, Regence Blue Cross Blue Shield of Oregon
- Dharia McGrew (she/her), Ph.D., director, state policy, PhRMA
- Tony Grillo (he/him), PharmD, vice president of financial analysis, Express Scripts
- Benjamin N. Rome (he/him), MD, MPH, assistant professor of medicine, Harvard Medical School and Brigham and Women's Hospital

Second panel – drug rebates

Presenter:

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

Prescription Drug Price Transparency Hearing

Mihir Patel, Chief Pharmacy Officer, Regence BlueCross BlueShield of Oregon

December 4, 2024

Regence – Who We Are

Oregon-based for more than 80 years

Regence BlueCross BlueShield of Oregon is a not-for-profit health insurer dedicated to improving the health and well-being of our members and the communities we serve.

With a rich history dating back to 1941, Regence has a long tradition of innovation, community involvement and customer satisfaction.

Regence partners with Prime Therapeutics to administer our pharmacy benefit; Prime is the pharmacy benefit manager for several not-for-profit BlueCross BlueShield plans nationwide.

Prescription drug spend

Regence BlueCross BlueShield of Oregon example

25%

25% of collected member premiums in the individual and small-group markets in 2023 were spent on prescription drugs.

$15

Regence saw per member per month overall drug spend increase by $15 from Jan. 2023 to Jan. 2024, from $110 to $125 PMPM.

$43M

In Regence's fully insured business, drug spend increased by $43 million from 2023 to 2024.

88%

88% of every member premium dollar goes directly toward member health care costs.

At Regence, 90% of drugs prescribed to our members are generic.

The remaining 10% are branded drugs (~1-2% are specialty drugs); a subset of these are eligible for manufacturer rebates.

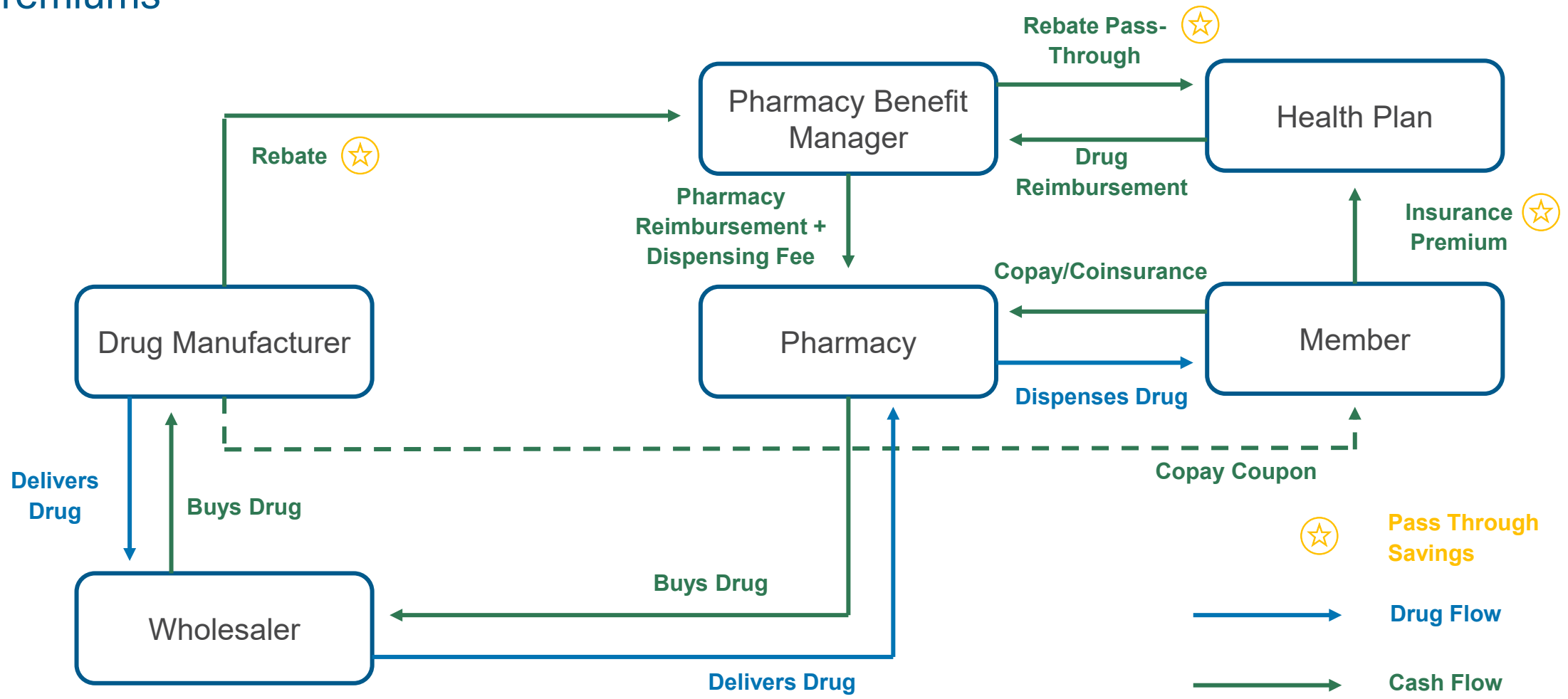
Pharmacy rebates

What they are and how they work

- Manufacturers negotiate to provide PBMs with rebates off the drug's list price.
- Drugs eligible for rebates are a select number of brand and specialty products; generics are not eligible for rebates.
- Health plans may contract with their PBM to obtain rebates on a relatively small number of costly drugs to achieve the best possible pricing on behalf of their members.
- This drives down overall costs for health plans and is directed at reducing premium costs across the membership.

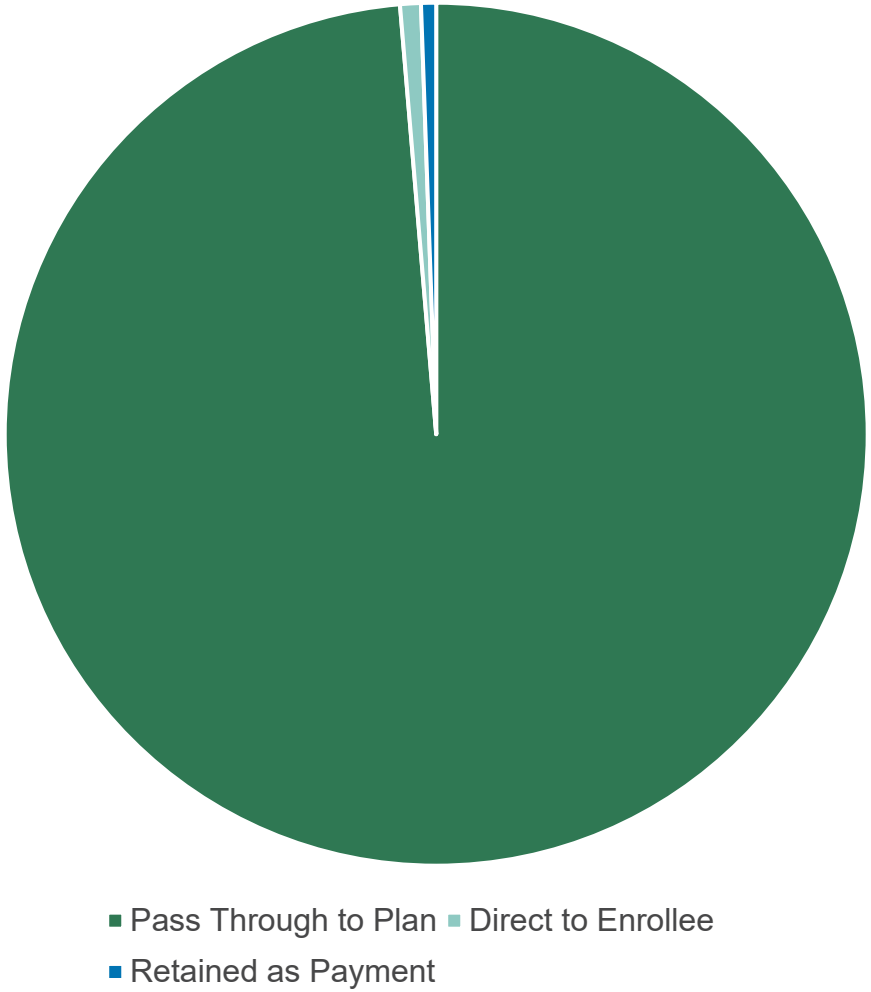
Pharmacy rebates

Where rebates fall in the flow of funds and how health plans use them to lower member premiums



Pharmacy rebates: Oregon data

Most rebates in Oregon are passed through to the plan to lower member premiums



PBMs serving Oregonians reported a total of $287.6M in rebates and other payments from manufacturers.

- 98.66% of aggregate rebates were passed through to health plan partners.
- 0.78% of aggregate rebates passed on directly to enrollees at point-of-sale.
- ~0.5% of aggregate rebates were retained by the PBMs.

This means that **99.5% of manufacturer rebates in the Oregon fully insured market are currently used to lower member cost-sharing, mostly through premiums**.

Source: https://dfr.oregon.gov/drugtransparency/Pages/DPT-pbm-data-2024.aspx

Point-of-sale rebate mandates

Impacts on consumers = increased costs

Members would receive cost savings until they hit their out-of-pocket maximum. In a pass-through model, cost savings are applied throughout the plan year.

A pass-through model, which the majority of Oregon plans already use, allows savings to be spread across the entire member pool and helps contain premium growth for all members. This makes sense because the entire pool of members also bears the cost of high-cost drugs.

Intentional plan design and supported consumer decision making can help reduce the burden of high-cost sharing for certain drugs.

Many members on rebate-eligible drugs are also eligible for coupons to help them meet their cost-share obligation.

Thank you

We are happy to take any questions.

Regence 

Second panel – drug rebates

Presenter:

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

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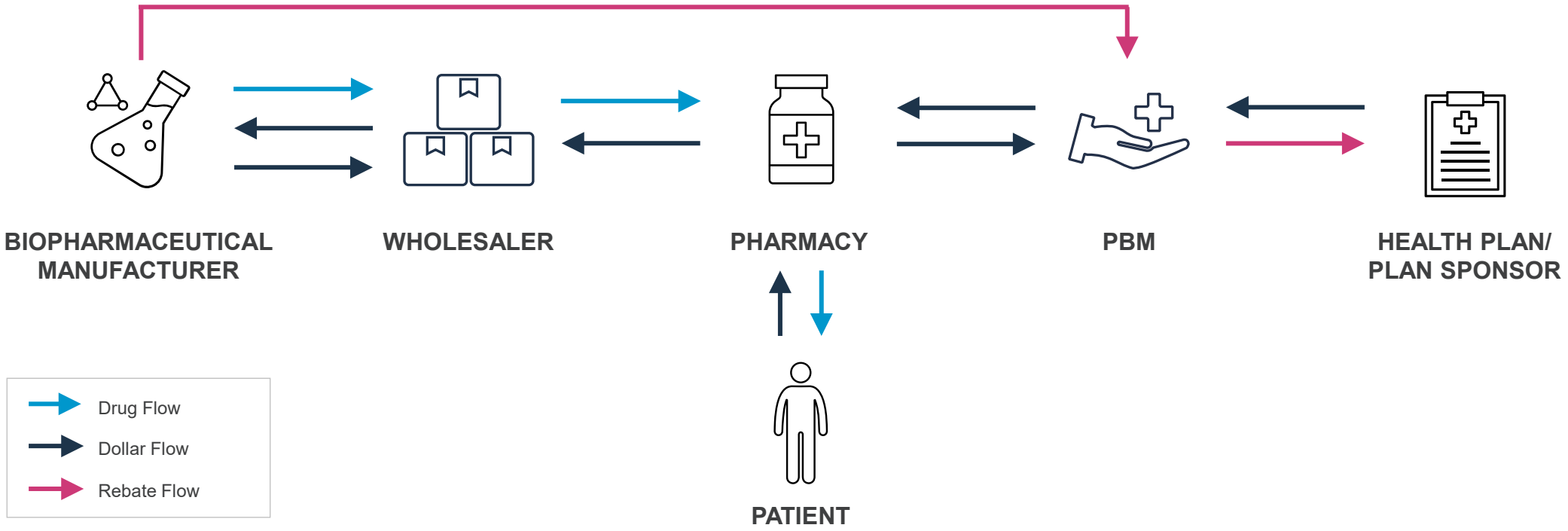
Annual Hearing on Drug Prices

Dharia McGrew, PhD
Director, State Policy
PhRMA

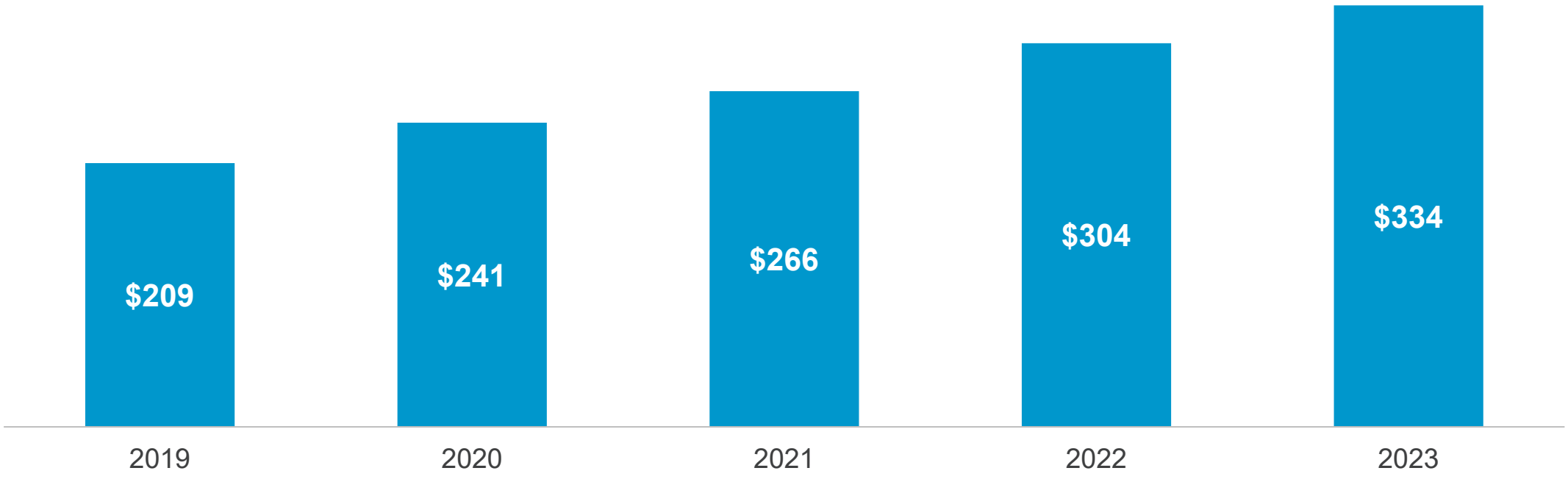
Many Stakeholders Have a Role in the Prescription Medicine Supply Chain



Source: PhRMA, Nov 2017. *Follow the Dollar: Understanding How the Pharmaceutical Distribution and Payment System Shapes the Prices of Brand Medicines.*

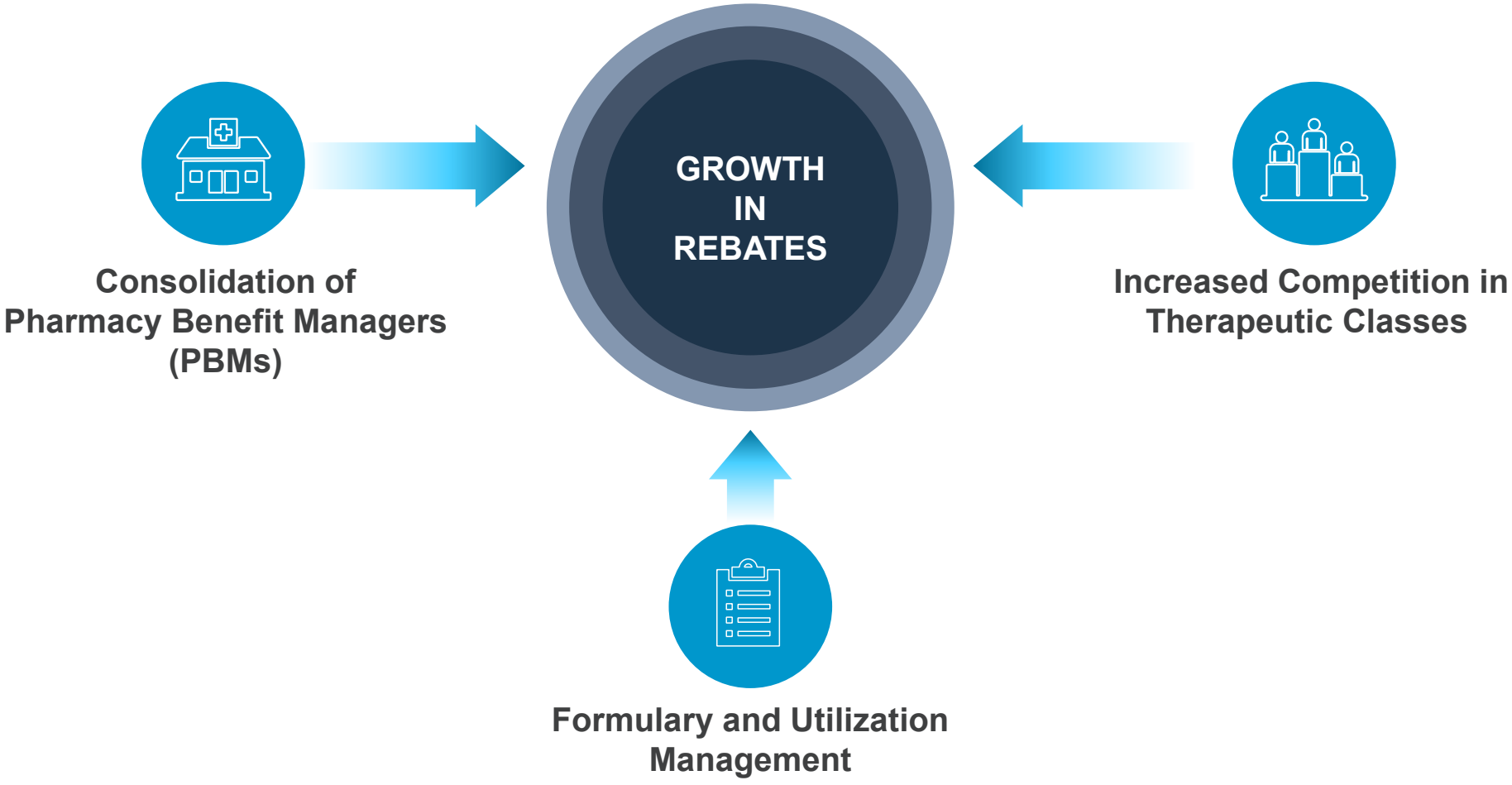
Rebates and Other Manufacturer Price Concessions Continue to Expand Year Over Year

Total Value of Manufacturers' Gross-to-Net Reductions for Brand Name Drugs ($B), 2019-2023



Note: Chart includes brand drugs both with and without patent protection.
Source: Fein, A. "The Gross to Net Bubble Reached $334 Billion in 2023 – But Will Soon start Deflating. July 2024. https://www.drugchannels.net/2024/07/pbm-power-gross-to-net-bubble-reached.html#:~:text=More%20than%20half%20of%20the,gross%2Dto%2Dnet%20reductions.

A Range of Factors Has Contributed to the Increasing Role of Rebates in the Medicine Supply Chain



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The Influence Pharmacy Benefit Managers (PBMs) Have Over Patient Access and Affordability Continues to Grow

Negotiating power is increasingly concentrated among a small number of PBMs.

Insurers & PBMs determine:

IF MEDICINE IS COVERED
on the formulary

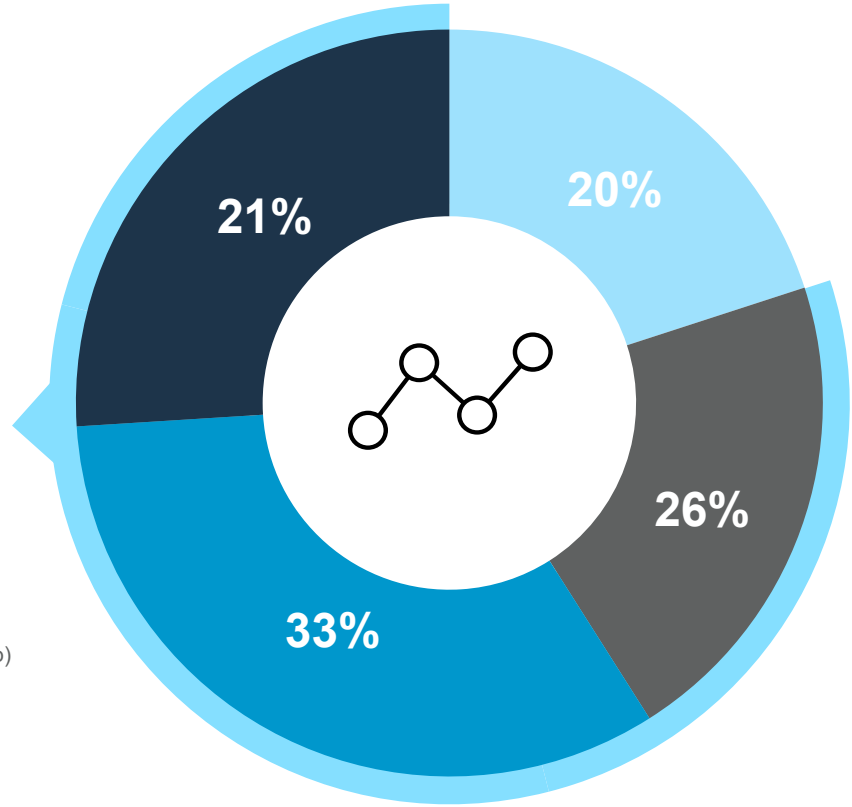
PATIENT OUT-OF-POCKET COST
based on tier placement

ACCESS BARRIERS
like prior authorization or fail first

PROVIDER INCENTIVES
through preferred treatment guidelines and pathways

Top 3 PBMs' Market Share:

80%



Source: Drug Channels Institute, March 2022.

According to Experts, PBMs May Have Incentives to Prefer Medicines with Higher List Prices and Large Rebates

Public sources have noted that manufacturer efforts to reduce list prices have been met with significant headwinds by PBMs

Contract terms that discourage list price reductions

Source: Gal A, Wilkes L, Chen A, et al. Bernstein Research. February 8, 2019.

Demand letters from PBMs requiring additional payments in the event of list price decreases

Source: Sagonowsky E. "UnitedHealthcare demands drug rebates even if pharma cuts list prices: analyst," February 2019. https://www.fiercepharma.com/pharma/letter-to-pharmas-unitedhealthcare-seeks-to-protect-drug-rebates-from-price-reductions

Excluding lower list price versions of brand medicines from formularies in favor of higher list price versions

Sources:
1. 2022 Prescription Drug List." UnitedHealthcare & Affiliated Companies. https://www.uhcprovider.com/content/dam/provider/docs/public/resources/pharmacy/pdl-commercial-effective-jan-2022.pdf; 2. 2022 National Preferred Formulary Exclusions." Express Scripts. March 22, 2022. https://www.express-scripts.com/art/pdf/NPF_Preferred_Formulary_Exclusions2022.pdf

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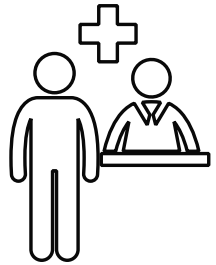
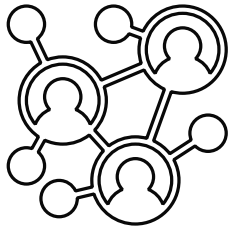
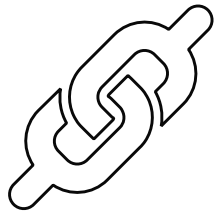
How Could the Current Rebate System Work Better for Patients and Payers?



Share rebate savings directly with patients at the pharmacy counter.



Address PBMs' incentives to cover medicines with high list prices and large rebates.



End price-based compensation for supply chain middlemen.

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Thank you

Questions?

Second panel – drug rebates

Presenter:

- Tony Grillo, PharmD, vice president of financial analysis, Express Scripts

Second panel – drug rebates

Presenter:

- Benjamin N. Rome, MD, MPH, assistant professor of medicine, Harvard Medical School and Brigham and Women’s Hospital

PORTAL
Program on Regulation, Therapeutics, And Law

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Oregon Prescription Drug Prices Public Hearing | December 4, 2024

Understanding Prescription Drug Rebates and Pharmacy Benefit Managers

Benjamin N. Rome, MD, MPH

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Program on Regulation, Therapeutics, and Law (PORTAL)
Division of Pharmacoepidemiology and Pharmacoeconomics
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Disclosures

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  - The Greenwall Foundation
  - The Elevance Public Policy Institute
  - The National Academy for State Health Policy
  - Colorado and Washington Prescription Drug Affordability Boards

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

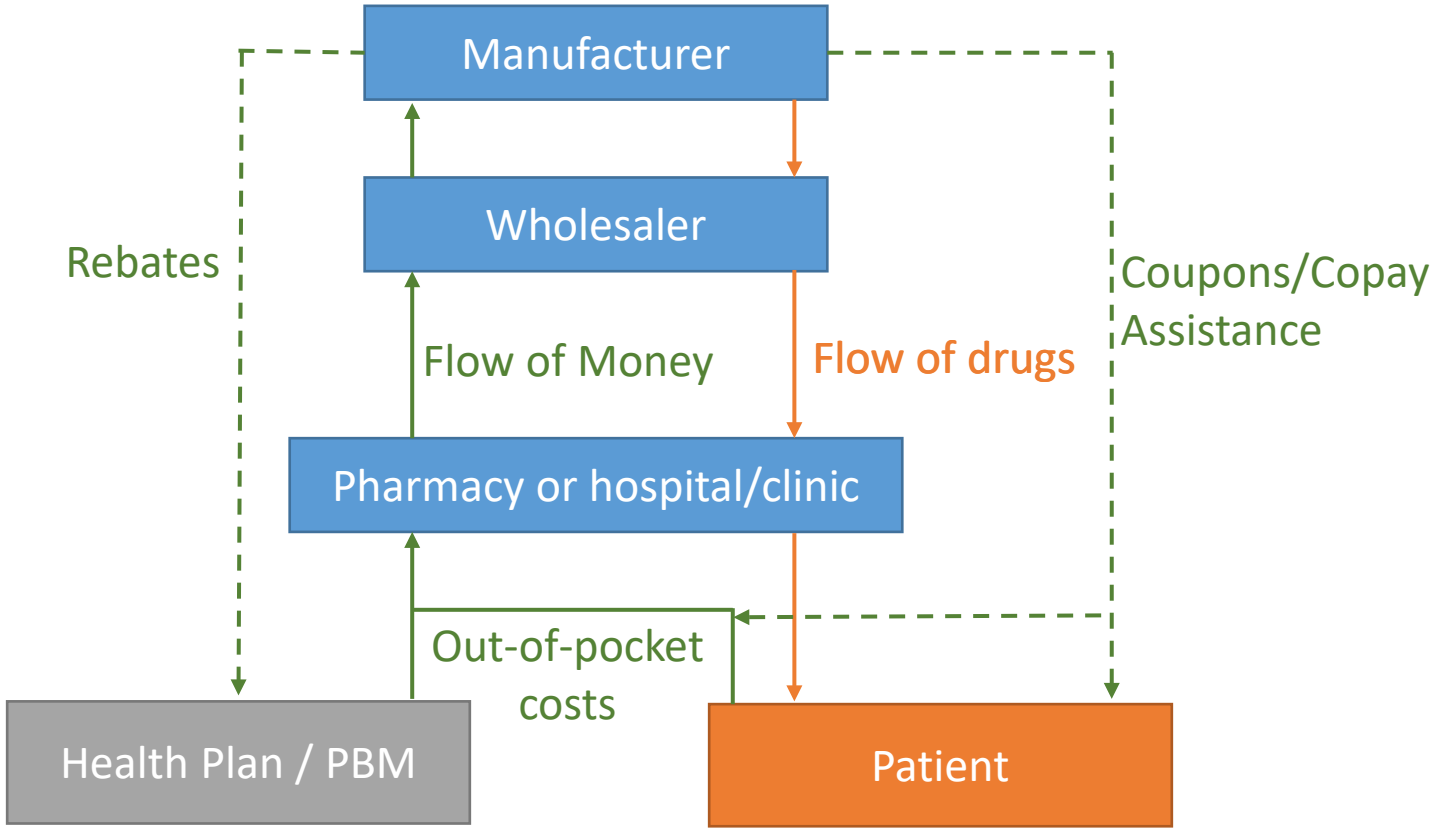
Supply Chain Overview

1. Drug manufacturers set the **list price**

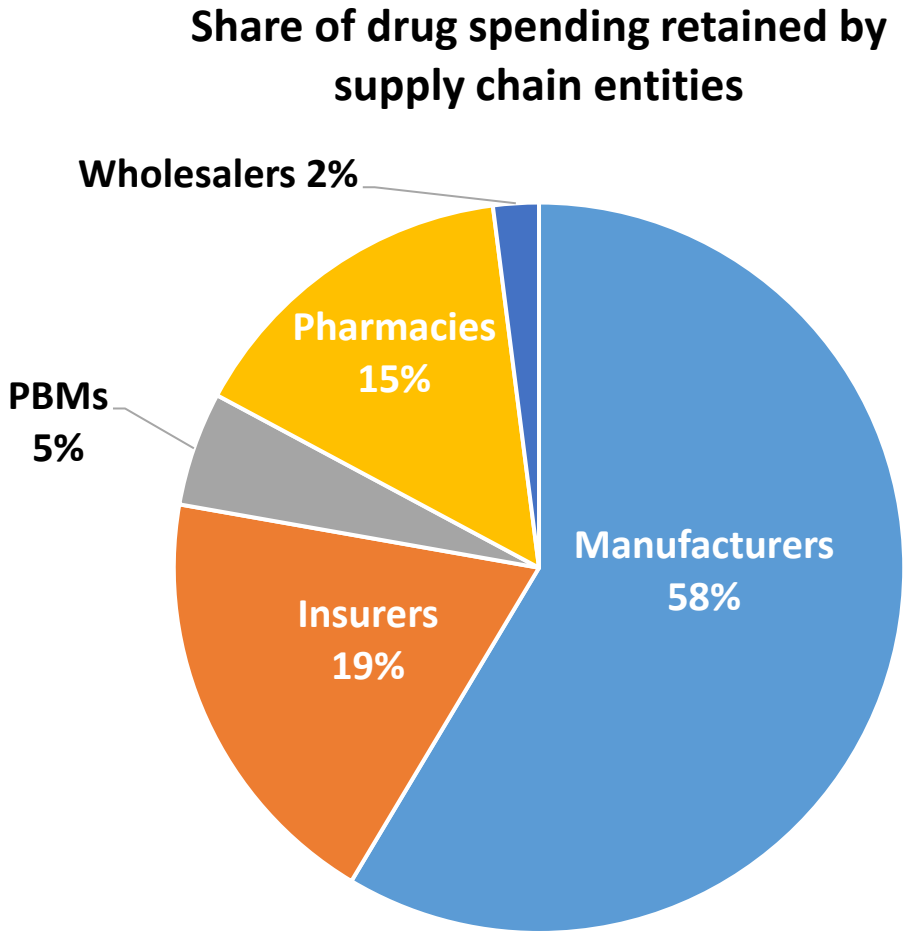
2. Health plans or pharmacy benefit managers (PBMs) set the formulary and **out-of-pocket costs**

3. Health plans / PBMs negotiate **rebates** in exchange for formulary access and preferred position
   - **Net price** = list price - rebates

4. Drug manufacturers offer **coupons** to offset out-of-pocket costs charged by insurance.



Cash Flow in the Supply Chain



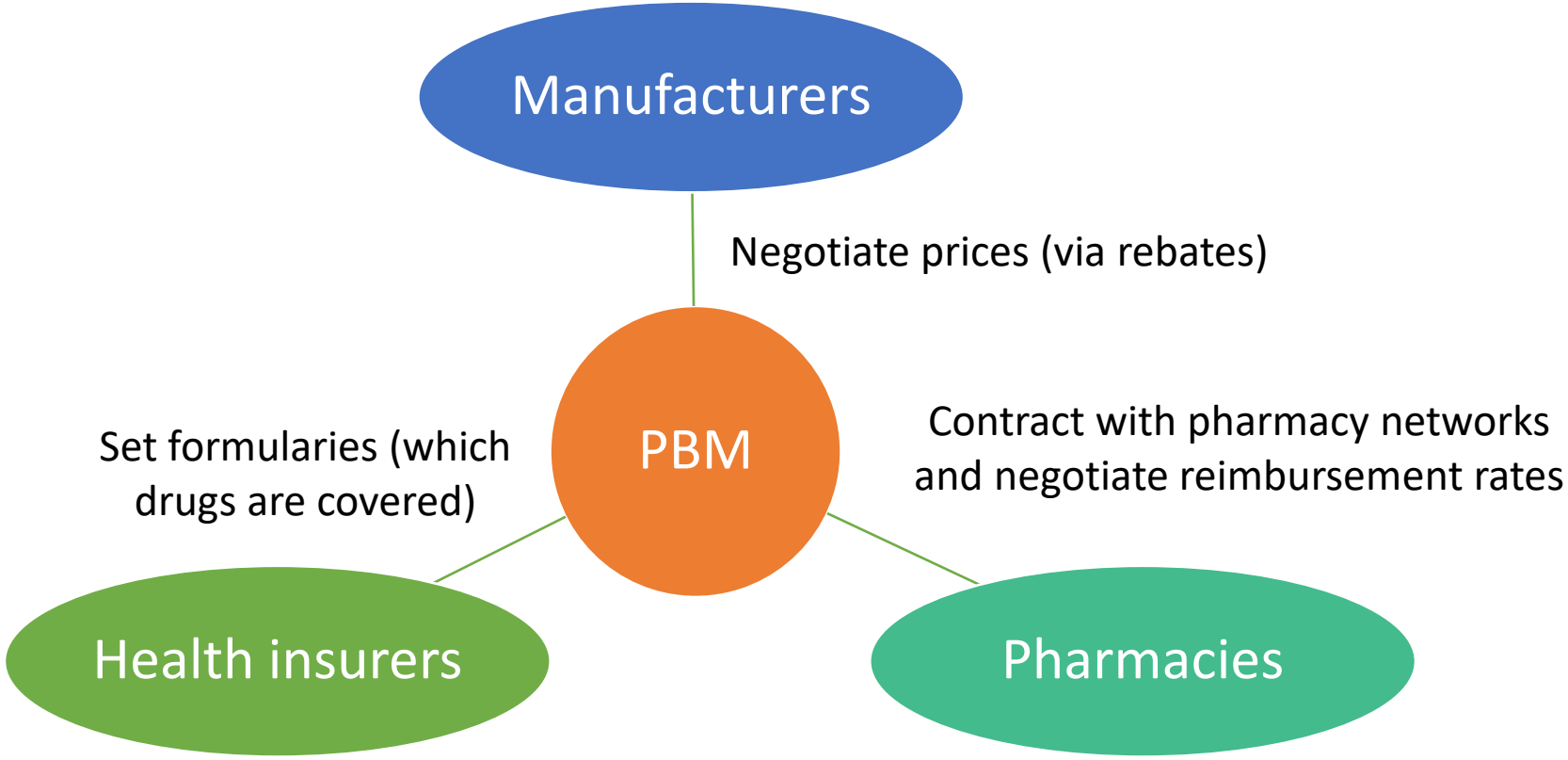
Manufacturers keep a higher share of US health care system money spent on brand-name drugs:

- **Brand-Name drugs:** 76%
- **Generics:** 35%

Sood, Shih, Van Nuys, Goldman. USC Schaeffer Center. 2017.

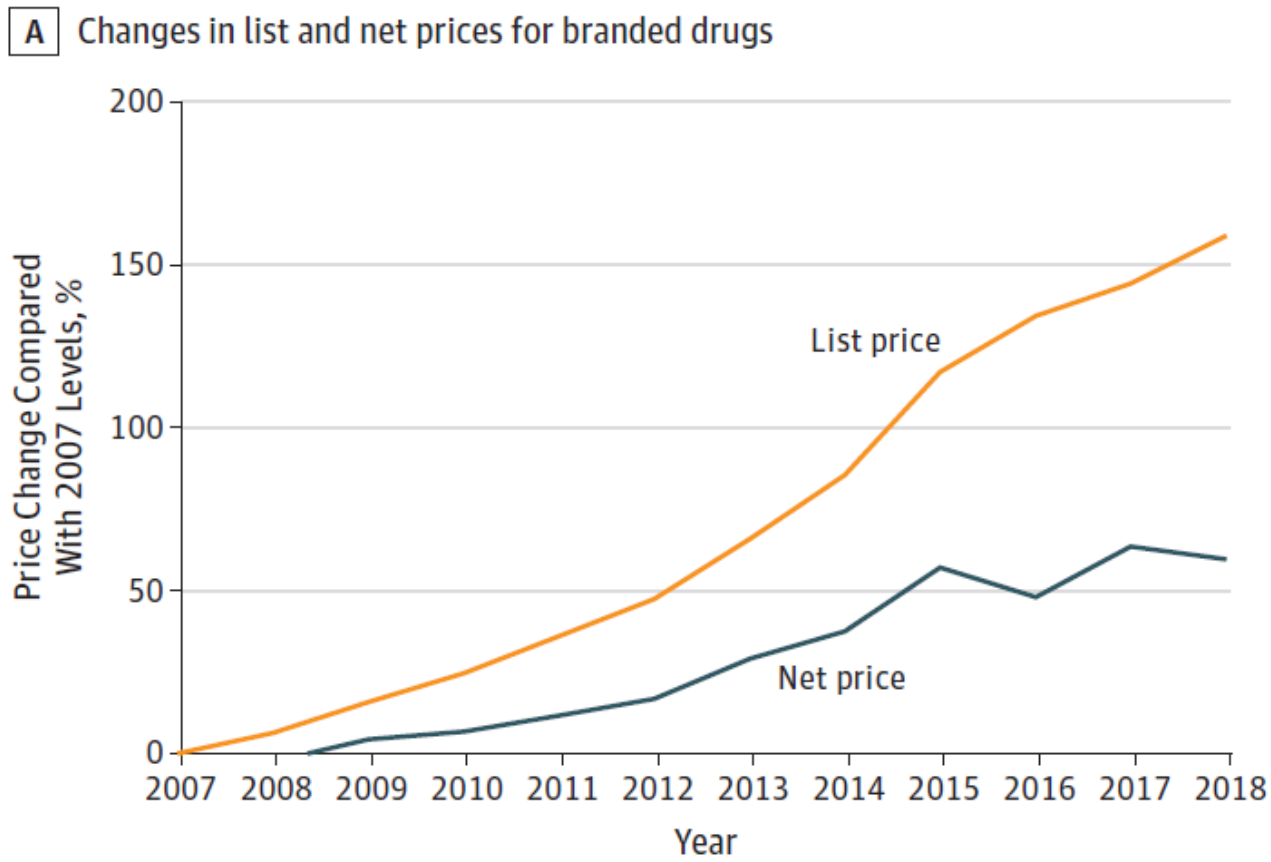
Pharmacy Benefit Managers (PBMs)

Most public and private insurers contract with PBMs to manage their prescription drug benefits and negotiate with manufacturers and pharmacies.



Cai, Rome. *New Eng J Med*. 2023.

Rebates have grown over time, leading to a large gap between list and net prices.



9.1%/year

4.5%/year

Inmacula Hernandez, et al. *JAMA*. 2020.

The size of rebates varies by drug type.

Chart 10-22 **Top 15 therapeutic classes of drugs covered under Part D, by spending, 2022**

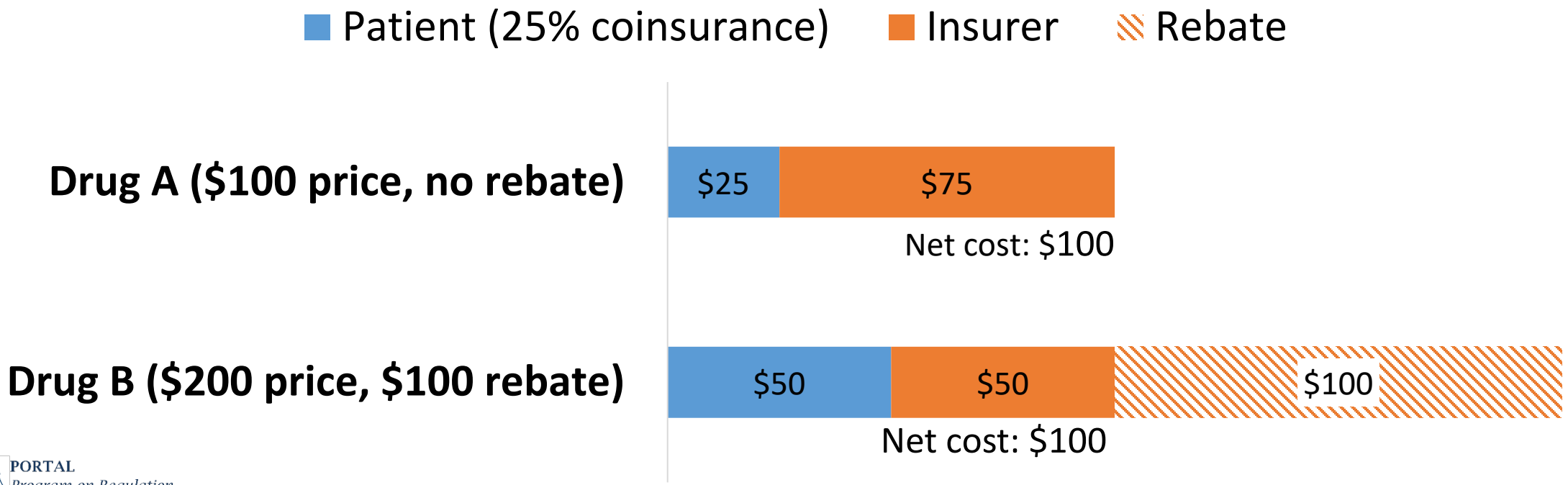
	Gross spending		Negotiated rebates as a share of gross spending	Coverage-gap discount (billions)
	Billions	Percent		
Diabetic therapy	$46.9	19.5%	≥50%	$6.2
* Antineoplastics	32.1	13.4	<10%	0.9
Anticoagulants	21.7	9.0	40% to 49%	3.5
Asthma/COPD therapy agents	16.6	6.9	40% to 49%	1.4
Disease-modifying anti-rheumatoid drugs	11.9	4.9	20% to 29%	0.4
* Antipsychotics (neuroleptics)	8.4	3.5	10% to 19%	0.1
* Antiretrovirals	7.9	3.3	<10%	0.2
Antihypertensive therapy agents	7.6	3.2	10% to 19%	0.5
Ophthalmic agents	5.9	2.5	30% to 39%	0.4
Antihyperlipidemics	5.4	2.3	10% to 19%	0.3
Dermatological (antipsoriatics)	5.2	2.2	10% to 19%	0.1
* Anticonvulsants	4.1	1.7	<10%	0.1
Multiple sclerosis agents	3.9	1.6	10% to 19%	0.1
* Antidepressants	3.0	1.3	<10%	0.1
Urinary incontinence treatment agents	3.0	1.3	40% to 49%	0.3
Subtotal, top 15 drug classes	183.9	76.5	28%	14.6
Total, all drug classes	240.5	100.0	24%	16.4

* Protected class drugs (required coverage)

MedPAC July 2024 Data Book.

Rebates can lead to higher costs for patients.

Rebates offset health plan spending and translate to lower premiums…but they do not lower patient out-of-pocket costs



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Rome, Feldman, Desai, et al. *JAMA Netw Open*. 2021.

Policy goals related to PBMs and Rebates

Improve **transparency** of supply chain and drug costs.

Maintain ability and incentives for PBMs to **aggressively negotiate** with drug manufacturers.

Remove **perverse incentives** to favor high-price/high-rebate drugs over lower priced drugs.

Protect patients from paying out-of-pocket costs based on artificially inflated list prices.

Cai, Rome. *NEJM*. 2023.
Rome. J Law Med Ethics. 2024.

Thank you!

- Looking forward to questions and discussion.

Questions for presenters on drug rebates?

- Mihir Patel, PharmD, chief pharmacy officer, Regence Blue Cross Blue Shield of Oregon
- Dharia McGrew, Ph.D., director, state policy, PhRMA
- Tony Grillo, PharmD, vice president of financial analysis, Express Scripts
- Benjamin N. Rome, MD, MPH, assistant professor of medicine, Harvard Medical School and Brigham and Women's Hospital

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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