

Oregon Prescription Drug Price Transparency Program

Annual Hearing: Wednesday, Dec. 16, 2020

Members of the Public who wish to provide testimony may sign up by typing a message in the chat box.



Statutory authority

Oregon Drug Price Transparency Act (2018 HB 4005)

- Creation of the program

Advance notice of price increases (2019 HB 2658)

- Additional reporting requirement

Program goals:

Price transparency

- Accountability for prescription drug pricing

Make policy recommendations

- Reduce effect on consumers and on state programs

Price transparency:

The program collects information from:

- **Drug manufacturers**
- **Health insurance companies**
- **Oregon consumers**

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Implementation challenges:

IT development

- Drug price transparency website

Data quality

- Data submitted by drug manufacturers

Data for 2019, 2020 – Limitations

All data is preliminary due to:

- **Ongoing compliance work**
- **Ongoing follow-up inquiries**
- **Ongoing trade secret analysis**

Data for 2019, 2020 – Things to know

- Analysis done by “Product Family”
- Aggregated data and trade secrets

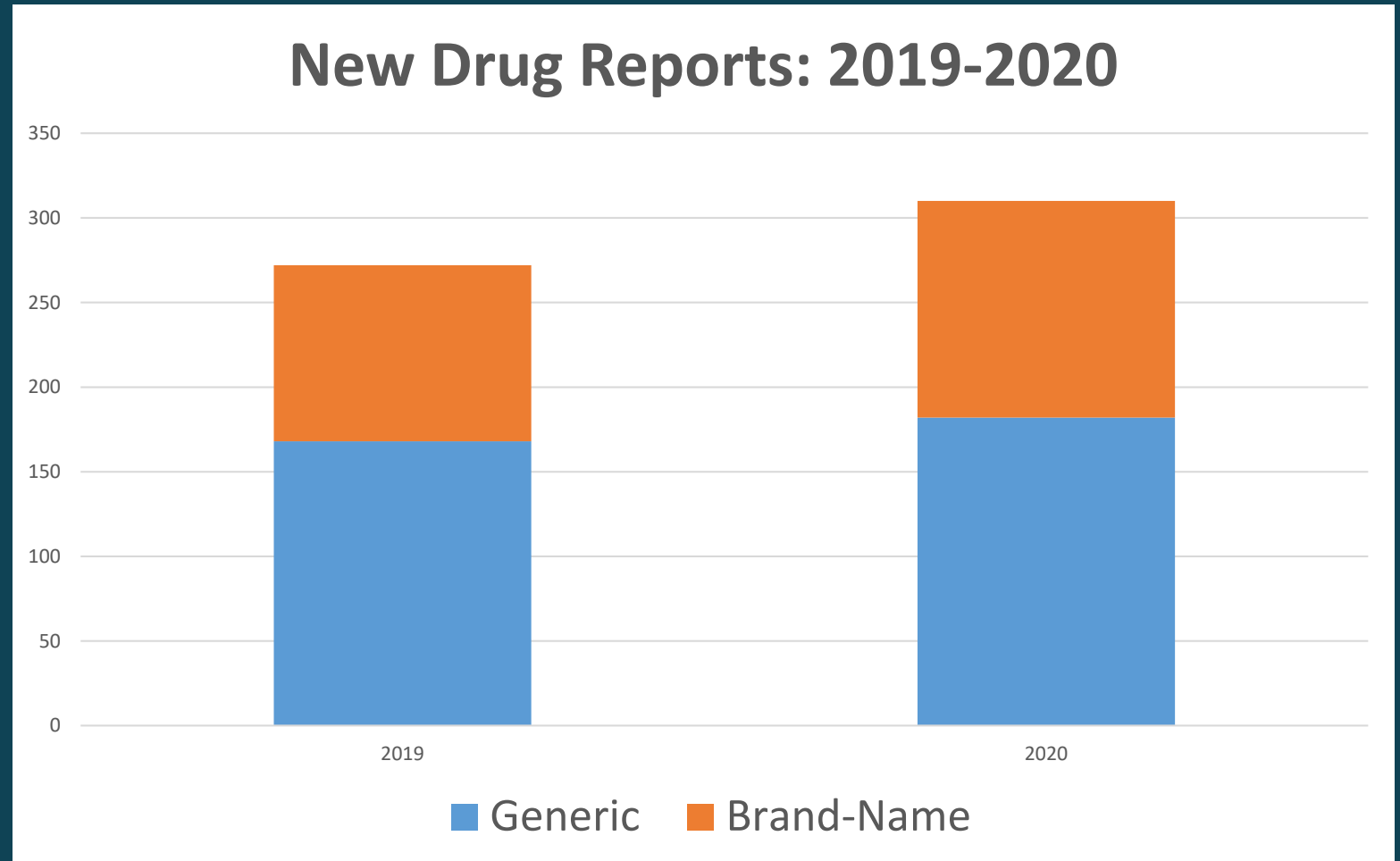
New specialty drug reports

2019

- 272 NDCs
- 168 generic (62%)
- 104 branded (38%)

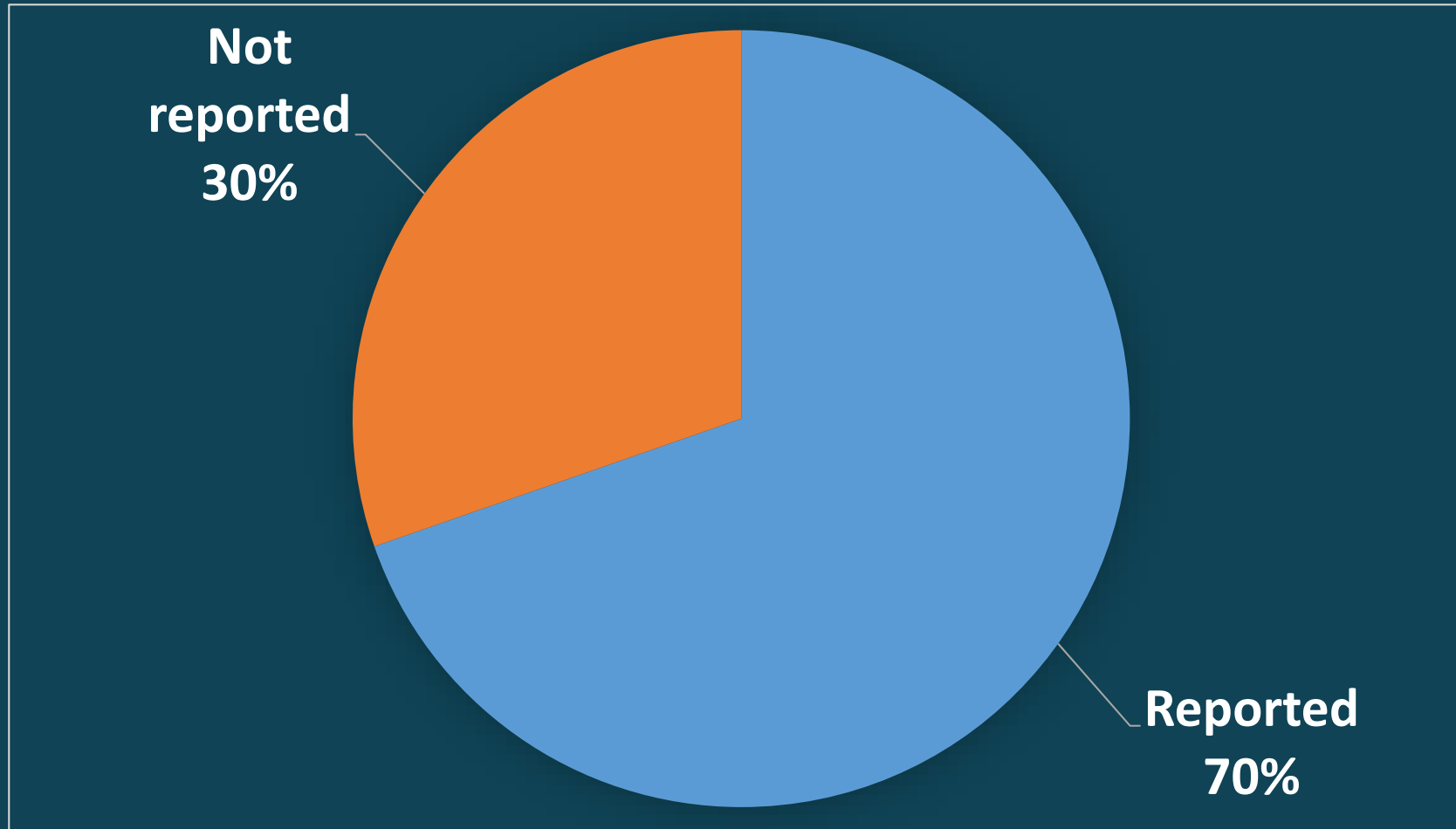
2020

- 310 NDCs (+15%)
- 182 generic (59%)
- 128 branded (41%)



Source: Oregon Drug Price Transparency Program. Preliminary data, subject to change.

New specialty drug reports – Estimated compliance



Source: Oregon Drug Price Transparency Program. Preliminary data, subject to change.

New specialty drug reports

- **Veklury (remdesivir)**: approved for treatment of severe COVID-19. 5-day, 6-vial course costs up to \$3,120
- **Tecartus**: CAR-T treatment indicated for cancer WAC price of \$373,000
- **Pyrimethamine (generic Daraprim)**: generic anti-parasitic drug introduced at a WAC price of \$29,250

Source: Oregon Drug Price Transparency Program. Preliminary data, subject to change.

Early Data for 2019, 2020: New Specialty Drugs

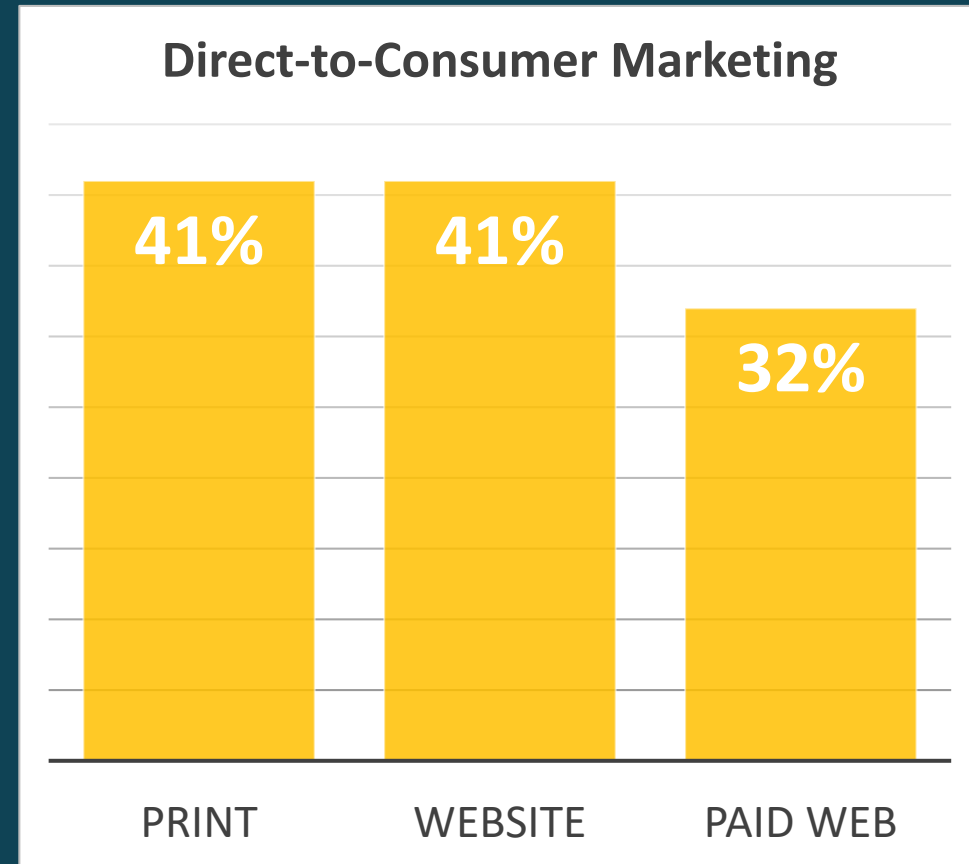
An example of “Marketing Description”:

XPOVIO[®] was approved by the FDA in July 2019 for the treatment of adult patients with relapsed or refractory multiple myeloma. On June 22, 2020, FDA approved XPOVIO[®] for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma. To market this new indication, Karyopharm designed activities to increase awareness and understanding with healthcare providers about the change to the FDA approved label. Marketing activities are planned to include education and training provided by our existing sales force and by contracted speakers to health care providers (HCPs), an updated XPOVIO[®] website, and other digital and print advertising for HCPs. Patient educational materials will also be provided to HCPs but, with the exception of the XPOVIO[®] website, no further direct-to-consumer advertising is planned. Karyopharm will offer a patient assistance program to qualifying patients.

Submitted by Karyopharm Therapeutics for NDC 72237010103, launched at a list price of \$22,000. Not claimed as a trade secret.

New specialty drug reports

Marketing themes



Source: Oregon Drug Price Transparency Program. Preliminary data, subject to change.

New Specialty Drugs

An example of “Pricing Methodology”:

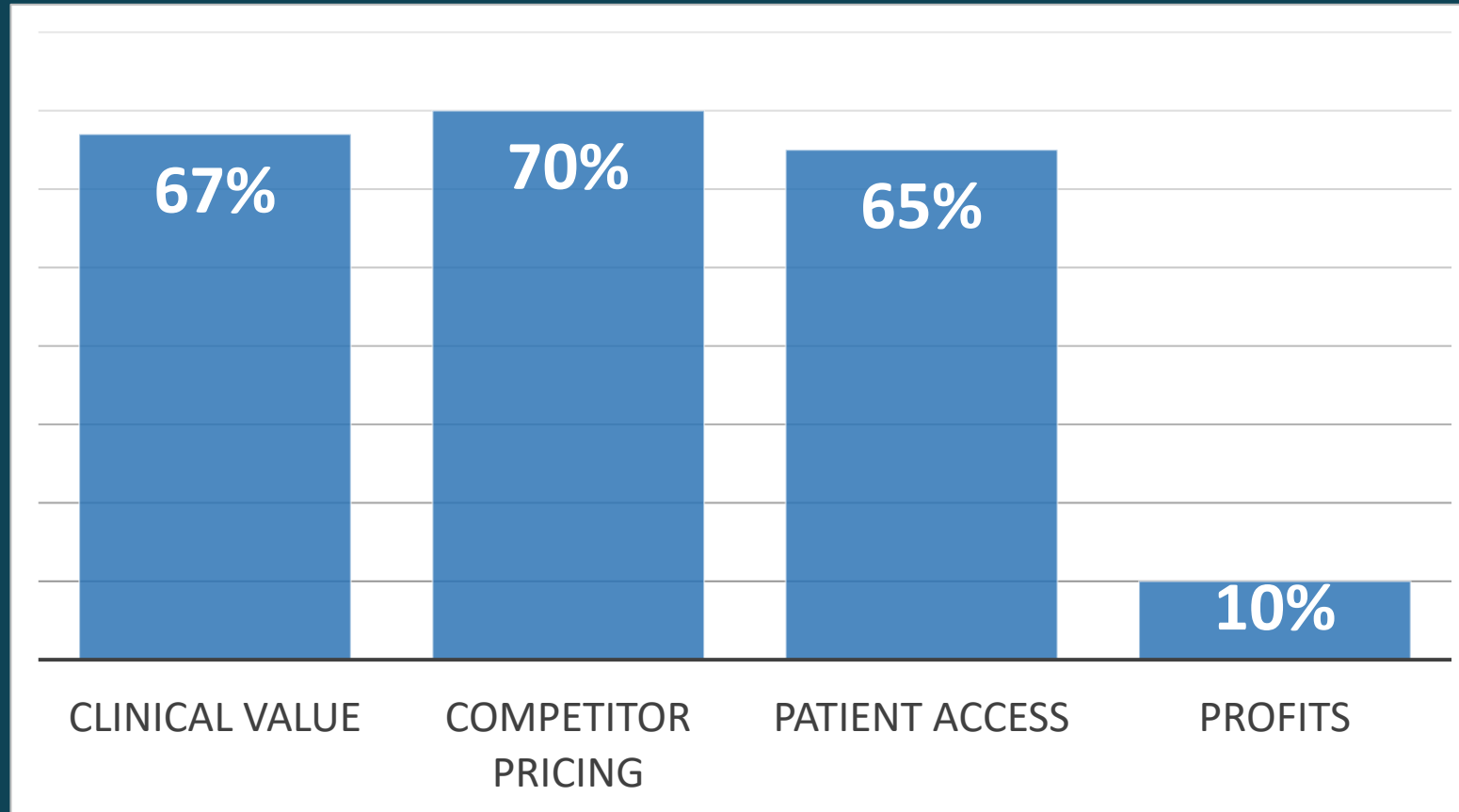
“We consider multiple factors when setting a list price for a medicine, including:

- The benefits the medicine brings to patients, healthcare systems and society - in terms of clinical outcomes and quality of life, longevity of life, and savings generated for other parts of the healthcare system such as reduced hospitalization and treatment costs.
- Market and business considerations, including:
- Ongoing research-investment costs; BMS invests more than 35% of its annual revenues in R&D, among the highest of any large company in any industry in the world;
- Medical- and patient-service costs; this includes funding growing patient assistance programs;
- Inflationary and capital-investment costs associated with manufacturing, storage and supply.”

Submitted by Bristol Meyers Squibb for NDC 59572073014, launched at a list price of \$21,158. Not claimed as a trade secret. ONUREG is a treatment for acute myeloid leukemia after chemotherapy.

New specialty drug reports

Pricing themes



Source: Oregon Drug Price Transparency Program. Preliminary data, subject to change.

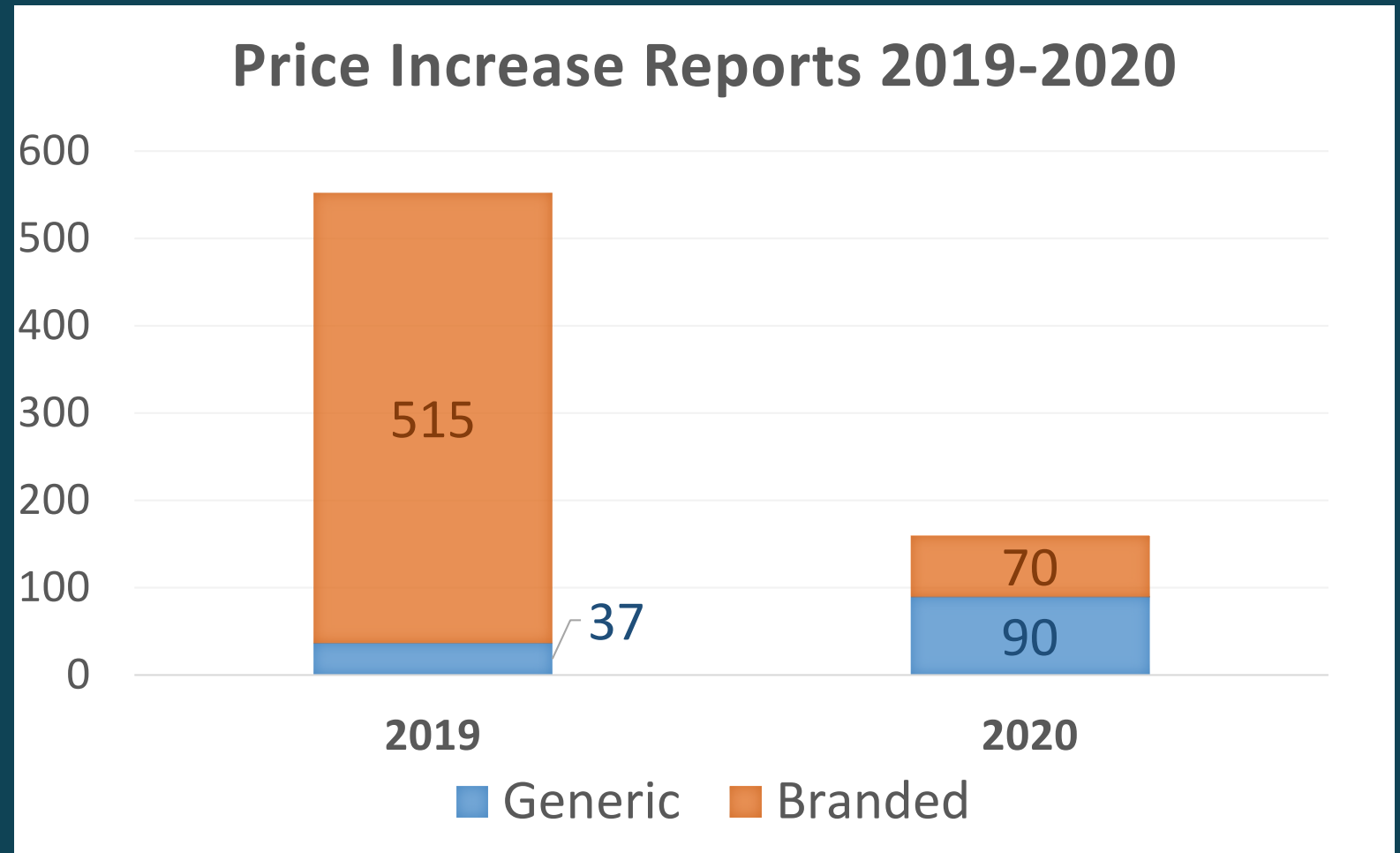
Price increase reports

2019

- 551 NDCs
- 37 generic (7%)
- 515 branded (93%)

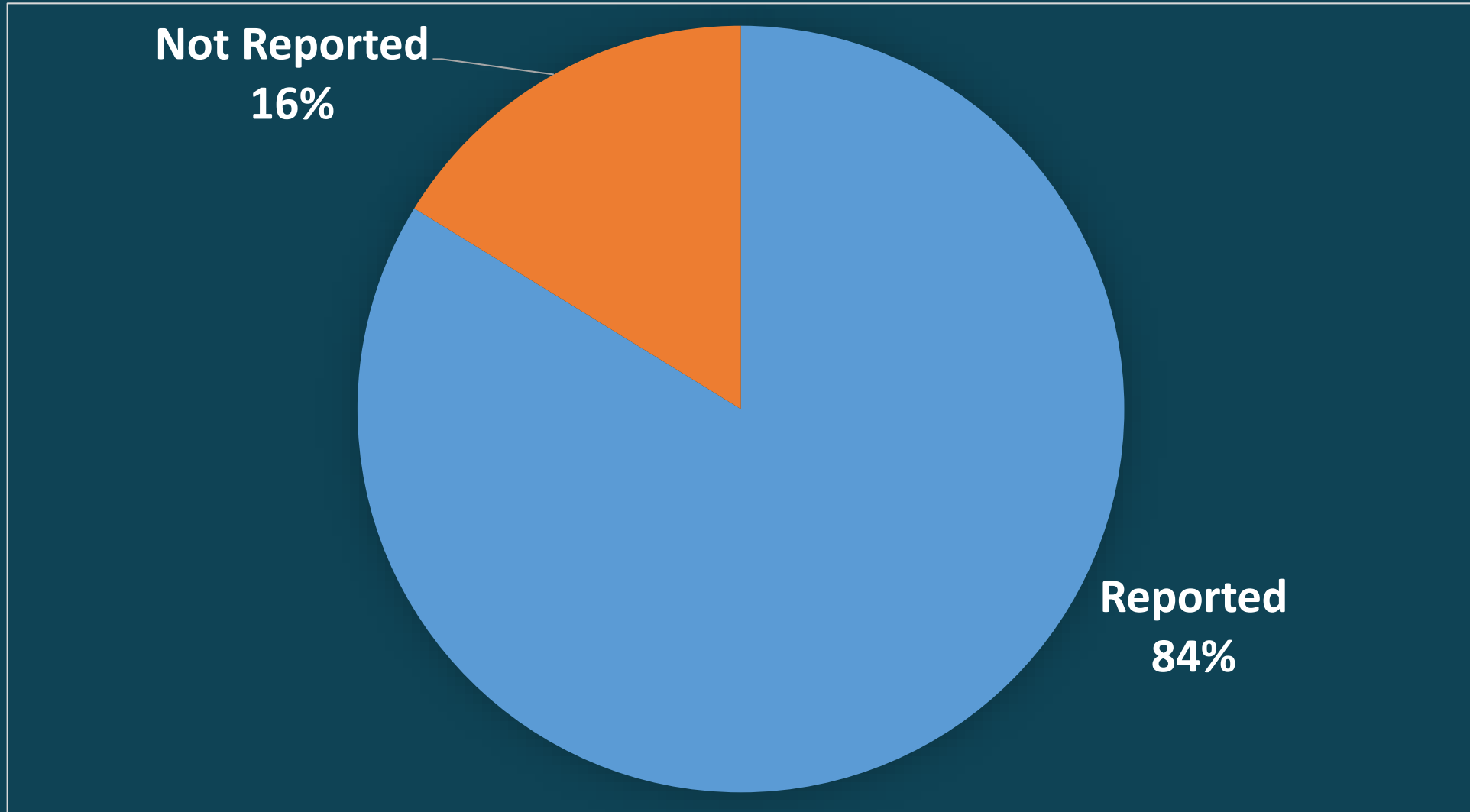
2020

- 160 NDCs (-70%)
- 90 generic (66%)
- 70 branded (44%)



Source: Oregon Drug Price Transparency Program. Preliminary data, subject to change.

Price increase reports - Compliance



Source: Oregon Drug Price Transparency Program. Preliminary data, subject to change.

Price Increase Reports

An example of a narrative submission for a price increase:

“Cosette Pharmaceuticals acquired this product in June of 2019. When we looked at the pricing of this product, as we do with all of our products, we carefully and holistically evaluated a variety of factors including accessibility and affordability of this treatment option for both patients and payors, the number of patients who take the product, the market conditions, the overall increase in the cost of labor and goods, the required capital investment in manufacturing facilities and systems, and the funding of research and new product development designed to meet the needs of patients and healthcare professionals today and in the future. In this instance, the price had to be adjusted in light of the declining net utilization, increase in cost of labor and goods, and financial costs and debt incurred with acquiring the product.”

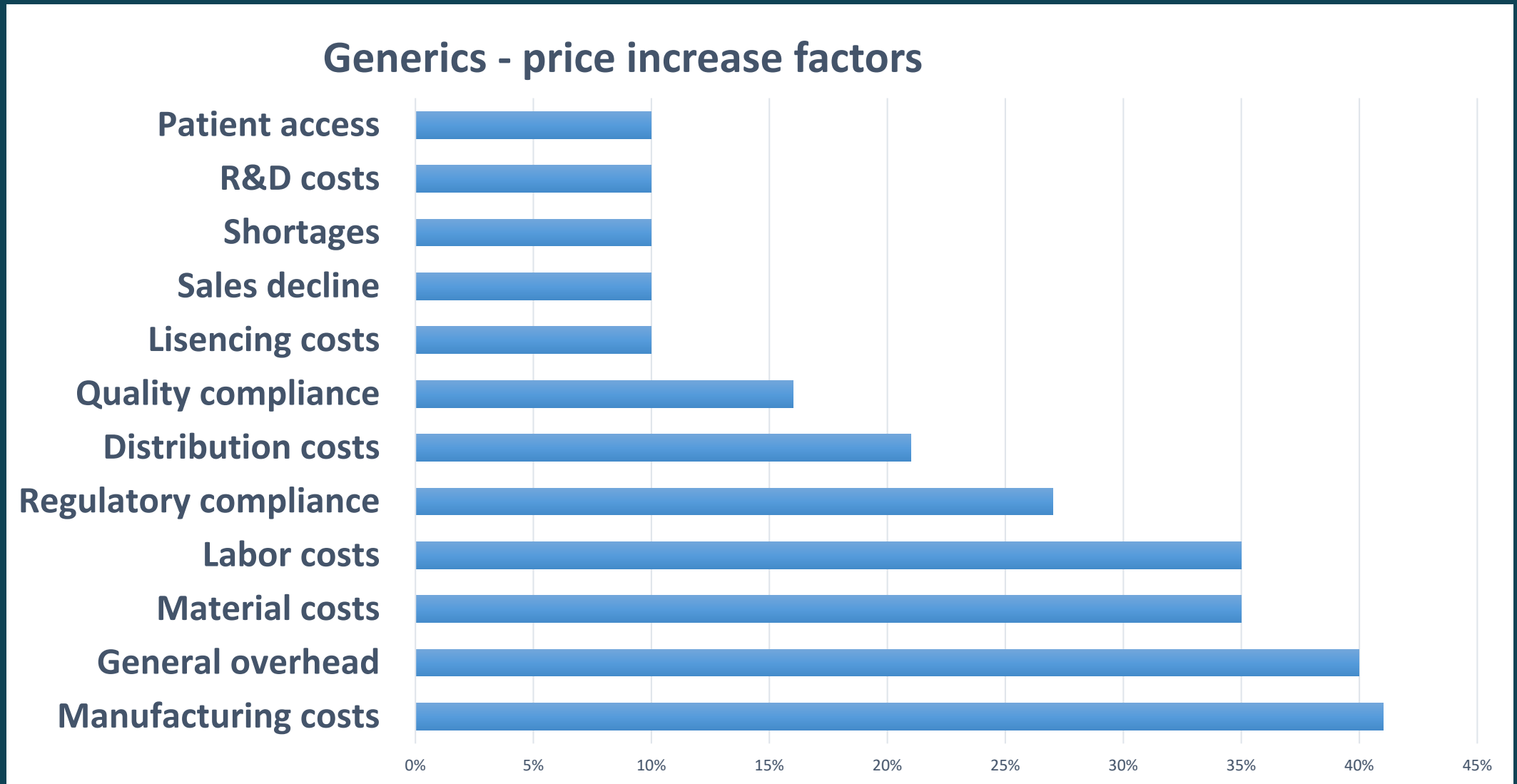
Narrative explanation of price increase of 17% for NDC 00713016612. Not claimed as a trade secret.

Price increase reports



Source: Oregon Drug Price Transparency Program. Preliminary data, subject to change.

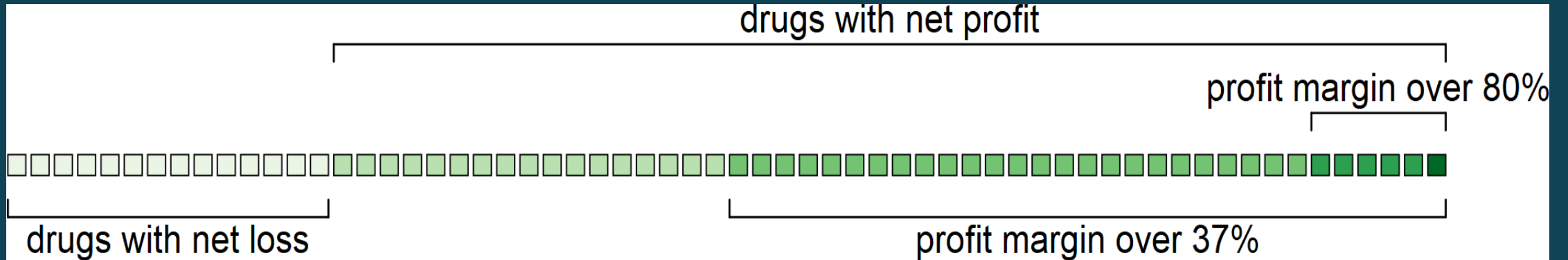
Price increase reports



Source: Oregon Drug Price Transparency Program. Preliminary data, subject to change.

Price increase reports

Drug manufacturer profit and revenue



Source: Oregon Drug Price Transparency Program. Preliminary data, subject to change.

Insurer reports

10 most expensive branded drugs per prescription

Drug	Used to treat	Avg Spent per Prescription
Yervoy	Cancer	\$43,525
Ocrevus	Multiple sclerosis	\$39,701
Soliris	Blood disease	\$34,985
Kalydeco	Cystic fibrosis	\$24,154
Trikafta	Cystic fibrosis	\$23,362
Symdeko	Cystic fibrosis	\$22,513
Keytruda	Cancer	\$15,613
Revlimid	Cancer	\$15,001
Xyrem	Narcolepsy	\$12,643
Mavyret	Hepatitis C	\$12,565

Source: Oregon Drug Price Transparency Program. Preliminary data, subject to change.

Insurer reports

10 most expensive generic drugs per prescription

Generic drug	Used to treat	Avg cost per prescription
Glatiramer	Multiple sclerosis	\$2,804
Temozolomide	Cancer	\$2,661
Lanthanum	Kidney disease	\$1,552
Phytonadione	Blood clotting	\$1,426
Imatinib	Cancer	\$1,218

Source: Oregon Drug Price Transparency Program. Preliminary data, subject to change.

Insurer reports

10 most costly branded drugs

Drug	Used to treat	Amount spent by insurance companies
Humira	Rheumatoid arthritis	\$80,509,117
Enbrel	Rheumatoid arthritis	\$33,771,085
Stelara	Crohn's disease	\$23,399,682
Truvada	HIV and hepatitis B	\$20,608,725
Biktarvy	HIV	\$18,042,219
Rituxan	Cancer	\$16,983,505
Cosentyx	Arthritis	\$15,746,169
Herceptin	Cancer	\$14,072,476
Remicade	Rheumatoid arthritis	\$13,635,198
Opdivo	Cancer	\$13,532,849

Source: Oregon Drug Price Transparency Program. Preliminary data, subject to change.

Insurer reports

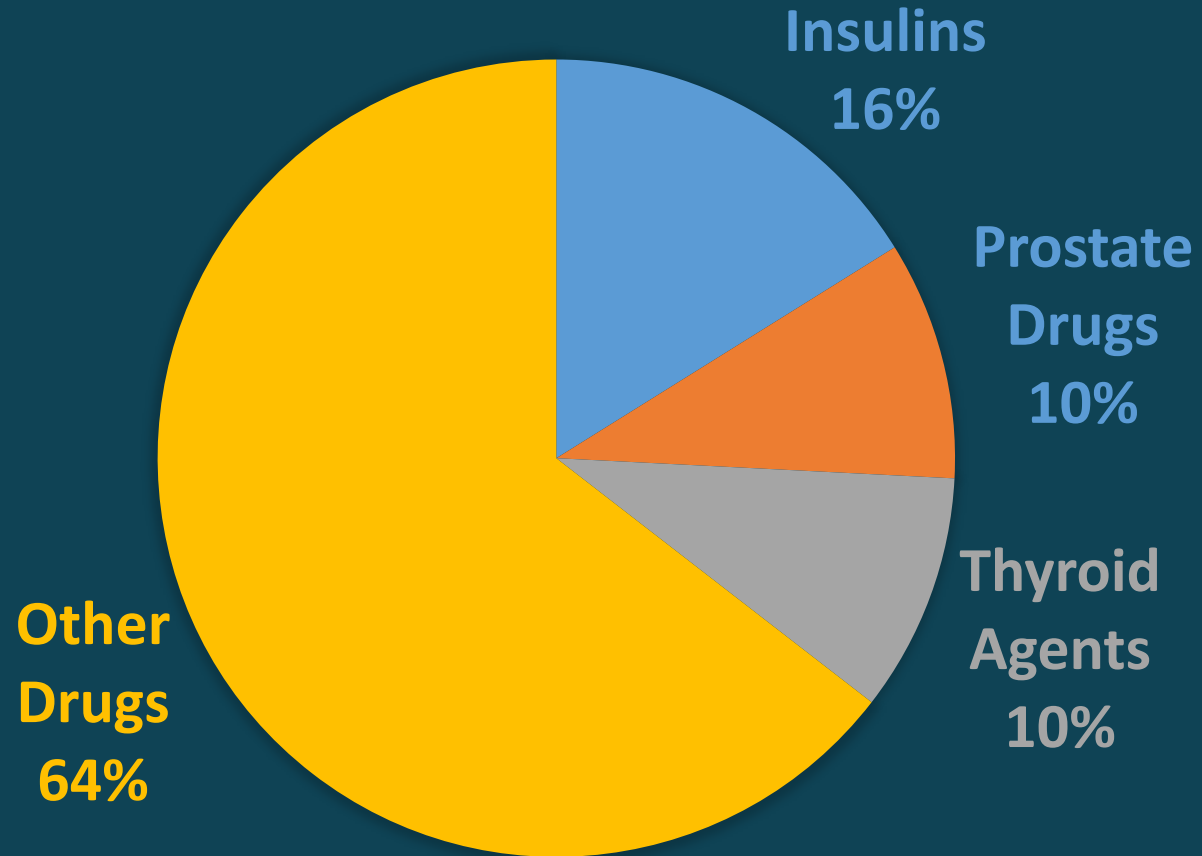
5 most costly generic drugs

Drug	Used to treat	Amount spent by insurance companies
Amphet-amine-Dextro-amphetamine	Narcolepsy and ADHD	\$6,223,708
Methylpheni-date	ADD and ADHD	\$6,175,683
Buprenorphine	Opioid dependence	\$4,435,548
Levothyroxine	Thyroid	\$3,742,458
Estradiol	Estrogen	\$2,979,520

Source: Oregon Drug Price Transparency Program. Preliminary data, subject to change.

Consumer reports

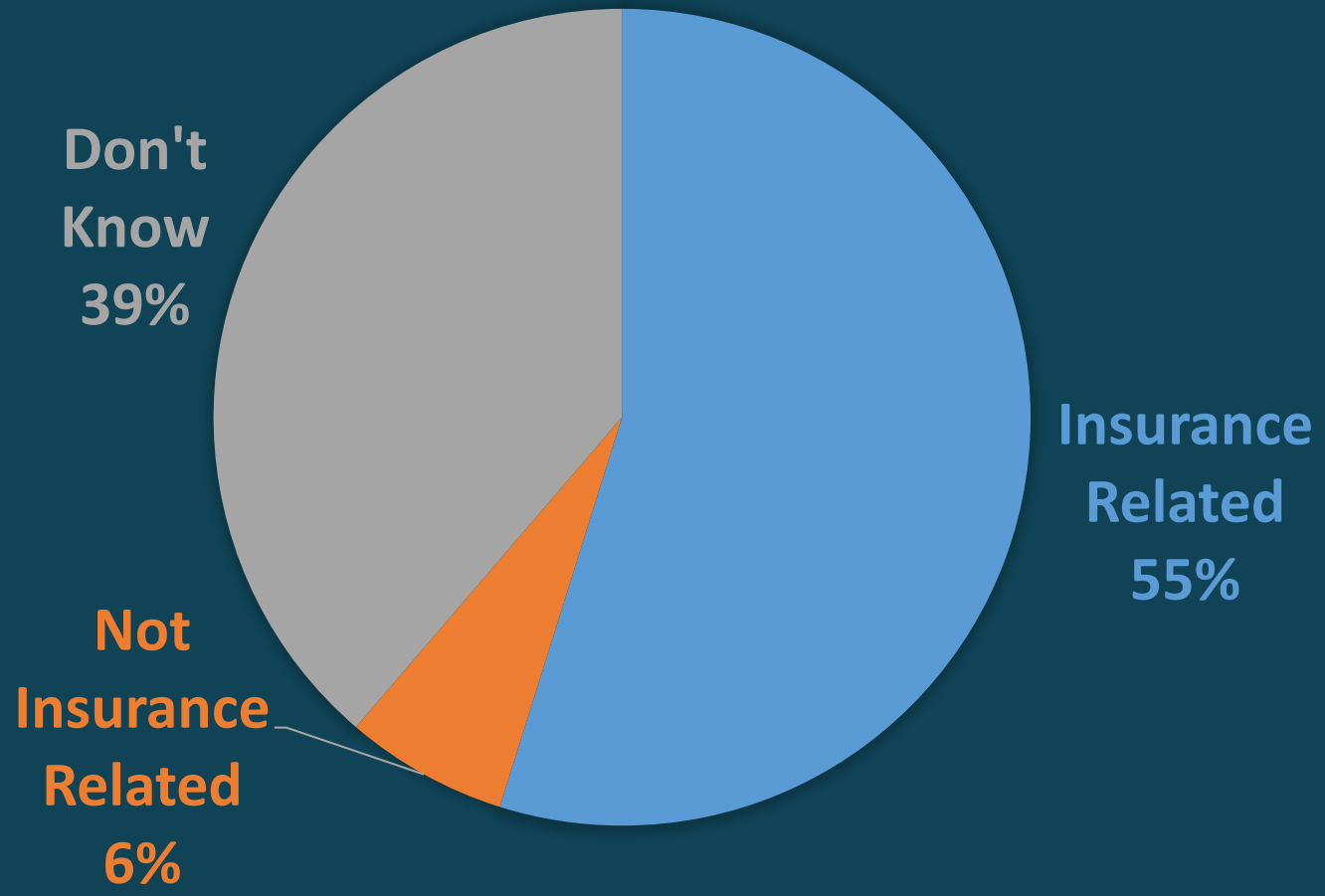
CONSUMER REPORTS BY DRUG CLASS



Source: Oregon Drug Price Transparency Program. Preliminary data, subject to change.

Consumer reports

REASON FOR PRICE INCREASE



Source: Oregon Drug Price Transparency Program. Preliminary data, subject to change.

Policy recommendations

Technical fixes to improve program implementation:

- **Protect consumer information**
- **Data access**
- **Insurance reporting**
- **Patient assistance programs**

Questions?

Program contacts and resources

Oregon Prescription Drug Price Transparency Program:

- Visit dfr.oregon.gov/drugtransparency
- Email rx.prices@oregon.gov
- Call 503-947-7200

Pricing Models for Remdesivir for COVID-19

Presentation at the Oregon Drug Price Transparency Public Hearing

Sarah Emond, MPP, Executive Vice President & Chief Operating Officer

December 16, 2020



INSTITUTE FOR CLINICAL
AND ECONOMIC REVIEW

Institute for Clinical and Economic Review (ICER)

- **Independent** health technology assessment group whose reviews are funded by non-profit foundations
- Develop **publicly available value assessment reports** on medical tests, treatments, and delivery system innovations for over 12 years
- Use cost-effectiveness analysis to determine **value-based price benchmarks**
- Convene regional independent **appraisal committees** for public hearings on each report

Two approaches to judging the fairness of price chosen for remdesivir

- Pricing pharmaceuticals in a pandemic offers opportunity for alternative pricing models; ICER used two approaches for remdesivir:
 - **Cost-recovery pricing:** Private companies develop vaccines and treatments, are rewarded with patent rights, but government and/or private insurers use an analysis of the *cost of development and production to set a ceiling price*.
 - **Value-based pricing:** Private companies develop vaccines and treatments and are rewarded with patent rights, but government and/or private insurers use some form of cost-benefit analysis to set a ceiling price *based on the degree of added benefit for patients*.
- Other approaches include: status quo, monetary prizes, compulsory licensing, and advanced market commitments

Cost-recovery: \$1,005 - \$1,600

- Minimum cost of producing the final finished product (\$5 - \$600)
- Research and development costs provided by the innovator (\$0 - \$1,000)

Price range for a full course \$5-\$600 using marginal costs of production, and \$1,005-\$1,600 if include manufacturer's forecasted 2020 clinical development expenses

Value-based pricing: \$70 - \$2,470

- Pricing based on clinical benefit depends on: severity of disease and value-based thresholds
- Moderate-to severe disease in the hospital: \$2,470 for a course of treatment
 - Average commercial payer price for a remdesivir treatment course is \$3,990
- Mild disease in the hospital: \$70 for a course of treatment
 - Average commercial payer price for a remdesivir treatment course is \$2,750

Price range for a full course is \$2,470 for moderate to severe disease (62% discount), and significantly lower if used for patients with mild disease

Policy implications

- Policymakers have opportunity to use evidence to inform novel pharmaceutical pricing in a pandemic
- Rapid emergence of new data requires revisiting clinical benefit calculations often
- Independent and transparent analysis of magnitude of clinical benefit scaled to price offers counter-point to manufacturer pricing

Resources to Support Pricing in a Pandemic

- <https://icer.org/explore-our-research/policy-papers/covid-19/>
 - Updated remdesivir report - November 10, 2020
 - Alternative Policies for Pricing Novel Vaccines and Drug Therapies for COVID-19 – July 1, 2020
 - Adaptations to the ICER methods for evaluation of therapies for COVID-19 – July 18, 2020
- <https://icer.org/news-insights/commentaries/icer-colloquium-series-pricing-in-a-pandemic/>
 - ICER Colloquium Series, Pricing in a Pandemic (series of three webinars)

Colorado's Drug Importation Program



December 16, 2020

Presented by: Lauren Reveley

Drug Importation Program Manager, State of Colorado

Legislative/Regulatory Framework

- Medicare Modernization Act of 2003
- Notice of Proposed Rulemaking (NPRM) Released December 2019
- Final Rule released September 24. Effective November 30

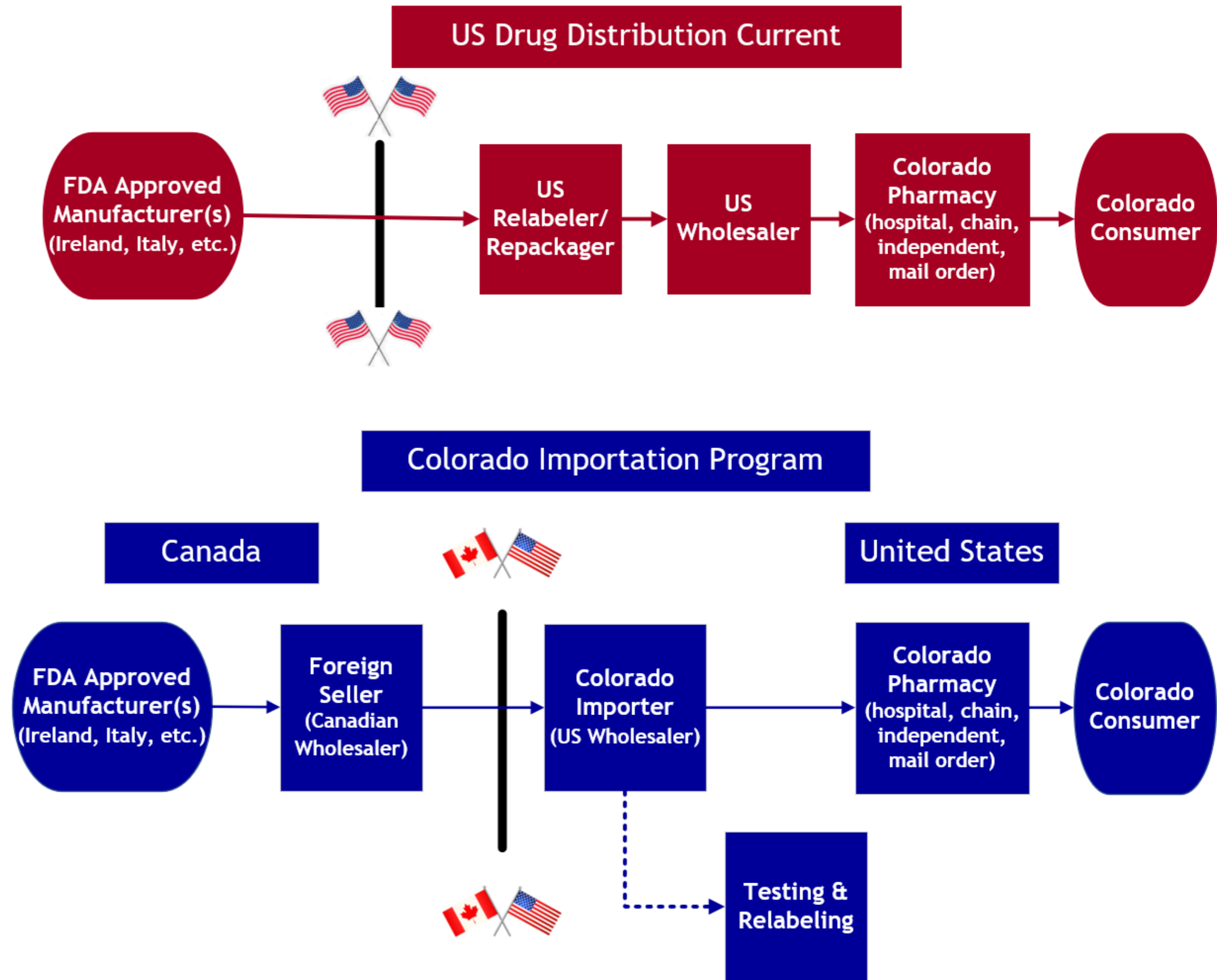
Features of the Final Rule

- . Supply Chain Requirements
- . Safety and Quality Standards
- . Drugs Eligible for Importation
- . Application Guidelines

Overview of Colorado's Importation Program

- Focus on the commercial market
- Little to no impact on the state's Medicaid Program
- Estimates a 61% savings on a list of analyzed drugs (includes a markup for the supply chain)
- Current program structure is in line with regulatory framework set forth by the FDA
- Hope to be operational by 2023

What Will Drug Importation Look Like?



Considerations for Importation Programs

- Importation programs are operational, as set forth by the federal rule effective November 30
- Imported drugs would present a cheaper option for consumers at the pharmacy counter

- Uncertainty at the federal level
- Canada's Interim Order
- Assessing health plan participation and coverage of imported drugs for consumers



Questions?

Maryland Prescription Drug Affordability Board

PDAB Program Overview

Oregon Prescription Drug Price Transparency Program
Annual Hearing

Presentation by: Van Mitchell

December 16, 2020



MARYLAND
Prescription Drug Affordability Board

Prescription Drug Affordability Board

- The Maryland Prescription Drug Affordability Board (PDAB) was created to study the prescription drug market in Maryland, and protect the State and its residents from the high costs of prescription drug products
- Over the next year, the Board will analyze Maryland's pharmaceutical distribution and payment system, review possible policy options to lower the cost of prescription drugs, and report its findings to the General Assembly
- Possible options include, but are not limited to, setting upper payment limits, a reverse auction marketplace, and implementing a bulk purchasing process



Prescription Drug Affordability Board: Board Structure and Members

- The PDAB is comprised of five members, and supported by a Stakeholder Council
- Board members possess expertise in various fields, including public policy, pharmaceuticals, economics, finance, and health care



Van T. Mitchell (Chair)



Gerard Anderson, PhD



Ebere Onukwughu, MS, PhD



George Malouf, M.D.



Joseph Levy, PhD



Prescription Drug Affordability Board: Budget and Staff

- The PDAB currently operates on a budget of approximately \$750,000, which is provided via a loan by the Maryland Health Care Commission (MHCC)
 - A bill providing a dedicated funding source for the Board via minimal fees on certain entities was vetoed in May 2020
- As a result of the statewide hiring freeze, the PDAB has had to wait to hire its full staff
 - The Board recently selected an Executive Director, and is working with various state agencies to obtain final approval to complete the hire
 - The Board's current staff is augmented by assistance through the MHCC



Prescription Drug Affordability Board: Board Meetings

- The Board held in-person meetings in January and February 2020
- Following the outbreak of the COVID-19 pandemic, the Board transitioned to virtual meetings
 - The Board held its first virtual meeting in June, with subsequent meetings occurring in September, October, and November 2020
- The Board will continue to hold virtual meetings in 2021, with its first scheduled for January 25, 2021



MARYLAND

Prescription Drug Affordability Board

Prescription Drug Affordability Board: Public Meetings – Key Takeaways

- Stakeholders are eager to help
 - CRISP (MD and DC HIE), carriers, and bipartisan support from local government leaders
 - Coordination across sister agencies to provide technical assistance and infrastructure support
- Carriers share experience with prescription drug costs and utilization
 - Three major areas of concern: expensive novel therapies, high utilization for chronic conditions, unchecked price inflation
- Increasing drug prices have caused serious affordability issues at the county and local level
 - Harford County Executive Glassman recently noted that drug costs for county employees and retirees experienced an average increase of 12% last year



Committee on Data Collection

- One of the Board's first tasks is to access a variety of data sources related to prescription drug pricing and utilization
 - This includes MOUs with peer states, partnerships across sister agencies, submissions by insurers and health information exchanges, and purchasing commercial data sets
- The Board authorized the formation of a committee of Board members to focus on needed data, identify possible sources, and determine overall best practices in securing the data
- The Board and Executive Director will utilize the committee's findings to inform later decisions on additional data acquisition and analytic support



MARYLAND

Prescription Drug Affordability Board

Obstacles & Limiting Factors

While the Board has made considerable progress, despite complications caused by the COVID-19 pandemic, it has had to overcome certain obstacles:

- Securing office space
- Fulfilling staffing needs
- Access to current, complete, and needed data
 - Confidentiality of certain data may frustrate Board's analysis
- Obtaining a dedicated funding source



Questions and Feedback

Please visit pdab.maryland.gov for updates on the PDAB and its progress on studying Maryland's pharmaceutical market.

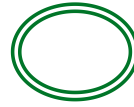


Oregon Dept. of Consumer and Business Services
Second Annual Prescription Drug Pricing Hearing
Dec. 16, 2020

Overview of Emerging Policy Models

Jennifer Reck, MA, Project Director
National Academy for State Health Policy
jreck@nashp.org

About NASHP



The National Academy for State Health Policy (NASHP) is an independent academy of, by, and for state health policymakers.

- Non-profit, non-partisan organization
- Helps states achieve excellence in health policy and practice
- Provides forums for work across branches and agencies of state government on critical health issues

Center for State Drug Pricing (2017)

Initial models for:

- Drug price transparency
- Importation
- Prescription Drug Affordability Boards
- Prescription Benefit Managers (PBMs)

Implementation support for:

- Drug price transparency
- Importation



State Legislative Action

Drug Pricing Laws 2017-2020					
Year	2017	2018	2019	2020	Total
Number of States Enacting Laws	13	28	37	17	48
Total Laws Enacted	18	45	62	40*	165*
PBM	8	32	33	21	94
Transparency	3	4	7	4	18
Importation	0	1	3	2	6
Affordability Review**	1	0	3	1	5
Volume Purchasing	0	0	2	0	2
Coupons/Cost Sharing	1	0	4	10	15
Study	0	1	5	1	7
Other	5	7	5	2	19

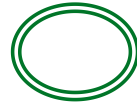
*Totals laws enacted are lower than column totals because a New Hampshire law contains multiple provisions.

** Includes New York's Medicaid drug cap and Massachusetts' enhanced negotiating authority.

- Since 2017, legislation to address prescription drug costs has been **introduced** in all 50 states.
- Since 2017, 48 states have **enacted** 165 laws to address prescription drug costs.



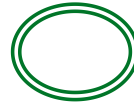
International Reference Rates



- **How it works:**

- The Superintendent of Insurance works with the state employee health plan to develop a list of the 250 drugs costing the state the most
- The state references Canadian prices from the four most populous provinces (available online)
- The lowest price becomes the international reference rate for payers in the state for the 250 drugs
- Savings to plans must be passed to consumers
- Setting rates can withstand legal challenges (unlike price setting)

International Reference Rates

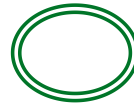


Drug Name & Dosage Source: National Average Drug Acquisition Cost (NADAC) data	US Price (NADAC)	Canadian Reference Rate*	Price Difference	Savings off US Prices
Humira syringe (40 mg/0.8 ml) (arthritis, psoriasis, Crohn's)	\$2,706.38	\$541.29	\$2,165.09	80%
1 ml of Enbrel (50 mg/ml syringe) (arthritis, psoriasis, Crohn's)	\$1,353.94	\$272.28	\$1,081.66	80%
1 ml of Stelara (90 mg/1 ml syringe) (arthritis, psoriasis, Crohn's)	\$21,331.28	\$3,267.64	\$18,063.64	85%
1 ml of Victoza (2-pak of 18 mg/3 ml pen)* (diabetes)	\$103.44	\$17.30	\$86.14	83%
Truvada tablet (200 mg/300 mg) (PrEP for HIV)	\$59.71	\$19.78	\$39.93	67%
Xeljanz tablet (5 mg) (rheumatoid arthritis)	\$76.07	\$17.50	\$58.57	77%
Eplcusa tablet (400 mg/100 mg) (hepatitis C)	\$869.05	\$541.32	\$327.73	38%
Zytiga tablet (250 mg) (cancer)	\$87.63	21.47	\$66.16	75%
			<i>Average discount based on 8 top selling drugs in 2018</i>	73%

*Converted based on \$1 CAN = \$0.76 USD

Canadian price per ml of Victoza established based on \$136.98 price for 2-pak of 3 ml pens - 6 mg/ml

Penalizing Unsupported Price Increase (UPI)



- **Background:**

- The Institute for Clinical and Economic Review (ICER) produces an annual report identifying the drugs with unsupported price increases outpacing 2x medical inflation that are the greatest drivers of net spending
- Unsupported price increases = unjustified by new clinical data

- **How it works:**

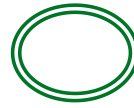
- State tax authority is used to assess penalties on manufacturers identified in annual ICER report as having a drug with an unsupported price increase
- Penalties = 80% of excess revenues (i.e., revenue from unsupported portion of price increase)
- Manufacturers must report information on total sales revenue in the state to the Tax Assessor to determine the penalty owed

- **Impact:** Because ICER's analysis targets drugs with the greatest impact on net spending, penalties can result in millions in revenue for a state
- Model Act specifies revenue must be used to offset Rx costs to consumers

2019 ICER UPI Analysis: Results

	Q42016 to Q42018 Wholesale Acquisition Cost (WAC) Increase	Q42016 to Q42018 Estimated Average Net Price Increase	US Spending Impact of Net Price Increases in 2017 and 2018 (in Millions)
Humira	19.1%	15.9%	\$1,857
Lyricea	28.3%	22.2%	\$688
Truvada	14.3%	23.1%	\$550
Rituxan	17.0%	13.8%	\$549
Neulasta	14.6%	13.4%	\$489
Cialis	26.2%	32.5%	\$403
Tecfidera	16.7%	9.8%	\$313

Additional New NASHP Model Legislation



Price Gouging 2.0

- Addresses key legal issues building on Maryland's experience
 - Links more directly to in-state transactions
 - Applies to generic and off-patent drugs
 - Fluoxetine (generic Prozac) increased from \$9 to \$69 in Jan. 2019 (+667%)
 - Considerable power to constrain generic drug prices & offer consumer relief

Licensing Sales Representatives

- Model Act requires:
 - State licensure of sales reps
 - Professional Education: Ethics, whistleblower protections, regulations
 - Reporting: Drugs marketed and extent of marketing to providers
 - Disclosure to providers: Cost of drug being marketed – and availability of generics



Trump Administration Regulations on Drug Pricing

Most Favored Nation Rule; Rebate Rule; Drug Importation; and Price Transparency

Most Favored Nation Rule

- Interim Final Rule requires provider groups to engage in negotiations with manufacturers or distributors to obtain prices for Part B drugs in line with new reimbursement rates.
- Mandatory across the country.
- IFR goes further than what was proposed by choose the target price to be the lowest price adjusted for per-capita gross domestic product of any OECD country with a GDP per capita at least 60 percent of that of the U.S.
- IFR acknowledges that 19% of Part B drug utilization may be eliminated because patients can no longer access the drugs from their providers.



Procedural, Implementation and Policy Issues

- Process: CMS initially issued an advance notice of proposed rulemaking and never issued a notice of proposed rule making.
 - An NPRM was submitted to the Office of Management and Budget but it was never cleared
 - CMS is using the COVID-19 pandemic as an excuse to by-pass the usual rulemaking process, but the existence of an NPRM that OMB did not clear undermines this argument
 - PHARMA is suing to stop implementation stating this was a violation of the Administrative Procedures Act and that the ANPRM said this was a test of a payment model
 - Implementation Problem – CMS may not be able to obtain data that truly reflects the information they need
 - May lower Medicare Advantage payments

Drug Rebate Final Rule

- Changes the Anti-Kickback regulations to create two narrow safe harbors:
 - To provide discounts for the consumer at the pharmacy counter
 - To protect arrangements between manufacturers and PBs that are fixed fee services – a practice that occurs in government contract bids
 - Removed Medicaid Managed Care Organizations because a number of commenters noted that the projected result of their inclusion would be to increase Medicaid costs for the states and the federal government



Issues with Drug Rebate Rule

- Sec. Azar was required to confirm that Drug Rebate Rule will not increase Federal spending, Medicare beneficiary premiums or patients' total out-of-pocket costs. Yet when he made that confirmation, he did not provide an explanation other than based on his experience in the industry and government. His assertion contradicted several projections to the contrary.
- HHS expects manufacturers will lower their prices.
- Was the NPRM withdrawn? CMS issued a press statement saying it was withdrawing the rule but there was no notice in the Federal Register.
- PHARMA has filed suit.



Drug Price Transparency

- In October 2020, HHS, Labor and Treasury issued a rule concerning transparency in coverage.
- The rule requires plans and insurers to disclose the negotiated rate of the drug, but in general, insurers do not need to disclose discounts, rebates or price concessions for a drug.



Drug Importation

- Current law allows for the importation of certain drugs from Canada under defined, limited circumstances and only if the Secretary of HHS certifies that importation poses no threat to the health and safety of the American public.
- Secretary Azar certified that importation poses no risk to health and safety and would result in significant cost savings.
- In September, HHS issued a final rule and FDA guidance creating two new pathways for the safe importation of drugs.



Issues with Importation

- Canada announced this month that it will take measures to protect their drug supply from bulk importation that could worsen drug shortages and will bar distribution outside their country if to do so would cause or worsen shortages.
- On Nov. 23, PHARMA, and two other organizations challenged the final rule in court alleging the Final Rule disregards key protections of the Food, Drug, and Cosmetic Act related to patient safety.
- The suit also argues that there is no supporting evidence for the Secretary's confirmation that to import drugs is safe and that HHS cannot quantify savings. They also argue the action violates the First amendment and raised questions concerning the Fifth Amendment takings clause.



Biden Administration

- Most Favored Nation Rule and the Drug Rebate rule were published inside the 60 day window before the next Administration so it can be held for review.
- Drug Importation as issue is not likely to go away. The next Secretary may not certify there is no risk to safety and health.
- AHA continues to challenge the health transparency rule in court but has lost most challenges. The drug price transparency is part of that rule.





Questions?

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