April 24, 2024

Dear PDAB,

As an older Oregonian, the best job I've been able to get within the last 7 years is a part-time job teaching at a Community College. While I love my college and the work I do, I just can't support my family on a part-time teacher's salary. My husband has been out of work for over 7 years, also due to his age. We are struggling financially, and while my husband now qualifies for Medicare, I do not. I can't afford commercial insurance, so I rely on the Oregon Health Plan.

The Oregon Health Plan has been a Godsend for us, but there are drawbacks. My preferred primary care physician is a Naturopath I've been seeing for almost 2 decades. Unfortunately, she doesn't take OHP insurance. I can certainly still see her, but OHP won't pay for prescriptions unless I see someone in their network. Consequently, if I want to go to the doctor I feel most confident in and most comfortable with, who has done the best for me in terms of my healthcare, I have to pay for my prescription medications out of pocket.

Let me explain what that means for me. If I were to get my medication prescribed by the physician I prefer to see, I would have to pay almost $400 out of pocket. Since I only bring home about $2,000 a month, that leaves me with $1,600 to make my house payment, buy groceries, put gas in my car so that I can commute to work, and pay for utilities and other expenses my family and I might have. I just can't make ends meet paying out of pocket for highly expensive prescription medications.

My only affordable alternative is to see an OHP assigned physician within the OHP network. The physician I'm seeing now has misdiagnosed me three times, once almost fatally. I don't want to see her. I waited six months to get in to see another doctor only to be told that she was no longer accepting new patients. The dearth of primary care physicians in Salem is problematic at best, but when I already have a comfortable alternative and can't utilize that physician due to the high cost of prescription medications, I am stuck with a physician who is not the best choice for me. The situation is barbaric and would be laughable if it weren't so dire.

I implore you to make two important decisions. The first is to make it possible for OHP to pay for prescription medications whether or not the prescribing physician is in-network. The second is that you make prescription medications affordable for all. Low-income seniors such as myself are the most vulnerable, but any low-income Oregonian shouldn't have to choose between purchasing their medication or paying the mortgage/rent.

Big Pharma has gotten so greedy that average Americans can't pay for prescription medication without insurance, and our current model is to have employer-provided insurance. Perhaps my biggest plea is that you take the information you discover from the Oregonians who respond to your request for information to the Oregon Legislature and advocate a Healthcare for ALL Oregonians program so that EVERYONE can have healthcare coverage and see their physicians of choice.

Sincerely,

Kathy Austin, Ph.D., Salem, OR

From: Michelle Cole
Sent: Wednesday, April 24, 2024 7:00 AM
To: PDAB * DCBS <pdab@dcbs.oregon.gov>
Subject: Prescription Drugs Cost Too Much!

Dear Prescription Drug Affordability Board,

I've met many Oregonians who say they are worried about prescription drug costs. This includes parents of children with medical needs and seniors who are making terrible choices between getting food or paying for their prescriptions. My own husband has refused to try meds that might help him because he is wary of costs.

Sincerely,
Ms. Michelle Cole
Tualatin

From: shearin linville
Sent: Thursday, April 25, 2024 8:05 AM
To: PDAB * DCBS <pdab@dcbs.oregon.gov>; Ron Wyden <campaign@wydenforsenate.com>; Senator Jeff Merkley <senator_merkley@merkley.senate.gov>
Subject: Prescription trickery by Insurance Companies

Just want to make sure you are aware of this trick by insurance companies. When purchasing plan D coverage our premium went down (2022). When checking however, they changed the tier of one of my husband's prescriptions and the co-pay went from $86 to $120. (90 day mail order RX)

I was able to purchase this exact 90 day prescription from Cost Plus Pharmacy (Mark Cuban) for $13.48 including pharmacist charges and mailing cost.

Pretty crafty of the insurance companies don't you think.....

Plus, I am sick of reapplying for part D coverage every single year. I just remember what the name of my drug coverage company is and it changes. Another huge amount of paperwork and drug coverage catalogs that you have to be a sleuth to figure out the changes, then a new card, then let your doctor office know....ad nauseum. If you don't use Part D coverage, there are consequences. So you must go through the hoops.

Shearin Linville
Jackson County, Oregon

Sent to the board on April 29, 2024

Retired and very tired of hoops to jump through each year for prescription drug coverage. Hundreds of plans to choose from. All increased pricing in one way or another each year. Very confusing for these senior citizens to have to deal with . I have one plan, my husband has another. We can barely keep it straight who has what. And setting up mail order every year, alerting our doctor’s office every year.....Makes us dream of living somewhere where health care comes out of taxes for everyone and you simply go to the doctor or pharmacy. I know that's expensive, but seems being poor would be preferable to feeling stressed. And, don't get me started on managed MC plans. Took me 3 years to get back to regular MC and co-ins plan after breast cancer in 2019. $2500 out of pocket day of surgery and uncovered radiation to the tune of $1600. No thanks. Prefer to know up front what I'm owing.

Shearin Linville
Retired in Jackson County, Oregon

Oregon Coalition for Affordable Prescriptions (OCAP)
Fighting to lower prescription drug prices

Note from John Mullin: In light of the last meeting of PDAB, I would like to reinforce OCAP's support for the affordability review and the report on the feasibility of establishing Upper Payment Limits. I have attached my testimony from the 11-8-2023 PDAB meeting, and I plan to present some brief oral comments at the May PDAB meeting.

To: Chair Patterson and the Oregon Prescription Drug Affordability Board

From: John Mullin, President, Oregon Coalition for Affordable Prescriptions

Date: 11/8/2023

Re: Testimony to Oregon's PDAB Board

Thank you for the opportunity to speak today on behalf of the Oregon Coalition of Affordable Prescriptions. We appreciate the diligent work and the dedication of the board in addressing critical issues surrounding prescription drug affordability and industry transparency. OCAP fully supported SB 844 and the creation of PDAB and remains committed to collaborating with you to achieve our shared goal of making prescription drugs more affordable for all Oregonians. OCAP also supported SB 192, which asks the PDAB to conduct a feasibility study around Upper Payment Limits, and we look forward to the results of that analysis in 2024.

Our overarching goals revolve around promoting industry transparency and ensuring prescription drug affordability. We firmly believe that every Oregonian should have access to the medications they need without undue financial burden. The creation of the PDAB is a significant step in the right direction, and we commend the board for its ongoing efforts to fulfill its statutory mandate.

We also wish to acknowledge the exceptional work carried out by the Department of Consumer and Business Services staff in advancing the cause of affordability, and for keeping a laser-focus on making work a unique piece of legislation. Their dedication to this crucial issue is commendable.

We understand that the task of selecting drugs for affordability review is not an easy one. At the last PDAB meeting, the list was narrowed down to 26 drugs. We recognize that this list can be unwieldy, and the decision on which drugs to prioritize must ultimately lie with the PDAB. OCAP fully supports the board in this regard and remains willing to assist in addressing process issues to ensure that the board can effectively fulfill its mission.

One concern that we would like to highlight is the use of data from 2022 for the review. It's essential to recognize that prescription drug landscapes are continually evolving, influenced by changes at the federal and state levels, including Medicare negotiation. As we approach 2024, the data used for the review will be two years old. It's crucial for the PDAB to consider how best to account for these changes to make informed and relevant decisions.

The urgency of the matter cannot be overstated. People across Oregon are struggling to afford their necessary medications. For example, through our outreach to Oregonians, we've heard stories about folks paying hundreds or even thousands of dollars a month for prescriptions and often having to make hard decisions about whether to cancel prescriptions or take less than prescribed in order to afford other basic necessities. These are the real stories that drive our commitment to this cause, and we believe that relief is needed as soon as possible.

In closing, we want to reiterate our support for the PDAB's efforts and our commitment to collaborating with the board to achieve industry transparency and prescription drug affordability in Oregon. Together, we can make a substantial difference in the lives of Oregonians who depend on access to affordable prescription drugs. Thank you for your attention and the opportunity to speak today.

May 2, 2024

Andrew Stolfi, Director
Oregon Department of Consumer and Business Services
350 Winter Street NE
Salem, OR 97309-0405

Dear Director Stolfi:

On behalf of the Oregon Bioscience Association (Oregon Bio) and Biotechnology Innovation Organization (BIO), we write to express our serious concerns with recent public remarks made by the executive director of the Prescription Drug Affordability Board (PDAB) within your department. During the April 17, 2024, meeting of the PDAB, the executive director provided a 20-minute editorial speech, making demonstrably false claims and stating them as fact, mocking stakeholders and individual companies, and impugning the motives of the entire biopharmaceutical industry. As an industry comprised of brilliant scientists in Oregon, and across the country, dedicating their careers to finding treatments and cures for patients, the statements were both unprofessional and insulting. Coming from an executive director that should be implementing a statute without bias or a personal agenda, the statements are unacceptable.

Oregon Bio, BIO, and our member companies have legitimate concerns related to any implementation of an upper payment limit on prescription drugs in Oregon. While the Oregon PDAB is structured based on a "model bill" being pushed in various states, several of which have been enacted, no state PDAB has ever implemented an upper payment limit. In fact, the intent of an upper payment limit in many of these statutes is not directly focused on lowering costs for consumers and no one knows whether it will work as intended. While the Oregon PDAB does not currently have statutory authority to develop or enforce an upper payment limit, the board is charged with planning for the implementation of one. The legitimate questions and concerns from the biopharmaceutical industry, and all other interested stakeholders, should be given consideration and not simply dismissed as misinformation and fear mongering.

Given the recent remarks made by the executive director, we seek assurances from your agency that the PDAB statute will be implemented impartially and that all stakeholders, feedback and data used in the Board's processes will be provided fair consideration. DCBS should provide unbiased staff support to the board members and advise the board without zealotry. We also request an appropriate opportunity to respond to the accusations that were made. Public comments at most PDAB meetings are time-limited to three minutes per organization, which

does not provide sufficient opportunity to respond to the claims made during the executive director's comments. We request up to ten minutes per organization to address the PDAB at a future board meeting.

Thank you for your commitment to ensuring the Board conducts its statutory duties in a fair, balanced, and unbiased manner.

Sincerely,

Liisa Bozinovic
Executive Director
Oregon Bioscience Association

Brian Warren
Senior Director, State Government Affairs
Biotechnology Innovation Organization

cc: The Honorable Tina Kotek, Governor of Oregon
The Honorable Deb Patterson, Chair, Senate Health Care Committee
The Honorable Cedric Hayden, Vice-Chair, Senate Health Care Committee
The Honorable Rob Nosse, Chair, House Behavioral Health and Health Care Committee
The Honorable Christine Goodwin, Vice-Chair, House Behavioral Health and Health Care Committee
Members, Prescription Drug Affordability Board

National
Multiple Sclerosis
Society

May 3, 2024

Oregon Division of Financial Regulation
Oregon Prescription Drug Affordability Board
350 Winter St. SE
Salem, OR 97309

RE: National Multiple Sclerosis Society Comments, MS generic medications and cost of living

Dear Chair Bailey, Vice Chair Burns, committee members Hartung, Judge, Laman, Murray,

Thank you for the opportunity to submit comments on the Oregon Prescription Drug Affordability Board. The National Multiple Sclerosis Society (Society) is pleased that the State of Oregon and the Prescription Drug Affordability Board (Board) are seeking public comments and input throughout each step in this process. The Society has been actively involved in the creation and implementation of Prescription Drug Affordability Boards nationwide, as we believe they provide important information about and review of the high cost of prescription medications. The Board and the Society share a common goal in ensuring affordable access to medications for all Oregon residents.

Background

Multiple sclerosis (MS) is an unpredictable disease of the central nervous system. Currently there is no cure. Symptoms vary from person to person and may include disabling fatigue, mobility challenges, cognitive changes, and vision issues. An estimated 1 million people live with MS in the United States. While there is not yet a cure, we do know that early diagnosis and treatment are critical to minimize disability. Significant progress is being made to achieve a world free of MS.

The Society, founded in 1946, is the global leader of a growing movement dedicated to creating a world free of MS. Oregon has a higher prevalence of MS than many states across the country, with a direct adjusted MS prevalence of 292 to 332 per 100,000 individuals[1]. There is a strong association between latitude and prevalence with higher prevalence estimates in northern latitudes.

[1] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10186207/figure/noi230024f3/ (attn. figure 3)

National
Multiple Sclerosis
Society

Costs of Living with MS

People with MS have a variety of healthcare needs including but not limited to addressing neurological symptoms, emotional and psychological issues, rehabilitation therapies to improve and maintain function and independence, and long-term care. These needs vary dramatically from person to person and can change year to year as the disease progresses.

MS is a highly expensive disease, with the average total cost of living with MS calculated at $88,487 per year[2]. MS may impact one's ability to work and can generate steep out-of-pocket costs related to medical care, rehabilitation, home & auto modifications, and more. For individuals with MS, medical costs are an average of $65,612 more than for individuals who do not live with this disease. Disease-modifying treatments (DMTs) are the single largest component of these medical costs. As of February 2024, the median annual brand price of MS DMTs is more than $107,000. Five out of seven of the DMTs that have been on the market for at least 13 years are priced over $100,000 annually and continue to see regular price increases.

Generic MS DMTs

Generic medications have a role in driving down high medication prices and making medications more affordable. As we see within the MS DMT class, the existence of generics does not guarantee affordability for people who rely on these medications. Today, there are multiple generics for three brand DMTs. While the generic prices have dropped considerably with multiple generics per brand and other market considerations, people with MS are struggling with the affordability of the generics. The generic dimethyl fumarate, for instance, ranged in price from $3,650 to $48,667. It is unclear how these generics are being covered in formularies. For example, even as a generic, the medication may still be on a specialty tier or a nonpreferred tier. This means that even though the generic may be the lowest priced option, a person with MS may still have a high copay or even coinsurance, where they are responsible for a percentage of the cost of the medication.

While we are not yet aware of data looking at generic tiering in private health insurance, data on the distribution of generic drugs on Part D formulary tiers was recently published by Avalere Health. That data shows a shift of generics away from generic tiers, which traditionally have lower cost- sharing for patients, towards preferred brand, non-preferred, and specialty tiers which have higher cost-sharing requirements. This could place medications out of reach for people living with MS and other high cost, chronic conditions.

[2] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9109149/

National
Multiple Sclerosis
Society

Additionally, as mentioned, though there are multiple generic options currently for the treatment of MS, which may work depending patient to patient, there is a wide range in price across the generics, and few generic companies offer financial assistance. If an Oregonian takes one of the higher priced generics, will patient assistance still be available? The decision on which generic is available to individuals is likely determined by the insurer, the pharmacy benefit manager (PBM), or the pharmacy used. In this example, the individual may be required to use a specific specialty pharmacy and not have the option to look for lower-cost options.

Oregonians living with MS face a multitude of financial challenges and the Oregon Board is in a unique position to confront a main driver, namely the high costs of necessary, life saving and life altering medications. The National Multiple Sclerosis Society thanks you for the opportunity to provide comments on the process directly to the Oregon Board and welcomes the opportunity to continue to work together on improving affordability and access to prescription medications. Should you have any questions, please contact Seth Greiner, Senior Manager of Advocacy, at seth.greiner@nmss.org.

Sincerely,

Seth Greiner
Sr. Mgr. Advocacy
National Multiple Sclerosis Society

Eli Lilly and Company

Lilly Corporate Center
Indianapolis, Indiana 46285
U.S.A.
+1.317.276.2000
www.lilly.com

January 31, 2024

By Email (*PDAB@DCBS.oregon.gov*)

Oregon Department of Consumer and Business Services
ATTN: Oregon Prescription Drug Affordability Board (the "Board")
P.O. Box 14480
Salem, OR 97309

Re: Prescription Drug Affordability Review of Trulicity®

Dear Board,

I write on behalf of Eli Lilly and Company ("Lilly"), the manufacturer of Trulicity®. According to the "Oregon PDAB prescription drug and insulin list for affordability review (PDF)"[1] published on the public website for the Oregon Prescription Drug Affordability Board ("Board"), the Board intends to review prescription drugs, including Trulicity®, as outlined in OAR 925.200.0010 and OAR 925.200.0020 during the February 21, 2024 Board meeting and determine whether the selected products "may create affordability challenges for health care systems or high out-of-pocket costs for patients."[2]

Trulicity® is for adults and children 10 years of age and older with type 2 diabetes used along with diet and exercise to improve blood sugar (glucose). Trulicity® is also used in adults with type 2 diabetes to reduce the risk of major cardiovascular (CV) events (problems having to do with the heart and blood vessels) such as death, heart attack, or stroke in people who have heart disease or multiple cardiovascular risk factors. Trulicity® is the only GLP-1 RA that provides this combination of benefits: powerful A1C reduction across 4 doses, proven CV benefit in both primary and secondary prevention patients, simply delivered.[3] In fact, in AWARD-11, Trulicity® provided sustained A1C reduction at 1 year of <7%.[4] Trulicity® acts like the natural human hormone, GLP-1, helping the body do what it's supposed to do naturally: reduces hepatic glucose production by decreasing glucagon secretion, slows gastric emptying

[1] Division of Financial Regulation : Prescription drug data : Oregon Prescription Drug Affordability Board : State of Oregon; https://dfr.oregon.gov/pdab/Pages/data.aspx
[2] ORS 646A.694.
[3] Treating Adults with Type 2 Diabetes | HCP | Trulicity (dulaglutide)
[4] Clinical Trials: Lowering A1C, Weight Change & CV Data | HCP | Trulicity (dulaglutide)

and releasing glucose-dependent insulin. Reductions in fasting and postprandial serum glucose were observed as quickly as 48 hours after the first dose of Trulicity®.[5]

We appreciate that you share Lilly's desire to help more Oregonians access lower-cost prescription drugs, including Trulicity®, and we are proud to lead the industry in making our products affordable. Lilly continues to advocate for patient choice, with most patients having the ability to choose the GLP-1 that is appropriate for them with the help of their healthcare provider. This choice has maintained healthy competition in the broader GLP-1 market. We feel we are both competitively priced based on the clinical value we provide and the class in which we compete. All eligible, commercially insured patients with coverage for Trulicity® pay as little as $25 for up to 12 pens with the $25 Trulicity ® Savings Card Program. Due to the combination of formulary access provided by payers and affordability programs provided by Lilly, patients in Oregon paid an average of $53 to $83 per month for their therapy in 2023.

As a cutting-edge pharmaceutical company, innovation is at the heart of what we do, particularly for people with diabetes. With the first animal-derived insulin, Lilly extended life expectancy for people with type 1 diabetes from a couple of years into a person's thirties. Now, following a century of innovation, life expectancy for people with type 1 diabetes is in their sixties. Type 2 diabetes is the most common diabetes diagnosis in adults, and the mortality rate for diabetes in the US remains higher than the average rate for other comparable countries. In addition, the share of the total population diagnosed has been increasing, from 2.5% in 1980, to 7.2% in 2017.[6] Diabetes significantly reduces a person's life expectancy. Even with modern insulin and devices, two thirds of people struggle to keep their disease under control. Trulicity® plays an important role as an innovative option accessible to patients. There's more work to do, not only on diabetes, but also many other diseases like Alzheimer's and cancer.

That's why Lilly consistently invests 25% of our total revenue into research and development—$7.1 billion last year and $8.5 billion budgeted this year. That enables us to introduce new medicines—19 in the last decade, including the first Covid antibody therapy, and more medicines in the pipeline. Earlier this year, we shared exciting results from a study on a promising new Alzheimer's medicine, which followed approximately $8.5 billion in research

[5] How Trulicity Works, MOA & FPG and PPG Reductions | HCP | Trulicity (dulaglutide)
[6] How have diabetes costs and outcomes changed over time in the U.S.? - Peterson-KFF Health System Tracker

and development for Alzheimer's and other neurodegenerative afflictions and literally decades of work, including previous late-stage failures of three other potential Alzheimer's medicines.

We appreciate that the Board shares our commitment to prescription drug affordability. We are proud of the impact that our efforts have had on making prescription drugs more affordable and believe the Board's review of Trulicity® will demonstrate the meaningful impact Trulicity® and our solutions have had for patients with type 2 diabetes.

Sincerely,

Cynthia Ransom
Sr. Director, Government Strategy

May 5, 2024

VIA ELECTRONIC FILING

Oregon Division of Financial Regulation
ATTN: Oregon Prescription Drug Affordability Board
350 Winter St. NE
Room 410
Salem, OR 97309-0405

RE: May 15, 2024, Oregon Prescription Drug Affordability Board Meeting and Re-Review of Ozempic®

Dear Members of the Oregon Prescription Drug Affordability Board:

Novo Nordisk appreciates the opportunity to resubmit written comments to the Oregon Prescription Drug Affordability Board (Board) regarding the re-review of Ozempic®. As we have stated previously, we disagree with the Board's inclusion of Ozempic® on the list of drugs that are subject to an affordability review - on both procedural and substantive grounds - and respectfully request that Ozempic® be removed from the list. Our previous comments to the Board focused on our concerns regarding the inconsistent data that the Board relied on to compile its' selected drug list and the incorrect grouping of Ozempic® and Rybelsus® together for its' initial review. The Board's own spending data demonstrated that Ozempic's average annual gross spending per enrollee and average patient out-of-pocket (OOP) costs were not meaningfully different than the other GLP-1 treatments selected by the Board as "therapeutic alternatives". While we appreciate the Board's attempt to update its affordability review process, significant concerns remain around transparency, data, metrics, standards, and decision-making processes used by the Board to determine the affordability of a drug. Additionally, as the Board intends to explore a framework for implementing an upper payment limit (UPL), we reiterate our concerns regarding the unintended consequences that setting an UPL will have on patients' access to their medications.

Novo Nordisk is a global healthcare company committed to improving the lives of those living with serious chronic conditions, including diabetes, hemophilia, growth disorders and obesity. The Novo Nordisk Foundation, our majority shareholder, is among the top five largest charitable foundations in the world. Accordingly, our company's mission and actions reflect the Foundation's vision to contribute significantly to research and development that improves the lives of people and the sustainability of society.

Given the substantial burden that diabetes and related chronic diseases have on patients, the Board should reconsider its selection of Ozempic for an affordability review, as this could adversely impact access to treatment and worsen health outcomes over time.

Throughout our company's hundred-year history, we have had a steadfast focus on improving the lives of patients living with chronic diseases. Chronic diseases are the single biggest threat to life expectancy in the United States, erasing more than twice as many years as all car accidents, suicide, homicides, and overdoses combined. Furthermore, chronic diseases are responsible for 7 in 10 deaths each year,[1] and they are the primary reason that Americans have lower life expectancy than those in peer nations.[2] Despite these statistics, real progress in treating and preventing serious chronic diseases continues to be undermined by misguided policies that singularly focus on a drug's list price. Novo Nordisk respectfully requests that the Board reconsider its decision to pursue Ozempic® for an affordability review, summarized in greater detail below:

Ozempic is a highly effective treatment option for Oregonians, and average patient costs are in line with other treatments evaluated by the Board.

Diabetes represents a particularly high lifetime burden of illness, but thanks to decades of research and development, people with diabetes now have highly effective new treatment options to treat and prevent complications arising from metabolic-related chronic diseases. Ozempic® is a once weekly GLP-1 receptor agonist (RA) indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes (T2D) and to reduce the risk of major adverse cardiovascular (CV) events (MACE) (CV death, non-fatal myocardial infarction (MI) or non-fatal stroke) in adults with T2D and established CV disease.[3] Research and clinical trials have demonstrated the superiority of GLP-1 RA to other antihyperglycemic drugs in improving glycemic efficacy, reducing weight and blood pressure, and delivering a cardioprotective effect – all without the risk of hypoglycemia.[4] These drugs have transformed treatment guidelines for the management of patients with diabetes and are widely recognized as a standard of care.[5]

The efficacy and safety of Ozempic® was evaluated in the SUSTAIN clinical trial program. For glycemic efficacy, Ozempic® was compared to several other antidiabetic medications including sitagliptin 100 mg, exenatide ER 2 mg, insulin glargine U-100, dulaglutide 0.75 mg and 1.5 mg, canagliflozin 300 mg, and liraglutide 1.2 mg. Mean reductions in A1C from baseline ranged from 1.2%-1.5% and 1.5-1.8% for Ozempic® 0.5 mg and 1 mg, respectively, after 30 to 56 weeks of treatment, compared to 0–1.4% with placebo and active comparators.

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[1] US Centers for Disease Control and prevention. Chronic Diseases https://www.cdc.gov/chronicdisease/center/index.htm
[2] "An Epidemic of Chronic Illness is Killing Us Too Soon." Washington Post. October 3, 2023. https://www.washingtonpost.com/health/interactive/2023/american-life-expectancy-dropping/
[3] Ozempic® Prescribing Information. Plainsboro, NJ: Novo Nordisk Inc. https://www.novo-pi.com/ozempic.pdf
[4] Latif W, Lambrinos KJ, Rodriguez R. Compare and Contrast the Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs) [Updated 2023 Mar 27]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK572151/
[5] American Diabetes Association. Standards of care in diabetes—2024. Diabetes Care. 2024;47(suppl 1):S1- S321.

Throughout the glycemic control trials, both the 0.5 mg and 1 mg doses of Ozempic® demonstrated superior improvements in A1C vs. comparators. Moreover, spending data compiled by the Board ("All Payer, All Claims") revealed that Ozempic® had lower annual patient OOP costs than the average for all GLP-1 treatments analyzed by the Board.[6] Taken together, Ozempic® is both highly effective and no more costly for Oregonians than other treatments evaluated. The Board's decision to singularly target Ozempic® for an affordability review is not supported by the totality of the evidence.

Novo Nordisk is committed to ensuring patients living with diabetes can afford our medications, and this is a responsibility we take seriously.

At Novo Nordisk, we strive to develop sustainable affordability options that balance patient affordability, market dynamics, and evolving policy changes. Novo Nordisk contracts with payers throughout the state, offering rebates to ensure formulary placement and appropriate patient access to our medications. In 2023, Novo Nordisk's cumulative rebates and discounts across our entire US portfolio amounted to 74% of gross sales (75% in 2022 and 75% in 2021).[7] In addition to paying rebates in the commercial market, manufacturers are also required to pay significant statutory discounts and rebates to the government. Under the current reimbursement paradigm, rebates play a central role in how insurers manage the prescription drug benefit. A recent analysis of data from SSR Health's net price database across 10 major manufacturers showed that the gap in value between list prices and net prices (after rebates and other reductions) among brand name drugs reached $300 billion in 2022. The unweighted average discount off the list price was 53.5%, or less than half the price.[8]

However, when examining the overall costs to health care systems in Oregon, the Board focused on wholesale acquisition costs (WAC), i.e. list prices, a poor indicator of the cost of a medication for most patients and health insurers. According to a recent analysis, brand-name drugs' list prices grew at mid-single-digit rates in 2023, however, net prices dropped for a sixth consecutive year – and by 7% after adjusting for inflation.[9] Despite the growing divergence between list and net prices, average OOP spending for most diabetes prescriptions in the U.S. remains low. According to an analysis by IQVIA, OOP spending was less than $30 across 83% of diabetes prescriptions (based on April 2020 claims data across payers).[10]

For patients who continue to struggle to afford their medication, either due to inadequate plan benefit design or a lack of coverage altogether, Novo Nordisk provides additional financial support through our affordability programs. We allow uninsured patients in financial need to access our products at no cost, and we also provide copay assistance for Ozempic® that

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[6] Oregon Prescription Drug Affordability Review Board. Affordability Review of Ozempic 20240221-PDAB-document-package.pdf (oregon.gov)
[7] Novo Nordisk. 2023 Annual Report. Novo Nordisk Annual Report 2023 (PDF)
[8] Fein, AJ. Gross-to-Net Bubble Update: 2022 Pricing Realities at 10 Top Drugmakers. *Drug Channels Institute*. 2023 Jun 13 [cited 2024 Jan 18]. Available from: https://www.drugchannels.net/2023/06/gross-to-net-bubble-update-2022-pricing.html
[9] Fein, AJ. U.S. Brand-Name Drug Prices Fell for an Unprecedented Sixth Consecutive Year (And Will Fall Further in 2024). https://www.drugchannels.net/2024/01/tales-of-unsurprised-us-brand-name-drug.html. January 3, 2024.
[10] IQVIA. *Diabetes Costs and Affordability in the United States*. 2020 Jun 29 [cited 2024 Feb 7]. Available from: https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/diabetes-costs-and-affordability-in-the-united-states

reduces a commercially insured patient's out-of-pocket cost to as little as $25. Novo Nordisk remains committed to ensuring access to our medications by reducing the out-of-pocket cost burden, simplifying a complex pricing system, and fostering better pricing predictability for the patients we serve.

A UPL could disrupt patient access to diabetes treatments in Oregon.

While we share the Board's interest in making prescription drugs affordable to patients, shortsighted policies that impose price controls will only undermine these efforts, as patient access is likely to be compromised. The largest Pharmacy Benefit Managers (PBMs) in the US exert significant control over the treatment options available to patients[11] through formulary designs that direct patients to medications that can generate the highest rebates from manufacturers. A recent GAO report found that "…plan sponsors frequently gave preferred formulary placement to highly rebated, relatively higher-gross-cost brand-name drugs compared to lower-gross-cost competitor drugs, which generally had lower rebates".[12] Because of these perverse incentives, products subject to a UPL may be *less* attractive to insurers and PBMs relative to competitors that can continue to offer higher rebates.

Numerous case studies underscore these unintended consequences within the prescription drug supply chain. In one recent example, a drug manufacturer launched a biosimilar of the long-acting insulin glargine at a 65% lower price relative to the reference product's WAC. After little formulary uptake, the biosimilar manufacturer opted to launch a higher-priced version of the same product, with the ability to now pay rebates at a similar level to the reference product. According to an IQVIA analysis, PBMs largely favored the higher-priced version because it allowed them to generate rebate revenue.[13]

Despite these risks, the Board has not taken steps to ensure that patients will be able to access products subjected to a UPL. There are presently no beneficiary protections or formulary requirements for patients seeking treatment for a product facing a UPL. This heightens the risk of downstream access barriers for patients, including an interruption in continuity of care, prior authorization hurdles in accessing a prescribed therapy, and improper utilization management tactics that force patients to switch or delay treatment.

The Board assumes that a UPL will work for all Oregonians—but recent evidence suggests otherwise. Policies that focus narrowly on list prices fail to recognize the complex dynamics within the supply chain and are more likely to cause foreseeable harm to patients' ability to access prescribed medications.

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[11] Fein AJ. "The Top Pharmacy Benefit Managers of 2021: The Big Get Even Bigger." Drug Channels. April 5, 2022. https://www.drugchannels.net/2022/04/the-top-pharmacy-benefit-managers-of.html

[12] Government Accountability Office (GAO). CMS Should Monitor Effects of Rebates on Drug Coverage and Spending. Statement of John E. Dicken, Director, Health Care Before the Subcommittee on Health, Committee on Energy and Commerce, House of Representatives. https://www.gao.gov/assets/gao-23-107056.pdf. September 19, 2023.

[13] IQVIA. Lessons from Semglee: Early Perspectives on Pharmacy Biosimilars. 2022 [cited 2024 Apr 25]. Available from: https://www.iqvia.com/-/media/iqvia/pdfs/us/white-paper/2022/lessons-from-semglee-early-perspectives-on-pharmacy-biosimilars.pdf

Thank you for the opportunity to provide comments and for your consideration of the issues raised in this letter. Should you have any questions or concerns, please contact Ryan Urgo, Head of Policy, at RVUR@novonordisk.com for additional information.

Genentech
A Member of the Roche Group

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May 7, 2024

Oregon Prescription Drug Affordability Board
350 Winter Street NE
Salem, OR 97309-0405
pdab@dcbs.oregon.gov

Re: Oregon PDAB Prescription Drug Affordability Review Process

Dear Members of the Oregon Prescription Drug Affordability Board:

Genentech continues to follow the Board's meetings and communications closely. We have provided written comments and suggestions to the Board on three previous occasions regarding the Board's processes and operations and ask the Board to review and acknowledge these prior letters. In addition, this comment letter focuses on our most recent observations from the April 17, 2024 Board meeting and our ongoing concerns.

While we appreciate the Board's postponement of the March 20, 2024 meeting to reevaluate its affordability review processes and approach, we do not believe the board has made meaningful changes. We continue to have three areas of significant concern that we outline below.

1. **The Board's discussions and actions continue to lack necessary clarity and rigor. From the initiation of the drug selection process, the Board has not engaged in significant discussion about each drug it intends to review and the rationale for such a review. At this time, it remains unclear how many drugs will undergo an affordability review which could adversely impact the Board's findings for its report to the legislature.**

2. **Stakeholder engagement efforts continue to be severely limited and may adversely impact the Board's decision making. The Board must invest more time soliciting, and ensuring stakeholder feedback is considered as part of drug affordability reviews.**

3. **The Board must develop additional tactics to collect and analyze the data required by statute instead of simply referring to data limitations.**

The following will provide more detail on these concerns and offer necessary remedies for the Board's immediate consideration.

1. **The Board's discussions and actions continue to lack necessary clarity and rigor. From the initiation of the drug selection process, the Board has not engaged in**

significant discussion about each drug it intends to review and the rationale for such a review. At this time, it remains unclear how many drugs will undergo an affordability review which could adversely impact the Board's findings for its report to the legislature.

Since October 2023, the Board has anchored to a small subset list of drugs under consideration for an affordability review. Yet, the Board has never individually discussed each of the drugs on the subset list nor provided a robust rationale for their selection for an affordability review. Following postponement of the March meeting, the Board issued a new schedule of affordability reviews to occur between May and October 2024, with a final vote taking place in November. The Board initially finalized a list of 12 brand drugs for review in December 2023. At the April 17, 2024 meeting, the Board discussed whether to move forward with an affordability review for two of the drugs previously selected. For one of these drugs, staff indicated there was an "Excel error" which may have led to this drug's erroneous inclusion on the final list of drugs for review. The presence of this error, and the fact that it had yet to be identified and remedied since the Board's final selection in December 2023, suggests the Board would benefit from a more thorough review of all the drugs previously selected for review to determine if a review is both appropriate and prudent. Similarly, the Board had previously reviewed three drugs that will undergo a second review in the revised schedule; however, the Board has not clarified what new data or opportunities for stakeholder engagement exist that could result in the second review yielding a different outcome than the first.

Furthermore, in various meetings the Board and staff have referred to statutory requirements regarding the number of brand drugs and insulin products it must include in its report to the legislature on the "list of prescription drugs that may create affordability challenges for health care systems or high out-of-pocket costs for patients in Oregon." The requirements and the Board's interpretation of the requirement under the statute have never been thoroughly clear. We believe it has been the Board's intention to identify nine brand name drugs to include in its report. With the high likelihood of reducing the number of brand drugs selected for review at its May meeting, the Board is establishing a biased construct for all remaining affordability reviews. If the Board intends to include nine brand drugs in its report to the legislature, nearly all of the affordability reviews scheduled to be conducted will have a foregone conclusion. The Board must ensure and clarify it is not beholden to identifying a specific number of drugs that "may" pose affordability challenges. Further, we recommend the Board should restart the full review process returning to the drug selection phase to ensure the Board is facilitating a fair and robust evaluation of each selected drug's value and affordability, and has a focused discussion on each drug for potential selection before proceeding with an affordability review.

2. **Stakeholder engagement efforts continue to be severely limited and may adversely impact the Board's decision making. The Board must invest more time soliciting, and ensuring stakeholder feedback is considered as part of drug affordability reviews.**

While we appreciate the Board has provided revised instructions for written and oral stakeholder comments, the Board has not undertaken efforts that fairly and openly ***seek input*** from critical stakeholders whose lived experience and expertise should be highly valued in this process. The only reference during the April Board meeting to changes in the Board's approach to seeking

input from these stakeholders was to allocating time during oral public comments during each drug affordability review to hear from specified stakeholder groups. However, the Board has not offered any more details on how much time each stakeholder would have to speak, or whether the Board would directly engage with each stakeholder during this time to ask questions to better understand their feedback. The Board meeting agenda for May 15, 2024 does not provide further clarity even with two drug reviews scheduled for this date. Moreover, the Board has not released nor referenced any new means for seeking input specifically from these stakeholders for the purpose of the drug affordability reviews. While we appreciate the Board has been conducting community listening sessions, these sessions were not designed to target specific stakeholders with critical, relevant experience with any of the drugs under the Board's review. We strongly urge the Board to develop additional tactics to seek input from stakeholders and specify how their input will be considered during each drug affordability review. These actions should be developed and implemented prior to proceeding with any drug affordability reviews.

3. **The Board must develop additional tactics to collect and analyze the data required by statute instead of simply referring to data limitations.**

At the April meeting, the Board reviewed changes to the drug affordability report template. While we appreciate the effort made by the Board and its staff to incorporate statutory references throughout the template, we are disappointed many of these references are accompanied by a statement noting, "limitations in scope and resources available for this statute requirement." While the statute and Board regulations indicate the Board shall evaluate certain data "to the extent practicable," we do not believe the Board has made significant effort to identify, seek nor analyze additional data sources to support inclusion of these data in their affordability reviews. In addition, on more than one occasion, at least one Board member has asked the staff to provide additional data metrics such as median and mean to allow for more meaningful evaluation and discussion by the Board. This request has not been fulfilled at this time and while staff indicated in April they would look into providing such metrics, limitations on not being able to do so were already expressed. The Board should not proceed with any scheduled affordability reviews until additional effort can be made to identify, obtain, analyze and validate these additional data.

As we have stated previously, it is critical the Board invests the appropriate time and resources to this process, even if it results in a delay in fulfilling the Board's duties. We strongly urge the Board to pause its drug affordability reviews until these limitations can be adequately addressed. We continue to welcome the opportunity to engage with the Board and its staff on these concerns. If you have any questions or wish to discuss our comments, please contact Tim Layton, Director of State Government Affairs at layton.timothy@gene.com or (206) 403-8224.

Sincerely,

Mary Wachter, RN
Executive Director
State & Local Government Affairs

Johnson & Johnson

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Via Electronic Submission

May 8, 2024

Shelley Bailey
Board Chair
Oregon Prescription Drug Affordability Board
pdab@dcbs.oregon.gov

Dear Board Chair Bailey:

We write to provide the Oregon Prescription Drug Affordability Board (the Board) with information on Johnson & Johnson's recent publication "Influence of Prescription Drug Affordability Boards and Upper Payment Limits on the State Drug Pricing Ecosystem" (the UPL White Paper).

At Johnson & Johnson, for more than 130 years, cutting-edge technologies and expert insight have helped us understand and address the serious health problems of today and unlock the potential medicines of tomorrow. We apply rigorous science and compassion to confidently address the most complex diseases of our time. We also recognize these medicines can only have an impact if patients can access them. We work tirelessly to improve access for patients across Oregon.

During the April 17, 2024 meeting, staff discussed Johnson & Johnson's UPL White Paper. In response, we have attached a copy of the UPL White Paper in its entirety, which is based on documented research and data. Additionally, we would like to highlight the following points in advance of the May 15th Board meeting on Senate Bill 192 – Upper Payment Planning Update:

- **An upper payment limit (UPL) will not lower patients' out-of-pocket costs.**[1] In a recent Avalere survey commissioned by the Partnership to Fight Chronic Disease, health plans stated "[p]ayers will not pass their savings (if any) onto individuals. It's not realistic and somebody will need to make up the differences."[2]

- **A UPL will negatively impact patient access.**[1] In the same Avalere survey, health plans stated "[u]tilization management will undoubtedly go up with UPLs, whether for the drugs subjected to them or for competition."[2]

- **A UPL does not consider the drug supply chain in its entirety.**[1] In recent comments to the Board, multiple commenters noted that a UPL does not consider the role that health

[1] Janssen. "Influence of Prescription Drug Affordability Board and Upper Payment Limits on the State Drug Pricing Ecosystem." Accessed May 6, 2024.
[2] Partnership to Fight Chronic Disease. "Health Plans Predict: Implementing Upper Payment Limits May Alter Formularies and Benefit Design But Won't Reduce Patient Costs." Accessed May 2, 2024.

plans and pharmacy benefit managers play in the supply chain, nor does it consider the negative impact on provider and pharmacy reimbursement, which may result in providers and pharmacies operating at a loss.[3]

Instead of a UPL, we recommend the following solutions to reduce patients' out-of-pocket costs without negatively impacting their access to the most appropriate, effective treatment options and sites of care:

- **Require that PBM rebates and discounts be directly shared with patients at the pharmacy counter.[4]**

- **Examine the use of utilization management tools (e.g., formulary exclusion lists, prior authorization, step therapy, and nonmedical switching) and evaluate how best to regulate them in the interest of patient access and out-of-pocket costs.[4]**

- **Prohibit diversion of cost-sharing assistance (i.e., copay accumulator programs, maximizer programs, and alternative funding programs) to ensure payment made by or on behalf of patients counts towards their cost-sharing burden.[5]**

We ask the Board to take these points, and others made in the UPL White Paper and our 2021 and 2022 Janssen U.S. Pricing Transparency Briefs, into consideration as you move forward with your recommendations on the UPL process.

As one of the nation's leading healthcare companies, J&J has a responsibility to engage with stakeholders in constructive dialogue to address these gaps in affordability, access and health equity as well as protect our nation's leading role in the global innovation ecosystem.

We know that patients are counting on us to develop and bring accessible medicines to market. We live this mission every day and are humbled by the patients who trust us to help them fight their diseases and live healthier lives.

Sincerely,

Mike Valenta

Michael J. Valenta
Vice President, Value, Access & Pricing, Strategic Customer Group
Johnson & Johnson Health Care Systems Inc.

[3] Oregon Prescription Drug Affordability Board. Public Comments. Accessed May 2, 2024.
[4] Janssen. "The 2021 Janssen U.S. Pricing Transparency Brief." Accessed May 6, 2024.
[5] Janssen. "The 2022 Janssen U.S. Pricing Transparency Brief." Accessed May 6, 2024.

Influence of Prescription Drug Affordability Boards and Upper Payment Limits on the State Drug Pricing Ecosystem

Image Info: Microscopic Biology.

janssen | PHARMACEUTICAL COMPANIES OF Johnson & Johnson

Abstract & Executive Summary

Abstract

State policymakers are turning to prescription drug affordability boards (PDABs) and upper payment limits (UPLs) on branded medications to lower state drug expenditures and improve affordability for patients. However, UPLs on branded medications remain new and untested, with minimal understanding of their short- and long-term impacts on the drug pricing ecosystem and patient access. As presented, UPLs may offer states a short-term option for reducing overall drug spending for the state.

However, because UPLs focus solely on the price of a drug instead of the entire drug supply chain ecosystem, they may have long-term negative impacts across benefit design, patient access, pricing, contracting and future innovation.

These impacts may prohibit states from achieving their intended effects across state-regulated commercial markets and, in fact, create new negative consequences, including reduced patient access to needed medications and little to no reduction of out-of-pocket costs for patients. States seeking to implement UPLs on branded medications should consider the downstream consequences of focusing on drug price setting, specifically for patients and providers.

Executive Summary

Over the past 10 years, stakeholders have increased their focus on the rising cost of healthcare, in particular drug pricing, patient access and affordability. Manufacturers, insurers and pharmacy benefit managers (PBMs) have been the primary focus of scrutiny. In response, **legislators have passed laws designed to curb government prescription drug spending, improve patient accessibility and affordability and increase transparency in the pricing process at both federal and state levels.**

The passage of the Inflation Reduction Act (IRA) in August 2022 has further prompted states to act against perceived rises in drug prices and spending. States have turned to prescription drug affordability boards (PDABs) and new price-setting measures such as upper payment limits (UPLs) for branded medications in hopes of reducing overall state drug spending and patient drug costs. Upper payment limits are not new in policymaking: for example, the Federal Upper Limit sets a reimbursement limit for some generic drugs. However, UPLs have not been used on branded medications where the manufacturer and the plans currently negotiate value and access. These new UPLs purportedly allow states to set limits on the amount that will be reimbursed for specified branded drugs across state-regulated commercial markets. More than 10 state legislatures have debated price-setting thresholds such as UPLs in the last legislative session. As of November 2023, no state has fully implemented a UPL; however, Colorado is finalizing UPL rulemaking and may choose to implement UPLs in 2024.

UPLs on branded medications may have unintended consequences for stakeholders, pricing and value via altered benefit designs, manufacturer contracting, provider incentives, patient access and future innovation. Further, as additional state legislatures debate the merits of PDABs and these new applications of UPLs on branded medications, there is limited research to understand the long-term consequences of such policies.

This paper aims to address potential intended and unintended consequences of PDAB and UPL implementation on branded medications for states and the broader healthcare ecosystem.

The Initial Development of PDABs and UPLs

Early Attempts to Address Drug Pricing in the States

National healthcare expenditures have grown substantially, increasing from **$74.1 billion** in 1970 to **$4.3 trillion** in 2021.[1]

While much of this increase is due to hospital expenditures, a growing percentage is due to higher prescription drug expenditures, attributable to increases in both volume and costs. While the absolute cost of drug spending has grown, it has maintained a stable percentage of **overall healthcare spending at 14 percent** for several years.[2]

As such, lowering drug costs and improving patient affordability have been priorities for state lawmakers for many years. However, since the passage of the Patient Protection and Affordable Care Act (ACA) and the expansion of the individual market through state marketplaces, legislation targeting drug expenditures has multiplied.[3]

Prior to the development of PDABs and UPLs, states debated several other legislative and regulatory efforts, including increasing manufacturer price transparency within the commercial prescription drug supply chain. Drug price transparency legislation, which included manufacturer reporting requirements and advance notification of price changes (e.g., drugs with a wholesale acquisition cost [WAC] increase greater than 10 percent over the previous 12 months), rose to the forefront of state legislative initiatives around 2016. At least 24 states have enacted such laws.

However, state drug price transparency laws have not reduced prescription drug costs and improved transparency in the way states intended.[4] Research indicates that price transparency alone has minimal impact on overall costs for consumers because the information reported under transparency laws does not typically lead to actionable reductions in drug prices and reduced prices do not necessarily result in cost savings for patients.[5]

In addition to early drug price transparency legislation, some states also sought price-capping initiatives in the commercial market and in Medicaid. For example, New York's Medicaid Drug Spending Cap was enacted in 2017, allowing the state Medicaid program to negotiate with manufacturers for supplemental rebates if spending was set to exceed the cap or if a new drug was launched with a "high cost."[6] Maryland enacted an anti-price gouging law in 2017 that intended to penalize manufacturers for unreasonably increasing the cost of drugs.[7,8] However, a Court of Appeals struck down the Maryland law the following year stating it violated the commerce clause by regulating transactions taking place outside the state.[9] After the court decision, states began considering PDABs and price setting as a way to reduce prescription drug prices without negotiations with manufacturers.

PDAB and UPL Development

1

Background

PDABs are established through state legislation to independently review state drug spend and recommend ways to lower spending.[10] In 2017, the National Academy for State Health Policy (NASHP) developed model PDAB legislative language including a definition of prescription drug price setting through UPLs. This language was designed to give PDABs the ability to determine, using a UPL framework, if a drug is "unaffordable" for state purchasers and consumers.[6] The intent of the original model bill was to bring different stakeholders of the prescription drug pricing process together to increase transparency and set price thresholds to limit how much the state would pay for identified drugs.[11]

The original framework encouraged Boards to consider factors such as:

- Cost of administering and delivering the drug,
- Food and Drug Administration (FDA) shortage list status,
- Price of the drug in other countries and
- Other relevant administrative costs.

The framework does not require, however, that the value of the drug or the patient benefits be considered when determining a UPL.[12]

Even more notably, the NASHP model bill does not explicitly address patient cost sharing or affordability as a factor, although states are able to include it if they deem it necessary. NASHP updated the model legislation in 2022 to tie UPLs to reference-based pricing such as Medicare "negotiated rates" as developed by the IRA.[13] To date, UPLs have been designed as a cost-saving measure for the state and the plans that work within the state and have not been assessed as a mechanism to directly reduce out-of-pocket costs for patients.

2

PDAB Development

Maryland enacted the first PDAB in 2019 followed by Maine, New Hampshire, Oregon, Ohio, Colorado and Washington.[14] The scope of these PDABs varies from state to state. The majority of PDABs include advisory boards to analyze and recommend ways to lower state spending on certain products; others are required to release reports on their analyses or findings. In March 2022, Maine's PDAB released its first annual report containing administrative and legislative recommendations on how to reduce prescription drug prices in the state.[15]

While the composition of PDABs varies by state, most boards are composed of state-appointed experts in various fields of healthcare and economics. Many states' PDABs also include other stakeholders such as healthcare providers, advocates, manufacturers and insurance professionals.[10] The varied backgrounds of PDAB members can lead to differentiation in selection criteria for affordability review execution. Based on their individual areas of expertise, certain members may value utilization while others may value health equity.

PDABs often focus on branded drugs with list prices and use across state-regulated plans, using standard thresholds such as price and volume, to identify which drugs will be evaluated. For example, PDABs in Colorado and Maryland seek to evaluate drugs with a WAC greater than $30,000 per year. Ohio and Maine developed PDABs solely as ways to report to state legislatures on future drug pricing initiatives and ways states could engage with the supply chain to lower costs.[16, 17] However, some PDABs have the purported authority to set UPLs for select drugs.[14, 18]

States also need to provide funding for Boards to maintain their functionality. Some states have appropriated funds from the state budget for their PDAB, such as Washington's $1,460,000 allocation for the 2023 fiscal year.[19] Other states, like New Hampshire, fund their Boards through fees collected from manufacturers, insurers and PBMs.[14] Most states are still working to operationalize their Boards, with only Colorado, Maine and Maryland having active Boards as of July 2023.

3

UPL Development

Of the eight enacted PDAB laws, the following contain UPL price limit threshold provisions: Washington, Colorado, Minnesota and Maryland.[14] The goal of establishing UPLs is to set rates that state purchasers will pay for a certain number of products across plans regulated by the state (e.g., individual market, small-group market). States may include Medicaid plans as part of their state purchasers; however, Medicaid rates are likely already more steeply discounted than a UPL rate due to rebates through the Medicaid Drug Rebate Program (MDRP). So far, Minnesota is the only state to directly tie UPLs to Medicare "maximum fair price" (MFP) decisions developed through the IRA, although rulemaking to formalize this process has not been established.[20]

Other states with the authority to set UPLs have initiated their own criteria and processes for affordability review. Some states have thresholds on the number of drugs for which a UPL can be established. Currently enacted UPLs require states to determine the UPL-setting process through rulemaking considered by the PDAB.[14] PDAB laws with UPLs do not impact Employee Retirement Income Security Act of 1974 (ERISA) self-funded and Medicare plans.[10] However, these plans may opt into UPLs if enacted language allows. While price caps do exist in other markets, this has largely been untested in the state-regulated plans; as such, the impact of PDABs and UPLs on branded products is unclear.

PDAB and UPL Development Timeline

- Maryland enacted the first PDAB in 2019, followed by Maine, New Hampshire, Oregon, Ohio, Colorado and Washington.
- Many states' PDABs also include other stakeholders such as healthcare providers, advocates, manufacturers and insurance professionals.
- PDABs in Colorado and Maryland seek to evaluate drugs with a WAC greater than $30,000 per year.
- Ohio and Maine developed PDABs solely as ways to report to state legislatures on future drug pricing initiatives and ways states could engage with the supply chain to lower costs.
- States also need to provide funding for Boards to maintain their functionality.
- Some states have appropriated funds from the state budget for their PDAB, such as Washington's $1,460,000 allocation for the 2023 fiscal year.
- New Hampshire funds their Boards through fees collected from manufacturers, insurers and PBMs.
- Most states are still working to operationalize their Boards, with only Colorado, Maine and Maryland having active Boards as of July 2023.
- Of the eight enacted PDAB laws, the following contain UPL price limit threshold provisions: Washington, Colorado, Minnesota and Maryland.
- So far, Minnesota is the only state to directly tie UPLs to Medicare maximum fair price (MFP) decisions developed through the IRA, although rulemaking to formalize this process has not been established.

Current State of Play and UPL Implementation

PDAB/UPL Development in Three Key States

Three states with established PDABs are working toward developing a UPL setting process, with Colorado being the furthest along and in the process of finalizing rulemaking for its UPL.[10] The Colorado PDAB has released a list of five prioritized drugs for affordability review, following the release of a dashboard that includes 604 eligible drugs for selection.[21]

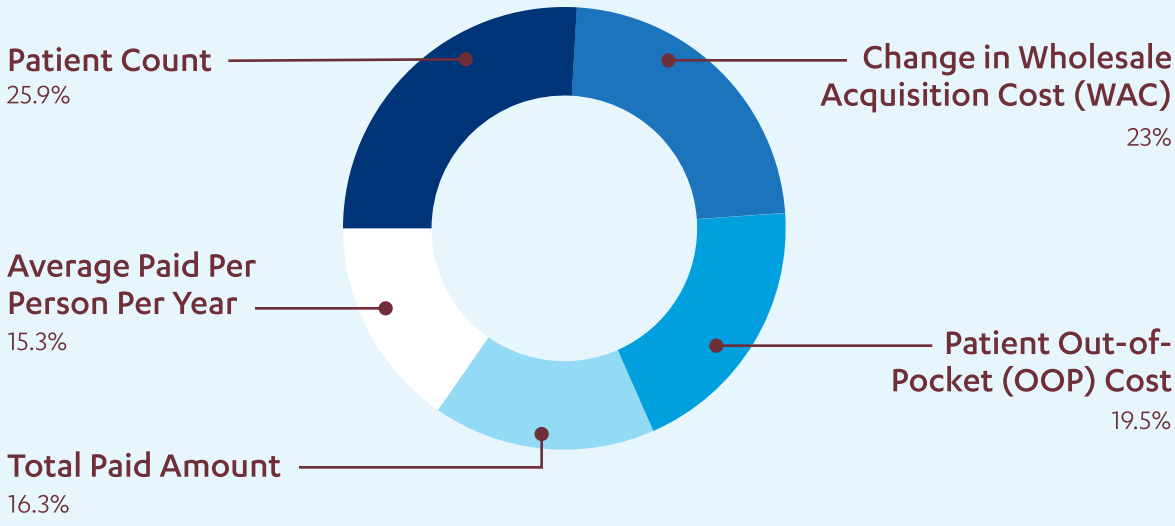
The 5 drugs selected for affordability review were:

1. Enbrel
2. Genvoya
3. Cosentyx
4. Stelara
5. Trikafta[22]

The Colorado PDAB plans to move forward with affordability reviews for the five selected drugs and may set UPLs for some, none or all of them, although the Board has the authority to set UPLs for up to 18 drugs (the CO PDAB has already announced it will not set an UPL for Trikafta).[23] The first UPLs in Colorado could take effect as early as 2024.

Each state's PDAB and UPL setting process and authorization can vary across items such as covered markets and targeted drugs. Maryland and Washington are two other states that have enacted PDABs. As a part of its 2021 legislative session, Maryland initiated the ability to include UPLs as part of its PDAB. Legislation that reestablishes this requirement and develops a plan of action to implement UPLs was enacted in the state's 2023 legislative session.[24, 25] Washington is one of the most recent states to enact a PDAB law that allows UPL setting. The Washington PDAB may set UPLs for up to 12 drugs beginning in 2027 and will begin identifying drugs to conduct affordability reviews by June 2023.[26] Though other states have enacted PDABs with abilities to set UPLs (i.e., Minnesota), Colorado, Maryland and Washington are the states that have begun taking steps to develop plans.

Factors Used to Determine the Priorities List of Eligible Drugs in Colorado Included:



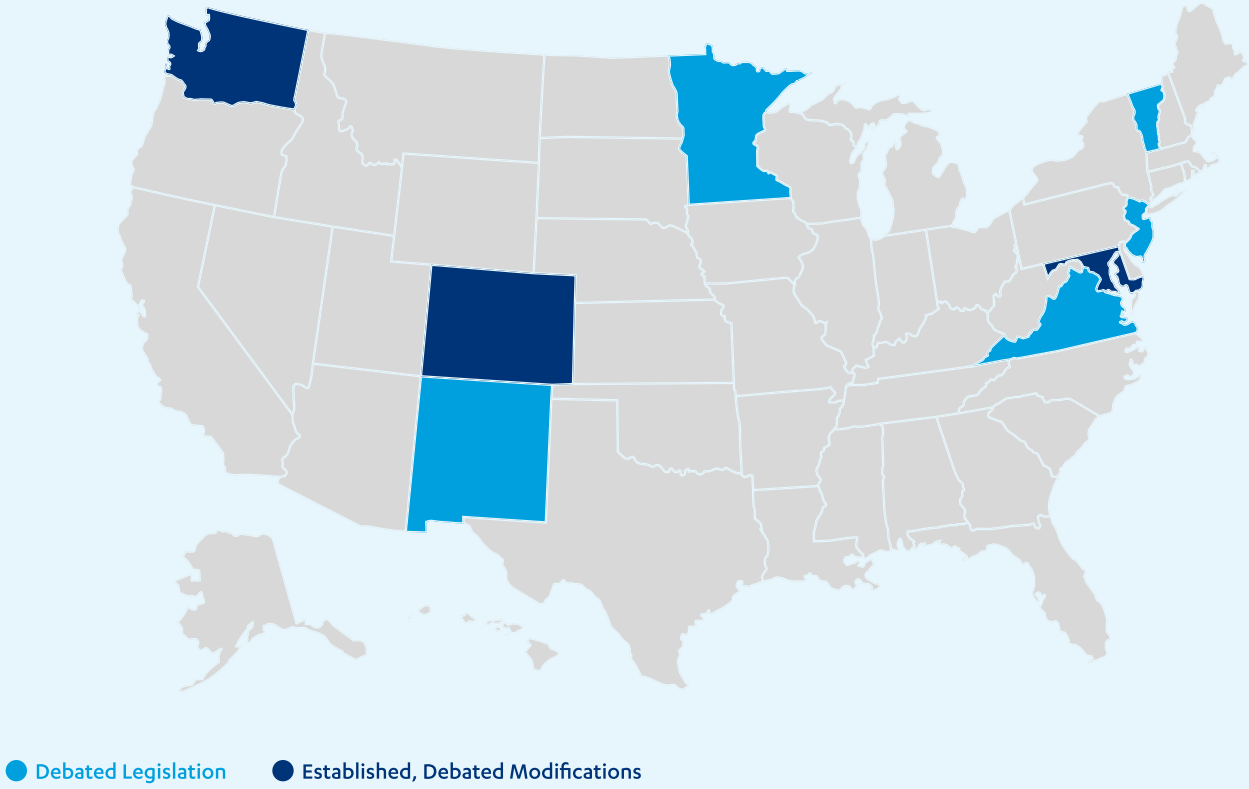
Key Characteristics of PDABs Across Three Enacted State Laws

	Colorado	Maryland	Washington
Bill Number	Colorado SB 175	Maryland HB 768	Washington SB 5532
Date Enacted	June 16, 2021	May 25, 2019	March 22, 2022
UPL Authorization	**Authorized.** The Colorado PDAB can set UPLs for up to 12 drugs within the first three years of implementation.[27]	**Progress toward authorization.** As a part of its 2021 legislative session, Maryland initiated the ability to include UPLs as part of its PDAB. However, no UPLs were set. HB 279 in Maryland's 2023 state legislative session gave the PDAB authority to set UPLs. If a UPL is established, the Maryland PDAB must report on UPL setting and the expansion of the UPL to other payers by December 1, 2026.[24]	**Authorized.** The Washington PDAB may set UPLs for up to 12 drugs, starting in 2027. A current bill seeks to move the Washington UPL ability forward by a year to 2026 as well as lower the thresholds for affordability review (e.g., WAC changes).[26]
Markets Covered	All state-regulated markets. This excludes self-funded plans that choose not to participate.	All public plans in the state.	All state-regulated markets. This excludes self-funded plans that choose not to participate
PDAB Drug Evaluation Criteria	• Brand-name drugs and biologics with a WAC ≥ $30,000 per year or course of treatment • Brand-name drugs or biologics with a WAC increase ≥ 10% during the previous 12 months • Biosimilars with a launch WAC that is not ≤ 15% lower than the referenced biologic • Generic drugs with a WAC ≥ $100 for a 30-day supply • Generic drugs with a WAC increase ≥ 200% in the previous 12 months[28]	• Brand-name drugs and biologics with a WAC ≥ $30,000 per year or course of treatment • Brand-name drugs with a price increase ≥ $3,000 in a year or course of treatment • Biosimilars with a launch WAC that is not ≤ 15% lower than the referenced biologic • Generic drugs with a WAC ≥ $100 for a 30-day supply • Generic drugs with a WAC increase ≥ 200% in the previous 12 months[29]	Prescription drugs that have been on the market for at least seven years, are not designated as rare disease treatments by the FDA and are one of the following: • Brand-name drugs and biologics with a WAC ≥ $60,000 per year or course of treatment • Brand-name drugs and biologics with a WAC increase ≥ 15% in a year • Brand-name drugs and biologics with a WAC increase ≥ 50% in three years • Biosimilars with a launch WAC that is not ≤ 15% lower than the referenced biologic • Generic drugs with a WAC ≥ $100 for a 30-day supply • Generic drugs with a WAC increase ≥ 200% in the previous 12 months[30]

To date, only Colorado has released a list of drugs selected for affordability review and possible UPL. However, Maryland notes in its annual cost review report that when the PDAB drug evaluation criteria are applied to their all-payer claims data (APCD), 707 brand-name national drug codes (NDCs) with WAC of over $30,000, 884 brand-name NDCs with increases of over $3,000, two NDCs of biosimilars not at least 15% less than the reference biologic and 483 NDCs of generic drugs costing $100 or more for a 30-day supply would be eligible for this review.[31]

Ongoing Legislative Efforts and IRA Implementation

In 2023 legislative sessions, at least five states have debated legislation to establish PDABs and UPLs (Minnesota, New Jersey, New Mexico, Vermont and Virginia) with Minnesota enacting its PDAB law in April 2023. All states with laws establishing PDABs with UPL authority prior to 2023 (Colorado, Maryland and Washington) have debated modifications to the process in their 2023 state legislative sessions.[32]



Beyond state legislation, Congress enacted major drug pricing reform through the IRA in August 2022.[33] The IRA's Medicare "negotiation" provision targets high-spend drugs, which could have downstream impacts on state PDAB and UPL development. For example, under Medicare "negotiation," a list of eligible drugs was released in September 2023 and the Secretary of the Department of Health and Human Services (HHS) will negotiate a "maximum fair price" (MFP) for each of the selected drugs to be effective in 2026.[34]

The MFP for each selected drug could impact UPL setting in states that enact laws tying UPLs to Medicare-negotiated rates. While federal "negotiation" is specific to Medicare, price-setting at the national level could trickle down to affect drug prices in state-regulated markets, and it can be expected that other states, like Minnesota, will tie the MFP to UPLs.

Affordability Ecosystem and Future Outlook for State Drug Pricing

Intended Outcomes of UPL Setting

1 Reduction in State Spending on Prescription Drugs

The goal of UPL setting is to establish payment limits for certain products to protect payers from high drug prices in the state and increase drug affordability for patients.

However, in states such as Colorado and Washington, where UPLs are limited to 12 products per year for the first three years, states may see nominal savings only if the products selected are tied to large enough state spending and volume.

Colorado's and Washington's laws purport to allow the PDABs to set no more than 12 UPLs a year until 2027, after which an unrestricted number of UPLs may be set. Early (e.g., pre-2027) savings from UPLs could mirror those projected by the Congressional Budget Office (CBO) for the IRA's Medicare "negotiation" provision.[35] This is because drugs selected in the first few years will likely include drugs that have significantly higher utilization and state expenditures per year than drugs selected in later years. For example, Maryland lists Humira as its top drug by spending for 2018-2019 in its annual cost review report, with the next product (Genvoya) listed as nearly half the total spending. By the tenth product listed on the report, the cost is less than one quarter of the top drug (Humira) by spend.[31] Within the next several years, states may see cost savings associated with UPLs on top drug expenditures. However, when UPLs are applied more broadly to unlimited products, their utility is likely to be limited.[36]

2 Patient OOP Cost Reductions

UPLs have also been touted as ways to lower patient out-of-pocket costs and improve patient adherence and access. In their initial efforts around UPLs, state policymakers anticipate, though they do not always mandate, that lowering payment rates for drugs will increase PBM "pass through" of rebates, allowing payers to pass on savings to patients through lower cost sharing or premiums. Historically, this has not happened.[28, 37] Within Colorado's statute, language states that any savings generated to the payer should be passed through to patients through out-of-pocket costs. However, how payers must do this, whether that be deductibles, premiums or lowered drug spending, has not been identified.[28]

Notably, since UPLs have typically only applied to state-regulated commercial health plans (e.g., exchange plans, small group), Medicaid and/or state employee plans, the broader impact on patient out-of-pocket costs may vary depending on whether other markets opt in (e.g., self-funded plans, large group). Though Medicaid may be included in UPL statutes, it is unlikely to have any impact due to low patient cost sharing and mandatory federal rebates for prescription drugs likely being lower than future UPL thresholds. Plans may be unlikely to make large changes to their benefit design structures for smaller markets, such as the exchange markets, leaving benefit design and patient access unchanged.

In addition, setting UPLs without consideration of overall plan economics and current market-based access incentives could inadvertently lead plans to favor non-UPL drugs over UPL drugs. Even if gross costs are lower for a UPL product, plans will base coverage decisions on the value of rebates and net cost to the plan, which could limit patient access to drugs with UPLs.

3

Increased Transparency

Mounting scrutiny on the drug pricing supply chain and increasing patient out-of-pocket costs have increased state efforts to improve transparency.[38] State policymakers are using PDABs to examine relationships between payers, PBMs, manufacturers and other stakeholders as they set UPLs.[39] Most notably, PBMs have been at the center of much of this scrutiny as their role in managing prescription drug benefits and negotiating payment rates is difficult to track. States, including Colorado and Washington, intend to leverage UPL setting information to reduce overall state drug costs and increase transparency and competition among manufacturers and payers.[40]

The PDAB and UPL process typically includes states requiring insurers to report top-spend drugs, either through existing or new reporting pathways, to inform PDAB review. However, much of the efforts to promote transparency through UPLs hinges on the information provided by an APCD. For example, the Colorado APCD is the state's most comprehensive source of health insurance claims information, representing lives across Medicare (Fee-for-Service and Advantage), Health First Colorado (Colorado's Medicaid program) and some commercial health insurance plans.[41] However, the APCD data has limitations, such as the ability to collect complete and accurate information without all ERISA plan contributions. This will impact the ability to use APCDs to support accurate analyses such as affordability reviews.[42]

Unintended Consequences of UPL Setting

UPLs have been enacted by state policymakers with the intention of lowering overall drug spending in the state, improving transparency across the supply chain and enhancing patient affordability. However, as UPLs ignore the interconnected market realities of the drug pricing ecosystem and supply chain, these price-setting thresholds may have unintended consequences across payer and PBM formularies, price-reporting metrics, provider reimbursement and patient plan and benefit options.

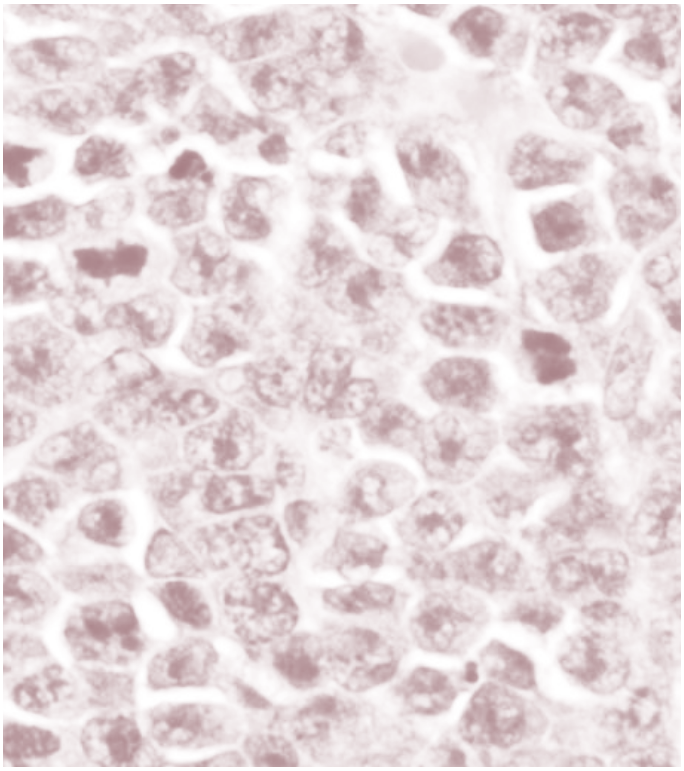
1

Benefit Design and Patient Access

UPL setting for select drugs may shape payer and PBM decision making in ways that could work counter to PDAB's primary intent and increase patient cost sharing or reduce patient access. For example, the process may act cyclically. Manufacturer-provided prescription drug rebates may alter how payers deliver and reform their benefit designs, and lower rebates may result in plans placing medications on higher formulary tiers, which means higher out-of-pocket costs for patients. In addition, this could then affect how patients access medication. The partial list of impacted stakeholders and unintended consequences are as follows:

Pharmacy Benefit Managers (PBMs)

The implementation of price setting in state-regulated commercial markets will have far-reaching effects on payer and PBM practices outside of states with UPLs. In response, PBMs may alter benefit designs to account for their changing rebate structure.[43, 44, 45] This, in turn, may impact patient access to medications and cost sharing, which are closely tied to a drug's placement on plan formularies (e.g., preferred vs. non-preferred).



Pictured: Lymph node.

Patient Cost Sharing

Firstly, UPLs do not necessarily ensure patients see reduced out-of-pocket costs. In addition, benefit design restructuring often results in increased patient cost sharing due to movement across tiers and could reduce patient access. Further, payers and PBMs may shape access by removing UPL products from formularies or reclassifying products to higher, non-preferred tiers. Any benefit design changes that move drugs into non-preferred or brand tiers or result in removal of a drug entirely from a plan's formulary will increase costs to patients (i.e., requires paying for the drug entirely or increases in cost-sharing amounts). Individuals seeking healthcare coverage on the exchanges are increasingly exposed to higher prescription drug cost sharing, as the individual and small group markets have more formulary tiers than large group plans. Nearly 95% of individual market and 93% of small group plans have four or more prescription drug tiers.[46] Additional tiers and PBM movement of drugs to higher tiers will mean higher out-of-pocket costs for patients, as cost sharing is higher for brand and specialty drugs. Additionally, according to HHS, the average deductible on an exchange plan increased from $2,405 to $2,825 in 2021, and the average annual deductible in employer-sponsored insurance has increased by more than 17% over the last five years, more than $2,000.[47, 48] Payer and PBM benefit design changes due to UPLs will have a higher likelihood of adversely impacting patient access, especially in states (e.g., Colorado, Washington) where UPLs will be applied to an unlimited amount of products post-2027.

Average Deductible on an Exchange Plan:

$2,405 2017

$2,825 2021

Average Deductible on Employer-Sponsored Insurance:

↑ 17% in the last 5 years

$2,000+ on average

Copay Assistance

As payers and PBMs implement benefit design changes following UPL application, there is likely to be an increased patient need for manufacturer cost-sharing (e.g., copay) assistance. Copay assistance helps to mitigate the impacts of increased plan and PBM cost-sharing requirements (e.g., deductibles, maximum out-of-pocket costs).[49] For many patients facing high out-of-pocket costs, manufacturer copay assistance programs provide a source of support that improves patient adherence and outcomes. For example, one study found that patients taking HIV or oncology brand medicines using copay assistance saved more than $1,700 in out-of-pocket spending in 2021.[50] As drugs are shifted to higher formulary tiers following UPL setting, increased patient demand for assistance could mean manufacturers reassess and alter eligibility considerations for their copay assistance programs and/or free drug/patient assistance programs (PAPs).

As additional patients seek out manufacturer copay assistance on commercial plans, the implementation of copay assistance diversion (e.g., copay accumulators or copay maximizers, which prohibit or limit manufacturer coupon assistance from counting toward a patient's deductible) could also rise. As such, copay assistance diversion programs could increase patient OOP burden further and prevent them from moving through their benefit.

Patient Choice

Additionally, depending on the volume of UPLs set in a given state, there is potential for market consolidation to limit patient choice. As UPLs grow, both across states and in volume as states become unrestricted in price setting, payers may consider removing themselves from state-regulated markets because of their decreased ability to make a profit based on the spread, decreasing plan choice among patients. Limited plan choice may make plans more sensitive to individuals with high-risk behaviors; as such, they may choose to deny coverage or increase premiums for these individuals.[51]

Plan Participation

While most employer-sponsored insurance is regulated by ERISA and therefore not subject to state PDABs and UPLs, UPL-setting states such as Colorado and Washington have allowed self-funded commercial employers to opt in to UPLs.[52] Self-funded employers could be more likely to opt into UPLs if the state sets a price threshold that is lower than the plan's existing negotiated price or if the plan's volume of UPL drugs is high enough. Higher product volume flowing through UPLs could further limit patient access through benefit design shifts.

Provider Reimbursement

UPL reimbursement pressures could also prompt providers to change referral, prescribing and acquisition patterns for drugs subject to price setting. Smaller practices may be disproportionately impacted by reimbursement cuts and could refer patients to larger sites of care (e.g., outpatient facilities). Where alternatives are available, providers may shift prescribing to other products where reimbursement is more stable.

In one literature review of prescribing habits in oncology, 15 of 18 studies found a correlation between reimbursement and care delivery and responsiveness to financial incentives, suggesting that some oncologists may alter treatment recommendations based on reimbursement considerations.[53]

Lowered reimbursement rates stemming from UPL setting may incentivize providers to prescribe pharmacy benefit drugs instead of medical benefit drugs or non-UPL drugs instead of UPL drugs. The negative financial impact on the traditional provider buy-and-bill system could play into a larger trend that encourages provider consolidation and referrals to larger entities and practices. Finally, UPLs may increase interest in alternatives to buy-and-bill, such as white-bagging, a practice where specialty pharmacies ship a patient's drug directly to the site of care.[54]

Investment in Research and Development

Finally, as manufacturers evaluate the therapeutic areas likely to be subjected to UPLs, they may reassess investment in research and development (R&D) for new therapies or biosimilar competitors to existing drugs. Similar to the potential impacts of the IRA's MFP on selected drugs, manufacturers may be unable to recoup R&D costs if the prices of selected drugs are capped. For example, if "negotiation" were to take place prior to a biosimilar entering the market, the MFP may be set low enough that it deters biosimilar market entry in general. Overall, this could reduce biosimilar launches and negate competition, which may in turn impact manufacturer investment decisions in high-value therapeutic areas that are likely to be subject to price limits such as UPLs.[55, 56]

2

Cascading Changes to Prescription Drug Price Reporting

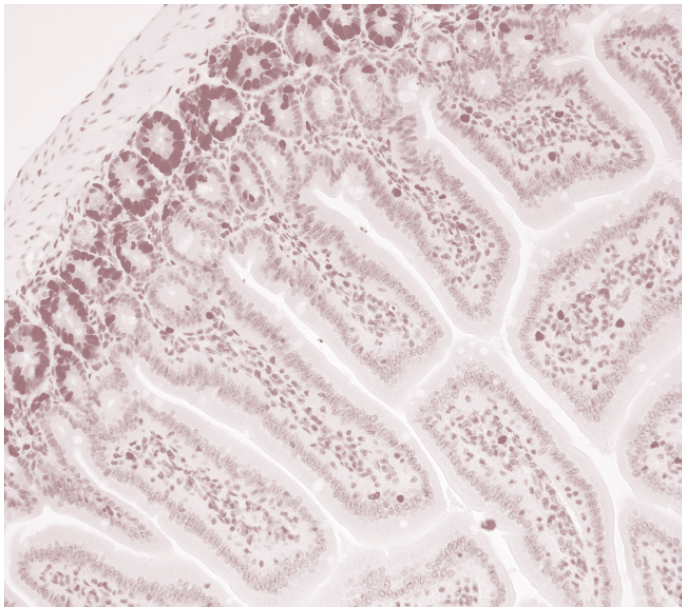
UPL implementation will place downward pressure on a broad range of healthcare stakeholders, including through price reporting metrics such as Medicaid Best Price (BP), Average Manufacturer Price (AMP) and Average Sales Price (ASP). The impact on price reporting metrics may vary, with changes to BP potentially having the largest ripple effect initially. Alternatively, UPL-induced changes to AMP and ASP would occur on a volume-weighted basis, which means that as additional states consider and implement UPLs, ASP and AMP would be affected to a greater degree. **These changes would have consequences that alter pricing outside of the intended markets.**

Medicaid Best Price	Focusing first on BP, base Medicaid Drug Rebate Program (MDRP) liability for brand name drugs is the greater of 23.1% of AMP or the difference between AMP and BP.[57] If a product's UPL were set lower than Medicaid BP, the UPL would set a new BP. If a UPL were to reset BP, markets outside of the UPL state would be affected as a lower BP would alter MDRP calculations and increase the manufacturer's MDRP liability in all states.[58] Additionally, UPL prices would also likely lower AMP on a volume-weighted basis, further altering the MDRP calculation. If BP is too low, it may disincentivize manufacturers from participating in the Medicaid channel.
ASP	Similar effects are expected for ASP for provider-administered drugs. If ASP is lowered due to a UPL, providers reimbursed on an ASP basis (e.g., ASP+6%) would face lower reimbursement, impacting providers outside of UPL states. This consequence is not unique to state UPLs and may be seen with MFP for "negotiated" drugs under the IRA. Once finalized, MFP may be lower than the current ASP, lowering provider reimbursement and creating cascading effects across commercial markets.[59] If provider reimbursement is too low, it may force providers to consolidate practices, contributing to the increasing workforce shortage and/or disincentivizing providers from prescribing or delivering appropriate medication to patients.
340B Pricing	UPL setting will also have cascading effects on the 340B drug pricing program. The 340B program requires manufacturers participating in Medicaid to offer outpatient drugs at a discounted price, no more than a calculated "ceiling price," to eligible entities.[60] Changes to best price and AMP resulting from UPLs will alter the 340B ceiling price (i.e., decreases in AMP could result in 340B entities nationwide purchasing drugs at higher prices). Further, as UPLs reduce insurers' payments for drugs and price reporting metrics, reimbursement for provider-administered drugs could also be negatively impacted, such as by setting a UPL that is lower than the 340B ceiling price, which will alter the margin.

Future of PDABs and UPLs

PDABs are debated and passed into law with the aspiration to be effective tools for states to address perceived rising drug prices and improve patient affordability. **However, much of their efficacy hinges on the ability to produce valuable solutions that work across the drug pricing supply chain and the unproven assumption that cost savings will be passed on to patients.**

To date, state stakeholder efforts to improve drug price transparency and lower costs have been stifled by a lack of long-term consideration and value initiatives. UPLs purportedly offer states a cost-effective short-term option for PDABs and states to lower overall branded drug spending; however, in the long term, their impacts across benefit design, patient access and pricing and contracting may further impede drug pricing reform across state-regulated commercial markets. Moreover, policy changes that focus exclusively on drug pricing at the manufacturer level do not always account for responses from other stakeholders, and hence may not deliver the intended shifts in patient access and affordability. As more states take this approach and select a greater number of drugs each year for UPLs, these issues may be compounded even further.



Pictured: Crypt cells.

In addition to the unintended consequences of UPLs described throughout this paper, future negative effects of price setting may include:

1. Alteration of payer and PBM benefit designs across states and markets (e.g., exchange, self-funded, Medicaid) to provide patients with less generous overall plan choice (e.g., adverse tiering) due to lowered reimbursement for products.
2. Changes in both payer and PBM contracting, as well as manufacturer contracting for products, altering provider reimbursement, 340B contracting and Medicaid rebates.
3. Reductions in manufacturer innovation and research in high-value areas subject to price limits, similar to the effects of the IRA.

In short, states evaluating UPLs may find that UPLs do not help them achieve all of their intended goals and create new negative consequences in the long term, often at the expense of patients and providers. States seeking to implement UPLs should consider the downstream consequences of price setting as UPLs' value may be limited—if not detrimental—in the long term.

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May 9, 2024

Via email (pdab@dcbs.oregon.gov)

Labor & Industry Building
ATTN: Oregon Prescription Drug Affordability Review Board
350 Winter Street NE
Salem, OR 97309

Re: Oregon PDAB Affordability Review Process

Dear Members of the Prescription Drug Affordability Review Board ("the Board"):

I write on behalf of Gilead Sciences, Inc. ("Gilead"), to express concerns regarding the Board's affordability review process, specifically the share of drugs that the Board is required to find unaffordable. Gilead is a research-based biopharmaceutical company that discovers, develops, and commercializes innovative medicines for people with life-threatening diseases in areas of unmet medical need, and has been a leading innovator in treatments for human immunodeficiency virus (HIV) for more than 30 years.

According to the statute establishing the Board, it "shall identify nine drugs" from among all eligible drugs "that the [B]oard determines may create affordability challenges for health care systems or high out-of-pocket costs for patients" in Oregon.[1] This is an arbitrary quota that hampers the Board's ability to apply its expertise and discretion when conducting affordability reviews.

Compounding this concern, the Board has identified only twelve prescription drugs for affordability reviews, despite initially identifying more than 400 drugs as eligible for affordability review in 2023.[2] Applying this arbitrary statutory quota, stacks the deck in favor of finding that the selected drugs pose affordability challenges or high costs, effectively predetermining the Board's decision that three quarters of these drugs will be found unaffordable. This quota applies regardless of what information is submitted about these drugs by manufacturers and stakeholders or other information identified by the Board, regardless of how the Board would otherwise exercise its discretion in applying the statutory criteria, and regardless of whether identifying those drugs as causing affordability challenges or high costs would actually achieve any savings to Oregonians. When applied in this manner, the statutory

[1] Or. Rev. Stat. § 646A.694.
[2] Oregon Prescription Drug Affordability Board. Prescription Drug Data, available at https://dfr.oregon.gov/pdab/Pages/data.aspx.

quota threatens to violate constitutional due process protections and the Oregon Administrative Procedures Act.

Moreover, the Board has indicated that it plans to vote at its May meeting on whether to remove two drugs from consideration. If these drugs are removed, the Board would be left with only ten drugs to review. Doing so would make the existing problem even worse by essentially guaranteeing that the Board must find that nearly all (90%) of the reviewed drugs pose affordability challenges or high costs.

Gilead urges the Board to address this concern by requesting that the legislature allow the Board to find fewer than nine drugs unaffordable. This would allow the Board to base its decisions on a thorough analysis of the relevant evidence under the statutory criteria rather than a compulsion to meet an arbitrary quota.[3]

If you have any questions or wish to notify Gilead about future PDAB actions, please do not hesitate to contact me at kristie.banks@gilead.com.

Sincerely,

DocuSigned by:
Kristie Banks
3B4BECBA5AB74F3...

Kristie Banks
Vice President, Managed Markets
Gilead Sciences, Inc

[3] There is precedent for such an approach. Although the Board was statutorily required to conclude its first review by the end of 2023, Executive Director Ralph Magrish "sent a letter to [Oregon state] legislative leadership on July 13th[, 2023] requesting an extension to complete drug affordability reviews." *See* Oregon Prescription Drug Affordability Board. July 19 2023 Board Meeting Minutes at 1, available at https://dfr.oregon.gov/pdab/Documents/20230719-PDAB-approved-minutes.pdf. Presumably that request was granted, as this first review process is now scheduled to conclude on November 20, 2024.

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

May 10, 2024

Shelley Bailey
Chair
Oregon Prescription Drug Affordability Board
350 Winter St. NE Room 410
Salem, OR

Re: Upper Payment Limit Approach

Chair Bailey,

On behalf of our members operating in Oregon, the National Association of Chain Drug Stores (NACDS) is writing to comment on the Prescription Drug Affordability Board's proposed Upper Payment Limit (UPL) Approach Fact Sheet which was disseminated on April 24. We fear that there may be a significant impact on the availability and accessibility of certain prescription drugs at a patient's neighborhood pharmacy through the unintended consequences of inadequate and unfair pharmacy reimbursement by some payers resulting from the implementation of a UPL for certain drugs. Specifically, the language found in the fact sheet mentions that all supply chain participants could "amend current business processes and/or pricing algorithms to be based upon the Oregon UPL." Even more concerning, the fact sheet states that downstream supply chain participants could "purchase or reimburse **at or below the UPL, but not above**" (emphasis added). As outlined below, allowing PBMs leeway to reimburse below the UPL will have dangerous and avoidable consequences for community pharmacies and threaten patient access to critical medications and health care services.

Reimbursement Overview
Pharmacy reimbursement is typically made up of two parts: 1) the product cost; and 2) a professional dispensing fee. The dispensing fee is calculated to incorporate the costs of a pharmacist's time reviewing the patient's medication history/coverage, filling the container, performing a drug utilization review, overhead expenses (rent, heat, etc.), labor expenses, patient counseling, medication therapy management and more to provide quality patient care. In 2016, the Centers for Medicare & Medicaid Services (CMS) required all states to adopt a more transparent reimbursement model under the 2016 Covered Outpatient Drug Final rule. That rule used actual acquisition costs and a professional dispensing fee to balance the need for affordable solutions and adequate reimbursement for actual costs.

Without the necessary guardrails, the proposed Upper Payment Limit Action Plan could inadvertently result in inadequate reimbursements to pharmacy providers and pharmacies by failing to make up the difference between the UPL and the pharmacy's cost to acquire the drug. This outcome could ultimately force pharmacies to either operate at a loss, make tough decisions regarding certain medications to stay afloat, or worse, close their doors permanently or completely. Careful consideration of the impact on pharmacies is important to help avoid unintended adverse downstream consequences on patient access to vital medications and overall health outcomes under these actions.

Proposed Solution to Ensure Access to Affordable Medications
The following proposals can easily address the issue of fair and adequate pharmacy reimbursement. First, the PDAB must ensure that the established UPL, at a minimum, covers the cost for the pharmacy to acquire/purchase the prescription drug. This means that a prescription drug product purchaser or third-party payer **cannot** reimburse a pharmacy licensed by the state for a prescription drug product in an amount less than a UPL for the prescription drug product. Second, the UPL must include a requirement for payers to provide a professional dispensing fee aligned with Oregon Medicaid's professional dispensing fee rates on any prescription claim subject to a UPL.

NACDS appreciates the board's endeavors to reduce prescription drug costs and enhance affordability for Oregonians. We strongly encourage the incorporation of adequate reimbursement safeguards in the proposed Upper Payment Limit Approach. This will ensure the PDAB protects all community pharmacies while continuing its vital work to alleviate patient costs. For questions or further discussion, please contact Sandra Guckian, Vice President of State Pharmacy & Advocacy, at SGuckian@NACDS.org.

Sincerely,

Steven C. Anderson, FASAE, CAE, IOM
President and Chief Executive Officer
National Association of Chain Drug Stores

###

NACDS represents traditional drug stores, supermarkets and mass merchants with pharmacies. Chains operate over 40,000 pharmacies, and NACDS' member companies include regional chains, with a minimum of four stores, and national companies. Chains employ nearly 3 million individuals, including 155,000 pharmacists. They fill over 3 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 900 supplier partners and over 70 international members representing 21 countries. Please visit NACDS.org.

724 Columbia St. NW, Ste. 310 • Olympia, WA 98501 • PHRMA.ORG

May 12, 2024

Oregon Prescription Drug Affordability Board
350 Winter Street NE
Salem, OR 97309-0405
pdab@dcbs.oregon.gov

Re: Oregon Prescription Drug Affordability Board: May 15, 2024 Agenda and Meeting Materials

Dear Members of the Oregon Prescription Drug Affordability Board ("Board"):

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is writing to comment on the agenda and discussion materials (collectively, the "Meeting Materials") for the Oregon Prescription Drug Affordability Board's May 15, 2024 meeting.[1] PhRMA represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. As discussed further below, PhRMA has a number of questions and concerns about the draft 2024 Generic Drug Report and affordability reviews included in the Meeting Materials.[2]

I. 2024 Report for the Oregon Legislature (Generic Drug Report)

The Meeting Materials include the revised draft "2024 Report for the Oregon Legislature, Generic Drug Report Pursuant to Senate Bill 844 (2021)" (the "Draft Generic Drug Report"). PhRMA continues to have significant concerns about the accuracy and reliability of the report, which incorporates significant misinformation regarding the practices of branded drug manufacturers. Consistent with PhRMA's prior comments, we emphasize that America's biopharmaceutical research ecosystem is the global leader in the development of innovative medicines, allowing patients in the U.S. to access new medicines faster than the rest of the world. This is the result of a carefully balanced policy environment that includes robust intellectual property protections that foster investment in groundbreaking research and development, while also promoting access for patients and the sustainability of the U.S. health care system.[3]

In light of significant mischaracterization and misunderstanding of the mechanisms underpinning the U.S. Intellectual Property system, PhRMA will be submitting an accompanying white paper, for review by members of the Board. This paper provides further background on the U.S. IP framework and is intended to dispel some of the common misconceptions perpetuated by the Draft Generic Drug Report.

PhRMA also reiterates our request that the Board clarify the extent to which the draft report was prepared by, and may reflect the specific views of, a third party contractor rather than the reasoned determination of the Board itself.[4]

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[1] *See* Board, Meeting Materials (May 15, 2024), *available at* https://dfr.oregon.gov/pdab/Documents/20240515-PDAB-document-package.pdf

[2] In filing this comment letter, PhRMA reserves all rights to legal arguments with respect to Oregon Senate Bill 844 (2021), as amended by Oregon Senate Bill 192 (2023) (collectively, the "PDAB Statute"). PhRMA also incorporates by reference all prior comment letters to the extent applicable.

[3] *See* Letter from PhRMA to Board (Nov. 23, 2022) (responding to presentation by Mr. Tahir Amin of the Initiatives for Medicines, Access & Knowledge (I-MAK)).

[4] *See* Letter from PhRMA to Board (June 20, 2022), 1-3 (describing necessary safeguards regarding potential conflict of interest or bias in the Board's independent contractors).

II. Revised Affordability Reviews

PhRMA recognizes the expanded information included in the revised affordability reviews, which now reflect more of the criteria enumerated in the PDAB Statute and the Board's implementing regulations.[5] PhRMA's prior letters have consistently reiterated our request that the Board comprehensively consider statutorily and regulatorily required criteria in its affordability review process.[6] We provide additional comments that apply generally to both of the Affordability Reviews under consideration at the May 15, 2024 meeting:

- The PDAB Statute requires the Board to accept testimony from patients and caregivers affected by a condition or disease treated by a prescription drug subject to affordability review.[7] The Board's regulations further require the Board to "*seek input from* patients and caregivers affected by a condition or disease that is treated by the prescription drug" subject to affordability review.[8] Specifically, pursuant to its own regulations, the Board must gather information from patients and caregivers on the impact of the disease, treatment preferences, the benefits and disadvantages of using the prescription drug, and available patient assistance in purchasing the prescription drug, and the Board must attempt to gather "a diversity of experience" among patients from different socioeconomic backgrounds.[9]

  Despite these statutory and regulatory requirements, the Board has not identified any process for soliciting patient and caregiver input. Providing an avenue for public feedback is not equivalent to actively "seek[ing] input," and the Board's activities stand in stark contrast with the work of the Board staff to actively seek input from constituent stakeholders through surveys, focus groups, and community forums related to the concurrently occurring UPL study.[10] PhRMA asks that the Board revise its affordability review process to actively seek input from impacted patients and caregivers as described in its regulations, and to take that information into consideration as part of its review process.

- We note that among the sources of information cited throughout the affordability reviews, the Board relies in places on blogs, articles, or websites from non-governmental or non-scientific sources. We ask the Board to clarify how it has evaluated the sources it cites for their accuracy, validity, and for potential biases in the information they provide, and further to clarify how the Board intends to consider those sources and weigh them against its statutory and regulatory considerations.

- We also note that the Board's revised affordability review reports include information on the "estimated average monetary price concession" for drugs subject to review, which the reports

[5] *Compare* Board, Meeting Materials (Apr. 17, 2024) at 11–17 *with* PDAB Statute § 646A.694(1)(a)–(m) *and* Or. Admin. R. 925-200-0020(1).

[6] *See* Letter from PhRMA to Board (Feb. 17, 2024) ("'Agencies are creatures of statute' and their actions 'may also be circumscribed the agency's own regulations.' The Board cannot fail to consistently consider statutorily required factors or ignore its own regulatory requirements without a valid explanation for why doing so is permissible under applicable laws and regulations. Likewise, the Board cannot simply recite facts and information without 'fully explain[ing] why those facts lead it to the decision it makes.'") (citations omitted).

[7] PDAB Statute § 646A.694(3).

[8] Or. Admin. R. 925-200-0020(2)(k)(A), emphasis added.

[9] *Id*.

[10] *See* Meeting Materials at 87-97.

indicate is drawn from data provided by carriers from the data call.[11] However, the reports also state that information on other statutory criteria may not be available to the Board.[12] PhRMA reiterates its concerns regarding the additional statutory criterion that requires the Board to consider the "Estimated total amount of price concession" provided to each PBM in the state.[13] As PhRMA previously described, we reiterate that manufacturers pay rebates directly to PBMs, which pass them on, in whole or in part, to health plans or employers according to the terms of the client's agreement with the PBM.[14] PhRMA ask that the Board clarify how it will implement the statute's required consideration of price concessions to PBMs to reflect that information in its affordability review reports.

We are aware that additional data related to price concessions to PBMs will be available to the Board in subsequent years, as aggregate price concession data provided by PBMs to DCBS pursuant to SB 192 (2023) will be available in October 2024.[15] PhRMA suggests that as that data becomes available, the PDAB should consider the total amount of discounts, rebates, and other price concessions received by PBMs, which may be a different amount than rebates received by the health plan, when considering the affordability of drugs under review. This will give the PDAB more transparency into how rebates move through the supply chain and provide a better lens through which to make determinations about the net costs of prescription drugs.

* * *

We thank you again for this opportunity to provide comments and feedback, and for your consideration of our concerns. Although PhRMA has concerns with the Meeting Materials, we stand ready to be a constructive partner in this dialogue. For informational purposes, we are enclosing a copy of PhRMA's May 8, 2024 letter to Governor Kotek, which discusses our concerns regarding the Executive Director's remarks at the Board's April 17 meeting. Please contact dmcgrew@phrma.org with any questions.

Sincerely,

Dharia McGrew, PhD
Director, State Policy

Merlin Brittenham
Assistant General Counsel, Law

Attachment: Letter to Governor Kotek re: Oregon Prescription Drug Affordability Board, May 8, 2024

[11] ORS 646A.694(1)(d) "The estimated average monetary price concession, discount or rebate the manufacturer provides to health insurance plans in this state or is expected to provide to health insurance plans in this state, expressed as a percentage of the price for the prescription drug under review …"
[12] Meeting Materials at 13.
[13] ORS 646A.694(1)(e) "The estimated total amount of the price concession, discount or rebate the manufacturer provides to each pharmacy benefit manager registered in this state for the prescription drug under review, expressed as a percentage of the prices …" *See* Letter from PhRMA to Board (Apr. 13, 2024), 1-2.
[14] Letter from PhRMA to Board (Apr. 13, 2024), 2.
[15] Oregon Drug Price Transparency Program, "Pharmacy benefit managers," https://dfr.oregon.gov/drugtransparency/pages/dpt-pharmacy-benefit-managers.aspx.

724 Columbia St. NW, Ste. 310 • Olympia, WA 98501 • PHRMA.ORG

May 8, 2024

The Honorable Tina Kotek
Oregon State Capitol
900 Court Street, Suite 254
Salem, OR 97301-4047

Re: Oregon Prescription Drug Affordability Board

Dear Governor Kotek,

The Pharmaceutical Research and Manufacturers of America is writing to express significant concerns with the accuracy, transparency, and processes of the Oregon Prescription Drug Affordability Board ("the Board"), as well as the conduct of the Board's Executive Director during the April 17, 2024, Board meeting. We know that as the Governor of the State of Oregon, you take the functioning and conduct of the entities under your control seriously, and we would like to respectfully highlight our concerns.

Board Analyses and Processes

Since the Board started meeting in 2022, PhRMA has consistently through 21 comment letters to date raised concerns about and requested clarification of the Board's work and processes, including:

- Requesting clarification about the data sources, analysis, and processes used by the Board;
- Noting concerns about the transparency and accuracy of the work of the Board;
- Requesting that the Board adopt procedures to allow for full and adequate opportunity for stakeholder comment and engagement on the issues before the Board; and
- Raising concerns about a lack of clear standards for how the Board would conduct the drug selection and affordability review processes.

In February, PhRMA respectfully requested that further action on the Board's affordability reviews be suspended until the Board implemented an affordability review process that appropriately considers all required statutorily and regulatorily enumerated criteria and is consistent with its obligations under the Oregon Administrative Procedures Act.[1] Specifically, we noted that the Board failed adequately to consider information relating to health equity, burden of disease, input from patients and caregivers, and relevant pricing and commercial data.

We remain concerned that the Board has not addressed our fundamental concern that the affordability reviews have been conducted in a manner that is inconsistent with the requirements of the Board's authorizing statute as well as its own regulations. Until these issues are addressed, PhRMA reiterates our request that further action on these affordability reviews be suspended.

[1] *See* Letter from PhRMA to Board Regarding Oregon Prescription Drug Affordability Board: Agenda and Meeting Materials Related Affordability Reviews (Feb. 17, 2024).

Remarks at the April 17 Board Meeting

More recently, PhRMA is concerned by remarks made by the Executive Director of the Board at the Board's April 17, 2024, meeting. The remarks reflect an obvious bias against the pharmaceutical industry and call into question the ability of the Board to carry out its statutory mandate in a fair and objective manner. Among other issues, we are concerned about the Executive Director's oversimplification and mischaracterization of the pharmaceutical supply chain and overtly biased political statements exceeding the Board's purview.

During the April 17th Board meeting, the Executive Director referred to PBMs as "drug dealers" and stated that PBMs are "not part of the supply chain."[2] He further claimed that manufacturers are the sole source of blame in the supply chain, stating that manufacturers "*by design and intention distort the marketplace with rebates*." Concern about the influence of PBMs on the supply chain have been raised by Oregon,[3] Congress, and the Federal Trade Commission,[4,5] with many of the investigations reaching conclusions directly contrary to the Executive Director's statement.

When investigating PBMs, the U.S. Senate Finance Committee concluded that, "PBMs have an incentive for manufacturers to keep list prices high, since the rebates, discounts, and fees PBMs negotiate are based on a percentage of a drug's list price—and PBMs may retain at least a portion of what they negotiate."[6] Oregon's Secretary of State performed an audit of PBM practices in the state, finding that "there is growing public interest in assessing the role, value of, and significant power and influence held by third-party organizations known as pharmacy benefit managers."[7] The Oregon Legislature has considered dozens of bills in the past few years to regulate and rein in the abusive practices of the PBMs.[8,9] In addition, PhRMA has supported proposals to address and reform PBMs' abusive practices.[10] Minimizing the well-documented role of PBMs in the supply chain and claiming, without supporting evidence, that manufacturers intentionally distort the marketplace with rebates conveys a drastic misunderstanding of the complexity of an issue that is central to the Board's remit.

In addition to a fundamental misunderstanding of the supply chain, the Executive Director's statements call into question his ability to impartially and fairly discharge the duties of the Board. For example, the Executive Director stated: "*I believe it would be appropriate for this board to have conversations and consider a recommendation to our state legislature to pass a bill to simply divest the state of its investments through PERS accounts and the state treasury to remove our support for such companies*." Other statements by the

[2] The Executive Director stated that "An upper payment limit would apply to insurers and their vendor PBMs, which are not part of the supply chain."
[3] Oregon Health Authority, "Pharmacy Benefit Managers: Poor Accountability and Transparency Harm Medicaid Patients and Independent Pharmacies," August 2023.. The Oregon Legislature has considered dozens of bills in the past few years to regulate and rein in the abusive practices of the PBMs. *See* "Drug supply companies squeezing pharmacies out of existence, Oregon lawmakers warn." January 26, 2023.; "Oregon set to tighten rules for pharmacy benefit managers. Here's what they do." March 10, 2024.
[4] Federal Trade Commission. "FTC Launches Inquiry into Prescription Drug Middlemen Industry." Press Release, June 7, 2022.
[5] Federal Trade Commission. "FTC Deepens Inquiry into Prescription Drug Middlemen." Press Release, May 17, 2023.
[6] Senate Finance Committee. "Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug," 2021.
[7] Oregon Health Authority, "Pharmacy Benefit Managers: Poor Accountability and Transparency Harm Medicaid Patients and Independent Pharmacies," August 2023..
[8] The Lund Report, "Drug supply companies squeezing pharmacies out of existence, Oregon lawmakers warn." January 26, 2023.
[9] The Lund Report, "Oregon set to tighten rules for pharmacy benefit managers. Here's what they do." March 10, 2024.
[10] PhRMA, "PhRMA Comments to OIG Proposed Rule to Reform the Rebate System," Apr. 8, 2019, https://www.phrma.org/cost-and-value/phrma-comment-letter-on-oig-safe-harbor-proposed-rule. PhRMA, "PhRMA Comments to FTC on the Impact of Pharmacy Benefit Managers' Business Practices," May 26, 2022, https://phrma.org/resource-center/Topics/Cost-and-Value/PhRMA-Comments-to-FTC-on-the-Impact-of-Pharmacy-Benefit-Managers-Business-Practices

Director imply that the Board's stance is adversarial to the biopharmaceutical industry and malign individuals and organizations that do not take the same opinion as the Board.[11]

* * *

These statements serve to exacerbate concerns raised in our previous comment letters that the work of the Board lacks transparency, clarity, and appropriate consideration of the views of all stakeholders during the affordability review process. Based on the concerns outlined in this letter, we request that the Board suspend activity until these issues are resolved. We thank you again for your consideration of our concerns. Although we have raised concerns and questions about the PDAB, PhRMA has consistently attempted to be a constructive and engaged stakeholder in this dialogue. We would welcome an opportunity to meet and discuss our concerns in detail. Please contact me at ELohnes@PhRMA.org with any questions.

Sincerely,

Eric Lohnes

Eric Lohnes
Deputy Vice President, State Advocacy

cc: Andrew Stolfi, Director, Department of Consumer and Business Services

[11] For example, the Executive Director stated, "So to those who have chosen to stand with manufacturers in this issue and their public relations departments, their marketing strategists, and sing these songs of fear and tears and doom and gloom, we invite you to join us in singing from our sheet of music about hope and meaningful changes…"