September 15th, 2025

VIA ELECTRONIC SUBMISSION

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

Re: Affordability Review for Ozempic® and Rybelsus®.

Dear Members of the Oregon Prescription Drug Affordability Board:

Novo Nordisk, Inc. (NNI) respectfully submits this letter to the Oregon Prescription Drug Affordability Board (PDAB) regarding the affordability review of Ozempic® and Rybelsus®. As a company dedicated to enhancing health and quality of life, Novo Nordisk takes pride in its extensive research and development efforts focused on providing innovative medicines that yield safe and effective therapeutic outcomes.

For decades, our researchers have worked diligently to discover and develop treatments for some of the most persistent and costly public health challenges in the United States and globally. This commitment has positioned Novo Nordisk as a leader in diabetes and obesity care, fundamentally transforming the medical management of these complex chronic diseases. Our efforts have also paved the way for advancements in treating other serious conditions, including heart, kidney, liver, and Alzheimer's diseases.

As previously stated, we disagree with the Board's decision to include Ozempic® and Rybelsus® on the list of drugs subject to an affordability review. While we appreciate the Board's ongoing efforts to refine the affordability review process, concerns remain about transparency, data integrity, metrics, standards, and the overall decision-making framework. The lack of access to the underlying data makes it challenging to respond thoroughly and accurately to affordability reviews. Ozempic® and Rybelsus® have been selected by the Centers for Medicare and Medicaid Services (CMS) for purposes of its Medicare Drug Price Negotiation Program. Historically, drugs subject to CMS negotiations were omitted from the Oregon PDAB's affordability reviews. This approach was reiterated by PDAB staff during the "Affordability Review Approaches" presentation at the Board's meeting on

March 19, 2025, building upon discussions from February 19, 2025. Nevertheless, Ozempic® and Rybelsus® were subsequently added to the list. Given these points, we urge the Board to exclude Ozempic® and Rybelsus® from its affordability reviews. If the Board will not exclude the drugs, then we urge members to conclude that Ozempic® and Rybelsus® do not create affordability challenges for health care systems or high out-of-pocket costs for patients in Oregon.

Clinical Information Ozempic® and Rybelsus®

Ozempic® (semaglutide injection) is a once weekly GLP-1 receptor agonist 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.[1] 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. Throughout the glycemic control trials, both the 0.5 mg and 1 mg doses of Ozempic® demonstrated superior improvements in A1C vs. comparators. Significant reductions in body weight from baseline were observed with Ozempic® 0.5 mg and 1 mg with mean decreases ranging from -7.6 lb. to -10.1 lb. and -9.0 to -14.3 lb., respectively.[2 3 4 5]

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[1] Ozempic® Prescribing Information. Plainsboro, NJ: Novo Nordisk Inc. https://www.novo-pi.com/ozempic.pdf.

[2] Sorli C, Harashima S, Tsoukas GM, et al. Efficacy and safety of once-weekly semaglutide monotherapy versus placebo in patients with type 2 diabetes (SUSTAIN 1): a double-blind, randomised, placebo-controlled, parallel-group, multinational, multicentre phase 3a trial. Efficacy and safety of once-weekly semaglutide monotherapy versus placebo in patients with type 2 diabetes (SUSTAIN 1): a double-blind, randomised, placebo-controlled, parallel-group, multinational, multicentre phase 3a trial

[3] Ahren B, Masmiquel L, Kumar H, et al. Efficacy and safety of once-weekly semaglutide versus once-daily sitagliptin as an add-on to metformin, thiazolidinediones, or both, in patients with type 2 diabetes (SUSTAIN 2): a 56-week, double-blind, phase 3a, randomised trial. Efficacy and safety of once-weekly semaglutide versus once-daily sitagliptin as an add-on to metformin, thiazolidinediones, or both, in patients with type 2 diabetes (SUSTAIN 2): a 56-week, double-blind, phase 3a, randomised trial.

[4] Ahmann AJ, Capehorn M, Charpentier G, et al. Efficacy and Safety of Once-Weekly Semaglutide Versus Exenatide ER in Subjects With Type 2 Diabetes (SUSTAIN 3): A 56-Week, Open-Label, Randomized Clinical Trial. *Diabetes Care.* 2018; 41(2):258-266. Link to Access the Full Text.

[5] Aroda V, Sc B, Cariou B, et al. Efficacy and safety of once-weekly semaglutide versus once-daily insulin glargine as add-on to metformin (with or without sulfonylureas) in insulin-naive patients with type 2 diabetes (SUSTAIN 4): a randomised, open-label, parallel-group, multicentre, multinational, phase 3a trial. Efficacy and safety of once-weekly semag-

[6] [7] [8] [9] [10] [11] In a cardiovascular outcomes trial, Ozempic® 0.5 mg or 1 mg compared to placebo demonstrated a relative risk reduction of 26% for the primary composite outcome of time to first occurrence of a 3-point MACE (CV death, non-fatal MI and non-fatal stroke).[12]

Rybelsus® (semaglutide oral) is co-formulated with an absorption enhancer to achieve adequate bioavailability with oral administration. It is administered once daily, in the morning at least 30 minutes before the first meal of the day with up to half a glass of water (approximately 4 fl oz). Rybelsus® should be initiated with the 3 mg dose, and use a 4-week dose escalation, up to 14 mg, to reduce the risk of gastrointestinal (GI) adverse events. The pharmacokinetic and pharmacodynamic profiles were pre-served in patient populations independent of age, ethnicity, and in patients with renal or hepatic impairment. Rybelsus® is indicated as an adjunct to diet and exercise to improve glycemic control in adults with T2D. The PIONEER Phase 3a clinical development program was comprised of 10 clinical trials that evaluated the safety and efficacy of once-daily Rybelsus® in more than 9,500 adult patients with T2D. All studies were designed to be randomized, parallel-group, multicenter trials. For glycemic efficacy, Rybelsus® was compared to several other antidiabetic medica-

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lutide versus once-daily insulin glargine as add-on to metformin (with or without sulfonylureas) in insulin-naive patients with type 2 diabetes (SUSTAIN 4): a randomised, open-label, parallel-group, multicentre, multinational, phase 3a trial

[6] Rodbard HW, Norwood P, Lingvay I, et al. Semaglutide Added to Basal Insulin in Type 2 Diabetes (SUSTAIN 5): A Randomized, Controlled Trial. *The Journal of Clinical Endocrinology & Metabolism.* 2018;103(6):2291-2301. Link to Access the Full Text

[7] Pratley RE, Aroda VR, Lingvay I, et al. Semaglutide versus dulaglutide once weekly in patients with type 2 diabetes (SUSTAIN 7): a randomised, open-label, phase 3b trial. *Lancet Diabetes Endocrinol.* 2018;6(4):275-286. Link to Access the Full Text.

[8] Lingvay I, Catarig AM, Frias JP, et al. Efficacy and safety of once-weekly semaglutide versus daily canagliflozin as add-on to metformin in patients with type 2 diabetes (SUSTAIN 8): a double-blind, phase 3b, randomised controlled trial. *Lancet Diabetes Endocrinol.* 2019;7(11):834-844. Link to Access the Full Text.

[9] Zinman B, Bhosekar V, Busch R, et al. Semaglutide once weekly as add-on to SGLT-2 inhibitor therapy in type 2 diabetes (SUSTAIN 9): a randomised, placebo-controlled trial. *The Lancet Diabetes & Endocrinology.* 2019;7(5):356-367. Link to Access the Full Text.

[10] Capehorn MS, Catarig AM, Furberg JK, et al. Efficacy and safety of once-weekly semaglutide 1.0 mg vs once-daily liraglutide 1.2 mg as add-on to 1-3 oral antidiabetic drugs in subjects with type 2 diabetes (SUSTAIN 10). *Diabetes Metab.* 2019; 46(2):100-109. Link to Access the Full Text.

[11] Kellerer M, Kaltoft MS, Lawson J, et al. Effect of once-weekly semaglutide versus thrice-daily insulin aspart, both as add-on to metformin and optimized insulin glargine treatment in participants with type 2 diabetes (SUSTAIN 11): a randomized, open-label, multinational, phase 3b trial. *Diabetes, Obesity and Metabolism.* 2022;24(9):1788-1799 Link to Access the Full Text.

[12] Marso S, Bain S, Consoli A, et al. Semaglutide and cardiovascular outcomes in patients with type 2 diabetes (SUSTAIN 6). *New Engl J Med.* 2016;375(19):1834-1844. Link to Access the Full Text.

tions, including empagliflozin 25 mg, sitagliptin 100 mg, and liraglutide 1.8 mg. The program also included a cardiovascular outcomes trial (CVOT), PIONEER 6, and 2 studies in Japanese patients (PIONEER 9 and 10). Rybelsus® demonstrated superior improvements in HbA1c (all doses) compared to placebo and most comparators in the PIONEER trials. It also provided superior reductions in body weight compared with placebo and most comparators. Participants who had a serious adverse event was similar in the Rybelsus® vs placebo or comparator group. In PIONEER 6, its primary objective of ruling out an 80% excess CV risk, confirming noninferiority to placebo for the primary outcome and CV safety.[13] [14] [15] [16] [17] [18] [19] [20] [21] [22] [23]

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[13] Aroda VR, Rosenstock J, Terauchi Y, et al. PIONEER 1: randomized clinical trial comparing the efficacy and safety of oral semaglutide monotherapy with placebo in patients with type 2 diabetes. *Diabetes Care.* 2019;42(9):1724-1732. Link to Access the Full Text.

[14] Rodbard HW, Rosenstock J, Canani LH, et al. Oral Semaglutide Versus Empagliflozin in Patients With Type 2 Diabetes Uncontrolled on Metformin: The PIONEER 2 Trial. *Diabetes Care.* 2019;42(12):2272-2281. Link to Access the Full Text.

[15] Rosenstock J, Allison D, Birkenfeld AL, et al. Effect of Additional Oral Semaglutide vs Sitagliptin on Glycated Hemoglobin in Adults With Type 2 Diabetes Uncontrolled With Metformin Alone or With Sulfonylurea: The PIONEER 3 Randomized Clinical Trial. *JAMA.* 2019;321(15):1466-1480. Link to Access the Full Text.

[16] Pratley R, Amod A, Hoff ST, et al. Oral semaglutide versus subcutaneous liraglutide and placebo in type 2 diabetes (PIONEER 4): a randomised, double-blind, phase 3a trial. *Lancet.* 2019;394(10192):39-50. Link to Access the Full Text.

[17] Mosenzon O, Blicher TM, Rosenlund S, et al. Efficacy and safety of oral semaglutide in patients with type 2 diabetes and moderate renal impairment (PIONEER 5): a placebo-controlled, randomised, phase 3a trial. *Lancet Diabetes Endocrinol.* 2019;7(7):515-527. Link to Access the Full Text.

[18] Husain M, Birkenfeld AL, Donsmark M, et al. Oral Semaglutide and Cardiovascular Outcomes in Patients with Type 2 Diabetes. *N Engl J Med.* 2019;381(9):841-851. Link to Access the Full Text.

[19] Pieber TR, Bode B, Mertens A, et al. Efficacy and safety of oral semaglutide with flexible dose adjustment versus sitagliptin in type 2 diabetes (PIONEER 7): a multicentre, open-label, randomised, phase 3a trial. *Lancet Diabetes Endocrinol.* 2019;7(7):528-539. Link to Access the Full Text.

[20] Buse JB, Bode BW, Mertens A, et al. Long-term efficacy and safety of oral semaglutide and the effect of switching from sitagliptin to oral semaglutide in patients with type 2 diabetes: a 52-week, randomized, open-label extension of the PIONEER 7 trial. *BMJ Open Diabetes Res Care.* 2020;8:e001649. Link to Access the Full Text.

[21] Zinman B, Aroda VR, Buse JB, et al. Supplement to: Efficacy, Safety and Tolerability of Oral Semaglutide Versus Placebo Added to Insulin +/- Metformin in Patients with Type 2 Diabetes: the PIONEER 8 Trial. *Diabetes Care.* 2019; 42(12):2262-2271. Link to Access the Full Text.

[22] Yamada Y, Katagiri H, Hamamoto Y, et al. Dose-response, efficacy, and safety of oral semaglutide monotherapy in Japanese patients with type 2 diabetes (PIONEER 9): a 52-week, phase 2/3a, randomised, controlled trial. *Lancet Diabetes Endocrinol.* 2020;8(5):377-391. Link to Access the Full Text.

[23] Yabe D, Nakamura J, Kaneto H, et al. Safety and efficacy of oral semaglutide versus dulaglutide in Japanese patients with type 2 diabetes (PIONEER 10): an open-label, randomised, active-controlled, phase 3a trial. *Lancet Diabetes Endocrinol.* 2020;8(5):392-406. Link to Access the Full Text.

Endogenous glucagon-like peptide-1 (GLP-1) has a <2-minute half-life.[24] Therefore, Novo Nordisk has developed injectable analogs with 13 hour (Victoza®) and 7-day half-lives (Ozempic®) for the treatment of type 2 diabetes.[25]

With Rybelsus®, Novo Nordisk continued to expand its portfolio in this area to include different delivery options. Timely treatment of type 2 diabetes is needed to reduce the risk of type 2 diabetes complications and yet many patients do not achieve current glycosylated hemoglobin (A1C) targets with the currently available treatment options. GLP-1 receptor agonists (RAs) provide effective glycemic control along with weight reduction and low risk of hypoglycemia. Rybelsus®, an oral GLP-1 RA, may lead to initiation of GLP-1 RA treatment earlier in the continuum of the disease and may improve acceptance and adherence for some patients compared with injectable formulations of GLP-1 RA. Rybelsus® is not intended to replace Ozempic® injection.

Research and Development Journey

In developing our GLP-1 drugs, Novo Nordisk pioneered something revolutionary. Our groundbreaking class of GLP-1 medications, which includes semaglutide, is a class-leading treatment option that allows patients to manage their diabetes, with positive health outcomes for comorbidities and related conditions.

Ozempic® was approved by the Food and Drug Administration ("FDA") in 2017 for the treatment of type 2 diabetes. It increases the body's production of insulin, a hormone that lowers blood sugar levels, and reduces production of glucagon, which increases blood sugar levels.[26] As the New York Times recently reported, Ozempic® is "changing diabetes treatment," as many patients "have been able to lower their insulin doses after starting Ozempic[®], and some have been able to go off insulin entirely."[27] And while the first GLP-1 agonists were introduced to treat patients with diabetes by promoting insulin production,

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[24] Drucker DJ et al. *Proc Natl Acad Sci USA* 1987;84(10):3434–3438; Drucker DJ, Nauck MA. *Lancet* 2006;368(9548):1696-1705; Holst JJ. *Physiol Rev* 2007;87(4):1409–1439.

[25] Victoza® Prescribing Information. Plainsboro, NJ: Novo Nordisk Inc. Victoza PI (novo-pi.com).

[26] Manoj Kumar Mahapatra, Muthukumar Karuppasamy & Biswa Mohan Sahoo, Semaglutide, a glucagon like peptide-1 receptor agonist with cardiovascular benefits for management of type 2 diabetes, *R. Endocrine & Metabolic Disorders* (2021), https://ncbi.nlm.nih.gov/pmc/articles/PMC8736331/.

[27] Dani Blum, How Ozempic Is Changing Diabetes Treatment, N.Y. Times (May 13, 2024), https://www.nytimes.com/2024/05/13/well/live/insulin-ozempic-diabetes.html; *see also* Paresh Dandona, Ajay Chaudhuri, and Husam Ghanim, Semaglutide in Early Type 1 Diabetes, N. Engl. J. Med. (2023), https://www.nejm.org/doi/full/10.1056/NEJMc2302677.

studies indicated that they also regulate the body's response to food, creating a sensation of fullness and reducing the desire to continue eating.[28]

The approval of Ozempic® and Rybelsus®, following decades of research and development, gave way to a paradigm shift in the treatment of type 2 diabetes and related comorbidities. Novo Nordisk continues to make significant investments in the science of chronic diseases to uncover the next major breakthrough. Indeed, we have conducted additional large-scale clinical trials (including SUSTAIN-6 and FLOW) involving tens of thousands of people in dozens of countries around the world. Semaglutide was shown to reduce the risk of major adverse cardiovascular events like heart attacks and strokes in adults with established cardiovascular disease and either obesity or overweight by 20% (SELECT), and to reduce the progression and mortality of kidney disease in adults with diabetes and chronic kidney disease by 24% (FLOW).[29]

As research has shown, these drugs can result in significant and sustained health improvements and have the potential to be transformative for the millions of Americans struggling with type 2 diabetes. The panoply of benefits and applications for GLP-1 medications like semaglutide is not yet known, and scientists—backed by Novo Nordisk's significant investment in ongoing research and development—are exploring its potential to treat a range of serious conditions.

Our researchers are continuing to learn more about the disease of diabetes, and what impact GLP-1s may have on other disease states. For example, Novo Nordisk has trials underway examining the use of semaglutide for treatment of liver disease and Alzheimer's disease, and there are some studies by others that show that GLP-1s may have the ability to

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[28] John Blundell et al., Effects of once-weekly semaglutide on appetite, energy intake, control of eating, food preference and body weight in subjects with obesity, *Diabetes, Obesity & Metabolism* (2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5573908/; *see also* Susan Cornell, A review of GLP-1 receptor agonists in type 2 diabetes: A focus on the mechanism of action of once-weekly agents, *J. Clinical Pharm. & Therapeutics* (2020), https://onlinelibrary.wiley.com/doi/pdfdirect/10.1111/jcpt.13230; Jean-Pierre Gutzwiller et al., Glucagon-like peptide-1 promotes satiety and reduces food intake in patients with diabetes mellitus type 2, *Am. J. Physiology* (May 1999), https://pubmed.ncbi.nlm.nih.gov/10233049/.

[29] The landmark SELECT study, funded by Novo Nordisk, demonstrated that semaglutide reduced the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) by 20% in adults with overweight or obesity and established cardiovascular disease. This trial involved more than 17,000 adults across 41 countries and 800 investigator sites. *See* Company announcement No 50 / 2023, Novo Nordisk (Aug. 8, 2023), https://www.novonordisk.com/news-and-media/news-and-ir-materials/news-details.html?id=166301. Additionally, Novo Nordisk's FLOW study demonstrated a 24% reduction in kidney disease progression and mortality in adults with type 2 diabetes and chronic kidney disease. Like the SELECT study, this trial was funded by Novo Nordisk and involved thousands of patients across hundreds of investigator sites in 28 countries. *See* Company announcement No 20 / 2024, Novo Nordisk (March 5, 2024), https://www.novonordisk.com/content/nncorp/global/en/news-and-media/news-and-ir-materials/news-details.html?id=167028.

treat or improve Parkinson's and various forms of addiction.[30] We are investing substantial resources, time, and dollars into these studies. While it will be years before many of them yield conclusive findings, researchers are optimistic about identifying even more ways in which these medicines can change and potentially save lives.

All of these findings make clear that the development of GLP-1 drugs like Ozempic® and Rybelsus® have been a monumental step forward for public health. GLP-1 drugs were named the 2023 Breakthrough of the Year by Science magazine, and experts describe them as "medical breakthroughs" on par with advancements like gene therapy and the mRNA technologies that produced COVID vaccines.[31] Just last year, Dr. Lotte Bjerre Knudsen—the Novo Nordisk scientist who led the company's work on liraglutide, the company's pioneering first GLP-1 medicine—was awarded a 2024 Breakthrough of the Year Award from the American Association for the Advancement of Science ("AAAS").[32] And as researchers around the world continue to explore uses and applications of GLP-1 therapies, the work of our scientists and their contemporaries has been heralded as so groundbreaking that it could be considered for a Nobel Prize.[33]

Financial Investment in Bringing Ozempic® and Rybelsus® to Market

On average, it takes 10 to 15 years to develop a new drug from initial discovery through regulatory approval.[34] This section describes how the journey to develop Ozempic® and Rybelsus® required a much longer than average sustained investment by Novo Nordisk. Since the early 1990s, the company's scientists encountered many roadblocks and observed competitors abandoning similar research or simply refusing to invest in GLP-1 medications at all. But year after year, Novo Nordisk persisted.

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[30] *See* R&D Pipeline, Novo Nordisk (accessed May 23, 2024), https://www.novonordisk.com/science-and-technology/r-d-pipeline.html; *see also* Nat'l Inst. on Alcohol Abuse & Alcoholism, Semaglutide shows promise as a potential alcohol use disorder medication (March 13, 2024), https://www.niaaa.nih.gov/news-events/research-update/semaglutide-shows-promise-potential-alcohol-use-disorder-medication; Wassilios G. Meissner, et al., Trial of Lixisenatide in Early Parkinson's Disease, *N. Engl. J. Med.* (April 2024), https://www.nejm.org/doi/pdf/10.1056/NEJMoa2312323.

[31] Jennifer Couzin-Frankel, Obesity meets its match: Blockbuster weight loss drugs show promise for a wider range of health benefits, *Science* (Dec. 14, 2023), https://www.science.org/content/article/breakthrough-of-the-year-2023.

[32] Meagan Phelan, Innovators Who Fought to Unlock GLP-1 Drug for Obesity Awarded Mani L. Bhaumik Breakthrough of the Year Award, American Association for the Advancement of Science (April 4, 2024), https://www.aaas.org/news/innovators-glp-1-obesity-bhaumik-breakthrough.

[33] *See* Megan Molteni & Elaine Chen, GLP-1 drugs are transforming diabetes, obesity and more. Could a Nobel be next?, Stat News (Sept. 30, 2023), https://www.statnews.com/2023/09/30/weight-loss-ozempic-nobel-prize-science/.

[34] Research & Development Policy Framework, PhRMA (accessed September 13, 2024), https://phrma.org/policy-issues/Research-and-Development-Policy-Framework.

Throughout the decades, Novo Nordisk constantly pushed this research forward, funding study after study to understand whether these drugs worked and could be used to improve the lives of those with chronic diseases.

Our investment in the science underpinning the discovery of Ozempic® and Rybelsus® dates back to the early 1990s, and by conservative estimates, totaled well over $10 billion. Under conservative estimates, Novo Nordisk undertook more than 100 phase II and III clinical trials for our GLP-1 medicines over the course of more than three decades, collecting more than 135,000 person-years of data.[35]

Importantly, these figures do not capture the full picture and cost of what it took to get to where we are today—because for every drug that works, there are nine that fail.[36] That is, for every medication that advances all the way to human testing, 90% fail during phase I, II, and III clinical trials.[37] And of the one-in-ten medications that do make it to the market, only a minority actually turn a profit.[38] Nevertheless, we continued with studies, trials, and lines of research over the years when both academia and the pharmaceutical industry showed little interest in exploring these treatments.

Producing Ozempic® and Rybelsus® at the scale needed to meet current (and rising) demand is complicated and expensive. Our company was founded on the development and commercialization of insulin, but manufacturing complex peptide treatments like insulin is extraordinarily difficult to do—and we spent the first five decades after insulin's discovery trying to find a way to scale production sufficiently to serve all patients who could benefit from it. Semaglutide, the active ingredient in Ozempic® and Rybelsus®, is also a complex peptide, and, today, we are once again making investments to solve the same challenge: increasing production capacity and closing the gap between supply and demand.

In the last year alone, we have committed to spending more than $25 billion on building production capacity—more than double the company's entire net profit in 2023. The overwhelming majority of this investment is being directed towards GLP-1 medication production. In 2024, Novo Nordisk spent $11 billion to acquire three manufacturing sites in Indiana, Italy, and Belgium from Catalent, one of the largest drug manufacturing contractors in

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[35] Each "person-year" is a year of data contributed by an individual participant in a study.

[36] Duxin Sun et al., Why 90% of clinical drug development fails and how to improve it?, *Acta Pharmaceutica Sinica B* (Feb. 11, 2022), https://pubmed.ncbi.nlm.nih.gov/35865092/.

[37] *Id.*

[38] John A. Vernon et al., Drug development costs when financial risk is measured using the Fama-French three-factor model, *Health Economics* (Aug. 2010), https://pubmed.ncbi.nlm.nih.gov/19655335/.

the world.[39] This is in addition to announcements made in late 2023 that we would invest $8 billion in manufacturing facilities in France and Denmark to increase production.[40] We continue to evaluate potential additional investments in expanding manufacturing capacity and intend to maintain elevated levels of capital expenditures—more than $7 billion each year—through at least 2026.

We have also recently announced a nearly $5 billion investment in manufacturing facilities in North Carolina for US-based development of semaglutide. Novo Nordisk's North Carolina investment has created jobs for thousands of Americans at more than double the average local income. The company also owns facilities in Colorado, Indiana, New Hampshire, and Virginia; in total, Novo Nordisk employs more than 8,300 people across the United States.[41]

Novo Nordisk has made these investments while reducing its carbon footprint. In 2020, the company achieved the goal of using 100% renewable energy across all global production, including in the U.S., where its North Carolina facility is completely powered by a nearby, purpose-built, 105-megawatt solar farm.

Novo Nordisk's Commitment to Patient Access

Novo Nordisk is firmly committed to ensuring that patients have affordable access to our medicines. Unfortunately, the U.S. healthcare system is dominated by middlemen who play a key role in both patient access and costs—the vertically-integrated healthcare conglomerates made up of insurers, pharmacy benefit managers ("PBMs"), specialty pharmacies, and opaque group purchasing organization contractors ("GPOs"). This system has created unintended consequences that can raise out of pocket costs for patients and interfere with affordable access to prescription drugs.

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[39] Press Release: Novo Nordisk to acquire three fill-finish sites from Novo Holdings A/S in connection with the Catalent, Inc. transaction, Novo Nordisk (Feb. 5, 2024), https://www.novonordisk.com/news-and-media/news-and-ir-materials/news-details.html?id=167017; Novo Holdings and Catalent, Press Release: Novo Holdings to Acquire Catalent, Businesswire (Feb. 5, 2024), https://www.businesswire.com/news/home/20240204431488/en/Novo-Holdings-to-Acquire-Catalent.

[40] Press Release: Novo Nordisk invests more than 16 billion Danish kroner in expansion of production facilities in Chartres, France, Novo Nordisk (Nov. 23. 2023), https://www.novonordisk.com/content/nncorp/global/en/news-and-media/news-and-ir-materials/news-details.html?id=166350; *see also* Press Release: Novo Nordisk invests more than 42 billion Danish kroner in expansion of manufacturing facilities in Kalundborg, Denmark, Novo Nordisk (Nov. 10, 2023), https://www.novonordisk.com/content/nncorp/global/en/news-and-media/news-and-ir-materials/news-details.html?id=166342.

[41] Novo Nordisk, Annual Report 2023, https://www.novonordisk.com/content/dam/nncorp/global/en/investors/irmaterial/annual_report/2024/novo-nordisk-annual-report-2023.pdf.

Today, the three biggest PBMs control prescription drug access for more than 80% of the market, exercising near-total control over the ability of hundreds of millions of Americans to get the medicines they need at affordable prices, and each of these PBMs is owned by one of the largest health insurance companies in the United States. While PBMs negotiate often substantial rebates from drug manufacturers, these payments are not typically applied to point-of-sale prices and patient coinsurance.[42]

Overall, Novo Nordisk pays 75 cents of every dollar of medicine it sells back into this complex system in rebates, discounts, and fees—meaning the "net" price Novo Nordisk ultimately receives for the medicines it sells is far below the published "list" price. And while the rebates Novo Nordisk pay to PBMs and insurers as a share of each dollar earned have increased dramatically over the last decade, this has not resulted in a proportionate reduction in out-of-pocket costs for patients at the pharmacy counter. As an independent study found, the gap between list prices and net prices persists even for the newest generation of GLP-1 medications, like Ozempic® and Rybelsus®.[43] In fact, the net price of Ozempic®—the amount that Novo Nordisk is actually paid for the medicine—has declined by about 40% since its introduction in the U.S.

Furthermore, Novo Nordisk continues to take steps to help patients afford their medication. On August 18th, 2025, Novo Nordisk introduced a new self-pay program for Ozempic®, allowing patients with a prescription to access the medication for $499 per month. This initiative specifically supports T2D patients who lack commercial insurance and who would otherwise pay prices at or above the WAC. Beyond this, NNI offers both a patient assistance program and copay assistance for patients for patients living with T2D. This includes offerings that reduce the price at the pharmacy counter to as little as $25 for a one-month supply of Ozempic® or $10 for Rybelsus® for patients with commercial insurance facing large co-pays. Additionally, the company's Patient Assistance Program (PAP) provides free Ozempic® to patients in need who are uninsured or receive insurance through Medicare and whose household income falls below 400% of the federal poverty line (approximately $120,000 for a family of four).[44] Such measures underscore the essential link between access and affordability, and any meaningful discussion about patient costs must include an examination of insurance benefit design and payer-related barriers.

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[42] Andrew Brownlee & Jordan Watson, The Pharmaceutical Supply Chain, 2013–2020, Berkeley Research Group (Jan. 7, 2022), https://www.thinkbrg.com/insights/publications/pharmaceutical-supply-chain-2013-2020/.

[43] Benedic N. Ippolito & Joseph F. Levy, Estimating the Cost of New Treatments for Diabetes and Obesity, American Enterprise Institute, 2-3 (Sept. 2023), https://www.aei.org/wp-content/uploads/2023/09/Estimating-the-Cost-of-New-Treatments-for-Diabetes-and-Obesity.pdf?x91208.

[44] *See* NovoCare, Patient Assistance Program, Novo Nordisk, https://www.novocare.com/diabetes/help-with-costs/pap.html.

Thus, to effectively address what patients actually pay at the pharmacy counter for their prescriptions, it is essential to consider the role of each actor in the system. Novo Nordisk is committed to benefit design reforms that remove the perverse incentive in the supply chain for plans to often prefer high rebates over lower-priced products (with comparatively lower rebates). Moreover, Novo Nordisk is concerned that a misplaced focus on the "list prices" of prescription drugs can result in significant unintended consequences on patient access. A recent Government Accountability Office report highlighted that "Part D 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."[45] If the Oregon PDAB is one day empowered to set upper payment limits (UPL) for drugs sold in the state of Oregon, the decision to do so could result in decreased access to those drugs as the dynamics in the current system favor drugs that have higher rebates. If a UPL is ever set in Oregon, its impact would undermine the PDAB's goal of lowering costs and promoting affordable access for Oregonians.

* * * *

In conclusion, it is essential that any evaluation of Ozempic® and Rybelsus® reflect their transformative impact on patient outcomes, their unmatched therapeutic advantages, and the considerable efforts NNI has undertaken to enhance affordability and access. Discussions about value and cost must consider the broader context—including real-world benefits, evolving insurance coverage, and proactive support programs. By embracing a comprehensive and informed perspective, we can ensure that patients continue to receive the highest standard of care while also addressing affordability in a meaningful and equitable way.

[45] Government Accountability Office. 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 [Internet]. 2023 Sep 19 [cited 2024 Jun 30]. Available from: https://www.gao.gov/assets/gao-23-107056.pdf.

Lilly USA, LLC

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September 15, 2025

VIA ELECTRONIC SUBMISSION

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

RE: Oregon Prescription Drug Affordability Board (PDAB): September 17, 2025 Meeting Materials

Dear members of the Oregon Prescription Drug Affordability Board,

Eli Lilly and Company (Lilly) appreciates the opportunity to provide our perspective on the Oregon PDAB ("the Board") meeting materials for September 17, 2025, which includes reviews of our products Mounjaro® and Trulicity®.[1] Lilly is one of the country's leading innovation-driven, research-based pharmaceutical and biotechnology corporations. Our company is devoted to seeking answers for some of the world's most urgent medical needs through discovery and development of breakthrough medicines and technologies and through the health information we offer. Ultimately, our goal is to develop products that save and improve patients' lives.

I. Lilly encourages the Board to recommend policies that meaningfully improve patient affordability instead of price controls

As we have stated in past comments, we remain strenuously opposed to government price-setting as a misguided approach for making prescription drugs more affordable and enabling patients to access prescribed treatments. Given these long-standing concerns, Lilly is pleased to see that some of the policy alternatives proposed by Board members for 2025 would meaningfully address issues in the pharmaceutical payment system without inviting the unintended consequences inherent with price-setting schemes.[2] The Board should continue exploring system-wide reforms that can address the divergence between list and net prices and do more to lower costs for patients than de facto price controls.

While Lilly shares the Board's goal of promoting affordable access to medicines for patients, the Board should not impose upper payment limits (UPLs) on medicines. Price controls will not accomplish the Board's goals but instead create a host of unintended consequences for patients, taxpayers, and other pharmaceutical supply chain stakeholders. Accordingly, we encourage the Board to not recommend UPLs to the Oregon legislature.

[1] Oregon Prescription Drug Affordability Board. "Agenda and meeting materials for September 17, 2025." https://dfr.oregon.gov/pdab/Documents/20250917-PDAB-document-package.pdf.
[2] Ibid. at pgs. 14-23.

State attempts to impose payment limits on medicines will harm patients. The pharmaceutical supply and payment system is complex, and the price that patients pay at the pharmacy counter is not directly impacted by UPLs imposed on medicines. Patients' cost-sharing obligations are solely determined by the formulary designs that are imposed by their health plans.[3] Prescription medicines are placed on cost sharing tiers, which determine the copay or coinsurance amount that a patient is obligated to pay. Imposing a "payment limit" on the amount a payer may reimburse a pharmacy provider has no direct bearing on a patient's cost-sharing obligations, which are established by the plan's benefit design structure. Instead, these reimbursement limits allow "savings" associated with lower reimbursement to be captured by payment system middlemen, with no direct financial benefit to patients.[4] To be sure, the distortions introduced by a UPL enable it to function as a de facto price control – with a similar potential for unintended consequences.

In fact, price controls are more likely to impair patient access to the very medicines subject to such policies – by adversely impacting national supply chains and creating access problems in affected markets. Manufacturers do not generally sell medicines into a specific state, but rather through national supply chain entities, like wholesalers and pharmacies. Accordingly, when a state-specific price control is imposed on a medicine, out-of-state sellers or dispensers may have to sell or dispense the drug at a financial loss or stop providing it in the state.[5] For example, payment limits on medicines may result in pharmacies losing money when they fill prescriptions because their reimbursement rates (set by the payment limit) are lower than their acquisition costs (not set by the payment limit). This hurts pharmacies' bottom lines, resulting in economic hardship, possible pharmacy closures, and pharmacy deserts that reduce patients' access to care. Alternatively, in-state pharmacies may refuse to fill unprofitable prescriptions, creating barriers to patients accessing their prescribed medications.

At a macro level, price controls introduce constraints on manufacturers that can lead to a reassessment of how to deploy resources towards research and development of innovative treatments and cures. These constraints are not limited to manufacturers directly affected by the policy itself – price controls within specific drug classes send a signal to other manufacturers that certain areas may not be profitable for future investment, which can have a chilling effect on private market competition. In the short term, manufacturers of

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[3] *See*, Hernandez I, Hung A. A primer on brand-name prescription drug reimbursement in the United States. J *Manag Care Spec Pharm*. 2024 Jan;30(1):99-106. doi: 10.18553/jmcp.2024.30.1.99. PMID: 38153864; PMCID: PMC10754395.

[4] *See*, American Cancer Society. "Prescription drug affordability boards and the impact on cancer care." December 2023. https://www.fightcancer.org/sites/default/files/prescription_drug_affordability_boards_12-23.pdf ("[P]lans are not required to pass these savings on in the form of lowered out-of-pocket costs for the patients using drugs subject to UPLs. Instead, the plans may use the savings to, for example, lower premiums for all beneficiaries while maintaining patient cost sharing for drugs subject to UPLs at the same level").

[5] *See*, National Alliance of State Pharmacy Associations. "Prescription drug affordability boards: potential risks to pharmacy reimbursement. September 12, 2025. https://naspa.us/resource/pdab/ ("Pharmacies may be reimbursed at rates below their acquisition costs for certain medications if UPLs are set too low. This discrepancy can lead to significant financial losses, particularly for independent community pharmacies that lack the purchasing power of larger chains.").

similar products, including generics and biosimilars, may be reluctant to compete for access in markets subject to price controls, which would undermine patient choice and harm the very beneficiaries the state purports to help.

For these reasons, Lilly encourages the Board to not recommend UPLs or other price control policies to Oregon's legislature. Such approaches are deeply flawed and rife with unintended consequences. A UPL would do nothing to help beneficiaries derive the most benefit from their plan design. Instead, the Board should continue to explore structural reforms that address warped supply chain incentives directly – enabling lower costs for patients at the point-of-sale and creating the conditions for list and net price parity.

II. Mounjaro® and Trulicity® are affordable for patients in Oregon

The primary focus of any cost review by the Board should be on patients, and Mounjaro and Trulicity are broadly affordable for Oregon patients. The Board's data shows that median patient out-of-pocket costs ($30/per claim for Mounjaro and $10/per claim for Trulicity) are affordable for the average patient.[6] To the extent that patients do face affordability challenges with Trulicity and Mounjaro, the Board must consider the influence of plan benefit designs on patient costs.

Health plans design formularies which determine patients' out-of-pocket cost obligations. According to the Board's data, 61 percent of plans place Mounjaro on a non-preferred tier whereas 34 percent of plans place Trulicity on a non-preferred tier.[7] Non-preferred tiers require patients to pay more for their medicine than if it was on the preferred tier. Patients subject to plan designs with large deductibles or high cost-sharing tiers are more likely to struggle to afford their medicines. In these circumstances, Lilly helps to reduce patient out-of-pocket costs for commercially insured patients, including those covered by health benefit plans making payments on behalf of a unit of state or local government. For example, patients that qualify for the Trulicity Savings Card pay as little as $25 per month for Trulicity.[8] Lilly also offers vouchers and electronic point-of-sale benefits that reduce patients' costs for Trulicity. The Board should take these factors into account when considering the affordability of medicines.

Finally, we encourage the Board to not use wholesale acquisition cost (WAC) in their selection or review processes as it does not reflect the net cost incurred by payers or patients after accounting for rebates and other price concessions. Therefore, WAC is not a useful measurement of affordability to either patients or the health system.

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[6] Oregon Prescription Drug Affordability Board. "Agenda and meeting materials for September 17, 2025." https://dfr.oregon.gov/pdab/Documents/20250917-PDAB-document-package.pdf, pgs. 71, 173.
[7] Ibid. at pgs. 86, 189.
[8] *See, e.g.*, Eli Lilly and Company, Trulicity Savings Card, available here.

III. The Board's drug affordability review methodology remains flawed and incomplete

Reiterating comments that Lilly submitted to the Board on April 25, 2025, we remain concerned about the methodology that the Board employs to measure and define affordability.[9]

It is unclear whether the primary focus of the Board's affordability review is on cost sharing for patients, specifically patient out-of-pocket costs, or for the health care system as a whole. The Board has not meaningfully defined what "affordability" means, and this shortcoming makes it virtually impossible for the Board to determine if a medicine creates "affordability challenges"[10]. Failure to meaningfully define key terms inhibits stakeholder input and needlessly amplifies the risk that the Board will ultimately apply its reviews in an arbitrary and inconsistent manner. We believe it is crucial to prioritize patient affordability and the patient out-of-pocket experience to ensure that Oregon patients can access the medications they need without undue financial burden.

In addition to the need for a consistent definition of affordability, it is critical that the drug selection methodology which the Board uses is free from bias. We remain concerned that gaps in data collection and availability can lead to the biased selection of medicines subject to review by the Board. Furthermore, the use of total gross drug spending data by the Board in the selection process can result in the biased selection of medicines with high aggregate spending that treat large populations of individuals with chronic medical conditions. Such medicines, even if affordable to patients, may be misconstrued as being unaffordable simply by virtue of them being commonly prescribed and highly utilized. Drug affordability means different things to payers, health systems, governments, and patients. The Board has not clearly addressed those differences in their drug selection methodology.

Finally, we are concerned about possible inconsistencies and data errors contained in the drug reviews provided in the meeting materials for the Board's September 17th meeting. For example, only two of the five reports contain the "rubric considerations" section, and the therapeutical alternative comparators are inconsistent across reports.[11] No explanation is given for these inconsistencies. Concerningly, there are instances where per-claim net spend appears higher than per claim gross spend which defies logic.[12] Again, there is no explanation given for these confounding data.

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[9] Eli Lilly and Company. "Re: Prescription Drug Affordability Review of Lilly Products." April 15, 2025 (pgs. 10-14). https://dfr.oregon.gov/pdab/Documents/Public-comments-drug-reviews.pdf.

[10] Oregon Prescription Drug Affordability board. "OAR 925-200-0020 conducting an affordability review." https://dfr.oregon.gov/pdab/Documents/OAR-925-200-0020.pdf.

[11] N.B., only Rybelsus® and Jardiance® reports include the "rubric considerations" element.

[12] N.B., for example, on page 16 of the Trulicity report, the "Data Cell" figure is $1,089 while the "APAC" figure is $1,073. Footnote 35 states that the Data Cell data includes "cost information after price concessions" while the APAC data does not. It is unclear how the median patient cost is lower *before* price concession than *after*.

Given these concerns – both on methodological and broader policy grounds – there are clear reasons why the Board should abandon recommending UPLs to the state legislature altogether. We encourage the Board to carefully consider our comments and examine more effective methods to reform the supply chain in the state of Oregon. We stand ready to work with the Board in support of policies to ensure that all Oregonians have affordable access to our medicines.

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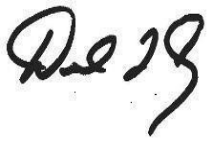
Lilly appreciates the opportunity to respond to the Board materials. We appreciate that the Board shares our commitment to prescription drug access and patient affordability. We are proud of the impact that our efforts have had on making prescription drugs more affordable for patients and believe Lilly medicines like those selected by the Board help make the lives of Oregon patients healthier and better.

Sincerely,



Derek L. Asay
Senior Vice President,
Government Strategy and Federal Accounts

To: Oregon Prescription Drug Affordability Board

From: Jennifer Taylor

Date: 9/21/2025

Topic: Medicare prescriptions

I am on SSDI. I had to switch to Medicare instead of a Medicare Advantage because I needed to see doctors that only take Medicare. I am on extra low income care but, can no longer afford my prescriptions.

September 16, 2025

Prescription Drug Affordability Board
350 Winter St., NE
Room 410
Salem, OR 97309
pdab@dcbs.oregon.gov

RE: 340B Transparency

Dear Chair Bailey and board members,

On behalf of Bridge Pamoja, a network of Black faith leaders and culturally specific organizations and leaders who serve Africans and African Americans in the Portland area, thank you for the opportunity to provide comments on the Oregon Prescription Drug Affordability Board's 2025 policy concepts. Bridge Pamoja applauds the recommendation by PDAB board member, Dr. Dan Hartung which suggests, "Following up on the report from Minnesota, Oregon could benefit from greater transparency in its 340B program." Added transparency in the 340B program would ensure that the program is benefiting those it was designed to serve.

The 340B program was created as a discount drug program to help vulnerable patients gain better access to medicines at hospitals and clinics treating a safety-net population. Participation in the 340B program has grown significantly since the program's inception in 1992. Consolidation in the health care space has increased since the creation of 340B. Vertically integrated companies that include a hospital, health plan, a pharmacy benefit manager and a contract pharmacy are profiting from 340B, but there is no clear evidence 340B discounts are being passed on to patients.

The impact on communities of color and socioeconomically disadvantaged communities is especially striking. 340B hospitals and contract pharmacies are expanding to more affluent communities and not helping the safety-net population the program was created to support. 340B hospitals buy up practices in wealthier areas to generate profit. According to a Jama Health Forum study, growth of 340B contract pharmacies is concentrated in "affluent and predominantly white neighborhoods" while declining in "socioeconomically disadvantaged and primarily non-Hispanic Black and Hispanic/Latino neighborhoods."

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In Minnesota's review of the 340B program, they found that the state's largest 340B hospitals generated 80% of statewide net revenue; meanwhile, safety-net federal grantee clinics generated the least revenue. In other words, the very clinics 340B was designed to support are benefitting the least from the program.

The rapid expansion of 340B and the program's lack of oversight and transparency has exacerbated challenges for communities of color and underserved patients. 340B entities, including hospitals and safety-net federal grantee clinics, have different requirements for reporting how they how they provide benefits to underserved patients. This has created an unfair disadvantage for some 340B program participants. The lack of reporting information makes it challenging to understand how 340B revenue is being allocated and whether it's being used to help patients. Implementing transparency requirements would shed light on how 340B revenue is being spent – either reinvested in patient care or invested elsewhere.

Bridge Pamoja supports the mission of 340B – to ensure access and reduce healthcare costs for underserved patients. However, we are concerned that some 340B entities may be manipulating the program for profit and not passing those savings on to the patient. This is especially alarming given the challenges related to health equity and access.

We agree with Dr. Hartung's recommendation that Oregon could benefit from more transparency in the 340B program. I hope you will include 340B transparency in your 2025 policy recommendations to ensure 340B savings are used to directly support patients.

Thank you for listening to my concerns.

Sincerely,

Pastor Mark Jackson
Chief Operating Officer
Bridge Pamoja

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AIMED ALLIANCE

September 24, 2025

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

Via Electronic Correspondence

RE: Drug Affordability Review Process

Dear Chair Bailey:

Aimed Alliance is a not-for-profit health policy organization that seeks to protect and enhance the rights of healthcare consumers and providers. We appreciate the Oregon Prescription Drug Affordability Board's ("PDAB" or "Board") previous recognition that meaningful drug affordability reforms require careful development and thoughtful implementation, as demonstrated in its decisions last year to temporarily pause its affordability reviews to refine its criteria and methodologies.

As the Board moves forward, we strongly urge it to maintain this same level of care and ensure that patient and stakeholder feedback is meaningfully prioritized, incorporated, and reconciled throughout the process.

I. Ensure the Drug Review Timeline Allows for Meaningful Data Review and Discussion

Aimed Alliance acknowledges the inherent challenges and complexity of conducting affordability reviews. As such, we are concerned by the Board's accelerated timeline and the experimental nature of its current process.

The volume of material being considered in the review packs, with six drugs reviewed in each meeting, makes meaningful deliberation difficult. Rushing through these reviews risks undermining both the quality of the Board's decisions and public confidence in its work. Our concern was further emphasized during the July meeting in which one board member stated, ***"I'm super concerned about process and the volume of drugs here."*** Similarly, another board member asked whether there would be an additional meeting to ensure enough time to ***"actually… have a good conversation about each one of them"***.[1] Aimed Alliance recognizes that board members have unique insights into the Board's process and decision-making. Thus,

[1] Oregon Division of Financial Regulation, *Oregon PDAB Meeting of July 16, 2025*, https://www.youtube.com/watch?v=wAl1u10eAM4.

Aimed Alliance finds these comments particularly concerning and indicative of the need to adopt a slower review process to ensure comprehensive review and consideration of each selected drug.

The difficulties associated with prescription drug reviews are not exclusive to Oregon. For example, in the April 2025 meeting of the Colorado PDAB, board members acknowledged that data submitted by a pharmacy benefit manager (PBM) had been mischaracterized, creating confusion between Medicare and commercial data sets. Although the Colorado Board stated this error would not affect its affordability reviews, it remained unclear to advocates and consumers how this mischaracterized data would not negatively influence the review processes.

Aimed Alliance does not intend for a slower process to halt, change, or alter the intent of the Oregon Board to develop upper payment limits for selected prescription drugs. However, considering the approach adopted and implemented by the Board for these six drugs will be replicated by the Board in future reviews, and potentially by other state PDABs, we urge the Board to develop a timeline and process that reflects the complexity and intricacies of these reviews, ultimately ensuring a credible, meaningful, replicable, and sustainable process that promotes public trust and engagement.

II. Prioritize the Patient Voice During the Affordability Review Process

Aimed Alliance appreciates the Board's commitment to incorporating the patient voice into the cost review process. Patients are the individuals most directly impacted by affordability determinations, yet their perspectives are too often underrepresented in healthcare decision-making.

For example, a recent patient-led study found that prescription drug affordability was complex and varied between individuals.[2] Importantly, the survey also found that access and affordability are often conflated, with 75% of respondents stating they skipped or stretched doses at least once due to insurance delays, not price. While less than 15% reported skipping or missing doses solely due to price.[3] As such, Aimed Alliance urges the Board to not only engage with patients through information surveys and public comment periods, but to also meaningfully integrate and reconcile patient-reported feedback and data with its final affordability determinations. Reconciling decisions with feedback informs consumers on how their information was helpful and encourages consumers to continually engage with these processes.

Moreover, reconciliation of feedback and decision-making can provide greater clarity to regulators, policymakers, and legislators on the types of supplemental reforms that may be necessary to better and more directly address consumer affordability. For example, if a primary reason consumers report a drug as unaffordable is out-of-pocket costs resulting from delays in prior authorization, rather than the actual price of the drug, it is important to reconcile why the Board would pursue a UPL for a drug whose unaffordability is not driven by its cost. However, insights like this may not be adequately derived from survey questions that are not designed with

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[2] EACH/PIC Coalition, *EACH/PIC Releases Results from Patient-Led Survey on Drug Affordability* (Aug. 4, 2025).
[3] *Id.*

patients, caregivers, and healthcare consumers in mind. Therefore, Aimed Alliance urges the Board to center patient-experience throughout its affordability reviews to adequately understand the factors that make a prescription drug "unaffordable."

III. Conclusion

In conclusion, Aimed Alliance urges the Board to maintain a thoughtful, evidence-based approach to drug affordability reviews that centers on patient experience and utilizes robust patient data. Aimed Alliance looks forward to continuing to engage with the Board as it conducts its affordability reviews. If you have any questions, please contact us at policy@aimedalliance.org.

Sincerely,

Olivia Backhaus
Staff Attorney

To: Oregon Prescription Drug Affordability Board

From: Diana Grob

Date: 9/30/2025

Topic: OCAP's public comment of September 14

I fully support and agree with OCAP's public comment/response to your recommendations dated 14 September 2025, regarding increasing Healthcare, prescription cost for Oregonians and your recommendations. I urge you to heed OCAP's recommendations and implement them, rather than continue in the narrow vein of focus that is your present plan. Thank you.

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

October 3, 2025

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

Re: Oregon Prescription Drug Affordability Board: September 17, 2025 Meeting Materials

Dear Members of the Oregon Prescription Drug Affordability Board:

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is writing in response to the Oregon Prescription Drug Affordability Board's (the "PDAB's" or "Board's") meeting materials for its September 17, 2025, meeting, including the "trade secret/confidentiality concerns" presentation, draft "2025 Policy recommendations," and scoring framework (collectively, the "Meeting Materials").[1] PhRMA represents the country's leading innovative biopharmaceutical research companies, which are focused on developing innovative medicines that transform lives and create a healthier world. Together, we are fighting for solutions to ensure patients can access and afford medicines that prevent, treat and cure disease. PhRMA member companies have invested more than $850 billion in the search for new treatments and cures over the last decade, supporting nearly five million jobs in the United States.

We provide below select comments and concerns with respect to the Meeting Materials.

I. Safeguarding Confidential Information

The Board's attention to the protection of confidential, proprietary, and trade secret information at its September meeting reflects its recognition of these important issues.[2] But PhRMA remains concerned that the Board has not implemented adequate safeguards to protect against the unlawful and unconstitutional disclosure of confidential, proprietary, and trade secret information.[3] State and federal law protect this information from disclosure; it cannot be disclosed publicly without violating state and federal prohibitions against the misappropriation of trade secrets.[4] PhRMA urges the Board to establish a clear process for the receipt, handling, and processing of manufacturers' confidential, proprietary, and trade secret information that is consistent with state and federal law. PhRMA also notes that all the states on the Board's comparison chart other than Oregon have a documented process or guidance for handling such information (or a draft of one).[5]

[1] September Meeting Materials (Sept. 17, 2025), *available at* https://dfr.oregon.gov/pdab/Documents/20250917-PDAB-document-package.pdf. 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) and Oregon Senate Bill 289 (2025) (codified at Or. Rev. Stat. § 646A.693 *et seq*.) (collectively, the "PDAB Statute"), and the Board's implementation of the PDAB Statute. PhRMA also incorporates by reference all prior comment letters to the extent applicable.
[2] Meeting Materials at 6-13.
[3] *See, e.g.*, Letter from PhRMA to Board (Mar. 6, 2025) at 1-2; Letter from PhRMA to Board (June 28, 2024) at 4; Letter from PhRMA to Board (Feb. 11, 2023) at 7-8.
[4] *See* 18 U.S.C. § 1839(5)(B)(ii)(II) (defining "misappropriation" under the federal Defend Trade Secrets Act); Oregon Uniform Trade Secrets Act, ORS 646.461-.646.475.
[5] Meeting Materials at 9.

Under the PDAB Statute, the Board has an independent obligation to safeguard from public disclosure all confidential information it receives.[6] PhRMA requests that the Board clarify, as part of its confidentiality policies, how it intends to review and determine that information provided by manufacturers is confidential and must be protected, as required under the law. The Board's obligation to protect confidential, proprietary, and trade secret information from disclosure applies to *all* such information it receives, even if the *submitter* did not specifically mark the information as such (e.g., in situations where a submitter may not be aware that it is in possession of confidential, proprietary, or trade secret information that was generated by or pertains to another entity).

Additionally, PhRMA reiterates its request that the Board establish a process for advance review of the Board's determination that any confidential, proprietary, or trade secret information is subject to public release, including a process that allows stakeholders to appeal such determinations.[7] The PDAB Statute's prohibition on the disclosure of confidential, proprietary, and trade secret information would be illusory—and would raise serious due process, takings, and other constitutional concerns—if the Board unilaterally disclosed the information without a pre-release opportunity for administrative and judicial review. The disclosure of such information pending a challenge to a publication decision is irreversible and risks causing irreparable harm to constitutional, statutory, and property rights.

II. Lack of Clear, Consistent, and Meaningful Standards in the Draft Scoring Framework

PhRMA continues to have concerns with the lack of clear, consistent, and meaningful standards in the "Methodology for Drug Reviews and Scoring Rubric and Worksheet" (the "Draft Scoring Framework").[8] Indeed, the Draft Scoring Framework continues to rely on vague and inconsistent terminology that needs to be clearly defined. While the aim of developing the Draft Scoring Framework may be to provide a consistent method for evaluating drug affordability, PhRMA is concerned that additional work is needed to provide consistent and transparent application of the Draft Scoring Framework in the Board's affordability review process. PhRMA highlighted several examples of concerns in the prior version of the Draft Scoring Framework that remain unaddressed.[9]

PhRMA reiterates its request that the Board revise the Draft Scoring Framework to address vague and inconsistent terminology, explain the differences between the scores in each domain, clarify how each metric is connected to patient affordability, and address other unresolved issues PhRMA identified in previous comments.[10]

PhRMA highlights the following additional concerns in the updates to the Draft Scoring Framework included in the Meeting Materials.

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[6] PDAB Statute § 646A.694(7)(b) (The Board "*shall* keep strictly confidential any information collected, used or relied upon for the review ... if the information is: (b) [c]onfidential, proprietary or a trade secret []."(emphasis added)). In addition, the Fifth Amendment's prohibition against taking private property without just compensation similarly prohibits the uncompensated disclosure of trade secrets. Courts have made clear that "when disclosure [of pricing information] is compelled by the government," even the "failure to provide adequate protection to assure its confidentiality ... can amount to an unconstitutional 'taking' of property." *St. Michael's Convalescent Hosp. v. California*, 643 F.3d 1369, 1374 (9th Cir. 1981) (brackets and quotation marks omitted). For further discussion, see, for example, Letter from PhRMA to Board (June 28, 2024) at 4 and Letter from PhRMA to Board (Aug. 1, 2023) at 1-2.

[7] *See* Letter from PhRMA to Board (Feb. 11, 2023) at 8.

[8] Meeting Materials at 24-28; Letter from PhRMA to Board (Aug. 18, 2025) at 1-4.

[9] *See* Letter from PhRMA to Board (Aug. 18, 2025) at 1-4.

[10] *Id.*

- **Questions not addressed by the review materials**: The Draft Scoring Framework contemplates consideration of metrics and questions which the Board does not appear to have sufficient information to consider. For example, one of the "Key questions" for the "Therapeutic alternatives" domain asks, "[d]o those alternatives have fewer access restrictions?" Since the carrier data call does not request plan-reported information regarding therapeutic alternatives, it is unclear how the Board could answer this question.[11] Similarly, a "Key question" for the "System & payer costs" domain asks, "[w]hat is the annual cost burden on *Medicaid*, Medicare, and commercial insurers?".[12] As PhRMA has previously noted, the affordability review reports do not recognize or discuss the mandatory and supplemental rebates negotiated between manufacturers and the Oregon Health Plan ("OHP"), which significantly reduce the amount that the State pays for prescription medications.[13] It is therefore unclear how the Board could consider this question.

- **Concerns with Maximum Fair Price ("MFP") Domain**: Medicare MFP is a price-setting mechanism established as part of the federal Inflation Reduction Act ("IRA"). It exists under a separate, federal statutory regime and is the product of different considerations than those required under the PDAB Statute. Importantly, MFP is specific to the Medicare program and its patient population, and it should not be extrapolated as a measure of affordability for the general population of Oregon. The Board should thus explain its rationale for assigning an impact score on the basis of MFP.[14] Additionally, one of the "Key questions" in the Draft Scoring Framework's MFP domain asks, "How does the current market price compare to the MFP?"[15] However, since the MFP is set to take effect in 2026, this would require looking at 2026 market data, which is not available for review.

  Stakeholders have significant concerns that federal price controls could cause plans and pharmacies to limit patient access to medicines. A recent survey of pharmacy owners from the National Community Pharmacists Association found that 19 percent of community pharmacists say they have decided not to stock the initial MFP price set drugs, "because they anticipate the program will cause cashflow problems and revenue loss."[16] An additional 67 percent say they are considering not stocking drugs in the program for the same reasons.[17]

  Further, experts predict that price controls in Medicare will shift incentives for research and development away from many diseases and illnesses, including those that disproportionately affect underserved communities, such as diabetes, heart disease, and some cancers.[18] Economists at the University of Chicago estimate that the IRA's price setting policies could raise overall health care spending by $50.8 billion over a 20-year period due to forgone savings from reduced medical care

[11] Meeting Materials at 24.
[12] *Id.* (emphasis added).
[13] *See* Letter from PhRMA to Board (Aug. 18, 2025) at 7.
[14] Meeting Materials at 28.
[15] Meeting Materials at 25.
[16] Report for Medicare Drug Price Negotiation Program and Financial Health of Pharmacy, September 2025, available via: https://ncpa.org/sites/default/files/2025-09/Sept-2025-NCPAsurvey-MDPNPandFinancialHealth.pdf.
[17] *Id.*
[18] Kenneth E. Thorpe, *Penny Wise and Pound Foolish: IRA Impact on Chronic Disease Costs in Medicare*, Health Affairs (June 27, 2024) ("[C]hronic disease . . . is the largest driver of health care costs and a significant source of disparate health outcomes in underserved and marginalized communities[.]").

utilization that medicines would have otherwise delivered.[19]

III. Preliminary 2025 Policy Recommendations

PhRMA supports the Board's continued exploration and development of many of the policy recommendations suggested by Board members that seek to address factors driving affordability concerns across the pharmaceutical supply chain broadly.[20] As discussed in previous letters, manufacturers often provide significant discounts, rebates, and other price concessions to pharmacy benefit managers ("PBMs") and health plans.[21] Many patients, however, do not benefit directly from these discounts because insurance companies and their PBMs do not pass the savings through to patients at the point of sale.[22] Oregon,[23] Congress,[24] and the Federal Trade Commission[25] have raised concerns about the influence of PBMs on the supply chain. In 2023, 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."[26] PhRMA supports policy recommendations that account for the wide array of factors in the supply chain that impact the ability of Oregonians to afford their medication, such as those recommendations that would require health insurance companies and their PBMs to pass rebates to patients at the pharmacy counter, delinking PBM fees from the price of a drug, and increasing PBM transparency.[27]

IV. Continued Concerns with Data and Inconsistency of Information Considered by the Board in Affordability Reviews

As PhRMA has explained in previous letters, the lack of clarity surrounding the data the Board relies upon to produce affordability review reports raises serious questions about their reliability, and ultimately whether the Board can satisfy its obligation to conduct affordability reviews in a manner consistent with its obligations under the PDAB Statute.[28] The Board should adopt procedures for reviewing and evaluating the accuracy and completeness of the information it will consider, and for permitting manufacturers and other stakeholders to provide input where information may be inaccurate or incomplete.

The affordability reports that the Board has issued to date are inconsistent and contain errors that have not

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[19] Philipson T.J., Di Cera G. Issue Brief: The Impact of Biopharmaceutical Innovation on Health Care Spending. The University of Chicago. Available at: https://ecchc.economics.uchicago.edu/2022/08/03/the-impact-of-biopharmaceutical-innovation-on-health-care-spending/.

[20] *See id.* at 18-23.

[21] *See* Letter from PhRMA to Board (Nov. 1, 2024) at 5.

[22] *See id.*

[23] Oregon Secretary of State, Audits Division, Pharmacy Benefit Managers: Poor Accountability and Transparency Harm Medicaid Patients and Independent Pharmacies (Aug. 2023).

[24] U.S. House Committee on Oversight and Accountability. The Role of Pharmacy Benefit Managers in Prescription Drug Markets. Published July 23, 2024. Available at: https://oversight.house.gov/report/pbm-report.

[25] Press Release, Federal Trade Commission, FTC Launches Inquiry into Prescription Drug Middlemen Industry (June 7, 2022); Press Release, Federal Trade Commission, FTC Deepens Inquiry into Prescription Drug Middlemen (May 17, 2023).

[26] Oregon Secretary of State, Audits Division, Pharmacy Benefit Managers: Poor Accountability and Transparency Harm Medicaid Patients and Independent Pharmacies (Aug. 2023).

[27] See Letter from PhRMA to Board (Oct. 6, 2023) at 2; Meeting Materials at 18-20.

[28] *See, e.g.*, Letter from PhRMA to Board (Aug. 18, 2025) at 4; Letter from PhRMA to Board (Jan. 11, 2025) at 3-5; *see also, e.g.*, *Lane Cnty. v. Land Conservation & Dev. Comm'n*, 138 Or. App. 635, 641 (1996) (explaining the "fundamental principle of administrative law" that agencies may not act in a manner contrary to their statutory authority). PhRMA specifically reiterates its prior comments that the Board is required under the PDAB Statute to consider all information outlined in the PDAB Statute. Or. Rev. Stat. § 646A.694(1)(e), (j).

been corrected by the Board.[29] The affordability review reports in the Meeting Materials also contain inconsistencies that should be corrected before the Board moves forward with any additional affordability reviews. For example, only two of the five reports include a table with "rubric considerations," without explanation as to why these drugs are being treated differently than others.[30] These inconsistencies call into question the reliability of the affordability reports. The Board should address these discrepancies so that each report contains consistent information to guard against inconsistent and arbitrary decision-making.

* * *

PhRMA and our member organizations appreciate your attention to our feedback. While we remain concerned about the current Meeting Materials, we are committed to engaging in constructive discussions as this process moves forward. Please contact dmcgrew@phrma.org with any questions.

Sincerely,

Dharia McGrew, PhD
Senior Director, State Policy
Sacramento, CA

Alexandra Hussey
Senior Director, Law
Washington, DC

[29] *See* Letter from PhRMA to Board (Aug. 18, 2025) at 4.
[30] Meeting Materials at 38, 142.

HIV+HEP
POLICY INSTITUTE

October 10, 2025

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

Re: Public Comment for October 15, 2025 Board Meeting

Dear Members of the Oregon Prescription Drug Affordability Board:

The **HIV+Hepatitis Policy Institute** appreciates the opportunity to comment on the Board's proposed policy recommendations for the 2025 legislative report. As a national patient advocacy organization that works to promote quality and affordable healthcare for individuals living with or at risk of HIV, hepatitis, and other chronic conditions, we witness every day how out-of-pocket costs, insurance design, and PBM practices shape whether patients can initiate and stay on treatment. We applaud the Board for putting forward pragmatic recommendations that can meaningfully improve access and affordability without restricting coverage or future drug development.

Putting Patients First: Direct Affordability and Access Reforms
We strongly support the recommendations that will have a direct and measurable impact on what patients pay for their medications:

- **Point-of-sale rebates.** Requiring that negotiated manufacturer rebates be passed directly to patients at the pharmacy counter would immediately reduce out-of-pocket costs for Oregonians. Today, most rebates are retained by PBMs and insurers rather than lowering what patients pay at the pharmacy, meaning those with high deductibles or coinsurance rarely see the benefit of these negotiated discounts. Ensuring rebates are applied at the point of sale would deliver real savings to patients, improve medication adherence, and help reduce long-term healthcare costs by preventing lapses in treatment. This reform ensures that the patients who generate the rebates flow to themrather than remaining within the system to the benefit of all enrollees.
- **Delinking PBM compensation from drug prices.** Replacing rebate-based or percentage-of-price fees with transparent service fees will realign incentives across the system, discouraging PBMs from favoring high-cost drugs and encouraging a focus on value and patient outcomes.
- **Elimination of PBM spread pricing in Medicaid and managed care.** Spread pricing allows PBMs to profit from the difference between what they charge the state and what they reimburse pharmacies. Removing this opaque practice will reduce waste and

ensure that taxpayer funds are used for patient care, not middleman markups. Sixteen states have already enacted laws banning or restricting PBM spread pricing, demonstrating bipartisan recognition that this practice drives unnecessary costs.[1]

These measures reflect a balanced approach that will drive savings to patients rather than shifting costs elsewhere in the healthcare system. They will help sustain medication adherence and prevent the downstream medical costs that arise when patients cannot afford their prescriptions.

Increasing Transparency Across the Drug Supply Chain

We commend the Board for advancing proposals that bring greater transparency and accountability to how drugs are priced and reimbursed.

- **PBM transparency for commercial plans.** Requiring full transparency in PBM operations will help policymakers and patients understand how funds flow through the system, where profits are retained, and how those dollars affect patient costs. PBMs play a significant role in determining what patients ultimately pay for their medications, yet their pricing, rebate, and network contracting practices are often opaque. Enhanced disclosure of spread pricing, rebate retention, and administrative fees would allow Oregon to identify inefficiencies and ensure that negotiated savings are passed through to patients rather than absorbed by intermediaries. This approach aligns with reforms already adopted in several other states seeking to hold PBMs accountable and promote fairer, more affordable access to prescription drugs.
- **Audit of the 340B program in Oregon.** We support the recommendation for a transparent review of how the federal 340B Drug Pricing Program operates within the state, including how program savings are used to support patient care and safety-net providers. The 340B program was created to help low-income and uninsured patients access affordable medications and to enable safety-net providers to expand services that support them. It plays a vital role in sustaining care for patients living with HIV through Ryan White clinics and community health centers and there already is great transparency for these grantees. However, questions have been raised nationally about how 340B savings for hospitals are tracked, whether all eligible patients are benefiting directly, and how consistently savings are reinvested in patient care. An audit would provide policymakers with objective data on its economic and public health impact, clarify how savings are reinvested in patient services, and identify opportunities to ensure funds reach the intended populations.

Greater visibility across the drug supply chain will allow policymakers to target reforms effectively while preserving programs that already work to expand access and improve outcomes.

Ensuring Fair and Transparent Pharmacy Reimbursement

We also support the Board's efforts to improve the transparency and fairness of pharmacy reimbursement. Pharmacies are a lifeline for many patients, particularly those managing HIV or

chronic conditions who depend on trusted local providers to help navigate adherence and access programs.

- **Use of verifiable acquisition cost data.** Basing reimbursement on objective, publicly available acquisition cost data rather than proprietary PBM lists will help ensure that pharmacies are paid fairly for dispensing medications. Oregon is well positioned to lead on this issue given its existing average actual acquisition cost data infrastructure.
- **Prohibiting below-cost dispensing requirements.** Pharmacies should not be forced to dispense medications below their cost to purchase and dispense. This reform will protect independent and rural pharmacies that serve as critical access points for vulnerable populations.
- **Any-willing-pharmacy provisions.** Allowing any qualified pharmacy to participate in plan networks will expand patient choice, especially in rural areas, and improve continuity of care.

Collectively, these changes will help preserve Oregon's pharmacy network and prevent closures that can disproportionately affect patients in smaller communities and those with complex health needs.

These recommendations will help ensure that savings flow directly to patients, preserve access to community and safety-net pharmacies, and strengthen programs like 340B that sustain care for vulnerable populations. Oregon's leadership in advancing practical, patient-focused solutions can serve as a model for other states seeking to balance affordability with access and future drug development. Thank you for the opportunity to comment and for your ongoing leadership on behalf of Oregon patients. We look forward to supporting the Board's work as these recommendations move forward to the legislature.

If you have any questions or need additional information, please feel free to contact our Government Affairs Manager, Zach Lynkiewicz, at zlynkiewicz@hivhep.org.

Sincerely,

Carl E. Schmid II
Executive Director

[1] MultiState, *State PBM Reform: How States Are Trying to Control Pharmaceutical Spending* (Jan. 6, 2025)

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Suite 1300
Washington, DC, 20005
202-962-9200

VIA Electronic Delivery
Oregon Prescription Drug Affordability Board
Department of Consumer and Business Services
350 Winter Street NE
Salem, OR 97309-0405

October 15, 2025

Re: October 2025 Oregon Prescription Drug Affordability Board Meeting

Dear Prescription Drug Affordability Board Members and Staff:

The Biotechnology Innovation Organization (BIO) appreciates the opportunity to provide comments for the Oregon Prescription Drug Affordability Board (PDAB)'s October 2025 meeting. Our comments below focus on the PDAB's policy recommendations for inclusion in the 2025 annual legislative report (policy recommendations) and the methodology for drug reviews and scoring rubric (Drug Review Scoring Framework).

BIO is the premier biotechnology advocacy organization representing biotech companies, industry leaders, and state biotech associations in the United States and more than 35 countries around the globe. BIO members range from biotech start-ups to some of the world's largest biopharmaceutical companies – all united by the same goal: to develop medical and scientific breakthroughs that prevent and fight disease, restore health, and improve patients' lives. BIO also organizes the BIO International Convention and a series of annual conferences that drive partnerships, investment, and progress within the sector. Learn more at bio.org.

General Comments

As BIO has previously commented, we remain concerned about the OR PDAB's Drug Review Scoring Framework used to measure and define affordability. An overt focus on cost savings for the state rather than patient value will harm patient access to lifesaving medication while failing to protect patients from harmful coverage restrictions imposed by plans and PBMs. The affordability review process and policy recommendations incorrectly conflate cost savings for the state with patient affordability. Instead, it is critical that the Board focuses on proposals that directly address patient access and patient affordability, for example rebate pass-throughs that directly lower patient out-of-pocket costs.

BIO also continues to be concerned by the insufficient time given for meaningful public and stakeholder participation in the affordability review process before the Board renders decisions. The Board's practice of setting unreasonably short comment periods continues to raise significant concerns about the ability for stakeholders to meaningfully review materials and provide comments. Further, the affordability review process has been prematurely rushed, undermining the credibility and accuracy of the data that is produced. We urge the Board to halt all affordability reviews until the Board properly solicits and incorporates' stakeholder feedback on the Drug Review Scoring Framework.

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Please note that our below comments on the policy recommendations and Drug Review Scoring Framework should not be interpreted as endorsing the Board's actions, and BIO's positioning remains that the Board should not implement its affordability review process.

Drug Review Scoring Framework

As BIO has previously mentioned in our August meeting comments, many of the domains in the rubric are ambiguous and subjective and are likely to result in biased selection and determinations. For instance, we are concerned that the use of total gross drug spending data can result in the selection of medicines with high aggregate spending that treat large populations of individuals with chronic medical conditions. Such medicines, even if affordable to patients, may be misconstrued as being unaffordable simply by virtue of them being commonly prescribed and highly utilized. We also continue to urge the Board to base reimbursement drug cost figures on objective, verifiable data sources, rather than PBM-owned and managed lists, which can be manipulated to increase PBM profits.

Policy recommendations for inclusion in the 2025 annual legislative report

BIO appreciates that the Board has included certain policy alternatives for the 2025 annual legislative report that would meaningfully address issues in the broader pharmaceutical payment system without the unintended consequences of a UPL. As we have stated in previous comments, we strongly oppose any recommendations that attempt to enact UPLs, including the recommendation to "institute and use upper payment limits only if all other changes of drug delivery system and its economics fail." It is evident that setting UPLs in any context creates unintended consequences for the drug coverage ecosystem and supply chain and would have profound negative repercussions for patient access. Instead, it is critical that any policy recommendations focus on proposals that directly address patient access to and affordability of medicines, for example the rebate pass-through and fee de-linking proposals. As the Board finalizes its policy recommendations for the 2025 legislative report, we encourage the Board to include analyses modeling anticipated patient costs or savings, in addition to state costs or savings, associated with each proposal.

Above all, we would like to express support for Vice Chair Amy Burns' recommendation to disband the PDAB. As the state of New Hampshire has demonstrated through the repeal of its PDAB, PDABs impose additional regulatory burden without delivering any measurable benefits for patients.[1] New Hampshire's decision underscores that resources should instead be redirected toward initiatives that more directly expand patient access and address patient out-of-pocket costs. As such, we also oppose any recommendation to expand the scope of the PDAB's jurisdiction. The Board continues to lack the perspectives and expertise

[1] New Hampshire Prescription Drug Affordability Board, Chapter 126 (RSA 126-BB), Repealed by 2025, 141:312, I, eff. July 1, 2025.

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required to undertake a larger scope of work. Further, taxpayers should not be required to fund an expansive PDAB that fails to produce meaningful benefits for patients. Expanding the PDAB's scope would inevitably necessitate additional resourcing, further increasing costs without clear benefits. At a time when the state is confronted with budget constraints and competing fiscal priorities, those limited resources would be better directed toward programs that directly improve patient access and patient affordability.

BIO supports the following policy alternatives that were included in the PDAB meeting materials for the 2025 annual legislative report:

- Eliminate spread pricing in Medicaid and managed care
- Delink PBM fees
- Allow any willing pharmacy provider to participate in plan network
- Increase commercial PBM transparency
- Outlaw the PBM requirement that pharmacies must contractually dispense medications below their cost to dispense
- Audit of 340B entities
- Point of sale rebates, similar to West Virginia law

We encourage the Board to continue its consideration of these policies while also considering further action to protect patient assistance programs. We also recommend that policy recommendations proposing increased transparency should include specific data elements and identify stakeholders who would be subject to new or amended reporting requirements.

***

BIO appreciates the opportunity to provide feedback to the Board through these October meeting materials. We look forward to continuing to work with the Board to ensure Oregon residents can access medicines in an efficient, affordable, and timely manner.

Sincerely,

Melody Calkins

Director, Health Policy

Biotechnology Innovation Organization

October 10, 2025

Via Electronic Mail
Oregon Prescription Drug Affordability Board
PO Box 14480
Salem, OR 97309
pdab@dcbs.oregon.gov

Re: October 15 Board review of insulin products

Dear Members of the Oregon Prescription Drug Affordability Board:

Sanofi appreciates the opportunity to submit comments to the Oregon Prescription Drug Affordability Board ("OR PDAB") regarding the Board's potential selection of certain insulin products for affordability reviews, pursuant to OAR 925-200-0010. We understand that the OR PDAB is considering whether to include one or more of Sanofi's insulin glargine products, including Lantus®, Toujeo®, and unbranded products, Insulin Glargine U-100 and Insulin Glargine U-300, in the subset list of prescription drug and insulin products for review. For the reasons described below, OR PDAB's consideration of Sanofi's insulin products is inappropriate and inconsistent with the goal of ORS 646A.694, which is to identify products that currently create affordability challenges for the health care system or high out-of-pocket costs for patients.

1. **The 2023 data is outdated and does not reflect the significant reductions in list prices and other market trends, which reduce Oregon's cost and spending metrics for Sanofi's insulins.**

To further our commitment to support patients directly at the pharmacy counter and accelerate the transformation of the U.S. insulin market, in January 2024, Sanofi reduced the list price of Lantus®, our most widely prescribed insulin in the United States, by 78%.[1] Additionally, beginning January 1, 2024, all commercially-insured patients who fill their Lantus® prescriptions at participating pharmacies have their out-of-pocket responsibility capped at $35 for a monthly supply. At the same time, Sanofi launched Insulin Glargine Injection U-300, an unbranded version of Toujeo®, at a list price that was 60% less than Toujeo's® list price. For additional information regarding the steps

[1] In conjunction with this pricing action, Sanofi withdrew the lower priced, unbranded version of Lantus, Insulin Glargine U-100, from the market because the new list price for Lantus was below the list price of Insulin Glargine U-100. At that time, Sanofi also reduced the list price of our short-acting Apidra® (insulin glulisine injection) 100 Units/mL by 70%.

Sanofi took in 2024 to drive insulin affordability, please see our 2025 Pricing Principles Report.[2]

Although payers, including PBMs and government and private insurers, ultimately decide which medicines to cover, how much to reimburse dispensing pharmacies, and patients' out-of-pocket responsibility, Sanofi's pricing actions have reduced pharmacy reimbursement and out-of-pocket costs for these products. Unfortunately, although Sanofi continues to provide lower cost options to payers and PBMs, patients often do not realize the full cost savings because incentives within the health system drive health plans and middlemen to favor high list prices and larger rebates over lower priced options.

Taken together, the scope of these changes mean that the OR PDAB's 2023 data simply do not accurately reflect current costs, utilization, and spending. At a minimum, the OR PDAB should not consider including Sanofi's insulin products in an affordability review unless and until it can review current data that reflects these changes.

2. Sanofi's insulin glargine products are highly utilized and affordable life-saving treatments for Oregon residents with diabetes.

The inclusion of Sanofi's insulin products, like Lantus®, among the top gross spending products is presumably a result of the number of patients who rely on these insulin products – not their prices. As demonstrated by Oregon's own 2023 data,[3] Sanofi's insulin glargine products are not among the highest cost insulin products on a per prescription or per patient basis across multiple metrics, including overall costs, payer payments, and patient out-of-pocket costs. Indeed, healthcare providers and patients choose Sanofi's insulin glargine products because of their well-established clinical benefits and their affordability.

We are proud of the meaningful ways in which our products have transformed the standard of care for patients, from the introduction of Lantus®, which provided significant improvements in basal insulin levels, to the introduction of Toujeo®, a next generation basal insulin that more closely mimics the body's endogenous insulin secretions, among others. In addition to delivering meaningful innovation in the types of insulin available to patients, we are proud of the role we have played in transforming the patient experience through the

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[2] Sanofi 2025 Pricing Principles Report: Action Driving Insulin Affordability, *available at* https://www.sanofi.us/assets/dot-us/pages/images/our-company/Social-impact/responsible-business-values/pricing-principles/Sanofi-2025-Pricing-Principles-Report_Action-Driving-Insulin-Affordability.pdf.

[3] *See* Insulin Preliminary Data, Oregon PDAB Data Dashboard, *available at* https://app.powerbigov.us/view?r=eyJrIjoiOGM2YjhlMWUtNzE2OC00MmU1LTk2MjktYWUzZGMyNTNmZmQ1IiwidCI6ImFhM2Y2OTMyLWZhN2MtNDdiNC1hMGNlLWE1OThjYWQxNjFjZiJ9.

development of devices to ease the daily burden of insulin administration, allowing for fewer injections and, in some cases, fewer refills and related patient copays.

We have coupled these clinical innovations with our progressive and industry-leading pricing principles, which reflect our commitment to sustainable pricing and transparency,[4] and a suite of innovative affordability programs to help people reduce their prescription medicine costs, regardless of their insurance status or income level. As a result, no Oregon patient has to pay more than $35 per month for their Sanofi insulin product.[5] Please also see the attached document from our 2025 Pricing Principles on Sanofi's actions to drive insulin affordability.[6]

Given these utilization and cost trends – even using 2023 data, Sanofi's insulin glargine products are not an appropriate target for the OR PDAB.

3. **The data the OR PDAB is relying on does not appear to take into account the significant rebates and other price concessions that Sanofi provides to payers.**

The "list price" of a medicine often receives the most attention in public discussions, but it does not reflect the price patients pay at the pharmacy counter, nor does it reflect the amount health insurance companies pay (or that Sanofi receives).

Sanofi provides significant discounts, rebates, and fees to different stakeholders across the healthcare value chain, including to payers and their pharmacy benefit managers ("PBMs"), to ensure our medicines are accessible to patients. Sanofi pays these price concessions to insurers (or their PBMs) after a medicine is dispensed to a patient so it is not captured in the "payer paid" amount. As a result, the "payer paid" and "overall spend" data have no relation to the net amount payers actually pay for Sanofi's insulin products.

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[4] *See* Sanofi 2025 Pricing Principles Report, *available at* https://www.sanofi.us/assets/dot-us/pages/images/our-company/Social-impact/responsible-business-values/pricing-principles/Sanofi-2025-Pricing-Principles-Report.pdf.

[5] Additional details regarding our programs are available at https://www.teamingupfordiabetes.com/sanofidiabetes-savings-program.

[6] Sanofi 2025 Pricing Principles Report – Action Driving Insulin Affordability, *available at* https://www.sanofi.us/assets/dot-us/pages/images/our-company/Social-impact/responsible-business-values/pricing-principles/Sanofi-2025-Pricing-Principles-Report_Action-Driving-Insulin-Affordability.pdf.

OR PDAB clearly recognizes the importance of understanding net spend to its analysis as it has collected this data for non-insulin products.[7] OR PDAB should consider payer spend net of rebates for insulin products as well.

For these reasons, Sanofi respectfully requests that the Board remove Lantus®, Toujeo®, Insulin Glargine U100, and Insulin Glargine U300 from consideration for the subset list of insulin products. Further, any consideration of these products should and at a minimum take into account updated data on insulin products before proceeding with any insulin product review.

Please feel free to contact me at with any questions at carissa.kemp@sanofi.com or (208) 954-6330.

Sincerely,

Carissa Kemp
Lead, State Government Relations, Sanofi

Enclosure:

Sanofi 2025 Pricing Principles Report – Action Driving Insulin Affordability

[7] *See* Carrier Preliminary Data, including Carrier Spend Net of Rebate and Carrier Spend Net of Rebate per Enrollee, Oregon PDAB Data Dashboard, *available at* https://app.powerbigov.us/view?r=eyJrIjoiOGM2YjhlMWUtNzE2OC00MmU1LTk2MjktYWUzZGMyNTNmZmQ1IiwidCI6ImFhM2Y2OTMyLWZhN2MtNDdiNC1hMGNlLWE1OThjYWQxNjFjZiJ9. The 2023 insulin data from the Oregon All Payer All Claims Database (APAC) is gross and not net of rebates. *See* Insulin Data Process, Oregon Prescription Drug Affordability Board (Jan 2025), *available at* https://dfr.oregon.gov/pdab/Documents/Insulin-Data-Process-Documentation.pdf.

Action Driving *Insulin Affordability*

Insulin affordability has been a longstanding challenge for people with diabetes. Manufacturer discounts provided to payors – intended to make insulin more affordable – have sadly not translated into reduced costs for patients at the pharmacy counter due to misaligned market dynamics.

More than 11% of the U.S. population lives with diabetes

Our industry must remain focused on identifying and implementing solutions that continue to widen patient access and increase system-wide affordability.

Given this mandate, **Sanofi has taken action to improve access and affordability for millions** by actively reshaping our approach to insulin pricing and patient support.

Sanofi put into place significant pricing changes in 2024.

- The price of Lantus® (insulin glargine injection) 100 Units/mL, our most widely prescribed insulin in the U.S., was reduced by 78%, and the list price of our short-acting Apidra® (insulin glulisine injection) 100 Units/mL was cut by 70%.
- Sanofi placed a $35 cap on out-of-pocket costs for a 30-day supply of Lantus for patients with commercial insurance or without insurance – paying the difference on what insurance companies charge patients at the pharmacy. This is an evolution of a program that began in 2018, when Sanofi became the first company to voluntarily introduce a program where uninsured patients could access one or more of our medicines at a set price.
- We launched an unbranded biologic for Toujeo® U-300 (insulin glargine) injection 300 Units/mL at 60% less than the list price to continue to provide lower cost options to payors and pharmacy benefit managers pharmacy benefit managers (PBMs). However, **patients have yet to realize the full cost savings because incentives within the health system drive health plans and middlemen to favor high list prices and larger rebates over this lower priced option.**

Our mission is to ensure that no patient falls through the cracks; therefore, our suite of patient support programs are designed to help most people reduce the cost of their insulin, including Toujeo U-300 (insulin glargine) injection 300Units/mL, Lantus (insulin glargine injection) 100 Units/mL, Apidra (insulin glulisine injection) 100 Units/mL and Admelog (insulin lispro injection) 100 Units/mL.

- 100% of commercially insured people are eligible for Sanofi's copay assistance programs, regardless of income or insurance plan design, ensuring patients pay no more than $35 for a 30-day supply.
- 100% of uninsured people are eligible for the Insulins Valyou Savings Program - regardless of income level - enabling them to buy one or multiple Sanofi insulins at $35 for a 30-day supply.
- Free medications are provided to qualified low- and middle-income patients through the Sanofi Patient Connection program. Some people facing unexpected financial hardship may be eligible for a one-time, immediate month's supply of certain Sanofi medicines while waiting for their application to be processed.

Sanofi also offers a commercial copay assistance program for patients taking SOLIQUA 100/33 (insulin glargine and lixisenatide) injection 100 Units/mL and 33 mcg/mL, an injectable prescription medicine that contains two diabetes medicines, insulin glargine and lixisenatide, where patients pay as little as $35 for a 30-day supply, with a maximum savings of $365 per pack, up to 2 packs, for each 30-day supply.

Sanofi Insulins in 2024: By the Numbers

Significant Price Reductions for Insulins in the U.S.

Lantus price reduced by
▼78%

Apidra price reduced by
▼70%

These reductions bring the aggregate list price of Sanofi insulins back to 2012 levels, decreasing rebates to industry middlemen and aiming to improve patient affordability.

Commitment to Affordable Insulin

$35 cap

Out-of-pocket costs for Lantus are capped at $35 for all patients with commercial insurance.

Bridging the Affordability Gap with Patient Support

102,988

# of times Insulins *Valyou* Savings Program was used

$25.7 million+

patient savings from use of Insulins *Valyou* Savings Program

$6.7 million+

patient savings stemming from our partnerships with GoodRx, Amazon Pharmacy, and other third-party partnerships to cap the cost of some Sanofi insulins at $35 a month for commercially insured patients.

COMMUNITY ACCESS NATIONAL NETWORK

Mailing Address:

Attn: Jen Laws
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October 10, 2025

Oregon Prescription Drug Affordability Board
Department of Consumer and Business Services
350 Winter Street NE
Salem, OR 97309-0405

RE: Determinations and Recommendations

Dear Honorable Members of the Oregon Prescription Drug Affordability Board,

The **Community Access National Network (CANN)** is a 501(c)(3) national nonprofit organization focusing on public policy issues relating to HIV/AIDS and viral hepatitis. CANN's mission is to define, promote, and improve access to healthcare services and support for people living with HIV/AIDS and/or viral hepatitis through advocacy, education, and networking.

While CANN is primarily focused on policy matters affecting access to care for people living with and affected by HIV, we stand in firm support of all people living with chronic and rare diseases and recognize the very reality of those living with multiple health conditions and the necessity of timely, personalized care for every one of those health conditions. State Prescription Drug Affordability Boards are of profound importance to our community.

Moving Towards Determinations

We appreciate the ongoing updates to the scoring rubrics and definitions. It would be helpful to ensure that Board deliberation is explanatory of how the domain charts and rubrics factor into affordability determinations. While the drug lists contain products of a wide variety, providing clarity on the application of the frameworks developed will bolster stakeholder confidence, lessening the concern that any decisions made are arbitrary. Given this body's data sufficiency and application of policy history being problematic (ie. selection of review of medications which have not fit selection criteria), uniform application of criteria is required to ensure even the perception of bias is eliminated.

Continuing Discussion on Legislative Policy Recommendations

We continue to encourage solutions that reduce opacity in the system, increase access for patients regarding cost and services, and strengthen pharmacies and their access to plan networks in relation to plan network access.

Eliminating spread pricing in Medicaid and managed care programs is a worthwhile suggestion for system and patient costs. Spread pricing makes it difficult to ascertain the actual costs of drugs and the profit obtained by PBMs as a result. Charging insurers more than pharmacies are reimbursed increases the cost burden on insurers, which can ultimately increase premiums for patients. It also obscures and steals potential savings from patients and adversely affects pharmacies with lower reimbursement rates. The legislature must understand the importance of this.

We also continue to support instituting one PBM for all Medicaid and managed care patients in Oregon. Fragmentation leads to inconsistency in care and creates an environment that makes it hard to monitor and rein in abusive PBM activity. Additionally, utilizing one PBM would enable the state to focus its energies on contracting to achieve all its desired goals that are in the best interests of patients and the system.
Outlawing the PBM requirement that pharmacies must contractually dispense medications below their cost to dispense is another notable suggestion. This would prevent pharmacies from procuring medicines at a loss. One concern is that this could potentially reduce patient access if pharmacies stop stocking certain medications as a result. However, conversely, it could force PBMs to reimburse appropriately to ensure that medications are purchased and utilized.

340B and Public Health Services Impact Need Monitoring

Given the potential for cost reduction actions to adversely affect 340B covered entities, we also encourage pursuing the policy suggestion of surveying covered entities regarding any revenue reductions or offered service impacts. Focused, well-structured inquiry would provide detailed insight that current reporting does not reveal. Understanding the total economic impact on eligible entities would reveal the level of fiscal dependence for their operations and show where 340B funds are being misused. Additionally, reporting would highlight any losses of Medicaid rebate dollars, potentially facilitating additional budget allocation.

Lastly, we encourage the Board to continue thinking outside the box of current statutory limitations to develop effective expansions of authority to request from the legislature. It is essential to ensure that patients and the system benefit from change, rather than creating change that only leaves entities such as PBMs whole.

Respectfully submitted,

Ranier Simons
Director of State Policy, PDABs
Community Access National Network (CANN)

On behalf of
Jen Laws
President & CEO
Community Access National Network

EACH PIC COALITION

October 13, 2025

Oregon Prescription Drug Affordability Board
Department of Consumer and Business Services
350 Winter Street NE
Salem, OR 97309-0405

RE: Public Comments on Draft Policy Proposals

Dear Members and Staff of the Oregon Prescription Drug Affordability Board:

The Ensuring Access through Collaborative Health (EACH) and Patient Inclusion Council (PIC) is a two-part coalition that unites patient organizations, allied groups, patients, and caregivers to advocate for drug affordability policies that put patient needs first.

We appreciate the opportunity to provide input as the board deliberates on the policy proposals it will include in its annual report to the Oregon legislature. We commend the board for considering systemic solutions and urge continued movement in that direction.

As the board has experienced directly, a narrow focus on the cost of individual drugs is complicated, time consuming, and unlikely to solve prescription drug affordability challenges experienced by Oregonians.

Effective health reform requires addressing structural drivers, insurance design, PBM incentives, and patient assistance, not isolated drug prices. Oregon has the opportunity to set a national example by advancing comprehensive, patient-centered solutions that strengthen the system rather than narrow its focus.

Our coalition's Patient Experience Survey found that affordability is determined less by list price and more by how insurance design, pharmacy benefit manager (PBM) practices, and access to financial assistance programs shape patients' real costs. Patients paying as little as $0–$10 per month still described their medications as unaffordable due to copay accumulator policies, denials of assistance, or overall financial strain from cumulative medical expenses.

To create policies that truly improve affordability, reforms must address the system as a whole. We therefore reiterate the policy areas we supported in September:

1. Enact PBM Reform and Transparency
Hold PBMs accountable by eliminating spread pricing, delinking PBM compensation from drug prices, and requiring transparency so savings are shared directly with patients. These reforms target patient-reported drivers of unaffordability and would help ensure that affordability improvements are meaningful at the patient level.

2. Ensure Fair Reimbursement
Ensure that reimbursement rates and dispensing fees reflect the true costs of providing care. Pharmacies, infusion centers, and physician offices must be able to dispense needed

medications without financial loss. Broadening networks and protecting fair reimbursement will preserve patient access—especially in rural and underserved areas.

3. Avoid Counterproductive Measures Like Upper Payment Limits (UPLs)
We continue to caution against UPLs, which cap what payers spend rather than what patients pay. Price setting measures are likely to trigger increased utilization management, formulary restrictions, or non-medical switching, worsening patient access without guaranteeing savings.

We urge you to continue centering patient experience in your deliberations, ensuring that all policy proposals safeguard access to care, and remain available as a resource to the board as these recommendations move forward.

Sincerely,

Tiffany Westrich-Robertson
tiffany@aiarthritis.org
Ensuring Access through Collaborative Health (EACH) Coalition Lead

Vanessa Lathan
vanessa@aiarthritis.org
Patient Inclusion Council (PIC) Coalition Lead

DIABETES PATIENT ADVOCACY COALITION

October 13, 2025

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

RE: Oregon Prescription Drug Affordability Board – October 15, 2025, Insulin Product Agenda

Dear Members of the Oregon Prescription Drug Affordability Board:

I am writing on behalf of the Diabetes Patient Advocacy Coalition (DPAC) board, our community of advocates, and all those affected by diabetes across Oregon to express concern with the inclusion of insulin glargine products on the October 15, 2025 agenda due to potential flaws in the data collected and published by the board, and the potential for reaching inaccurate conclusions as a result. By way of background, DPAC is comprised of advocates dedicated to influencing state and federal policies to positively impact the diabetes community. We prioritize affordability, access to care, and health equity as issues that must be addressed to improve diabetes care for all Americans via our advocate voices in Oregon and across America. The organization has worked for over a decade to lower the price of insulin paid for by patients at pharmacy counters through our advocacy efforts to enact insulin copay cap laws across the United States.

We are perplexed by the inclusion of insulin glargine products in the board's upcoming review, especially given recent market realities, including real reductions in out-of-pocket costs thanks to insulin copay caps adopted by governors, state legislatures, Medicaid and Medicare programs, cost reductions and purchasing assistance programs by manufacturers to help patients – especially those lacking means – obtain these insulin products at reduced or no cost, in some instances. Indeed, the board's own findings state that many insulin glargine products have experienced real reductions in list price and in the co-pays paid by patients at pharmacies across Oregon between 2018 and 2024. It is also worth noting that none of the insulin glargine products selected for review by the board are undergoing pricing reviews by the Centers for Medicare and Medicaid Services (CMS).

DPAC also respectfully submits to the board a concern that the committee is considering outdated information as it reviews patient availability, affordability, and accessibility of insulin glargine products. As an example, the board's published findings for this class of insulin product state that data shared with the board on list prices is from 2018 – 2024. Yet, the data assembled for this meeting by the board from the state's all claims all payor database is only published for the year 2023. Further clouding the data available, it was only in January 2025 that Oregon's copay cap for insulin products, limiting 30-day copays to $35 per insulin prescription, took effect.

Given the data and marketplace limitations referenced herein, DPAC is not certain the board will be able to draw adequate conclusions about insulin glargine product pricing. We also encourage the board not to move towards an upper payment limit for insulin glargine products given these consequential data limitations. DPAC appreciates the board's consideration of our comments and for having the opportunity to submit our comments on your important work to the benefit of Oregonians. We stand ready to work with members of the board and all of Oregon's residents to prevent, detect, and treat diabetes in the most efficacious way possible.

Sincerely,

Erin Callahan

Chief Operating Officer
Diabetes Patient Advocacy Coalition

Eli Lilly and Company

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October 13, 2025

VIA ELECTRONIC SUBMISSION

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

RE: Oregon Prescription Drug Affordability Board (PDAB): October 15, 2025 Meeting Materials

Eli Lilly and Company (Lilly) appreciates the opportunity to provide our perspective on the Oregon PDAB ("the Board") meeting materials for October 15, 2025, which includes reviews of our insulin product Basaglar Kwikpen®. Lilly is one of the country's leading innovation-driven, research-based pharmaceutical and biotechnology corporations. We are committed to equitable and affordable access to our medicines so that our innovations can transform more people's lives.

Lilly shares the Board's goal of improving patient outcomes by making effective treatments accessible, but Lilly continues to have serious concerns about the Board's affordability review process. To that end, Lilly urges the Board to take into consideration the recommendations and concerns outlined below in its review of Basaglar Kwikpen®:

Basaglar Kwikpen® is Affordable in Oregon

For years, Lilly has implemented multiple insulin affordability solutions, including our Lilly Insulin Value Program to reduce patient out-of-pocket costs. As a result of our efforts, anyone—whether they are uninsured or use commercial insurance—is eligible to buy their monthly prescription of Lilly insulin for $35 or less, regardless of the number of pens or vials they are prescribed in a month.[1] In 2023, Lilly automated its $35 out-of-pocket monthly cap for people with commercial insurance at participating retail pharmacies, which were approximately 85 percent of pharmacies nationwide at launch.[2] In 2024, the average monthly out-of-pocket cost for Lilly insulins was $14.86—a 62 percent decrease since 2017.[3]

Lilly also donates medicines to charitable organizations such as the Lilly Cares Foundation, an Indiana nonprofit corporation separate from Lilly, established in 1997, that is recognized by the Internal Revenue Service as a tax-exempt organization under Section 501(c)(3) of the Internal Revenue Code. Lilly Cares provides Lilly medications for free to qualifying patients.[4] Patients in households with annual adjusted gross incomes of up to 400 percent of the federal poverty level

1 Lilly. Lilly Insulin Value Program. https://insulinaffordability.lilly.com/ (terms and conditions apply).
[2] Lilly, 2024 Sustainability Report 39 (2025), available here.
[3] *Id.* at 40
[4] Lilly Cares Foundation. Available Medications. https://www.lillycares.com/available-medications

are currently eligible for free insulin through Lilly Cares (currently $62,600 for an individual or $128,600 for a family of four).[5]

The list price for Basaglar Kwikpen® has remained the same since 2017, despite significant increases in the CPI-U.[6] Moreover, state health care system entities can already access Basaglar Kwikpen® at deeply discounted prices.

The Oregon Medicaid Program receives substantial rebates for insulin products such as Basaglar Kwikpen® paid under the Medicaid Drug Rebate Program ("MDRP").[7] According to MACPAC analysis of fiscal year 2020 data, brand-name drugs averaged total rebates of 61.6 percent, consisting of a basic rebate averaging 38.3 percent and inflation-related rebates averaging 23.3 percent.[8] Furthermore, Lilly offers supplemental rebates to Oregon and other state Medicaid programs, guaranteeing an affordable net unit price for Oregon Medicaid beyond that which is required under the MDRP.

Many Oregon health care entities participate in the 340B Program, which is designed to ensure the price offered to 340B entities includes the same total discount as Medicaid, guaranteeing these entities likewise benefit from the significant mandatory rebates paid.

Oregon PDAB Data Confirms Basaglar Kwikpen® is Affordable

Data included in the affordability review materials confirms Basaglar Kwikpen® is affordable. Based on the All Payer All Claims reporting (APAC), which includes both public and private payers, the median patient out-of-pocket cost is $0, and the median out-of-pocket cost per claim is $0.[9]

Basaglar Kwikpen® Provides Value to Patients and the Health System

Any assessment of affordability must also include meaningful consideration of both medication costs and benefits. Diabetes is one of the costliest chronic conditions in the United States, with $3 billion in expenditures in Oregon alone.[10] These costs include medications, diabetes management supplies, clinic, and hospital costs. Effective blood glucose management, achieved in part through medication, can significantly reduce the risk of costly and life altering complications such as eye disease, kidney disease, cardiovascular disease, and other conditions.

[5] Lilly Cares Foundation. https://www.lillycares.com/how-to-apply#check-eligibility
[6] Oregon Prescription Drug Affordability board. October 15 Meeting Materials. https://dfr.oregon.gov/pdab/Documents/20251015-PDAB-document-package.pdf p. 4, Table 5.
[7] The Medicaid rebate formula ensures that state Medicaid programs, including the Oregon Medicaid Program, access the Medicaid Best Price, i.e., the lowest price available to most other purchasers.
[8] Medicaid and CHIP Payment and Access Commission (MACPAC). Trends in Medicaid Drug Spending and Rebates. October 2022. https://www.macpac.gov/publication/trends-in-medicaid-drug-spending-and-rebates/
[9] Oregon Prescription Drug Affordability board. October 15 Meeting Materials. https://dfr.oregon.gov/pdab/Documents/20251015-PDAB-document-package.pdf p.59, Tables 24 and 25
[10] American Diabetes Association. The Burden of Diabetes in Oregon. https://diabetes.org/sites/default/files/2024-03/adv_2024_state_fact_oregon.pdf

Basaglar Kwikpen® is a widely used and effective treatment for diabetes. The Kwikpen delivery system is highly rated and preferred by patients for ease of use.[11] Providers have voiced serious concerns about the impact of PDABs and risks to patient care, including nonmedical switching.[12] The risks to patient health of nonmedical switching are well documented, including increased likelihood of adverse events, reduced adherence and long-term complications.[13] Such potential ill outcomes are especially important to consider in terms of impact of the Board's findings on insulins.

Substantive and Procedural Concerns Undermine the Affordability Review Process

Drug Review Data and Methodology Concerns are Unaddressed

We remain concerned about data and methodology that the Board is using to assess affordability. For example, the carrier-submitted data for Basaglar Kwikpen® consists of 983 claims, while the APAC data consists of more than 87,000 claims.[14] The carrier-submitted data thus represents only 1 percent of claims data in the state for Basaglar Kwikpen®, suggesting it is likely unrepresentative, unreliable, and should not be used to make an affordability determination. The unrepresentative nature of the data is particularly concerning as two key parameters on the Board's proposed scoring rubric include price concessions and preferred status on formulary, both of which appear to be solely determined from this carrier-submitted dataset. This risks creating bias in scoring and further undermining the affordability review process. Furthermore, claims data frequently are inaccurate with respect to patient out-of-pocket costs, because secondary insurance or patient assistance programs that further reduce patient cost-sharing are not reflected. Similar to concerns included in our prior letter on data for Trulicity[15], there are again instances where per-claim net spend appears higher than per claim gross spend for Basaglar Kwikpen®, which is not possible.[16]

Since the Board allowed only five days (including a weekend) for comments, this is not a complete or exhaustive list of all of the methodological and data concerns Lilly has regarding the Board's approach. We will modify or supplement this letter, as necessary and appropriate.

Data and Methods Issues Continue to Undermine the Board's Affordability Review

As in our September 15th letter, we continue to reiterate our concerns about the methodology the Board employs to measure and define affordability. It is unclear whether the primary focus of the Board's affordability review is on cost sharing for patients, specifically patient out-of-pocket

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[11] Louise Heron, Matthew Reaney, Norbert Hermanns, Linda Abetz, Laura Gregg; Perceptions of Usability and Design for Prefilled Insulin Delivery Devices for Patients With Type 2 Diabetes. *Diabetes Spectr* 1 February 2013; 26 (1): 16–28. https://doi.org/10.2337/diaspect.26.1.16

[12] Value of Care Coalition. Specialty Doctor Survey Reveals Concerns about PDABs. https://valueofcarecoalition.org/blog/specialty-doctor-survey-reveals-concerns-about-pdabs/

[13] Ellingson L. Position on non-medical switching for diabetes patients. *J Diabetes Metab Disord Control*. 2017;4(5):138-139. DOI: 10.15406/jdmdc.2017.04.00123

[14] Oregon Prescription Drug Affordability board. October 15 Meeting Materials. https://dfr.oregon.gov/pdab/Documents/20251015-PDAB-document-package.pdf p. 35, Table 1; p.44, Table 7

[15] Eli Lilly and Company. "RE: Oregon Prescription Drug Affordability Board (PDAB): September 17, 2025 Meeting Materials." September 15, 2025.

[16] N.B., for example, on page 21 of the Insulin review Basaglar Kwikpen® commercial cost per claim is $311 from APAC data while on page 24 carrier-submitted data average plan spend per claim ranges from $331-$537. Carrier-submitted data includes cost information after price concessions while the APAC data does not.

costs, or for the health care system as a whole. The Board has not meaningfully defined what "affordability" means, and this shortcoming makes it virtually impossible for the Board to determine if a medicine creates "affordability challenges."[17] Failure to meaningfully define key terms inhibits stakeholder input and needlessly amplifies the risk that the Board will ultimately apply its reviews in an arbitrary and inconsistent manner. We believe it is crucial for the Board to consider affordability within the context of the patient's out-of-pocket experience, as well as Basaglar's role as a more affordable treatment option relative to other branded basal insulin competitors.

In addition to the need for a consistent definition of affordability, it is critical that the drug selection and review methodology which the Board uses is free from bias. We remain concerned that gaps in data collection and availability can lead to the biased selection of and determinations of medicines.

For example, the use of total gross drug spending data by the Board in the scoring rubric can result in bias against medicines with high aggregate spending that treat large populations of individuals with chronic medical conditions. These medicines, even if affordable to patients, may be misconstrued as being unaffordable simply by virtue of them being commonly prescribed and highly utilized. Drug affordability means different things to payers, health systems, governments, and patients. The Board's methodology does not distinguish between spending increases from price vs. those from volume and effectively penalizes higher utilization of a more affordable option. The Board has not clearly addressed those differences in their drug selection methodology and rubric scoring.

In addition, the reliance on carrier-submitted data for assessing price concessions and patient access as part of the affordability review may also lead to bias in assessment of affordability given the small sample size and disparities and inconsistencies in data with APAC data. In carrier-submitted data, Basaglar Kwikpen® is reported as requiring prior authorization 73 percent of the time and being on a non-preferred formulary 96 percent of the time[18]; however, the report elsewhere states "Basaglar Kwikpen® has the most utilization among the drugs, with 87,066 claims in the commercial and Medicaid markets," which suggests much broader coverage than indicated in the carrier-submitted data.[19]

The Board Provides Insufficient Timelines for Meaningful Public Comment

The Board must also allow sufficient time for meaningful public and stakeholder participation in the affordability review process before rendering decisions.[20] The Board's practice of setting unreasonably short comment periods continues to raise significant concerns about the ability for stakeholders to meaningfully review materials and provide comment, including its legal obligations to establish a process for patient and caregiver outreach and input.[21]

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[17] Oregon Prescription Drug Affordability Board. "OAR 925-200-0020 conducting an affordability review." https://dfr.oregon.gov/pdab/Documents/OAR-925-200-0020.pdf.
[18] Oregon Prescription Drug Affordability board. October 15 Meeting Materials. https://dfr.oregon.gov/pdab/Documents/20251015-PDAB-document-package.pdf p. 57, Table 23
[19] Oregon Prescription Drug Affordability board. October 15 Meeting Materials. https://dfr.oregon.gov/pdab/Documents/20251015-PDAB-document-package.pdf p. 49
[20] OAR 925-200-0020(k)
[21] Or. Rev. Stat. § 646A.694(3); OAR 925-200-0020(2)(k)(A).

Better Solutions that Actually Address Patient Affordability are Available

Lilly is pleased to see that some of the policy alternatives proposed by Board members for 2025 would meaningfully address issues in the pharmaceutical payment system without inviting the unintended consequences inherent with price-setting schemes. The Board should continue to explore reforms that address warped supply chain incentives that expose patients to higher cost sharing obligations. Addressing such issues would enable lower costs for patients at the point-of-sale and create the conditions for list and net price parity. The Board should also consider further policies to protect patient assistance – while Oregon has already taken an important step through the banning of accumulator adjustment programs, the state could take action on other schemes that exploit patient assistance such as maximizers and alternative funding programs.

Lilly appreciates the opportunity to respond to the materials provided by the Board. We value the Board's shared commitment to improving prescription drug access and patient affordability. Lilly is proud of our initiatives aimed at reducing costs for patients and believes our medicines positively contribute to the health and well-being of patients in Oregon.

Sincerely,

Senior Director, Government Pricing & Payer

Lilly USA, LLC

October 13, 2025

Oregon Prescription Drug Affordability Board
c/o Department of Consumer and Business Services
350 Winter Street NE
Salem, OR 97309-0405

TO: Members of Oregon Prescription Drug Affordability Board

I am providing this information for the Board's review out of significant concerns regarding the drug reviews you are conducting for the selected antidiabetic drugs. While I applaud the Board in convening these meetings to receive input, information, and opinions from stakeholders to address affordability challenges, I am particularly troubled that you are focusing on the drug list prices and not the patient's total cost risks limiting access to essential medications while creating longer term negative health outcomes.

I am a pediatrician and pediatric rheumatologist and spent my career caring for young people with chronic or disabling conditions. Many of my patients and their family members rely on specialized, innovative and, unfortunately, expensive therapies. My primary focus is always ensuring the well-being of my patients, but as a result of your legislative charges, I fear that the Board's analyses and decisions cannot reflect this same mandate.

During the Board's September meeting, I was pleased to observe your review of PDAB policies implemented in other states, as well as the thoughtful presentations on board member recommendations, including the stakeholder recommendation to expand the scope to review broader health policies. While we have concerns about the other approaches taken in certain states, it is encouraging to see that stakeholder correspondence is receiving thorough consideration and meaningful review here, a level of engagement that distinguishes your process from efforts elsewhere. Additionally, the Board's decision to allocate several months for careful review on all drugs under review reflects a more responsible approach that prioritizes thoroughness over a rush in the process.

However, I have observed the significant challenges the Board faces in determining what constitutes as "affordable" medication, a determination that has proven extraordinarily difficult. The complexity of ensuring that medications are affordable, accessible and available has created struggles for boards all over the country. Oregon should strongly consider pausing its own proceedings to observe the outcomes and lessons learned from other state's experiences. A pause would not only allow the board to step back from a process that is clearly presenting difficulty but would also help address the Board's inability to effectively address upper payment limits. Which raises an even bigger question; why continue to spend time and resources on a mechanism that cannot achieve its intended cost-reduction goals? The reality is that prescription drug affordability is a national systemic issue that cannot be resolved through state-level list price reviews alone and represents yet another interference in the patient-clinician personalized decision-making.

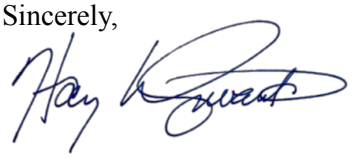
In reviewing the policy concepts posted with your agenda for this meeting, it is notable to add that even Vice Chair Amy Burns has recommended disbanding the Oregon PDAB in favor of considering alternative initiatives to address prescription drug affordability. Similarly, Board member John Murray has suggested that UPLs should only be employed as a last resort, acknowledging the serious concerns about negative impacts to an already fragile healthcare system that UPLs have created at the federal level. These recommendations from within the Board itself underscore a growing recognition that the current process may not be achieving its intended outcomes.

Everyone shares your goal to lower prescription drug costs, and I applaud your efforts in listening to stakeholders and giving thoughtful consideration to the letters and input you receive. However, I still remain deeply concerned that your charge and the current process's narrow focus on drug list prices, rather than the total cost to patients, risks limiting access to essential medications while creating longer-term negative health outcomes. A more comprehensive approach that addresses the entire cost structure, including the role of pharmacy benefit managers, price concessions, and other intermediaries would better serve Oregon patients and more effectively achieve the affordability goals we all share.

All clinicians and patients are eager to collaborate with the Board to ensure affordability decisions reflect real-world patient needs with a more thoughtful, patient-centered approach. As it stands, however, the Board's actions could inadvertently restrict access to effective cost-saving medications for those Oregon residents who need them the most. We encourage the Board to address the multiple deficiencies and restrictions placed upon it by asking the legislature to consider expanding your ability to develop methods of lowering actual drug costs, not just the list prices of drugs purchased by the State and Oregonians.

Thank you for your attention to this critical issue.

Sincerely,



Harry L. Gewanter, MD, FAAP, MACR
Board Member, Let My Doctors Decide Action Network

OCAP OREGON COALITION FOR AFFORDABLE PRESCRIPTIONS

October 10, 2025

Oregon Prescription Drug Affordability Board
350 Winter Street NE
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pdab@dcbs.oregon.gov

Dear Chair Bailey, Vice Chair Burns, and PDAB Members,

Thank you for your service to Oregon patients and to our healthcare system. We also want to extend a warm welcome to your newest board member, Michele Koder, and to your incoming executive director, Sarah Young.

As the Oregon Coalition for Affordable Prescriptions (OCAP), we represent Oregonians across the state who struggle every day to afford the medications they need. Our mission is to improve prescription drug affordability and transparency for every Oregonian. To that end, we want to be clear: our organization does not accept funding from the pharmaceutical industry.

The Oregon PDAB was created with a clear mission: *to protect Oregonians and our state's healthcare system from the high costs of prescription drugs*.[1]

Unfortunately, Oregon patients and our healthcare system continue to strain under the weight of high prescription drug costs. Recent reports show that **in 2024, the Oregon Health Authority spent more than $1 billion (after rebates)[2] alone, on prescription drugs for patients enrolled in the Oregon Health Plan.** In 2024 more than 50,000 OHP patients delayed filling a prescription because of cost, and more than 45,000 skipped or reduced medication so that a prescription would last longer.[3]

At the same time, the federal cuts enacted through H.R. 1 ("The Big Beautiful Bill") are beginning to ripple through our state's economy. At last month's legislative days, the state economist reported that Oregon's revenue is expected to drop by $641 million due to these federal reductions.[4] As prescription drug costs rise and federal support

[1] Deb Patterson et al., "Relating to the Price of Prescription Drugs," Pub. L. No. 844 (2022), https://olis.oregonlegislature.gov/liz/2021R1/Downloads/MeasureDocument/SB844/Enrolled.
[2] Drug Use and Research Management Program, "Pharmacy Utilization Summary Report: January 2024 - December 2024," August 28, 2025, https://www.orpdl.org/durm/reports/utilization/2025/DUR_Utilization_2025_Q2.pdf.
[3] Oregon Health Insurance Survey Program, "Cost Dashboard," Oregon.gov (Oregon Health Authority, 2024), https://www.oregon.gov/oha/HPA/ANALYTICS/pages/ohis-cost.aspx.
[4] Michael Kennedy and Carl Riccadonna, "Oregon's Economic and Revenue Forecast" (Oregon Department of Administrative Services, August 2025), https://olis.oregonlegislature.gov/liz/2025I1/Downloads/CommitteeMeetingDocument/309843.

declines, our state faces growing pressure to do more with less, especially for low-income families, seniors, and people with chronic conditions. When medications are unaffordable, hardworking families end up being the ones who pay.

Your work on affordability reviews is vital, and we urge you to remain focused on this goal. High-cost medications don't just put patients' health at risk; they contribute to increased insurance premiums and state health spending—taking money from Oregon communities and small businesses.

Finally, we believe there are other state examples that we can learn from. **On October 3, the Colorado PDAB became the first in the nation to set an Upper Payment Limit (UPL) on a high-cost prescription drug (Enbrel).**[5] According to a recent Colorado PDAB Report, Enbrel cost Coloradans and their health plans over $83 million in 2023, with the average Coloradan paying $4,638 out of pocket.[6] Colorado's PDAB set its UPL at the same level as the federally negotiated Maximum Fair Price (MFP) under Medicare Part D or approximately $30,356 per year (In 2023, the average insurance plan paid $53,049 for Enbrel).[7]

Lower drug spending keeps money in people's paychecks, helps small businesses insurance costs from rising, and will mean fewer premium hikes and more predictability for employers. This move is pro-consumer, pro-small business, and pro-economy.

We are closely following the policy implementation and invite you, as PDAB board members, to do the same. While industry stakeholders and groups they fund consistently make claims about possible reductions in access due to a UPLs, it is also true that most of those entities have significant financial stakes in maintaining the status quo. Their claims must be evaluated carefully against real-world data and independent evidence. **Medication is not accessible if people cannot afford it.**

Your work on the Oregon PDAB has the power to deliver meaningful relief for patients and long-term savings for our healthcare system. We urge your completion of robust affordability reviews, and delivery of meaningful policy recommendations that will protect Oregonians and our healthcare system as we face increased federal threats.

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[5] Celine Castronuovo, "Colorado Adopts First State Payment Cap for Amgen's Enbrel," Bloomberg Law, October 3, 2025, https://news.bloomberglaw.com/health-law-and-business/colorado-finalizes-first-state-payment-cap-for-amgens-enbrel.

[6] "Upper Payment Limit (UPL) Benchmark Data: Enbrel and Therapeutic Alternatives" (Colorado Prescription Drug Affordability Board, May 23, 2025), https://docs.google.com/spreadsheets/d/1KoAKUS1gIH6ssgGwJH2hZlF0IgL4tf4E/edit?gid=1408830193#gid=1408830193.

[7] "Upper Payment Limit (UPL) Benchmark Data: Enbrel and Therapeutic Alternatives" (Colorado Prescription Drug Affordability Board, May 23, 2025), https://docs.google.com/spreadsheets/d/1KoAKUS1gIH6ssgGwJH2hZlF0IgL4tf4E/edit?gid=1408830193#gid=1408830193.

Every Oregonian deserves to be able to afford the medications they need to live healthy and productive lives.

Thank you for the opportunity to submit these comments. Our board is available to support your work in any way we can. You can reach us at info@affordablerxnow.org or through BethAnne Darby at Strategies 360 Oregon.

Sincerely,
The Oregon Coalition for Affordable Prescriptions Board
John Mullin, Board Chair (Seanduine; Health and Human Service Advocate)
Christi Marcotte, (Oregon Health Care Professional)
Charlie Fisher (OSPRIG)

Regence | 200 SW Market Street, 11th Floor
Portland, OR 97201

October 13, 2025

Prescription Drug Affordability Board
350 Winter St. NE
Room 410
Salem, OR

SUBMITTED VIA EMAIL

RE: Proposed Policy of Expansion of PDAB Authority

Dear Members of the Oregon Prescription Drug Affordability Board,

We thank the Prescription Drug Affordability Board and Staff for the opportunity to comment on the Board's proposed policy recommendations to the legislature. As one of the state's largest health insurers, Regence is committed to addressing persistent and emerging health needs for the nearly 1 million Oregonians we serve. Consistent with our values as a tax-paying nonprofit, 90% of every premium dollar pays for our members' medical claims and expenses.

We are writing to the Board to express concern over the policy proposal to expand the PDAB's authority to provide further review of Oregon's drug delivery system. The PDAB was created with a clear and specific mandate: **to evaluate the potential financial burden that high-priced medications impose on Oregon residents and the health care system.**

The Board's statutory responsibilities are well-defined and include:

- Collecting and evaluating information concerning prescription drug costs in Oregon
- Performing affordability reviews of prescription drugs
- Studying the prescription drug distribution and payment system
- Making recommendations to the Legislative Assembly to make prescription drugs more affordable

Of all the policy proposals put forward this year, **85% fall outside the Board's statutory authority**. Many of these proposals impact provider reimbursement rather than consumer affordability, which represents a significant departure from the Board's core mission of addressing prescription drug costs for Oregon residents.

Additionally, all the proposals expanding into PBM regulation fundamentally shift the Board's focus from **consumer-facing drug affordability** to **provider reimbursement structures**. This distinction is critical because provider

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reimbursement issues are complex and require specialized regulatory oversight and more diverse expertise than is represented by the Board. Additionally, these issues have been debated by the legislature over several legislative sessions and via focused stakeholder workgroups over the past 18 months. We believe that, instead of expanding the scope of the PDAB and thus diluting its resources and attention, PBM and provider reimbursement issues should be elevated to the legislature through existing avenues. The PDAB's mission is prescription drug affordability for Oregon consumers and this inappropriate broadening of its charges will undermine the Board's ability to achieve this mission.

We respectfully urge the Board to:

1. **Maintain focus on its statutory mandate** of prescription drug affordability for Oregon consumers;
2. **Withdraw the proposed expansion** into drug delivery system regulation and PBM oversight;
3. **Concentrate resources** on the core responsibilities outlined in the Board's establishing statute; and

Oregonians need the PDAB to remain focused on its essential mission of making prescription drugs more affordable. Expanding into areas outside of the Board's expertise and authority risks undermining the important work the PDAB was established to perform. Poorly informed policy proposals risk increasing the consumer burden of cost and impeding drug access. Again, we do not believe the Board is equipped to comprehensively assess all aspects of the prescription drug delivery system and are concerned about the impact such an enhanced scope would have on Oregonians.

Thank you for your consideration of these concerns. I look forward to the Board's continued focus on prescription drug affordability within the scope of its statutory authority.

Sincerely,

Mary Anne Cooper
Director of Government Relations
Regence BlueCross BlueShield of Oregon