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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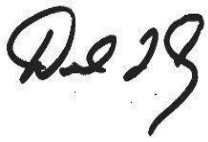
Lilly appreciates the opportunity to respond to the Board materials. We appreciate that the Board shares our commitment to prescription drug access and patient affordability. We are proud of the impact that our efforts have had on making prescription drugs more affordable for patients and believe Lilly 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.

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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,

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