



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

To: Chair Patterson and the Oregon Prescription Drug Affordability Board
From: John Mullin, President, Oregon Coalition for Affordable Prescriptions
Date: 11/8/2023
Re: Testimony to Oregon's PDAB Board

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

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

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

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

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



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

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

November 12, 2023

Oregon Prescription Drug Affordability Board
350 Winter Street NE
Salem, OR 97309-0405

Dear Chair Patterson and Members of the Board:

On behalf of the Biotechnology Innovation Organization (BIO) and the Oregon Bioscience Association (OR Bio), thank you for the opportunity to provide public comment. These comments relate to the agenda item for your upcoming November 15, 2023, board meeting entitled “Board review of policy submissions.”

As the Board moves to discuss policy submissions from the public for consideration in its annual recommendations to the legislature, we hope to provide meaningful insight into one submission in particular. In a submission on behalf of the Oregon Coalition of Affordable Prescriptions, a proposal was made to modify Oregon’s current statutory framework for the substitution of biosimilar and interchangeable biologic products by pharmacists. We urge you to not include this proposal in your recommendations to the legislature, as it would enable substitutions that could risk patient safety, would contradict federal law, and you as a board have not studied the issue or even discussed this in any public forum.

Biologics are complex medicines manufactured from living organisms. Unlike traditional “small molecule” drugs, biologics are not chemically synthesized but rather are manufactured from living cells by programming a particular cell line to produce a desired therapeutic substance in a highly controlled sterile environment. Each individual biologic therapy is a complex, heterogeneous mixture, which in many cases cannot be well characterized by current science. Because of this complexity, even minor differences in manufacturing processes can cause variations in the end product. Consequently, two biologics made using different cell lines and differing manufacturing processes will rarely, if ever, be exactly the same.

Follow-on biologics, or “biosimilars,” are biologic products manufactured using different cell lines and manufacturing processes with the goal of closely mirroring the composition and treatment profile of an innovator product produced by another company. Due to the innate complexity of biologics in general, however, the production of biosimilar products can invariably lead to some differences between the composition of a biosimilar and the original innovator product, and these differences could potentially lead to clinical differences in a patient’s experience or reaction. In other words, unlike generic copies of traditional small molecule drugs, biosimilar biologic products are similar to, but not the same as, an innovator therapy.

The federal Food and Drug Administration (FDA) has developed guidance regarding the regulatory pathway for the approval of biosimilar and interchangeable biologic products. This approval pathway was established by federal law, and distinguishes clearly between biologic products that are “biosimilar” to an innovator biologic—meaning they are “highly similar” to an innovator product—and biologic products that meet a heightened standard to be deemed “interchangeable.” The

standard for interchangeability in the law is a stringent one; one that is consistent with the FDA's role in protecting patient safety. In order to deem a biologic product interchangeable with an innovator product, FDA must determine that a biologic is not only "biosimilar," but also that it "can be expected to produce the same clinical result as the [innovator] product in any given patient." Further, if a patient might be switched back and forth between two products, the FDA must determine that there is no additional risk in such switching compared to using the innovator product alone.

Federal law governs the regulation and licensing of biologics, biosimilars, and interchangeable biologics, while state law governs how healthcare providers prescribe, dispense, administer, and substitute these products. Oregon's laws for pharmacist substitution of biologic products closely mirrors statutes in every other US state, adhering to a consensus model that includes the following five key principles:

- Substitution should occur only when the FDA has designated a biologic product as interchangeable
- The prescribing physician should be able to prevent substitution
- The prescribing physician should be notified of the substitution
- The patient, or the patient's authorized representative, should, at a minimum, be notified of the substitution
- The pharmacist and the physician should keep records of the substitution

The policy submission recommending to allow pharmacists to substitute a prescribed biologic with any biosimilar—instead of interchangeable products only—would undermine a core patient safety provision in current law. Federal law specifically created the category of interchangeable biologics to designate products that can be "substituted for the original product without consulting the prescriber, much like how generic drugs are routinely substituted for brand name drug" (from FDA's *Biosimilar and Interchangeable Biologics: More Treatment Choices*). Only in this situation can patients and their care team be assured that all reasonable efforts have been undertaken to assess the possible adverse effects on a patient, in terms of diminished safety or effectiveness, when one biologic product is substituted for another. In these cases, the FDA has thoroughly evaluated the possibility for immunogenic reactions, side effects, and other safety or efficacy differences to help ensure that a patient will react favorably to a given treatment if there is a substitution of an interchangeable biologic for an innovator product, or vice versa.

Thank you for your commitment to improving affordability of prescription medicines for Oregon patients and for your consideration of these comments.

Sincerely,



Liisa Bozinovic
Executive Director
Oregon Bioscience Association



Brian Warren
Senior Director, State Government Affairs
Biotechnology Innovation Organization

November 12, 2023

Oregon Prescription Drug Affordability Board
350 Winter Street NE
Salem, OR 97309-0405

Dear Chair Patterson and Members of the Board:

On behalf of the Biotechnology Innovation Organization (BIO) and the Oregon Bioscience Association (OR Bio), thank you for the opportunity to provide public comment. As the Board moves forward with selecting a prioritized subset of prescription drugs eligible for affordability review and with conducting affordability reviews on these products, we ask for greater clarity and transparency in the process, methods, and data used.

We have concerns with data in the drug list the board has been using, particularly with the prices shown under the category “package WAC.” As you are aware, a single drug can have multiple strengths, dosage forms, and packages. OAR 925-200-0010 states that “[f]or drugs with multiple nation drug codes (NDC), a measure of central tendency will be used for a price comparison.” However, the “measure of central tendency” used to create the number reported in the board’s list has not been shared publicly. There are numerous ways to calculate an average for a set of data, each with its own strengths and weaknesses depending on characteristics of the data being compared. Our members, whose own products appear on this list, have not been able to recreate some of the numbers reported.

Additionally, we ask that the board provide greater clarity about its intended next steps in the affordability review process. We understand that this is a new program being implemented for the first time. You as board members and the staff supporting your work are faced with the challenging task of designing and carrying out a statutory framework that has its own challenges. Please be assured that our members take seriously the work this board is doing and intend to comply with all requirements. However, in order to do so in a timely and meaningful manner, we respectfully ask for renewed discussion about how the board intends to move forward with its next steps.

Lastly, to ensure accurate information is being considered by the Board and to help minimize confusion among manufacturers and inconsistencies with publicly facing information, we encourage the creation of an inquiry form or other process for manufacturers and other stakeholders to submit questions, comments, and/or objections outside of the public comment process. While public comments are the best way to provide input to you as board members about decisions you will make, that process is not intended to be deliberative nor is it the best venue for bringing concerns to your attention about incorrect data, for example.

Thank you for your commitment to improving affordability of prescription medicines for Oregon patients and for your consideration of these comments.

Sincerely,

A handwritten signature in black ink that reads "Liisa Bozinovic". The signature is written in a cursive, flowing style.

Liisa Bozinovic
Executive Director
Oregon Bioscience Association

A handwritten signature in blue ink that reads "Brian Warren". The signature is written in a cursive, flowing style.

Brian Warren
Senior Director, State Government Affairs
Biotechnology Innovation Organization

November 10, 2023

VIA ELECTRONIC FILING

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

Re: Oregon Prescription Drug Subset List

Dear Members of the Oregon Prescription Drug Affordability Board:

Bristol Myers Squibb (“BMS”) appreciates the opportunity to submit written comments to the Oregon Prescription Drug Affordability Board (the “Board”) on its subset of prescription drugs to prioritize for affordability review. For the reasons below, we respectfully ask that ELIQUIS® (apixaban) be removed from the prioritized subset and not subject to the affordability review process.

At BMS, we are inspired by a single vision—transforming patients’ lives through science. We are in the business of breakthroughs—the kind that transform patients’ lives through lifesaving, innovative medicines. Our talented employees come to work every day dedicated to the mission of discovering, developing, and delivering innovative medicines that help patients prevail over serious diseases. We combine the agility of a biotech with the reach and resources of an established pharmaceutical company to create a global leading biopharma company. In oncology, hematology, immunology, and cardiovascular disease—with one of the most diverse and promising pipelines in the industry—we focus on innovations that drive meaningful change.

BMS supports public policies that promote patient access to new and effective medical treatments and help ensure patients benefit from the innovation that defines the U.S. health care system. BMS has long supported efforts in Oregon to meaningfully enhance patient access and improve affordability by lowering out-of-pocket costs for patients.

Oregon law states that the Board shall identify drugs “that the [B]oard determines may create affordability challenges for health care systems or high out-of-pocket costs for patients in this state” and instructs the Board to consider multiple factors in determining which drugs to prioritize for affordability review.¹ We are concerned that the current methodology, data sources, and criteria used by the Board to identify drugs for affordability review may not accurately prioritize those drugs that may pose affordability challenges for patients. We believe that ELIQUIS® (apixaban), which is developed and commercialized by an alliance between BMS and Pfizer, should be removed from the prioritized subset of prescription drugs as its inclusion is inappropriately based on its volume of use by clinicians and patients in Oregon rather than its costs to health care systems and patients. Indeed, the statutory affordability review process contemplates

¹ Or. Rev. Stat. Ann. § 646A.694(1); Or. Admin. R. 925-200-0010.

many factors beyond volume alone, focusing on products presenting actual affordability issues for patients. We also wish to emphasize the clinical attributes of ELIQUIS and evidence of its benefits to patients, the healthcare system, and society.

Background on ELIQUIS

ELIQUIS is a best-in-class direct oral anticoagulant (“DOAC”) indicated to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation (“NVAF”), for the treatment and prevention of Deep Vein Thrombosis (“DVT”) and pulmonary embolism (PE), and to decrease the risk of DVT blood clots after hip or knee replacement surgery.² Atrial fibrillation (“AFib”) is the most common type of irregular heartbeat that often causes the heart to beat too quickly and can lead to blood clots, stroke, heart failure and other heart-related complications if left untreated.³ As the U.S. population ages, the number of persons with AFib is projected to increase to more than 12 million by the year 2030.⁴ AFib is associated with an approximately fivefold increased risk of ischemic stroke. The risk of having a stroke is nearly twice as high for non-Hispanic Black adults as for White adults and non-Hispanic Black adults and Pacific Islander adults have the highest rates of death due to stroke.³ Stroke-related costs in the U.S. came to nearly \$56.5 billion between 2018 and 2019 which included the cost of health care services, medicines to treat stroke, and missed days of work.⁵ Effective treatment to reduce the risk of stroke is an important benefit to Oregon’s health care system and patients where stroke-related care commonly leads to costly hospitalizations and extended rehabilitation needs.

The Board’s apparent focus on insurer-reported data does not account for the actual costs borne by patients and lacks transparency.

Our understanding is that, in identifying the initial subset of drugs to prioritize for affordability review, the Board gave decisive weight to Drug Price Transparency (“DPT”) carrier data and the so-called “CCO list.”⁶ We remain concerned with this approach given the limitations of the DPT carrier data, the lack of transparency into the Board’s methodology for compiling and weighing the data, and the manufacturers’ inability to independently verify or dispute the accuracy of the data.

The fact that ELIQUIS was included on the DPT list of “top 25 most costly drugs” reflects the volume of clinical utilization of ELIQUIS and the number of Oregonians who benefit from treatment with this drug. Yet, the DPT “top 25 most costly drugs” list, which is based on total annual plan spending, fails to consider the totality of the subsidies that BMS provides to purchasers and carriers in Oregon so that Eliquis remains accessible and affordable for patients. Currently, Eliquis is widely available to patients, with over 90% open access among commercial plans and low out-of-pocket costs. On average, NVAF patients with commercial

² ELIQUIS® (apixaban) Package Insert. Bristol-Myers Squibb Company, Princeton, NJ and Pfizer Inc, New York, NY https://packageinserts.bms.com/pi/pi_eliquis.pdf.

³ Why Atrial Fibrillation Matters. <https://www.heart.org/en/health-topics/atrial-fibrillation/why-atrial-fibrillation-af-or-afib-matters>.

⁴ Centers for Disease Control and Prevention. (2022, October 14). Atrial fibrillation. Centers for Disease Control and Prevention. https://www.cdc.gov/heartdisease/atrial_fibrillation.htm.

⁵ Centers for Disease Control and Prevention. (2023, May 4). Stroke Facts. Centers for Disease Control and Prevention. <https://www.cdc.gov/stroke/facts.htm>.

⁶ [October 18, 2023 Agenda Packet](#), at 6 (stating the recommendation from Chair Akil Patterson to “[c]ombine total cost and carrier cost. Look at the DPT drug data to mesh with the top 25 of the CCO data.”).

insurance pay only \$38 per month for Eliquis, and 5 out of 10 pay \$20 per month or less.⁷ Moreover, when accounting for the volume of use based on the number of enrollees on Eliquis in the DPT carrier data, Eliquis ranks 29th in total annual spend per enrollee out of the 34 products on the Board's prioritized subset of prescription drugs.⁸

More generally, we are concerned about the lack of transparency with respect to how drugs have been selected for the prioritized subset of prescription drugs. As the Pharmaceutical Research and Manufacturers of America (“PhRMA”) discussed in a recent comment letter, the Board has not specified how it has weighed the seven regulatory factors articulated in Or. Admin. R. 925-200-0010.⁹ Furthermore, over the course of the past several months, the Board has added, deleted, and in some cases re-added drugs to the “Top Drugs to Review” table with limited explanation.¹⁰ Manufacturers have had limited to no opportunity to independently verify or dispute the data upon which the Board relied.

The Board should consider evidence of ELIQUIS’S benefits to patients, the healthcare system, and society.

The Board’s methodology for selecting drugs to prioritize for affordability review does not reflect the clinical and economic benefits of ELIQUIS. The clinical benefits of ELIQUIS in patients with NVAF and venous thromboembolism (“VTE”) have been demonstrated in both the clinical trial and real-world clinical practice settings. In several U.S. real-world data analyses, ELIQUIS use was associated with a similar or lower risk of stroke-related hospitalizations, as well as a consistently lower risk of bleeding-related hospitalizations, when compared to other oral anticoagulants, including other products in the DOAC class. These findings were also consistent across different populations and data sources, including Medicare, Commercial, Veterans Affairs, and Department of Defense.

In addition to the clinical benefits of ELIQUIS, the economic benefits were found to be associated with reduced healthcare resource utilization and costs across various populations with NVAF and VTE studied in U.S. real-world data analyses. Specifically, these analyses demonstrated that ELIQUIS was associated with similar or lower all-cause healthcare costs and consistently lower all-cause medical costs—particularly those associated with major bleeding events—when compared to other oral anticoagulants. Considering the economic burden of NVAF in the U.S. has been predicted to approach \$30 billion annually by 2050¹¹, and is largely driven by costs associated with hospitalization, ELIQUIS provides clinicians and health care systems in Oregon with a less costly approach to reducing the risk of stroke and treating and preventing blood clots.

With this extensive and growing breadth of real-world clinical and economic evidence, ELIQUIS has solidified its market leadership position as the #1 most prescribed oral anticoagulant which is reinforced by its differentiated placement on clinical guidelines.

⁷ Pricing information. AFib Pricing Information for Rx ELIQUIS® (apixaban) | Safety Info (October 2022).

<https://www.eliquis.bmscustomerconnect.com/afib/price>.

⁸ Revised Prescription Drug Subset List (Excel). Oregon Prescription Drug Affordability Board. Accessed November 10, 2023.

<https://dfr.oregon.gov/pdab/Pages/data.aspx>.

⁹ PhRMA Letter to Oregon Prescription Drug Affordability Review Board, at 1.

¹⁰ *Id.* at 3.

¹¹ Kim MH, Lin J, Hussein M, et al. Cost of atrial fibrillation in United States managed care organizations. *Adv Therapy*. 2009;26(9):847–857.

Conclusion

Given low out-of-pocket costs for patients and the significant clinical and economic benefits of ELIQUIS to the healthcare system, we strongly urge the Board to remove ELIQUIS from the prioritized subset of prescription drugs. ELIQUIS is already widely accessible and affordable for the vast majority of Oregonians, and its inclusion on the list is unwarranted.

Thank you for the opportunity to provide comments and for considering our concerns. Should you have any questions or concerns, please contact Aakash Patel, Director, Cardiovascular & Immunology Policy at aakash.patel@bms.com and Anne Murray, Director, State Government Affairs, U.S. Policy & Government Affairs at anne.murray@bms.com.

Sincerely,

/s/

Stephanie A. Dyson

Senior Vice President

U.S. Policy & Government Affairs



A Member of the Roche Group

600 Massachusetts Ave. NW, Suite 300
Washington, DC 20001
Phone: (202) 296-7272
Fax: (202) 296-7290

November 10, 2023

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

Re: Oregon PDAB Prescription Drug Affordability Review & Drug Selection Processes

Dear Members of the Oregon Prescription Drug Affordability Board:

We are writing today to share our concerns with you regarding the Board's approach to selecting prescription drugs for affordability reviews and respectfully seek urgent guidance and transparency from the Board and staff on this process.

Genentech has been following the Board's meetings and communications closely. Unfortunately, the Board's actions, communications, and timelines continue to create a substantial amount of confusion among manufacturers and other interested stakeholders. For example, the vote taken by the Board on the subset of drugs for an affordability review was not immediately clear to those in attendance during the October 18, 2023 meeting, and only became clear through the Board's follow-up communications. However, the status of that October 18, 2023 vote on drug selection once again became unclear following the release of the Board's agenda and meeting materials for your upcoming meeting on November 15, 2023.

The agenda for the Board's meeting on November 15, 2023 was released, edited, and re-released, seemingly seeking to clarify the intention of the Board's proposed actions for the November meeting. A second revised agenda with new discussion items released on November 7, 2023 continues to leave manufacturers and other interested stakeholders without a clear understanding of the Board's prior decisions, forthcoming discussions and decision timelines, and the current status of the Board's drug selection for affordability reviews. In addition, the meeting materials released on November 7, 2023 contain the results of a Board member survey to rank affordability review criteria. To our knowledge, it was not announced nor discussed that such a survey would be conducted and result in proposed weighting of criteria for drug affordability reviews. Given the importance of the Board's deliberation of these criteria, we are disappointed the public was not provided insight to the survey in advance nor provided a direct opportunity to submit feedback that could inform the Board's prioritization and weighting. These actions are just a few examples of the challenges with the lack of transparency in the Board's processes and inadequate effort to solicit and consider stakeholder feedback.

We respectfully request the Board, as soon as possible, provide much clearer guidance regarding the drug subset lists, forthcoming Board actions and associated timelines, and specific opportunities for stakeholder engagement. We also urge the Board to provide more dedicated opportunities to solicit and consider feedback from manufacturers and other stakeholders in their ongoing deliberations. These elements are essential to support an effective, robust, and transparent process allowing for both data validation and engagement from all stakeholders.

If you have any questions or wish to discuss our comments, please contact Tim Layton, Director of State Government Affairs at layton.timothy@gene.com or (206) 403-8224.

Sincerely,

A handwritten signature in black ink that reads "Mary Wachter". The signature is written in a cursive, flowing style.

Mary Wachter, RN
Executive Director
State & Local Government Affairs

CC: Kristina Narayan, Health Advisor, Office of the Governor

Genentech

A Member of the Roche Group

600 Massachusetts Ave. NW, Suite 300
Washington, DC 20001
Phone: (202) 296-7272
Fax: (202) 296-7290

November 10, 2023

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

Re: November 2, 2023 Revised Drug Subset - Removal of HEMLIBRA®

Dear Members of the Oregon Prescription Drug Affordability Board:

On November 2, 2023, the Board released a “revised prescription drug subset list” expanding the number of medicines included in the Board’s previously approved subset of 26 drugs from the October 18, 2023 meeting to a new subset of 36 drugs, including drugs previously identified for exclusion. One such drug previously excluded is Genentech’s medicine, HEMLIBRA® (emicizumab-kxwh), for the treatment of adults and children with hemophilia A.

HEMLIBRA is solely designated by the Secretary of the Food and Drug Administration as a drug for a rare disease or condition under 21 U.S.C. 360bb. Per ORS 646A.694 (2), such a drug is not eligible to be subject to an affordability review by the Board:¹

646A.694 Annual affordability determination for identified drugs and insulin products; criteria for and limitations on determination; confidentiality; rules. (2) A drug that is designated by the Secretary of the United States Food and Drug Administration, under 21 U.S.C. 360bb, as a drug for a rare disease or condition is not subject to review under subsection (1) of this section.

We respectfully ask the Board to promptly and publicly remove HEMLIBRA from the Board’s drug subset list and reaffirm drugs designated under 21 U.S.C. 360bb. Per ORS 646A.694 (2) are not eligible to be subject to an affordability review. If you have any questions or wish to discuss our comments, please contact Tim Layton, Director of State Government Affairs at layton.timothy@gene.com or (206) 403-8224.

Sincerely,



Mary Wachter, RN
Executive Director
State & Local Government Affairs

¹ Oregon Revised Statutes. ORS 646A.694 (2). https://www.oregonlegislature.gov/bills_laws/ors/ors646a.html



A Member of the Roche Group

600 Massachusetts Ave. NW, Suite 300
Washington, DC 20001
Phone: (202) 296-7272
Fax: (202) 296-7290

November 10, 2023

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

Re: Proceeding with a review of OCREVUS® Is Unnecessary

Dear Members of the Oregon Prescription Drug Affordability Board:

In a letter dated October 13, 2023, we shared our concerns over the limitations of the data the Board used in its drug selection process. Today, we reiterate those concerns, and provide detailed information on OCREVUS® demonstrating its value and affordability to patients and the healthcare system.

On October 18, 2023, the Board identified OCREVUS as part of the subset of 26 drugs selected for an affordability review. As it remains unclear when, and whether, the Board is initiating affordability reviews on this subset, we are sharing the following information to demonstrate OCREVUS: **(1) provides significant value to multiple sclerosis patients, the healthcare system and society;** and **(2) is affordable, particularly in the context of other FDA-approved therapeutic alternatives.**

Therefore, proceeding with an affordability review of OCREVUS would be both unnecessary and inappropriate.

1. OCREVUS PROVIDES SIGNIFICANT VALUE TO MULTIPLE SCLEROSIS PATIENTS, THE HEALTHCARE SYSTEM & SOCIETY

Multiple sclerosis (MS) is a chronic autoimmune disorder that can lead to permanent neurological disability. An estimated 1 million individuals in the US are living with MS,¹ including more than 7,000 people in Oregon.² People with MS are typically diagnosed in their prime, between 20 and 40 years of age, and are more often women (3:1).³ Symptoms of MS include weakness, fatigue, vision changes, pain and balance problems.⁴ As these symptoms commonly first present in the third decade of life, MS has long-term impact on not only a patient's quality of life, but also serious economic consequences.

¹Wallin MT, Culpepper WJ, Campbell JD, et al. The prevalence of MS in the United States: A population-based estimate using health claims data. *Neurology*. 2019;92(10):e1029-e1040.

² *MS Registry | Providence Oregon*, <https://pacificnwms.org/>. Accessed 30 October 2023.

³ Ford H. Clinical presentation and diagnosis of multiple sclerosis. *Clin Med (Lond)*. 2020 Jul;20(4):380-383. doi: 10.7861/clinmed.2020-0292. PMID: 32675142; PMCID: PMC7385797.

⁴McGinley MP, Goldschmidt CH, Rae-Grant AD. Diagnosis and Treatment of Multiple Sclerosis: A Review. *Jama*. 2021;325(8):765-779.

The annual excess medical costs among persons with MS are estimated to average over \$65,000 per year.⁵ Additionally, when considering the broader costs of the disease across society, the annual cost to the US is estimated at nearly \$85 billion.^{6,7,8} Major contributors to the high socioeconomic burden of MS are disease progression and disability accumulation, as burden and costs increase with disease severity.

Disease-Modifying Therapies (DMTs) that can reduce disease activity and slow disease progression have transformed the treatment landscape for patients with MS. Research has shown that early treatment of MS with high-efficacy DMTs, like OCREVUS, can reduce the risk of relapse and delay disease progression, which has separately been associated with improved long-term clinical and economic outcomes.^{9,10}

OCREVUS is a therapeutic monoclonal antibody - the first and only FDA-approved DMT indicated for the treatment of adults with either relapsing forms of multiple sclerosis (RMS) or primary progressive multiple sclerosis (PPMS).^{11,12} While the majority of MS is categorized as relapsing, PPMS is an even more debilitating form characterized by steadily worsening symptoms, typically without distinct relapses or periods of remission.¹³ OCREVUS is the only FDA approved therapy for patients with PPMS available today.¹⁴

The value OCREVUS brings to the treatment of MS is based on robust scientific evidence which demonstrates OCREVUS is affordable and therefore an inappropriate candidate for an affordability review. We expand on several proven benefits of OCREVUS treatment below.

OCREVUS Has Established Long-Term Benefits in Slowing Disease Progression

Last month, Genentech was proud to announce new 10-year milestone data from open-label extensions of Phase III studies in RMS and PPMS that show benefit in slowing long-term disability progression.¹⁵ After ten years of continuous treatment with OCREVUS, 77% of patients with RMS were free from disability progression, and 92% were still walking unassisted. In patients with PPMS, 36% were free from disability progression, and 80% of those patients treated continuously with OCREVUS over ten years could still walk. Importantly, the 10-year safety data from over 6,000 patients continues to reinforce the consistent long-term safety profile of OCREVUS.

⁵Bebo B, Cintina I, LaRocca N, et al. The economic burden of multiple sclerosis in the United States: estimate of direct and indirect costs. *Neurology*. 2022; 98(18):e1810–17.

⁶Whetten-Goldstein K, Sloan FA, Goldstein LB, Kulas ED. A comprehensive assessment of the cost of multiple sclerosis in the United States. *Mul Scler*. 1998; 4(5):419–25.

⁷Bebo B, Cintina I, LaRocca N, et al. The economic burden of multiple sclerosis in the United States: estimate of direct and indirect costs. *Neurology*. 2022; 98(18):e1810–17.

⁸Adelman G, Rane SG, Villa KF. The cost burden of multiple sclerosis in the United States: a systematic review of the literature. *J Med Econ*. 2013; 16(5):639–47.

⁹Nicholas, J., et al. Annual Cost Burden by Level of Relapse Severity in Patients with Multiple Sclerosis. *Adv Ther* 38, 758–771 (2021).

¹⁰Filippi M, et al. Early use of high-efficacy disease-modifying therapies makes the difference in people with multiple sclerosis: an expert opinion. *J Neurol*. 2022 Oct;269(10):5382-5394. doi: 10.1007/s00415-022-11193-w.

¹¹OCREVUS (ocrelizumab) Prescribing Information. Genentech, Inc. 2016.

¹²National Multiple Sclerosis Society. Treating PPMS. Available at

<http://www.nationalmssociety.org/What-is-MS/Types-of-MS/Primary-progressive-MS/Treating-Primary-Progressive-MS>.

¹³Ford H. Clinical presentation and diagnosis of multiple sclerosis. *Clin Med (Lond)*. 2020 Jul;20(4):380-383. doi: 10.7861/clinmed.2020-0292. PMID: 32675142; PMCID: PMC7385797.

¹⁴OCREVUS (ocrelizumab) Prescribing Information. Genentech, Inc. 2016.

¹⁵Hauser et al. Safety of Ocrelizumab in Multiple Sclerosis: Updated Analysis in Patients with Relapsing and Progressive Multiple Sclerosis Presented at the 9th JointECTRIMS-ACTRIMS Meeting. Milan, Italy. 11–13 October 2023.

Early Use of OCREVUS Reduces Healthcare Utilization and Costs

A recent retrospective claims study demonstrated that patients who initiated OCREVUS as a first-line treatment had better clinical outcomes and lower events often associated with relapse¹⁶ than those who initiated it as second-line or later.¹⁷ Patients on first-line OCREVUS also had lower healthcare resource use, including a lower probability of hospitalization, and longer time to events often associated with relapse compared to those who used OCREVUS as second line treatment or later. Notably, these findings of first-line OCREVUS use correspond to an annual savings of approximately \$11,500, compared to those who were treated second-line or later.

OCREVUS Treatment Improves Work Productivity and Reduces Work Impairments

As MS onset occurs during the most productive years of an individual's life, a reduction in the ability to do routine activities, including working, results in a substantial economic burden.^{18,19} Based on a recent national survey of MS patients treated with DMTs, patients on OCREVUS were more likely to be employed and experienced less work and activity impairments than those treated with other DMTs.²⁰

While the aforementioned studies start to identify dollars saved and/or avoided, the societal and economic impact of slowing disease progression and delayed disability are undeniably linked.

2. OCREVUS IS AFFORDABLE, PARTICULARLY IN THE CONTEXT OF OTHER FDA-APPROVED THERAPEUTIC ALTERNATIVES

Drug Price Transparency Carrier Reported Data Overlook Critical Metrics of Affordability

As discussed in our October 13 comment letter, OCREVUS was cited in 2022 Drug Price Transparency (DPT) Carrier reports as the most costly drug per prescription in Oregon, with an "average price per prescription" of \$31,057. However, OCREVUS is administered every six months^{21,22} which is significantly less burdensome on patients than some other MS therapies that require weekly or monthly injections or infusions. In fact, many other FDA-approved high-efficacy DMTs for MS typically cost more on an annual basis to healthcare systems and society. But, because of the frequency of their administration, the resulting "cost per prescription" was lower for other DMTs. As you can see, in this instance, the carrier report methodology penalizes OCREVUS for having a lower patient treatment burden of twice yearly dosing.

When comparing like time periods (e.g., on an annual or average monthly basis), the cost of OCREVUS is approximately 28% below the average price of the other approved MS DMTs.²³ Therefore, focusing on a single data point, such as "average cost per prescription," as a cost driver,

¹⁶Events often associated with relapse were defined as any inpatient stay with primary diagnosis of MS; or an outpatient visit with an MS diagnosis with evidence of high-dose steroids, IV corticosteroids, adrenocorticotropic hormone, or plasma exchange within 30 days of the outpatient visit. All patient characteristics, use of DMTs, and outcomes were identified using claims data.

¹⁷ Geiger CK et al. Real-World Clinical and Economic Outcomes Among Persons With Multiple Sclerosis Initiating First- Versus Second- or Later-Line Treatment With Ocrelizumab. *Neurol Ther.* 2023 Oct;12(5):1709-1728.

¹⁸Nicholas JA, Electricwala B, Lee LK, Johnson KM. Burden of relapsing-remitting multiple sclerosis on workers in the US: a cross-sectional analysis of survey data. *BMC Neurol.* 2019;19(1):258.

¹⁹Chen, Jing, et al. "Effects of multiple sclerosis disease-modifying therapies on employment measures using patient-reported data." *Journal of Neurology, Neurosurgery & Psychiatry* 89.11 (2018): 1200-1207.

²⁰Neuberger, Edward E., et al. "Work productivity outcomes associated with ocrelizumab compared with other disease-modifying therapies for multiple sclerosis." *Neurology and Therapy* 10 (2021): 183-196.

²¹ OCREVUS (ocrelizumab) Prescribing Information. Genentech, Inc. 2016.

²² First dose split into 2 treatments, for a total of 3 treatments in the first year.

²³Genentech (2023 July). OCREVUS® (ocrelizumab) Multiple Sclerosis (MS) WAC Flash Card.

<https://www.ocrevus.com/content/dam/gene/ocrevus/resources/ocrevus-ms-wac-price-flashcard.pdf>.

without regard for the dosing regimen or association of the medicine's use in reducing other healthcare costs, is inappropriate and may lead to inaccurate assumptions of a medicine's affordability and value.

When assessing a medicine's affordability, it is important to consider the impact of the treatment regimen on patients - specifically whether the regimen supports how well people take their medications (adherence), but also for how long they take them (persistence). Metrics of adherence and persistence can serve as two measures of affordability, first with regard to patient affordability, and second as offsets of other healthcare expenditures to health systems and payers.

OCREVUS Dosing Supports Affordability Through Improved Adherence and Persistence

In a real-world study, OCREVUS was found to have an adherence rate of 80% compared to other MS medicines that were approved by the FDA on or before 2019 (55%, 35%, and 54% for oral, injectable, and other intravenous (IV) treatments, respectively) over two years.²⁴ Furthermore, people with MS who were adherent to medication had substantially lower medical costs compared with those who were non-adherent.²⁵ Specifically, patients who were persistent with medication for 12 months showed a reduction in mean total non-drug related medical costs of approximately \$10,000 compared with non-persistent patients. These savings nearly doubled (~\$19,000) after 24 months of persistence. A similar pattern was observed for adherent versus non-adherent patients (reduction in costs at 12 months was about \$8,500 and about \$16,000 at 24 months).

These findings support that OCREVUS is affordable for health systems given real-world evidence of reduction in mean total non-DMT medical costs. We believe these data on real world OCREVUS adherence and persistence also suggest that affordability barriers are not keeping patients from accessing and staying on OCREVUS.

OCREVUS' Price History Highlights a Focus on Affordability

When OCREVUS launched in 2017, Genentech set the annual wholesale acquisition cost (WAC) at \$65,000 per year – 25% less than our clinical trial comparator (interferon beta-1a) and nearly 20% below the average WAC for other approved MS medicines at the time.²⁶ Now, in 2023, at \$75,102 per year, the WAC for OCREVUS is still approximately 28% less than the average price for other MS medications.²⁷ We believe our pricing approach along with the proven clinical profile of OCREVUS have contributed to positive insurance coverage decisions that have improved access for people living with MS.

In its nearly seven years on the market, OCREVUS pricing has consistently been conservative and has not triggered price increase advance notice nor reporting requirements under Oregon's transparency laws. Between launch in 2017 and 2023, OCREVUS WAC price increases averaged 2.44% per year (cumulative average growth rate, 2017-2023), which is lower than the annual increases in Consumer Price Index for All Urban Consumers (CPI-U) which averaged 3.54% per

²⁴ Pardo G et al. Adherence to and Persistence with Disease-Modifying Therapies for Multiple Sclerosis Over 24 Months: A Retrospective Claims Analysis. *Neurol Ther.* 2022 Mar;11(1):337-351. *Note, this study was conducted using claims data from April 2016 through December 2019.*

²⁵ Pardo G et al. The Association Between Persistence and Adherence to Disease-Modifying Therapies and Healthcare Resource Utilization and Costs in Patients With Multiple Sclerosis. *J Health Econ Outcomes Res.* 2022 Apr 26;9(1):111-116.

²⁶ Genentech (2022 November, 22). *Adapting our drug pricing model amidst systemic healthcare challenges.* <https://www.gene.com/stories/adapting-our-drug-pricing-model-amidst-systemic-healthcare-challenges>.

²⁷ Genentech (2023 July). *OCREVUS® (ocrelizumab) Multiple Sclerosis (MS) WAC Flash Card.* <https://www.ocrevus.com/content/dam/gene/ocrevus/resources/ocrevus-ms-wac-price-flashcard.pdf>.

year.²⁸ Additionally, the OCREVUS Average Sales Price (ASP) (annually \$68,542), which Medicare and some commercial health plans use as the basis for patient cost-sharing for physician-administered drugs, has increased only 1.03% per year (cumulative average growth rate).²⁹ This low ASP growth rate supports patient affordability with minimal year-over-year change in patient out-of-pocket expenses. Additionally, the ASP accounts for financial concessions that reduce costs for commercial insurers and other healthcare stakeholders; Genentech also provides additional required concessions in Medicaid and 340B, which further reduce costs for government payers and safety net providers.

OCREVUS' Available Patient Assistance Support Patient Affordability

Genentech's commitment to patient access for OCREVUS goes beyond responsible launch pricing and limited price increases. Commercially-insured patients using OCREVUS, who are covered through their plan's medical benefit, are typically required to pay co-insurance (i.e., patient cost sharing obligation that is a percentage of the reimbursed drug's cost). This co-insurance amount can vary based on an insurance plan's benefit design. However, with Genentech's financial assistance programs, commercially-insured patients can pay as little as \$0 for their OCREVUS treatment. Genentech also supports patients affordability by providing financial assistance (up to \$1,500 per year) for commercial-insured patients out of pocket infusion costs.³⁰ Finally, the OCREVUS patient support program was recently rated "best-in-class" in neurology across a peer group of 24 pharmaceutical and biotech companies based on direct feedback from 500 medical doctors and their support staff as part of comprehensive and independent outreach about their patient support program experience.³¹

Based on the evidence presented in this letter, we urge the Board to remove OCREVUS from its subset of drugs selected for an affordability review. If you have any questions or wish to discuss our comments, please contact Tim Layton, Director of State Government Affairs at layton.timothy@gene.com or (206) 403-8224.

Sincerely,



Mary Wachter, RN
Executive Director
State & Local Government Affairs

²⁸ Bureau Labor Statistics, CPI-U, All items, Unadjusted (Jan 2017 - Jan 2023).

²⁹ CMS ASP Pricing Files, <https://www.cms.gov/medicare/payment/all-fee-service-providers/medicare-part-b-drug-average-sales-price/asp-pricing-files>. Accessed 1 November 2023.

³⁰ "Financial Assistance Options | OCREVUS® (ocrelizumab)." OCREVUS.

<https://www.ocrevus.com/patient/financial-support/assistance-options.html>. Accessed 1 November 2023.

³¹ Nuvera Life Sciences Consulting Benchmarking. *The PURE Report 2023 Award: Best Pharma Support Programs*. <https://thepurereport.com/the-annual-pure-award/>. Announced 3 November 2023.

Terri J. Lee
Vice President
State Government Affairs & Policy
US Market

Merck
UG3A-94
351 N Summeytown Pike
PO Box 1000
North Wales PA 19454-2505
Tel 267-305-4073
Terri.Lee@merck.com



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

Members of the Oregon Prescription Drug Affordability Board,

Merck appreciates the opportunity to submit the following comments as written testimony for the upcoming meeting on November 15, 2023.

We are writing to express our concerns regarding the Board's approach to selecting drugs for prescription drug affordability reviews, the accuracy of the data being used for analysis, and the potential implications in the assessment of whether a drug is considered affordable.

We have significant concerns regarding the accuracy of the Wholesale Acquisition Cost (WAC) information on the Working Drug List the Board used during the selection process. We believe the WAC information is inconsistent with historical WAC information as reported by commonly used pricing services such as AnalySource and Medi-Span.

In particular, the Board only identifies a single package WAC for products that have multiple packages, each with a different WAC. The process for selection of eligible drugs outlined in 925-200-0010 states that "For drugs with multiple nation drug codes (NDC), a 'measure of central tendency' will be used for a price comparison." However, the Board has not provided any more specificity on the "measure of central tendency" and methodology being used to calculate this WAC information. We urge the Board to provide more details on this process and to use a consistent approach when comparing the WAC prices of different products.

Importantly, and for example, the historical WAC information for the periods reflected on the Working Drug List is not consistent with the **WAC information for KEYTRUDA (pembrolizumab) for either package provided by Merck.** The Board's data shows a package WAC of \$6,845.81 in the beginning of 2022 and a package WAC of \$7,122.25 at the end of 2022. We are providing the WAC information for both packages in the table below:

Package Description	Vial Count per package	Jan 1, 2022 Price Per Package	Jan 1, 2022 2022 Price per Vial	Dec 31, 2022 Price Per Package	Dec 31, 2022 Price per Vial
KEYTRUDA INJ 100MG LIQUID (NDC 00006-3026-02)	1	\$ 5,134.36	\$ 5,134.36	\$ 5,341.76	\$ 5,341.76
KEYTRUDA INJ 100MG LIQUID 2 CT (NDC 00006-3026-04)	2	\$ 10,268.72	\$ 5,134.36	\$ 10,683.52	\$ 5,341.76

We request that the Board provide more transparency as to its data sources and the methodologies used in the analysis of the data. While we appreciate the Board including information on the Data Sources and Definitions, we believe this information is incomplete as it does not describe the source and methodologies used to calculate the Beginning 2022 and End 2022 package WAC package.



We are concerned that the Board's decisions and related future actions may be based on flawed or inaccurate data resulting in mischaracterizations of the affordability of products.

In addition, the Board should establish a secure and confidential process by which manufacturers can ask questions or provide input on data that is inaccurate or incomplete. It is critical that there is transparency in the process for all interested parties to understand the source of information and methodology used to support any analysis by the Board to make decisions.

Lastly, we recommend the Board prioritize patient access and out of pocket costs considerations in the process moving forward. The Board appears not to have considered patient out of pocket costs when identifying products for affordability reviews. As the Board continues its work, we urge it to prioritize patient out of pocket costs and other critical patient access and affordability metrics.

We hope these comments help facilitate a process that is transparent, methodologically sound, and emphasizes patient-focused measures of affordability. We urge the Board to:

- 1) Provide more transparency on the data being utilized by the Board and any methodology utilized in the analysis of the data.
- 2) Correct any data that is incomplete or inaccurate.
- 3) Develop a secure and confidential system for manufacturers to ask questions or provide input on data that is inaccurate or incomplete.
- 4) Develop a process for manufacturers, patients, and providers to engage with the Board in addition to the public comment period of the PDAB meetings.
- 5) Prioritize patient access and out-of-pocket cost considerations in the process moving forward.

As the Board continues its work to assess affordability, we urge the Board to consider the clinical value of KEYTRUDA to Oregon cancer patients. Merck has made unprecedented investments in clinical development for KEYTRUDA, resulting in 37 approved indications for patients diagnosed with 16 types of cancers. Merck stands behind the pricing of our products. Merck has a long history of responsibly pricing our medicines and vaccines to reflect their value and to sustain our investments in R&D and continue to bring our medicines and vaccines to patients.

In addition to the concerns outlined herein, we continue to have broader concerns about the potential for the Board's work and future actions to adversely impact patient access to medicines and future innovation.

We thank the Board for the opportunity to provide these written comments.

Sincerely,

A handwritten signature in black ink, appearing to read "Terri Lee".

Terri Lee
Vice-President,
State Government Affairs & Policy

A handwritten signature in black ink, appearing to read "Elliott Zarett".

Elliott Zarett
Associate Vice President,
US Oncology Market Access
& Policy

November 10, 2023

VIA ELECTRONIC FILING

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

Re: Oregon Prescription Drug Priority Subset List

Dear Members of the Oregon Prescription Drug Affordability Board:

Bristol Myers Squibb (“BMS”) appreciates the opportunity to submit written comments to the Oregon Prescription Drug Affordability Board (the “Board”) on its subset of prescription drugs to prioritize for affordability review. For the reasons below, we respectfully ask that OPDIVO® (nivolumab) be removed from the prioritized subset and not subject to the affordability review process.

At BMS, we are inspired by a single vision—transforming patients’ lives through science. We are in the business of breakthroughs—the kind that transform patients’ lives through lifesaving, innovative medicines. Our talented employees come to work every day dedicated to the mission of discovering, developing, and delivering innovative medicines that help patients prevail over serious diseases. We combine the agility of a biotech with the reach and resources of an established pharmaceutical company to create a global leading biopharma company. In oncology, hematology, immunology, and cardiovascular disease—with one of the most diverse and promising pipelines in the industry—we focus on innovations that drive meaningful change.

OPDIVO is a programmed death receptor-1 (PD-1)-blocking antibody, which is used for the treatment of cancer in eleven (11) tumor types and has ten (10) orphan designations by the Secretary of the United States Food and Drug Administration (“FDA”) under section 360bb of title 21 of the United States Code. Oregon’s statute states that “[a] drug that is designated by the Secretary of the United States Food and Drug Administration, under 21 U.S.C. 360bb, as a drug for a rare disease or condition is not subject to review.”¹ OPDIVO therefore is categorically exempt from inclusion in the Board’s process. The Board’s preliminary categorization of this product as “Both Orphan and Non-Orphan”² does not reflect OPDIVO’s categorical exclusion under the unqualified language of the statute, which exempts any drug with an orphan designation.

¹ See Or. Rev. Stat. 646A.694(2); see also Or. Admin. R. 925-200-0020(1)(m) (stating that such a drug “is not subject to an affordability review”).

² See [PDAB Working Drug List](#).

As OPDIVO's exclusion is statutorily mandated³, the Board should remove OPDIVO from the prioritized subset of prescription drugs on that basis alone. Even so, there are other compelling reasons for its exclusion. For instance, Oregon law states that the Board shall identify drugs "that the [B]oard determines may create affordability challenges for health care systems or high out-of-pocket costs for patients in this state" and instructs the Board to consider multiple factors in determining which drugs to prioritize for affordability review.⁴ Yet the current methodology, data sources, and criteria used by the Board to identify drugs for affordability review may not accurately prioritize those drugs that may pose affordability challenges for patients. Should the Board choose not to adhere to statutory requirements and consider OPDIVO eligible somehow for affordability review, we respectfully request the opportunity to provide the Board more information on these issues, with respect to OPDIVO specifically, before any such decision is made.

In sum, given straightforward application of Oregon law concerning the scope of the Board's ability to review prescription drugs (i.e., expressly excluding those designated for a rare disease or condition), we strongly urge the Board to remove OPDIVO from the prioritized subset of prescription drugs.

Thank you for the opportunity to provide comments and for considering our concerns. Should you have any questions or concerns, please contact Richard Meyers, Director, State & Federal Policy, U.S. Policy & Government Affairs at richard.meyers@bms.com and Anne Murray, Director, State Government Affairs, U.S. Policy & Government Affairs at anne.murray@bms.com.

Sincerely,

/s/

Stephanie A. Dyson

Senior Vice President

U.S. Policy & Government Affairs

³ See *supra* note 1 and accompanying text.

⁴ Or. Rev. Stat. Ann. § 646A.694(1); Or. Admin. R. 925-200-0010.

November 11, 2023

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

Re: Oregon Prescription Drug Affordability Board: Agenda and Meeting Materials for November 15, 2023 Meeting

Dear Members of the Oregon Prescription Drug Affordability Board:

The Pharmaceutical Research and Manufacturers of America (“PhRMA”) appreciates the opportunity to review and comment on the Board’s agenda and discussion materials (the “Meeting Materials”) for the Oregon Prescription Drug Affordability Board’s (“Board’s”) upcoming November 15, 2023 meeting.¹ PhRMA represents the country’s leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives.

We provide below our comments and concerns with respect to the Meeting Materials, including PhRMA’s ongoing concerns related to lack of adequate transparency with respect to the Board’s affordability review processes and criteria and how the Board intends to weigh and consider manufacturer-provided information. PhRMA appreciates the Board’s work to develop processes and materials with respect to implementation of its responsibilities under Oregon Senate Bill 844 (2021), as amended by Oregon Senate Bill 192 (2023) (collectively, the “PDAB Statute”). However, PhRMA remains concerned on these and other topics, as described in greater detail below.²

I. 2023 PDAB Top Drug List – Methodology and Associated Data Sources³

PhRMA continues to have concerns about the lack of transparency with respect to the methodology and data underlying the Board’s 2023 PDAB Top Drug List (“Drug List”). As PhRMA has discussed in prior comments, greater transparency is needed in the Board’s methodology to ensure that manufacturers and other stakeholders have clear insight into how the Board is operationalizing its decision-making.⁴

PhRMA is particularly concerned that the Board has not provided a concrete methodology for how it has grouped products for purposes of their inclusion in Drug List and how it has calculated the price and other metrics for each such grouping. Each grouping is listed with average pricing information across distinct products with varying dosing and package size, without adequate explanation as to how these calculations were made. We remind the Board that the definition of “prescription drug” under the PDAB Statute expressly accounts for whether “a drug” has FDA labeling that contains certain requisite warnings (or whether federal or state law otherwise requires the product to be dispensed only by prescription or restricted to use by health

¹ Available at <https://dfr.oregon.gov/pdab/Documents/20231115-PDAB-document-package.pdf>.

² In filing this comment letter requesting changes to the Proposed Rules, PhRMA reserves all rights to legal arguments with respect to the Oregon PDAB statute. PhRMA also incorporates by reference all prior comment letters to the extent applicable.

³ See Meeting Materials at 7–29.

⁴ *Gordon v. Bd. of Parole & Post Prison Supervision*, 343 Or. 618, 633 (2007). See Letter from PhRMA to Board (Apr. 16, 2023); Letter from PhRMA to Board (June 23, 2023); Letter from PhRMA to Board (Oct. 15, 2023).

care practitioners), and in doing so requires the Board to expressly consider prescription drugs based on their distinct FDA labels and not as part of a broader grouping.⁵

PhRMA asks the Board to provide a clear and precise methodology for how it has grouped separate products together within the Drug List, and to consider whether its methodology for doing so is consistent with the requirements of the PDAB Statute. Grouping distinct products together for the purpose of affordability reviews, without a legal basis and transparent methodology for doing so, risks arbitrary and capricious consideration of those drugs by the Board.⁶

II. Survey on Affordability Review Criteria⁷

PhRMA is also concerned by the Board’s proposed rankings of the importance of different affordability review criteria based on its recent survey of Board members. The results of that survey show that Board members regard “information [that] manufacturer[s] choose[] to provide” as being lowest in importance relative to all other factors surveyed, including input from other stakeholder groups.⁸ Further, the Meeting Materials indicate that these survey results will be used to direct PDAB staff research and to develop a “weighted rank” for drugs as part of the Board’s affordability review process.⁹

Manufacturers may have important information and insights directly bearing on the Board’s affordability analyses of specific prescription medicines. PhRMA urges the Board not to prejudge any information provided by manufacturers through weighted ranking because doing so would “disregard [] the facts and circumstances of the case” and raise due process concerns.¹⁰ We urge the Board not to categorically devalue manufacturer input into the affordability review process as contemplated in the Meeting Materials and to consider any information provided by manufacturers equally with other information reviewed by the Board.

III. Process to Address Data Issues

Given the potential for errors and discrepancies in the broad range of data sources that it will be considering, PhRMA continues to urge the Board to establish processes to help ensure data accuracy and to allow manufacturers to request technical feedback on the Board’s complex methodology. As explained in PhRMA’s September 16, 2023 comment letter, the Board should establish a process for a manufacturer to review the Board’s data and raise any technical questions or concerns with the Board before it moves forward with the affordability review process.¹¹ Further, this process should include a mechanism that allows a manufacturer

⁵ ORS § 646A.689(1)(h) (emphasis added).

⁶ *Sachdev v. Oregon Med. Bd.*, 312 Or. App. 392, 404–05, 494, review denied, 368 Or. 637 (2021).

⁷ See Meeting Materials at 44–53.

⁸ Meeting Materials at 48, 52. For example, the Board’s survey results provide a ranking of 8.6 out of 10.0 for “Input from Patients and Caregivers,” 7.1 for “Input from Individuals with Scientific or Medical Training,” 5.0 for both “Input from Safety Net Providers” and “Input from Payers,” and 1.4 for “Any information a manufacturer chooses to provide.”

⁹ Meeting Materials at 53.

¹⁰ See *Milwaukie Co. of Jehovah’s Witnesses v. Mullen*, 214 Or. 281, 296 (1958). Additionally, PhRMA questions whether prejudging manufacturer-provided information by categorically devaluing it in the manner contemplated by the Board would deprive manufacturers of a meaningful opportunity to participate in the affordability review process.

¹¹ See Letter from PhRMA to Board 2 (Sept. 16, 2023). As explained in PhRMA’s September 16, 2023 comment letter, such process should include the Board developing an inquiry form to allow manufacturers to submit questions, comments, and objections; committing to responding to any inquiries with a reasonable time frame.

to provide confidential, proprietary, or trade secret information to the Board in connection with its questions or concerns, without such information being subject to improper use or disclosure.¹²

IV. Board Feedback on Policy Recommendations¹³

PhRMA appreciates the Board’s consideration of a broad array of policy options, and the continued focus on factors that impact consumer affordability or prescription drugs. A full range of factors drives such out-of-pocket costs, including benefit design (e.g., cost-sharing requirements such as coinsurance and deductibles, and accumulator adjustment and copay maximizer programs) and rebates, discounts, and other price concessions and reductions paid by drug manufacturers to pharmacy benefit managers (“PBMs”) and health insurance plans that the PBMs and plans are not sharing directly with patients at the point-of-sale. As described in our October 6th letter, we believe this Board can consider recommending several policies to lower out-of-pocket costs without a reduction in health care choice, quality, or access.¹⁴ We look forward to providing further comments on the policy recommendations that the Board presents to the Oregon Legislature.

* * *

We thank you again for this opportunity to provide comments and feedback, and for your consideration of our concerns. Although PhRMA has concerns with the Meeting Materials, we continue to stand ready to be a constructive partner in this dialogue. Please contact dmcgrew@phrma.org with any questions.

Sincerely,



Dharia McGrew, PhD
Director, State Policy



Merlin Brittenham
Assistant General Counsel, Law

¹² Confidential, trade secret, or proprietary information provided to the Board by manufacturers or others should be kept confidential consistent with the Board’s obligation under the PDAB Statute and under state and federal law. ORS § 646A.694(7). For further discussion, see, e.g., Letter from PhRMA to Board 3 (Oct. 15, 2023); Letter from PhRMA to Board 7–8 (Feb. 11, 2023) (examples of letters outlining PhRMA’s confidentiality concerns in additional detail, and explaining the confidentiality obligations of the Board under state and federal law).

¹³ See Meeting Materials at 30–43.

¹⁴ See Letter from PhRMA to Board October 6, 2023.