Thank you for the opportunity to comment on the discussion of the affordability of glucagon-like peptide (GLP-1) agonists. These medications are essential for people with type 2 diabetes as ways to lower their blood glucose and help them manage their diabetes. In particular GLP-1 can result in large benefits both in lowering blood glucose and body weight.

The American Diabetes Association (ADA) has been the leading organization advocating for people with diabetes for more than eight decades. Much of this work centers around access and affordability of care. People with diabetes must have access to medications and tools they need to manage the disease. Managing diabetes requires a holistic, multifaceted, person-centered approach that accounts for the complexities associated with diabetes and the complications and comorbidities people with diabetes are at risk for across an individual's life span. The American Diabetes Association *Standards of Care* recommends that person-specific factors for treatment should be individualized for achieving glycemic goals and should consider weight goals, the individual's risk for hypoglycemia, and the individual's history of risk factors for cardiovascular, kidney, liver, and other comorbidities and complications of diabetes.[1]

The ADA *Standards of Care* recommends that pharmacologic therapy be started at the same time type 2 diabetes is diagnosed and that approaches that provide the efficacy to achieve treatment goals should be considered. In general, higher-efficacy approaches have a greater likelihood of achieving glycemic goals, with the following having a very high efficacy for glucose lowering: the GLP-1 RAs dulaglutide and semaglutide. Weight management is a distinct treatment goal, along with glycemic management in individuals with type 2 diabetes, as it has multifaceted benefits, including improved glycemic management, reduction in hepatic steatosis, and improvement in cardiovascular risk factors. The glucose-lowering treatment plan should therefore consider approaches that support weight management goals, with semaglutide and tirzepatide currently having the highest weight loss efficacy among agents approved for glycemic management.[2]

While we share concerns over cost and wanting to ensure that patients can afford their medication, we must also balance that with ensuring access to treatment and minimizing barriers to care. We encourage the committee to take steps to ensure that the discussion, decisions, and policy-recommendations are patient-centered and do not result in access issues for patients.

Ensuring people with diabetes have access to the treatment and tools necessary to manage their disease can help them reduce the risk of developing devastating and costly complications including cardiovascular disease, kidney disease, and amputations. Protecting access to these medications and interventions to control diabetes can create cost savings and are ultimately cost-effective.[3] The ADA *Standards of Care* highlights the importance of weight loss, which can be achieved through the use of the medications, to reduce A1C and fasting glucose and may promote sustained diabetes remission.[4] The 2024 *Standards of Care* recommends that GLP-1 as preferred pharmacotherapy for obesity management in people with diabetes because of the greater weight loss efficacy.[5] We respectfully encourage the

[1] https://diabetesjournals.org/care/article/47/Supplement_1/S158/153955/9-Pharmacologic-Approaches-to-Glycemic-Treatment
[2] https://diabetesjournals.org/care/article/47/Supplement_1/S158/153955/9-Pharmacologic-Approaches-to-Glycemic-Treatment
[3] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2909081/
[4] https://diabetesjournals.org/care/article/47/Supplement_1/S145/153942/8-Obesity-and-Weight-Management-for-the-Prevention
[5] https://diabetesjournals.org/care/article/47/Supplement_1/S5/153943/Summary-of-Revisions-Standards-of-Care-in-Diabetes

committee to take the efficacy of these medications into account along with the cost-savings from preventing complications that increase the burden on both the patients and the health care system.

If you have any questions please contact me at ckemp@diabetes.org.

Genentech
A Member of the Roche Group

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February 21, 2024

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

Re: Oregon PDAB Prescription Drug Affordability Review Process

Dear Members of the Oregon Prescription Drug Affordability Board:

Thank you for the opportunity to provide feedback on the Board's approach and process for conducting drug affordability reviews. Genentech has been following the Board's meetings and communications closely to understand the Board's views and how we can best engage to share information relevant to the Board's processes. We previously submitted written comments to the Board in October and November 2023 regarding the Board's processes and operations. This comment letter focuses on our most recent observations and concerns.

As an initial matter, **we are concerned with the current vacancies on the Board, especially given the January 26, 2024 public resignation of Chairman Akil Patterson.** Senate Bill 192 (2023) established an eight-member board, to be appointed by the Governor and confirmed by the Senate. Although a majority of the Board (five members) shall constitute a quorum, the current three vacancies reduce the diversity of perspectives that would enrich the Board's discussions and drug affordability review process in contrast to what would be expected with a fully-seated Board. In contrast to other state Boards, Oregon's statute did not establish a stakeholder advisory council to guide the Board's decision making, which further emphasizes the need for the Board itself to represent varied perspectives. To ensure the Board's discussions and drug affordability reviews benefit from a diversity of experience, we strongly suggest that the Board consider further delaying its drug affordability reviews until the full Board is seated and can be fully informed of the operations and actions of the Board.

While we understand the Board's efforts have been previously delayed and there are statutory deadlines of which to be mindful, the decisions before the Board should not be rushed nor taken lightly. Discussions and following decisions regarding a drug's affordability, even in the absence of an Upper Payment Limit, could have implications in and beyond Oregon. As such, it is critical the Board invests the appropriate time and resources to this process, even if it results in a delay in fulfilling the Board's duties.

In addition to the aforementioned issue of an incomplete Board, we continue to have significant concerns about the Board's processes, limited stakeholder engagement and outreach, and an acknowledged lack of access to critical data which can impact the assessment of a drug's

affordability. We are providing feedback on the following three concerns and ask the board to address these shortcomings before proceeding with any future drug affordability reviews.

1. **The Board's general approach, meeting operations, and lack of clear processes for stakeholder engagement continues to create confusion. The Board should provide a well documented, transparent and consistent approach to data review, stakeholder engagement, and consideration of data factors to support a fair assessment of affordability across diseases and treatments.**

2. **Stakeholder engagement efforts have been severely limited and may adversely impact the Board's decision making. The Board should invest more time soliciting stakeholder feedback as part of a robust review process prior to making decisions on drug affordability.**

3. **The Board continues to rely on a limited set of data elements, and has deprioritized data from manufacturers which would provide a more complete picture of drug affordability. The Board should ensure complete review of draft affordability reports and manufacturer-submitted data prior to making a decision on a drug's affordability.**

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

1. ***The Board's general approach, meeting operations, and lack of clear processes for stakeholder engagement continues to create confusion. The Board should provide a well documented, transparent and consistent approach to data review, stakeholder engagement, and consideration of data factors to support a fair assessment of affordability across diseases and treatments.***

We have commented previously on the lack of clarity that has resulted from the Board's interaction and decisions during their Board meetings. There have been numerous meetings, including the Board's most recent meeting on January 26, 2024, where the Board's action items and decisions were not immediately clear - neither to the Board members themselves, nor to those attending the meeting. For example, during the affordability review of Tresiba and Tresiba FlexTouch, more than one Board member appeared to be unsure of the actual task the Board was performing in conducting the affordability review and required the eventual clarification from staff to specify the action and decision that was before the Board. This exchange highlights that the Board's approach could benefit from increased clarity and direction in the decisions to be made at each meeting, by whom the decision must be made, and the instructions for doing so. The speed at which the Board has sought to advance through their required actions may also be contributing to a lack of clarity in operational processes and decision making. <u>We believe these issues can be addressed with more robust meeting materials and a summary at the start of each meeting that clearly outlines the decisions before the board, and the expected outcomes of those decisions.</u>

Moreover, it is critical the Board establish predictable and reliable processes for all forms of engagement with manufacturers and other stakeholders. Each affordability review undertaken by the Board should follow the same procedures and adhere to a consistent approach to provide confidence in a fair and equitable review process. It was extremely unexpected to witness the Board engage in a question and answer dialogue with a representative of the drug manufacturer during an affordability review on January 26, given no prior notice of this possibility. As an engaged manufacturer, we have asked for, and would welcome the opportunity to have a dialogue with the board about the value of our medicines in an appropriate forum. However, all stakeholders, including manufacturers, should be afforded the benefit of preparation for such engagement and dialogue. We urge the Board to reconsider its current processes and make the necessary adjustments to ensure the review process is predictable and consistent for manufacturers and all other interested stakeholders and allows for a meaningful exchange of information.

2. ***Stakeholder engagement efforts have been severely limited and may adversely impact the Board's decision making. The Board should invest more time soliciting stakeholder feedback as part of a robust review process prior to making decisions on drug affordability.***

OAR 925-200-0020 indicates as part of conducting drug affordability reviews, the Board ***will seek*** input from patients and caregivers and individuals who possess scientific or medical training related to the drug under review. While we appreciate the Board has provided instructions for written and oral stakeholder comments, the Board has not undertaken efforts that fairly and openly ***seek input*** from critical stakeholders whose lived experience and expertise should be highly valued in this process.

The Board's outlined processes for conducting drug affordability reviews have alloted for extremely limited time for live stakeholder engagement - just 20 minutes of public comment per drug. Although stakeholders can submit written comments to the Board in advance of their drug affordability review deliberations, it remains unclear if these comments are being thoroughly reviewed by the Board in advance. This is particularly disconcerting as the Board weighted information from patients and caregivers at 8.6 out of 10 in level of importance, yet has made what appears to be limited effort to engage patients and their caregivers, actively solicit their input, or ensure patients are aware that a medicine they may be taking is undergoing an affordability review by the Board.

Stakeholder engagement tactics undertaken by Boards in other states have included focus groups, open public surveys, and direct stakeholder meetings. Boards are also partnering with patient organizations that represent the impacted community to engage those with lived experience and solicit their input. To align with the Board's weighting of input from patients and caregivers as highly important, we strongly urge the Board to adopt these or other tactics to immediately seek stakeholder feedback.

3. ***The Board continues to rely on a limited set of data elements, and has deprioritized data from manufacturers which would provide a more complete picture of drug***

affordability. The Board should ensure complete review of draft affordability reports and manufacturer-submitted data prior to making a decision on a drug's affordability.

In addition to allotting only 20 minutes for public comment during an affordability review, the Board has also dedicated only 20 minutes to reviewing the draft drug affordability report and discussing its contents. Once again, this is an extremely limited amount of time to dedicate to what is the primary directive of the Board. In fact, during the January 26 reviews, staff spent approximately two minutes highlighting the data, primarily the cost tables, in each drug's draft affordability report, and did not review the clinical sections of the report. The report was only discussed in more depth if a question or comment was raised by a Board member. This approach does not adequately review the substantial data required to be part of a drug affordability review, nor does it allow for thoughtful discussion by the Board on each required data element. As a best practice, we ask the Board to reconsider and revise the time allotted to each drug affordability review to ensure all required data elements are fully discussed and considered. For example, in instances where clinical outcomes associated with a drug may have substantial impact on a patient's total cost of care, or cost to the healthcare system, it will be essential for these data to be appropriately reviewed and thoughtfully considered. Furthermore, we urge the Board to reevaluate the weighting of data and information shared by a drug manufacturer. In many instances, a drug manufacturer is the most robust source of data associated with clinical outcomes, cost offsets, and/or other data essential to determining a drug's value and affordability. This data should not be discounted, nor deprioritized, as it currently has been in the Board's weighting exercise. An overly narrow, and subjective, approach to considering data in the affordability review fails to recognize many of the drug characteristics that drive overall treatment value and shape patient and physician choice of treatment that should contribute and assist in the Board's assessment of drug affordability.

Due to the aforementioned concerns, **we ask the Board to allow for a fully-appointed Board to be present for the remaining drug affordability reviews, and provide time for the staff and Board to remedy and improve upon the deficiencies with the current affordability review process.**

We continue to welcome the opportunity to engage with the Board and its staff on these concerns. If you have any questions or wish to discuss our comments, please contact Tim Layton, Director of State Government Affairs at layton.timothy@gene.com or (206) 403-8224.

Sincerely,

Mary Wachter, RN
Executive Director
State & Local Government Affairs

AIMEDALLIANCE

February 25, 2024

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

Re: Call for Inclusion of Patient Voice and Lived Experience in Drug Review Process

Dear Members of the Oregon Prescription Drug Affordability Board:

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 opportunity to comment on the Oregon Prescription Drug Affordability Board's affordability review process. Aimed Alliance urges the Board to consider the following recommendations:

1. **Prioritize patient voice and lived experience in the drug review process;**
2. **Ensure the drug review processes embraces diverse community perspectives; and**
3. **Adopt an exclusion for rare disease drugs.**

I. Introduction

The escalating costs of healthcare in the United States poses a significant challenge for healthcare consumers nationwide. In response to this pressing issue, numerous states have introduced legislation establishing prescription drug affordability boards (PDABs) aimed at addressing the prices of prescription medications and ensuring equitable access to affordable drugs. Typically, these boards are tasked with setting upper payment limits (UPLs) for specific prescription drugs.[1]

As PDABs undertake the task of reviewing drug affordability, it is imperative that they uphold their commitment to ensuring prescription drug affordability for *healthcare consumers.* This commitment is essential for enhancing healthcare accessibility, alleviating financial burdens, advancing public health outcomes, and promoting equity within the healthcare system.

II. Oregon's PDAB Should Prioritize Patient Access and Affordability

As advocates for patient-centric health care policies, Aimed Alliance urges the Board to consider the role of the patient voice and lived experience in the drug review process. Involving patients in the decision-making process can provide insights into disease management, access challenges, treatment preferences, and other pertinent considerations associated with various prescription drugs.[2]

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[1] Aimed Alliance, *Enacted Prescription Drug Affordability Boards*, https://aimedalliance.org/wp-content/uploads/2024/01/AA-PDAB-Enacted-Chart-Jan-2024.pdf.
[2] Alex Krist, et al., *Engaging patients in decision-making and behavior change to promote prevention*, 240 STUDENT HEALTH TECHNOLOGY INFORMATION 284-302 (2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6996004/.

Moreover, research consistently highlights the benefits of actively involving patients in healthcare decisions. For instance, studies demonstrate engage patients has a positive effect on improving health outcomes, enhancing satisfaction with the care experience, lowering costs, improving quality of care, and increasing accessibility.[3] By incorporating patients in the drug review process, the Board can help ensure that their voices are heard and their needs are recognized.[4] It also enables the Board to access a wealth of firsthand knowledge, that may not be documented in empirical data, that is essential for making well-informed and patient-centered decisions.[5]

Aimed Alliance also encourages the Board to ensure that the drug review process incorporates a multitude of diverse community perspectives. Recognizing the unique needs and challenges faced by different communities is crucial to fostering inclusivity and equity within the decision-making processes.[6] For instance, individuals living in rural areas confront significant barriers to accessing health care due to sparse provider availability and extended travel distances to seek care, while individuals in more urbanized areas may experience different access challenges.[7]

Importantly, in Oregon, 16 percent of the state, approximately 660,000 residents, live in rural areas.[8] For many, the nearest clinic is located more than 100 miles away.[9] In these areas, financial hardship and limited access to health care services impact health care access and the ability to manage chronic conditions, significantly impacting overall health outcomes for residents.[10] Thus, it is imperative that the Board takes into account these complex realities when evaluating drug access and affordability in Oregon.

By actively seeking input from a broad range of stakeholders, including patients, caregivers, and community representatives, the Board can develop a fair and comprehensive drug review framework. In recognizing the multifaceted challenges faced by patients and caregivers, it is imperative that the Board also acknowledge its shared responsibility in engaging these communities. Patients and caregivers must manage work and family commitments, treatment regimens, and financial strains—all while striving to navigate complex healthcare systems to care for themselves or their loved ones. Therefore, the onus cannot solely rest on consumers to advocate for their needs; the Board must actively reach out and involve these stakeholders in the decision-making process. To ensure these efforts reach the intended communities, the Board

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[3] *Id.*; Lisa Baumann, et al., *Public and patient involvement in health policy decision-making on the health system level – A scoping review*, 126 HEALTH POL. 1023-38 (Oct. 2022), https://www.sciencedirect.com/science/article/pii/S0168851022001919.
[4] Alex Krist, et al., *Engaging patients in decision-making and behavior change to promote prevention*, 240 STUDENT HEALTH TECH. INFO. 284-302 (2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6996004/.
[5] *Id.*
[6] *Improving Cultural Competence to Reduce Health Disparities for Priority Populations*, EFFECTIVE HEALTH CARE, https://effectivehealthcare.ahrq.gov/products/cultural-competence/research-protocol (Jul. 8, 2014).
[7] *Why Health Care Is Harder to Access in Rural America,* U.S. Gov. ACCOUNTABILITY OFF., (May 16, 2023), https://www.gao.gov/blog/why-health-care-harder-access-rural-america.
[8] *Id.*
[9] *Id.*
[10] *Id.*

should engage local stakeholders and leaders who are already connected, trusted, and working within these communities.

Lastly, the process of engagement must extend beyond the initial review stage. Once the Board establishes a UPL, the Board should continuously monitor how the UPL impacts access and affordability. Establishing clear channels for consumers to voice concerns regarding any access barriers stemming from pricing policies is critical to ensuring equitable access to essential medications. By fostering a culture of transparency and responsiveness, the Board can effectively address emerging challenges following adoption of the UPL.

III. Rare Disease Exclusion

Aimed Alliance urges the Board to consider creating an exclusion for rare disease drugs within the drug review framework. Patients with rare diseases often face significant challenges in accessing life-saving medications due to the substantial research and development costs involved, coupled with the relatively small patient populations they serve.[11] In fact, the development of drugs for rare diseases is particularly scarce; with the U.S. Food and Drug Administration (FDA) reporting that, of the approximately 7,000 known rare diseases, less than 10 percent have an FDA-approved treatment available.[12] Given the high prices and limited treatment options for rare diseases, the establishment of a UPL by the Board carries heightened significance in this context and could decrease access to these treatments, and disincentivize investment and research into rare disease treatments. Therefore, Aimed Alliance urges the Board to recognize the unique challenges confronting patients with rare disease and consider creating an exclusion for rare disease drugs from the drug review process.

IV. Conclusion

In conclusion, Aimed Alliance encourages the Oregon Prescription Drug Affordability Board to champion a drug review process that centers on patient voice and lived experience, embraces diverse community perspectives, and excludes rare disease drugs from consideration. We appreciate the opportunity to comment on this issue and commend the Oregon Prescription Drug Affordability Board for its efforts to improve access to affordable prescription drugs for the residents of Oregon.

Sincerely,

Ashira Vantrees
Counsel

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[11] Takeya Adachi et al., *Enhancing Equitable Access to Rare Disease Diagnosis and Treatment around the World: A Review of Evidence, Policies, and Challenges*, 20 INTERNATIONAL JOURNAL OF ENVIRONMENTAL RESEARCH AND PUBLIC HEALTH (Mar. 2023), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10049067/.

[12] *Rare Disease Cures Accelerator*, U.S. FOOD AND DRUG ADMIN., https://www.fda.gov/drugs/regulatory-science-research-and-education/rare-disease-cures-accelerator#:~:text=However%2C%20of%20the%20approximately%207%2C000,and%20progression%20of%20each%20disease. a

Feb 29, 2024

Chair Deb Patterson
Senate Committee on Health Care
900 Court St. NE, S-411,
Salem, Oregon 97301

Chair Rob Nosse
House Committee on Behavioral Health and Health Care
900 Court St. NE, H-472
Salem, Oregon 97301

Dear Chair Patterson and Chair Nosse:

As organizations representing patients, people with disabilities and older adults, we are writing with regard to our concerns about the implementation of the State Prescription Drug Affordability Board and the need for oversight from legislators. When the bill creating the board passed, we were assured that its processes would be transparent, provide for robust engagement of patient and disability stakeholders and avoid reference to discriminatory evidence related to the effectiveness and value of treatments being evaluated. We have been very disappointed. At this stage, it is now clear that our efforts to engage the board members and staff in addressing our concerns are not working. As you know, the board itself is not operating at full capacity and is trying to recruit new members.[1] Therefore, we urge the legislature to pause the board's activities and initiate legislative oversight of the board's implementation.

On December 4, 2023, several organizations reached out to the board to ask it to address our concerns about board representation, the lack of engagement opportunities for expert advisors living with a condition treated by the selected drugs for review, the transparency of its deliberations, including its use of measures such as the quality-adjusted life year (QALY) and equal value of life year gained (evLYG) to measure the effectiveness and value of treatments, and finally the need to emphasize patients in affordability reviews. To date, we have not received a response or been given an opportunity to meet. In fact, their processes have only gotten worse. Our prior letter to the board is provided to you as an addendum to this letter.

We continue to be concerned that the board's meetings do not welcome patient input. The board's agenda does not provide any guidance on the information being sought from patients to help in their deliberations. The time allotted for patient input is very limited and does not provide for a robust back and forth discussion between the board members and concerned patients and people with disabilities. It is not clear to us what information is being considered by the board and on which patients and people with disabilities could be providing input. The affordability review timeframes for each treatment under consideration are very short during the meetings with little engagement opportunity. There is not a separate dedicated engagement opportunity for patients and

[1] https://dfr.oregon.gov/pdab/Documents/20240131-PDAB-applicant-summary.pdf

and people with disabilities related to each drug being reviewed, which is highly inconsistent with the process in other states. In summary, the board process is confusing and instills little confidence that its conclusions will accurately represent the effectiveness and value of treatments under consideration.

The lack of public testimony to-date is a strong indicator that the current process is not working. In the December meeting, public comment was limited to 1 minute per person.

The legislation creating the board, SB 844, stated, "The board shall accept testimony from patients and caregivers affected by a condition or disease that is treated by a prescription drug under review by the board and from individuals with scientific or medical training with respect to the disease or condition." The legislation also listed several criteria focused on the patient experience of accessing drugs being evaluated, including "health inequities for communities of color," "impact on patient access" and "estimated average patient copayment or other cost-sharing," yet the affordability review seems less focused on patient affordability than costs borne by the state. We share concerns about health system costs, but do not want the board's work to be at the expense of patients for whom existing therapeutic alternatives may not be the most clinically effective. We want to understand how the board is defining existing therapeutic alternatives and whether they are as effective as the treatments being reviewed. It is insufficient for the state to conclude less expensive alternatives are just as effective without hearing from patients. The goal of this process should be to ensure patients have access to the treatment that is most effective to treat their disease or condition. This requires a robust feedback loop and dedicated time to engaging patients and people with disabilities, including time for the board to respond, ask questions and solicit additional information.

Additionally, when the legislature passed SB 844, patients and people with disabilities were assured that QALYs and similar measures were barred from the board's consideration. Yet, the Institute for Clinical and Economic Review (ICER), an entity that calls QALYs the gold standard and that has developed the similar evLYG measure, as well as associated pro-QALY entities such as the Program on Regulation, Therapeutics, and Law (PORTAL), are deeply engaged in the board's work. Therefore, it is of the utmost importance for the evidence under consideration by the board to be transparent to the public to allow for patients and people with disabilities to weigh in with the board if consideration of certain evidence may be in conflict with its statute. We have shared these concerns with the board, yet we continue to be kept in the dark about the underlying evidence that may support its decisions.

In closing, we hope that the legislature will consider our concerns, pause the board's implementation, and conduct much-needed oversight of its activities. Thank you for your consideration and efforts to advance a health system that is equitable and allows for patients to affordably access the most clinically effective treatment.

Sincerely,

Organizations:
AiArthritis
ALS Northwest
Biomarker Collaborative

Caring Ambassadors Program
Cystic Fibrosis Research Institute
Exon 20 Group
ICAN, International Cancer Advocacy Network
MET Crusaders
National Bleeding Disorders Foundation
Pacific Northwest Bleeding Disorders
Partnership to Improve Patient Care
PD-L1 Amplifieds
The Bonnell Foundation: Living with cystic fibrosis
The ALS Association
The Coelho Center for Disability Law, Policy and Innovation
The Headache and Migraine Policy Forum

Individuals:
Laura Bonnell
Mary Canton
Lance Christian
Joy Krumdiack
Robbie Thurman-Noche

cc: Governor Kotek
Members of the Oregon Legislature
TK Keen, DCBS
Ralph Magrish, DCBS
PDAB committee