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February 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 Draft Outline: Affordability Reviews for Eligible Prescription Drugs

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 Draft Outline titled "Affordability Reviews for Eligible Prescription Drugs" ("Draft Outline") published February 8, 2023 by the Oregon Prescription Drug Affordability Board ("Board") for discussion at the Board's February 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, concerns, and recommendations with respect to the Draft Outline. PhRMA appreciates the Board's work to discuss potential policies with respect to its responsibilities under Oregon Senate Bill 844 (2021) (the "PDAB Statute"). PhRMA has concerns, however, about the approach contemplated by the Draft Outline. Among other things, and as detailed below, the Draft Outline does not propose clear standards for how the Board will conduct the drug selection or affordability review processes, and lacks adequate safeguards to ensure the confidentiality of all trade secret, confidential or proprietary information used in the affordability review process.

I. Lack of Clear and Meaningful Standards

As an overarching concern, the Draft Outline lacks adequate detail about how the drug selection and affordability review process will be operationalized. The Draft Outline does not provide a principled and specific methodology for the selection or evaluation of eligible drugs. Rather, it primarily provides a laundry list of factors that the Board will, to the extent practicable, consider in selecting drugs for reviews or conducting reviews, as well as a list of broad categories of input the Board will seek from specified stakeholders. The lack of specificity in the Board's proposed outline inhibits the ability of stakeholders to meaningfully provide comments on the Board's proposed methodologies.

Specifically, the Draft Outline does not include concrete standards and requirements regarding how the Board intends to make use of the information it obtains from these disparate sources, including how information will be weighed, compared, and considered both independently and relative to other information and factors. Because the Draft Outline lacks meaningful standards for consistent decision-making, it fails to give stakeholders visibility into whether, how, and under what circumstances the Board will use various categories of information.

[1] PhRMA also continues to have concerns about the Board's Temporary Procedural Rule OAR 925-100-0003, as described in our letter to the PDAB, and about the constitutionality of the Oregon PDAB statute more generally. *See* Letter from Pharmaceutical Research and Manufacturers of America to Or. Prescription Drug Affordability Board (Oct. 19, 2022). In filing this comment letter requesting changes to the Draft Outline, PhRMA reserves all of its legal arguments with regard to those issues.

Mechanisms to ensure consistent decision-making are not merely sound public policy, they are also required by law. A central tenet of the Oregon Administrative Procedures Act ("APA") is that "decisions by administrative agencies be rational, principled, and fair, rather than ad hoc and arbitrary."[2] An "administrative agency [has] a responsibility to establish standards by which [a] law is to be applied."[3] Publication of a list of data sources that will be considered, "to the extent practicable," does not constitute meaningful standard-setting.[4] Agencies may "make policies for even application" but do not have unbridled discretion to treat each case on an ad hoc basis.[5]

PhRMA highlights the following as examples of the lack of clear standards within the Draft Outline:[6]

- **Prioritization Selection Process and Affordability Review Process (General)**. The Draft Outline contemplates that the Board will select a subset of eligible drugs for prioritization for an affordability review based on consideration of certain information, including the class of the drug (and any therapeutic equivalents) and certain aggregated data related to factors like "health equity impact," "[h]istorical and current pricing data," "expenditures associated with the prescription drug," "utilization associated with the prescription drug," and "information regarding the estimated manufacturer net-cost and net sale amounts."[7] The Draft Outline provides no explanation as to how these varied types of information will be weighed or balanced. The section of the Draft Outline describing the affordability review process presents the same issue, as it enumerates factors as varied as "[t]he number of residents in th[e] state prescribed the prescription drug" and "[t]he relative financial impacts to health, medical or social services costs as can be quantified and compared to the costs of existing therapeutic alternatives."[8] Without some specific and principled methodology for how the Board will be using such information, it is impossible to ensure that these data sources will be evaluated in a fair, even-handed, and statutorily permissible manner.

- **Out-of-Pocket Costs and All-Payer All Claims ("APAC") Data**. As part of selection and affordability reviews, the Draft Outline contemplates the Board considering certain APAC data, including information bearing on out-of-pocket costs and/or cost-sharing data. PhRMA is unclear how the Board intends to use this information and whether the Board's approach will appropriately account for the full range of factors driving such out-of-pocket costs, including benefit design (e.g., cost-sharing requirements such as coinsurance and deductibles, and copay accumulator adjustment[9] and maximizer programs[10]) and fees, rebates, and other price concessions paid by drug manufacturers to PBMs and health insurance carriers that the PBMs and carriers are not sharing directly with patients at the point of sale. These factors, which are determined by carriers and PBMs, are contributing to the inability of Oregonians to afford their health

[2] *Gordon v. Bd. of Parole & Post Prison Supervision*, 343 Or. 618, 633 (2007).
[3] *Id.* It would also be facially inadequate if the Board purported to move forward by applying unwritten standards. "Unwritten standards and policies are no better than no standards and policies at all. Without written, published standards, the entire system of administrative law loses its keystone." *Id.* at 70.
[4] Draft Outline §§ 4(a), 4(b), 4(b)(J).
[5] *Id.* at 72. The lack of clear standards also impedes the ability of stakeholders to provide full and fair comment to the Board's proposals, including the current Draft Outline. Without greater clarity with respect to how the Board specifically intends to use various information categories, it is impossible for stakeholders to meaningfully comment on the propriety of the Board's contemplated approach.
[6] We note that this list is provided to illustrate a broader issue and is non-exhaustive.
[7] Draft Outline § 3.
[8] *See id.* § 4.
[9] Accumulator adjustment programs are insurance benefit designs that exclude the value of manufacturer-sponsored cost-sharing assistance from a patient's accrual of out-of-pocket expenses toward out-of-pocket limits through a plan benefit year.
[10] Copay maximizer programs are insurance benefit designs that generally restructure patients' cost sharing obligations for a particular drug to equal the full value of manufacturer cost sharing assistance available for that drug. Such programs skirt the protection of the Affordable Care Act's annual limit on cost sharing for some plans by designating medications as non-Essential Health Benefits.

care. Yet it is not clear what consideration the Board will give to the relationship between patient out-of-pocket expenses and the benefit design choices and fee and rebate practices of carriers and PBMs. The context for how out-of-pocket costs are determined should be considered alongside those costs so that the proper weight can be given to the relationship between patient out-of-pocket expenses and the benefit design choices and fee and rebate practices of carriers and PBMs.

- **Price Concession, Discount, or Rebate Information**. According to the Draft Outline, the Board will consider as part of the affordability review certain information about estimated average price concessions, discounts or rebates,[11] as well as, to the extent practicable, estimated manufacturer net-sales or estimated net-cost amounts (including rebates, discounts, and price concessions) for the prescription drug and therapeutic alternatives, and manufacturer financial assistance information.[12] Greater clarity is needed around how the Board intends to make use of this information.[13] As with patient cost-sharing and plan design, there are a multitude of factors that impact the ultimate out-of-pocket cost to a patient. The Board should adopt an affordability review methodology that clearly weighs this information within the universe of market factors at play.

II. Procedures for Evaluating the Reliability of Information

PhRMA asks that the Board also adopt procedures for reviewing and evaluating the accuracy and completeness of the information it will consider, and for permitting manufacturers and other stakeholders to provide input where information may be inaccurate or incomplete.

A. Reliability of Net-Sales and Net-Cost Information

With respect to estimated manufacturer net-sales or estimated net-cost amounts (including rebates, discounts, and price concessions) it is not clear from the Draft Outline where the Board intends to obtain this information; how the Board will assess the reliability of the information; and how the Board will weigh this information when taken together with other information the Board is considering as part of its holistic review. Certain sources of information may be unreliable or only offer only a selective portion of the full picture relevant to the Board's assessment. Use of erroneous data would impact the reliability of the Board's assessments.

B. Reliability of All-Payer All Claims Information

The Board has also indicated that it will rely on Oregon's APAC Reporting Program for information regarding cost-sharing. However, despite its name, the APAC does not include all payers, and thus, does not capture claims data for all insured individuals in Oregon. Rather, the APAC categorically excludes various groups—including certain smaller-sized commercial health plans, individuals insured through various federal programs (such as service members or veterans insured under TRICARE or the Veterans Health Administration), and other sub-populations.[14] There are also notable gaps in the APAC even in some categories of insured individuals not categorically excluded

[11] Draft Outline § 4(a)(D)-(E).
[12] Draft Outline § 4(J).
[13] PhRMA also cautions against the use of estimated net sales or net cost information to form comparisons for drugs the Board considers to be therapeutic alternatives. While the statute contemplates consideration of information regarding both the comparator drug and therapeutic alternatives, this does not give the Board license to make unprincipled "apples to oranges" comparisons. *See* Section V, *infra*.
[14] Oregon All Payer All Claims Database (APAC): An Overview 7 (2018), *available at* https://www.oregon.gov/oha/hpa/analytics/apac%20page%20docs/apac-overview.pdf.

from the database. For example, for self-insured health plans, well over 60% of enrollees may not be represented in the dataset based on the state's own estimates.[15]

When using claims data, the Board should consider and account for the context in which those data are generated and collected, including any gaps or potential inaccuracies in this data, as well as the broader societal and economic trends or processes that may have impacted the data. To this end, we ask that the Board adopt mechanisms to verify APAC-based data points in light of the recognized limitations of all-payer claims databases and the variable societal and economic context in which data are generated. Stakeholders should also be given an opportunity to review and critique any APAC data that the Board intends to rely upon and provide additional or alternative data or context for the Board's consideration.

C. Procedures for Stakeholder Feedback

PhRMA also urges the Board to adopt greater procedural protections to allow impacted stakeholders to provide feedback on the Board's reviews and recommendations, particularly in connection with affordability review reports submitted to the Health Care Cost Growth Target program and the interim committees of the Legislative Assembly.[16] Because of the voluminous and complex nature of the data considered by the Board, and the variety of sources it is drawn from, the Board should give impacted stakeholders a reasonable opportunity to review and provide written responses to and relevant additional information for draft affordability review reports before final reports are submitted to these bodies. Any responses or feedback received from stakeholders should be presented for the consideration of the legislature and Health Care Cost Growth Target program with the Board's final report.[17]

These procedural safeguards are important ones. Under the APA, agency policy decision-making should, whenever possible, be undergirded by full and fair interchange of ideas and information between the agency and interested stakeholders.[18] In addition, it is vital that the Board make every effort to ensure that reports to the Legislature and other government bodies are as accurate and complete as practicable to avoid erroneous or incomplete information that could inappropriately influence decision-making. This is especially true here because the Board's reports may include recommendations that, if implemented, would have significant repercussions across the State of Oregon for Oregonians' access to prescription medicines.

III. Consideration of Drugs Approved Through an Expedited Pathway

PhRMA requests clarification about the Board's proposal to consider whether a drug was approved through an "expedited pathway" as part of selecting drugs for affordability review.[19] The Draft Outline does not explain how the Board intends to weigh this information in its decision-making, and we ask that the Board clarify how it plans to use the information. Prescription drugs approved through FDA's accelerated approval pathway are critical for the treatment of many diseases.[20] Medicines granted accelerated approval must adhere to the same statutory standards for safety and effectiveness as medicines receiving a traditional FDA approval, including substantial

[15] *See* Oregon Health Authority, All Payer All Claims Reporting Program, https://www.oregon.gov/oha/hpa/analytics/Pages/All-Payer-All-Claims.aspx (last visited Feb. 9, 2023).
[16] *See generally* Draft Outline § 4(d).
[17] Any confidential or otherwise sensitive information in stakeholder opposition statements should (and must) also be fully redacted in accordance with the statute's confidentiality requirements before being provided to the legislature or any other person or entity.
[18] *Cf., e.g., Sun Ray Drive-In Dairy, Inc.,* 16 Or. App. at 71 ("The policies of an agency in a democratic society must be subject to public scrutiny.").
[19] Draft Outline § 3(A)(a).
[20] Nat'l Org. for Rare Diseases, FDA's Accelerated Approval Pathway: A Rare Disease Perspective (2021), available atNRD-2182-Policy-Report_Accelerated-Approval_FNL.pdf (rarediseases.org).

evidence of effectiveness based on adequate and well-controlled clinical investigations.[21] The availability of FDA's accelerated approval pathway is important because the development of innovative medicines is a lengthy and complex process, taking an average of 10 to 15 years. The accelerated approval pathway has expedited the availability of drugs that offer substantial health gains, making therapies available to patients many years (a median of 3.2 years) earlier than under traditional pathways.[22] In fact, research has shown that drugs approved through the accelerated pathway "offered larger health gains, compared to drugs approved through conventional review processes."[23]

IV. Health Equity Considerations

PhRMA supports helping to create systemic and long-lasting change to improve health equity across underserved communities. PhRMA and its members are actively engaged in working with patients, community groups, and policymakers to address social determinants of health and to drive proactive research that improves health outcomes. America's biopharmaceutical companies maintain frontline commitment to developing treatments or cures for thousands of debilitating and life-threatening conditions, including those like Alzheimer's disease,[24] certain cancers,[25,26] and many common chronic and rare diseases. Many of these conditions disproportionately impact communities of color, including sickle cell disease and metachromatic leukodystrophy in African American and Hispanic populations, and lupus and sarcoidosis across indigenous communities. Patients of color with rare diseases face extraordinary challenges and experience a disproportionate burden in accessing care.

PhRMA is concerned that, as proposed, the Board's Draft Outline will not adequately further the interest of health equity. In particular, the Draft Outline appears at many points to presume that medications are driving health inequity when—in fact—improving access to medication is a proven way to improve the quality of life, as well as survival rates, of patients with one or more often-significant chronic health conditions. There are ample data showing that access to medication is a solution for improving health equity, yet growing evidence demonstrates that underrepresented racial and ethnic minority populations are disproportionately burdened by out-of-pocket costs and medical debt that prevent access to needed medicines: Black Americans (24%) and Hispanic Americans (21%) with insurance are much more likely to report that they would not be able to afford their out-of-pocket costs if they had a major medical event or became seriously ill, compared to 17% of white Americans.

Timely and continuous use of prescription medicines as recommended by a healthcare provider is key to effective disease management, particularly for chronic conditions. Many studies underscore the important role that medicine plays in improving patient outcomes and lowering health care costs:

- Spending $1 on medicines for adherent patients with congestive heart failure, high blood pressure, diabetes or high cholesterol can generate $3 to $10 in savings on emergency room visits and hospitalizations.[27]

[21] See FDA, Guidance for Industry Expedited Programs for Serious Conditions – Drugs and Biologics (May 2014), available at https://www.fda.gov/media/86377/download.
[22] Beakes-Read, G., Neisser, M., Frey, P. et al. Analysis of FDA's Accelerated Approval Program Performance December 1992–December 2021, Ther Innov Regul Sci (2022), available athttps://doi.org/10.1007/s43441-022-00430-z.
[23] James D. Chambers et al., Drugs Cleared Through the FDA's Expedited Review Offer Greater Gains Than Drugs Approved by Conventional Process, 36 HEALTH AFFAIRS 1408, 1408 (2017).
[24] 2020 Alzheimer's disease facts and figures. Alzheimer's and Dementia. https://alz-journals.onlinelibrary.wiley.com/doi/full/10.1002/alz.12068.
[25] Cancer Stat Facts: Prostate Cancer. SEER. https://seer.cancer.gov/statfacts/html/prost.html
[26] Multiple Myeloma Research Foundation. https://themmrf.org/multiple-myeloma/black-patients/.
[27] M.C. Roebuck, et al. "Medication Adherence Leads to Lower Health Care Use and Costs Despite Increased Drug Spending." Health Affairs 30 no. 1 (2011): 91-9.

- Improved medication adherence among patients with diabetes could result in over 1 million avoided emergency department visits and hospitalizations annually, for potential savings of $8.3 billion each year.[28]
- Initiation of disease-modifying therapy in patients with multiple sclerosis was associated with significant reductions in health care resource utilization (emergency room or urgent care visits, and hospital inpatient stays) and non-prescription medical costs (up to $5,700).[29]
- Since the introduction of Part D, nearly 200,000 beneficiaries are estimated to have lived at least one year longer, with and average increase in longevity of 3.3 years, because of improved access to medication.[30]
- Better use of medicines could eliminate $213 billion in U.S. health care costs annually, amounting to 8 percent of the nation's health care costs.[31]

V. Consideration of Therapeutic Alternatives

PhRMA strongly recommends the Board use caution when considering information regarding therapeutic "alternatives" to particular medications. Drugs within a particular therapeutic class will often have significant differences, including in their chemical formulas, mechanism of action, and safety and effectiveness profiles, even though the drugs treat a similar clinical indication. A patient who can safely and effectively use one drug in a therapeutic class may experience increased risk of negative outcomes (e.g., drug interactions, side effects, treatment failures) with another drug in the class. Patients respond differently to treatment because of a number of factors, such as genetics, age, sex, socioeconomic status, drug-drug interactions, diet, environment, and co-morbidities. This means that treatments that are the best option for some individuals are not as effective for others.[32]

The Board should carefully consider when and under what circumstances it will consider information regarding therapeutic alternatives, especially those that are not therapeutically *equivalent*. Accordingly, the Board should establish a definition of "therapeutic alternative" that requires a drug to have been shown through peer-reviewed clinical studies to have similar therapeutic effect, a similar safety profile, and expected outcome when administered to patients in a therapeutically equivalent dose in order to be considered a therapeutic alternative. Additionally, in any situation where the Board considers therapeutic alternatives, patients with unique requirements, such as immunocompromised patients, pediatric patients, women—particularly those who are pregnant—and the elderly, who require multiple medications for acute and chronic illnesses, should be given special consideration.

VI. Protections Against use of Quality-Adjusted Life Years (QALYs)

PhRMA recognizes that, as contemplated in the Draft Outline, the Board will not use quality-adjusted life year (QALY) or similar information to evaluate relative financial effects.[33] Exclusion of QALY-related measures is

[28] A. Jha, et al. "Greater Adherence to Diabetes Drugs is Linked to Less Hospital Use and Could Save Nearly $5 Billion Annually." Health Affairs 31 no. 8 (2012): 1836-46.
[29] Nicholas J et al. Comparison of Disease-modifying Therapies for the Management of Multiple Sclerosis: Analysis of Healthcare Resource Utilization and Relapse Rates from US Insurance Claims Data. PharmacoEconomics Open. 2017. Available at: https://link.springer.com/article/10.1007/s41669-017-0035-2
[30] Semilla, et al. Reductions in Mortality Among Medicare Beneficiaries Following the Implementation of Medicare Part D. *Am J Manag Care. 2015;21:S165-S172*
[31] IMS Institute for Healthcare Informatics. Avoidable costs in US healthcare: the $200 billion opportunity from using medicines more responsibly.http://www.imshealth.com/files/web/IMSH%20Institute/Reports/Avoidable_Costs_in%20_US_Healthcare/IHII_AvoidableCosts_2013.pdf. June 2013.
[32] McRae, J., Onukwugha, E. Why the Gap in Evaluating the Social Constructs and the Value of Medicines?. PharmacoEconomics (2021). https://doi.org/10.1007/s40273-021-01075-w
[33] Draft Outline § 24(b)(F)(ii).

consistent with the statutory prohibition against the use of QALYs.[34] This statutory prohibition reflects the legislature's recognition that, consistent with the views of experts, QALYs discriminate against older adults, chronically ill individuals, many communities of color, and people with disabilities by placing a lower value on their lives.[35] Measurements accounting for "clinical efficacy" often obscure the distinct needs of disadvantaged populations, including communities of color, by rendering judgments about value based on "average" study results, which often reflect primarily white populations and ignore diversity in preferences and other factors that impact health, such access to care, education, and literacy. For example, the value of a lifesaving treatment for Black patients can be automatically valued up to 10% less than for white patients due to biased value metrics such as the QALY.[36]

However, PhRMA believes that the Draft Outline should further clarify how the Board will consistently ensure that it does not utilize information based on QALYs, including materials that may indirectly rely on QALYs, such as meta-analyses. PhRMA also notes that the way the QALY restriction is currently structured in the Draft Outline leaves some ambiguity as to whether the Board proposes to prohibit consideration of QALYs in all circumstances or only with respect to the factor enumerated under Section 4(b)(F). The statute unequivocally prohibits any consideration of QALY-related information, and PhRMA recommends that the Board clarify its Draft Outline to eliminate that ambiguity.

VII. Inadequate Confidentiality Safeguards

PhRMA appreciates the Board's proposed provisions in the Draft Outline to protect confidential, proprietary, and trade secret information, but is concerned that the provisions are not sufficiently protective. The proposed provisions do not implement adequate safeguards for manufacturers' trade secret, confidential, and proprietary information, threatening the unlawful and unconstitutional disclosure of such information.

State and federal law protect manufacturers' confidential, trade secret and proprietary information from disclosure; such information cannot be publicly disclosed without violating state and federal prohibitions against the misappropriation of trade secrets.[37] In addition, the Fifth Amendment's prohibition against taking private property without just compensation similarly prohibits the uncompensated disclosure of trade secrets.[38] Courts have made clear that "when disclosure [of pricing information] is compelled by the government," even the "failure to provide adequate protection to assure its confidentiality ... can amount to an unconstitutional 'taking' of property."[39]

Consistent with these state and federal requirements, the Legislature incorporated into the PDAB statute an independent obligation on the PDAB to "keep strictly confidential any information" that is "[c]onfidential, proprietary or a trade secret," including "[i]nformation submitted to the department by a manufacturer under ORS 646A.689."[40] Under the Draft Outline, however, the PDAB would rely primarily on the *submitter* of information to

[34] 2021 Or. Laws ch. 589, § 2(4)(a) (codified at ORS 646A.697).
[35] *See, e.g.*, National Council on Disability. Quality-Adjusted Life Years and the Devaluation of Life with Disability. (Nov. 2019), *available at* https://ncd.gov/sites/default/files/NCD_Quality_Adjusted_Life_Report_508.pdf
[36] Broder, M, Ortendahl, J. Is Cost-Effectiveness Analysis Racist? Partnership for Health Analytic Research. 2021. Available at: https://blogsite.healtheconomics.com/2021/08/is-cost-effectiveness-analysis-racist/
[37] *See* 18 U.S.C. § 1839(5)(B)(ii)(II) (defining "misappropriation" under the federal Defend Trade Secrets Act); Oregon Uniform Trade Secrets Act, ORS 646.461 to .475.
[38] *See, e.g., Ruckelshaus v. Monsanto Co*., 467 U.S. 986, 1002–04 (1984). The Fifth Amendment's Taking Clause applies against the states under the Fourteenth Amendment.
[39] *St. Michael's Convalescent Hosp. v. California*, 643 F.3d 1369, 1374 (9th Cir. 1981) (brackets and quotation marks omitted).
[40] ORS 646A.694(7).

designate materials as confidential, trade secret, or proprietary.[41] But the PDAB's obligation to "keep [such information] strictly confidential" applies to *all* such information, even if the submitter did not specifically mark the information for protection.[42]

This distinction is especially important because the PDAB is soliciting information from multiple stakeholders that possess relevant information obtained from other entities.[43] If a submitter possesses confidential information of another entity, there is a significant risk that the submitter may not appropriately label such information as confidential and commercially sensitive because the submitter may not recognize that the information is treated as such by the other entity. This is particularly problematic because, in situations where one entity submits information obtained from a second entity, the second entity may receive no notice of the submission, and thus will have no opportunity to "designate the specific information it deems to be confidential," as contemplated by the Draft Outline.[44] PhRMA therefore urges the Board to revise its Draft Outline to make clear that the PDAB will independently review *all* information received to identify potential trade secret, confidential, and proprietary information. The Draft Outline should also state that, prior to disclosure, the PDAB will consult with any party whose information was submitted by another party.

In addition, the PDAB should clarify that stakeholders have a mechanism for advance review of the PDAB's determination that any such information is subject to public release, and should allow stakeholders to appeal such determinations. The statute's prohibition on the disclosure of trade secret, confidential, and proprietary information would be illusory—and would raise serious due process, takings, and other constitutional concerns—if the PDAB retained unilateral discretion to release the information without a pre-release opportunity for administrative and judicial review.

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We thank you again for this opportunity to provide comments and feedback on the Draft Outline and for your consideration of our concerns and requests for revisions. Although PhRMA has concerns with the Draft Outline, we stand ready to be a constructive partner in this dialogue. If there is additional information or technical assistance that we can provide as these regulations are further developed, please contact dmcgrew@phrma.org with any questions.

Sincerely,

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Merlin Brittenham
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[41] *See* Draft Outline § 4(e)(C)
[42] ORS 646A.694(7).
[43] *See, e.g.*, ORS 646A.694(5).
[44] Draft Outline § 4(e)(C).