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November 22, 2023

Via email (*pdab@dcbs.oregon.gov*)

Oregon Division of Financial Regulation
ATTN: Oregon Prescription Drug Affordability Review Board (PDAB)
350 Winter St. NE
Room 410
Salem, OR 97309-0405

OPPOSE Proposed Policy Recommendation #2: Changes to Oregon's Generic Substitution Requirement as Applied to Biologic Products and Biosimilars

At the PDAB's November 15 meeting, the Board voted to advance for further discussion and potential adoption at the December 13 meeting the second recommendation in the "Summary of proposed policy recommendations submitted to the Prescription Drug Affordability Board" ("the proposal"), which recommends gutting Oregon's law relating to pharmacy substitution of interchangeable biological products.[1] The recommendation is based on specific stakeholder-proposed language that would amend ORS 689.522 to permit substitution of biosimilars that have not been approved as interchangeable by the U.S. Food and Drug Administration (FDA) and without notice of substitutions to patients. The Board also discussed automatic or mandatory substitution as a component of the recommendation.

The Oregon PDAB November 14 Agenda Packet claims that the proposal would "align the [Oregon] statute with current federal language"[2] and "lead to wider adoption of biosimilars due to mandatory substitution." We believe both assertions are incorrect.

As a leader in biosimilar development, with six FDA-approved biosimilars marketed in the US and more biosimilar products in our pipeline, Amgen strongly opposes these proposed changes to ORS 689.522 that are ostensibly intended to help promote access to biosimilars. Changes like these would undermine the scientifically appropriate federal statutory standard for interchangeability by nullifying the FDA's role in assessing interchangeability for the purposes of pharmacy substitution. Under federal law, FDA's assessment of interchangeability is foundational to determining that a biosimilar may be substituted at the

[1] Oregon PDAB November 15 Agenda Packet at page 61. Available here: https://dfr.oregon.gov/pdab/Documents/20231115-PDAB-document-package.pdf.
[2] Oregon PDAB November 15 Agenda Packet at page 61. Available here: https://dfr.oregon.gov/pdab/Documents/20231115-PDAB-document-package.pdf.

pharmacy for the reference product without the intervention of the prescriber.[3] Accordingly, the requirement that a biosimilar be deemed interchangeable in order to be eligible for pharmacy substitution is a core component of substitution laws enacted in every state across the country, as well as the District of Columbia and Puerto Rico, and is in alignment with the federal law.

With 11 biosimilars in our portfolio (marketed or in development) and substantial ongoing investments in biosimilar research and development, Amgen advocates for effective policies to promote success of the marketplace with biosimilars so that biosimilars can bring competition and meaningful cost savings to the healthcare system. The long-term viability of a marketplace with biosimilars that achieves meaningful cost savings and multiple public health benefits depends on, among other things, ensuring scientifically appropriate regulatory standards, including FDA's assessment of interchangeability. This assessment involves, among other things, evaluating whether a particular biosimilar may be safely substituted at the pharmacy in light of potential differences in delivery device or administration between the biosimilar and a prescribed reference product.

Biologics dispensed at the pharmacy tend to be administered via self injection. Substitution could occur among biologics with differences in delivery devices, instructions for use of the delivery devices, or routes of administration, particularly in light of the fact that a biosimilar may not always be approved and marketed for all of the dosage forms or routes of administration of the reference product. Pharmacy substitution may occur without, for instance, the benefit of the prescribing physician educating the patient on changes in dosing and administration; this may pose heightened concerns for biologics, given that they tend to be injected, as opposed to typical AB-rated generic drugs, which tend to be dispensed in oral dosage forms. **A sound scientific assessment of interchangeability by FDA facilitates pharmacy substitution by minimizing risk of administration errors or mis-dosing, events that can result in diminished efficacy or safety risks to patients.**

In addition, the proposal would create a pharmacy substitution standard for biological products that is less than what is in place for non-biological products in Oregon. FDA's assessment of therapeutic equivalence for generics, which is part of the approval process to support pharmacy substitution of generics, takes into account differences in dosage form and other characteristics. **By removing the interchangeability designation as a requisite for pharmacy substitution of biosimilars, the proposed recommendation would effectively hold complex biologics to a less robust standard than even less complex AB-rated generic drugs**.

Further, the proposal's elimination of Oregon's requirement for patient notification of substitution would remove a vital tool that supports patient therapeutic management and pharmacovigilance. Many patients managing chronic medical conditions have worked to achieve stability on a biologic medication, sometimes trying different therapies to achieve optimal management. Providing notice to the patient of substitution can help alert the patient to potential formulation, delivery device or

[3] 42 U.S.C. 262(i)(3) ("The term 'interchangeable' or 'interchangeability', in reference to a biological product that is shown to meet the standards described in subsection (k)(4), means that the biological product may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.").

administration differences, and can help the patient or physician attribute any adverse events to the appropriate product for purposes of pharmacovigilance.

The biosimilars market is already well functioning with an even brighter future ahead. As of November 2023, 45 biosimilar products had been approved and 37 products had been launched since 2015. Since introduction, biosimilars have rapidly grown in adoption and have attained significant share in the majority of therapeutic areas in which they have been introduced.[4] For therapeutic areas with biosimilars launched in the last three years, the average share was 75%.[5] **This significant growth in biosimilar adoption has occurred in an environment where, as of April 2021, all 50 states, as well as the District of Columbia and Puerto Rico, share Oregon's requirement that a biosimilar be deemed interchangeable to permit pharmacy substitution**. Indeed, many biologics are administered in a clinical setting by healthcare professionals and are not dispensed at the pharmacy. Proposals like this, that would undermine patient safeguards in pharmacy substitution laws in hopes of further increasing biosimilars uptake, are misguided.

We look forward to the opportunity to continue this discussion with the Board. We would be happy to provide any further information needed on the importance of the interchangeability assessment and communication of the product dispensed to the patient to maintaining a healthy biosimilar market and to promoting safe medication administration, pharmacovigilance, and biosimilar access for Oregon's patients.

Regards,

Leah A Christl, PhD

Leah Christl, PhD

Vice President, Global Regulatory Affairs and Strategy, Biosimilars and General Medicine Therapeutic Area Head

[4] Data on file, Amgen; Biosimilar Market Share Trends; July 2022.

[5] Data on file, Amgen; Biosimilar Market Share Trends; July 2022; OBU Customer Data Pack Weekly (IQVIA DDD + Chargeback).

December 6, 2023

Oregon Prescription Drug Affordability Review Board
350 Winter St. NE
Room 410
Salem, OR 97309-0405
Via email pdab@dcbs.oregon.gov

To Whom it May Concern:

The American Cancer Society Cancer Action Network (ACS CAN) appreciates the opportunity to comment on proposed changes to Oregon's statute related to pharmacy substitution of biologic products. ACS CAN advocates for evidence-based public policies to reduce the cancer burden for everyone. As the American Cancer Society's nonprofit, nonpartisan advocacy affiliate, ACS CAN is making cancer a top priority for public officials and candidates at the federal, state, and local levels.

The development of biologic drugs has provided cancer patients and their physicians with access to improved therapeutic options. As generics have done for small-molecule drugs, interchangeable biosimilars have the potential to increase price competition on older biologic drugs and result in lower cost burdens for cancer patients. However, as biosimilar substitution policies are developed and refined, they must focus on ensuring the safety and efficacy of all biologic drugs.

ACS CAN is concerned with the proposed change to eliminate the requirement that biosimilar substitution be restricted to only products that the Food and Drug Administration (FDA) has designated as an interchangeable biologic product. Robust evidence is needed to prove sufficient equivalence in terms of safety and efficacy between innovator biologics and those deemed as "interchangeable biosimilars." FDA ensures the integrity of this designation and such a designation can be withheld or removed if evidence shows a clinically meaningful difference in safety or efficacy between products either in isolation, or when products are used sequentially. We urge you to maintain the requirement that pharmacy substitution only happen under circumstances where the FDA has deemed a product to be interchangeable.

We also have significant concerns with the elimination of language that requires notification to patients for whom a biosimilar product is being substituted. Biologics are manufactured in living organisms and are therefore much more complex than manufactured pharmaceutical generics. In addition, biosimilars are not necessarily exact replications of their reference biologic product and as such, a patient's response may be different to the substituted product.

Patients undergoing treatment for cancer can be taking both biologic products as well as traditional small-molecule drugs. When there is an interchangeable biosimilar, both the patient and the prescribing physician should be notified of the actual biologic dispensed via written and electronic means in real time to ensure an accurate patient medical record. In the event of an adverse reaction, it will be important to have a timely and accurate record of any biologic or biosimilar dispensed to a patient. Therefore, we urge you to maintain the patient notification requirement.

On behalf of the American Cancer Society Cancer Action Network, thank you for the opportunity to comment. If you have any questions, please feel free to contact me at jamie.dunphy@cancer.org or 503.956.8412.

Sincerely,

Jamie Dunphy
Oregon Government Relations Director
American Cancer Society Cancer Action Network

December 8, 2023

VIA ELECTRONIC FILING

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

Dear Members of the Oregon Prescription Drug Affordability Board:

GSK appreciates the opportunity to submit comments to the Oregon Prescription Drug Affordability Board regarding its subset of prescription drugs to prioritize for affordability review. For the reasons listed below, **we respectfully ask the Board to remove Shingrix and Ventolin HFA from the existing subset of prescription drugs that may be selected for an affordability review.**

GSK is a science-led global healthcare company with a special purpose to unite science, talent, and technology to get ahead of disease together. We focus on science of the immune system, human genetics, and advanced technologies to impact health at scale. We prevent and treat disease with vaccines, specialty, and general medicines. GSK supports policy solutions that transform our healthcare system into one that rewards innovation, improves patient outcomes, and achieves higher value care.

GSK is concerned that the current methodology, data sources, and criteria used by the Board to identify drugs for affordability review may not accurately prioritize drugs that may pose affordability challenges for patients. The data as presented fails to explicitly consider the impact that insurance coverage has on consumer out-of-pocket costs and instead only captures part of the current healthcare system. Before entering the affordability review process, GSK encourages the Board to reevaluate the current methodology to fully understand prescription drug affordability challenges in Oregon.

Shingrix

In the interest of continued public health for the people of Oregon, GSK is concerned over the inclusion of Shingrix, a vaccine used to prevent herpes zoster (shingles) in adults 50 years and older and 18 years and older who are or may be immunocompromised, on the current subset list. Shingrix is an essential recombinant subunit vaccination proven to be more than 90% effective in preventing shingles in adults 50 years and older. The Advisory Committee on Immunization Practices (ACIP) recommends that immunocompetent adults aged 50 and older as well as adults aged ≥19 years who are or will be immunodeficient or immunosuppressed because of disease or therapy receive Shingrix. [iii] Because 1 in every 3 people in the US will get shingles in their lifetime, this preventative treatment is of vital importance. There is no alternative prophylactic or effective prevention option for Shingles, which makes unencumbered access to Shingrix critical.

Further, vaccines already undergo a cost-effectiveness and economic value assessment process by the ACIP and the Centers for Disease Control and Prevention (CDC) after FDA approval. Vaccines are reviewed and recommended by the ACIP before they can be accessed by the public or covered by insurance. In its role, the

ACIP advises the HHS Secretary, as delegate to the Director of the CDC, on the use of vaccines for infectious disease prevention; the CDC Director reviews, adopts, and publishes ACIP vaccine recommendations.

When reviewing a vaccine, ACIP considers "disease epidemiology and burden of disease, vaccine safety, vaccine efficacy and effectiveness, the quality of evidence reviewed, economic analyses, and implementation issues," as specified in its charter.[iii] In the Evidence to Recommendations (EtR) Framework ACIP uses to guide its evidence analysis,[iv] the Committee assesses a product's cost-effectiveness within the Resource Use domain to determine if "the intervention is a reasonable and efficient allocation of resources." This assessment includes evidence from submitted analyses, a description of the Committee's determinations, and the appraised level of certainty associated with the evidence. To ensure that submitted economic analyses are uniform, high quality, understandable, and transparent, the CDC together with ACIP developed Guidance for Health Economics Studies (updated in 2019).[v] Often, the health economics models developed by biopharma companies, such as GSK, are further tested and validated against CDC-developed analyses to ensure rigorous technical review.

The current data subset does not reflect that all ACIP-recommended vaccines, including Shingrix, are covered without cost-sharing for all publicly and privately insured individuals, meaning out-of-pocket costs are non-existent. Regardless of a product's list price, all ACIP-recommended vaccines are covered without cost-sharing for all publicly and privately insured individuals, as mandated by the following statute and regulation:

- Commercial plans: 42 U.S.C. §30gg-13(a)(2)
- Medicare Part B: 42 U.S.C. §1395x(s)(10) and 42 C.F.R. 410.57
- Medicare Part D: 42 U.S.C. §1395w-102(e)
- Medicaid/Children's Health Insurance Program (CHIP): 42 U.S.C. §300gg-13(a)(2) (Medicaid Expansion) and 42 U.S.C. §1396o-1 (Traditional Medicaid)

Additionally, federal safety net programs provide access to vaccines without cost-sharing for uninsured and under-insured (i.e., adults enrolled in non-Affordable Care Act [ACA]-compliant plans, including grandfathered and short-term limited-duration plans) individuals.

Finally, per affordability review rulemaking (925-200-0010: Selecting Prescription Drugs for Affordability Reviews), adopted by the PDAB in August 2023, criteria for selection of products for affordability review will include "cost and availability of therapeutic alternatives to the prescription drug in the state, including any relevant data regarding costs, expenditures, availability, and utilization related to the prescription drug and its therapeutic alternatives."[vi] GSK respectfully adds that high utilization of a vaccine such as Shingrix is the goal of any state vaccination program and to prevent associated medical costs, including Oregon's.[vii] Vaccines should not be subject to an affordability review based on high or increasing utilization.

Given the public health implications of vaccination, the current ACIP recommendations for immunocompetent adults aged 50 and older as well as adults aged ≥19 years who are or will be immunodeficient or immunosuppressed because of disease or therapy to receive Shingrix, there being no other vaccines for herpes zoster on the market today, the non-existent out-of-pocket costs for patients and the

economic utility of vaccines on the Oregon healthcare system, we urge the Board to remove Shingrix from the existing subset of prescription drugs that may be selected for an affordability review.

Ventolin HFA
Ventolin HFA is an essential prescription medication in the treatment and/or prevention of bronchospasms in people who have reversible obstructive airway disease or exercise-induced bronchospasms.

OAR 925.200.0020 requires the Board to consider the availability of therapeutic equivalents and the average patient's out-of-pocket cost when prioritizing prescription drugs for an affordability review. Using the Board's own data, Ventolin HFA is used by the largest number of people and has the smallest average cost per prescription on the current subset list, with more than 68,000 enrollees and an average prescription cost of $25.11. Furthermore, Ventolin HFA has seen a decrease in the average year-over-year price as well as the wholesale acquisition cost for 2022, indicating an already affordable prescription drug becoming even more affordable. For these reasons, we urge the Board to remove Ventolin HFA from the existing subset of prescription drugs that may be selected for an affordability review.

Thank you for the opportunity to provide comments and for considering our concerns. Please feel free to contact Christian Omar Cruz at Christian.O.Cruz@gsk.com with any questions.

Sincerely,

Harmeet Dhillon
Head, Public Policy
GSK

[i] National Institute of Health. Shingles vaccination of adults 50–59 and ≥60 years, U.S. (2020). Available here.
[ii] ACIP. Evidence to Recommendations Framework for Use of Recombinant Zoster Vaccine in Immunocompromised Adults Aged ≥19 Years (2022). Available here.
[iii] US Department of Health and Human Services. Charter of the ACIP. Available here.
[iv] Centers for Disease Control and Prevention. ACIP Evidence to Recommendations Framework. Available here.
[v] Centers for Disease Control and Prevention. Guidance for Health Economics Studies Presented to ACIP. (2019). Available here.
[vi] Oregon PDAB Rulemaking. 925-200-0010. (2023). Available here.
[vii] Vaccines and Immunization. Oregon Immunization Program. Available here.

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

SAFE
COMMUNITIES
COALITION

December 8th, 2023

Dear Members of the Oregon Prescription Drug Affordability Board:

We write today on behalf of SAFE Communities Coalition & Action Fund, a non-profit organization whose purpose is to support pro-vaccine policies and legislation. We appreciate your consideration of our comments for your upcoming meeting on December 13th, 2023. We ask that the board not consider any vaccine as part of their review process.

The process of reviewing and recommending vaccines for the American public, including cost-effectiveness, has already been given great consideration at the federal level by the Advisory Committee on Immunization Practices (ACIP) and the Centers for Disease Control and Prevention (CDC). ACIP's Evidence to Recommendation Framework, used when vaccines are reviewed for recommendation, already considers many of the economic factors that may be considered by OR PDAB.

Vaccines are one of the most important pillars of public health in Oregon and across the nation. We must ensure, as is already done by ACIP, that vaccines remain affordable, accessible, and widely utilized. Anything less undermines the public's health and puts our communities, schools, and those most susceptible to vaccine-preventable diseases at risk.

Thank you for your consideration and the work that you do to make sure that all Oregonians have access to affordable healthcare.

Northe Saunders
Executive Director
SAFE Communities Coalition & Action Fund
info@safecommunitiescoalition.org

December 8, 2023

VIA ELECTRONIC FILING

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

Dear Members of the Oregon Prescription Drug Affordability Board:

ViiV Healthcare (ViiV) appreciates the opportunity to submit comments to the Oregon Prescription Drug Affordability Board regarding its subset of prescription drugs to prioritize for affordability review. For the reasons listed below, **we respectfully ask the Board to remove Triumeq / Triumeq PD from the subset list of drugs subject to the affordability review process, and to further consider that HIV medicines already undergo substantial analysis and discounting.**

ViiV is the only independent, global specialist company devoted exclusively to delivering advancements in human immunodeficiency virus (HIV) treatment and prevention to support the needs of people with HIV and those vulnerable to HIV. From its inception in 2009, ViiV has had a singular focus to improve the health and quality of life of people affected by this disease and has worked to address significant gaps and unmet needs in HIV care. In collaboration with the HIV community, ViiV remains committed to developing meaningful treatment advances, improving access to its HIV medicines, and supporting the HIV community to facilitate enhanced care and treatment. ViiV is proud to be part of the nation's success in reducing the number of new HIV cases and increasing viral suppression rates.[1,2]

ViiV would like to highlight the value of HIV treatments in the following ways:

HIV Treatment as Prevention
As a public health issue, HIV is unique because it exists in the U.S. healthcare landscape as an infectious disease epidemic and a life-long chronic condition for patients requiring treatment. Further, scientific advancements in the treatment and prevention of HIV have the potential to eradicate the disease and end the epidemic. This work is even more important because of the stark disparities in HIV outcomes that exist between certain groups based on age, race, ethnicity, and geographic region, as well as between sexual and gender identities.[3] Should the Oregon Prescription Drug Affordability Board move select HIV treatments for an affordability review, these important advancements may be inhibited.

[1] AIDS Vu: United States https://aidsvu.org/local-data/united-states/. Accessed December 4, 2023.
[2] America's HIV Epidemic Analysis Dashboard. Ending the HIV Epidemic in the US. https://ahead.hiv.gov/. Accessed December 4, 2023.
[3] To End HIV Epidemic, We Must Address Health Disparities. https://www.nih.gov/news-events/news-releases/end-hiv-epidemic-we-must-address-health-disparities. Accessed December 7, 2023.

More tools are available now than ever before that work in tandem to end the HIV epidemic in the United States. Effective HIV treatment is not only beneficial to the patient, suppressing the virus, reducing complications, and promoting the wellness of persons with HIV, once a person with HIV achieves viral suppression, the HIV treatment also eliminates the risk of sexual transmission of HIV to others.[4] This "treatment as prevention" (TasP) benefits the whole population's health by eliminating secondary transmission. However, only 65 percent of diagnosed individuals had achieved viral suppression as of 2020, according to the CDC.

The average estimated lifetime HIV-related care cost for 1 individual is $939,946 (primary infection; 2022 US dollars).[5,6] People with HIV infection transmit the virus to an estimated average of 0.8 additional individuals in their lifetime (secondary infection).[7] Therefore, when accounting for both primary and secondary infections, the average estimated lifetime HIV-related costs for an infection averted is $1,691,902 ($939,946 + 0.8*$939,946). Many barriers to viral suppression found in the U.S. healthcare landscape – inadequate health coverage, lack of access to treatment, failure of retention in medical care – have the potential to be addressed through policy changes. Investments in viral suppression and treatment as prevention hold the potential to not only end the HIV epidemic but save the U.S. economy millions in healthcare costs associated with new infections.

Despite groundbreaking treatments that have slowed the progression and burden of the disease, treatment of the disease is low – only half of diagnosed and undiagnosed people with HIV are retained in medical care, according to the Centers for Disease Control and Prevention (CDC).[8]

Efforts to End HIV

In the U.S., an estimated 1.1 million people are living with HIV, and there are approximately 38,000 new HIV diagnoses each year.[9] As of 2021, there were 7,484 people living with HIV in Oregon, and 202 people were newly diagnosed with HIV in the state in 2021.[10]

In 2019, the Department of Health and Human Services (HHS) released the "Ending the HIV Epidemic Initiative: A Plan for America" (EHE).[11,12] This bold plan aims to leverage scientific

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[4] HIV.gov. Viral Suppression and Undetectable Viral Load. February 1, 2023. https://www.hiv.gov/hiv-basics/staying-in-hiv-care/hiv-treatment/viral-suppression/. Accessed December 8, 2023.

[5] Cohen JP, Beaubrun A, Ding Y, Wade RL, Hines DM. Estimation of the incremental cumulative cost of HIV compared with a non-HIV population. Pharmacoecon Open. 2020 Dec;4(4):687-96. Accessible at: https://pubmed.ncbi.nlm.nih.gov/32219732/. Accessed December 8, 2023.

[6] Davis AE, Brogan AJ, Mellott CE, Fraysse J, Oglesby A. Cost-Effectiveness Analysis of CAB-LA for PrEP in the United States. Presentation at ISPOR 2022, Washington, DC. Available at: https://www.ispor.org/heor-resources/presentations-database/presentation-paper/intl2022-3472/14049/cost-effectiveness-of-every-two-month-cabotegravir-long-acting-cab-la-compared-with-daily-oral-emtricitabine-ftc-tenofovir-disoproxil-fumarate-tdf-for-pre-exposure-prophylaxis-prep-to-prevent-hiv-1-infection-in-the-united-states. Accessed December 8, 2023.

[7] Farnham PG, Gopalappa C, Sansom SL, Hutchinson AB, Brooks JT, Weidle PJ, et al. Updates of lifetime costs of care and quality-of-life estimates for HIV-infected persons in the United States: late versus early diagnosis and entry into care. J Acquir Immune Defic Syndr. 2013 Oct 1;64(2):183-9. Accessible at: https://pubmed.ncbi.nlm.nih.gov/23615000/. Accessed December 8, 2023.

[8] Centers for Disease Control and Prevention (CDC). Monitoring Selected National HIV Prevention and Care Objectives by Using HIV Surveillance Data. May 23, 2023. https://www.cdc.gov/hiv/library/reports/hiv-surveillance/vol-28-no-4/content/national-profile.html#:~:text=During%202021%2C%2075.3%25%20of%20964%2C002,test%20in%2048%20jurisdictions%20with. Accessed December 8, 2023.

[9] HIV.gov. About Ending the HIV Epidemic in the US: Overview. December 4, 2023. https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview/. Accessed December 8, 2023.

[10] AIDSVu: Oregon. https://aidsvu.org/local-data/united-states/west/oregon/. Accessed December 4, 2023.

[11] The White House. 2021. National HIV/AIDS Strategy for the United States 2022–2025. Washington, DC. https://files.hiv.gov/s3fs-public/NHAS- 2022-2025.pdf. Accessed December 8, 2023.

[12] HIV.gov. About Ending the HIV Epidemic in the US: Overview. August 1, 2023. https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview/. Accessed December 8, 2023.

advances in HIV prevention, diagnosis, treatment, and outbreak response to end the HIV epidemic in the United States. The goal of the EHE is to reduce new HIV infections in the United States by 90 percent by 2030.

The state of Oregon has been aligned with this national effort. The Oregon Health Authority (OHA) launched its own initiative to end HIV in the state, the "End HIV Oregon" strategy[13] following a two-year planning process with community members from across Oregon, facilitated by the Program Design and Evaluation Services (PDES) staff.[14] The End HIV Oregon strategy centers around three goals of access to HIV testing, accelerating prevention efforts including pre-exposure prophylaxis (PrEP), and promoting effective HIV treatment to promote viral suppression.

The End HIV Oregon website states that the state vision is "100 percent of Oregonians taking HIV medications to achieve the health goal of being virally suppressed," and lists the noteworthy accomplishment of the state in achieving viral suppression among 82 percent of Oregonians with HIV.[15] The End HIV Oregon accomplishments will only be jeopardized if access to antiretrovirals, prevention options, and the other necessary medications utilized by people with HIV is limited.

The Oregon PDAB could Hinder Efforts to End HIV

One DHHS recommended antiretroviral used to treat HIV is Triumeq, a product currently on Oregon's list of PDAB considerations. Triumeq is essential in the treatment of HIV and is indicated for the treatment of HIV-1 infection in adults and pediatric patients. There was considerable complexity in the development of Triumeq that led to additional research time, all around developing a tablet with 3 active ingredients. Two essential steps in the HIV life cycle are replication – when the virus turns its RNA copy into DNA – and integration – the moment when viral DNA becomes part of the host cell's DNA. These processes require two enzymes called reverse transcriptase and integrase. Triumeq PD, the first dispersible single tablet regimen containing dolutegravir, a once-daily treatment for children living with HIV, enables NRTIs and integrase inhibitors to interfere with the action of the two enzymes to prevent the virus from replicating and further infecting cells. Furthermore, it is important to note that Triumeq is a key part of the Department of Health and Human Services' HIV Clinical Guidelines.

The data the Board intends to consider fails to account for the landscape of HIV treatment access systems that already exist in the state, and already-negotiated prices for HIV medications within systems like the AIDS Drug Assistance Program (ADAP). Triumeq is already made accessible and affordable to patients through numerous avenues, including the ViiV patient Assistance program, ViiV Connect,[16] and through the Oregon ADAP, called CAREAssist.[17] CAREAssist helps HIV positive individuals who need financial help to pay for

[13] End HIV Oregon. https://www.endhivoregon.org/#end-hiv-2. Accessed December 4, 2023.
[14] Oregon Health Authority. End HIV Oregon launches. https://www.oregon.gov/oha/PH/PROVIDERPARTNERRESOURCES/EVALUATIONRESEARCH/PROGRAMDESIGNANDEVALUATIONSERVICES/Pages/Features-EndHIV.aspx. Accessed December 4, 2023.
[15] End HIV Oregon. https://www.endhivoregon.org/#end-hiv-2. Accessed December 4, 2023.
[16] Home | ViiVConnect
[17] Oregon Health Authority. CAREAssist. State of Oregon. https://www.oregon.gov/oha/ph/DiseasesConditions/HIVSTDViralHepatitis/HIVCareTreatment/CAREAssist/Pages/index.aspx Accessed December 6, 2023

their HIV medications. CAREAssist can pay for medications and medical services for those who qualify.[18]

The ADAP Crisis Task Force (ACTF) is a group of state AIDS directors and ADAP coordinators that negotiates reduced drug prices on behalf of ADAPs in all 50 states, the District of Columbia, and the U.S. territories.[19] The AIDS Crisis Task Force performs rigorous evaluations of FDA-approved HIV treatments as well as economic analyses, and other factors to negotiate supplemental discounts for the ADAP program. The ACTF has successfully negotiated an average discount of more than 50 percent off the wholesale acquisition cost for antiretroviral drugs, while simultaneously minimizing the need for formulary restrictions, prior authorization, and delays in making new drugs available to patients.[20] Therefore, subjecting ACTF-recommended HIV medications to PDAB negotiations, after they have already undergone rigorous analyses, is redundant. In addition, establishing price controls frequently hinders research and development for innovative treatments. Products currently on the market provide funding for entities to engage in innovative research. Setting a limit on prescription drug prices will set a limit on innovation for patients in need.

Recommendations

ViiV makes the following recommendations to the Board:

1. **Remove Triumeq / Triumeq PD from Consideration:** ViiV urges the Board to remove Triumeq / Triumeq PD from the current subset. Access to Triumeq is vitally important for the patients in Oregon who rely on this medication to manage HIV-1. Subjecting this unique and important prescription to an affordability review may unintentionally jeopardize access.
2. **Further Evaluate the fact that HIV Medications already Undergo Substantial Analysis and Discounting beyond mandated rebates.** ViiV encourages the Board to consider the role that the ADAP Crisis Task Force (ACTF), voluntary supplemental discounting, and rebate allowances under the 340B Drug Pricing Program play in the financing and affordability of HIV treatments. The data being used to prioritize prescription drugs does not account for available rebates and voucher programs that are available to a variety of patients. Failure to consider the positive impacts these programs continue to have on the affordability of HIV treatments would be an oversight by the Board.
3. **Revaluate How Affordability Reviews Will Impact Long-Term Innovation**. By subjecting currently approved products to affordability reviews, the Oregon Prescription Drug Affordability Board could inadvertently stifle innovation. Deeming an important treatment "unaffordable" could limit access to funds that make research for innovative treatments possible. Without proper funding, companies in the private marketplace will struggle to develop new, innovative treatments and as a result, patients will be negatively impacted.

ViiV is committed to working with the Board to ensure access to HIV treatment for people with HIV in the state of Oregon. Thank you for your consideration of these comments.

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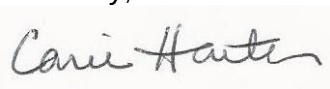
[18] Oregon Health Authority. CAREAssist Forms and Applications. https://www.oregon.gov/oha/PH/DiseasesConditions/HIVSTDViralHepatitis/HIVCareTreatment/CAREAssist/Pages/Forms.aspx. December 8, 2023.

[19] NASTAD.org. ADAP Crisis Task Force. December 2022. https://nastad.org/sites/default/files/2022-12/PDF-ACTF-Fact-Sheet-December-2022.pdf. Accessed December 8, 2023.

[20] NASTAD.org. ADAP Crisis Task Force. December 2022. https://nastad.org/sites/default/files/2022-12/PDF-ACTF-Fact-Sheet-December-2022.pdf. Accessed December 8, 2023.

Please feel free to contact me at (770) 710-9620 or carie.a.harter@viivhealthcare.com should you have any questions.

Sincerely,



Carie Harter
Senior Director
Government Relations
ViiV Healthcare

OREGON STATE PHARMACY ASSOCIATION
19363 Willamette Drive #260 • West Linn, Oregon 97068
(503) 582-9055 • www.oregonpharmacy.org • info@oregonpharmacy.org

December 9, 2023

Oregon Prescription Drug Affordability Board (PDAB)
Department of Consumer and Business Services
Salem, OR

Dear Chair Patterson and members of the board:

On behalf of all Oregon community pharmacists, I am contacting you regarding concerns we have with the Upper Payment Limit (UPL) topics of SB 844 and SB 192 of the Prescription Drug Affordability Board (PDAB). We want to confirm that community pharmacies will be protected with recommendations made to legislatures by the PDAB. In SB 844, Section 7 (a) it says "*Establishing upper payment limits for all financial transactions in this state involving a drug and specifying the methodology used to* ***determine the upper payment limit that does not undermine the viability of any part of the prescription drug supply chain.***"

The consistent concern community pharmacists have raised with the current language is that there are no guarantees community pharmacies would not be under-reimbursed for the cost of the drug. In short, pharmacies may not be able to acquire the drugs below the UPL or Maximum Fair Price (MFP), yet their reimbursement would be subject to those limits.

If pharmacies cannot feasibly provide these drugs, they are likely to stop carrying them, thereby reducing constituents' access to their needed medications. This is particularly concerning because many of the drugs subject to the UPL/MFP will be infusions and high-cost chemotherapy and specialty drugs. We understand it is not the intent for pharmacies to get squeezed between payers and manufacturers. However, without explicit protections for community pharmacies, I remain concerned they will be penalized by state legislation utilizing the current language.

While well-intentioned, due to these unintended consequences resulting from the Prescription Drug Affordability Board language, **I am requesting the PDAB board to recommend to the Oregon legislature to require payers to reimburse pharmacies at cost.**

To ensure we keep our community pharmacies' doors open, I recommend a cost-plus-fee reimbursement model for pharmacies. This would provide further transparency of drug costs between payers, PBMs, and pharmacies. When pharmacies are reimbursed at cost, it stabilizes pharmacies and prevents significant losses such as store closures, reduced working hours, or access barriers for individuals and communities. This will save taxpayers and patients money because the transparency will eliminate "spread pricing" that was discovered in the 3 Axis Advisors report titled,

OREGON STATE PHARMACY ASSOCIATION
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"Understanding Pharmacy Reimbursement Trends in Oregon."[1] In addition, there is no valid data that the PBMs can provide that prove premiums increase in commercial insurance plans. In fact, the National Community Pharmacist Association (NCPA) has data that shows premiums DO NOT increase in states that provide meaningful PBM reform.[2]

I appreciate your willingness to consider this request as part of your policy recommendations to the state legislators. Thank you for your work to help all Oregonians!

Sincerely,
Brian Mayo
Executive Director

[1] https://oregonpharmacy.org/2022/10/27/oregon-report/
[2] https://ncpa.org/sites/default/files/2022-03/pbm-regulations-one-pager.pdf

December 11, 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 December 13, 2023, board meeting entitled "Board discussion and vote on policy recommendations and letter for the Oregon Legislature."

As the Board continues its discussion of 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

December 4, 2023

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

Subject: Consumer Engagement

Dear Members of the Oregon Prescription Drug Affordability Board:

On behalf of 25 community-based organizations and people living with challenging health conditions, we are writing to express our concern about the Prescription Drug Affordability Board's (PDAB) process for engaging people with disabilities and chronic conditions, depriving it from incorporating their experiences and voices in its decisions. Therefore, we would like to provide the following comments and recommendations:

- Board representation: There is no representation of patients or people with disabilities on the Board. While the statute creating the PDAB did not require inclusion of patients and people with disabilities on the board, it also did not exclude from the board people with the required expertise who also identify as people living with a chronic condition or disability. Therefore, we urge efforts to identify people to serve as board members that are qualified people with disabilities or chronic conditions. Also, we urge the current board to recommend to the legislature that seats be explicitly added to the board for patients and people with disabilities.
- Engagement Opportunities: We are concerned that the PDAB meeting agendas have not formally involved expert advisors living with a condition treated by the selected drugs for review, nor have the meetings to date given priority to hearing their testimony. For example, Colorado held separate meetings for each of the 5 drugs selected for review, with one meeting specifically for patients and one meeting for clinicians treating the specific population of patients and researchers. Colorado also has an advisory council that reports to the board, which includes patients and people with disabilities. We request that the board work with patients and people with disabilities to schedule engagement opportunities, one for patients and one for clinicians and researchers, as part of its deliberations related to affordability. These engagement sessions should provide an opportunity for communication between the board and stakeholders, consistent with state law.

- Transparency of Deliberations: During Oregon's legislative debate creating the PDAB, it was a priority for many in the patient and disability communities to ensure that its process did not rely on evidence that is discriminatory or biased, which would exacerbate existing health inequities. Therefore, many of our organizations supported provisions barring the use of quality-adjusted life years (QALYs) or similar formulas. Yet, the board is engaged with the Program on Regulation, Therapeutics, and Law (PORTAL), which has presented to the board options for considering comparative cost and benefit that explicitly includes 1) using existing health technology assessments which historically rely on QALYs or similar measures such as the equal value of life year gained (evLYG), 2) referencing the evidence rating from the Institute for Clinical and Economic Review (ICER), an entity which calls QALYs the "gold standard," and 3) directly using QALYs and evLYG as part of reviews. Therefore, we urge the Board to publicly disclose for comment the evidence under consideration from third parties related to clinical effectiveness, cost effectiveness, and any comparators used in judgements of therapeutic benefit. This step is essential to protect the process from being undermined by considerations of evidence that is biased, discriminatory, or unlawful. Similarly, the board should avoid using a flawed comparator to judge whether a treatment is affordable or effective.
- Emphasis on Patients in Affordability Review: The statute creating the PDAB allows for the selection of treatments that the board determines "may create affordability challenges for health care systems or high out-of-pocket costs for patients." We are concerned that the Board has brought in third parties to advise their process such as PORTAL, a third party whose work is focused on achieving savings for payers as opposed to achieving lower out-of-pocket costs for patients. As the process moves forward, we urge the board to work closely with organizations representing patients and people with disabilities to ensure that their real world affordability concerns are driving the board's determinations.

It will be important for the board to balance input from patients, people with disabilities, providers, and researchers. For example, at the most recent PDAB meeting on November 15, we appreciated a guest physician's excellent presentation on the various ways she prescribes insulin to her patients. However, the board did not ask questions to the provider that would have been useful such as whether the drug worked in some populations and not others or whether one easier to adhere to than another? Also, the patient's experience was missing from the presentation. For real communication, we would have preferred the board elicit the patient experience by asking targeted questions such as whether one drug caused the patient to access the emergency room more frequently than the other, or which was cheaper for overall out-of-pocket costs or had fewer side effects resulting in more productivity. This kind of nuanced information could be elicited as part of engagement opportunities for impacted stakeholders.

We respect you have been given an enormous task and would like to work with the committee to develop a more robust process for community engagement. The statute does not prohibit the board from directly engaging patients and people with disabilities. In fact, the law states, “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.” Additionally, the statute conveys an expectation that the evidence under consideration will be disclosed to the public as long as it is not a trade secret or otherwise prohibited from being shared.

Oregon's goal of increased health equity demands the inclusion of patients and people with disabilities in this process. Thank you for your vital work in reducing the cost of prescription drugs for all Oregonians. We look forward to hearing from you.

Sincerely,

ALS Northwest, Portland, OR
Answer2Cancer Inc., Portland, OR
Caring Ambassadors Program, Oregon City, OR
Cystic Fibrosis Research Institute, Palo Alto, CA
Disability Rights Oregon, Portland, OR
Eastern Oregon Center for Independent Living, Pendleton, OR
HIV Alliance, Roseburg, OR
ICAN, International Cancer Advocacy Network, Phoenix, AZ
National Bleeding Disorders Foundation, New York, NY
National Psoriasis Foundation, Portland, OR
Pacific Northwest Bleeding Disorders, Corvallis, OR
Partnership to Improve Patient Care, Washington, DC
Project Access Northwest, Seattle, WA
The Community for Positive Aging, Portland, OR

<u>Individuals</u>
Bailey Burkhalter, Medford, OR
Mary Canton, Tigard, OR
Joanna M Cooper, Riddle OR
Jacqueline Gethner, Portland, OR
Jeffrey Graves Pendleton, OR
Joy Krumdiack, Bellingham, WA
Christopher J McFarland MPH CADC I, Corvallis, OR
Robbie Noche, Portland, OR
Hannah Roy, Ontario, OR
Paul Terdal, Portland, OR
Micheal Thurman, Portland, OR

Respectfully submitted by Lorren Sandt, Caring Ambassadors Program

December 11, 2023

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

RE: November 15th Insulin Drug List

Dear Members of the Oregon Prescription Drug Affordability Board:

On November 15th, the Board released a preliminary list of insulins that will be subject to an affordability review. During the November 15th meeting the Board decided to narrow the insulin list by filtering and excluding drugs that were selected by the Centers for Medicare and Medicaid Services (CMS) for "negotiation" under its Medicare Drug Price Negotiation Program.

After reviewing the filtered insulin drug list as determined by the Board, we believe that the underlying data contained errors that led to the improper inclusion of insulin aspart. The following NDCs were identified in the Excel file entitled "Insulin Data Analysis 2021 through 2022 v5" as generics and not subject to the Drug Price Negotiation Program:[1]

- 73070010011 - Insulin Aspart Injection Solution
- 73070010215 - Insulin Aspart PenFill
- 73070010315 - Insulin Aspart FlexPen

Year	Insulin Type FDA	Proprietary name	Non-proprietary name	Claimants	Brand or generic	Drug has a therapeutic equivalent or biosimi...	Drug part of IRA CMS negotiation list
2022	Rapid-Acting	Insulin Aspart	Insulin Aspart	847	Generic	None Listed	No
2022	Rapid-Acting	Insulin Aspart FlexPen	Insulin Aspart	1,401	Generic	None Listed	No
2022	Rapid-Acting	Insulin Aspart PenFill	Insulin Aspart	195	Generic	None Listed	No

This information is not correct. **In fact, these insulin aspart NDCs are unbranded biologic products that have been selected by CMS for its Medicare Drug Price Negotiation Program**. Accordingly, under the Board's determined drug selection process, insulin aspart should not be subject to an affordability review. We respectfully request that the Board remove insulin aspart from consideration for potential affordability review.

[1] https://www.cms.gov/files/zip/selected-drug-list-initial-price-applicability-year-2026.zip

If you have any questions or wish to discuss our comments please contact Ryan Urgo, Senior Director of Policy at RVUR@novonordisk.com.

Sincerely,

Jennifer Duck
Vice President, Public Affairs
Novo Nordisk

From: David J Ladwig
Sent: Thursday, December 7, 2023 5:41 PM
To: PDAB * DCBS <pdab@dcbs.oregon.gov>
Subject: Observations on Today's PDAB Report meeting

These are observations about today's meeting. Many of the later presenters -PHarMA, the PBM organization, the generics manufacturers' organization – gave testimony short on facts, and made claims contradicting data presented in the first portion of the meeting.
A version of a paper I presented to Mid Valley Health Advocates in July of 2021 with an update on PHarMa's claims and actual performance.
While early data in presentation showed that generics were often priced just below comparable branded drugs, and that there was little difference between prices if more than one company was manufacturing the same drug, the presenter from the generics manufacturer was reporting how much generics were saving in overall healthcare costs. An early slide mentioned the state entering into generics manufacturing, nothing later followed up on that idea. The patent monopoly of drug manufactures and the games they play to extend their monopoly are one of the biggest factors keeping costs high; this is best exemplified by year over year pricing going up far more rapidly than underlying inflation. And there is comparable indication of distorted oligopoly profit maximization among the generics manufacturers to the detriment of everyone except the generic manufacturers' bottom lines.
The PBM presenter was blaming drug manufacturers, and the PHarMA rep indicted that pharmacy companies were pricing the drugs at an amount that allowed them to continue research and development for future drugs. Somewhere in presentations today, it was claimed PBM's had profits greater than most companies in the US. In one of my slides in PowerPoint, AHIP – insurance providers – blames manufacturers and indicates that they work with PBM's to keep drug prices for customers as low as possible.

I'm not sure how it would be done, but I think meetings like this would be more productive in the longer term if there was a way for marked disparities to be called out. And also, ways to allow viewers of the meeting such as myself to ask questions. I am a retired health economist, and I believe some questions would be beneficial to the Committees' work, and to the intended audiences for the reports.

Thank you,

David Ladwig
Philomath, Oregon

Oregon, PhRMA and Pricing

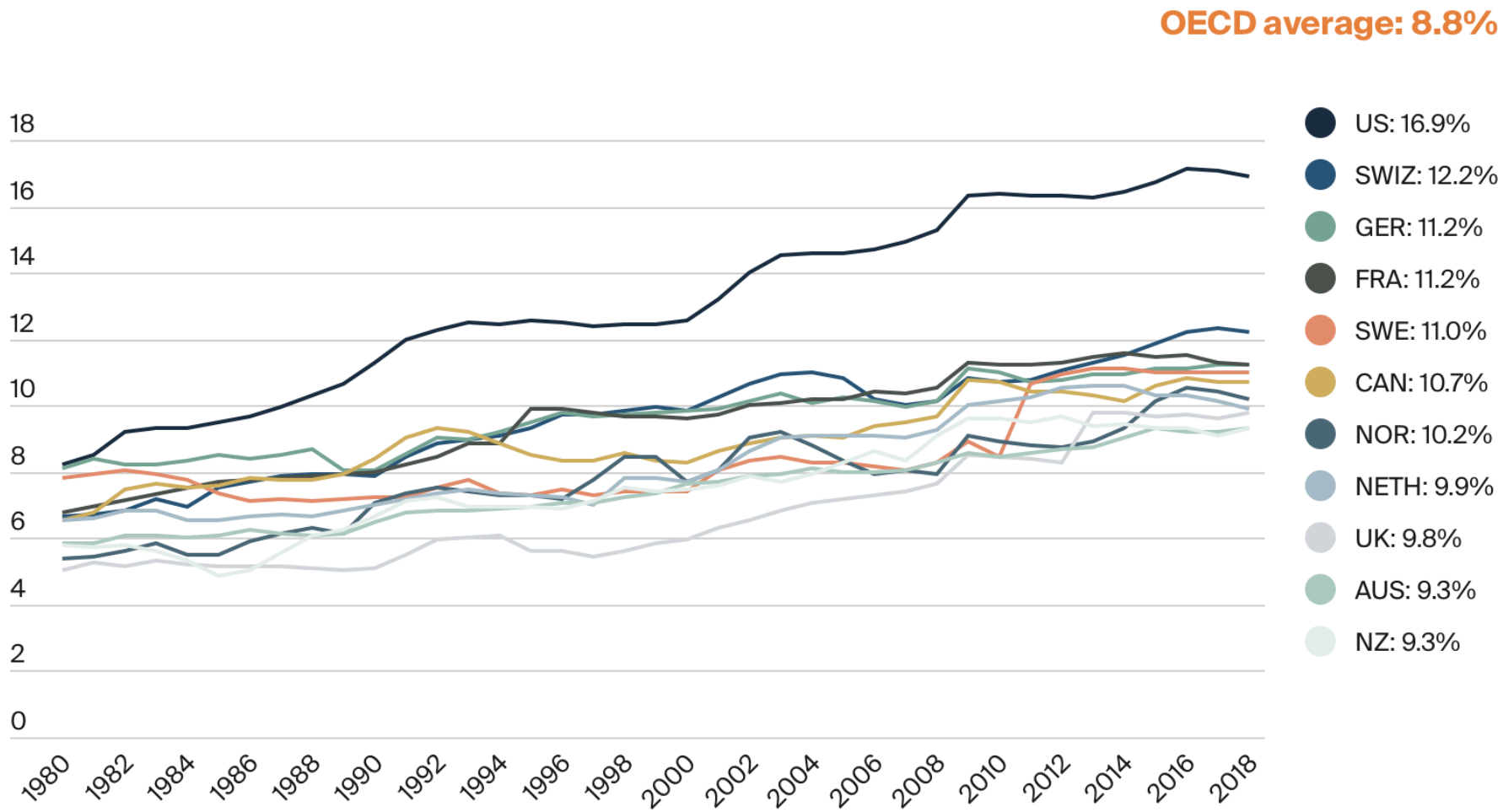
Version 5, December 7, 2023

David Ladwig

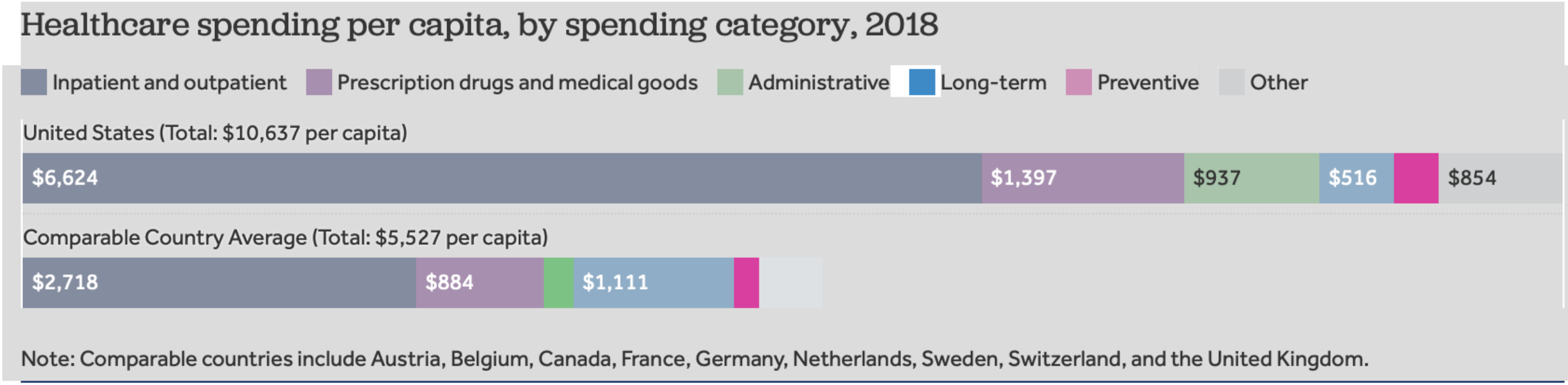
Profits in Pharmaceutical Industry

- Profits of 35 large pharmaceutical companies compared with those of 357 large, nonpharmaceutical companies from 2000 to 2018, the median net income (earnings) expressed as a fraction of revenue was **significantly greater for pharmaceutical companies compared with nonpharmaceutical companies (13.8% vs 7.7%).**
- **Importance** Understanding the profitability of pharmaceutical companies is **essential to formulating evidence-based policies to reduce drug costs while maintaining the industry's ability to innovate and provide essential medicines.**

The U.S. Spends More on Health Care Than Any Other Country



The U.S. spends twice as much as comparable countries on health, driven mostly by higher payments to hospitals and physicians

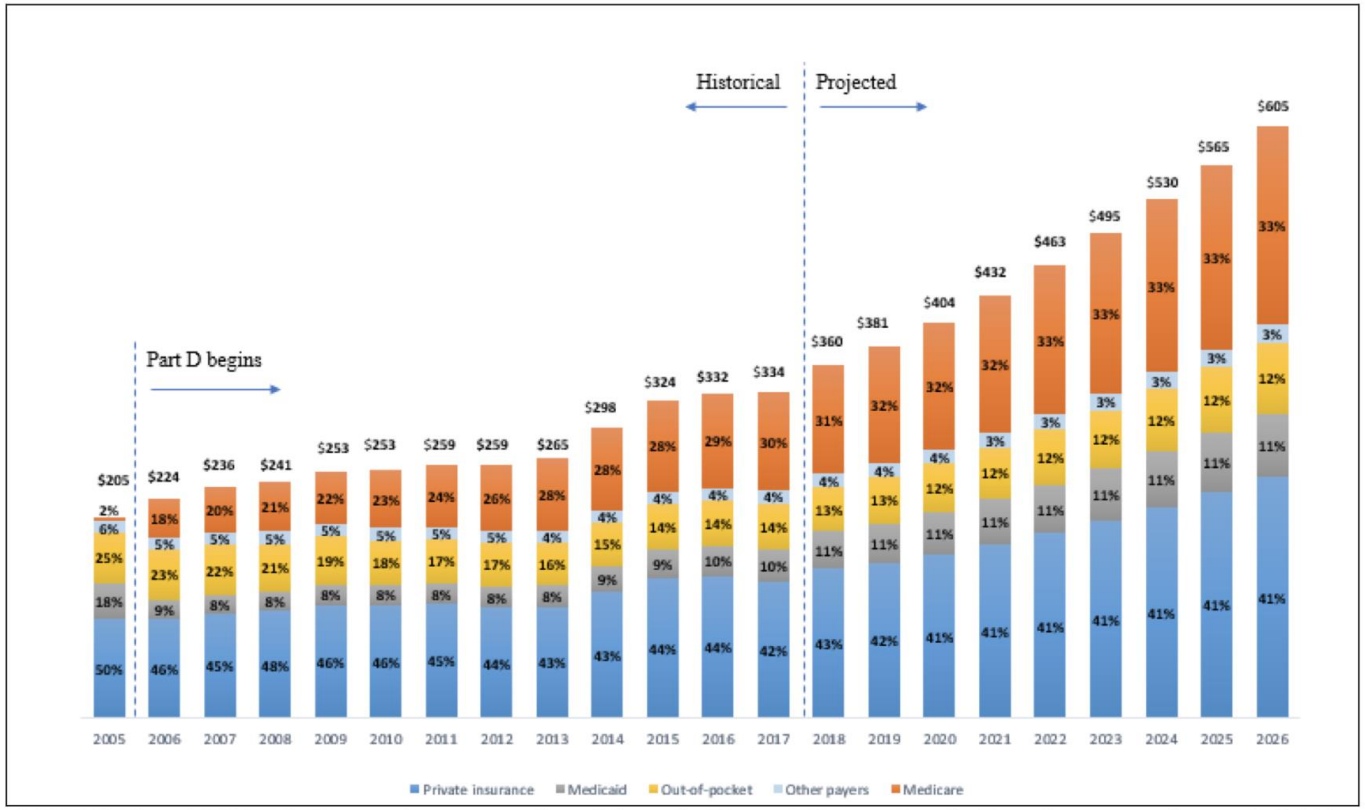


Source: KFF analysis of OECD Health Statistics • Get the data • PNG

Peterson-KFF
Health System Tracker

Increasing Costs of Drug Spending

Figure 1. Historical and Projected Prescription Drug Spending by Payer, 2005-2026 [30]



SOURCES and NOTES: *Figure 1 was reproduced from the Henry J Kaiser Family Foundation article entitled "10 Essential Facts About Medicare and Prescription Drug Spending." Data were provided by the Henry J. Kaiser Family Foundation. The figure only includes Medicare Part D data.*

	Medicare
	Other Payers
	Out of Pocket
	Medicaid
	Private Insure

From Most Revealing Moments From a Major Drug-Pricing Hearing

- According to research published on the Health Affairs blog, the 15 drug companies that made the 20 best-selling drugs worldwide in 2015 made $116 billion in excess revenue from premium drug prices in the U.S. Meanwhile, they spent only $76 billion on global research and development.
- **If Humira were its own company, the drug would be among the fortune 500 companies all by itself.** This was a little factoid lobbed by Senator Debbie Stabenow of Michigan. (And appears to be from this Axios story, which reports that, because of the $38,000 drug's $18.4 billion revenue, "if Humira were a standalone company, it would be larger than many Fortune 500 conglomerates, such as General Mills, Halliburton, or Xerox.")
- **"The government has to step up and change the rules."** This, from AstraZeneca CEO Pascal Soriot, is a rare call for more government regulation from a giant company. It is also, however, throwing the ball back into the legislators' court.

- https://www.theatlantic.com/health/archive/2019/02/drug-pricing-hearing-moments/583678/

Where PHarMa companies spending goes

- A previous Accountable. US report found that the $125 billion the top five pharmaceutical companies — which included Thermo Fisher instead of Merck — spent on stock buybacks and dividends from 2019 through 2021 outpaced the $112 billion they spent on R&D through the same period. #!
- AbbVie spent $11 billion on sales and marketing in 2020, compared to $8 billion on R&D. Pfizer spent $12 billion on sales and marketing, compared to $9 billion on R&D. Novartis spent $14 billion on sales and marketing, compared to $9 billion on R&D. #2
- Of the 10 drug manufacturers examined, 7 of them spent more on selling and marketing expenses than they did on research and development. For this group of 10 companies alone, selling and marketing expenses exceeded R&D spending by $36 billion, or 37%. Moreover, this use of dollars occurred during a year dedicated to the development of new treatments and vaccines to overcome the COVID-19 crisis. # 3

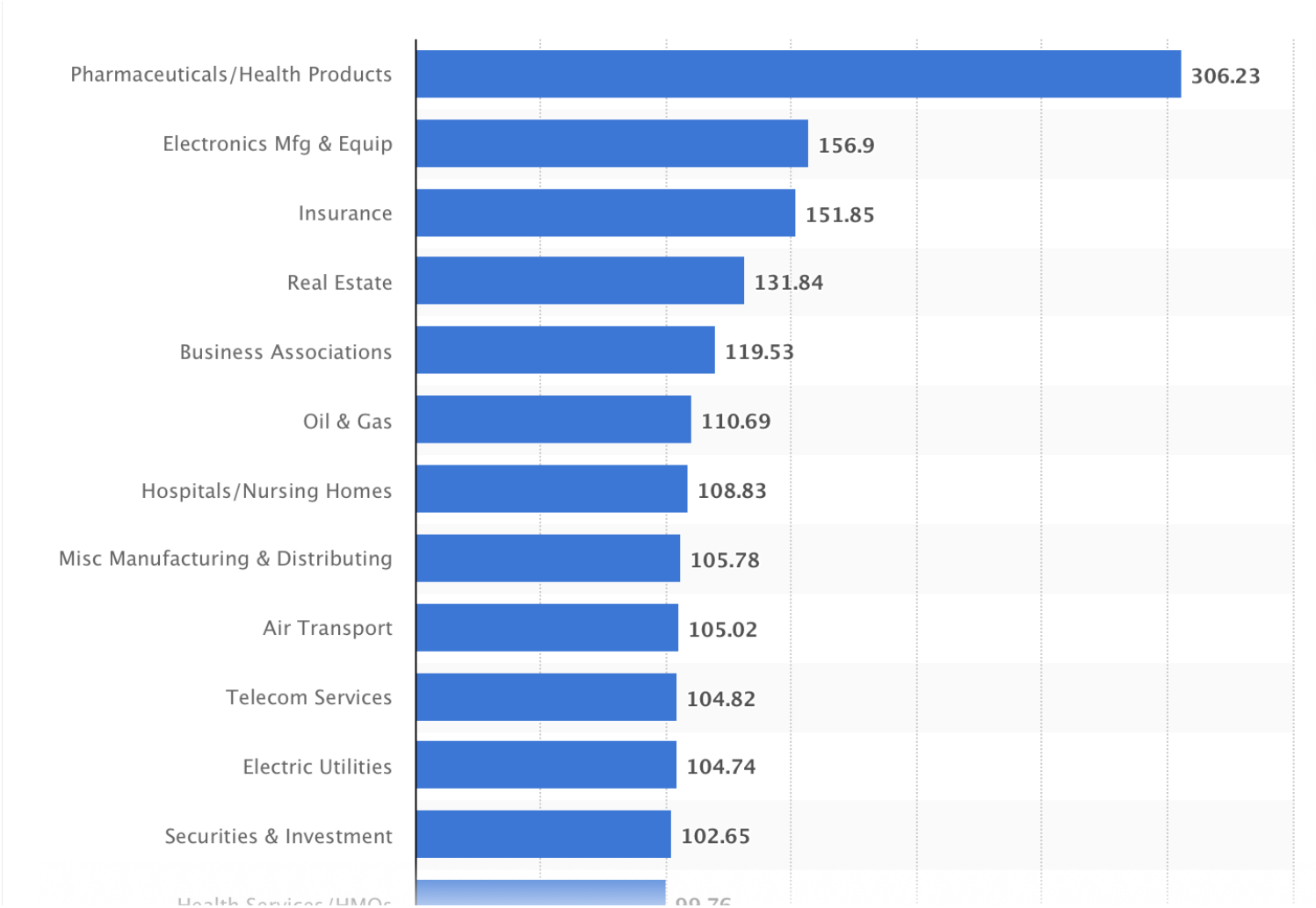
Just how expensive do prescription drugs need to be to fund innovative research?
By Ezekiel J. Emanuel

- Excessive drug prices are the single biggest category of health-care overspending in the United States compared with Europe, well beyond high administrative costs or excessive use of CT and MRI scans. And unlike almost every other product, drug prices continue to rapidly rise over time. HHS estimates that over the next decade, drug prices will rise 6.3 percent each year, while other health-care costs will rise 5.5 percent.
- compared prices of the top 20 best-selling drugs in the United States to the prices in Europe and Canada. They found that the cumulative revenue from the price difference on just these 20 drugs more than covers all the drug research and development costs conducted by the 15 drug companies that make those drugs—and then some
- 'our estimate of the income generated by sales of the product. It is the anticipated income stream, rather than repayment of sunk costs, that is the primary determinant of price.' Hank McKinnell, a past CEO of Pfizer
- The Pew Charitable Trusts reports that only about 42 new antibiotics with the potential to treat serious bacterial infections were in clinical development for the U.S. market in December 2018. Six hundred drugs for cancer and only 42 for serious infections seems like profit maximization, not a case of sensible research priorities that reflects "value in preventing and treating disease."

Big Money in Politics

- The Pharmaceutical Research and Manufacturers of America raised nearly $527 million last year (2020) and spent roughly $506 million, new tax returns obtained by OpenSecrets reveal. That's a record haul for the organization, which is funded by the world's most powerful pharmaceutical companies.

Leading lobbying industries in the United States in 2020, by total lobbying spending *(in million U.S. dollars)*



Pharmaceutical industry on track to spend more than $1 million lobbying to defeat Oregon drug pricing bill

- Industry trade group PhRMA reported spending more than $790,000 on lobbying in Oregon during the first quarter of the year, more than four times as much as any other entity. The group has seven registered lobbyists working in the state.
- The prospect that Oregon could create a Prescription Drug Affordability Board empowered to set upper limits on how much individual and insurance group buyers could pay for the most expensive drugs has attracted national political spending for and against the proposal.
- Supporters of drug price limits dispute PhRMA's claim that potential caps would undermine industry research and development of medicines.

Note from PDAB: This written comment arrived after the 72-hour deadline.

SafeBiologics
ALLIANCE for SAFE BIOLOGIC MEDICINES

December 12, 2023

Oregon Division of Financial Regulation
Oregon Prescription Drug Affordability Review Board (PDAB)
350 Winter St. NE
Room 410
Salem, OR 97309-0405

Re: OPPOSE Proposed Policy Recommendation #2: Changes to Oregon's Generic Substitution Requirement as Applied to Biologic Products and Biosimilars

We are writing to express our strong opposition to the policy under consideration by the Prescription Drug Affordability Review Board (PDAB) to amend ORS 689.522 so as to permit the pharmacy-level substitution of non-interchangeable biosimilars.

Since 2010, the Alliance for Safe Biologic Medicines (ASBM) has worked to keep patients at the center of policy discussions surrounding biosimilar medicines. Our organization is comprised of patients, physicians, pharmacists, and manufacturers of both originator biologics and biosimilars. From 2013-2021, ASBM worked alongside state medical and pharmacy societies nationwide, including in Oregon, to pass legislation permitting biosimilar substitution in all 50 states - for interchangeable biosimilars. We believed then and believe now that biosimilars create much-needed competition and result in savings to our health system. We also know that physicians and patients have strong concerns with inappropriate switching for non-medical reasons.

While automatic pharmacy substitution of generics is widely accepted among physicians, with biosimilars the practice is highly controversial. Indeed, it is banned in many countries, including in nearly all of the advanced countries of Western Europe[1]. While a 2021 survey[2] revealed 89% of U.S. prescribers have high confidence in the safety and efficacy of biosimilars, a majority (58%) oppose third-party switching of a patient's biologic medicine for non-medical (e.g. cost, coverage) reasons. 69% consider it "very important or critical" that patients and physicians decide the most suitable biologic to use- be it the originator or one of the biosimilars to that product.

This is because treatment plans are not one-size-fits-all. Patients often try many safe and effective medicines before finding one that works best for them. For this reason, physicians are reluctant to switch patients' medicine unnecessarily or inappropriately.

Interchangeable biosimilars effectively address these concerns by providing additional data to the FDA showing that safety and efficacy do not diminish if the interchangeable is substituted in place of the originator.

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[1] Sustainable biosimilar policies in Europe *https://www.gabionline.net/biosimilars/research/Sustainable-biosimilar-policies-in-Europe*

[2] U.S. Prescribers' Attitudes and Perceptions About Biosimilars *http://gabi-journal.net/us-prescribers-attitudes-and-perceptions-about-biosimilars.html*

As Congress and the FDA intended, the interchangeable biosimilar designation has proven successful in promoting confidence in biosimilars, and in their automatic and third-party substitution: **57% of physicians said they'd be more likely to prescribe an interchangeable biosimilar; 59% said that an interchangeability designation makes them more comfortable with a pharmacy-level substitution of a biosimilar in place of the originator.**[1]

The interchangeable designation has not only boosted physician and patient confidence, it has done so without becoming a barrier to biosimilar uptake and savings. European biosimilar uptake varies by country and product but hovers within the 20-80% range. Similarly, in the U.S. filgrastim, trastuzumab, and bevacizumab biosimilars have an uptake rate of 80%. Rituximab biosimilars stand at 60% and infliximab, pegfilgrastim, and erythropoietin-stimulating agent (ESA) biosimilars have 40% market share. U.S. biosimilars have generated $21 Billion in savings in the past six years alone.[3]

States like Oregon were able to gain physician support for their biosimilar substitution legislation due to the assurances provided in the legislation that only interchangeable biosimilars would be substituted without prescriber approval.

They were able to secure support from patient advocacy organizations conditional on patients being notified if their medicine were to be switched. The proposal under consideration by the PDAB strikes at the heart of these reasonable protections, and betrays the promises made to physicians and patients.

We share the PDAB's goals of affordable access to medicines and believe that biosimilars have a role to play. But the commitments Oregon made to physicians and patients that they would not be switched to non-interchangeable biosimilars, and would be notified of any switch, should be honored. **We urge you to reject this proposed change and to stand with patients, physicians, and manufacturers who are all invested in the responsible use of biosimilars.**

Thank for the opportunity to voice our concerns on this critical matter.

Sincerely,

Michael S. Reilly

Michael S. Reilly, Esq.
Executive Director, Alliance for Safe Biologic Medicines

[3] *https://www.amgenbiosimilars.com/commitment/2022-Biosimilar-Trends-Report*

ASBM Steering Committee Members:
Alliance for Patient Access
American Academy of Dermatology
Autoimmune Association
Association of Clinical Research Organizations
Colon Cancer Alliance
Global Colon Cancer Association
Global Healthy Living Foundation
Health HIV
International Cancer Advocacy Network
Kidney Cancer Association
Lupus and Allied Diseases Association, Inc.
National Hispanic Medical Association
National Psoriasis Foundation
ZeroCancer