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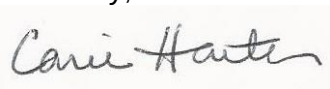
[18] Oregon Health Authority. CAREAssist Forms and Applications. https://www.oregon.gov/oha/PH/DiseasesConditions/HIVSTDViralHepatitis/HIVCareTreatment/CAREAssist/Pages/Forms.aspx. December 8, 2023.

[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
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