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

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