From: David J Ladwig <dladwigj@gmail.com>
Sent: Wednesday, December 13, 2023 10:28 AM
To: STILES Melissa G * DCBS <Melissa.G.STILES@dcbs.oregon.gov>
Cc: David J Ladwig <dladwigj@gmail.com>; david J. Ladwig <dladwigj@yahoo.com>
Subject: Re: Observations on Today's PDAB Report meeting

I had to think a little about suggestions to address my concerns. I know that. OHPB allows public comment that can include material / presentations to that point in the meeting. Meeting organizers offer no response at that time; I believe they commit to trying to address comments at later time.

I suggest that presenters both from within PDAP and extended staff as well as external presenters commit to listening to questions, and submit answers within a set time frame - maybe two weeks to a month. And that answers not addressing question, or contradictory to other information be further questioned and discussed. I think. This ongoing dialogue / discussion is the best way to help engage public and to answer their questions. And it would also be a fruitful method to address conflicts that PDAP board and staff feel uncomfortable broaching on their own.

Thank you,

David

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

Date: 01/04/2024

Name: Grace Nelson

Organization: Retiree

Comments:

71-year old with Medicare, original, and state provided retiree supplement for drug coverage. I am receiving, with three people in household, about $30,000 net income. The "cheapest" way to cover my heart failure meds is a choice where I pay about $1400 per month, ~$18,000 per year. Obviously this doesn't work. We are told we are in the donut hole. That needs to be fixed. The net result of this expense is the person dies (doesn't take their meds) or imports the meds (a LOT cheaper), or travels to Mexico for care (a difficult thing for someone disabled from illness. I have attached my "payment" amount from Medicare under the best option I could choose--and no one I know can afford that. Without healthcare, people are becoming disabled sooner or dying sooner. Maybe this is why people are leaving Oregon? Oregon seems to be a great place to live and covers our 17 year old, thank god. It's just unfair to have a yearly medication bill that is half our income if we did things the right way. That is all. Most expensive meds out of 14 are Xarelto, Entresto and Jardiance, all to keep me out of the hospital for heart failure. Also, I need to lose a lot of weight, but the monthly out of pocket for Ozempic is impossible, about $500-$1500, again leading to bad, expensive outcomes. Soon, I may need dialysis without assistance with meds, which is even more expense.

AiARTHRITIS
INTERNATIONAL FOUNDATION FOR AUTOIMMUNE & AUTOINFLAMMATORY ARTHRITIS

"We don't represent the patient voice, we *are* the patient voice."

January 8th, 2024

Oregon Prescription Drug Affordability Board
Labor & Industry Building
350 Winter Street NE
Salem, OR 97309-0405

RE: Public Comments - Oregon Prescription Drug Affordability Board (PDAB) - January 17, 2024 Board Meeting

Dear Members of the Oregon Prescription Drug Affordability Board:

The International Foundation for Autoimmune & Autoinflammatory Arthritis (AiArthritis), a patient organization led by people affected by AiArthritis diseases, is grateful for the opportunity to submit public comments throughout this drug affordability process. We hope the Board will consider these statements as you continue forward with your drug affordability program.

About AiArthritis. AiArthritis is a leader in advancing education, advocacy, and research for those impacted by autoimmune and autoinflammatory arthritis (AiArthritis) diseases through peer-led guidance, collaboration, and resources that are driven by patient-identified issues and patient-infused solutions. As we are led by patients we understand how important it is to be able to access safe, efficacious, and affordable treatments. As patients living with heterogeneous conditions, we also understand there is no one-size-fits-all drug - even for those diagnosed with the same disease. Through lived experience, we also know that disrupting continuity of care often leads to uncontrolled disease, comorbidities, and significantly decreased rates of remission.

We will also be leading a national coalition, called Ensuring Accessibility through Collaborative Health (EACH) with a second tier patient coalition, called the Patient Inclusion Council (PIC). The mission will be to implement a national network of those impacted by affordability reviews to help navigate processes, identify and lead opportunities to engage, and advocate for patient involvement every step of the way. Although we understand the meeting on the 17th will focus on insulin (which is not a drug under the AiArthritis umbrella), as the leader of the coalition, we are submitting comments that focus *on patient voice inclusion in the process.*

Patient and Patient Organization Involvement in the Process. On behalf of patients and care partners residing in Oregon, we thank the state for recognizing a need to address the high costs of prescription drugs**.** ***However, we are uncertain how much patients will be involved in the process.*** Those utilizing the drugs in review must be heard and their perspectives counted when analyzing the data. Failure to properly include their input can result in biased and statistically insignificant data, resulting in actions by the state that could impede therapeutic access and stymie innovation.

I attended the Board meetings at the end of 2023, in addition to reviewing processes planned for drug reviews, and am extremely concerned about the lack of patient perspectives thus far in the process - including on the Board or stakeholder council, past or planned patient focus groups, surveys, or interviews, or anything other than written and oral comment opportunities. This is concerning as most patients are not exposed to the process of publicly submitted comments and, therefore, would not participate. This would result in insufficient

data collection and lends to the question, "What threshold numbers has the Board put into place to establish 'adequate input' from the stakeholder group most impacted by your decisions?" Furthermore, what methods are put into place to demonstrate how testimony will be considered and implemented into your decision making process?

We do appreciate the Board's willingness to also include an oral comment period at meetings and we are enthusiastic to see the time for these comments has expanded from 10 minutes to 20 minutes. However, how will the Board guarantee a certain percentage of response time will be designated for patient/caregiver input?

Suggestions to Enhance Patient Involvement.There are dozens of Patient Organizations and coalitions who are able and willing to help the Board to ensure the patient stakeholder group has an equal representation in your process. While not perfect, we do applaud the Colorado PDAB staff for making considerable efforts to collect substantial data from those who will be most impacted by your decisions. Examples include:

- Having a dedicated and responsive administrative staff who is willing not only to communicate with patient organizations, but also with patients who are uncomfortable speaking orally or are unsure how to properly submit written comments.
- Hosting listening sessions and publishing coordinating surveys (the latter which were reopened recently through the end of January to ensure they obtain enough patient data to make a responsible decision.) In saying this, their failure to include patients in the question design will ultimately result in flawed data points. See our letter to the CO PDAB for additional recommendations that Oregon could implement.

Regarding innovation. Price control policies are not guaranteed to directly impact the price that most patients pay for highly innovative therapies – as stated above, the savings will generally be accrued by the commercial or public payer/PBM. Instead, patients will suffer from unnecessary delays in connecting patients with highly innovative therapies, fewer treatment options, and more barriers to accessing the life-changing care they need.

In closing, as an organization that operates through peer-to-peer collaboration, we look at this as an opportunity to be an extension of the Board and invite you to lean on us for additional information or guidance as needed. We appreciate every opportunity given to patients that enables us to have a voice in matters involving our healthcare. Thank you for considering our suggestions and do not hesitate to reach out to me at tiffany@aiarthritis.org with any questions.

Sincerely,

Tiffany Westrich-Robertson

Chief Executive Officer
Person living with non-radiographic axial spondyloarthritis
International Foundation for Autoimmune & Autoinflammatory Arthritis

Chronic Disease Coalition

Oregon Prescription Drug Affordability Board (PDAB)
350 Winter St. NE Room 410
Salem, OR

Jan. 16, 2024

Chair Patterson, Vice Chair Bailey, and members of the board,

On behalf of the Chronic Disease Coalition, thank you for the opportunity to provide our thoughts and feedback as the PDAB begins its work.

Headquartered in Portland, the Chronic Disease Coalition is a national nonprofit organization dedicated to raising the patient voice and perspective in healthcare policymaking. The coalition was founded in 2015 to advocate for people living with long-term or lifelong health conditions. Our patient advisors and partners represent common diseases (e.g., diabetes, kidney disease, arthritis), rare diseases (e.g., Guillain-Barré syndrome, hypoparathyroidism), and many other conditions whose scale and scope are still not understood.

As we represent the broadest possible spectrum of chronic disease patients, these comments are not about any specific medication. Rather, we simply want to urge you to recognize the relationship between drug costs, treatment development, and the cost to patients, and support reforms that directly benefit patients.

Without a doubt, chronic disease patients need their treatments to be more affordable. Unfortunately, elevating the price information of a small number of lifesaving drugs could affect the cost of other drugs in similar categories, as well as impact manufacturers' willingness and ability develop new treatments.

We know the PDAB's legislative mandate makes manufacturer prices a starting point in discussing affordability measures, but any given drug's list price usually doesn't align with patient costs. We must look at the full picture if we are going to make real progress on this issue. Other tried-and-true reforms have direct benefits to patients. For example, bans on copay accumulator programs help patients with their out-of-pocket costs, as do rebate pass-through mandates.

We also have an obligation to the next generation of patients to encourage the development of the next generation of treatments. We must recognize that all our innovations — for diseases known and unknown — come from the private sector. There is a pressing need to balance the need for affordable medication with the need to develop better treatments.

Oregon is looked to by other states as a model for PDAB policy and governance, but we need to do this work in the real context of the healthcare system and by focusing on reforms that immediately and directly benefit patients. We appreciate your public service as we all work toward the shared goal of more effective, more affordable health care.

Sincerely,

Nathaniel Brown
Director of Advocacy
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(971) 219.5561