

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 Europe¹. While a 2021 survey² 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.

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, 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.

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



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
nathaniel@chronicdiseasecoalition.org
(971) 219.5561

January 23, 2024

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

Re: Oregon Prescription Drug Affordability Board: Agenda and Meeting Materials Related to January 17, 2024 Meeting

Dear Members of the Oregon Prescription Drug Affordability Board:

The Pharmaceutical Research and Manufacturers of America (“PhRMA”) appreciates the opportunity to review and comment on the Board’s agenda and discussion materials (the “Meeting Materials”) for the Oregon Prescription Drug Affordability Board’s (“Board’s”) January 17, 2024 meeting.¹ PhRMA represents the country’s leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives.

We provide below our comments and concerns with respect to the Board’s January 17, 2024 Meeting Materials—including with respect to the timing of the public comment process contemplated by the Board for its meeting; lack of information regarding net prices; and certain other concerns. PhRMA appreciates the Board’s work to develop potential processes and materials with respect to implementation of its responsibilities under Oregon Senate Bill 844 (2021), as amended by Oregon Senate Bill 192 (2023) (collectively, the “PDAB Statute”). However, PhRMA has concerns on these and other topics, as outlined in greater detail below.²

I. Timing Concerns and Public Comment Process

PhRMA has concerns about the fairness and adequacy of the public comment process established by the Board for affordability reviews. Specifically, the Board has established a comment process where manufacturers must submit comments “for specific drugs under board review” by a published deadline at least twelve days prior to the Board meeting; at that meeting, the Board will review and discuss the affordability report for each drug under review, and may vote on each drug’s affordability.³ As a result of these deadlines, manufacturers will not have an opportunity to comment on and respond to any information published in the Board’s affordability review reports ahead of the Board’s vote on the

¹ See Meeting Materials, available at <https://dfr.oregon.gov/pdab/Documents/public-comment-instructions.pdf>.

² In filing this comment letter requesting changes to the Proposed Rules, PhRMA reserves all rights to legal arguments with respect to the Oregon PDAB statute. PhRMA also incorporates by reference all prior comment letters to the extent applicable.

³ See, e.g., PDAB, Public Comment Process for Prescription Drugs Under Board Review 1–2, available at <https://dfr.oregon.gov/pdab/Documents/public-comment-instructions.pdf> Patients, caregivers, and “other public commentors” have a separate deadline that follows the manufacturer deadline. For example, for the January 17, 2024 PDAB meeting, the deadline for manufacturer comments was January 5, while the deadline for comments by the general public was January 8, but the affordability reports for drugs to be discussed at the meeting were not published until January 10. The comment deadlines for that meeting were not changed when the meeting date was shifted to January 26, 2024.

affordability of each drug. If the Board takes a vote on the “affordability” of the drugs considered under these circumstances, manufacturers will have not had any chance to respond to the information on which that vote is based.

This lack of opportunity to comment is fundamentally at odds with the language and intent of the PDAB Statute, which states that the Board must “[p]rovide an opportunity for public comment at each open meeting of the board; and ... [p]rovide the public with the opportunity to submit written comments on any pending decision of the board.”⁴ Inherent in the statutory requirement to provide opportunity for testimonial and written comment is that such opportunity to comment be meaningful. Any other approach would be inconsistent with both the purpose of the statute and the basic requirements of due process.⁵

The Board should revise its process for public comment accordingly. All stakeholders should have an opportunity to comment on draft affordability reports before any affordability vote takes place for a given drug.

II. Gross Versus Net Pricing

PhRMA is also concerned that the Board’s Meeting Materials lack any information on rebates or net pricing and instead focus exclusively on gross pricing metrics. As PhRMA has repeatedly emphasized, the impact of rebate amounts on actual costs should not be dismissed or minimized in the Board’s determinations.⁶ In 2022 alone, manufacturers paid approximately \$256 billion in rebates and discounts that were not passed on to patients due to the independent decisions of plans and their pharmacy benefit managers (“PBMs”).⁷ Further, rebates lowered the price that plans paid for medicines by an average of 49%.⁸ As such, the price paid by plans on a specific medicine, as reported in the first two affordability reviews before the Board, does not reflect net cost and may lead to an inflated assumption of cost to the healthcare system.

Not only is the Board’s failure to consider net pricing likely to result in erroneous and misguided evaluations of costs for particular drugs under review, this oversight also encourages false comparisons. For example, the Board’s Meeting Materials describe differences between “subject drug[s]” and “therapeutic alternative[s]” while focusing exclusively on gross price metrics like Wholesale Acquisition Cost.⁹ Without consideration of the net cost of these drugs, this approach could result in fundamentally misleading evaluations regarding the true cost of the drugs and their purported alternatives—which in turn could result in inaccurate determinations of the affordability of the drugs under review.

⁴ PDAB Statute § 646A.693(12)(a)–(c).

⁵ See, e.g., *Joint Anti-Fascist Refugee Comm. v. McGrath*, 341 U.S. 123, 164 (1951) (Frankfurter, J., concurring) (explaining that due process prohibits pretextual or “sham” procedures).

⁶ See, e.g., Comment Letter from PhRMA to Board 2 (Oct. 15, 2023), August 23, 2023 Meeting Minutes, at 3.

⁷ Drug Channels Institute. The 2022 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers. March 2023.

⁸ IQVIA. Use of Medicines in the US.: Spending and Usage Trends and Outlook to 2026, April 2022.

⁹ Meeting Materials 17.

Moreover, the Board’s failure to address rebates and discounts is inconsistent with the Board’s own regulations—which contemplate consideration of the “estimated average monetary price concession, discount or rebate” to the extent practicable.¹⁰ The Board has provided no explanation for why it has not provided information about such estimated price concessions, discounts, or rebates. The administrative record therefore lacks any information to explain this apparent inconsistency with the Board’s own rules. Recognizing this inconsistency, the Board should revise its process to require that it addresses any factors enumerated in the statute that it did not consider during the affordability review for a particular drug.¹¹

* * *

We thank you again for this opportunity to provide comments and feedback, and for your consideration of our concerns. Although PhRMA has concerns with the Meeting Materials, we stand ready to be a constructive partner in this dialogue. Please contact dmcgrew@phrma.org with any questions.

Sincerely,



Dharia McGrew, PhD
Director, State Policy



Merlin Brittenham
Assistant General Counsel, Law

¹⁰ OAR § 925-200-0020(1)(d).

¹¹ See, e.g., ORS § 646A.694(1)(d).



OREGON STATE PHARMACY ASSOCIATION

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(503) 582-9055 • www.oregonpharmacy.org • info@oregonpharmacy.org

January 22, 2024

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

Dear Chair Patterson and members of the board:

During the December PDAB meeting, members of the board and staff commented on Rep. Nancy Nathanson's Pharmacy Benefit Manager (PBM) bill that would be proposed during the 2024 legislative session. We are asking you to **please support HB 4149!**

In 2023 alone, Oregon had 36 pharmacies close. Two more have already announced they will close later this month. Following the release of the [Oregon Secretary of State's audit on PBMs](#) in August, the Oregon Health Authority recommended that the state "should enact legislation that focuses on patient and pharmacy protections and increasing transparency in the prescription drug supply chain."

If this PBM bill does not pass, more pharmacies will close, truly. This will add to the already congested workload pharmacies have, since the remaining pharmacies have had to pick up the covered lives for those pharmacies that are closing. We already have a significant problem with patient pharmacy access; their prescriptions have to be filled somewhere.

Real-time patient access matters to parents when their child has strep throat, to seniors who rely on personalized attention and medication counseling, and to every Oregonian in need of vaccines to fight communicable diseases.

Here is a breakdown of policies within HB 4149 (2024), should it pass into law:

- PBMs must become licensed in the state of Oregon.
- DCBS will assign staff devoted to enforcing and arbitrating PBM infractions.
- Pharmacies will have enforceable protection against overburdensome audits.
- PBMs may not retaliate or threaten retaliation against pharmacists.
- Patients can choose which pharmacy they'd like to go to, regardless of plan.
- Adjudication fees are eliminated and additional transparency measures set.
- PBM contracts are subject to DCBS scrutiny, along with any amendments.
- Prescription payments under the medical assistance program are unchanged.
- Pharmacies and health systems see meaningful, modest 340B protections.
- Pharmacies paid a minimum dispensing fee of \$10, to be adjusted in rule by 2026.

We still have significant concerns with the Upper Payment Limit (UPL) topics of SB 844 and SB 192 of the Prescription Drug Affordability Board since that has not been resolved, yet. 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.***"

Leading Pharmacy, Advancing Healthcare



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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 further and ongoing 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, "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 following the desperately needed changes listed above. 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>