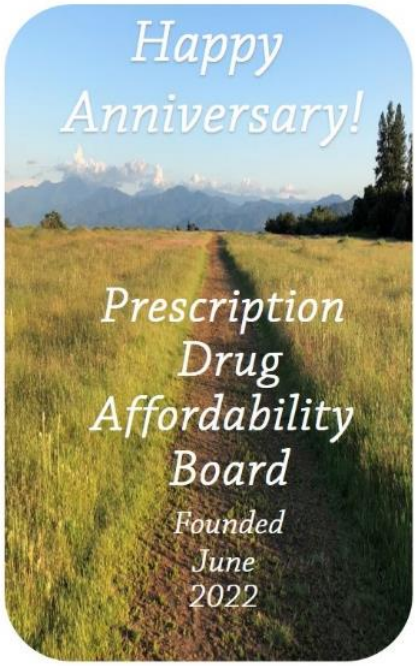
Oregon Prescription Drug Affordability Board

THE QUARTERLY

# PDAB celebrates its one-year anniversary





Akil Patterson


Shelley Bailey


Richard Bruno


Amy Burns


Daniel Hartung


Robert Judge


John Murray


Rebecca Spain

The Prescription Drug Affordability Board (PDAB) is celebrating its first anniversary by reflecting on all it has accomplished in the past 12 months. The highlights include:

- Creating an affordability review rule to help guide the board's selection of nine drugs that are the least affordable for Oregonians.
- Providing five recommendations to the Oregon Legislature of ways to relieve the burden of high priced prescription drugs for Oregonians. These recommendations evolved into Senate Bill 192, which passed the Senate and House.
- Producing three reports for the Legislature to explain why prescription drugs have become unaffordable and what can be done about it.

"This past year, we launched the board, selected our chair and vice chair, and began the work of creating and submitting our first reports," PDAB Chairperson Akil Patterson said. "The task of informing the public on the process of creating a system for rule setting and narrowing the board's scope of work was critical. We look forward to continuing work on this process in the months to come."

Following final passage of PDAB's rules for reviewing drug affordability, the board can go back to the Legislature and explain the importance of being able to understand how the supply chain affects the cost of prescription drugs to consumers.

"Our board will continue to be an advocate for the people of Oregon, and we will focus on what we have coined 'solution-based presentations,' where we expect and demand that all partners come to the table with reasonable solutions to address some of our hardest questions," Patterson added. "Most importantly, the questions include 'Why are life-saving medications priced so high?' and 'Where can we help everyday Oregonians save money on life-saving medications without negatively impacting the lives and families of those who sell, manufacture, and create these medications?'"

PDAB has met 14 times since it was launched in June 2022. Its members are made up of volunteers who take time out of their professions as doctors, professors, pharmacists, business leaders, researchers, and advocates.

# PDAB member profiles

**What or who inspired you to go into the medical field?**

I loved biology and neuroscience in college and wanted a "helping" career. So I looked at medicine as a way to combine those interests. Sure enough, I was most drawn to neurology during medical school and continued my training from there.

*Dr. Rebecca Spain is a leading researcher in the study of treatments for multiple sclerosis at OHSU and Veteran Affairs in Portland.*

**As a member of the OHSU Brain Institute, you are leading a five-year study on the effects of lipoic acid on multiple sclerosis (MS). What is lipoic acid, and what led you to research it as a possible benefit for MS patients?**

Lipoic acid is an antioxidant made by our own bodies and found in foods. It is a popular over-the-counter supplement. Because oxidative stress is part of the damage to the brain and spinal cord in multiple sclerosis (MS), my mentor, Dr. Dennis Bourdette, started studying lipoic acid in the mouse model of MS. I continued the investigation of lipoic acid in clinical trials involving people with progressive MS, a form of MS that has few effective treatments. These trials are supported by the U.S. Department of Veterans Affairs, National MS Society, and MS Society of Canada.

## PDAB Board Member Dr. Rebecca Spain

Rebecca Spain, MD, MSPH, FAAN, is the associate director of clinical care for the Veterans Affairs (VA) Multiple Sclerosis (MS) Centers of Excellence-West, regional director for the VA Portland Health Care System (HCS), and an associate professor of neurology at Oregon Health & Science University (OHSU). She is a researcher with the OHSU Brain Institute.

She received her medical doctorate degree from Case Western Reserve University in 2002. After her medical internship at Brown University, she completed her neurology residency at Thomas Jefferson University in Philadelphia. She continued at Jefferson for a two-year MS fellowship studying the effects of MS on the retina of the eye and obtained a master's degree in public health.

She joined the clinical faculty at the VA Portland HCS and OHSU in 2008. Her research focuses on studying and treating progressive forms of MS with an emphasis on wellness approaches.

Dr. Spain joined PDAB in June 2022.

## Dr. Rebecca Spain continued

**What have you and your research team learned so far?**
The first clinical trial involving 51 participants showed that those taking lipoic acid had less atrophy, or shrinking, of the brain indicating a neuroprotective effect. Based on this, I am now conducting a multi-center clinical trial involving 115 people with progressive MS at 10 U.S. sites and one in Canada. We want to see if lipoic acid, in addition to neuroprotection, will also help with walking function. We will find out the results of the study in early 2024.

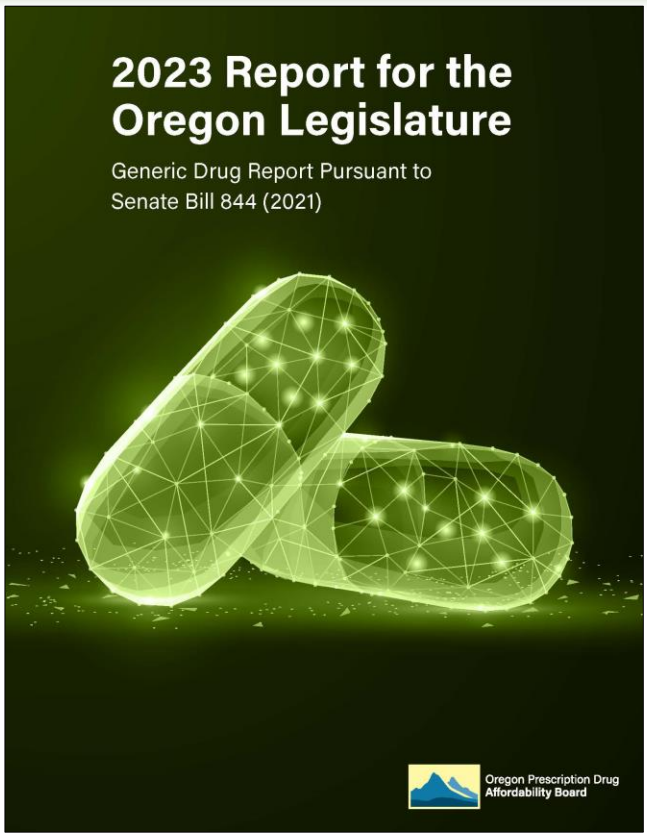
**What has been most significant so far in your work as associate director of clinical care for the Multiple Sclerosis Centers of Excellence (MSCoE) with Veterans Affairs (VA)?**
My work with the VA MSCoE is more like a public health job as it allows me to make decisions and create programs that will reach all 20,000 veterans with MS receiving care in the VA system. I love it when I write an article about a new MS medication, or how to manage an MS symptom, and I get a message from a patient or provider telling me they learned something new that really helped.

**Why is your work on the Prescription Drug Affordability Board important to you?**
MS drugs are some of the most expensive out there, and I see firsthand the irreversible damage that comes from missing MS medications as direct or indirect consequences of their costs. We've also learned that just having more MS drugs and even generic versions don't bring the costs down. My goals on the PDAB board are to help bring medication cost relief to Oregonians, and also to shine a spotlight on a system that isn't serving the patients and their families who need it most.

**What do you enjoy doing in your free time?**
I love playing tennis, listening to audiobooks, and spending time with my family and golden doodle.

Learn more about Dr. Spain's work:

- "Multiple sclerosis: antioxidant may slow disease progression," Medical News Today.
- "Aerobic exercise improves fitness and cognition in relapsing remitting multiple sclerosis," Neurology.
- "Approach to symptom management in multiple sclerosis with a focus on wellness," National Center for Biotechnology Information.
- Brain Institute at Oregon Health & Science University (OHSU)
- "Rebecca Spain, MD: transforming MS treatment," OHSU Foundation.




# PDAB publishes the 2023 generic drug report

PDAB published its second generic drug report and presented it to the Oregon Legislature in June.

The board devoted a portion of the report to biologics and biosimilars and their role in providing more affordable treatment options for patients. Biologics are drugs derived from living systems and have a complex manufacturing process. Biosimilars are less costly to manufacture, can be used interchangeably with biologics, and are more affordable. Learn more on Pages 12-15 of the report.

The report is a requirement of Senate Bill 844, the board's founding legislation. Board members contributed their expertise from their areas of specialty. The report is available online.

# Legislature approves Rx bill

The Oregon Senate and House approved Senate Bill 192. The bill that advances PDAB's efforts to curb high drug costs will go to the governor for signing into law. Under the bill, PDAB would develop a plan to establish upper payment limits (UPL), or price controls, for some of the most unaffordable prescription drugs in Oregon. The bill will also change the board's three alternates to full members, effective in September.

"We believe taking the time over the next year to engage stakeholders on UPL methodologies, resources needed, how UPLs would be implemented and enforced for PEBB/OEBB-covered lives, other state health benefit programs, and persons with employee-sponsored or commercially purchased health care insurance, will allow us to bring back a plan and pathway that will create public value for Oregonians and help address drug affordability in our state in the most meaningful and inclusive way possible," Ralph Magrish, executive director, told the House Committee on Rules on June 22.

# Board passes Rx drug affordability review rules

PDAB approved its affordability review rules on May 17. The rules guide board review of high-priced prescription drugs. The rule informs PDAB on the costs of prescription drugs by providing criteria for reviewing information from drug manufacturers, health insurance carriers, pharmacy benefit managers, and other sources. Oregon law requires the board to identify nine prescription drugs and at least one insulin product that may create affordability challenges for health care systems or patients in Oregon. The board will present this list to the Oregon Legislature in December.

For the affordability review rule, a public hearing was held June 22, with public comments accepted through June 29. The board is scheduled to approve the final rule on July 19, effective Aug. 1, 2023.

# Jane Horvath tutors Oregon House committee

Jane Horvath, of Horvath Health Policy, spoke to the Oregon House Committee on Behavioral Health and Health Care on May 24 about why prescription drugs cost so much and what states can do about it.


*Jane Horvath presented this slide about rising drug prices.*

She said the average launch price of new chronic illness medicines jumped from $2,115 to $180,000 between 2017 and 2021. New cancer medicines rose 53 percent to $283,000 in 2022. The median launch price for all new medicines (chronic illness, rare disease, cancer) was $257,000 in 2022. Prescription drug costs consume 23 percent of health care premiums. State taxes support some or all of the pharmacy benefits for 25 percent to 35 percent of residents in many states. (Refer to the footnotes in Horvath's testimony.)

Furthermore, Horvath said costs to bring drugs to market have declined but prices still skyrocket. Research and development costs are lower ($2 billion per drug today, down from $2.7 billion per drug in 2015), while the success rate is higher, as 12 out of 100 prescription drugs made it to market compared to 10 out of 100 in 2015. She suggested the following policies that states could pursue to "unwind the dysfunctional pharmaceutical marketplace to better serve patients, the health care system, and even manufacturers."

- Transparency on costs and discounts. The current system is built on secrecy that allows anti-consumer, anti-competitive behavior to thrive, she said. The Oregon drug price transparency law provides some important transparency.
- Transparent prices should move through the supply chain to the point of service and to the consumer.
- Rate setting to establish what consumers will pay for certain high-cost drugs, particularly since there are now market signals that favor increased launch prices.

Read Jane Horvath's letter. View the presentation slides. Watch the recorded hearing.

**JANE HORVATH**, a paid consultant with the Oregon Prescription Drug Affordability Board, has worked with states on prescription drug costs for many years. She represented the National Association of Medicaid Directors when the Medicaid rebate program was created. She served as a staff member on the U.S. Senate Committee on Finance, as deputy assistant secretary for legislation in the U.S. Health and Human Services Department, worked in the pharmaceutical industry for more than a decade, and worked for the National Academy for State Health Policy to help develop drug affordability board legislation. Her work is funded by foundations, including Arnold Ventures.

# Rx Classroom

Board members heard two presentations during board meetings in the second quarter of 2023 to increase their understanding of pharmaceutical trends. Below is a summary.

**Sarah Emond, EVP and COO, Institute for Clinical and Economic Review (ICER),** gave a presentation in April about the nonprofit organization, independent of industry, doing health technology assessments. ICER does analyses of new drugs, looking at comparative clinical effectiveness, and whether price increases are supported by new evidence. She provided a list of ICER funding sources. She provided a link to a recent paper about using health technology assessments to advance health equity. ICER has a contract with the Oregon PDAB to assist with analysis as the board begins its affordability review process.

Oregon law prohibits PDAB from using quality-adjusted life years (QALY) when the board conducts affordability reviews. Emond told board members ICER worked with the disability community to develop an alternative metric to ensure ICER is valuing life extension the same for every patient, regardless of disability or status. The equal value of life years gained (evLYG) metric is available in every ICER report and can be used to help know what a fair price is for a new medicine. All of ICER reports are publicly available. Furthermore, ICER will evaluate clinical trial diversity and provide a rating for how well the clinical trial did in recruiting and studying the drug in a population that matches the prevalence for the disease. ICER will use the Health Improvement Distribution Index to estimate the effects a new treatment could have in addressing overall health disparities.
View the board presentation on Pages 7-19.

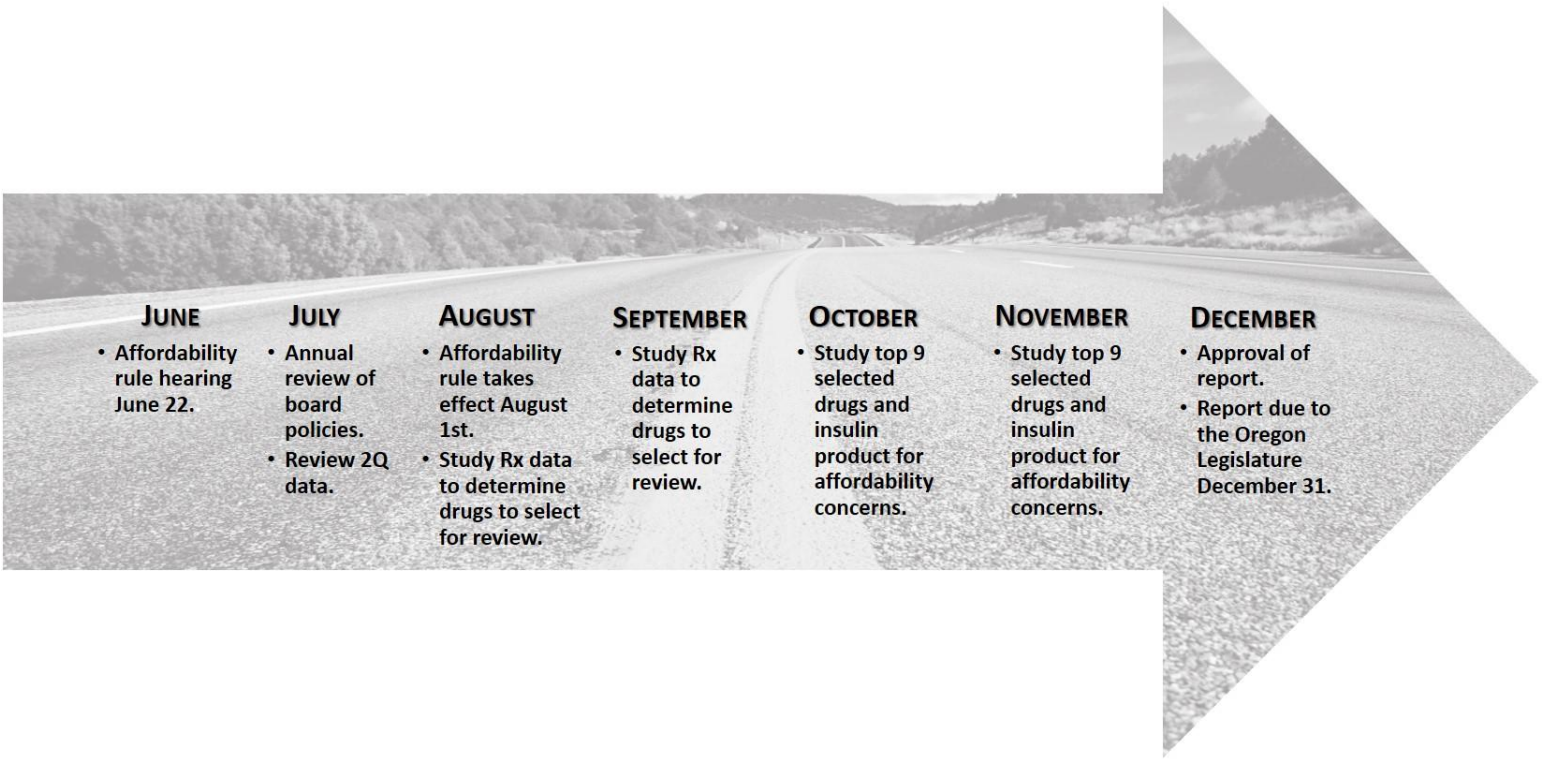
**Sean Dickson, senior vice president of pharmaceutical policy and strategy, America's Health Insurance Plans (AHIP),** gave a presentation in May from the insurance carrier perspective on high drug costs. He provided these recommendations: accelerate the availability of biosimilars, reform the system for provider-acquired drugs, and address drug manufacturers' abuse of charitable structures. Reforming the system for provider-acquired drugs would mean having the drugs delivered to the hospital by a specialty pharmacy. This will bring about a cost savings by avoiding hospital markups on the drugs, which can be as high as 120 percent. By comparison, physician-owned offices typically markup drugs 8 percent to 10 percent. He cited an AHIP study comparing reimbursement amounts for hospitals and independent provider offices.

He talked about "pay for delay," the practice of brand-name manufacturers paying generic companies to delay production when patents expire. Patents create a monopoly, which increases the price of the prescription drug. He said one challenge of taking on the pay-for-delay practice is manufacturers have found ways to achieve the same deals without using the historical structure. For example, seeking approval for a generic and biosimilar from the Federal Drug Administration (FDA) can be costly, with many barriers. These barriers encourage the use of pay-for-delay deals. One of the reasons the generic manufacturer will engage in this pay-for-delay process is because of the high litigation cost for getting the drug approved and patents dismissed. He said it is important to address the underlying incentives for why those strategies are being used.
View the presentation on Pages 9-22.

# Board roadmap: Setting the course for 2023

PDAB is looking down the road to prepare for the next stage of fulfilling the board's mission of making prescription drugs more affordable for Oregonians. The board roadmap below outlines steps to accomplish each month for the remainder of 2023, ending with a report due to the Oregon Legislature by Dec. 31, 2023. The report will discuss price trends, prescription drug reviews, and board recommendations, and ways to help curb the rising cost of prescription drugs in Oregon.

To follow the board's progress, sign up to receive board meeting agendas, which are posted to the website two weeks before the meetings. Meeting materials are posted to the website one week before the meeting. Sign up to receive email notifications about agendas and materials. Another good way to follow the board's route is to attend the monthly board meetings, which are held online using Zoomgov. Register here for the July 19 board meeting. Register for all the remaining 2023 board meetings on the board calendar page.



# 2023 CALENDAR

## Prescription Drug Affordability Board

**Register for Zoomgov meetings**

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|---|---|---|
| Meeting 1 | Wednesday, January 18 | 9:30 – 11:30 a.m. |
| Meeting 2 | Wednesday, February 15 | 9:30 – 11:30 a.m. |
| Meeting 3 | Wednesday, March 15 | 9:30 – 11:30 a.m. |
| Meeting 4 | Wednesday, April 19 | 9:30 – 11:30 a.m. |
| Meeting 5 | Wednesday, May 17 | 9:30 – 11:30 a.m. |
| Meeting 6 | Wednesday, June 21 | 9:30 – 11:30 a.m. |
| Meeting 7 | Wednesday, July 19 | 9:30 – 11:30 a.m. |
| Meeting 8 | Wednesday, August 23 | 9:30 – 11:30 a.m. |
| Meeting 9 | Wednesday, September 20 | 9:30 – 11:30 a.m. |
| Meeting 10 | Wednesday, October 18 | 9:30 – 11:30 a.m. |
| Meeting 11 | Wednesday, November 15 | 9:30 – 11:30 a.m. |
| Meeting 12 | Wednesday, December 13 | 9:30 – 11:30 a.m. |