October 30, 2024

Ms. Shelley Bailey, MBA
Chair, Oregon Prescription Drug Affordability Board
Department of Consumer and Business Services
350 Winter Street NE
Salem, OR 97309-0405

Mr. Ralph Magrish,
Executive Director, Oregon Prescription Drug Affordability Board
Department of Consumer and Business Services
350 Winter Street NE
Salem, OR 97309-0405

Dear Chair Bailey and Mr. Magrish:

We are writing as patients, people with disabilities, caregivers and their representative organizations to express our deep concerns about the Prescription Drug Affordability Board's (PDAB) work and its alignment with state and federal law. While we are relieved to hear that the PDAB is considering recommendations to the legislature to better support engagement of patients and people with disabilities, we remain concerned about the implications for access and affordability, such as the potential for dispensing fees to be passed on to patients. Our concerns are amplified by the Board's conversation around the potential use of cost effectiveness analyses, contrary to the state and federal laws that bar use of discriminatory value assessments in reimbursement and coverage decisions.

During the October 16, 2024 meeting of the PDAB, a Board member asked whether the use of value assessments would be permissible. The response was a resounding yes, with the caveat that the quality-adjusted life year (QALY) could not be considered. Specifically, the work of the Institute for Clinical and Economic Review (ICER) was mentioned, and the use of the equal value of life year gained (evLYG) measure of cost effectiveness. It was stated that ICER and evLYGs were permitted for use in the PDAB's decisions.

Since creation of the PDAB, patients and people with disabilities have shared their opposition to the Board's use of biased and discriminatory value assessments, including QALYs and evLYGs. When the PDAB was created, it was communicated to patient and disability advocates that the language in the statute would prevent the Board from considering these types of measures that devalue people with disabilities, including patients with serious chronic conditions. At the time, it was not transparent that the language in the statute was developed by ICER and therefore intended to have a loophole for consideration of the evLYG. We do not interpret the language as allowing for use of ICER's evLYG measure, which is developed using the same inputs as the QALY. We have shared with the Board our concerns about the involvement of PORTAL Research and OHSU, entities strongly aligned with ICER with the same funders as ICER. As you can imagine, the recent Board conversation only serves to entrench our distrust of a process that views entities supporting the use of QALYs and similar measures as its trusted advisors.

Not only are QALYs and similar measures barred from use by federal law, but they are also barred by state law. Federal regulations governing Section 504 of the Rehabilitation Act bar health care decisions made using measures that discount gains in life expectancy under § 84.57, as well as

methods of utility weight generation used in a way that discriminates under § 84.56's prohibition of discrimination based on biases or stereotypes about a patient's disability. In fact, HHS interpreted § 84.57 to be broader than section 1182 of the Affordable Care Act which bars the use of QALYs and similar measures in Medicare coverage and reimbursement decisions.

Also, the state legislature passed SB 1508 barring consideration of a quality of life in general measure, either directly or by considering a source that relies on a quality of life in general measure, in decisions related to the provision of and payments for health services. This language supplements the language in the PDAB law, providing a broader scope for the ban on use of discriminatory value assessments, closing any loopholes that be perceived in the PDAB law barring use of QALYs and similar measures. For example, SB 1508 clearly encompasses the evLYG which devalues disabled lives the same as the QALY in expected life years and uses the same health utilities that rely on biases and stereotypes from public surveys. It is contrary to state law to reference evLYG, QALY or related ICER studies.

Simply put, there is no one-size-fits-all measure of cost effectiveness that should be used as a benchmark for value. It is important for the PDAB to understand the alternative measures that it may be considering, including their limitations and tradeoffs. Their use and potential for use should be disclosed to the public and allow for patients and people with disabilities to share perspectives on the quality of the measure and its impact on health equity.

It has been a source of great frustration for patients and people with disabilities that ICER views the QALY as the gold standard for valuing health care. The fact that the PDAB views ICER and entities that are aligned with ICER's methodologies as credible sources will taint the work of the PDAB and our ability to trust its stated intentions to help patients. It will be essential for the PDAB to disclose the evidence on which it is relying so that it may be held accountable to the law's restrictions on use of QALYs and similar measures, as well as to the expectation that it is relying on high quality evidence.

Thank you for your consideration. We look forward to the PDAB clarifying if and how it will use cost effectiveness analyses or value assessments, how it will ensure any policy recommendations put forward to the legislature do not increase cost for patients, as well as how it will value input from patients and people with disabilities.

Sincerely,

ADAP Advocacy
Aimed Alliance
Answer2Cancer Inc.
Biomarker Collaborative
Cancer Support Community
Caring Ambassadors Program
Center for Autism and Related Disorders
Community Access National Network
Community Liver Alliance
Depression and Bipolar Support Alliance (DBSA)
Disability Rights California
Disablity Rights Oregon

Epilepsy Foundation America
Exon 20 Group
HIV + Hepatitis Policy Institute
ICAN, International Cancer Advocacy Network
Lupus and Allied Diseases Association, Inc.
MET Crusaders
National Infusion Center Association (NICA)
Pacific Northwest Bleeding Disorders
Partnership to Improve Patient Care
PDL1 Amplifieds
PlusInc
The Bonnell Foundation
The Coelho Center for Disability Law, Policy and Innovation
The Hepatitis C Mentor and Support Group, Inc.
United Mitochondrial Disease Foundation

Individuals in Support
Paul Terdal
Health Hats
jacki gethner

cc: Governor Kotek
Members of the Oregon Legislature
TK Keen, DCBS

National
Multiple Sclerosis
Society

November 1, 2024

Oregon Division of Financial Regulation
Oregon Prescription Drug Affordability Board
350 Winter St. SE
Salem, OR 97309

RE: National Multiple Sclerosis Society, policy comments

Dear Members of the Oregon Prescription Drug Affordability Board:

Thank you for your continued engagement with all stakeholders and for focusing on the patient's perspective. The National Multiple Sclerosis Society (Society) appreciates the Prescription Drug Affordability Board's (Board) leadership and investigation into the high cost of prescription medications. We encourage the Board to continue its review of all practices that limit access to needed life-changing therapies and increase the price that patients pay for those therapies.

Multiple sclerosis (MS) is an unpredictable, often disabling, disease of the central nervous system, which interrupts the flow of information within the brain and between the brain and the body. Symptoms range from numbness and tingling to blindness and paralysis. The progression, severity, and specific symptoms of MS in any one person cannot yet be predicted, but advances in research and treatment are moving us closer to a world free of MS. The Society works to cure MS while empowering people affected by MS to live their best lives. To fulfill this mission, we fund cutting-edge research, drive change through advocacy, facilitate professional education, collaborate with MS organizations around the world, and provide services designed to help people affected by MS move their lives forward.

Costs of living with MS

People with MS have a variety of healthcare needs including, but not limited to, addressing neurological symptoms, emotional and psychological issues, rehabilitation therapies to improve and maintain function and independence, and long-term care. These needs vary dramatically from person to person and can change year-to-year as the disease progresses.

MS is a highly expensive disease, with the average total cost of living with MS calculated at $88,487 per year[1]. MS may impact one's ability to work and can generate steep out-of-pocket costs related to medical care, rehabilitation, home & auto modifications, and more. For individuals with MS, medical costs are an average of $65,612 more than for individuals who do not live with this disease. Disease-modifying treatments (DMTs) are the single largest component of these medical costs. As of February 2024, the median annual brand price of MS DMTs was more than $107,000. Five out of

[1] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9109149/

National
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Society

seven of the DMTs that have been on the market for at least 13 years are priced at over $100,000 annually and continue to see regular price increases.

Public input and meeting processes
The Society appreciates the efforts in public transparency and accountability that the Oregon Board has demonstrated since its establishment. The Board has made their meetings accessible to all Oregonians via online broadcasts and shared materials, as well as by providing multiple forms and points of outreach to interested and concerned stakeholders. These initial efforts should be recognized, applauded, and built upon for continued success. However, we strongly suggest the agenda packet and other materials be posted in a timelier manner, allowing for proper review by both the public and interested parties. Providing the full agenda packet at least two weeks in advance of all meetings would greatly benefit and increase stakeholder engagement and participation.

Stakeholder participation
Robust public participation from patients, patient groups, and other direct contact stakeholders is key to understanding the true impact of the high cost of prescription drugs. The Society appreciates the Board's continued outreach to patient groups and other stakeholders and highlights the recommendations from the October 16 meeting Agenda Packet regarding the "…desire to establish an advisory committee or council that includes representatives of the constituent community including patients, providers, caregivers, and others…" The Society supports outreach and inclusion of patients and others with direct, lived experience regarding the prescription drug under consideration. The Society recommends the Board enact a more formalized process to include the patient voice in all discussions and deliberations moving forward.

Upper payment limits
The Society maintains its support for policies related to upper payment limits (UPLs). The Society understands the complex nature of these policy discussions and therefore we appreciate the flexibility highlighted during the Board discussions.

The Society supports Upper Payment Limits and looks forward to the Boards robust discussions around any prescription drugs selected for study. The Society views UPLs as having the potential to lower out-of-pocket costs for patients by directly addressing the dollar cost of prescription medications. High out-of-pocket costs are typically due to co-insurance, which is when the patient must pay a percentage of the wholesale acquisition cost (WAC), or list price, as opposed to a flat copay amount. This is especially true for MS DMTs. A lower UPL would in turn create lower out-of-pocket costs for those who must pay co-insurance.

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UPL resources needed for implementation
Depending on what mode or modes of UPL methodologies the board considers, additional resources may be necessary to ensure continued access to up to date data to confront any challenges identified in the review processes as well as to maintain continued public and stakeholder group participation. As previously referenced in this letter, the Society encourages the establishment of a formalized patient advisory group or council to provide direct lived experience and expertise from patients and patient groups.

Again, *the Society fully supports the study and establishment of UPLs* and continues to view UPLs as having the potential to lower out-of-pocket costs for patients by directly addressing the dollar cost of prescription medications. Any realized savings should be used to improve healthcare outcomes in the state.

Board proposed policy recommendations SB 844 "clean-up"
The Society offers the following comments on selected passages from the proposed policy recommendations presented at the October 2 meeting.

Up to nine drugs per year
The Society appreciates the Boards focus on affordability balanced with capacity. The Society supports giving the board more flexibility by removing the statutorily mandated "nine drugs a year" to the proposed language of "up to nine drugs a year".

Enhanced PBM and insurer reporting, maximizers and accumulators
The proposal to implement reporting on copay maximizer and accumulator programs should provide more data on how these programs may alter access to, and costs of, medications for Oregon consumers. The Society supports full reporting on both copay maximizer and copay accumulator programs. Additionally, the Society suggests the board look at the data around alternative funding programs or AFPs, as these are the third type of insurance program that change a plan's prescription spending.

Enhanced Patient Assistance Program Reporting
Patient Assistance Programs (PAPs) are vital for people living with MS in affording their medications. People living with MS often face a high deductible and cost-sharing burdens and are responsible for thousands of dollars in out-of-pocket costs—even with health insurance. Because patients are responsible for all their health care costs until their annual deductible is met, prolonging the deductible period by not counting copay assistance funds can put other medical needs financially out of reach. The Society recommends that all forms of third-party financial assistance be applied to a person's annual deductible and out-of-pocket costs/copays.

The National Multiple Sclerosis Society knows that the price of the medication is but one aspect of what makes access to these high-cost prescriptions out of reach for many people with MS and

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other conditions. The Society will continue to look at the entire healthcare system and encourages legislatures and boards like this to continue their work in addressing all aspects of the prescription drug supply chain that get between patients and their medications.

Respectfully,

Seth M. Greiner
Senior Manager, Advocacy
Seth.Greiner@NMSS.org

724 Columbia St. NW, Ste. 310 • Olympia, WA 98501 • PHRMA.ORG

November 1, 2024

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

Re: Comments On Draft Upper Payment Limit Study

Dear Members of the Oregon Prescription Drug Affordability Board:

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is writing in response to the Oregon Prescription Drug Affordability Board's (the "Board's") Senate Bill 192 Upper Payment Limit ("UPL") Draft Study ("Draft UPL Study"), recently discussed at its October 16, 2024 meeting.[1] PhRMA represents the country's leading innovative biopharmaceutical research companies, which are laser focused on developing innovative medicines that transform lives and create a healthier world. Together, we are fighting for solutions to ensure patients can access and afford medicines that prevent, treat and cure disease.

PhRMA continues to have concerns that any UPL scheme would set arbitrary limits on drug prices and ignore policy options that could lower the cost of medications for people in Oregon.[2] UPLs could restrict patient access to medicines, result in fewer new treatments for patients, and ultimately do not carry any guarantee that savings will be passed on to patients. These concerns are not addressed in the Draft UPL Study nor were they considered at the Board's recent October 16 meeting.[3] As discussed in greater detail below, PhRMA is particularly concerned that the Draft UPL Study oversimplifies the complexities and challenges of a UPL scheme, is based on a number of flawed and unsupported assumptions, and fails to demonstrate that the potential benefits of a UPL would outweigh the risks. PhRMA cautions the Board against moving forward with recommending the Draft UPL Study given the lack of meaningful consideration of these critical issues.[4]

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[1] *See* Draft UPL Study (October 16, 2024), *available at* https://dfr.oregon.gov/pdab/Documents/UPL-draft-report-20241009.pdf.

[2] A proposed UPL scheme would raise concerns under the Supremacy Clause of the U.S. Constitution, among other constitutional concerns. *See, e.g.*, *BIO v. District of Columbia*, 496 F.3d 1362 (2007); *Amgen v. Colo. Prescription Drug Affordability Rev. Bd.*, No. 1:24-cv-00810 (D. Colo. filed Mar. 22, 2024). In filing this comment letter, PhRMA reserves all rights to legal arguments with respect to Oregon Senate Bill 844 (2021), as amended by Oregon Senate Bill 192 (2023) (collectively, the "PDAB Statute"). PhRMA also incorporates by reference all prior comment letters to the extent applicable.

[3] As PhRMA has previously explained, we also have concerns regarding the limited timeframe that the Board has afforded for review of and comment on materials in advance of past meetings did not allow a full and adequate opportunity for meaningful participation by stakeholders on the important and complex issues before the Board, including the Draft UPL Study. *See, e.g.,* Letter from PhRMA to Board (Sept. 15, 2024), 2. *See also* Letter from PhRMA to Board (Oct. 12, 2024).

[4] PhRMA also emphasizes that if UPL authority is ultimately enacted by the Oregon Legislature, the Oregon Administrative Procedures Act ("APA") requires that a separate rulemaking be conducted to establish the specific definitions, standards, and processes that will govern any UPL processes. As detailed below, the Draft UPL Study fails to provide adequate specificity that stakeholders would need to understand how a UPL would be operationalized and would not be sufficient to implement a future UPL process. Even if granted the statutory authority to impose a UPL, the Board could not implement a UPL consistent with the requirements of the Oregon APA unless the Board first adopts comprehensive regulations governing each procedural step, factor, and methodology described in the Draft UPL Study through notice-and-comment rulemaking. A UPL process implemented without notice-and-comment rules providing consistent and transparent guidelines to govern it would undermine the ability of the Board to conduct its work in a manner that is "rational, principled, and fair, rather than ad hoc and arbitrary," as required under the Oregon APA. *Gordon v. Bd. of Parole & Post Prison Supervision*, 343 Or. 618, 633 (2007). *See also, e.g.*, Letter from PhRMA to Board (Feb. 11, 2023), 2 (providing a more detailed discussion of the Board's obligations under the APA).

I. The Draft UPL Study Oversimplifies the Complexities and Challenges of a UPL Scheme

PhRMA is very concerned that the Draft UPL Study fails to account for the significant complexities and challenges inherent in any UPL implementation process. Developing and implementing a process that would establish and monitor UPLs in the pharmaceutical supply chain in Oregon would require navigating a highly regulated and interdependent system involving a number of stakeholders and would present a wide range of legal, logistical, and market-based challenges. Instead of addressing these issues head-on, the Draft UPL Study provides an overly simplistic picture of how a UPL scheme might operate. In reality, UPL implementation would unavoidably involve challenges that are far more difficult to resolve. The Draft UPL Study drastically oversimplifies the complexity of the pharmaceutical payment and reimbursement system and the operational concerns posed by UPLs across a variety of supply chain entities, and we urge the Board to further revise its draft to directly address those issues.

Since the Board began its activities in 2022, PhRMA has raised significant administrative and operational concerns about the process and work of the Board, including with respect to implementation of UPLs.[5] The Board itself has recognized that these issues need additional time and consideration in order to be fully addressed, as evident by its decision on June 26, 2024 to postpone further affordability reviews until 2025 while it reviews and improves its affordability review criteria and methods.[6] The Board should, in the same manner, continue to work toward developing the Draft UPL Study in order to provide additional, and far more detailed, policy proposals regarding the adoption of a UPL plan before moving forward.

PhRMA highlights the following non-exhaustive examples regarding the Draft UPL Study's oversimplification of the complexities associated with developing and implementing a UPL scheme.

- **Draft UPL Methodologies Lack Sufficient Detail to Meaningfully Evaluate.** While the Draft UPL Study describes several potential methodologies to set a UPL, each presents its own set of challenges and concerns. Taken altogether, the discussion of potential approaches lacks key details on how each of these methods would be implemented and operationalized. The lack of specificity in the report inhibits the ability of stakeholders to meaningfully comment.[7] PhRMA reiterates previously shared concerns as to each specific method based on the limited information that the Board has provided:[8]

    - The "Net Cost" approach suggests setting UPLs based on the average net price after rebates and discounts, but it lacks clarity on which specific net price to reference, making it difficult to evaluate risks and implementation challenges.[9]
    - The "Reference Pricing to Existing Benchmarks" approach raises concerns about using benchmarks like the Maximum Fair Price under the Medicare Drug Price Negotiation Program, which is still in its early stages and won't take effect until 2026. It will take years to understand its effect on patient affordability and access. Additionally, using international drug prices as benchmarks is problematic due to the documented negative impact of government price setting

[5] PhRMA has filed 30 comment letters to date with the Oregon PDAB, detailing, among other things, our ongoing concerns with the Board's affordability review process and procedures and the Draft UPL Study. *See, e.g.*, Letter from PhRMA to Board (Sept. 15, 2024); Letter from PhRMA to Board (May 12, 2024); Letter from PhRMA to Board (Feb. 17, 2024); Letter from PhRMA to Board (Oct. 15, 2023).
[6] Board, June 26, 2024 meeting minutes, at 1, https://dfr.oregon.gov/pdab/Documents/20240626-PDAB-approved-minutes.pdf.
[7] *See* Letter from PhRMA to Board (Sept. 15, 2024), 2.
[8] PhRMA refers the Boards to its September 15 letter to the Board for additional information regarding its concerns with the UPL methods in the Draft UPL Study. *See* Letter from PhRMA to Board (Sept. 15, 2024), 3-6.
[9] Draft UPL Study, at 19.

on patient access in other countries.[10]

- The "Reference Pricing to Therapeutic Alternatives" approach could lead to inappropriate comparisons and pricing based on erroneous assumptions that might not account for patient needs or provider expertise.[11]
- The "Launch Price Indexing" approach lacks detail on how launch prices would be adjusted for inflation.[12]
- The "Percentage off of WAC" approach doesn't account for the rebates, discounts, and other price concessions already provided to the government, PBMs, and health insurers by drug manufacturers, potentially leading to arbitrarily set UPLs that could harm patient access.[13]
- The "Payer Return on Investment" approach is also concerning as it relies on pharmacoeconomic research and Cost Effectiveness Analyses which may use discriminatory metrics that should be avoided due to their potential to entrench health inequities.[14]
- The "Budget Impact-Based" approach is minimally detailed, making it hard to evaluate how the Board would determine the "given budget" that the UPL would be measured against, and how the Board would determine what percentage or threshold of the budget that the expenditure on a particular drug would be capped at.[15]

- **The Draft's Discussion Oversimplifies UPL Implementation and Operational Requirements.** The Draft UPL Study provides only a high level overview of potential approaches to implementing a UPL, which drastically oversimplifies the complexity and interconnected nature of the pharmaceutical supply chain.[16] For example, the Draft UPL Study notes that a UPL "will work best if the UPL applies statewide—to all purchases, payments, billings, and reimbursements of public and private purchasers, payers, and patients," but contradicts itself in the appendices to the Draft UPL Study by acknowledging that "[s]tates cannot require that Medicare B, nor C and D plans reimburse pharmacies and providers at the UPL" due to federal Medicare preemption.

  The process of establishing, implementing, and monitoring a UPL would carry significant administrative and operational burdens and concerns, which the Draft UPL Study fails to address. Results of the Board-directed stakeholder feedback report highlighted these concerns were present throughout the entire supply-chain. For instance, The August meeting materials highlight "A number of participants also expressed concerns regarding administrative burden, stating that adding a UPL to existing complex processes, in a highly regulated environment, would increase the level of effort required to serve patients, perform routine business operations, and manage contracts."[17] Additionally, those same meeting materials describe that "participants found it challenging to discuss UPL methodologies and frequently requested information regarding how a UPL would be developed and implemented."[18] The Board should not minimize the complexity of these issues and should recognize in the Draft UPL Study that they add significant complexity to UPL processes.

[10] *Id.*
[11] *Id.* at 20.
[12] *Id.*
[13] *Id.* at 20-21.
[14] *Id.* at 21.
[15] *Id.*
[16] *See, e.g.*, Draft UPL Study at 18, 55, 58.
[17] Board, August 21, 2024 meeting materials, at 27.
[18] *Id.*

The study similarly downplays the potential interplay between a UPL and the 340B program as well as broader market effects. The Oregon Primary Care Association testified in the Board's July meeting that a UPL would be "just not workable given the overlay of the federal [340B] program and how it works and was designed to work with federally qualified health centers and other covered entities."[19] The 340B program itself is already incredibly complex, and both the Government Accountability Office and the Health and Human Services Office of Inspector General have identified significant issues with diversion of 340B prescriptions to ineligible individuals and duplicate Medicaid and 340B discounts paid on the same unit of medicine despite statutory prohibitions.[20] Recent research as also found the 340B program increases costs for employer-sponsored health plans,[21] which can lower state income tax collections and increase costs for state and local government health plans.[22] It is crucial for the Board to be aware of these complexities and the potential for misdirection of 340B funds and further abuse.

- **The Board Cannot Reasonably Pursue Multiple Simultaneous UPL Approaches**. The Draft UPL Study contemplates that the Board "may want to specify several different approaches it would use as appropriate but maintain flexibility to use additional approaches when needed."[23] But the Draft UPL Study does not explain how could reasonably develop, implement, and select between multiple different approaches to UPL-setting, nor does that idea appear to be consistent with the complexity of developing and implementing even a single UPL-setting method. Although four states have enacted laws that would allow them to set a UPL for certain medicines, no state has implemented a UPL to date.[24]

  Further, the assumptions that the report makes about various methods of implementing UPL approaches underscore the lack of understanding of the complexity and interconnected nature of the pharmaceutical supply chain. For example, wholesalers and plans often have contracts that span entire regions, making restricting sales within a state operationally burdensome. In the pharmaceutical supply chain, retail drugs typically move from manufacturers to wholesalers (and to dispensers) throughout the United States based on WAC. Utilizing a different metric (for instance, a UPL) solely for Oregon would present significant complexities that the Board has not addressed. PhRMA encourages the board to seek more detailed input from supply chain stakeholders, including wholesalers, to better understand the complexity of the pharmaceutical supply chain and the potential impact of changes to business operations.[25]

- **Challenges Faced by Other States with UPL Authority.** While the Draft UPL Study references others states that have enacted laws that would allow for the setting of UPLs for certain medicines, it overlooks the challenges those states have faced in implementing their UPL regimes.[26] The policies for evaluating

[19] Board, July 24, 2024 meeting, testimony of Marty Carty, Oregon Primary Care Association, https://youtu.be/VntX-UHodJ0?si=0OkEM6_E3qQssuMg&t=7993.
[20] Drug Pricing Program: HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements. December 2020.; OIG. State Efforts to Exclude 340B Drugs from Medicaid Managed Care Rebates. June 2016; GAO. 340B Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement. January 2020.
[21] IQVIA. The Cost of the 340B Program Part 1: Self-insured Employers. 2024.
[22] North Carolina State Treasurer. Overcharged: State Employees, Cancer Drugs, and the 340B Drug Pricing Program. May 2024.
[23] Board, August 21, 2024 meeting materials, at 39.
[24] *See* Letter from PhRMA to Board, June 28, 2024, at 2.
[25] In addition, PhRMA is concerned that attempting to implement multiple UPL-setting approaches would cause the Board to improperly apply different methodologies across different drugs, resulting in arbitrary and capricious decision-making by the Board. Courts have consistently held that agency actions are arbitrary and capricious where they treat similarly situated entities or products differently without providing a reasonable justification for such differential treatment, or where they exhibit unexplained inconsistencies with the agency's prior decisions. *See, e.g.*, *Melody Music, Inc. v. FCC*, 345 F.2d 730, 733 (D.C. Cir. 1965).
[26] Draft UPL Study at 11-14.

affordability and establishing UPLs in these states have consistently lacked clear, specific, and meaningful standards.[27] For example, the policies incorporate extensive lists and categories of information and data sources that they must (or may) consider as part of the multi-step affordability review and UPL-setting process, but have been devoid of specific rules that explain *how* the implementing agencies would utilize such information in a consistent and balanced way to make informed assessments about questions of affordability and the need for a UPL.

- **The Draft UPL Study Does Not Address Diversion Concerns.** The Draft UPL Study downplays the significant diversion risks that implementation of a UPL would pose. For example, there is no mechanism described in the Draft UPL Study to limit access to UPL-priced drugs to entities that are statutorily authorized recipients. The Draft UPL Study references the Drug Supply Chain Security Act ("DSCSA"), suggesting that the DSCSA could be used to avoid diversion under a UPL framework.[28] Despite passage in 2013, the DSCSA has not yet been fully implemented. Furthermore, this reliance on the DSCA is misplaced as it incorrectly presumes that pricing information is included in the data tracked for drugs under the DSCSA. While the DSCSA is designed to track the distribution of pharmaceuticals to help enhance drug distribution security, it does not require the tracking and reporting of pricing data that would be needed to monitor for diversion under a UPL framework.[29] Relying on the DSCSA as a safeguard against diversion is impractical. PhRMA stresses that the Board should not underestimate the challenges associated with monitoring and policing diversion.

- **The Board Has Not Considered the Role of Manufacturer Rebates and PBMs.** The Draft UPL Study emphasizes that, "[a]ny conversation about the drug supply chain must recognize the influence of manufacturer-paid rebates on the distribution of drugs."[30] This characterization ignores the fact that negotiation of rebates between manufacturers and payers and their PBMs is a two-way agreement subject to market-driven forces and the relative leverage between the negotiating parties.

  As discussed at length in previous letters, manufacturers provide significant discounts, rebates, and other price concessions to PBMs and health plans, but many patients do not benefit directly from these discounts due to the refusal by insurance companies and their PBMs to pass these savings through to patients at the pharmacy counter. Concern about the influence of PBMs on the supply chain have been raised by Oregon,[31] Congress, and the Federal Trade Commission.[32] In 2023, Oregon's Secretary of State performed an audit of PBM practices in the state, finding that "there is growing public interest in assessing the role, value of, and significant power and influence held by third-party organizations known as pharmacy benefit managers."[33] The failure of the Draft UPL Study to account for these factors in its discussion of the supply chain demonstrates the lack of complexity in its analysis of how a UPL may impact them.

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[27] *See, e.g.*, Letter from PhRMA to Board (June 23, 2023); Letter from PhRMA to Washington PDAB (Apr. 11, 2024); Letter from PhRMA to Maryland PDAB (June 30, 2023); Letters from PhRMA to Colorado PDAB (Nov. 14, 2022) (regarding draft affordability review and UPL regulations).

[28] Draft UPL Study at 22.

[29] *See* Food and Drug Administration, DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs Guidance for Industry, at 2 (September 2023), https://www.fda.gov/media/171796/download.

[30] Draft UPL Study at 8.

[31] Oregon Health Authority, *Pharmacy Benefit Managers: Poor Accountability and Transparency Harm Medicaid Patients and Independent Pharmacies* (Aug. 2023).

[32] Press Release, Federal Trade Commission, FTC Launches Inquiry into Prescription Drug Middlemen Industry (June 7, 2022); Press Release, Federal Trade Commission, FTC Deepens Inquiry into Prescription Drug Middlemen (May 17, 2023),

[33] Oregon Health Authority, *Pharmacy Benefit Managers: Poor Accountability and Transparency Harm Medicaid Patients and Independent Pharmacies* (Aug. 2023).

II. The Draft UPL Study Relies on Flawed Assumptions Instead of Facts

As described below, the Draft UPL Study relies on a number of flawed assumptions, drawing broad conclusions without providing sufficient facts to support them. Instead, the report incorporates, without qualification, a limited number of sources, many of which also fail to cite research or other information that supports their assertions. PhRMA highlights the following non-exhaustive examples regarding the Draft UPL Study's unsupported assumptions regarding implementation of a UPL scheme:

- **Unfounded Assumptions of Supply Chain Behavior:** the Draft UPL Study is predicated upon assumptions regarding the behavior of various entities in the supply chain, contributing to the oversimplified view that a UPL would work neatly under the existing system.[34] For example, the Draft UPL Study notes that health plans and PBMs may voluntarily change key aspects of their business model based on agreement with the Board.[35] As stated in one of the appendices "[a] board should have *the agreement* of as many commercial and employer health plans as possible to modify their formularies to reflect the lower product cost (the UPL) pharmacies and other providers will charge. Plans should be *asked to reconsider* utilization tools applied to the drug product if those policies address cost rather than clinical issues." However, none of these changes to business models are required or incentivized and in fact recent research suggests health plans would do the exact opposite of what the Draft UPL study suggests. According to a payer expert that was surveyed about the Colorado PDAB, "Payers will not pass their savings (if any) onto individuals. It's not realistic and somebody will need to make up the differences," and in addition "utilization management will undoubtedly go up with UPLs [upper payment limits], whether for the drugs subjected to them or for competition."[36]

- **Assumptions Not Supported by Research:** in discussing the benefits of statewide UPLs, the report states that "UPLs should improve market function for prescription products that have a UPL."[37] But neither the appendix document nor the Draft UPL Study offers any additional background on the basis for this assumption, or for the other assumptions in the report regarding various aspects of the market, including patient access.[38] PhRMA notes that the report frequently relies on sources that are not peer-reviewed or validated. For example, much of the discussion of the draft UPL Approaches appears to reflect input from a single source that may provide a biased basis of information used to develop the UPL Study.

- **Insufficient Analysis of Available Data Sources:** The draft UPL Study notes in multiples places that granular, claims-level, or pharmacy-specific data may be required, but not readily available.[39] However, the study does not identify the specific sources from which the Board would acquire the data, whether they are available to the state, or what additional restrictions or limitations may apply to their use.[40] For example, the description of the "Reference Pricing to Therapeutic Alternatives" approach fails to specify

[34] *See, e.g.*, Draft UPL Study at 22 (explaining that "a statewide UPL is generally intended to be self-enforcing" because supply chain entities "have no incentive" not to enforce a UPL, without acknowledging the complexities of the various incentives facing such entities).
[35] *Id.* at 49.
[36] Partnership to Fight Chronic Disease, "Health Plans Predict: Implementing Upper Payment Limits May Alter Formularies And Benefit Design But Won't Reduce Patient Costs," March 2024.
[37] *See, e.g.*, Draft UPL Study at 28; Horvath Health Policy, Upper Payment Limits at 57 (2024).
[38] *Id.* at 57 (discussing changes that could or 'should' happen in the market, without sources to support these claims.).
[39] *See, e.g.*, Draft UPL Study at 29, 30.
[40] *Id.* at 19-22 (discussing possible data sources to "[c]onsider" using, while also noting drawbacks to such data).

how the Board would ascertain the prices of drugs that it determines can be used in place of the selected drug, despite the Board's previous difficulties in assessing pricing of therapeutic alternatives.[41]

The Board should not move forward with its Draft UPL Study without first analyzing what specific data would be needed and whether it may be available to the Board. PhRMA previously expressed similar concerns regarding the lack of specificity in data sources that the Board intended to use for affordability reviews.[42] The Board did not address that issue, and instead conducted several affordability reviews without a significant portion of the data that it was required to review under its statute and regulations.[43] The lack of data was one of the reasons that Board members voted to suspend affordability reviews in June 2024.[44] PhRMA once again asks the Board to clarify the exact sources of information that would be used for each UPL approach, and how the Board would verify the accuracy of such data.[45]

- **Data Quality Concerns:** the Draft UPL Study also fails to provide adequate processes and safeguards to verify the reliability of data used to support a potential UPL. The UPL-setting process, similar to the Board's affordability reviews, would be dependent on the accuracy and completeness of the information being relied upon in the Board's decision-making. Information bearing on the criteria for evaluating affordability or setting a UPL is likely to be drawn from a variety of sources, including reports from insurers, manufacturer data, and various other third-party sources. Certain sources of information may be unreliable or offer only a selective portion of the full picture relevant to the Board's selection of drugs for affordability review.

- **Inadequate Consideration of Resources Required for Implementation:** the Draft UPL Study does not meaningfully address or analyze the resources required to implement a UPL. While the Draft UPL Study characterizes UPLs as "self-enforcing," it nonetheless contains a lengthy list of regulatory authorities and investments by the state that would be necessary.[46] And while it acknowledges the significant resources that would be needed, it is limited to general statements without cost projections; further,

[41] *See* Ozempic Affordability Review updated (May 15, 2024), 12, https://dfr.oregon.gov/pdab/Documents/20240515-PDAB-document-package.pdf#page=5 (explaining that estimated net price for therapeutic alternatives "is not included due to lack of information in discounts, rebates, and other price adjustments"). The Draft UPL Study also discusses the possibility of using "[c]ommercial products" to "assist with determining the estimated impact and availability of rebates in the non-Medicaid space" but provides no further information regarding such products or the data underlying these estimations. Draft UPL Study at 22.

[42] Letter from PhRMA to Board (Oct. 15, 2023), 1-3.

[43] *See, e.g.*, Humulin R U-500 KwikPen Affordability Review - version 2, at 9-10 (Jan. 26, 2024), https://dfr.oregon.gov/pdab/Documents/Affordability-Review-Humulin-R-U-500-v2.pdf (acknowledging drawbacks of using package wholesale acquisition cost (WAC) as an indication of historic price trends for the drug and noting that "[n]o additional data or information was found or provided to reflect the relative financial effects of the prescription drug on broader health, medical, or social services costs, compared with therapeutic alternatives or no treatment" and "[n]o additional data or information was found or provided to quantify the total cost of the disease and the drug price offset"); Ozempic Affordability Review updated, at 12 (May 15, 2024), https://dfr.oregon.gov/pdab/Documents/20240515-PDAB-document-package.pdf#page=5 (explaining that estimated net price for therapeutic alternatives "is not included due to lack of information in discounts, rebates, and other price adjustments"); Trulicity Affordability Review updated, at 9 (May 15, 2024), https://dfr.oregon.gov/pdab/Documents/20240515-PDAB-document-package.pdf#page=42 (same). *See also* ORS § 646A.694(1)(f), (1)(g), (1)(j); OAR 925-200-0020(1)(j), (2)(i)(A), (2)(i)(B).

[44] Board member Robert Judge stating at the June 26th meeting "There are huge gaps … in the data that we have to make an informed decision on an affordability review that's consistent, and has consistent criteria for making a determination." *See* https://youtu.be/9z2VkDiR_XA?si=_W7reQ5nXVkmYc_P&t=926.

[45] PhRMA has consistently stressed in our comments that, under the Board's existing authority, it has not adequately addressed how it will maintain confidentiality of the materials it receives as part of its affordability reviews. Letter from PhRMA to Board (May 14, 2023), 5; Letter from PhRMA to Board (Apr. 16, 2023), 8; Letter from PhRMA to Board (June 20, 2022), 3-4. These concerns would be heightened if the Board were also given authority to establish UPLs, particularly if, as part of the UPL process, the Board sought to obtain sensitive financial or commercial information from additional stakeholders.

[46] Draft UPL Study at 22-23

the Draft UPL Study states that it would be premature to complete an analysis of the costs to implement a UPL.[47] As the Board is aware, it is required by SB 192 to provide the Oregon Legislature with an analysis of "the resources needed by the board to implement the plan."[48] The limited discussion of the resources needed to implement a UPL in Oregon is inconsistent with the Board's statutory direction. PhRMA asks the Board to revise its Draft UPL Study to provide a substantive analysis of the resources that would be needed to support UPL-setting activities.

III. The Draft UPL Study Fails to Demonstrate that Potential Savings from a UPL Outweigh the Substantial Risks

The Draft UPL Study fails to demonstrate how a UPL will generate savings, nor does it show that any savings would outweigh the potential risks associated with establishing and implementing a UPL in the state. This failure is the result of the many process concerns discussed above and underscores the lack of consideration given to numerous aspects of adopting a UPL. PhRMA urges the Board to revisit its draft analysis in order to objectively evaluate both the potential risks and benefits associated with UPL-setting.

PhRMA highlights the following non-exhaustive examples regarding the Draft UPL Study's failure to address the various considerations required to objectively and accurately assess the value of a UPL scheme.

- **Lack of Cost Savings for Patients:** PhRMA is concerned that the Draft UPL Study fails to demonstrate how a UPL would result in cost savings or otherwise benefit patients in Oregon. The UPL process described in the Draft UPL Study would focus on capping the prices set by the biopharmaceutical manufacturers and ignore the function of other stakeholders in determining what patients ultimately pay for medicines, including insurers, PBMs, wholesalers, and the government. The important role that these entities play in determining drug coverage and patient out-of-pocket costs seems to be overlooked by the Draft UPL Study. There is also no mechanism described in the Draft UPL Study to require that savings generated by the various UPL approaches that the Draft UPL Study would ultimately flow to Oregon patients. For example, the report acknowledges analyses suggesting that implementing a UPL could introduce costs or otherwise fail to generate savings,[49] but does not engage with these possibilities and largely ignores consideration of whether imposing UPLs would result in any patient benefits.[50] The fiscal modeling submitted by the Oregon Health Authority (OHA) in September's meeting materials projected that 90% of state employees would see no change in their prescription cost sharing with a UPL.[51] Furthermore, for the state Medicaid program, OHA's fiscal modeling found that there

[47] Draft UPL Study at 28.
[48] ORS 646A.685(1)(b).
[49] Draft UPL Study at 26-27 (discussing PEBB/OEBB analysis and modeling exercise undertaken by the Oregon Health Authority ["OHA"]) ("Potential savings and costs are indeterminate at this time … the most likely outcomes range from a cost savings of $18.7 million (price reduction exceeds existing rebates) to a combined increase of $12.1 million in plan spend (where the modest price reduction is less than existing rebates).")
[50] *See* Myers & Stauffer, Constituent Group Engagement Report Draft (Aug. 14, 2024), https://dfr.oregon.gov/pdab/Documents/OR-PDAB-UPL-Report-Draft-20240821.pdf.
[51] Board, "PDAB Upper Payment Limit (UPL) Analysis: Oregon Educators Benefit Board (OEBB) and the Public Employees' Benefit Board (PEBB) / Medicaid FFS and CCO," included in the Meeting Materials for the PDAB's Oct. 2, 2024 meeting, at 35-36. PhRMA analysis based on the model's statements that: "enrollment is based on average 2024 enrollment of 141,065 and 136,536 members for PEBB and OEBB respectively"; and that "For PEBB, future member cost share is set equal to current member cost share per unit … because all plans have a copay structure for prescription drug claims." OHA modeled 80% of OEBB member cost share would not change and "roughly 20 percent of OEBB members have a prescription drug plan based around coinsurance rather than copay. For those members, their cost will decrease with the cost of the drug." Taken together, the modeling assumes that 90% of state employees will not see changes to their member cost sharing.

would most likely be no reduction in costs to the state.[52]

- **Minimization of Stakeholder Concerns:** the Draft UPL Study consistently minimizes the areas of concern raised by stakeholders in the supply chain. While those concerns and limitations are acknowledged in the report,[53] the report does not discuss or respond to the concerns raised in the constituent listening sessions, and it underplays the risk of unintended consequences to the healthcare system.[54] For example, the report notes patient impact concerns centering on potential manufacturer responses as well as responses by PBMs or payers that would shift utilization to non-UPL drugs through formulary and benefit design, but the report never meaningfully addresses these concerns. Any cogent analysis of establishing a UPL scheme must confront such concerns and how they would have to be addressed.

  Additionally, the Draft UPL Study fails to address the impact that a UPL would have on pharmaceutical innovation. Implementing price controls would diminish the incentives for biopharmaceutical manufacturers to invest in and introduce new medicines and could limit the prescription drug options available to Oregon residents. There are a range of policy alternatives to UPLs that more directly and effectively address issues of affordability and access, while also better preserving incentives for innovation and investment in research and development of new and potentially transformative medicines.

* * *

On behalf of PhRMA and our member companies, thank you for consideration of our comments. Although PhRMA has concerns about the Draft UPL Study, 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
Sacramento, CA

Merlin Brittenham
Assistant General Counsel, Law
Washington, DC

[52] *Id.* at 34 ("For both Fee for Service (FFS) and Coordinated Care Organizations (CCO), the modeling assumed no changes to existing rebates. Both assumptions mean that actually attainable savings will be lower. Additionally, due to state and federal budget mechanics, OHA advised that reductions in cost from implementing a UPL would more likely be reinvested in other OHP services rather than directly reducing state costs.").
[53] Draft UPL Study at 16.
[54] Myers & Stauffer, Constituent Group Engagement Report Draft (Aug. 14, 2024).

Johnson & Johnson

Johnson & Johnson Health Care Systems, Inc.
1125 Bear Tavern Road
Titusville, NJ 08560

T +1-800-526-7736
jnj.com

Via Electronic Submission

November 12, 2024

Shelley Bailey
Board Chair
Oregon Prescription Drug Affordability Board
pdab@dcbs.oregon.gov

Dear Board Chair Bailey:

Johnson & Johnson writes to express concerns regarding the Report on Pharmacy Benefit Manager (PBM) Drug Price Transparency as presented to the Oregon Prescription Drug Affordability Board (the Board or OR PDAB) during the October 16, 2024 Board meeting. J&J respectfully submits a copy of the "2023 Johnson & Johnson Innovative Medicine U.S. Pricing Transparency Report" (the J&J Transparency Report). We urge the Board to **1) recommend policy solutions that would further increase transparency around practices of PBMs and their affiliated entities that increase costs and limit access for patients; and 2) recommend patient-centered solutions, such as requiring that PBM rebates and discounts be directly shared with patients at the pharmacy counter as an alternative to upper payment limits (UPLs).**[1]

During the October 16, 2024 meeting, OR PDAB staff presented information from the Drug Price Transparency Program (DPT) Report on data collected from PBMs. The DPT Report noted that 18 of 59 PBMs received over $287M in rebates and payments from manufacturers[2], of which they passed approximately $283 million to insurers and only $2.2 million (1 percent) to plan enrollees. The remaining 41 PBMs claimed they were exempt from reporting.

As reflected in the J&J Transparency Report, rebates, discounts, and fees have been increasing, net prices have been decreasing, and yet, patient out-of-pocket costs have continued to rise. This begs the question, where is this money going? We would like to highlight the following points in advance of the November 20th Board meeting:

- **Johnson & Johnson's rebates, discounts, and fees have risen significantly from 2016-2023, particularly for private insurers and PBMs, and our net prices have declined.** Between 2016 and 2023, rebates, discounts and fees to commercial insurers have grown eight times from $1.7B (2016) to $13.4B (2023). Nearly one-third of our discounts, rebates, and fees go to health insurers and PBMs. [3]

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[1] Johnson & Johnson, *2023 Johnson & Johnson Innovative Medicine U.S. Pricing Transparency Report*, https://transparencyreport.janssen.com/transparency-report-2023. Last visited October 30, 2024 [J&J 2023 Transparency Report].
[2] Oregon Prescription Drug Affordability Board, Agenda (Oct. 16, 2024), https://dfr.oregon.gov/pdab/Documents/20241016-PDAB-document-package.pdf.
[3] J&J 2023 Transparency Report, *supra* note 1.

- **Patients are not directly benefitting from lower net prices.** J&J's net prices have declined by nearly 20% over the past seven years, and yet, patients still face multiple access challenges based on their plans' benefit design.[4]

J&J urges the Board to take action that would further increase transparency around the practices of PBMs and their affiliated entities that increase costs and limit access for patients. For example, the DPT Report does not capture any vertical integration between the 18 PBMs and the insurers that received approximately $283 million in rebates. As the Federal Trade Commission noted in its recent Interim Staff Report, "[v]ertically integrated PBMs may have the ability and incentive to prefer their own affiliated businesses, which in turn can disadvantage unaffiliated pharmacies and increase prescription drug costs."[5] The DPT Report also does not appear to capture the administrative fees that PBMs retain. Yet, a recent Nephron Research report showed that PBMs are moving toward a model of collecting opaque fees from manufacturers, pharmacies, health insurers, and employers to avoid policymakers' efforts to enhance transparency.[6] Likewise, the OR PDAB Report does not reflect profits that PBMs capture through spread pricing, in which PBMs overcharge payers, underpay pharmacies, and retain the difference—a practice that PBMs will be required to report on in Oregon beginning in April 2025.[7]

Finally, while the DPT Report shows that PBMs pass 1 percent of their rebates on to patients, it does not capture how much PBMs are collecting from patients in turn. Research has shown that, on average, patients enrolled in plans with three or more tiers pay between 25 percent and 38 percent out of pocket for their prescription drugs.[8] Additionally, when in the plan's deductible phase, a patient pays 100 percent of prescription drug costs until the deductible is met. Conversely, during that time, PBMs pay zero percent of the prescription drug cost but still collect rebates, and in some cases, copay assistance, from manufacturers.

Although J&J acknowledges these challenges, we are steadfast in our commitment to supporting affordable access to our innovative therapies and lowering patient costs. We support patient-centered reforms that would:[9]

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[4] J&J 2023 Transparency Report, *supra* note 1.

[5] Federal Trade Commission, *Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies*, Interim Staff Report (July 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.

[6] Stephen J. Ubl, "New Analysis Shows PBMs Use Fees as a Profit Center," PhRMA (Sept. 18. 2023), https://phrma.org/Blog/New-analysis-shows-PBMs-use-fees-as-a-profit-center.

[7] OR HB 4149 (2024).

[8] KFF, *2023 Employer Health Benefit Survey* (Oct. 18, 2023), https://www.kff.org/report-section/ehbs-2023-section-9-prescription-drug-benefits/#:~:text=%5BFigure%209.6%5D.-,Among%20covered%20workers%20in%20plans%20with%20three%20or%20more%20tiers,tier%20drugs%20%5BFigure%209.6%5D.

[9] Janssen, The 2021 Janssen U.S. Pricing Transparency Report, https://transparencyreport.janssen.com/_document/the-2021-janssen-u-s-transparency-report?id=00000186-0e8d-da28-a1fe-9edd83aa0001 (last visited Nov. 7, 2024).

- **Require that PBM rebates and discounts be directly shared with patients at the pharmacy counter.**

- **Examine the use of utilization management tools (e.g., formulary exclusion lists, prior authorization, step therapy, and nonmedical switching) and evaluate how best to regulate them in the interest of patient access and reducing out-of-pocket costs.**

- **Prohibit diversion of patient cost-sharing assistance (i.e., copay accumulator programs and maximizer programs) to ensure payment made by or on behalf of patients counts towards their cost-sharing burden.**

J&J asks the Board to take these points into consideration as you move forward with your recommendations on PBM transparency. To that end, we thank Chair Bailey for her recommendation to consider passthrough rebates as an alternative to UPLs. Requiring that PBM rebates and discounts be directly shared with patients at the pharmacy counter is a more patient-centered option.

As one of the nation's leading healthcare companies, J&J has a responsibility to engage with stakeholders in constructive dialogue to address these gaps in affordability, access and health equity as well as protect our nation's leading role in the global innovation ecosystem.

We know that patients are counting on us to develop and bring accessible medicines to market. We live this mission every day and are humbled by the patients who trust us to help them fight their diseases and live healthier lives.

Sincerely,

Blasine Penkowski
Chief Strategic Customer Officer
Johnson & Johnson Health Care Systems Inc.

2023 Johnson & Johnson
Innovative Medicine

U.S. pricing transparency report

Creating the next era of healthcare advancements for patients

Johnson&Johnson

cp-468421v4 10/24

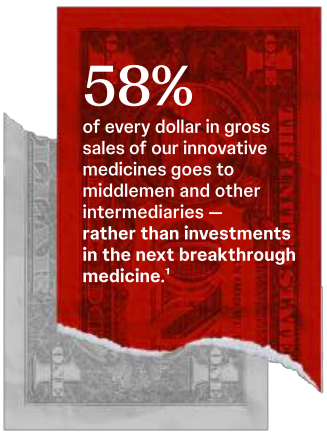
2023 at a glance

J&J Innovative Medicine is advancing the next era of medical innovation through our continuous R&D investments. Our net prices have continued to decline since 2016, but despite that, patients' cost exposure and access challenges are increasing because of distorted insurance benefit design.[1]

Rebates and discounts to middlemen and private insurers continue to grow

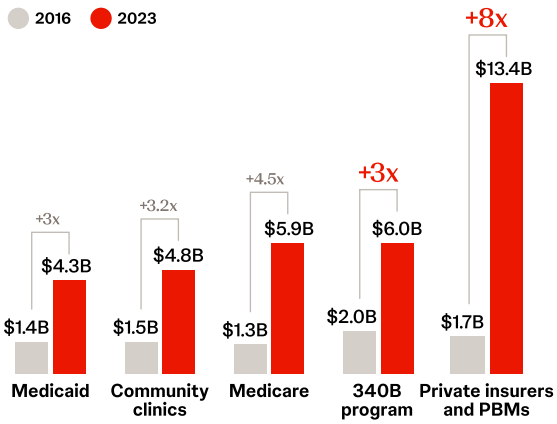
Our rebates, discounts and fees reached **$42.8 billion in 2023.**[1]

The result:



Since 2016, the first year of the Transparency Report, our rebates, discounts and fees have grown each year.

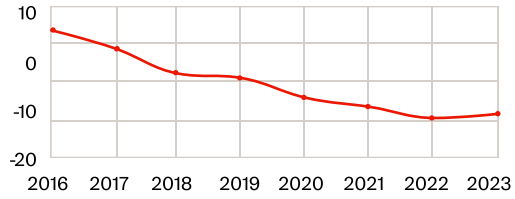
Growth in rebates, discounts and fees, 2016–2023[1]



Our net prices have declined by 18.6% since 2016[1]

The gap between U.S. list prices, which is what we charge insurance companies, and net prices for brand-name medicines, which is after rebates and discounts provided to private insurers and other intermediaries, **grew by 45% from 2017 to 2022.**[2]

J&J Innovative Medicine net price change (compounded %)[1]



Higher premiums and increasing cost exposure are a growing burden for families

The continuous growth in health insurance premiums is associated with limiting growth in wages for families, while patient cost exposure increases faster than the net cost of medicines that insurers and middlemen pay.[3,4]

By one estimate total out-of-pocket costs to patients may escalate to $800 billion by 2026...

... equivalent to placing a **$4,500** tax on every U.S. worker[5]

Our R&D: Developing the next generation of medicines

$12B

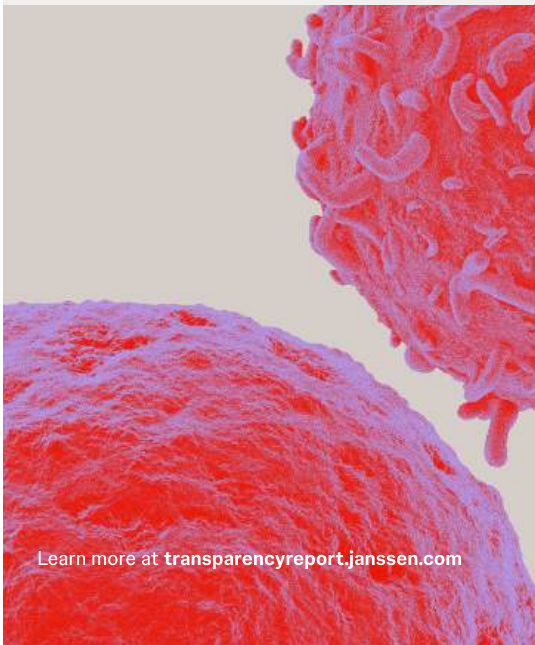
J&J Innovative Medicine total investments in 2023 to research and develop treatments and cures[1]

>124%

Amount spent on R&D in 2023 compared to sales and marketing[1]

94

Current number of new products and indications listed for pharmaceutical development[6]



Learn more at **transparencyreport.janssen.com**

Introduction

The inspiration and possibility of discovering the next breakthrough treatment for patients energizes our scientists, researchers and medical professionals to relentlessly pursue cutting-edge science every day. This complex, interconnected and often misunderstood system is supported through private sector investment and scientific expertise, public sector infrastructure and targeted public policy.

What has this healthcare innovation ecosystem delivered for patients?

Across the healthcare innovation ecosystem, more than 600 critical treatments have been discovered that are meeting the unmet healthcare needs of millions of patients living with rare diseases:[7]

- The development of a first-of-its-kind, FDA-approved CAR-T therapy harnessing a patient's own immune system, or T cells, to fight cancer.[8, 9]
- The discovery of a potential breakthrough therapy to treat pregnant individuals at high risk of severe hemolytic disease of the fetus and newborn (HDFN) — a serious and rare condition that occurs when a mother's immune system attacks her unborn child's blood cells.[10, 11]

However, these advancements in healthcare do not guarantee benefits for patients. More needs to be done to protect our nation's innovation ecosystem, especially when the following is considered:

- One out of every five Americans lives with some form of mental illness, including more than one of every 20 adults who live with severe mental illness.[12]
- Millions more will suffer from debilitating diseases like psoriasis that, left untreated, can severely undermine a patient's quality of life.[13]
- By 2030, 22.1 million individuals in the U.S. will be newly diagnosed with cancer.[14]

By putting patients' healthcare needs first, it is possible to propel America's leadership role in delivering the next era of healthcare advancements benefiting patients, the healthcare system and society.

So how does the nation protect and spur the next wave of healthcare advancements for patients?

It starts with continual investments into research and development. Every year, the private sector commits upwards of a quarter trillion dollars to research and develop innovative medicines.[15] Since 2016, J&J Innovative Medicine alone has invested **$77.7 billion** in research and development to deliver the next era of treatments and cures.[1] Our investments to discover the next generation of breakthrough treatments focus on a wide spectrum of diseases including cancer, neurological diseases, mental illnesses and tough-to-treat autoimmune diseases. J&J Innovative Medicine expects to achieve eight approvals by the FDA in 2024.[16] By 2030, J&J Innovative Medicine expects to launch or file more than 70 novel therapies and expanded treatment options for patients.[17]

Second, **patients need access to critical treatments and cures.** J&J Innovative Medicine supports access through negotiations that lower the prices (our net prices) of medicines paid by middlemen as well as other intermediaries.

Since 2016, J&J Innovative Medicine has invested **$77.7 billion** in research and development to deliver the next era of treatments and cures.[1]

$77.7B

$42.8B

In 2023 alone, we provided **$42.8 billion** in rebates, discounts and fees to insurers, pharmacy benefit managers (PBMs), hospitals, government programs and other healthcare entities.[1]

In 2023 alone, we provided $42.8 billion in rebates, discounts and fees to insurers, PBMs, hospitals, government programs and other healthcare entities.[1] Since 2016, these negotiations have lowered our U.S. net prices by **18.6%**.[1]

We also support patient access through free product provided both directly to patients as well as donated through the Johnson & Johnson Patient Assistance Foundation, Inc. (JJPAF), which totaled **$3.8 billion in 2023.**[1] Our patient access support programs helped more than **1.1 million patients** get their medicines in 2023.[18]

Third, **targeted policies are needed to bolster medical innovation and make it easier for patients to get their medicines.** Due to increasing payer restrictions and cost exposure policies, only 46% of the prescriptions patients received from their doctors for novel medicines were filled at the pharmacy counter in 2023.[19] Benefit design needs to change so that patients aren't just nominally insured but are also covered. Policies should work to close the "affordability gap"—the difference between the actual prices insurers and intermediaries pay for medicines and what these middlemen charge patients. Policies are also needed to prevent misguided government price setting and regulations from undermining the nation's R&D innovation ecosystem.

Our eighth U.S. Pricing Transparency Report provides key data, analysis and insights that will help advance solutions to create a more sustainable, equitable and innovative healthcare system.

We issue this report annually to help shape future policy that supports patients and fosters innovation. By bolstering the current patient-centric innovation ecosystem, together our nation will advance human health more in the next decade than we have in the last century.

J&J's R&D investments:

Making the hope of innovation a reality for patients in the next decade ... and beyond

Johnson & Johnson aims to drive scientific breakthroughs that improve health for everyone. We know a great idea can come from anywhere, and we are proud of our strong record of cultivating data-driven innovation and targeting our scientific know-how to meet patient needs.

Since 2016, J&J Innovative Medicine has invested more than $77.7 billion in R&D, nearly double what we spent on marketing and sales in the same timeframe.[1] This growing investment enables our scientists to rigorously pursue new medicines from early discovery through clinical development, informed by comprehensive safety and efficacy studies.

Our investments to discover the next generation of breakthrough treatments focus on a wide spectrum of diseases, including cancer, neurological diseases, mental illnesses and tough-to-treat autoimmune diseases. J&J Innovative Medicine expects to achieve eight approvals by the FDA in 2024.[16]

As we look to the future of medicine, J&J Innovative Medicine is focused on continuing to lead where medicine is going. **Today, we have 94 new products and indications listed for pharmaceutical development.[6] Through 2030, we expect to launch or file more than 70 novel therapies and expanded treatment options for patients.[17]**

94 New products and indications we have listed for pharmaceutical development.[6]

Number of novel therapies and expanded treatment options for patients we expect to launch or file by 2030.[17] **70+**

Protecting the health of mothers and babies

Hemolytic disease of the fetus and newborn (HDFN) is a serious and rare disease that was once responsible for thousands of infant deaths each year.[20] HDFN also puts the health of mothers at risk.[11] While medical advancements have been made to treat HDFN (including blood transfusion), these treatments also carry risks.[21]

J&J has been leading research to discover treatments for HDFN. FDA granted Breakthrough Therapy Designation (BTD) for a J&J Innovative Medicine treatment that is a novel approach for patients at risk of severe HDFN who need safe, non-surgical solutions to help address the serious health consequences of this condition.[10, 11]

How important is leading the U.S. as a global hub for R&D?[15]

Based on a comprehensive measure, industry R&D funding is even larger than conventionally reported: Every year, the private sector commits upwards of a quarter trillion dollars to research to develop innovative medicines. The U.S. is the undisputed global hub for biopharmaceutical R&D: In 2021, approximately 48% of all global companies engaged in biopharma R&D were headquartered in the U.S., accounting for 55% of worldwide R&D investments and 65% of all development-stage funding. The R&D intensity, or the share of revenues pharmaceutical companies reinvest back into research, is highest for U.S.-based companies. R&D intensity is 30% for publicly listed firms in the U.S., ranking above any other country's biopharmaceutical innovation sector.

Learn more at **transparencyreport.janssen.com**

A success story for patients: Private-sector R&D investments coupled with effective government policy helps meet unmet patient needs

An orphan drug is one intended for use in a rare disease, which is defined as a disease that affects fewer than 200,000 people in the United States.[7] More than 7,000 rare diseases have been identified, and an estimated one in 10 Americans lives with a rare disease; half of them are children.[7] Still, about 95% of rare diseases don't have a treatment approved by the U.S. Food and Drug Administration (FDA), according to the Rare Disease Company Coalition.[22] To encourage manufacturers to address this unmet patient need, in 1983 the federal government passed the Orphan Drug Act (ODA). Under the ODA, a company may qualify for research grants, tax credits for qualified clinical trials and potential seven-year market exclusivity after a drug's approval, among other benefits.[23]

The result: Before the ODA was passed, the FDA had approved just 38 orphan drugs to treat rare diseases. Today, more than 650 orphan drugs have been approved by the FDA — with more in development.[22]

Orphan drugs approved to treat rare diseases **before the ODA passed[22]**

Orphan drugs approved to treat rare diseases **after the ODA passed[22]**

Tackling the hardest unmet patient needs

J&J Innovative Medicine uses its unique experience, scientific know-how and technology to help patients with unmet needs. Our scientists are relentlessly searching for the next breakthrough in areas of medicine that can make the biggest difference, including discovering treatments for rare diseases like pulmonary arterial hypertension, rare inherited retinal diseases, rare maternal/fetal diseases, blood cancers (including multiple myeloma and non-Hodgkin's lymphoma), AL amyloidosis and myasthenia gravis.[23]

Harnessing the next generation of personalized treatments with precision medicine

Teams of J&J scientists, researchers and medical experts are focused on innovative treatments in the emerging field of precision medicine. Precision medicine relies on identifying individual patient characteristics, such as a patient's genetic profile, to be included in clinical trials of therapies and treatments.[24, 25] If these treatments or therapies are then approved, they can be quickly and properly adopted in healthcare systems around the world. The goal is to treat patients with greater precision — and greater success. J&J Innovative Medicine has been at the forefront of precision medicine with the delivery of a first-of-its-kind targeted treatment for an aggressive form of bladder cancer (which received FDA Breakthrough Therapy Designation in 2019)[26]; the first targeted therapy approved by the FDA for advanced non-small cell lung cancer in patients with a specific genetic mutation (2021)[25]; and first-line targeted treatment for prostate cancer patients who carry a certain mutation and for whom chemotherapy is not clinically indicated (2023).[25]

J&J Innovative Medicine is at the forefront of precision medicine, using genetic profiles to discover treatments, like gene therapies, for previously untreatable diseases. We are leading where medicine is going. The challenge ahead is supporting greater patient access and advancing policies that bolster, not undermine, the next era of medical breakthroughs.

Patients need affordable access to medicines

Affordable access to medicines is a major concern for patients and their families. At J&J Innovative Medicine, we understand our dual responsibilities: (1) to develop the next generation of medicines across a vast continuum of diseases for the patients of tomorrow and (2) to help support affordable access to our medicines.

To meet these responsibilities we have to patients, the healthcare system and society, we consider three factors when pricing our medicines:

01 We price our medicines based on the value they bring to patients, the healthcare system and society.

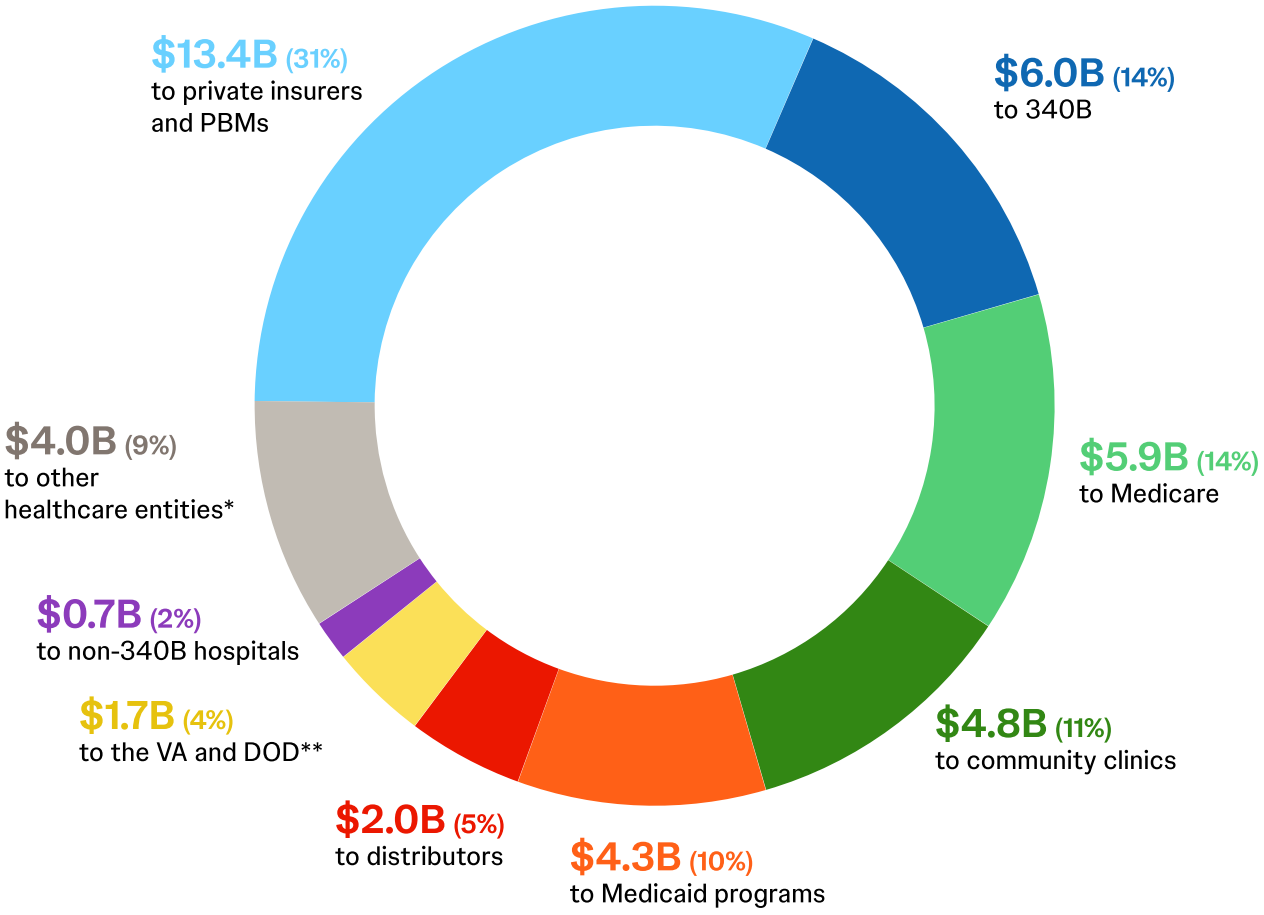
02 We price our medicines to further support patient access.

03 We price our treatments so we can continue innovating and developing new medicines for the patients of today and tomorrow.

Our negotiations with private payers and PBMs lead to lower net drug prices. Our net prices have declined by nearly 20% over the past seven years.[1] Despite lower net prices paid by insurers for our medicines, millions of patients are still facing higher costs and barriers to access. Some payers are even taking patient assistance from patients. The choice moving forward is to keep the current system or move toward a system that ensures (1) rebates are passed on to patients to lower their cost exposure and (2) patient assistance is not diverted away from the patients it is meant to help.

$42.8 billion paid in rebates, discounts and fees

In 2023, we provided **$42.8 billion in rebates, discounts and fees** to insurers, pharmacy benefit managers (PBMs), hospitals, government programs and other healthcare entities.[1]



*"Other healthcare entities" refers to other sites of care, less known payer organizations and other healthcare intermediaries.
All figures according to Johnson & Johnson internal financial accounting. Figures have been rounded.
**Department of Veterans Affairs and Department of Defense

The summary

01

42% of all discounts, rebates and fees go to government programs[1]

02

Nearly 1/3 of discounts, rebates and fees go to health insurers and PBMs[1*]

03

Patients are not directly benefiting from these growing savings

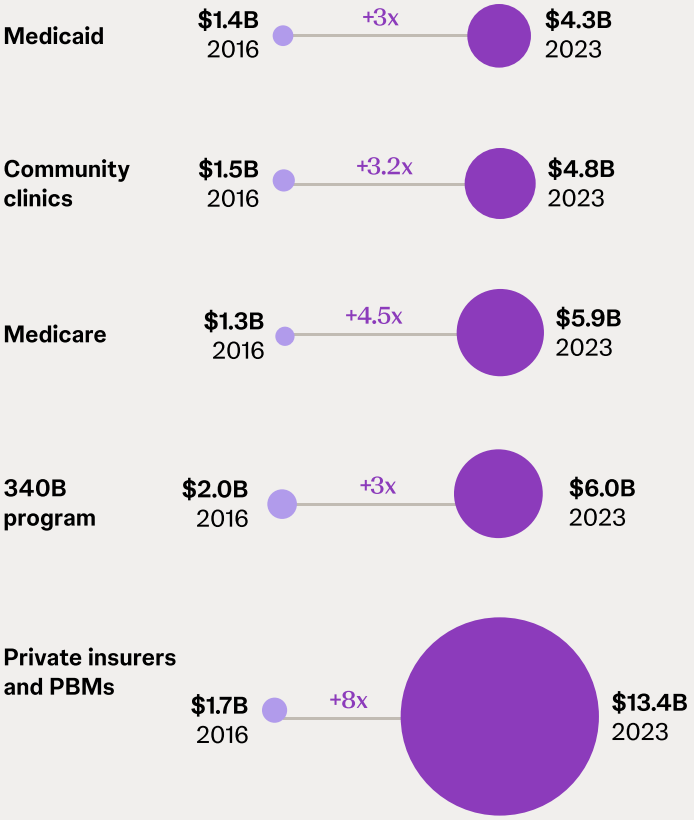
Drug list prices are simply a starting point. Manufacturers like J&J Innovative Medicine support patients' access to their medicines through vigorous private-market negotiations with health insurance companies, PBMs and other intermediaries that dispense medications (e.g. hospitals and clinics). J&J Innovative Medicine negotiates lower net prices to expand access and to make drugs more affordable for patients, not to benefit middlemen and other intermediaries.

Despite a more than $250 billion growth in industry-wide rebates and discounts in 2022 — which has lowered net prices — middlemen are making it harder for patients to get the medicines they need.[2, 28, 37] These middlemen, who control access to medicines through insurance design, have made changes including programs that divert financial assistance away from patients, changes to the types of medicines covered and changes to the extent of coverage.

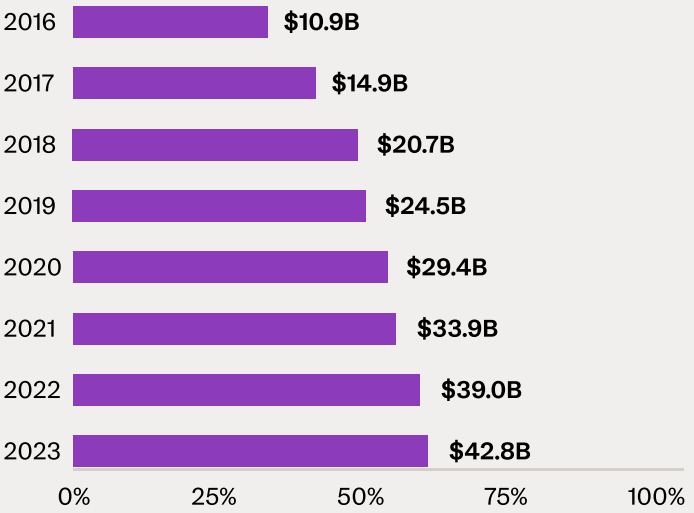
J&J Innovative Medicine's net prices have declined by nearly 20% since 2016[1]

Soaring inflation has impacted every sector of the U.S. economy. Prices on American goods were more than 20% higher in January 2024 than they were seven years earlier.[29] Since 2016, our net prices have declined by 18.6%.[1]

Rebates, discounts and fees from 2016 to 2023[1*]



Rebates, discounts and fees as a % of gross sales[1*]



*Figures have been rounded.

How J&J Innovative Medicine directly supports patients

In 2023, our CarePath program helped more than 1.1 million U.S. patients access their prescribed treatments.[18] We delivered more than $3.8 billion of free product provided both directly to patients as well as donated through the Johnson & Johnson Patient Assistance Foundation, Inc. (JJPAF), an independent, nonprofit organization.[1]

Underinsurance leaves patients financially exposed

The share of Americans without *any* health insurance hit an all-time low in 2023, but 23% of working-age adults with insurance coverage are now classified as being *under*insured.[31, 32] That means their insurance benefit design leaves them open to significant financial risks that effectively make healthcare unaffordable.[31] Vulnerable patients are disproportionately impacted by this financial hardship.[31]

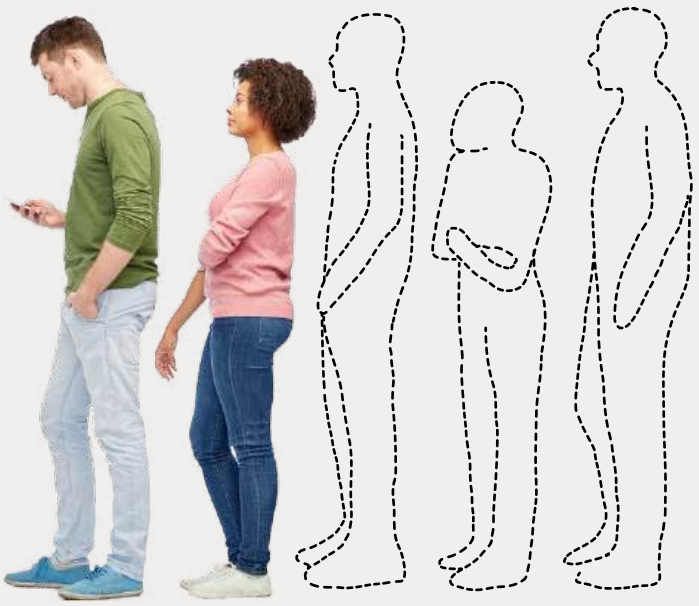
Pharmacy benefit managers create barriers to access

In theory, PBMs manage prescription drug benefits for insurers. In practice, PBMs have become medical middlemen, often impeding provider and patient healthcare decision-making. To restrict the types of medicines covered, PBMs use programs like prior authorization, step therapy and formulary exclusions, which can even eliminate access to certain medicines.[7] PBMs' growing use of restrictions and opaque operating models are creating significant hurdles for providers and patients to make the right healthcare decisions based on clinical evidence.

Distortions in health insurance benefit design are changing what it means to be insured

When health insurance works as intended, insured patients can affordably access their treatments when they need to. But for millions of Americans, health insurance does not fulfill this basic purpose.[30]

When patient costs exceed $250, **more than half** of patients abandon their newly prescribed treatment.[33]



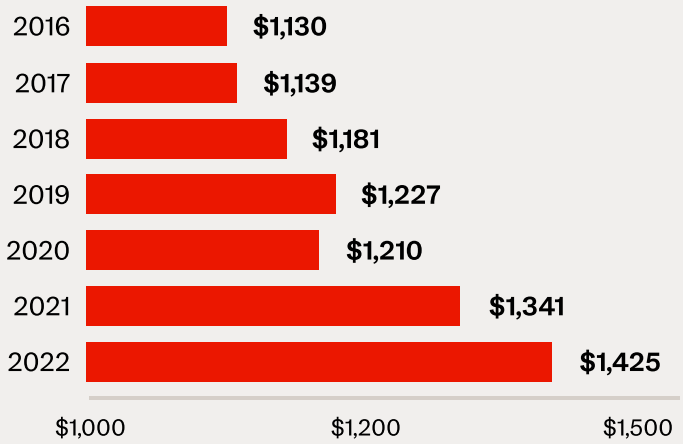
When patients' cost exposure rose to $10 and above, the total number of abandoned prescriptions rose by 24% to 52 million in 2022.[33]

Out-of-pocket costs cut access to critical treatments

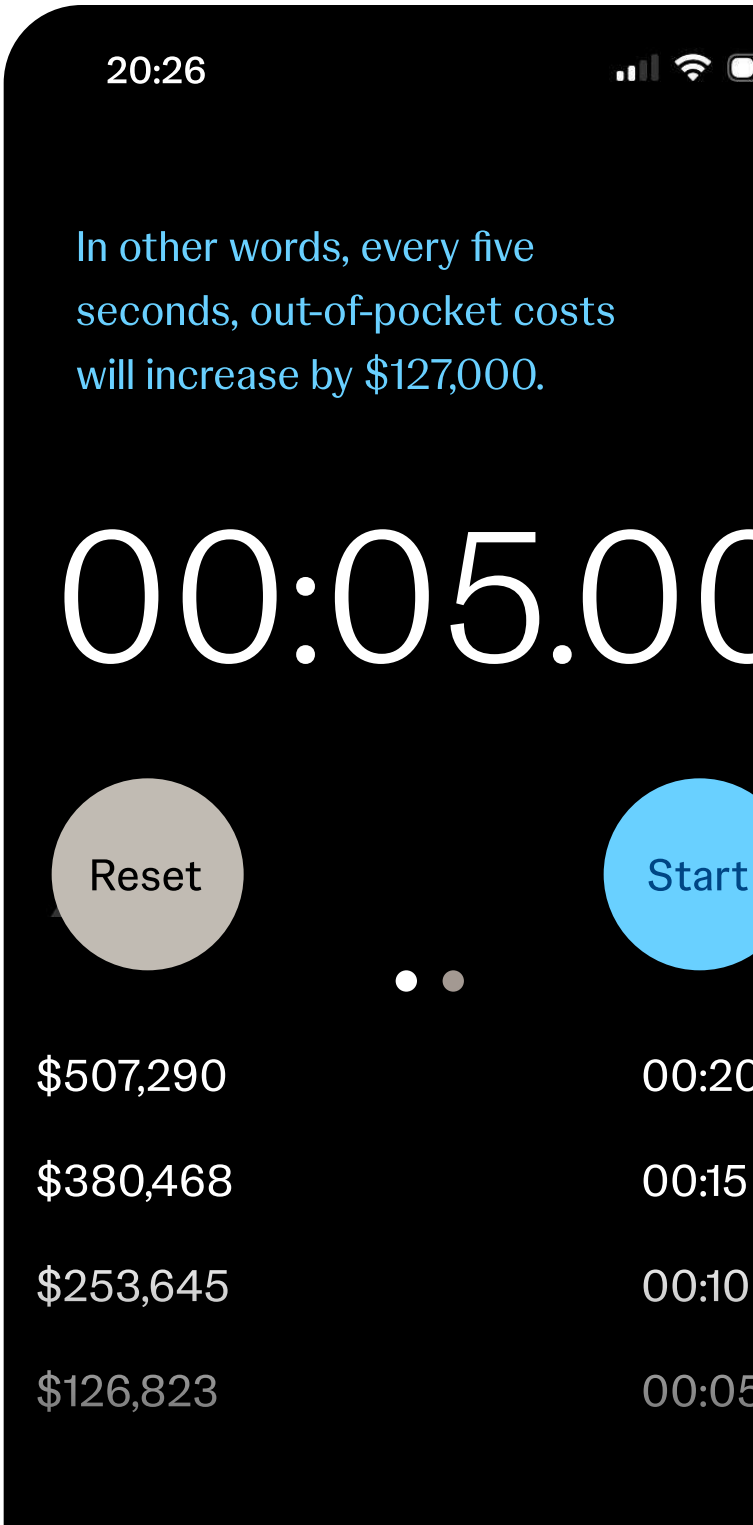
Even when insurance covers needed treatments, high deductibles and cost-sharing requirements can still make care inaccessible. Half of all adults, and 68% of low-income adults, said they could not pay an unexpected $1,000 medical bill.[34] Another report found 37% of Americans lack enough savings to cover an unexpected $400 expense.[34] Meanwhile, patient cost exposure continues to climb, causing per capita out-of-pocket patient costs to increase 26% from 2016 to 2022, totaling $1,425 in annual costs.[35] The continuous growth in health insurance premiums is associated with limiting growth in wages for families, while patient cost exposure increases faster than the net cost of medicines that insurers and middlemen pay.[3, 4] By one estimate, total out-of-pocket costs to patients may escalate to $800 billion by 2026—equivalent to placing a $4,500 annual tax on every U.S. worker.[5] As health insurance premiums continue to increase for Americans, many are falling into an affordability gap between what insurance will cover and an individual's ability to pay. For example, in Affordable Care Act (ACA) marketplace plans, families are exposed up to $18,900 before the 2024 cap on out-of-pocket costs kicks in.[36] This does not include premium payments or out-of-network care.

Between 2016 and 2022, out-of-pocket costs rose 26%.[35]

Per capita OOP expenditures, 2016-2022[29]



According to an independent study, total OOP costs are expected to grow at an annual rate of 9.9% which would result in almost $800 billion in consumer OOP healthcare spending in 2026.[5]



Patients are not directly benefiting from lower net prices

While private insurers pay lower net prices, patients still pay higher and higher costs. Why? Because the patient cost-sharing amounts set by insurance plans are often based on the initial list price, not the negotiated lower net price the private insurer pays. This is different than the costs patients typically pay for other negotiated healthcare services like hospital stays and doctor visits.[37, 38] **The gap between U.S. list prices, which is what we charge insurance companies, and net prices for brand name medicines, which is after rebates and discounts provided to private insurers and other intermediaries, grew by 45% from 2017 to 2022.[2]**

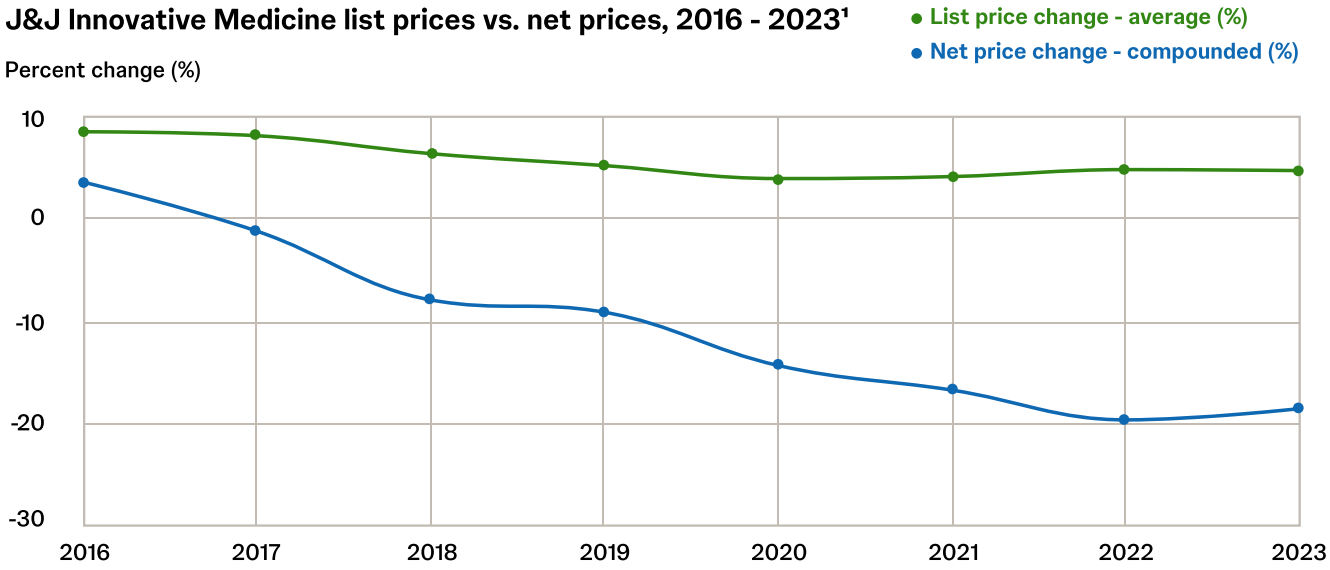
> “The choice moving forward is to keep the current system or move toward a system that lowers patients’ cost exposure, improves patient access and makes sure patient assistance is for patients only.

Patient assistance diversion programs undermine patient care

As patients face higher out-of-pocket costs due to insurance design, manufacturers have expanded patient assistance programs.

However, insurers, PBMs and other entities are deploying programs to divert these funds away from patients. These diversion programs take manufacturer assistance meant for patients by manipulating their benefit design around this assistance, effectively raising out-of-pocket costs for patients. These diversion programs make it more likely patients will abandon their treatments.[39] And critically, non-white patients are roughly 30% more likely to be exposed to these diversion programs.[40] Some third party intermediaries are also using alternative funding programs (AFPs), which can cause patients to be denied or receive delayed coverage of a needed treatment or medicine.[41] Ultimately, patient assistance should be for patients only, not third party intermediaries or middlemen.

J&J Innovative Medicine list prices vs. net prices, 2016 - 2023[1]



Understanding the policy challenges to the healthcare innovation ecosystem

Johnson & Johnson is committed to bringing life-saving medicines to patients, but the innovation ecosystem also needs policies and regulations that bolster scientific advancement. Discovering and developing life-saving medicines requires significant resources and cooperation between researchers and regulators. On average, it takes more than 12 years and $4 billion, including cost of capital for the total lifecycle, to bring a new medicine to market.[42, 43] There is inherent risk in this process, as approximately 93% of the drugs that enter clinical trials (and 97% of drugs addressing the nervous system) fail before they can make it to market.[44] Incentivizing risk-taking is a critical part of advancing medicine for patients, but many policies (either enacted or under consideration) could severely undermine the innovation ecosystem that has delivered healthcare benefits for patients.

Federal government price setting

The Inflation Reduction Act's Drug Price "Negotiation" Program enables the federal government to set prices on Medicare Part D and B drugs. Concerns are mounting that government-mandated prices could upend the ecosystem that makes discovery and development of these medicines possible, as well as the ability to expand existing treatment options to new patient populations.[45] In fact, one analysis shows the IRA could mean that 130 drugs are not discovered or developed over the next 10 years.[46] Industry analysis indicates that federal price controls have already shifted research and development away from small molecule medicines (tablets and pills), despite the numerous benefits these types of drugs have for patients.[47]

Prescription drug affordability boards (PDABs)

State policymakers are turning to prescription drug affordability boards (PDABs) and upper payment limits (UPLs) on branded medications to attempt to lower state drug expenditures and improve affordability for patients.[48] However, UPLs on branded medications remain new and untested, with minimal understanding of their short- and long-term impacts on the drug pricing ecosystem and patient access. UPLs' long-term impacts across benefit design, patient access and pricing and contracting may further impede drug pricing reform across state-regulated commercial markets. Moreover, policy changes that focus exclusively on drug pricing at the manufacturer level do not always account for responses from other stakeholders and hence may not deliver the intended shifts in patient access and affordability.

As more states take this approach and select a greater number of drugs each year for UPLs, these issues may be compounded even further.

There is no guarantee that PDABs will save patients any money at the pharmacy counter. Many state PDAB laws do not explicitly require cost savings to be passed on to the patients taking the medications subject to price controls.[48]

PDABs may also fail to consider the value and benefit to the patient.[48] PDABs could target the most innovative medicines, which would disproportionately impact patients who require specialized medicines.[48] PDABs have begun to evaluate drugs intended for vulnerable patients with chronic, life-threatening conditions, including those living with HIV, Crohn's disease or cystic fibrosis, who cannot afford to lose access to their medications.[49]

International Reference Pricing

Some policymakers have also proposed benchmarking U.S. drug price negotiations to prices in foreign countries, ignoring differences in healthcare system structure, reimbursement systems, economic circumstances, standard of care and local priorities across countries.[50]

The U.S. has benefited historically from investing in earlier access and more innovative treatments for its population. A recent analysis demonstrated that the U.S. makes available to its population through public plans 85% of new medicines, versus the 40-60% provided by established European markets.[51] As price reflects local value, setting prices based on prices in other countries also imports that country's local value system. For instance, 56% of Medicare beneficiaries who received physician-administered medicines for breast cancer would not have had access if England's National Institute for Health Care Excellence (NICE) criteria had been used.[52] Patients' timely access to prescription medicines is critical in driving better health outcomes.

The United States is globally admired for its leadership in biopharmaceutical innovation. This success stems from several key factors, including a strong domestic market and a policy environment that has historically supported basic science research and robust intellectual property protections for the private sector and which has avoided government price-setting of innovation. These policy choices have fostered significant private investment in R&D. This investment has activated the world's most advanced biomedical research infrastructure, comprehensive biomedical education and talent development, a thriving biotech startup scene and strong collaboration among academia, government and industry. This robust system delivers unmatched results — 65% of all drugs launched by G20 countries in 2021 were first launched in the United States.[51] By linking the U.S. health system to countries with completely different health economies and value systems, policymakers risk:

- Removing patient treatment options without reducing patients' costs.
- Straining providers' reimbursements, potentially forcing some to cut vital patient services.[53]
- Undercutting the innovation ecosystem that develops lifesaving treatments.
- Diminishing a critical part of the nation's economic engine and national security strength.

Intellectual property rights

The U.S. patent system sets standards that enable innovative companies to bring new products to market in every industry. In healthcare, companies strive to solve the nation's greatest medical challenges, even if it takes years of costly research to find and realize those solutions. Our patent system achieves this by requiring inventors to disclose their product details in return for time-limited rights to those inventions. The U.S. medical innovation ecosystem was built on this framework, and it now supports a robust pipeline of more than 800 treatments being developed across the biopharmaceutical industry.[54]

Limiting the ability to protect inventions or enforce patent rights associated with pharmaceutical innovation would upend the R&D innovation ecosystem that advances treatments for patients today, as well as pharmaceutical innovations for years to come.

"Marching in"

The 1980 Bayh-Dole Act was passed to promote the use of critical inventions and spur collaboration between government-funded entities and innovative companies with the expertise and capabilities necessary to develop and commercialize innovative products.[55] Since its passage, it has directly contributed to $1.3 trillion in economic growth, 4.2 million more jobs and 11,000 new startup companies.[56] As an additional measure to ensure inventions were utilized, the Act gave the federal government limited rights to "march in" if licensed innovative companies were not taking reasonable steps to advance those inventions towards commercialization. Due to the overwhelming success of the Bayh-Dole Act in fostering public-private sector collaboration, no federal agency has ever utilized this policy. The Bayh-Dole Act was never intended to be used as a price-setting mechanism, nor as a tool to seize intellectual property rights based on a government-dictated "reasonable" price. If the government "marches in" and licenses patent rights to widely available treatments, public-private sector collaboration and the innovation ecosystem will suffer.[57]

65% 65% of all drugs launched by G20 countries in 2021 were first launched in the United States.[51]

340B Program: How diversion and duplicate discounts are hurting vulnerable patients

The 340B program was designed by Congress to be a very limited, targeted program enabling manufacturers to restore deep discounts that manufacturers historically had provided voluntarily to safety net providers. However, the program has grown out of control as for-profit pharmacy chains and larger health systems have used it to boost profits without directly benefiting patients either in the hospital or at the pharmacy counter. The 340B program now accounts for nearly one out of every five dollars of manufacturer discounts.[60] In July 2023, more than 33,000 pharmacy locations—more than half the entire U.S. pharmacy industry—were contracted to dispense 340B drugs.[59] This represents a 2,400% increase since 2010.[59, 60]

As the 340B program has grown, two problematic trends have become clear: diversion and duplicate discounts. In critical program integrity provisions in the 340B statute, Congress prohibited both diversion and duplicate discounting. Diversion happens when a 340B provider dispenses 340B discounted drugs to non-eligible patients. The risk of diversion increases as the 340B program grows. Federal government audits have made more than 500 diversion-related findings among covered entity audits over an eight-year period.[61]

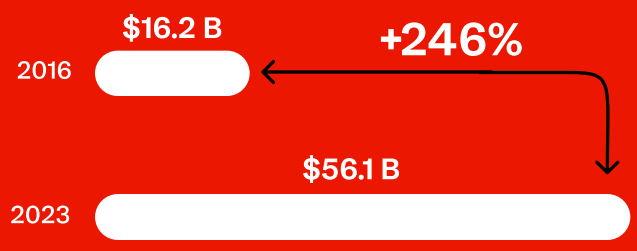
Duplicate discounts happen when a manufacturer sells a drug to a 340B provider at the 340B discount price and then pays a Medicaid rebate on that same drug. This risk, too, grows as the 340B program grows. The Government Accountability Office (GAO) found more than 400 instances of noncompliance related to duplicate discounts among audited covered entities.[61] GAO further noted that "HHS does not have reasonable assurance that states and covered entities are complying with the prohibition on duplicate discounts," and that "drug manufacturers [are] at risk of providing duplicate discounts."[63]

Indeed, because the Medicaid rebate program has expanded to include drugs provided through Managed Medicaid, the risk of duplicate discounting is even greater.

The evidence is unclear on whether vulnerable patients are actually benefiting from the 340B program's immense growth. Research shows the most profitable 340B hospitals are spending very little on charity care.[64] Certain 340B-covered entities purchase drugs at discounted rates and contract with external pharmacies to dispense those drugs at much higher prices. One 340B hospital made headlines in 2022 for charging seven times the amount it paid for a particular cancer drug.[65] 340B hospitals in North Carolina made headlines in 2024 for marking up cancer infusion drugs 5.4 times the 340B acquisition cost — nearly twice the mark-up rate of non-340B hospitals.[66] A recent academic study reaffirmed criticism that "the 340B program is being converted from one that serves vulnerable patient populations to one that enriches hospitals and their affiliated clinics."[67]

According to new research in the New England Journal of Medicine, 340B hospitals now capture 64% of the insurance spending on pharmaceuticals they administer.[68] 340B discounts are not free. There is a very real cost to the larger healthcare ecosystem of increasing 340B discounts beyond the limited scope Congress intended. As the 340B program grows each year, unfettered 340B discounts reduce the resources available for future investments into tomorrow's treatments and cures. Without common-sense reform, our nation's innovation ecosystem will be undermined. **Read more in our 340B Issue Brief.**

Purchases by covered entities at discounted 340B prices have also risen.[58, 62]



340B fast facts

84.8% Higher price markup by 340B hospitals versus non-340B hospitals in North Carolina for state employees from 2020-2022[66]

12x Increase in the amount of 340B brand spending received by providers and their contract pharmacies, since 2013[69]

$10B Estimated 340B profits captured by for-profit contract pharmacies in 2023, not directly benefiting underserved populations in need[70]

Valuing pharmaceuticals in the U.S.

When the U.S. innovation ecosystem works as intended, supported by policies that promote innovation, it leads to more effective and personalized treatments that are available faster, earlier intervention and smarter, less invasive healthcare for patients today and in the future.

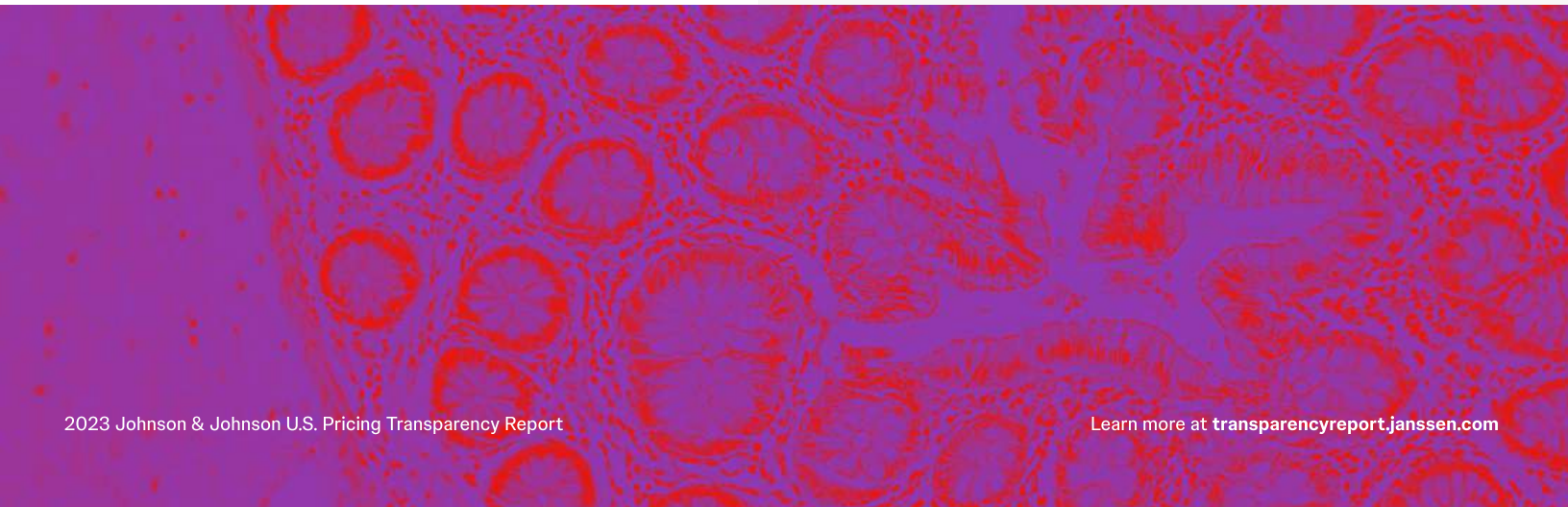
Misunderstanding the value of medicines

Each patient has unique needs, and the healthcare ecosystem should support all patients in getting timely, affordable access to the treatments that are best for them. Unfortunately, insurance companies routinely exclude certain medications from formularies and put in place financial barriers to limit use, often based on what works best for the average patient. This "one size fits all" approach to coverage can lead to patients being denied the treatment that is most valuable to them just because they are different from the average.[71]

Rather than fixing the problems with insurance that prohibit patients from getting the best care, some argue that the U.S. should implement a top-down population-level "value assessment" process like those used in some countries where the government dictates prices and decides on access. While these assessments begin with comparing important evidence about a treatment's efficacy, safety and quality (among other factors) versus other treatment options, they ultimately prioritize the payer perspective.[73] Even though they are based on incomplete information, the results are used as proxies for the value of medicines in the real world.

Evidence from top-down population-level value assessment systems, like those found in Europe, indicates that access challenges could be exacerbated if the U.S. adopted similar value assessment frameworks. Undervaluing medicines will not fix access problems for today's patients, and it distorts the innovation ecosystem by disincentivizing investment in the science needed to develop the treatments of tomorrow.

When the U.S. innovation ecosystem works as intended, supported by policies that promote innovation, it leads to **more effective and personalized treatments that are available faster, earlier intervention and smarter, less invasive healthcare.**



U.S. patients benefit from the earliest access to the broadest, most innovative set of therapies in the world, helping patients more easily find the treatments that work for them the best.

U.S. patients have medicines sooner

Of the 37 drugs the U.S. Food and Drug Administration (FDA) approved in 2022, 68% were first approved in the U.S.[74]

In Canada, publicly insured patients waited an average of 2.5 years longer than Americans with Medicare to have access to newly approved drugs.[75]

U.S. patients have more options

78% of drugs launched by G20 nations between 2012 and 2021 were available in the U.S. within one year of their launch, compared to just 38% in the United Kingdom and 21% in Canada.[51]

If existing U.S. top-down value assessments for treatments for multiple myeloma, multiple sclerosis and non-small cell lung cancer were applied in Medicare Part B, most patients could be forced to switch their current treatment (multiple sclerosis: 99%, non-small cell lung cancer: 85% and multiple myeloma: 83%).[76]

U.S. patients battling cancer benefit from better access

Of the 124 new cancer medicines approved globally from 2012 to 2021, American patients have access to 94% of these treatments, compared to the average of 46% in other G20 countries.[51]

Patients' needs should determine value

At Johnson & Johnson we are guided by Our Credo. Our first responsibility is to "the patients, doctors and nurses, to mothers and fathers and all others who use our products and services."[77] We need a system that supports clinically nuanced, patient-centric access to medicines so that each individual person can easily obtain the therapy that they and their doctor determine is best. This is why we believe that respect for individual patient values must be center stage in any solution and any value assessment.

We support valuations of medicines that adhere to the following principles:

Patient-centered:

A patient-centered approach is fundamental to achieve the most efficient use of medicines, not waste resources and ensure that access to treatments is nondiscriminatory. This approach respects patient autonomy by placing every patient's outcome at the forefront of decision-making.

Decentralized and locally relevant:

Valuations must consider the specific needs of local health systems. Treatment needs in rural areas or underserved communities, for instance, may differ significantly from treatment needs in metropolitan areas or communities that are adequately resourced.

Deliberative and flexible:

Valuations should be done in a deliberative way and not use strict decision rules or oversimplified metrics, like the discriminatory quality-adjusted life year (QALY), expected value of life years gained (evLYG) or healthy years in total (HYT). Instead, the full diversity of healthcare values must be considered, prioritizing those of patients.

Holistic:

Valuations must not rely on information from a small set of simple summary statistics, such as average life expectancy and average cost, but instead consider the full range of impacts to the patient, healthcare system and society. Valuations that are incomplete will distort the marketplace, resulting in both today's and tomorrow's patients receiving suboptimal care.

Clinically driven:

Clinically driven valuations best preserve the opportunity to maximize the health of every patient and should prioritize their health and safety. Financing of medicines should be considered separately and addressed through insurance solutions.

Building an equitable health system for every patient

Johnson & Johnson strives to eliminate the threats that racial and social inequities pose to public health. Every day across our organization, researchers and advocates work to identify community partners, programs and funding opportunities to help make health inequity a thing of the past. For instance, we launched Our Race to Health Equity in 2020, a $100 million program that aims to help close the racial gap in U.S. healthcare.[78]

Already, this program has committed more than $52 million to advance efforts across four key areas:[78]

01

Building community health capacity

By the end of 2022, 307,000 U.S. HCPs and researchers were provided support to develop management and community care skills.[78]

02

Making clinical trials more representative

Every patient is unique. To develop cures and treatments that serve *all* patients, clinical trial participants should reflect the diverse populations we serve. We have launched several initiatives to diversify clinical trials, such as Research Includes Me, a community-focused campaign to engage Black and Brown communities and elevate discussions around clinical trials. For more information, please visit www.researchincludesme.com.[78]

03

Engaging and educating communities

My Health Can't Wait is a community wellness initiative that connects people of color in the U.S. with vital health information and resources. To date, the initiative has reached over 100,000 people, delivered 16,000 health screenings and distributed 35,000 packets of educational materials to communities of color.[79] J&J's My Health Can't Wait initiative will also sponsor several patient-focused initiatives that are helping create greater urgency around specific health inequities that disproportionately impact communities of color. This includes the "Save Legs. Change Lives." initiative, which is addressing peripheral arterial disease-related amputations that disproportionally affects Black and Hispanic Americans.

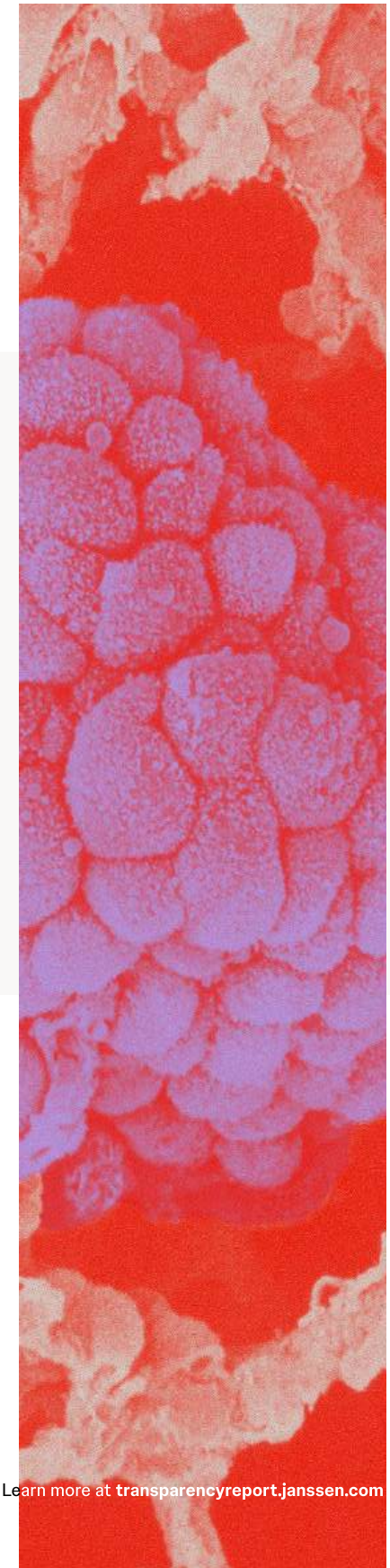
04

Delivering culturally competent care

To tackle the role of unconscious bias in our health system, we recently co-launched a cross-sector initiative called Unconscious Bias and Disparities in Healthcare: A Call to Action, a program that helps health providers in communities of color alter their daily practices to improve patient experiences. Additionally, we continue to sponsor the Alliance for Inclusion in Medicine Scholarship Program, a scholarship fund designed to produce more doctors from historically underrepresented groups. In recent years, J&J has donated more than $2 million in scholarships.[78]

Our values

Everything we do at Johnson & Johnson is guided by Our Credo. Our first responsibility is to “the patients, doctors and nurses, to mothers and fathers and all others who use our products and services.”[77]



We pursue health solutions that keep patients at the center:

- Preserve the unmatched U.S. innovation ecosystem that delivers transformative treatments to the patients who need them
- Protect the patient-physician relationship and eliminate the undue influence of commercial middlemen on patient health decisions
- Reduce the racial and socioeconomic disparities that undermine public health outcomes
- Ensure patients have affordable access to effective treatments, both now and in the future

Our values inform our policy ideas so that we advance solutions that create a more sustainable, equitable and innovative healthcare system.

We also consider the experiences of our patients, who use our medicines every day, the perspectives of our scientists and researchers discovering the next medical breakthrough and our concerns about the misaligned incentives in the marketplace.

Specifically, we think the following reforms are needed:

Reform PBMs to prevent patient access hurdles, lower patient costs and promote patient-provider decision-making:

Patients would benefit from greater PBM transparency and having their costs based on net price, not list price. Patients should not face restrictive utilization management programs that interfere with patient access, affordability and treatment choice. Medical decision-making should remain between a provider and the patient. Reforms should also ensure that patients more directly benefit from the savings provided by rebates and discounts. Federal and state legislatures should pursue policies that increase PBM transparency, accountability and delink PBM fees from list prices.

Reform the 340B Program to benefit patients:

We support the original intent of the 340B program and believe increased transparency and accountability in the program will improve access to care in vulnerable communities. Federal legislation, the *340B Affording Care for Communities and Ensuring a Strong Safety-Net Act (340B ACCESS Act)*, includes critical reforms to 340B and is supported by J&J.[80] Federal reforms, like those included in the 340B Access Act, are needed to eliminate duplicate discounts and diversion, provide a robust patient definition and require 340B discounts to be shared directly with needy patients at the pharmacy counter.

Stop patient assistance diversion programs:

Patients should be protected from these types of harmful programs operated by middlemen. First, CMS should enforce the rule that health plans must count patient assistance toward out-of-pocket limits unless there is a generic option. Second, Congress should pass the HELP Copays Act, which would prohibit copay accumulator programs unless an appropriate generic equivalent is available.[81] At the state level, lawmakers can pass legislation (at least 19 states have done so already) that ensures cost-sharing assistance is counted toward patient out-of-pocket contributions, prohibits third parties from altering or conditioning the terms of health plan coverage or benefit design on the availability of financial or product assistance for a prescription drug and requires disclosures about these programs to patients.[43, 82]

Prevent the spread of alternative funding programs (AFPs): More transparency and oversight can mitigate the harms AFPs cause for patients and the larger healthcare system. The Federal Trade Commission and state regulators should review AFP industry practices. Consumers are at the most risk with the deceptive business practices of AFPs. The federal government should take steps to increase oversight of AFP practices in employer-sponsored plans. Congress and states should pursue legislation that prohibits the use of AFPs by group health plans, health insurance issuers and other entities.

Johnson & Johnson seeks to collaborate with stakeholders across the U.S. healthcare system to advance the important work of pursuing novel healthcare solutions that benefit patients. We believe together, we can find solutions to address the mental health crisis, modernize regulatory pathways, provide critical access to affordable medicines and enhance diversity in clinical trials.

At Johnson & Johnson, we are leading where medicine is going.

Citations

Notes on this report. All information in this report refers to the U.S. operations of the Janssen Pharmaceutical Companies of Johnson & Johnson, unless noted otherwise. Financial and nonfinancial information covers the period between January 3, 2023, and January 2, 2024, except where noted. The methodologies used for analyses in this report may be different from those used by other organizations. This report is not audited and is not intended to address all our required disclosures.

Additional resources. In this report, we refer to locations where you can find more information about specific Janssen U.S. and Johnson & Johnson programs, disclosures, and patient resources. Financial performance information for our parent company and its subsidiaries, as well as its "Cautionary Note Regarding Forward-Looking Statements" and "Risk Factors," can be found in Johnson & Johnson Annual Reports at jnj.com/about-jnj/annual-reports. Information on corporate sustainability measures can be found at the Johnson & Johnson Health for Humanity Report at healthforhumanityreport.jnj.com.

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Biotechnology Innovation Organization
1201 New York Avenue NW
Suite 1300
Washington, DC, 20005
202-962-9200

VIA Electronic Delivery

November 17, 2024

Oregon Prescription Drug Affordability Board
Department of Consumer and Business Services
350 Winter Street NE
Salem, OR 97309-0405

Re: Prescription Drug Affordability Board Upper Payment Limit Board Draft Report-DRAFT

Dear Oregon Prescription Drug Affordability Board (PDAB)

The Biotechnology Innovation Organization (BIO) appreciates the opportunity to comment on the Oregon Prescription Drug Affordability Board's (PDAB or Board)'s Draft Prescription Drug Affordability Board Upper Payment Limit Report (Draft Report).

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO's members develop medical products and technologies to treat patients afflicted with serious diseases, delay their onset, or prevent them in the first place. In that way, our members' novel therapeutics, vaccines, and diagnostics not only have improved health outcomes, but also have reduced healthcare expenditures due to fewer physician office visits, hospitalizations, and surgical interventions. BIO membership includes biologics and vaccine manufacturers and developers who have worked closely with stakeholders across the spectrum, including the public health and advocacy communities, to support policies that help ensure access to innovative and life-saving medicines and vaccines for all individuals.

General Comments

BIO and our members have long argued that the underlying structure and utilization of an upper payment limit (UPL) is flawed and should not be enacted. UPLs will harm patient access to lifesaving medication while failing to protect patients from harmful plan designs, and other restrictive coverage strategies and barriers imposed by plans and PBMs. It is evident that setting UPLs without consideration for the drug coverage ecosystem and supply chain could have profound negative repercussions for patient access. BIO urges the Board to fully consider the impact of UPLs on patient access and to carefully examine additional feasibility concerns before the Board proceeds with any additional exploration of the use of an UPL in Oregon (OR). It is important that the Draft Report underscores the need to better understand the drivers of affordability challenges before being fixated on the single proposed solution of an UPL. We continue to encourage the Board to consider other affordability solutions, such as accumulator adjustment program bans and rebate models to ensure that rebates are passed through to patients, as alternatives to an UPL.

Please note our recommendations on the Draft Report do not resolve the more fundamental issues of UPL effectuation and BIO's positioning remains that UPLs should not be enacted.

Executive Summary (p.4)

Biotechnology Innovation Organization
1201 New York Avenue NW
Suite 1300
Washington, DC, 20005
202-962-9200

BIO appreciates that the Draft Report highlights various stakeholders' concerns with UPL implementation and acknowledges that the majority of respondents voiced that it is unlikely that a UPL would result in cost-savings. The Draft Report notably also acknowledged the administrative and operational hurdles with developing a UPL. Despite this, the Draft Report notes that the Board still plans to continue with a "structured, phased approach" to develop OR's UPL framework. BIO urges the Board to not move forward with recommending UPL authority in light of the significant concerns raised by stakeholders.

BIO is also concerned that the Draft Report provides a biased account of how other states have navigated challenges related to UPL methodologies, which is informed by the same consultants that support the work of the PDABs in other states. This account does not adequately represent the fact that states are not far enough along in the UPL development process to fully understand the impact of any of the methodologies or strategies referenced in the Draft Report. It is critical that the Draft Report avoids making premature assumptions about UPLs when in fact the broader and longer-term impacts have yet to be realized.

Finally, it is problematic that the Draft Report fails to include a conflict-of-interest disclosure, particularly given that major sections of the Draft Report were not written by the Board itself. It is critical that the Board is informed by impartial and evidence-based analysis, and at a minimum, all parties that informed the Draft Report should submit a conflict-of-interest disclosure to ensure a fair, transparent, and accountable policy process.

Transaction Relationships in the Supply Chain (p.13)

The Draft Report makes biased and inaccurate claims that drug manufacturers "wield significant influence over drug costs and affordability, as they are responsible for setting the initial list price." This claim significantly oversimplifies market and supply chain dynamics and misattributes blame to manufacturers, leading to a biased narrative that blatantly ignores the multifaceted drug ecosystem. This misattributed blame fails to consider that manufacturers do not have control over net cost, patient OOP cost, and utilization, and the ability for a manufacturer to validate this information is very limited. Instead, the true drivers that impact patient OOP cost are determined by the patient's health plan design. Pharmaceutical benefit managers (PBMs) and plan sponsors have continued to shift more cost-sharing responsibility to patients, causing patients to struggle to afford and adhere to their medications. Instead of recognizing the drivers of patient OOP costs, the Draft Report claims that "payers play a crucial role in controlling affordability and ensuring access to medications by actively managing drug coverage." It is deeply troubling that this language is clearly skewed in favor of certain parties within the supply chain over others. It is even more concerning that the Draft Report ignores the reality of patients who face barriers to access and are charged significant OOP costs from their health plans. BIO urges the drafters to strike the language "wield significant influence over drug costs and affordability" and instead consider a holistic and balanced account of factors such as plan benefit design, copay structures, and other factors that impact patient OOP spending.

The Draft Report also claims that "more than 98% of rebates are passed through to payers." This figure is significantly misleading and fails to consider that the savings often do not get passed down to patients. Further reforms into PBM transparency are needed to fully

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1201 New York Avenue NW
Suite 1300
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202-962-9200

understand PBM practices, including price-shifting tactics that negatively impact patient access and affordability. BIO urges the drafters to remove this figure from the Draft Report.

Plan for Establishing an Oregon-Specific UPL (p.18)

While the Draft Report states that "the board has engaged in an extensive and intensive process… to assess the feasibility of establishing a UPL in Oregon," the Draft Report fails to mention any research that was specifically conducted to address concerns raised by the many stakeholders regarding patient access and other considerations. The Draft Report itself admits that it has not been able to access data to properly analyze the impact of a UPL, stating that "legislative and regulatory support will be required to appropriately gain access to the data needed to fully evaluate the impact on supply chain" (p. 31). Accordingly, the Board should fully consider stakeholder concerns before any additional examination of the use of an UPL in Oregon.

UPL Potential Methodologies (p.19 & Throughout Horvath UPL Report)

BIO is concerned that the proposed models prematurely suggest that they will support the PDAB's missions of "improving affordability." As stated above, the Board does not have sufficient information to thoroughly understand the implications of the UPL, including the impacts on stakeholders in the supply chain and the effects on patient access. It is extremely misleading for the Draft Report to provide support for these methodologies without fully vetting the impact of the models and assessing the impact on patient access, provider reimbursement, and other impacts on the supply chain. Given these significant unknowns, BIO urges the drafters to remove all language in the UPL Approach chart that suggests that the method supports PDAB's mission to improve affordability.

It is also critical that the drafters remove any assertion that any potential UPL methodology will reduce costs for payers, reduce OOP costs for patients, or improve access for consumers. These claims are baseless and unsupported; there is no assurance that any potential savings will be passed on to lower OOP for patients. Instead, it is evident that any potential UPL methodology could disrupt patient access, as revealed by the numerous concerns expressed in the PDAB's own stakeholder interviews and focus groups.

BIO has concerns with each of the potential methodologies suggested throughout the Draft Report, outlined below.

> *Net Cost*: It is deeply problematic that the Draft Report is considering using information about a manufacturer's estimated or actual net price, which is highly confidential and/or trade secret information. As the Draft Report states, the methodology would "increase transparency by revealing the true cost of drugs after rebates." It is important that the Draft Report clearly specifies that it will not disclose any confidential, proprietary, and trade secret information. Further, the assertion that "leveraging publicly available ASP data..(can) ensure that patient OOP costs are based on reimbursement rates that reflect net price" is a vast oversimplification and not indicative of the current reality of many patients, where OOP costs do not reflect the rebates/discounts that health plans or PBMs receive. Finally, the methodology does not reference how it will impact Medicaid Best Price or other statutory amounts,

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Suite 1300
Washington, DC, 20005
202-962-9200

which is critical if the Draft Report intends to recommend that the UPL be set below the current average net price.

Reference Pricing to Existing Benchmarks: The Draft Report's language in this section attempts to oversimplify a myriad of existing benchmarks into a single specific category, which requires significant nuance. Each benchmark that is referenced must be independently examined, as they each have very distinct specific circumstances and requirements. For instance, an attempt to use international reference pricing as a benchmark divorces a product's reimbursement from the value it provides in favor of prices set by foreign governments based on factors that are not applicable to the U.S. market. International reference pricing does not account for possible variations in drug pricing due to differences in healthcare systems, market sizes and conditions, such as competition or negotiation practices, and pricing structures between countries. Further, most countries outside the United States use discriminatory measures of value, such as QALY analysis, to assist in price setting. Studies have shown that countries that use QALYs have severe restrictions on patient access to innovative medicines in other countries. For example, one study has shown that between 2002 and 2014, 40% of medicines that treat rare diseases were rejected for coverage in the United Kingdom.[1] It is evident that the language in this section ignores and oversimplifies all of these considerations.

Reference Pricing to Therapeutic Alternatives: BIO opposes the use of this methodology, which demonstrates a lack of perceived value between therapeutic options, a lack of consideration for the complexity of dosing, and a lack of understanding for pricing complexities in the attempt of making prices equal across competitor sets. The lowest net price is influenced by many factors and using this methodology may actually result in Best Price implications for products under review if competitive net price is below the product under review. Given these complications, it is unlikely that states will be able to effectively operationalize this methodology.

Launch Price Indexing: BIO opposes the launch price-based methodology, which ignore the clinical and economic value of drugs and their market factors and instead only address a partial context of price changes, which is significantly misleading and provides an inaccurate interpretation of pricing data. There are innumerable factors that impact a drug's pricing over time, whether it be new indications, new data such as Health Economics and Outcomes Research (HEOR)/Real World Evidence and new indication trial data, changes in production, or changes in the ecosystem. Accordingly, list price increases can reflect countless marketplace dynamics, including discounts to supply chain entities, new clinical data that increases the product's value, or increases in supply chain costs. It is notable that this methodology could also have implications on Medicaid Best Price when utilized in the commercial

[1] Mardiguian, S., Stefanidou, M., et al. "Trends and key decision drivers for rejecting an orphan drug submission across five different HTA agencies." Value in Health Journal. 2014. https://www.valueinhealthjournal.com/article/S1098-3015(14)03070-8/fulltext

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market.

Value: While BIO appreciates the switch from "payer return on investment" to "value," given that payers do not pass down savings to patients, it is concerning that the Draft Report chooses to reference quality-adjusted life years (QALYs) as a potential tool for deriving a value-based UPL. QALYs inherently devalue how some individuals rate quality of life utility measures, and consequently are discriminatory. Equal Value of Life Years Gained (evLYG) are similarly problematic as they do not fully capture quality of life improvements. Instead, value should be considered for distinct patient populations and differential disease states, informed by the patient experience, and metrics should be viewed holistically and prioritize patient-centered endpoints. BIO encourages the Board to further examine additional strategies that are aligned with a drug's value.

Budget Impact-Based: BIO opposes the use of budget impact-based UPLs, which could unfairly penalize highly effective drugs that have high upfront costs but long-term positive patient outcomes. Budget impact analyses need to consider the long-term savings from treating previously unaddressed conditions, which may not be apparent in short-term budget calculations. In addition, the Draft Report does not provide any information on how the threshold will be determined or set to ensure that patients' needs are met. It is problematic that the methodology could be determined by arbitrary cut points and potentially lead to the rationing of drug utilization.

Path to Net Pricing for Informed Decision Making (p.27)

In its attempt to estimate net pricing, the Draft Report ignores the significant complexity of the pharmaceutical supply chain and the sheer impossibility of collecting all the price concessions given to all entities that purchase or cover a given drug across the supply chain. Attempting to gather data on net pricing would entail information from potentially hundreds of different stakeholders and require entities to divulge their own proprietary data, and possibly even protected health information (PHI). While the vendors listed may be able to collect upfront insights, there would still be significant data gaps that could not be resolved.

Analysis of How UPL Would Be Enforced (p.29)

In its explanation of UPL enforcement, the Draft Report oversimplifies supply chain dynamics and makes premature assumptions regarding the impact of a UPL on stakeholders in the supply chain. As stated above, there has not been any concrete data or outcomes demonstrating the impacts of a UPL on the market, given that no state has implemented one yet. In addition, the Draft Report prematurely de-emphasizes the risk of diversion, citing the Drug Supply Chain Security Act (DSCSA) as an effective deterrent. This is another premature assumption as there has not been any concrete data or outcomes to suggest this, given that DSCSA has not yet been fully implemented.

Analysis of how UPLs Could be Implemented (p.30)

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Washington, DC, 20005
202-962-9200

It is problematic that the Draft Report does not provide any discussion on the impact of patients, and instead focus on an abstract mention of "the state's health care system." It is critical that the Board focus its affordability review solely on those patients who have direct experience using and paying for the particular drug under review and who are the ones directly impacted by such Board decisions and their consequences. Further, it is important that the section address the underlying issue for the state: maintaining two different systems- a system for drugs that have a UPL and a system for those that do not have a UPL.

Current Analysis of Potential Costs and Savings (p.31)

In the assessment of potential cost savings, it is important that the Draft Report give due attention to the potential impact of an UPL on rebates. The report briefly admits that "in general, if implementation of a UPL results in all rebates being removed, only the more aggressive UPL scenarios result in plan savings." It is critical that the Draft Report critically assess what a UPL's impact on rebates could do the affordability, accessibility, and sustainability within the healthcare system, and most importantly assess potential adverse outcomes for patients.

Medicare Maximum Fair Price Analysis (p.34)

The Draft Report suggests that using MFP across the eleven modeled drugs would yield $37 million in savings, which is a clear overestimation given that these drugs are already heavily rebated. Even compared with the other cost savings scenarios listed, such as the supposed $18.7 million in savings in PEBB/OEBB, it is evident that $37 million is overstated. The analysis does not even consider other measures passed in the IRA such as the inflation penalty, indicating a clear exaggeration of savings.

Amid IRA MFP effectuation, it is important that policymakers work together to ensure better data and linkages to validate claims and to eliminate duplicate discounts. Despite efforts to build compliance with MFP effectuation, it is evident that there are still significant operational issues that require the sharing of claims-level data.

Future Analysis of Potential Costs and Savings (p.34)

Rather than framing this section as an analysis of costs, this section should more accurately be depicted as the process needed in order to estimate costs and savings. The Draft Report must acknowledge that the potential impact on cost and savings will be informed by market response that have not yet been accounted for.

UPL Report by Horvath Health Policy

The UPL Report by Horvath Health Policy (UPL Report) provides a theoretical overview of how UPLs could function, and it is important that the Board regard this UPL Report as merely a single consultant's opinion on the potential impact of UPLs. The UPL Report cannot and should not be viewed as a comprehensive assessment, as it fails to understand impacts on the supply chain and most importantly impacts on patient access and OOP costs for patients. The UPL Report consistently lacks background or information to support its

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1201 New York Avenue NW
Suite 1300
Washington, DC, 20005
202-962-9200

assumptions regarding market impact and continuously fails to consider that patients remain particularly vulnerable to the downstream effects of UPLs due to the significant unknowns related to implementation. As voiced by many stakeholders, patients may face increased utilization management for UPL drugs and competitors in a therapeutic class, including step therapy and prior authorization, and increased barriers within formulary designs. It is also deeply concerning that the UPL Report seems to target manufacturer patient assistance programs in reference to the UPL, meanwhile failing to mention how PBMs and health plans consistently refuse to pass down manufacturer-provided discounts, rebates, and price concessions to patients at the pharmacy counter.

Finally, the UPL Report does not adequately account for the significant manufacturing complexity needed to develop valuable innovative therapies. Many innovative therapies require sophisticated, costly, and often specialized manufacturing processes. For instance, personalized cell therapies that must be manufactured individually for each patient, gene therapies that require complex viral vector production, and plasma-derived therapies that require extensive plasma collection, complex fractionation processes, and stringent safety measures. A rigid UPL process would not be able to appropriately assess and price these innovative therapies, potentially discouraging their development or limiting patient access.

***

BIO appreciates the opportunity to provide feedback to the Oregon PDAB through this Draft Report. We look forward to continuing to work with the Board to ensure Oregonians can access medicines in an efficient, affordable, and timely manner. Should you have any questions, please do not hesitate to contact us at 202-962-9200.

/s/

Melody Calkins
Director
Health Policy and Reimbursement

Oregon Coalition for Affordable Prescriptions (OCAP)
Fighting to lower prescription drug prices

Members of the Prescription Drug Affordability Board,

My name is John Mullin, and I am here today representing the Oregon Coalition for Affordable Prescriptions (OCAP), a non-profit organization dedicated to advocating for meaningful transparency on the causes of high prescription drug prices and the reduction of prescription drug costs for Oregonians. On behalf of OCAP, I want to begin by expressing our gratitude to the Prescription Drug Affordability Board (PDAB or "Board") for your tireless commitment to carefully examine the impact of high drug prices on residents of Oregon, state and local governments, employers, commercial health plans, health care providers, and pharmacies, including your recent efforts to prepare a report on upper payment limits (UPL). Your work reflects a deep dedication to addressing the financial burden that prescription drugs place on Oregonians, and we commend your thorough research and stakeholder engagement.

Your ongoing work and the release of the report is a milestone in the Board fulfilling the reporting requirements outlined in SB 192. While we recognize that the pharmaceutical market is complex and decisions about UPL implementation are difficult, we encourage the board to move forward with its work. In learning from the experiences of other states like Maryland and Colorado, we know legal and political challenges are likely and anticipate the road to implementation will be long. However, the time to act is now, and we encourage the PDAB to continue moving forward with confidence.

The OCAP and PDAB have a shared mission of working to make prescription drugs more affordable for Oregonians and ensuring Oregonians have access to critical and life-saving medications. We look forward to collaborating with you as this work moves forward and exploring all the policy levers that can help address the root causes of high prescription drug prices.

Thank you for your hard work and thoughtful deliberation and consideration as we continue to make progress toward a healthier, more equitable future for all Oregonians.

ENSURING ACCESS THROUGH COLLABORATIVE HEALTH

November 17, 2024

Oregon Prescription Drug Affordability Board
Department of Consumer and Business Services
350 Winter Street NE
Salem, OR 97309-0405

RE: Public Comments on the UPL Report

Dear Members and Staff of the Oregon Prescription Drug Affordability Board:

The Ensuring Access through Collaborative Health (EACH) Coalition is a network of national and state patient organizations and allied groups that advocate for treatment affordability policies that consider patient needs first.

While we applaud the board's commitment to supporting patients and lowering the costs of prescription medications, we are concerned that upper payment limits (UPLs) can further complicate an already complex healthcare marketplace and result in worse outcomes for patients.

We respectfully urge the board to consider the concerns of patient organizations outlined in this letter. We offer our organization as a resource to board members seeking to connect with patient organizations and patients.

UPLs Could Compromise Patient Access to Medications

While UPLs are intended to lower costs for patients, the reality is that they will create a new incentive structure for payers that could compromise patient access to the selected medications due to increased utilization management or reshuffling of formularies.

Payers in our health marketplace do not necessarily derive the most value from the lowest-cost drugs. According to reporting on PBMs by the New York Times, "Even when an inexpensive generic version of a drug is available, PBMs sometimes have a financial reason to push patients to take a brand-name product that will cost them much more."

Ultimately, this could mean that insurers and PBMs will place drugs subject to UPLs on higher formulary tiers or implement other utilization management tactics to steer patients away from these drugs. This could lead to higher out-of-pocket costs for patients who could face higher copay or coinsurance rates to retain access to that drug or alternatively be forced to switch to a more expensive drug that results in higher profits for their PBM.

These plan-prompted changes are collectively known as non-medical switching. Non-medical switches in medication can also cause unnecessary complications for patients. At a minimum, a switch in medication will require more doctor visits to monitor the efficacy of a new medication. Further, if the switch results in side effects or worsened outcomes, patients could face medical interventions or hospitalization and the additional costs borne out by both.

This eventuality was outlined by the Centers for Medicare and Medicaid Services in their May 3, 2024 Guidance on Medicare Drug Price Negotiation, "CMS is concerned that Part D sponsors may be incentivized in certain circumstances to disadvantage selected drugs by placing

selected drugs on less favorable tiers compared to non-selected drugs, or by applying utilization management that is not based on medical appropriateness to steer Part D beneficiaries away from selected drugs in favor of non-selected drugs."

Upper Payment Limits Don't Necessarily Translate to Patient Savings

The board's draft report states, "The UPL amount will be widely known in the State, and consumers will be aware of what they should be charged when paying for a drug." However, this grossly ignores the reality of the American health system.

Patients are rarely provided with a projected cost of their healthcare or medications, nor are they allowed to choose their treatments based on costs. Instead, patients and doctors choose medications that work best for their individual needs and are beholden to the rates set by insurers and PBMs to access that treatment. It is also these stakeholders that determine if cost-savings realized by the payer are subsequently shared with patients. Unfortunately, in most cases, they are not.

Minimize Uncertainty and Protect Patients

We applaud the board's efforts to seek ample input from market stakeholders and patient organizations on the UPL process. The board held multiple listening sessions, and town halls, conducted stakeholder outreach through questionnaires, and provided opportunities for written and verbal comments.

The results of these sessions are outlined in the report and demonstrate that there are significant concerns from the majority of stakeholders regarding UPLs and broadly, a lack of understanding both of the process and how healthcare in Oregon will be impacted by UPL implementation.

Despite these findings, the board has so far not responded to any of the concerns raised by stakeholders during these sessions. Further, the draft report does not appear to address any of the issues raised by stakeholders by altering course or making alternative policy recommendations.

Therefore, we strongly urge the board and staff to utilize the authority of the board to fully explore with all healthcare stakeholders how UPLs will be implemented and identify in advance any adverse impact on patients. We also urge the board to work with the state legislature to put in place safeguards for patients before moving forward with UPL policies. This will protect patients from increased utilization management, compromised access to drugs under review, and other unintended consequences of the board's actions.

In continuation of that point, while our health system and the policies that impact it are complicated, one principle is simple: every change that we make and policy we implement should ultimately benefit patients. We urge the board to keep this principle as a singular focus as it evaluates the impact of its cost reviews and UPLs.

We urge the board to utilize this organization and its members as a direct conduit to understanding and incorporating patient and caregiver perspectives, as well as those of patient organizations who have an understanding of the life cycle of disease from the lens of prevention, diagnosis, and disease management.

ENSURING ACCESS THROUGH
COLLABORATIVE HEALTH

We appreciate your laudable efforts to improve our health system and your steadfast commitment to protecting patients. We look forward to working together to achieve these goals.

Sincerely,

Tiffany Westrich-Robertson
Ensuring Access through Collaborative Health (EACH) Coalition

Genentech
A Member of the Roche Group

600 Massachusetts Ave. NW, Suite 300
Washington, DC 20001
Phone: (202) 296-7272
Fax: (202) 296-7290

November 15, 2024

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

Re: Oregon Prescription Drug Affordability Board Drug Selection & Affordability Reviews

Dear Members of the Oregon Prescription Drug Affordability Board:

Throughout the last year, Genentech has monitored and engaged in the Board's activities with interest and has submitted prior written comments addressing the Board's processes, and has participated in two manufacturer stakeholder meetings. Most recently, the Board's discussions have focused on SB 192 legislative requirements that the Board develop a plan for future legislative consideration around the implementation of an upper payment limit. As we shared in the two manufacturer stakeholder discussions, we have similar concerns about the complexities and challenges that have been identified with an upper payment limit as a tool for addressing drug affordability. Earlier this year, we were encouraged by the Board's decision in June to pause all prescription drug affordability reviews in 2024 and revisit your processes and data sources before beginning a new drug selection and review process in 2025. As we believe we have all experienced, this process alone is challenging enough, and we strongly recommend that the Board focus on this work before requesting new authorities from the legislature.

With that in mind, as the Board prepares to resume discussions on drug selection and affordability, we urge the board to adopt the following recommendations to ensure future processes yield a reliable, consistent, and data-driven result. We offer three key areas for the Board's consideration:

1. The Board must clearly establish its affordability goals and reevaluate its prioritization of affordability review criteria before embarking on a new drug selection and affordability review process.
2. The Board must address data limitations by broadening its data sources and contextualizing these data as part of the drug selection process.
3. The Board must implement enhanced methods of both soliciting and incorporating stakeholder feedback into its drug selection and affordability review processes.

The Board must clearly establish its affordability goals and reevaluate its prioritization of affordability review criteria before embarking on a new drug selection and affordability review process.

As the Board returns to a discussion on drug selection and conducting affordability reviews, the Board must first discuss and prioritize its affordability goals, including a defined framework of what affordability is, for whom it applies, and its views on how best to understand affordability through varying criteria and corresponding data. Focusing first on a robust discussion of the Board's affordability goals can create clarity for all stakeholders in the Board's focus and intentions while also establishing alignment for the following steps in the Board's drug selection and review processes. For example, if the Board's affordability goals are driven by an assessment of drug affordability for Oregonians, it may require solicitation and deeper analysis of certain national and Oregon-specific data, such as plan benefit designs, to fully understand patient out-of-pocket spending. Insights from Oregon-specific data (such as the all payer claims database) should be interpreted alongside consideration of the limitations of the data in capturing factors that impact patient spend, including but not limited to indirect and indirect costs of their disease that may be impacted by treatment (e.g., changes in total cost of medical care over time, negative health outcomes avoided, travel costs impacted by dosing frequency, use of rescue medications, use of copay assistance). These factors should then be clearly identified as part of the criteria for drug selection.

If the Board's affordability goals include an assessment of affordability for health systems and payers, the Board must ensure it assesses appropriate data on cost offsets delivered by the medicine under potential review. Genentech believes it is imperative for the Board to consider the many factors aside from a drug's price that shape affordability and the value of a medicine, including but not limited to the role of benefit design, the supply chain, and drug delivery method in a patient's out-of-pocket costs as well as how a drug contributes to cost offsets in other care.

To aid in defining the Board's affordability goals, Genentech urges the Board to consider implementing the following recommendations:

- The Board should revisit its drug affordability review criteria and seek input from third-party stakeholders on prioritized criteria;
- Following public discussion of these review criteria and incorporation of stakeholder feedback, the Board should conduct a new survey of Board members to establish a new calculated average rank to be applied in any future drug selection weighting exercises; and,
- The Board should, with appropriate notice and opportunity for public comment, update its drug affordability rules to align with its identified affordability goals and ensure such rules appropriately align with the Board's statutory authority; we recommend the Board begin this work by revisiting its proposed rule language presented and discussed on March 15, 2023, which included a more robust section (3) on "Selecting Drugs for Affordability Review" than what was adopted in the final rule, published as OAR 925-200-0010. In particular, the earlier draft specifically highlighted important data elements that should be included and discussed in the drug selection process, such as health equity and patient out-of-pocket costs.

Implementing these recommendations will support a more thorough, well-defined and transparent approach to both the drug selection and affordability review processes.

The Board must address data limitations by broadening its data sources and contextualizing these data as part of the drug selection process.

The Board's statute directs the Department to provide the Board with data, as reported under ORS 646A.689 (2) and (6) and ORS 743.025, to initiate its drug selection and drug affordability review processes. In its 2023 drug selection process, the Board focused heavily on limited cost data on a narrow subset list of drugs prioritized based on the state's Drug Price Transparency programs. However, the 2023 process, as we have commented previously, was conducted without regard for the necessary context associated with specific data. In 2025, it is essential the Board incorporate broader sources of data with which to contextualize aggregated data.

Specifically, following decisions regarding the Board's affordability goals, the Board should revisit its data call solicitation and accelerate this solicitation to allow for consideration of additional data and context during the Board's drug selection deliberations. The Board should be transparent about the methods that will be used to narrow initial lists of drugs eligible for an affordability review, and these deliberations should be conducted in public meetings of the Board and be open for input from interested stakeholders, including manufacturers. Transparency regarding data sources, methods used to create any necessary calculations, and a broader set of data will enhance the Board's deliberations while also providing necessary clarity to third-party stakeholders. In addition, such transparency will support the ability of third parties to validate the data used to inform the Board's decision-making.

When conducting the drug selection process, we urge the Board to individually discuss each of the drugs on any subset list and provide a robust rationale for their possible selection for an affordability review, including reference to the data sources and methods used to identify the drug for possible selection. In undertaking an approach to discuss each drug appearing on any subset list of drugs for selection, the Board can avoid many of the challenges encountered in 2023 and ensure the drugs it ultimately selects for an affordability review have been thoroughly evaluated and are appropriate to undergo a drug affordability review. We urge the Board to refine these processes and ensure all steps in the drug selection process are transparent, well-defined, and well-understood by the Board's stakeholders.

The Board must implement enhanced methods of both soliciting and incorporating stakeholder feedback into its drug selection and affordability review processes.

The statute requires that "[t]he board shall accept testimony from patients and caregivers affected by a condition or disease that is treated by a prescription drug under review by the board and from individuals with scientific or medical training with respect to the disease or condition." While acceptance of testimony is required by statute, it should not be the only method by which the Board engages with third-party stakeholders. We strongly urge the Board to develop additional tactics to seek input from stakeholders and specify how their input will be considered and incorporated into each part of the Board's drug selection and affordability review process. These actions should be identified and discussed publicly prior to proceeding with any drug affordability reviews.

For example, stakeholder engagement tactics undertaken by Boards in other states have included focus groups, open public surveys, and direct stakeholder meetings. Boards are also partnering with patient organizations that represent the impacted community to engage those with lived experience and solicit their input. Further, some boards are currently considering means by which to host expert testimony or other informational hearings, which would afford the Board and stakeholders more opportunity for public dialogue and interaction in contrast to a simple open comment period with no opportunity for direct engagement with Board members. It will be essential to identify several tactics to incorporate in a revised approach to drug selection and affordability reviews.

We strongly encourage the Board to meet directly with interested third-party stakeholders, including patients, caregivers, and providers and the advocacy organizations representing them to design a myriad of meaningful and appropriate engagement strategies and tactics.

Thank you for your consideration of our feedback in your ongoing deliberations. We believe it is essential for the Board to thoroughly revisit the drug selection and drug affordability processes before conducting affordability reviews in 2025 or advancing any other actions of the Board. If you have any questions or want to discuss our feedback, please contact Tim Layton, Director of State Government Affairs at layton.timothy@gene.com or (206) 403-8224.

Sincerely,

Mary Wachter
Executive Director
State & Local Government Affairs

COMMUNITY ACCESS NATIONAL NETWORK

Mailing Address:

Attn: Jen Laws
PO Box 3009
Slidell, LA 70459

Chief Executive Officer:

Jen Laws
Phone: (313) 333-8534
Fax: (646) 786-3825
Email: jen@tiicann.org

November 15, 2024

Oregon Prescription Drug Affordability Board
Department of Consumer and Business Services
350 Winter Street NE
Salem, OR 97309-0405

RE: Comment on Proposed UPL Legislative Report Draft

Honorable Members of the Oregon Prescription Drug Affordability Board,

The Community Access National Network (CANN) is a 501(c)(3) national nonprofit organization focusing on public policy issues relating to HIV/AIDS and viral hepatitis. CANN's mission is to define, promote, and improve access to healthcare services and support for people living with HIV/AIDS and/or viral hepatitis through advocacy, education, and networking.

While CANN is primarily focused on policy matters affecting access to care for people living with and affected by HIV, we stand in firm support of all people living with chronic and rare diseases and recognize the very reality of those living with multiple health conditions and the necessity of timely, personalized care for every one of those health conditions.

Today, we write with exceptional concerns and suggestions regarding the proposed draft of the UPL Legislative Report.

Cost/Necessary Additional Appropriations Due to UPL Impacts Requires Consideration of UPL as a Failed Approach

Data weakness should not be diminished or washed over (page 32)

In the *Current Analysis of Potential Costs and Savings* section the Board lists a range of potential Upper Payment Limit (UPL) scenarios. It was acknowledged that the interpretations were largely theoretical due to the variations in quality and completeness of data. Additionally, the potential "savings" are described as being nearly equal to potential "costs". Insisting on additional UPL action without greater clarity diminishes the potential magnitude of the negative implications of a UPL. It is important to remember that CMS projected any 'savings' would likely be due to cost-shifting -- any governmental savings, no matter how minimal, would result in increased out-of-pocket costs for patients. The Centers for Medicare and Medicaid Services' National Health Expenditure Projections (2023-2032) also explains how the Inflation Reduction Act is expected to result in increases in Medicare spending due to institution of drug price negotiations,

otherwise referred to as the "Maximum Fair Price" (MFP). National Health Expenditure growth is expected to outpace average GDP growth largely due to hospital and provider payments and Medicaid enrollment is expected to decline. These are all health expenditure issues, directly affecting patients financially in which a UPL does not address. Similarly, imposition of the MFP is not necessarily expected to cause overall "savings", rather cost shift, as discussed further below.

Clarification Needed to Effectively Describe WAC Manipulation by PBMs
Transaction Relationships in the Supply Chain: Manufacturers (page 13)

This section asserts that drug manufacturers are solely responsible for, control, and set the Wholesale Acquisition Cost (WAC). There is nuance in that this is not unequivocally true. The recent complaint filed by the Federal Trade Commission against Pharmacy Benefit Managers (PBMs) explains that while manufacturers offer multiple WACs per medication, PBMs often select higher WAC medications since that allows PBMs to obtain a larger rebate retention which increases the overall WAC. The following citations from the FTC complaint illustrate this:

139. Rather than cutting list prices on their existing insulin products and risking losing formulary access, Lilly, Novo, and Sanofi each launched new, unbranded low WAC products. These low WAC insulin versions were identical to the high WAC versions in all clinical respects. The only differences were that they did not include branding and were significantly lower list price.

143. The insulin manufacturers continued to offer the high WAC, highly rebated versions while pricing their low WAC insulin at roughly "net price parity" with the branded versions. Essentially, although the low WAC version had a different list price, the smaller rebate it offered resulted in a net price roughly equivalent to that of its high WAC counterpart. Manufacturers adopted this pricing strategy "so that the payer would be neutral" or "indifferent" between the two versions.

144. The PBM Respondents, however, were not indifferent between the high WAC and low WAC insulin versions. Instead, they methodically disfavored the low WAC insulin products on their flagship commercial formularies, preferring only the high WAC versions, with high rebates and fees.

PBMs Gatekeep Formularies and Plan Design, Patient Experiences in "Affordability" and Access
Transaction Relationships in the Supply Chain: Pharmacy Benefit Managers (PBMs) (page 14)

In this section, it is important to emphasize PBM gatekeep formularies. According to the FTC, the three largest pharmacies administer approximately 80% of all prescriptions in the United States. Additionally, they base the coverage, tier, prior authorization and other formulary decision metrics on what is profitable to PBMs, not what is 'affordable' for patients or government payers.

Roles Should be Better Defined
Transaction Relationships in the Supply Chain: Pharmacy Benefit Managers (Payers) (page 14)

The report conflates the roles of "payers," PBMs, and Managed Care Organizations (MCOs) in the case of Medicaid. These roles should not be commingled. Employers and governmental bodies should be ascribed the role of payer separate from PBMs. Much of what is currently attributed to payers is managed by PBMs and MCOs.

Plight of Independent Pharmacies Needs Greater Emphasis as Access and System Sustainability Issue
Transaction Relationships in the Supply Chain: Pharmacies (page 15)

This section does not explicitly address concerns raised by non-chain, independent pharmacies. A UPL's impact must be explicitly described within this particular context of the ecosystem. These independent pharmacies are faltering because of PBM under-reimbursement. According to the National Community Pharmacists Association, 32% of independent pharmacies are exploring closing in 2024.

Perverse Incentives Drive PBM Practices
Perverse incentives caused by PBM practices (page 16)

The report effectively notes how PBMs may use rebates to identify preferred formulary placement. However, the report doesn't mention the perverse incentives this causes. The FTC complaint explains that PBM profitability is the product of a focus on rebate chasing as a priority. This results in selecting higher WAC because higher list price = better formulary placement. This adversely affects affordability for patients and the system because the better formulary placement is not based on clinical benefit or medical necessity for patients. The board would be served well to encourage investigations similarly situated to those of OH (Attorney General Dave Yost) and Indiana's overspending to the tune of $1B because of PBM greed. Investigating these situations as they do or do not apply to Oregon would have a more direct benefit to both the state and patients in Oregon, without the risks a UPL poses on access.

CMS Data Needs to be Included
UPL Potential Methodologies (page 19)

This discussion Fails to mention CMS' National Health Expenditure Projections (2023-2032) analysis conclusions. CMS expects both patient and system costs to rise most significantly related to hospital care and physician and clinical services, whereas CMS projects prescription drug spending to slow. It is important to note CMS *also* projects that implementation of the MFP will largely cost shift rather than "save", reducing government spending while increasing patient out-of-pocket costs. A UPL, either as established by MFP or independently, similarly risks such a shift, further reducing patient "affordability" and access.

Reference Pricing is Problematic, Disregards Statutory Prohibition on use of QALYs, and Runs Counter to Federal Non-Discrimination Rules
Other countries' prices should not be used as references (page 20)

The "Reference Pricing to Existing Benchmarks" section includes referencing pricing to other countries. Other countries use discriminatory quality metrics, such as Quality Adjusted Life Years (QALYs), which are prohibited by Oregon's convening statute and by federal non-discrimination rules, *inviting unnecessary litigation*. Referencing other countries' pricing considerations directly undermines statutory requirements. The board considering international reference of any kind should be prohibited as it is a "back door" vehicle of QALY use.

The U.S. Department of Health and Human Services and Centers for Medicare and Medicaid Services finalized federal rules recognizing "quality adjusted life years" and similarly situated metrics as necessarily discriminatory toward persons with chronic health conditions and older patients. Those same rules, integrating protections under the Americans with Disability Act and Section 504 are directly addressed in terms of "cost containment" efforts as detailed below from 89 FR 4006, Nondiscrimination on the Basis of Disability In Programs or Activities Receiving Federal Assistance (Section: Value Assessments [84.57]);

Comment:
The Department requested comment on how value assessment tools and methods may provide unequal opportunities to individuals with disabilities. Numerous commenters indicated that value assessment methods could limit people with disabilities' access to health care goods and services, including pharmaceutical interventions, and expressed concern that the use of the QALY unfairly limited access to emerging pharmaceutical interventions that could extend the lives of people with disabilities.

Response:
While the nondiscriminatory use of value assessment is an important tool for health care cost containment, the Department agrees that discriminatory usages of value assessment harm people with disabilities and provide unequal opportunities.

Comment:
One commenter argued that the use of the QALYs and other methods of value assessment that frequently entail discounting the value of life extension on the basis of disability are not discriminatory because they are "only one step" in a process of decision-making, noting that policymakers also take into account other factors in their ultimate decision-making.

Response:
Although recipients may make use of multiple factors to influence their decision-making, the use of a measure of value that assigns lower value to extending the lives of people with disabilities to determine eligibility, referral, or provision or withdrawal of an aid, benefit, or service can be nonetheless discriminatory.

Additional Data Limitations
There are additional limitations of the Oregon APAC data (page 27)

APAC data does not capture denials or other actions by payers which may negatively impact patient experience and affordability. Furthermore, APAC data is not often audited for actuarial assessment. Any use of APAC data must recognize the limitations and that all data points provided are done solely through the lens of PBM stakeholders.

We Applaud the 340B Impact Analysis
We applaud the 340B revenue impact analysis (page 28)

We thank you for your discussion of the UPL's possible impacts on 340B providers and pharmacists. Additionally, we'd like to add that you must also include potential for funding allocation to Medicaid and other state payers, like the State AIDS Drug Assistance Programs (ADAP), which might face similar concerns.

Request for Additional Authority is Inappropriate, given Report Content
All told, the Board's Own Report Evidences No Need for Additional Authority (page 30)

The board has self-identified the condition of not presently having sufficient data or a developed, amplified, "fleshed-out" plan. As such it would appear presently inappropriate to seek additional statutory authorities when they may not fit within the plans that the board finally develops. Additionally, ineffectively requesting the additional authorities now could adversely affect the granting of requests for additional powers that result after more deliberation and information gathering.

Clarification of Factors Driving Patient Costs
Correction needed under "Current Analysis of Potential Costs and Savings" (page 32)

Patient copayments and other aspects of plan design are NOT based on the total cost of a medication but based on profitability to the PBM (see FTC complaint). The Board's conclusions in this respect are troubling considering these facts and further support this not being the appropriate juncture at which to seek additional authority.

Pertinent Data cannot be Omitted
Senate Bill 192 requires a thorough analysis of the costs of implementing a plan: Future Analysis of Potential Costs and Savings (page 34)

This section states that a detailed analysis is premature currently. The Board does not have the option to disregard the cost of implementation from various stakeholders in the supply chain. Disregarding the requisite analysis also necessarily means the Board has not considered all costs associated with implementing a UPL - further undermining the likelihood of any "savings" and only increasing the potential costs as unpleasant surprises for the legislature to grapple with later down the line.

340B Risks are Facts not Merely Personal Interpretation
340B effects are not just survey perspectives but actual fact (page 39)

The observation section on page 39 catalogs the adverse effects of a UPL on 340B covered entities, especially FQHCs, as concerns listed by survey respondents. This information should be listed as factual assessment and not just community interpretation. The 340B risks to the health equity efforts of covered entities, such as FQHCs, should be listed as facts under the **340B Covered Entities** segment of the *Future Analysis of Potential Costs and Savings* section of the report beginning at the end of page 36 going into page 37. Categorizing these effects under community survey response diminishes the issue as 'subjective opinion' or 'emotional response' instead of data-driven fact.

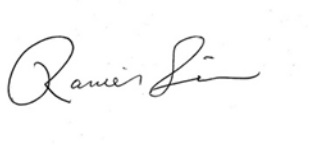
Recommendations Continue to Fail to Establish Monitoring Metrics

One of the most significant failures of this report is the lack of monitoring metrics designed to evaluate continued patient access to lifesaving and life-sustaining medications. Similarly, the lack of the metrics also fails to continue assessments of patient "affordability" because of either legislative or Board actions.

In totality, the Board's effort regarding this report is extensive and should be applauded. However, by and large the conclusions of the report can be summarized as "we don't know, things could be bad but let us find out anyways". This approach recklessly disregards not only patient access to care, but the legislature's fiduciary duty to taxpayers, and significantly consequential impacts on providers and the state's public health programs.

We encourage you to consider our commentary in the development of the legislative draft letter. We also appreciate all your continued mindful efforts in effectively deliberating what is best for Oregon patients as well the healthcare system.

Respectfully submitted,



Ranier Simons
Director of State Policy
Community Access National Network

On behalf of

Jen Laws
President & CEO
Community Access National Network

November 14, 2024

Oregon Prescription Drug Affordability Board
c/o Department of Consumer and Business Services
350 Winter Street NE
Salem, OR 97309-0405

TO: Members of Oregon Prescription Drug Affordability Board

As a physician who has spent decades caring for patients whose families struggled to access and afford their needed medicines, I urge you to reconsider approving the Senate File 192 Upper Payment Limit draft report and seek additional and more diverse stakeholder input. I am deeply concerned that the proposed implementation of UPLs could inadvertently restrict access to necessary medications for patients, especially those with rare or complex conditions.

As a board-certified pediatrician and rheumatologist, I have dedicated my career to serving children and youth with chronic or disabling conditions. Many of my young patients, including those with juvenile idiopathic arthritis or lupus, depend on specialized, innovative and, unfortunately, expensive therapies. At your October 16th meeting, board members acknowledged the lack of physician input in developing this report; remedying this deficit prior to filing your final report would be valuable. While I fully support the creation of a constituent advisory board, this should not be substituted for robust public input opportunities.

Currently, the public has limited ability to engage—just one minute of stakeholder comments for every nine minutes of Board discussion is scheduled at your November 20th meeting. Oregonians and Oregon lawmakers deserve recommendations informed by comprehensive and extensive stakeholder feedback. Physicians and patients are concerned that the current approach risks overlooking individual patient needs and could disadvantage certain populations.

I understand and support the urgency of addressing prescription drug costs, but the proposed UPL implementation has the potential to actually decrease access to critical medications for those who need them most. The draft's suggested options lack sufficient safeguards to ensure that affordability measures do not undermine the availability of essential treatments.

Focusing solely on UPLs to address treatment costs is akin to pulling on a single thread in a large quilt. By targeting one price in a multi-faceted drug pricing ecosystem, I believe this approach is too narrow to address the root causes of high out-of-pocket costs. As raised during the Board's recent discussions, this strategy risks falling short of its mandate to improve affordability for patients since it does not directly address the patients' payments.

Among the many complexities not yet considered in creating a UPL is the role of national and out-of-state group purchasing organizations and the unique cost structures for infusible or other administered medicines. Medications can only remain accessible if providers can afford to purchase and administer them; restrictive UPL policies may jeopardize these critical care sites, resulting in decreased access to care. The Coalition of State Rheumatology Organizations, National Infusion Center Association and others have highlighted these challenges, underscoring the fact that these are not isolated state-level concerns. Ensuring that medications remain locally available and affordable is critical to prevent patient care disruptions and unintended outcomes.

I urge the Board to seek authority to review and provide recommendations that include the roles of **all** players in the system, since payors and pharmacy benefit managers (PBMs and others are involved in setting both the list prices and patient costs. Without examining the entire drug supply and distribution chain, we cannot achieve the goal of improving access to affordable, life-saving drugs. Effective solutions must focus on what patients actually pay, not inflated list prices.

I commend your discussion around providing policy recommendations for Senate Bill 844 and your recognition of the need for more data and broader stakeholder input. While this may extend the timeline, it will ultimately better serve Oregonians.

In conclusion, I am concerned that the Board's current focus seems overly fixated on meeting arbitrary legislative deadlines rather than prioritizing the lives and well-being of the patients directly impacted by the Board's decisions. Physicians and patients remain committed to working with you to ensure affordable medications for all Oregonians, but to accomplish this goal will require a more thorough, comprehensive, and extensive consideration.

Thank you for your attention to this critical issue.

Sincerely,

Harry L. Gewanter, MD, FAAP, MACR
President, Virginia Society of Rheumatology
Board Member, Let My Doctors Decide Action Network