Boehringer Ingelheim

Mr. Jean-Michel Boers
President and CEO
Jean-michel.boers@
boehringer-ingelheim.com

Boehringer Ingelheim USA Corporation
900 Ridgebury Rd/P.O. Box 368
Ridgefield, CT 06877-0368

Oregon Prescription Drug Affordability Board
Sent Via Email: PDAB@DCBS.Oregon.gov

Re: Oregon Prescription Drug Affordability Board's Constituent Focus Groups Surveys: Pharmaceutical Manufacturer Survey on the Use of Upper Payment Limits (UPLs)

Dear Members of the Oregon Prescription Drug Affordability Board:

On behalf of Boehringer Ingelheim Pharmaceuticals, Inc., we would like to provide feedback to the "Pharmaceutical Manufacturer Survey" issued by the Oregon Prescription Drug Affordability Board ("Board") regarding the use of upper payment limits.

Founded in 1885 and independently owned since, Boehringer Ingelheim is a research driven company with 53,000 employees around the world dedicated to the discovery and development of breakthrough therapies that transform lives, today and for generations to come. As a leading research-driven biopharmaceutical company, we create value through innovation in areas of high unmet medical need focused on breakthrough therapies and first-in-class innovations.

Boehringer understands the scrutiny over prescription drug prices. The U.S. healthcare system is complex and often does not work for patients, especially the most vulnerable. In some instances, patients face prices at the pharmacy counter that are out of reach. While we understand that there is a need to find ways to concurrently reduce state budget expenditures and reduce patient out of pocket costs, we note some important considerations with respect to the use of an upper payment limit ("UPL") and offer solutions that may address the root of the problem.

An Upper Payment Limit is Unlikely to Reduce Cost for Patients:

Applying an upper payment limit to a prescription drug for the insurer or pharmacy benefit manager ("PBM") will not directly help people at the pharmacy counter. Pharmacy counter prices are controlled by the patient's insurance plan in the form of copay or co-insurance.

Generally, pharmaceutical manufacturers provide significant discounts and rebates off the list price of their medicines to insurers, PBMs and other parties. Unfortunately, these discounts are commonly withheld from patients by these other entities. As insurers and PBMs increasingly shift the cost of care to patients, patients are faced with high out-of-pocket costs at the pharmacy counter. To help alleviate the burden of these tactics', Boehringer offers additional financial support for patients designed to support and assist patients who are unable to afford their medication because they are either uninsured or are exposed to high out-of-pocket costs due to their health plan design, i.e. the underinsured. Commercial health plans and PBMs have progressively developed various tactics — including copay

accumulators, copay maximizers, and alternative funding—that siphon patient assistance and we urge the Board to consider their direct harm to patients.

Furthermore, because of the PBM system, prescription drugs subject to an UPL will result in less favorable price concessions to PBMs which will result in PBMs shifting utilization to more expensive drugs with more favorable rebate terms to the PBM. PBMs and other middlemen seek greater rebates from manufacturers that rarely reach patients while claiming they are providing cost savings to their customers. Their goal is not to ensure the best patient outcome but to continue to extract rebates for formulary access.

An Upper Payment Limit Would Likely Hurt Patient Access and Undermine Medical Decision-Making:

Boehringer shares the Board's goal of ensuring patients have access to medicines and life-saving treatments; however, implementing an UPL may further restrict access for some patients.

Given the interconnected nature of the pharmaceutical supply chain, we are increasingly concerned that the substantial rebates and discounts provided by pharmaceutical manufacturers do not directly benefit the patient nor offset their costs at the pharmacy counter. We are concerned that the application of an UPL could exacerbate access barriers for patients – partly due to the perverse financial incentives PBMs and insurers reap – and additionally undermine the patient and physician medical decision-making process. At the sole discretion of PBMs and insurers, if they are not satisfied with rebate negotiations, they may identify another prescription drug as "preferred" and place the low-rebate (UPL-applied) drug on a less preferred tier, increasing the patient out-of-pocket costs. Additionally, the PBM and health plan may choose to remove the treatment from their formulary altogether, which could impose on the medical decisions made between physicians and their patients. A patient might be forced to forego the treatment selected by their physician, for a product deemed as "preferred" by their health plan solely due to financial incentives.

Conclusion

Boehringer recognizes the prescription drug access and cost challenges patients are burdened with, and we are committed to promoting policies that protect patients in Oregon. We encourage meaningful reforms that will help lower the price patients pay for medicines at the pharmacy, such as making monthly costs more predictable, preventing deceptive alternate funding programs (AFPs), and sharing negotiated savings on medicines with patients.

We thank you for considering feedback on the use of UPLs and consideration of our concerns. Steadfast in our commitment to our patients and access to life-saving treatments, we stand ready to be a constructive partner in this initiative.

Regards,

Bridget Walsh
VP, Government Affairs and Public Policy
Boehringer Ingelheim Pharmaceuticals, Inc.

Pharmaceutical Manufacturers

*Name of person completing survey: ***Blasine Penkowski, Chief Strategic Customer Officer***

*Name of facility/entity: Johnson & Johnson Health Care Systems Inc.

*Email: ***bpenkows@ITS.JNJ.com***

*Organization Type (Carrier, Hospital or Health System, 340B Covered Entity, Pharmacy, Pharmaceutical Manufacturer, Pharmacy Benefit Manager, Advocacy Group, Wholesaler/Distributor, Group Purchasing Organization (GPO), Pharmacy Services Administrative Organization (PSAO))

Pharmaceutical Manufacturer

When thinking about drug affordability, how much concern do you have about the impact of the cost of drugs on patients?

- Very concerned
- Somewhat concerned
- Not concerned
- Not applicable
- ***Other – J&J is concerned about both patient access to and affordability of innovative medications due to high out-of-pocket costs and burdensome benefit utilization management. However, an upper payment limit (UPL) is not the solution. J&J urges the Oregon Prescription Drug Affordability Board (the Board) to make the following policy recommendations to the Oregon Legislature:***
    1. ***Require that rebates and discounts that PBMs receive from manufacturers be directly shared with patients at the pharmacy counter;***
    2. ***Examine the use of utilization management tools and evaluating how best to regulate them in the interest of patient access and minimizing out-of-pocket (OOP) costs; and***
    3. ***Prohibit diversion of cost-sharing assistance to ensure payment made by or on behalf of patients counts towards their cost-sharing burden.***

How do you anticipate that an upper payment limit would impact your organization's revenue and budgetary considerations?

- Positive impact
- Neutral impact
- Negative impact
- Not applicable
- ***Other – A UPL is an untested, unprecedented method, the impact on revenue or budget is unknown. We also have concerns about potential legal issues surrounding UPL operationalization. Furthermore, we are greatly concerned that a UPL will negatively impact patient access and will not lower patients' OOP costs. According to a recent Avalere survey, health plans have stated that utilization management will increase.[1] We are also concerned that a UPL will have negative unintended consequences for other entities throughout the supply chain, including providers, pharmacies, and wholesalers. If providers and pharmacies do not receive adequate reimbursement that covers their administrative costs, they may suffer financial losses and choose not to offer a drug subject to a UPL. As a result, Oregon patients may not be able to access their medications.***

How do you perceive the potential effects of an upper payment limit on patient *access* to necessary medications?

[1] Partnership to Fight Chronic Disease. "Health Plans Predict: Implementing Upper Payment Limits May Alter Formularies and Benefit Design But Won't Reduce Patient Costs." Accessed June 27, 2024.

• Create opportunities for a positive impact on patient access
• Neutral impact on patient access
• ***Create challenges to patient access***

What kind of impact do you think an upper payment limit would have on a patient's *ability* to afford their medications?
• Positive impact
• Neutral impact
• ***Negative impact***

What challenges might your organization face in adjusting to the constraints imposed by an upper payment limit (select all that apply)?
• Increased administrative burden
• Supply chain disruptions due to shortages or inability to sell into a market
• ***Compliance with regulatory requirements***
• ***Other (please specify) – A UPL is an untested, unprecedented method, with no existing system for implementation. In addition, UPLs will be in conflict with existing contracts across the entire supply chain. We also have concerns about potential legal issues surrounding UPL operationalization. Furthermore, we are greatly concerned that a UPL will negatively impact patient access and will not lower patients' OOP costs. According to a recent Avalere survey, health plans have stated that utilization management will increase.[1] We are also concerned that a UPL will have negative unintended consequences, including administrative burden, for other entities throughout the supply chain, including providers, pharmacies, and wholesalers. If providers and pharmacies do not receive adequate reimbursement that covers their administrative costs, they may suffer financial losses and choose not to offer a drug subject to a UPL. As a result, Oregon patients may not be able to access their medications.***

What challenges do you foresee for your company if an upper payment limit is implemented? (Select all that apply)
• Reduced revenue
• Limited R&D funding
• ***Compliance concerns***
• Competitive disadvantages
• ***Other (please specify) – A UPL is an untested, unprecedented method, and the impact on revenue or budget is unknown. We also have concerns about potential legal issues surrounding UPL operationalization. Furthermore, we are greatly concerned that a UPL will negatively impact patient access and will not lower patients' OOP costs. According to a recent Avalere survey, health plans have stated that utilization management will increase.[1] We are also concerned that a UPL will have negative unintended consequences for other entities throughout the supply chain, including providers, pharmacies, and wholesalers. If providers and pharmacies do not receive adequate reimbursement that covers their administrative costs, they may suffer financial losses and choose not to offer a drug subject to a UPL. As a result, Oregon patients may not be able to access their medications.***

The Oregon PDAB Is also interested in hearing about alternative policy approaches and recommendations that you may have. The following questions will provide you with an opportunity to provide more detailed information on approaches, recommendations, or concerns.

How could upper payment limits create meaningful cost savings for all consumers and purchasers?

• ***UPLs are unlikely to create any cost savings for consumers or purchasers. Patient OOP cost is set by health plans as a part of insurance benefit design, and health plans often base patients' coinsurance on the list***

price of a drug rather than the discounted net price plans receive.[2] A recent Avalere survey commissioned by the Partnership to Fight Chronic Disease further supports this assertion. In the survey, health plans stated "Payers will not pass their savings (if any) onto individuals. It's not realistic and somebody will need to make up the differences."[1] Interviewed plans also stated that they were unlikely to lower plan deductibles or maximum out-of-pocket limits as a result of a UPL.[1]

How would your organization utilize savings resulting from an upper payment limit (if applicable)?
• ***Not applicable.***

What could be potential administrative burdens or operational challenges associated with implementing an upper payment limit?
• ***There is no current system for operationalizing UPLs. We have concerns about potential legal issues surrounding UPL operationalization. Moreover, as UPLs ignore the interconnected market realities of the drug pricing ecosystem and supply chain, these price-setting thresholds may have unintended consequences across payer and PBM formularies, price-reporting metrics, provider reimbursement and patient plan and benefit options.[3]***

Moreover, UPLs are unlikely to create any cost savings for consumers or purchasers. Patient OOP cost is set by health plans as a part of insurance benefit design, and health plans often base patients' coinsurance on the list price of a drug rather than the discounted net price they receive.[2] A recent Avalere survey commissioned by the Partnership to Fight Chronic Disease further supports this assertion. In the survey, health plans stated "Payers will not pass their savings (if any) onto individuals. It's not realistic and somebody will need to make up the differences."[1] Interviewed plans also stated that they were unlikely to lower plan deductibles or maximum out-of-pocket limits as a result of a UPL.[1]

What recommendations, if any, do you have regarding the potential administrative burdens or operational challenges associated with implementing an upper payment limit?
• ***We recommend not implementing a UPL, and instead, we urge the Board to make the following policy recommendations to the Oregon Legislature:***

1. ***Require that rebates and discounts that PBMs receive from manufacturers be directly shared with patients at the pharmacy counter;***
2. ***Examine the use of utilization management tools and evaluating how best to regulate them in the interest of patient access and minimizing OOP costs; and***
3. ***Prohibit diversion of cost-sharing assistance to ensure payment made by or on behalf of patients counts towards their cost-sharing burden.***

Are there alternative policy approaches that you believe would be more effective in addressing drug affordability while preserving innovation and investment in research and development?
• ***Yes, we urge the Board to make the following policy recommendations to the Oregon Legislature:***

1. ***Require that rebates and discounts that PBMs receive from manufacturers be directly shared with patients at the pharmacy counter;***
2. ***Examine the use of utilization management tools and evaluating how best to regulate them in the interest of patient access and minimizing OOP costs; and***
3. ***Prohibit diversion of cost-sharing assistance to ensure payment made by or on behalf of patients counts towards their cost-sharing burden.***

How can policymakers ensure that an upper payment limit policy is implemented in a manner that promotes transparency, fairness, and affordability for both payers and patients?

---

[2] PhRMA. "Commercially-Insured Patients Pay Undiscounted List Prices for One in Five Brand Prescriptions, Accounting for Half of Out-of-Pocket Spending on Brand Medicines." Accessed June 27, 2024.
[3] Janssen. "Influence of Prescription Drug Affordability Board and Upper Payment Limits on the State Drug Pricing Ecosystem." Accessed June 27, 2024.

• Given the complexity of the healthcare ecosystem, a UPL cannot be implemented in a manner that promotes transparency, fairness, or affordability for payers and patients. A UPL is an untested, unprecedented method, and the impacts on revenue or budget are unknown. We also have concerns about potential legal issues surrounding UPL operationalization. Furthermore, we are greatly concerned that a UPL will negatively impact patient access and will not lower patients' OOP costs. According to a recent Avalere survey, health plans have stated that utilization management will increase.[1] We are also concerned that a UPL will have negative unintended consequences for other entities throughout the supply chain, including providers, pharmacies, and wholesalers. If providers and pharmacies do not receive adequate reimbursement that covers their administrative costs, they may suffer financial losses and choose not to offer a drug subject to a UPL. As a result, Oregon patients may not be able to access their medications.

What specific factors or considerations should policymakers take into account when setting an upper payment limit for prescription drugs?

• A UPL is an untested, unprecedented method, and the impact on revenue or budget is unknown. We also have concerns about potential legal issues surrounding UPL operationalization. Furthermore, we are greatly concerned that a UPL will negatively impact patient access and will not lower patients' OOP costs. According to a recent Avalere survey, health plans have stated that utilization management will increase.[1] We are also concerned that a UPL will have negative unintended consequences for other entities throughout the supply chain, including providers, pharmacies, and wholesalers. If providers and pharmacies do not receive adequate reimbursement that covers their administrative costs, they may suffer financial losses and choose not to offer a drug subject to a UPL. As a result, Oregon patients may not be able to access their medications.

To avoid unnecessary spending of taxpayers' dollars, we urge the Board to make the following policy recommendations to the Oregon Legislature:

1. ***Require that rebates and discounts that PBMs receive from manufacturers be directly shared with patients at the pharmacy counter;***
2. ***Exam the use of utilization management tools and evaluating how best to regulate them in the interest of patient access and minimizing OOP costs; and***
3. ***Prohibit diversion of cost-sharing assistance to ensure payment made by or on behalf of patients counts towards their cost-sharing burden.***

June 28, 2024

VIA ELECTRONIC FILING

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

Dear Members of the Oregon Prescription Drug Affordability Board:

GSK and ViiV Healthcare (ViiV) appreciate the opportunity to jointly submit a comprehensive response to the Oregon Prescription Drug Affordability Board's (Board) survey, as part of the development of a plan to establish upper payment limits (UPLs) required by Senate Bill 192.

GSK is a science-led global healthcare company with a special purpose to unite science, technology, and talent to get ahead of disease together. We focus on science of the immune system, human genetics, and advanced technologies to impact health at scale. We prevent and treat disease with vaccines, as well as specialty, and general medicines.

ViiV is the only independent, global specialist company devoted exclusively to delivering advancements in human immunodeficiency virus (HIV) treatment and prevention to support the needs of people with HIV and those vulnerable to HIV. From its inception in 2009, ViiV has had a singular focus to improve the health and quality of life of people affected by this disease and has worked to address significant gaps and unmet needs in HIV care.

We reviewed the survey questions that were sent out to manufacturers and appreciated the interest in hearing stakeholder perspective on this important issue. However, we felt that many of questions did not leave room to expand on the nuances of UPL proposals. Therefore, we have elected to jointly submit this letter that explains the impact that UPLs will have on patients and access to medications.

Patient accessibility to medication has always been, and remains, a top priority for both GSK and ViiV. While there are many solutions that could have a positive impact on patient affordability and accessibility, establishing UPLs is not one of them.

GSK and ViiV are concerned that added complexity and lack of transparency on UPLs could drive supply chain costs higher over time and exacerbate patient access concerns. Numerous operational challenges associated with implementing UPLs exist, which are likely to create financial and logistical burdens for all stakeholders involved in the drug supply chain, including pharmacies, wholesalers, providers, payers, and patients.

For example, effectuating a UPL price through the supply chain could necessitate new pharmacy and wholesaler acquisition/tracking systems and the introduction of payment streams that do not exist today. Further, any challenges in pharmacy and wholesaler supply operations can directly lead to gaps in patient access, particularly if a patient's local pharmacy is unable to operationalize and comply with the UPL-driven requirements.

Also critical for patients, payers have indicated that drugs subject to UPLs or other drugs in their therapeutic class could have more utilization management (e.g., prior authorization) once a UPL is implemented, as well as cause changes in formulary tiering, which could increase patients' out of pocket costs.[1] UPLs are also likely to have long-term effects on the prescription drug ecosystem, including provider access, copay assistance needs, and manufacturer research and development (R&D).

Equally concerning, affordability reviews that inform upper limit decisions target the most innovative medicines, disproportionately impacting patients with diseases where there is high unmet need and where low-cost treatment options are often not available.

GSK and ViiV support policy solutions that transform our healthcare system into one that improves patient outcomes, achieves higher value care and rewards innovation. Policies that can positively impact patients include:

- Requiring pharmacy benefit managers (PBMs) to pass manufacturer rebates to patients at the pharmacy counter;
- Requiring PBMs to be paid a flat fee based on the value of the services they provide, rather than a percentage of a drug's list price; and
- Closing policy loopholes in health insurer coverage that allow copay accumulator adjustment programs, copay maximizer programs, and alternative funding programs to interfere with patient cost savings.

In summary, medications prescribed should be based on the best clinical outcomes as decided by providers and patients and not strictly by cost considerations. Imposing arbitrary UPLs guided by misinformed affordability reviews may limit access to life-saving medicines and vaccines and indirectly harm patients' health. GSK and ViiV urge the Board to consider these unintended consequences as it seeks to implement Senate Bill 192 and how its plan to establish an UPL may impact access to vital medications and vaccines for Oregonians.

Thank you again for the opportunity to engage with the Board and your survey efforts. We welcome a continued dialogue on this issue and look forward to future engagement with you on solutions that maintain and increase access to vital medications in Oregon. Please feel free to contact Christian Omar Cruz at Christian.O.Cruz@gsk.com with any questions.

Sincerely,

Harmeet Dhillon
Head, Public Policy
GSK

Carie Harter
Senior Director, Government Relations
ViiV Healthcare

[1] Avalere. April 2024. "Research Explores Health Plan Perceptions of PDABs and UPLs." Accessed at https://avalere.com/insights/research-explores-health-plan-perceptions-of-pdabs-and-upls.

PhRMA
RESEARCH • PROGRESS • HOPE

670 Maine Ave SW WASHINGTON, DC 20004 • 202-835-3400 • PhRMA.org

June 28, 2024

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

Re: Oregon Prescription Drug Affordability Board: Pharmaceutical Manufacturer Survey Dated June 14, 2024

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 "PDAB" or "Board") Pharmaceutical Manufacturer Survey distributed June 14, 2024 ("Manufacturer Survey").[1] PhRMA represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. PhRMA is concerned that any proposed Upper Payment Limit ("UPL") scheme would arbitrarily cap pharmaceutical prices, fail to recognize the complexity of the pharmaceutical supply chain, and would overlook meaningful policy alternatives that would substantially reduce the cost of medicines for Oregonians. A proposed UPL scheme would also raise concerns under the Supremacy Clause of the U.S. Constitution, among other constitutional concerns.[2]

PhRMA continues to have significant concerns about the impact that UPLs would have on Oregonians. UPLs could restrict patient access to medicines and result in fewer new treatments for patients, and ultimately do not carry any guarantee of savings being passed on to patients. Further, the UPL process raises fundamental administrative and operational questions and concerns and creates risks of arbitrary decision-making by the Board. PhRMA cautions the state against considering moving forward with any UPL plan given the risks and legal questions associated with such price controls. Below, PhRMA provides more details about its concerns in its responses to the questions posed in the Board's Manufacturer Survey.[3]

I. How could upper payment limits create meaningful cost savings for all consumers and purchasers?

PhRMA is concerned that UPLs would not translate into meaningful cost savings for patients. UPLs focus on limiting the prices set by the biopharmaceutical industry and ignore the function of other stakeholders in determining what patients ultimately pay for medicines, including insurers, pharmacy benefit managers ("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 proposed UPL scheme. For example, PBMs and payers – which dictate the terms of coverage for medicines and the amount a patient ultimately pays – negotiate substantial rebates and discounts from manufacturers. If payers, PBMs, distributors, and other direct purchasers are not required to pass UPL-related discounts onto patients, it would ignore the role that these entities play in issues of consumer (i.e., patient) affordability.

[1] Manufacturer Survey (June 4, 2024), *available at* https://mslc.qualtrics.com/jfe/form/SV_39ijG1FM8LzFDMy.
[2] *See, e.g.*, *BIO v. District of Columbia*, 496 F.3d 1362 (2007); Amgen v. Colo. Prescr. Drug Affordability Rev. Bd., No. 1:24-cv-00810 (D. Colo. filed Mar. 22, 2024).
[3] 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").

Pharmaceutical manufacturers pay substantial rebates and discounts – approximately $267 billion in 2023 alone.[4] By focusing exclusively on the amounts paid by the direct purchaser (e.g., often the PBM or payer), UPL price controls do not ensure that existing rebates and discounts make their way to offsetting patient costs at the pharmacy counter.[5] This has real consequences for patients. According to research from the Berkeley Research Group ("BRG"), rebates, discounts, and fees account for an increasing share of spending for brand medicines each year, while the share received by manufacturers has decreased over time. In 2021, net prices for brand medicines were, on average, 53% lower than the list prices due to significant rebates, discounts, and other payments from manufacturers.[6] Simultaneously, the growth rate of prescription drug costs has slowed in recent years, with average net prices for brand medicines grew by 3.0% in 2023, below the rate of inflation for the fifth year in a row. Looking ahead, average net price growth is projected to be -1 to -4% per year through 2028.[7] Increased rebates and discounts have largely offset these modest increases in list prices and reflect the competitive market for brand medicines, yet UPLs would not require that these existing rebates and discounts are actually carried forward by plans and PBMs to patients to make their medicines more affordable.

II. What could be potential administrative burdens or operational challenges associated with implementing an upper payment limit?

Establishing UPLs would carry significant administrative and operational burdens and concerns. UPLs restrict patients' access to medicines and result in fewer new treatments. In a recent study of health plan payers interviewed by Avalere about the impacts of a potential UPL, most payer interviewees indicated that "if a drug were to become subject to a UPL, then providers may experience challenges acquiring the product. Interviewees elaborated that provider reimbursement based on a selected drug's UPL may not be adequate relative to their acquisition costs."[8] The same study found that payers did not expect UPLs to lower patient out-of-pocket costs: "Most payers (five of six) did not anticipate that UPL-related savings would be passed on to patients in the form of lower premiums, deductibles, or cost sharing." This study highlights some the supply chain concerns and the potential impacts of UPLs on patients access to prescription drugs.

This concern is further demonstrated by the experience of states that have enacted UPL authority; four states have enacted laws that would allow them to set a UPL for certain medicines, but no state has implemented a UPL to date. Existing state UPL proposals drastically over simiplify the complexity of the pharmaceutical payment and reimbursement system and have created operational concerns across a variety of supply chain entities. For example, the Maryland Department of Public Health expressed concerns to the state legislature that a UPL could put federal matching dollars at risk for the state's Medicaid program and inadvertently cost the state more money than it might save.[9] Maryland's board has been meeting regularly since 2020, but has just begun the process of affordability reviews.[10] In November 2022, adoption of Colorado's rulemaking on the UPL was delayed to address concerns raised by stakeholders and give the board more time to work on the rule; the Colorado Hospital Association had notably raised concerns about the unintended consequences the

[4] IQVIA. "Use of Medicines in the U.S. 2024: Spending and Usage Trends and Outlook to 2028." April 2024.
[5] *See* A. Fein, *The 2020 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers*, Drug Channels Institute (Mar. 2020).
[6] IQVIA. "Use of Medicines in the U.S. 2024: Usage and Spending Trends and Outlook to 2028." Published April 2024.
[7] *Id.*
[8] Research Explores Health Plan Perceptions of PDABs and UPLs. April 2, 2024. Accessed at https://avalere.com/insights/research-explores-health-plan-perceptions-of-pdabs-and-upls.
[9] Letter to House Health and Government Operations Committee from Maryland Department of Health re: HB 279, February 2, 2023. https://mgaleg.maryland.gov/cmte_testimony/2023/hgo/1OoeMJLHVifacq1rfNcQYND5k-v0L8ThH.pdf.
[10] *See* Maryland PDAB, "Board Selected Drugs and any applicable information," https://pdab.maryland.gov/Pages/board-selected-da-info.aspx (subsection of page on "Timeline Information for Cost Review").

UPL would have on hospital revenue and on their ability to bulk purchase drugs which further highlights concerns throughout the supply chain on the adoption of a UPL.[11]

Since Oregon's Prescription Drug Affordability Board began operation in 2022, PhRMA has raised signification administrative and operational concerns about the process and work of the Board.[12] The Board itself recognizes that there are issues that need to be addressed, as shown by its decision to on June 26, 2024 to postpone further affordability reviews until 2025 while it reviews and improves its affordability review criteria and methods. These issues and concerns would be exacerbated by the addition of a UPL scheme, which would significantly expand the potential consequences of the Board's work. We reiterate the following non-exhaustive list of challenges and concerns that we have previously raised with the Oregon PDAB and similar Boards in other states:

- **Lack of Clear, Specific, and Meaningful Standards**. Across states that have implemented affordability review or UPL regulations to date, the rules for evaluating affordability and establishing UPLs have consistently suffered from an overriding lack of clear, specific, and meaningful standards.[13] These rules incorporate extensive lists and categories of information and data sources that 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. PhRMA is concerned that any UPL-setting process in Oregon would similarly lack clear and concrete standards to guide the Board's discretion in establishing a UPL.

  Further, the vagueness of the standards adopted to date raises concerns regarding whether it would be lawful to impose UPLs based on such standardless evaluations. Notably, under the Oregon Administrative Procedures Act ("APA"), agencies are required to render decisions in a manner that is "rational, principled, and fair, rather than ad hoc and arbitrary."[14] As such, courts have long held that agencies like the Board must "make policies for even application" across regulated entities and products," which is directly contrary to affordability review and UPL rules that authorize evaluations based on undefined and unascertainable standards.[15]

- **Data Quality Concerns**. PhRMA also questions whether the Board would 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 fidelity 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. Oregon's affordability review process to date has been rife with persistent errors, causing the board to

[11] Colorado PDAB, Draft Meeting Minutes, Friday November 18, 2022, https://drive.google.com/file/d/1qHM7PkGBGlXzVmq_T-kkQU85EEWUdt8f/view; Colorado Hospital Association, letter to CO PDAB, October 6, 2022, "Re: CHA Comments on Oct. 7 rulemaking hearing regarding the Proposed Draft Rule Part 4 – Upper Payment Limit Methodology."

[12] PhRMA has filed 27 comment letters to date with the Oregon PDAB, detailing, among other things, our ongoing concerns with the Board's affordability review process and procedures. *See, e.g.*, Letter from PhRMA to Board (May 12, 2024); Letter from PhRMA to Board (Feb. 17, 2024); Letter from PhRMA to Board (Oct. 15, 2023).

[13] *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).

[14] *Gordon v. Bd. of Parole & Post Prison Supervision*, 343 Or. 618, 633 (2007).

[15] *Sun Ray Drive-In Dairy, Inc. v. Oregon Liquor Control Comm'n*, 16 Or. App. 63, 72 (1973).

alter the number of drugs eligible for affordability review on multiple occasions, even after the list was finalized and the work of reviewing drugs had begun.[16]

- **Confidentiality Concerns**. UPL-setting is also likely raise substantial confidentiality concerns. 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.[17] State and federal law protect manufacturers' confidential, trade secret, and proprietary information from disclosure; such information cannot be publicly disclosed without violating state and federal prohibitions against the misappropriation of trade secrets. Further, the Fifth Amendment's prohibition against taking private property without just compensation prohibits the uncompensated disclosure of trade secrets, and courts have made clear that "when disclosure [of pricing information] is compelled by the government," even the "failure to provide adequate protection to assure its confidentiality ... can amount to an unconstitutional 'taking' of property."[18] The U.S. District Court for the District of Oregon recently ruled that the "public disclosure" of manufacturers' trade secrets violates the Fifth Amendment "[u]nless just compensation is provided" at the time of disclosure.[19] 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 stakeholders.

III. Are there alternative policy approaches that you believe would be more effective in addressing drug affordability while preserving innovation and investment in research and development?

Implementing price controls diminishes the incentives for biopharmaceutical manufacturers to invest in and introduce new medicines and could limit the prescription drug options available to Oregon residents. Research shows that "[i]t is simply not true that government can impose significant price controls without damaging the chances for future cures."[20] Experts estimate a 50% decrease in the price of medicines would result in a 25% to 60% decrease in the number of new drugs in the pipeline.[21] U.S. patients enjoy earlier and less restrictive access to new therapies,[22] a finding that is reinforced by HHS's own analysis of Medicare Part B drugs which showed that only 11 of the 27 drugs examined (41%) were available in all 16 comparator countries, nearly all of which have single-payer healthcare systems.[23] In countries where governments set medicine prices, patients have access to fewer treatment options. For example, the U.S. has access to nearly 85% of all medicines launched between 2012 and 2021, while just 61% are available in Germany, 59% in the

[16] See, for example, the issues highlighted in PhRMA's comments regarding the Board's May 2024 and November 2023 meetings and meeting materials. Letter from PhRMA to Board (May 12, 2024); Letter from PhRMA to Board (Nov. 11, 2023).
[17] 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.
[18] *St. Michael's Convalescent Hosp. v. State of Cal.*, 643 F.2d 1369, 1374 (9th Cir. 1981).
[19] *PhRMA v. Stolfi*, --- F. Supp. 3d ----, 2024 WL 1177999 (D. Ore. Mar. 19, 2024), *appeal pending*, No. 24-1570 (9th Cir. filed Mar. 15, 2024).
[20] Kennedy, J. The Link Between Drug Prices and Research on the Next Generation of Cures. Information Technology & Innovation Foundation. Sept. 9, 2019. Available at https://itif.org/publications/2019/09/09/link-between-drug-prices-and-research-next-generation-cures.
[21] Abbot, T. and Vernon, J. The Cost of US Pharmaceutical Price Reductions: A Financial Simulation Model of R&D Decisions. National Bureau of Economic Research. Available at https://www.nber.org/papers/w11114; Civan, A. & Maloney, M. (2009). The Effect of Price on Pharmaceutical R&D. The B.E. Journal of Economic Analysis & Policy, 9(1).
[22] IQVIA Institute, Global Oncology Trends 2017, Advances, Complexity and Cost. May 2017.
[23] U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation (ASPE). Comparison of U.S. and International Prices for Top Medicare Part B Drugs by Total Expenditures. October 25, 2018.

U.K., 51% in Japan, 52% in France, 45% in Canada, and 34% in Australia.[24]

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. PhRMA would like to highlight some proposed policies that we believe can help patients better afford their medications, without putting access to care at risk.

Biopharmaceutical manufacturers provide significant discounts, rebates, and other price concessions to PBMs and health carriers, but many patients don't benefit directly from these discounts. On average, pharmaceutical companies rebate approximately 53% of a medicine's list price back to insurance companies and middlemen like PBMs.[25] While health insurers claim that at least a portion of these discounts are used to reduce premiums, research shows that sharing these rebates and discounts directly with patients at the pharmacy counter would have little impact on premiums and significantly benefit consumers.[26] Studies predict that requiring health insurers and PBMs to share negotiated discounts and rebates at the pharmacy counter could save some patients $900 annually in out-of-pocket expenses without significantly increasing their premiums.[27] A study of recently enacted legislation in Arkansas requiring health insurance companies and PBMs to share rebates with patients found no evidence that the policy has caused premium increases.[28] Patients should benefit directly from negotiated rebates and discounts, and health insurers and PBMs should no longer be able to retain those price concessions.

In addition to rebates, PBMs have recently been increasingly profiting off fees and other compensation that are tied to the list price of a medicine, which has created perverse incentives in the marketplace. The largest PBMs wield significant sway over the marketplace, both by virtue of their market share and their relationships with other market participants including health plans, pharmacies, and other providers.[29] The combined market share of the three largest PBMs has grown significantly, from 48% in 2010 to 80% in 2021,[30] and just six companies control 96% of the PBM market.[31] Concern about the influence of PBMs on the supply chain have been raised by Oregon,[32] Congress, and the Federal Trade Commission.[33] When investigating PBMs, the U.S. Senate Finance Committee concluded that, "PBMs have an incentive for manufacturers to keep list prices high, since the rebates, discounts, and fees PBMs negotiate are based on a percentage of a drug's list price – and PBMs may retain at least a portion of what they negotiate."[34] Oregon's Secretary of State performed an

---

[24] PhRMA analysis of IQVIA Analytics Link and U.S. Food and Drug Administration, European Medicines Agency, Japan Pharmaceuticals and Medical Devices Administration, Health Canada and Australia Therapeutic Goods Administration data. Note: Sample includes new active substances launched globally from January 1, 2012 to December 31, 2021. Updated June 2022.
[25] IQVIA. "Use of Medicines in the U.S. 2024: Spending and Usage Trends and Outlook to 2028." April 2024.
[26] PCMA, https://www.pcmanet.org/rx-research-corner/the-path-of-a-rebate-from-drug-companies-through-pharmacy-benefit-companies-to-the-employer-and-all-the-way-to-patients/12/04/2023/. Dec 4, 2023
[27] Milliman. "Measuring the Impact of Point of Sale Rebates on the Commercial Health Insurance Market." July 2021. https://www.milliman.com/-/media/milliman/pdfs/2021-articles/7-6-21-measuring-the-impact-of-point-of-sale-rebates.ashx.
[28] Milliman. "Premium Impacts of POS Rebate Implementation in the ACA Market in the State of Arkansas" January 2024.
[29] https://www.drugchannels.net/2021/04/the-top-pharmacy-benefit-managers-pbms.html.
[30] Fein AJ. "The Top Pharmacy Benefit Managers of 2021: The Big Get Even Bigger." Drug Channels. April 5, 2022.
31 Sweeney E. "Lawmakers ask FTC for retrospective review of PBM mergers," Fierce Healthcare. July 2018.
[32] Oregon Health Authority, "Pharmacy Benefit Managers: Poor Accountability and Transparency Harm Medicaid Patients and Independent Pharmacies," August 2023.. The Oregon Legislature has considered dozens of bills in the past few years to regulate and rein in the abusive practices of the PBMs. *See* "Drug supply companies squeezing pharmacies out of existence, Oregon lawmakers warn." January 26, 2023.; "Oregon set to tighten rules for pharmacy benefit managers. Here's what they do." March 10, 2024.
[33] Federal Trade Commission. "FTC Launches Inquiry into Prescription Drug Middlemen Industry." Press Release, June 7, 2022; Federal Trade Commission. "FTC Deepens Inquiry into Prescription Drug Middlemen." Press Release, May 17, 2023.
[34] Senate Finance Committee. "Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug," 2021.

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."[35]

These abusive practices of PBMs not only raise pharmacy costs for patients, but they also contribute to higher overall costs in the health care system. A study by the Washington State Pharmacy Association and 3-Axis Advisors analyzed millions of pharmacy claims and found that PBMs are driving up costs by charging employers more than necessary to participate in plans, retaining increasingly more than pharmacies are reimbursed (a practice known as "spread pricing"), and steering plans and patients to their affiliated mail-order pharmacies, allowing them to retain more profit from each transaction.[36] A study of Oregon pharmacy claims found in one example, PBMs were marking up a generic drug by as much as 800%, and profiting approximately $1.9 million on the spread pricing of just one drug.[37]

Instead of untested proposals, patients need concrete reforms that will help lower the price they pay for medicines at the pharmacy. PhRMA urges the Board to consider common-sense policies to address the lack of oversight of out-of-pocket pharmacy costs set by health insurers and middlemen. State policymakers can:

- Require middlemen to share the savings – rebates, discounts, and other price concessions they receive from manufacturers – directly with patients at the pharmacy counter;
- Make manufacturer coupons count toward deductibles and other out-of-pocket requirements so that patients get the full benefit of programs meant to help them access their medicines;
- Help patients from day one by requiring all plans to cover certain medications used to treat chronic conditions with no deductible; and
- Tying the fees pharmaceutical supply chain middlemen charge to the services they provide, not the list price of a medicine.

* * *

On behalf of PhRMA and our member companies, thank you for consideration of our comments. Although PhRMA has concerns about the potential addition of UPL authority in Oregon, we stand ready to be a constructive partner in this dialogue. Please contact dmcgrew@phrma.org with any questions.

Sincerely,

Dharia McGrew, PhD
Director, State Policy

Merlin Brittenham
Assistant General Counsel, Law

[35] Oregon Health Authority, "Pharmacy Benefit Managers: Poor Accountability and Transparency Harm Medicaid Patients and Independent Pharmacies," August 2023..
[36] Three Axis Advisors, "Understanding Drug Pricing from Divergent Perspectives State of Washington Prescription Drug Pricing Analysis", June 2024. https://cdn.ymaws.com/www.wsparx.org/resource/resmgr/pbm/3aa_washington_report_202406.pdf
[37] Three Axis Advisors, "Understanding Pharmacy Reimbursement Trends in Oregon: The High Costs of Low Prices", October 2022. https://oregonpharmacy.org/wp-content/uploads/2022/10/Oregon_Report_20221027-FINAL.pdf