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October 3, 2024

Lily Sobolik, Senior Policy Advisor
Oregon Department of Consumer and Business Services
Division of Financial Regulation
350 Winter Street NE
Salem, OR 97309-0405

Re: Oregon Prescription Drug Price Transparency Program September 2024 Revisions to Draft Rule

Dear Ms. Sobolik:

The Pharmaceutical Research and Manufacturers of America ("PhRMA") appreciates the opportunity to review and comment on the second round of the Oregon Department of Consumer and Business Services' ("Department's") draft revisions to the Rules for the Oregon Prescription Drug Price Transparency Program ("DPT" or "Program"), which were discussed at the Rules Advisory Committee ("RAC") meeting on September 18, 2024 ("Draft Revisions").[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 appreciates the Department's ongoing work to review the regulations of the Program and supports the Department's decision to make the price-increase reporting requirements voluntary as an appropriate implementation of the Court's judgment in *PhRMA v. Stolfi*.[2] However, PhRMA has concerns about several changes in the Draft Revisions that appear to conflict with the Program Statute, and which would create undue burdens on manufacturers. We provide below our comments, concerns, and recommendations with respect to the second set of Draft Revisions. We urge the Department to continue refining the ideas in its Draft Revisions in a manner consistent with our below comments and the requirements of the DPT Statute.

I. Date of Introduction of New Drugs, draft OAR 536-200-0505

PhRMA supports the proposal to revise the definition of the "date of introduction" for a drug product from ". . . the date the product is first *listed for sale* in the United States" to ". . . the date the product is first *available for purchase* in the United States."[3] As we stated in our September 9, 2024 comment letter, the "listed for sale" date is ambiguous and diverges from the approach taken by other states which have defined a drug's introduction as the date it is "made available for purchase" within the state.

II. New Prescription Drug Reporting Requirements, draft OAR 836-200-0531

[1] *See* Draft Revisions, *available at* https://dfr.oregon.gov/help/committees-workgroups/Documents/RAC/DPT/20240919-drug-price-transparency-rac-rule-draft.pdf.
[2] 2018 Or. Laws ch. 7 (H.B. 4005) (codified as amended at O.R.S. § 646A.689) (the "DPT Statute"). PhRMA also incorporates by reference all prior comment letters to the extent applicable. *See also* No. 19-cv-01996, 2024 WL 1177999 (D. Or. March 19, 2024). *See* Letter from PhRMA to the Department regarding Oregon Prescription Drug Price Transparency Program Proposed Rule Draft (Sept. 9, 2024).
[3] Draft Revisions § 836-200-0520(4) (emphasis added).

PhRMA is concerned because the Draft Revisions to the Program's new drug reporting requirements go well beyond what is required to be reported under the Program Statute and include a series of well over a dozen novel data elements.[4]

Below, PhRMA provides details about our concerns and the discrepancies between the new drug reporting requirements in the Draft Revisions and the requirements of the DPT Statute.

A. Marketing Costs

The DPT Statute requires manufacturers to provide, as an element of new prescription drug reporting, "[a] description of the marketing used in the introduction of the new prescription drug."[5] The existing DPT rules likewise require reporting of "[a] description" by manufacturers, further specifying elements that manufacturers can address in their description, "if applicable."[6] The Draft Revisions, however, would alter this requirement by mandating that, instead of a "description," manufacturers report a significant volume of proprietary information regarding the marketing of a reported prescription drug.[7] As drafted, the requirement that manufacturers report a significant volume of data regarding their marketing of a prescription drug plainly exceeds the Department's authority under the DPT Statute.[8] Recognizing that a laundry list of reporting items is substantially different from a "description" as required by the statute, the Department should clarify that the listed elements in this subsection may be included in a manufacturer's "description of the marketing used in the introduction of the new prescription drug," as applicable.[9]

B. Pricing Methodology

Similarly, the Draft Revisions would also add a series of "factors" (i.e., data elements) that manufacturers would need to include as part of reporting "[t]he methodology used to establish the price of the new prescription drug."[10] The Draft Revisions go well beyond the scope of the statutory requirement, which only requires manufacturers to provide a "methodology," specifically the methodology that was *actually* "used" in determining pricing of the new drug.[11] Some of the factors listed may not be involved in a given manufacturer's pricing decision for a new drug, and in order to be consistent with the requirements of the statute, PhRMA asks that the Department continue to provide manufacturers with the flexibility to identify factors relevant to their pricing methodology via a narrative description of those factors.[12]

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[4] Oregon case law is clear that "[a]n agency may not, by rule, expand its power beyond that provided by statute." *Lee v. Or. Racing Comm'n*, 142 Or. App. 114, 117 (1996).

[5] DPT Statute § 646A.689(6)(a).

[6] OAR 836-200-0530(4)(c) ("A description of the marketing used in the introduction of the new prescription drug including spending on direct-to-consumer marketing such as paid advertising, as well as spending to promote the drug to physicians, if applicable").

[7] Draft Revisions § 836-200-0531(1)(c) ("The types of marketing, target audience, and associated actual costs for the four quarters prior to launch and planned costs for the four quarters following launch used in the introduction of the new prescription drug, with any associated explanation: (A) Types of marketing includes digital (e.g., consumer or industry websites, social media), TV or audio, and other types of promotion; (B) Target audience includes consumers, health care professionals, pharmacy benefit managers, insurance carriers, and other entities in the pharmaceutical supply chain.").

[8] *See* The American Heritage Desk Dictionary, 5th Ed. (defining "description" as "a statement, written account, or picture describing something"; defining "describe" as "[t]o give an account of in speech or writing."). As Oregon courts have noted, a "description" does not require granular detail; a "'description' can be accomplished with few or many words, as long as the words chosen" identify and describe the subject being described. *Cf. State v. King*, 278 Or. App. 65, 69 (2016) (explaining the plain language meaning of "description" in the context of interpreting a criminal statute).

[9] *Cf. State v. King*, 278 Or. App. 65, 69 (2016) (explaining the plain language meaning of "description" in the context of interpreting a criminal statute); *see* DPT Statute § 646A.689(6)(b).

[10] Draft Revisions § 836-200-0531(1)(d).

[11] Draft Revisions § 836-200-0531(1)(d); DPT Statute § 646A.689(6)(b).

[12] But see Draft Revisions § 836-200-0531(1)(d) ("The methodology used to establish the price of the new prescription drug, including all factors, with any associated impact or explanation … Factors include, but are not limited to …") (emphasis added). *See also* Letter from PhRMA to Department, Aug. 27, 2018, at 3, requesting that the department recognize the "wide range of factors and considerations taken into account by individual companies" when reporting on pricing methodologies.

PhRMA also seeks clarity on what the Department is referring to by factor (g), "[o]ther costs not specifically associated with the prescription drug," as it is not clear what types of costs manufacturers would be expected to report under this factor.[13]

C. Research and Development Costs

The DPT Statute requires manufacturers to report "research and development costs associated with the prescription drug that were paid using public funds."[14] The Draft Revisions would expand the narrow statutory requirement to provide the *amount* of costs to also require reporting of detailed information describing the sources and use of such public funds—such as the institution name, program name and location, dates when research was conducted, and dates when products used for research and development efforts were purchased.[15] As above, the Draft Revisions would expand this rule beyond the Department's authority under the statute. Further, PhRMA is concerned that the Draft Revisions would require manufacturers to report information that may not be available to them.

The imposition of these requirements appears to be based on a fundamental misunderstanding of the complementary roles played by the public and private sectors in fueling innovation and access to new medicines. The biomedical research ecosystem of the United States is built on a system of technology transfer that recognizes that appropriate incentives for public-private collaboration need to be in place to ensure discoveries made by the National Institutes of Health (NIH) and other federal agencies do not simply remain on the shelf as interesting ideas that generate very few new products. While the NIH plays an important role in fostering basic research in life sciences that have identified new disease mechanisms, these discoveries are far from fully developed therapies, but rather a jumping off point for private industry to invest in the development of a potentially useful medicines for patients.

A rich body of research also underscores the significant amount of private sector investment that is necessary to take the necessary risks to realize the potential of basic research conducted at NIH.[16] In the absence of these substantial investments and the risk shouldered by the private sector, the foundational basic research discoveries facilitated by government-generated research may never transcend the lab to benefit patients or society.

D. Confidentiality Concerns

In addition, the Draft Revisions raise concerns that confidential and proprietary trade secret information that manufacturers report might be disclosed to the public. The Department is statutorily prohibited from disclosing trade secret information, which would apply to much of the information that the Draft Revisions ask for manufacturers to report.[17] PhRMA asks that the Department clarify that stakeholders will have a mechanism for advance review of the Department's determination that any such information is subject to public release, and should allow stakeholders to appeal such determinations. The DPT Statute's prohibition on the disclosure of trade

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[13] Draft Revisions § 836-200-0531(1)(d)(G).
[14] DPT Statute § 646A.689(3)(e).
[15] DPT Statute § 646A.689(6)(f); Draft Revisions § 836-200-0531(1)(h) (emphasis added).
[16] An analysis of the contribution of NIH funding to new drug approvals between 2010 and 2016 found that although NIH funding contributed to published research associated with every one of the 210 new drugs approved by the FDA in those years, 90% of the NIH funding supported basic research related to the biological targets for drug action rather than the drugs themselves. Galkina Cleary, E., Beierlein, J. M., Khanuja, N. S., McNamee, L. M., & Ledley, F. D. (2018). Contribution of NIH funding to new drug approvals 2010-2016. Proceedings of the National Academy of Sciences of the United States of America, 115(10), 2329–2334. https://doi.org/10.1073/pnas.1715368115. Another analysis of NIH grants linked to FDA approved medicines, found the private sector's investment in the development of medicine was 66 times greater than the NIH's funding contributions. Schulthess D, Bowen HP, Popovian R, Gassull D, Zhang A, Hammang J. The Relative Contributions of NIH and Private Sector Funding to the Approval of New Biopharmaceuticals. Ther Innov Regul Sci. 2023 Jan;57(1):160-169.
[17] *DPT Statute § 646A.689(10)(a)(A).*

secret information would be illusory—and serious due process, takings, and other constitutional concerns would arise—if the Department retained unilateral discretion to release the information without a pre-release opportunity for administrative and judicial review.[18]

E. First Amendment Concerns

The proposed amendments to the new drug reporting requirements also raise serious First Amendment concerns. As discussed above, the Draft Revisions propose to amend these requirements to ask for detailed disclosures about a manufacturer's strategic decision-making, including the costs of researching, developing, and marketing new prescription drugs.[19] The Draft Revisions would also require manufacturers to disclose extensive information about where and when certain publicly funded research was conducted, which is information that a manufacturer may or may not have on hand.[20] All of this information would then be disclosed to the public by publication on DCBS's website.[21]

These requirements are highly burdensome, significantly overbroad, and not adequately tailored to serve valid governmental interests. They violate manufacturers' First Amendment rights for the same reasons as the price-increase reporting requirements struck down in *PhRMA v. Stolfi*.[22]

In *X Corp. v. Bonta*, the Ninth Circuit recently invalidated a California law requiring certain social media companies to create and file reports about their terms of service and content-moderation practices.[23] The Ninth Circuit held that the required reports "d[id] not satisfy the usual definition of commercial speech" because they do not "communicate[] the terms of an actual or potential transaction," they were "not advertisements," and there was "no economic motivation in their content." The Court accordingly subjected the reporting requirement to strict judicial scrutiny, under which governmental regulation of speech is invalid unless the government can show that it is narrowly tailored to serve a compelling governmental interest. The Court also held that the California law could not satisfy that exacting standard.

The same analysis applies to the proposed new drug reporting requirements, as they do not satisfy the definition of commercial speech; nor are they narrowly tailored to serve a compelling governmental interest. The Department should not add burdensome new reporting requirements on top of the existing reporting requirements for new drugs.[24] Indeed, consistent with the recent holdings in *PhRMA v. Stolfi* and *X Corp.*, the Department should revise the draft new drug reporting requirements to call for less (and more appropriately targeted) information, not more.

III. Additional Information Requests, draft OAR 836-200-0535

The DPT Statute limits the Department to making "a" single written request for supporting documentation or additional information concerning a submission from a reporting manufacturer.[25] The Draft Revisions appear to expand on the statutory requirement to give the Department the ability to submit an open-ended number of requests.[26] PhRMA asks that the Department clarify that its authority is limited to a single request, consistent

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[18] *See Pharmaceutical Research and Manufacturers of America (PhRMA) v. Stolfi*, No. 19-cv-01996, 2024 WL 1177999 (D. Or. March 19, 2024)

[19] Draft Revisions § 836-200-0531(c)-(d).

[20] Draft Revisions § 836-200-0531(h),

[21] DPT Statute § 646A.689(9).

[22] 2024 WL 1177999.

[23] ---F.4th---, 2024 WL 4033063 (9th Cir. Sept. 4, 2024).

[24] OAR 836-200-0530(4)(d).

[25] DPT Statute § 646A.689(7)(a). Specifically, the DPT Statute authorizes the Department to issue a request for information following receipt of "the report or information described in subsections (2), (3), (5) or (6)" and does not authorize the department to issue a request following receipt of information under subsection (7).

[26] Draft Revisions § 836-200-0535(1).

with the statutory language. Additionally, PhRMA requests an explanation for why the Department is proposing to remove the provisions requiring it to respond to a manufacturer's request within 15 days.[27] PhRMA recognizes that the staff indicated that this change is intended to clarify that reporting extensions will automatically take effect upon receipt by the Department of a manufacturer's notice, but we ask that the Draft Revisions explicitly reflect that idea.

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

Sincerely,

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[27] Draft Revisions § 836-200-0535(5).