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Via Electronic Submission

March 3, 2025

Andrew Stolfi, Director
c/o Karen Winkel, Rules Coordinator
Oregon Department of Consumer and Business Services
350 Winter St. NW
Salem, OR 97301
dfr.rules@dcbs.oregon.gov

Re: Prescription Drug Price Transparency Program Updates, Proposed Rules: OAR 836-200-0500 to 836-200-0560 (1/27/25)

Dear Director Stolfi:

Johnson & Johnson offers the following comments to the Oregon Department of Consumer and Business Services ("Department" or "DCBS") on the Prescription Drug Price Transparency Program Updates, Proposed Rules: OAR 836-200-0500 to 836-200-0560.[1]

At J&J, for more than 130 years, cutting-edge technologies and expert insight have helped us understand and address the serious health problems of today and unlock the potential medicines of tomorrow. We apply rigorous science and compassion to confidently address the most complex diseases of our time. We also recognize these medicines can only have an impact if patients can access them. We work tirelessly to improve access for patients across Oregon and around the globe.

We share the goal with the State of improving affordability and access to lifesaving medicines for patients. In fact, 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. For more information, please see J&J's 2023 "U.S. Pricing Transparency Report," which is prepared annually by the company.[2]

Unfortunately, the Department's new reporting requirements fall far short in lowering costs and easing access burdens for patients. The proposed rule would substantially change requirements, goes beyond the Department's stated goal of "clarifying existing definitions of key terms," and is in direct contradiction of the Department's additional goal of "minimiz[ing] the administrative

[1] Notice of Proposed Rulemaking, Office of the Secretary of State, https://dfr.oregon.gov/laws-rules/Documents/Proposed/20250224-pdab-program-updates.pdf (last visited Feb. 26, 2025) ([hereinafter "OR PROPOSED RULEMAKING"]).
[2] *2023 Johnson & Johnson Innovative Medicine, U.S. Pricing Transparency Report*, Johnson & Johnson, https://transparencyreport.janssen.com/transparency-report-2023 (last visited Jan. 17, 2025).

burden and cost of the program for the state and the industry."[3] We respectfully ask the Department to consider the following concerns and solutions:

- The proposed definition of "new prescription drug" imposes new requirements on every New Drug Code (NDC), which are unduly burdensome and unnecessary, and conflicts with other sections of the proposed rule.[4] DCBS should remove "approved at a later date" from the regulatory definition of "new prescription drug" and resolve the inconsistencies.
- The proposed definition of "dosage" is unclear and may lead to confusion in reporting. The proposed language should be revised to address this issue.
- The addition of "one or more" written requests for supporting documentation or additional information from the manufacturer is open ended and could be administratively burdensome. Instead, the original regulatory language should be restored so that DCBS may only submit one written request to the manufacturer.
- The proposed process for submitting information claimed to be Trade Secret is unclear, and the standard is difficult to prove. The proposed language should be fixed to address these issues.

A. The proposed definition of "new prescription drug" imposes new requirements on every NDC, which are unduly burdensome and unnecessary, and conflicts with other sections of the proposed rule.

The proposed regulation entirely changes the definition of "new prescription drug," defined as "a prescription drug that has received initial approval under an original new drug application (NDA), abbreviated new drug application (ANDA) or biologics license application (BLA)," by including drugs that are "approved later."[5] This added language is not a clarification, but now poses a new requirement on every NDC, including new package sizes. This change greatly increases the reporting frequency and imposes an excessive burden on manufacturers, particularly during a time when manufacturers are focused on patient access to much needed new medicines while also learning the market dynamic, addressing market need, and adjusting package sizes accordingly. Requiring reporting on drugs that are "approved later" will significantly increase the level of effort and resources for both manufacturers and DCBS without providing a proportional benefit to Oregon patients or taxpayers. This is contrary to the stated purpose of the proposed rules, which is to reduce administrative burden and cost for both the Department and industry.[6]

The change is unnecessary because manufacturers are already required to report to DCBS when new drugs received "initial approval" under an original new drug application under 21 U.S.C. 355(b), under an abbreviated new drug application under 21 U.S.C. 355(j), or under a biologics

[3] OR PROPOSED RULEMAKING, *supra* note 1.
[4] *Id.*
[5] *Id.*
[6] *Id.*

license application under 42 U.S.C. 262.[7] Any further reporting could be redundant. Therefore, DCBS should remove "approved at a later date" from the regulatory definition of "new prescription drug."[8]

The proposed definition for "new prescription drug" also defines "introduction date" as the "initial market entry" date.[9] This definition is quite broad and would put the industry in difficult place to navigate compliance. Moreover, this definition conflicts with the "introduction date" used in 836-200-0520 (4) of the proposed regulations, which states that, for new prescription drug reporting, "the date of introduction is the FDA start marketing date or the date the product is first available for purchase in the United States, whichever is later."[10] DCBS should resolve this conflict by adopting the definition in section 836-200-0520 (4).

B. The definition of "dosage" is unclear and not an appropriate measurement of a medication's price.

The proposed regulation defines "dosage" as "the highest amount, strength, ***and*** frequency that a patient would take the drug as recommended by its prescribing label."[11] The amount, strength, and frequency of a medication may not correlate. The highest strength may not be the highest frequency, for example. In such an instance, it is unclear how a manufacturer would be required to report. The proposed language should be revised to address this issue.

C. The addition of "one or more" written requests for supporting documentation or additional information from the manufacturer is open ended and may be administratively burdensome.

The proposed regulation states that DCBS may request "*one or more written requests* for supporting documentation or additional information to the manufacturer."[12] The addition of "one or more" written requests allows for an open-ended number of requests from the Department to manufacturers. If numerous requests are sent, it will increase manufacturers' administrative burden and cost to submit multiple responses, in addition to increasing the administrative burden and cost to DCBS to then analyze those responses. This is inconsistent with the intended goal of this proposed rule, which states "the proposed rule changes are necessary to … minimize the administrative burden and cost of the program for the state and the industry."[13] In addition to Oregon, 21 other states also require some form of manufacturer

[7] *Id.*
[8] *Id.*
[9] *Id.*
[10] *Id.*
[11] *Id.*
[12] *Id.*
[13] *Id.*

reporting, which also contributes to administrative burden and complexity.[14] Instead, the original regulatory language should be restored so that DCBS may only submit one written request to the manufacturer.

D. The proposed process for submitting information claimed to be Trade Secret is unclear and the standard is difficult to prove.

The proposed regulation includes new language on the process in which manufacturer information can be deemed a Trade Secret and exempt from public disclosure. It states that a manufacturer must submit "a detailed written explanation, including factual information demonstrating the information is exempt from disclosure."[15] This process creates a standard that is difficult to prove. In essence, the manufacturer is required to establish that the sensitive information is not in the public domain (i.e., proving a negative). It should be permissible for manufacturers to affirm that the information is not generally known or readily accessible to the public, rather than being required to demonstrate the potential for "unintentional" public knowledge. Furthermore, obligating manufacturers to demonstrate the existence of "unintentional" public knowledge places an excessive burden on the industry and directly contradicts the Department's aim to reduce the administrative burden and costs associated with the program for both the state and the industry. It is unclear how a manufacturer could meet this standard successfully, creating the risk that confidential information is shared publicly. Currently, multiple states (e.g., California, Nevada) only ask manufacturers to report data that is available in the public domain.[16] Recognizing how difficult it is to prove the negative, these states do not require manufacturers to prove that the information is not in the public domain.[17] The Department should align proposed regulations with those states' standards.

As one of the nation's leading healthcare companies, J&J has a responsibility to engage with stakeholders in constructive dialogue to address gaps in affordability, access and health equity as well as protect our nation's leading role in the global innovation ecosystem. Our mission is clear: we are focused on developing innovative medicines to help patients fight their diseases. We live this mission every day and are humbled by the patients who trust us to help them live healthier

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[14] 2023 State Drug Transparency Law Development Update, *Goodwin Law*, https://www.goodwinlaw.com/en/insights/publications/2023/11/alerts-lifesciences-state-drug-transparency-law-development-update?utm_source=alrts&utm_medium=email&utm_campaign=LFSC%20&utm_term=&utm_content=20231107_alrts_lfsc_2023%20State%20Drug%20Transparency%20Law%20Development%20Update (last visited Feb. 28, 2025).

[15] OR PROPOSED RULEMAKING, *supra* note 1.

[16] *State Price Transparency Reporting (SPTR): Laws, Experience, Outlook, From Legal and Operational Perspectives*, Informa Connect, https://informaconnect.com/uploads/d466354c-4532-4e0e-8e37-da38f58c2b50_MDRP-StatePriceTransparencyReporting(SPTR).pdf (Feb. 28, 2025); *Prescription Drug Pricing and Cost Transparency in California*, California State Library, https://www.library.ca.gov/wp-content/uploads/crb-reports/Prescription_Drug_Pricing_and_Cost_Transparency_in_California-Oct_2022v3.pdf (last visited Feb. 28, 2025).

[17] *Id.*

lives.

Please do not hesitate to contact me if you have any questions or if there is an opportunity for further dialogue with respect to the New Rules.

Sincerely,

Terrell Sweat

Terrell Sweat
Director, U.S. State Government Affairs
Johnson & Johnson Services, Inc.