

October 15, 2018

Jesse O'Brien
Senior Policy Analyst
Oregon Dept. of Consumer & Business Services, Division of Financial Regulation
350 Winter St. NE
Salem, OR 97301

RE: Pharmaceutical Research and Manufacturers of America Comments on Preliminary Draft House Bill 4005 Rules Distributed on September 24, 2018.

Dear Mr. O'Brien:

Thank you for holding the Rules Advisory Committee (RAC) meetings and for distributing the preliminary draft House Bill 4005 rules. The Pharmaceutical Research and Manufacturers of America (PhRMA) continues to appreciate the opportunity to participate and looks forward to working with you throughout the regulatory development process. HB 4005 requires expansive reporting from biopharmaceutical manufacturers, and as such, it is crucial that the requirements of the bill are carried out in a manner that is fair, predictable, and as administratively simple as possible for both manufacturers and the state.

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. Since 2000, PhRMA member companies have invested more than \$600 billion in the search for new treatments and cures, including an estimated \$71.4 billion in 2017 alone.

As we expressed in our previous written responses and at the RAC meetings, PhRMA would like to reiterate the importance of protecting against the disclosure of confidential trade secret information, as required by law. Unless the Department of Consumer and Business Services (DCBS) revises the proposed rules, including Rule 836-200-0520 concerning the protection of trade secrets, HB 4005 as implemented would raise serious constitutional concerns. It is well established that trade secrets are private property, and, as such, the state cannot "take" (i.e., disclose) trade secrets without providing just compensation. Nor may the state deprive manufacturers of their property interests in their trade secrets without being afforded due process. Under the rules as drafted, however, we are concerned that the state could publish a manufacturer's most confidential and proprietary trade secrets on the Internet without providing manufacturers with notice of its decision or an opportunity to be heard. The final rules must

ensure at a minimum that manufacturers are afforded these most basic of due-process protections.

The unprecedented breadth of HB 4005's disclosure obligations, as reflected in the proposed rules, also presents serious questions under other constitutional provisions, including the Dormant Commerce Clause, the Supremacy Clause, and the First Amendment. Although PhRMA in this comment letter does not address all of these constitutional concerns, PhRMA would urge DCBS and the Task Force on the Fair Pricing of Prescription Drugs to consider these issues, including in potential future legislative changes and final rules. If HB 4005 is implemented in the manner currently contemplated by the proposed rules, we are concerned that the statute would regulate prices that manufacturers charge for prescription drugs (including patented prescription drugs) in transactions throughout the country, including transactions taking place entirely outside Oregon. In this regard, we note that the comprehensive transparency requirements tie expressly to wholesale acquisition cost (WAC) as defined in a federal statute for nationwide applicability. Moreover, the disclosures required are sweeping, and in many instances wholly irrelevant to any legitimate state interest. As one example, the proposed regulations require disclosure of the 10 highest prices for the drug in countries other than the United States. Similarly, the regulations require disclosure of public funding for the relevant product, including funding from foreign governments. It is unclear what bona fide purpose there is for such information, and many of the other disclosure requirements. A state statute applied in this manner would violate well-settled principles of constitutional law.

Below, we provide our comments on the preliminary draft HB 4005 Rules distributed on September 24, 2018.

Comments on Definitions: 836-200-0500

836-200-0500 (1)—Definition of New Prescription Drug

The definition of "new prescription drug" in this section is problematic because it is ambiguous. In the first half of the definition, it states that a new prescription drug is a drug receiving initial approval under a NDA, ANDA, or BLA; however, the second half of the sentence could be interpreted to apply to existing approved drugs. As put forward in RFI #1¹, PhRMA believes HB 4005 refers to a new drug as a novel drug product. To correct the inconsistency, the following definition of "new prescription drug" should be adopted. "New prescription drug" means the initial prescription drug approval under an original new drug application under Section 355(b) of Title 21 of the United States Code, under an abbreviated new drug application under Section 355(j) of Title 21 of the United States Code, or under a biologics license application under Section 262 of Title 42 of the United States Code." This definition ensures that changes to existing approved drugs, such as packaging changes, will be excluded, and prevents such changes from unintentionally triggering the definition and consequent reporting.

836-200-0500 (4)—Definition of "Reporting Manufacturer"

¹ RFI response #1 (8.17.18) Section 1

PhRMA recommends elimination of this definition in the preliminary draft rule. The definition of “reporting manufacturer” put forward by DCBS goes beyond what is set out in subsection (2) and (6) in Section 2 of HB 4005, which clearly lays out which manufacturers are required to report, and which manufacturers are not. Additionally, the term is confusing; under the proposed definition there would be reporting “reporting manufacturers” who report under HB 4005, and non-reporting “reporting manufacturers” who do not report under HB 4005. This proposed definition effectively makes all manufacturers defined in Section 2(1)(d) a reporting manufacturer, potentially subject to civil penalties, and with reporting obligations laid out in the following section of this preliminary draft rule: Sections 836-200-0501 (registration), 836-200-0502 (2) (attestation), and 836-200-0504 (expectations of “reporting manufacturers”). This definition finds no basis in HB 4005 and should be eliminated.

836-200-0500 (5)—Definition of “Public Funds”

DCBS is putting forward a definition of public funds: “Funds granted, loaned, or otherwise provided by a federal, state, or local government entity.” We understand that the disclosure requirements include “public funds” for the product. The federal government exercises authority over provision of public funds for the development of new medicines. We are uncertain as to why the state would need such information or why such information would be beneficial to the state’s transparency goals.

836-200-0500 (6)—Definition of “Timely” or “Timely Manner”

In the PhRMA RFI #2² response we stated that “timely” and “timely manner” should be tied to the specific timelines laid out in the bill, particularly Sections 2(2) and (6), and 5(1), and should be consistent with the department prescribed periods in Section 2(7) of HB 4005. Subsection (a) appears to be generally consistent with these comments. Subsections (b) and (c) are potentially problematic. “Provided in manner favorable” in (b) and “not unreasonably delayed” in (c) are both vague and unnecessary since the specific timeframes are laid out in Section 2(2) and (6) of the legislation and in 836-200-0510 of the preliminary draft rule.

836-200-0500 (7)—Definition of “Inaccurate Information”

“Inaccurate information” in this subsection is focused on intentional acts. We agree with this approach, as unintentional mistakes should not subject companies to risk of penalties. We recommend defining “inaccurate information” to mean provision of “knowingly false” information.

836-200-0500 (8)—Definition of “Incomplete Information”

² RFI response #2 (8.27.18) Section 3

The proposed definition for this term reaches beyond the statute. The statute asks for specific information, not “all relevant available information.” This definition unnecessarily expands the obligation on manufacturers beyond the requirements of HB 4005. Incomplete information should be defined to mean reports or notifications that do not include information explicitly required by HB 4005.

Comments on Registration Requirements: 826-200-0501—Registration Requirement

Section 826-200-0501 requires all reporting manufacturers, as defined in Section 826-200-0500 (4) of this preliminary draft rule, to register with DCBS. As with the definition in 836-200-0500 (4), PhRMA recommends elimination of this section. Extending a registration requirement to all “reporting manufacturers” goes beyond what is clearly set out in statute. With no basis to be found in HB 4005 for this requirement, it should not be included in the proposed rule.

Comments on Threshold for Reporting Drug Price Increase: 836-200-0502

836-200-0502 (2) and (4)—Manufacturer attestation

Per PhRMA comments in the definitions section 836-200-0500 (4), and the registration requirements section 826-200-0501, the manufacturer attestation in this subsection extends beyond what is allowed in statute and should not be included in the proposed rule.

Comments on Expectations of Reporting Manufacturers: 836-200-0504

836-200-0504 (1)—Good-faith effort and reasonable investigation

This subsection is unnecessary and reduces the clarity provided in the statute. Adding a vague and ambiguous “good-faith effort” requirement not contained in HB 4005 makes manufacturer expectations less clear and unnecessarily increases the risk of civil penalties, which are significant—up to \$10,000 a day pursuant to section 3(2) of HB 4005.

HB 4005 lays out the various expectations placed on manufacturers throughout Section 2 of the bill, specifically the reporting requirements in subsections 3 and 5, the notification requirements in subsection 6, and the supplemental information request authority granted to DCBS in subsection 7. The specific information required to be reported is laid out in these subsections, and the timelines for doing so in subsections 2 and 6, are clear. As required by HB 4005, the department sets forth the timeline for subsection 7 supplemental information requests in Section 836-200-0510 of this preliminary draft rule.

Expectations of reporting manufacturers should simply be that submission of reports and notices be timely as defined by statute under 836-200-0510.

Comments on Form and Manner Requirements for Drug Pricing Reporting: 836-200-0505

HB 4005 seeks very detailed information pertaining to existing prescription drug price increase reporting, new drug notification, and patient assistance programs. PhRMA suggests simplifying the disclosure requirements as much as possible, limiting disclosure to information available in the public domain, and establishing a procedure that allows manufacturers to designate and protect from public disclosure confidential trade secret information as required by law.

There are a number of instances in Section 836-200-0505 of the preliminary draft rule which potentially indicates manufacturers are required to report or give notice beyond what is required in HB 4005. Phrases such as “at least the following information,” and “included but not limited to,” do not appear in HB 4005, are potentially confusing, and should be removed.

Comments on Additional Information Requests: 836-200-0510

Reiterating our position in response to RFI #1³, HB 4005 requires DCBS to prescribe by rule the period of time by which, after receiving the report of information included in subsections (2), (3), (5), or (6) of Section 2, DCBS may make a written request to the manufacturer for supporting documentation or additional information concerning the report, and the period of time allowed by the manufacturer to respond to the request. The request for information is divided into two parts, subsection 2(7)(a)(A) and 2(7)(a)(B).

Section 2(7)(a)(A) requires the department to prescribe by rule the time period “following the receipt of the report or information during which the department may request additional information.” The department should have a maximum of 30 days, following the receipt of the report, during which the department may request additional information.

Section 2(7)(a)(B) requires the department to prescribe by rule the time period “following a request by the department for additional information during which a manufacturer may respond to the request.” A manufacturer should have a minimum of 90 days to respond, and the DCBS rule should include explicitly or by reference the flexibility included in Section 2(7)(a)(B)(b), granting the department ability to extend the period of time, as necessary, on a case-by-case basis.

Comments on Information Claimed to Be Trade Secret: 836-200-0520

Section 836-200-0520 fails to provide adequate protection for trade secrets that are entitled to protection from disclosure under state and federal law. In three ways, the proposed rule diverges from the conventional process for resolving disputes over whether information is a trade secret. Unless DCBS revises the proposed rule to conform to standard practices, HB 4005’s disclosure provisions, as implemented through Section 836-200-0520, would present serious constitutional concerns.

³ RFI response #1 (8.17.18) Section 2

1. The Department Should Provide Manufacturers with Notice of and Opportunity to Challenge any Decision to Disclose Information that Manufacturers Designate as a Trade Secret

DCBS should revise the proposed rule to make clear that the department will not disclose any information that a manufacturer designates as a trade secret without first (i) notifying the manufacturer of its intent to disclose the information and (ii) providing the manufacturer an opportunity to challenge the department's decision.

This is the process that the federal government follows when it responds to requests for information under the Freedom of Information Act. Under FOIA, when there is a request for information that has been designated as a trade secret, the government agency decides in the first instance whether the requested information falls within the FOIA exemption for "trade secrets and commercial or financial information from a person and privileged or confidential." 5 U.S.C. § 552(b)(4). If the agency withholds the requested information on the ground that it qualifies for the exemption, then the requester may file a challenge to that agency determination in federal court. *Id.* § 522(a)(4)(B). Alternatively, if the agency decides that the requested information is not protected and could be made public, the party that originally submitted the information to the agency may itself bring a "reverse FOIA" action in federal court to prevent disclosure. *See, e.g., Chrysler Corp. v. Brown*, 441 U.S. 281, 285 (1979).

Nevada has adopted a similar process in connection with its recent enactment of SB 539, which, like HB 4005, requires pharmaceutical manufacturers to disclose pricing information, including information that would qualify as a trade secret under state and federal law.⁴ SB 539's implementing regulations provide that before disclosing information that a manufacturer has designated as a trade secret, the Nevada Department of Health and Human Services must undertake an initial review to determine whether the department believes that the requested information is a trade secret. *See* Approved Regulation, § 3(b). If, after undertaking this initial review, the department determines that the information is a trade secret, then it will not disclose the information. *Id.* § 4. Alternatively, if the department decides that the requested information is not protected and could be made public, the department must (i) notify the manufacturer and (ii) provide the manufacturer an opportunity to challenge the department's decision in court. *Id.* § 5. If the manufacturer initiates a challenge in court, the department will not disclose the information until final resolution of the action, including any appeals. *Id.* § 6(b)

DCBS should revise the proposed rule to adopt a similar process in Oregon that provides notice to the manufacturer of the department's decision to publish information that the manufacturer has designated as a trade secret. The department then should provide manufacturers with a reasonable amount of time to challenge the department's decision in a court of competent jurisdiction. Without such a process in place, HB 4005 would present serious constitutional concerns, as manufacturers would be at risk of having their valuable trade secrets destroyed

⁴ *See* Approved Regulation of the Department of Health and Human Services, LCB File No. 042-18, [http://dhhs.nv.gov/uploadedFiles/dhhsnv.gov/content/HCPWD/Sec%20of%20State%20Official\(1\).pdf](http://dhhs.nv.gov/uploadedFiles/dhhsnv.gov/content/HCPWD/Sec%20of%20State%20Official(1).pdf).

without due process of law. Moreover, we note that the disclosures required under the Nevada law are less comprehensive than those required under the Oregon law, so adequate protection of trade secrets is even more critical here.

2. The Department Should Simplify the Process for Designating Information as a Trade Secret

The proposed rule also departs from standard records-request procedures in requiring manufacturers to support their request for confidentiality with a “written explanation” of why the information is exempt from disclosure. FOIA imposes no such requirement.⁵ Instead, under FOIA, companies typically label information as “confidential” if they believe that it satisfies a confidentiality exemption from disclosure. Some companies may also—voluntarily—provide additional explanation to the agency as to why the information qualifies for an exemption to bolster the administrative record. But there is no *requirement* under FOIA that companies justify their confidentiality designations when they are submitted.

If the department retains the “written explanation” requirement, it should, at a minimum, revise the requirement to conform it with the state law definition of a trade secret. As drafted, the proposed rule requires manufacturers to explain five factors that do not necessarily correspond with the definition of “trade secret” under Oregon law. Instead, if the “written explanation” requirement is retained, the requirement should be simply to explain why the information is a “trade secret” within the meaning of ORS 646.461; that is, why the information “derives independent economic value, actual or potential, from not being generally known to the public or to other persons who can obtain economic value from its disclosure and use” and “is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.” ORS 646.461(4).

Finally, the statute provides no basis for placing the burden of proof on the manufacturer to establish that information in a filing is conditionally exempt from disclosure as a trade secret. If the department has questions about a manufacturer’s trade-secret designation, the department should contact the manufacturer for further explanation or information. There should not be a presumption, however, that if the department believes that the manufacturer has failed to meet its “burden of proof” in its initial filing, the Department may then disclose the information without further consultation with the manufacturer. This is especially important as all parties work together in good faith to understand HB 4005’s novel and extensive reporting requirements.

3. The Department Should Define “Public Interest” in a Manner that Does Not Permit the Disclosure of any Information that Qualifies as a Trade Secret under State or Federal Law

⁵ See 5 U.S.C. § 552.

In RFI #2⁶ PhRMA commented that DCBS should take steps to ensure that information designated as proprietary and confidential trade secret information is protected from public disclosure. DCBS should thus define “public interest” in a manner that does not permit the disclosure of any information that qualifies as a trade secret under federal laws, such as the Trade Secrets Act, the Freedom of Information Act, and the Defend Trade Secrets Act, or state laws, such as the Oregon Uniform Trade Secrets Act. The “public interest” exception should not be interpreted so broadly that it nullifies the requirement that confidential and business sensitive trade secrets designated as such by the manufacturer be exempt from public disclosure by the State or otherwise conflicts with federal trade secret protections.

A failure to clarify the “public interest” exception in this manner would raise serious constitutional concerns. In *Phillip Morris, Inc. v. Reilly*, 312 F.3d 24 (1st Cir. 2002), the First Circuit struck down a similar Massachusetts law that would have allowed the state to disclose a cigarette manufacturer’s trade-secreted ingredient list to the public if doing so could reduce the risks to “public health.” The First Circuit held that a state cannot, consistent with the Takings Clause, destroy valuable trade secrets in this manner simply because the state may determine that doing so is in the “public health” or “public interest.” *See id.* at 44. Under a straightforward application of *Reilly*, HB 4005 would be unconstitutional unless DCBS clarifies that the “public interest” exception cannot swallow the rule that trade secrets must be exempted from public disclosure.

Comments on Assessments Against Prescription Drug Manufacturers: 836-200-0550

The department levies a fee against all manufacturers in the preliminary draft rules. PhRMA commented In RFI#1⁷ stating that the fee allowed in Section 2(12), if levied, should be solely on manufacturers that are required to file a report, and should be collected in a manner that is fair, efficient, and minimizes the administrative burden to the manufacturer. The rule should reinforce the strict parameters placed in subsection 12 that the fee is to be used *solely* to pay the costs of the department in carrying out the provisions of Section 2 of the bill.

PhRMA believes the fee should only be imposed on those manufacturers that trigger the specific reporting thresholds laid out in subsections 2 and 6 of Section 2 in HB 4005.

Comments on Civil Penalties: 836-200-0560

HB 4005 authorizes significant penalties on manufacturers in Section 3. In RFI #2⁸ PhRMA commented that the civil penalties should be clearly outlined in rule for late submissions in Section 2(8)(a), and lack of timely response in Section 2(8)(c). “Failing to provide information” in Section 2(8)(b) should not apply to instances where a manufacturer cannot produce the requested information⁹ or instances issuing from the extension authority granted the

⁶ RFI response #2 (8.27.18) Section 6

⁷ RFI response #1 (8.17.18) Section 3

⁸ RFI response #2 (8.27.18) Section 4

⁹ *Ibid.* RFI response #1 on section 2(7)(a) (RFI #1 ???)

department in Section 2(7)(b) for requesting supporting documentation and additional information.

Concerning inaccurate and incomplete information under Section 2(8)(d), we suggest limiting the penalty provisions to untimely submissions in line with other states with similar laws. Penalties should be reasonable and fair. There should be an exemption from penalty, or a low maximum, attached to an initial infraction.

Comments on Required Materials for Rate Flings for Individual or Small Employer Health Benefit Plans: 836-053-0473

Section 5(1) of HB 4005 requires insurers that issue policies or certificates of health insurance for sale in Oregon that include a prescription drug benefit to include in their rate filings under ORS 743.018 information regarding drugs reimbursed by the insurer. Required information includes:

- The 25 most frequently prescribed drugs;
- The 25 most costly drugs as a portion of total annual spending;
- The 25 drugs that have caused the greatest increase in total plan spending from one year to the next; and
- The impact of the costs of prescription drugs on premium rates.

Biopharmaceutical manufacturers pay significant rebates and discounts, and an accurate accounting requires that they be included in the reporting related to drugs reimbursed by insurers contained in Section 5. In RFI #1¹⁰, PhRMA commented that the following information should be required reporting in subsection 1(b), (c), and (d).

Section 5(1)(b) requiring reporting of the 25 most costly drugs as a portion of total annual spending should be clarified in rule to be net of all rebates and discounts. Manufacturers pay billions of dollars in rebates each year, \$150 billion in 2017, and an accurate accounting of cost necessarily requires that “cost” is defined as net of all rebates and discounts. Additionally, insurers should include as part of their reporting an accounting of medical cost offsets attributable to those drugs.

Section 5(1)(c) requiring reporting of the 25 drugs that have caused the greatest increase in total plan spending from one year to the next, similar to Section 5(1)(b), should frame total plan spending in the context of net costs, accounting for rebates and discounts. Insurers should include as part of their reporting an accounting of the medical cost offsets attributable to those drugs and the results of their adherence programs or strategies if such programs or strategies have been implemented by the insurer.

Section 5(1)(d) requiring reporting of the impact of the costs of prescription drugs on premium rates should, as in the two previous subsections, frame the analysis in terms of net costs. Such

¹⁰ RFI response #1 (8.17.18) Section 4

reporting should include information on utilization and be in the form of an actuarial attestation. For the drugs reported in subsection 5(1)(b) and 5(1)(c) the insurer should report the impact of costs of prescription drugs on premiums in a per member/per month amount.

Thank you for the opportunity to submit these comments. PhRMA looks forward to continuing to work with DCBS throughout the RAC and official rulemaking process.

Sincerely,

Linda Carroll-Shern

Linda Carroll-Shern
Deputy Vice President, State Advocacy
Pharmaceutical Research and Manufacturers of America
1115 West Bay Drive NW STE 205
Olympia, Washington 98502



Joanne Chan
Assistant General Counsel, Law
Pharmaceutical Research and Manufacturers of America
950 F Street, NW, Suite 300
Washington, DC 20004