

November 1, 2018

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RE: Pharmaceutical Research and Manufacturers of America Comments on the Second Draft HB 4005 Rules Distributed on October 19, 2018.

Dear Mr. O'Brien:

Thank you for holding the Rules Advisory Committee (RAC) meetings and for distributing the second 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.

PhRMA has previously submitted four comment letters in which a number of concerns are highlighted, many of which remain unresolved. In this response, we focus on a subset of those concerns. Please find below select comments on the Second Draft HB 4005 Rules distributed on October 19, 2018.

Protection of Trade Secret Information—836-200-0520

Federal and state law prohibit the Department of Consumer and Business Services (DCBS) from disclosing manufacturer trade secrets. *See* 18 U.S.C. § 1836 (Defend Trade Secrets Act); ORS §§ 646.463, 646.465 (Oregon Uniform Trade Secrets Act). Additionally, as mentioned in our prior comments, the U.S. Constitution prohibits DCBS from "taking" (i.e., disclosing) manufacturer trade secrets without providing just compensation or depriving manufacturers of their property

interests in their trade secrets without being afforded due process. Thus, it is critical that the final rule adopt a process that ensures that trade secrets are not disclosed. In RFIs #2¹ and #4² PhRMA explained how DCBS should revise the proposed rule to ensure that information designated as proprietary and confidential trade secret information is protected from public disclosure.

In the most current draft of the rule, Section 836-200-0520 continues to fail to provide adequate protection for trade secrets that are entitled to protection from disclosure under state and federal law. In addition to the problems identified in PhRMA's prior comments, which we incorporate by reference, we raise two additional concerns with the latest proposed revisions to the prior version of the proposed regulations.

First, there is no reason for the Department to classify only certain of the "informational elements" listed in Section 836-200-0505 as "eligible for conditional exemption from disclosure." Under the Oregon Public Records Law, all trade secrets are exempt from disclosure. ORS § 192.345. If the Department were to restrict the informational elements eligible for conditional exemption from disclosure to those elements listed in Section 836-200-0520(1), then the Department would be prejudging that other elements are not "trade secrets" within the meaning of the Public Records Law. Whether particular information is a trade secret, however, is a "question of fact" that "requires an ad hoc evaluation of all the surrounding circumstances." *Kaib's Roving R.P.H. Agency, Inc. v. Smith*, 239 P.3d 247, 250 (Or. Ct. App. 2010). Rather than conclude categorically that certain informational elements can never be trade secrets, the Department should decide a manufacturer's request on a case-by-case basis with the benefit of the manufacturer's views. Accordingly, the Department should revert to the language of the preliminary draft rule, which presumed that all informational elements required to be disclosed were eligible for conditional exemption from disclosure.

Second, while PhRMA commends the Department for adding a notice period in Section 836-200-0520(4), the provision fails to afford manufacturers with required due process. Under the proposal as drafted, manufacturers will have no meaningful opportunity to challenge a Department decision to disclose trade secrets. Because the proposed rule provides no mechanism for a manufacturer to appeal to the Department itself, manufacturers who receive notice that the Department intends to publish their trade secrets within 15 days would be forced to bring a challenge in court. Because the proposed rule provides no stay of disclosure pending the outcome of litigation, manufacturers would be forced to seek a temporary restraining order or preliminary injunction every time they challenge a decision to disclose, and they would need to do so within 15 days of notice. This would impose significant legal costs and burdens on the manufacturers who would have to bring such claims, the Department who would have to defend the claims, and the courts who would have to hear and decide them. Regulations that virtually guarantee such frequent emergency litigation would be unfair, unsound, and unworkable.

¹ RFI response #2 (8.27.18)

² RFI response #4 (10.15.18)

The Department should instead follow the lead of the Nevada Department of Health and Human Services and stay any decision to disclose information designated as a trade secret until legal action challenging the Department’s decision is resolved. See SB 539 Regulation § 6(b). At a minimum, the Department should extend the notice period to 60 days to provide manufacturers with adequate time to evaluate the Department’s decision, retain counsel, and prepare the relevant legal filings.

Unless DCBS revises the proposed rules, HB 4005 as implemented would raise serious constitutional concerns. The final rules must ensure at a minimum that manufacturers are afforded the basic due-process protections identified above and in PhRMA’s prior comments.

Definition of New Prescription Drug—836-200-0500 (6)

The definition of “new prescription drug” in this section continues to be 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 #1³, PhRMA believes HB 4005 refers to a new drug as the first novel drug product approved under an NDA, ANDA, or BLA. 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 reporting will be focused on new drugs, and 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.

Patient Assistance Program Reporting—836-200-0505 (3)

This section requires additional reporting if a manufacturer provides funding for an independent patient assistance program that reduces consumer out-of-pocket costs for a drug meeting specific conditions. PhRMA believes this goes beyond the clear scope and intent of HB 4005, where, in Section 2 (5), the type of patient assistance program reporting is limited to programs “offered by the manufacturer.” The current draft rule expands beyond HB 4005 by requiring manufacturer reporting related to patient assistance programs offered by “independent patient assistance programs.” Additionally, from a practical standpoint, this provision requires

³ RFI response #1 (8.17.18)

manufactures to report on information they do not have access to. PhRMA believes this provision is inconsistent with the clear language of HB 4005 and guidance from the U.S. Department of Health and Human Services' Office of the Inspector General,⁴ is not workable, creates unnecessary risk of penalties, and should, as a result, be removed.

Assessments Against Prescription Drug Manufacturers—836-200-0550

The Department levied a fee against all manufacturers in the preliminary draft rules and continues to do so in the second draft. PhRMA commented in RFI #1⁵ and RFI #4⁶ 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. PhRMA continues to believe 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, and would ask the Department to remove the assessment against all manufactures in subsection (1) of this Section of the draft rule.

Civil Penalties—836-200-0560

HB 4005 authorizes significant penalties on manufacturers in Section 3. In RFIs #2⁷ and #4⁸ PhRMA commented that the civil penalties should be reasonable, fair, and clearly outlined in rule. The Department included a two-tiered approach in the most recent draft which limits “inadvertent” violations to \$250 per day and “knowing” violations to the statutory maximum of \$10,000 per day. PhRMA believes there should be an exemption from penalty for a first-time inadvertent violation in subsection 2(a) and a lower limit, maximum of \$1,000 per day, for a first-time violation in subsection 2(b).

Definition of “Public Funds”—836-200-0500 (9)

DCBS is putting forward a definition of public funds, “Funds granted, loaned, or otherwise provided by a federal, state, or local government entity.” As stated in RFI #4⁹, we understand that the disclosure requirements include “public funds” for the product, but that the federal government exercises authority over provision of public funds for the development of new medicines and it is unclear what the value is to the state in collecting such information. Compounding these concerns, the expanded definition put forward by the Department in the

⁴ Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs (Federal Register /Vol. 79, No. 104/Friday, May 30, 2014/Notices)

⁵ RFI response #1 (8.17.18)

⁶ RFI response #4 (10.15.18)

⁷ RFI response #2 (8.27.18)

⁸ RFI response #4 (10.15.18)

⁹ RFI response #4 (10.15.18)

most recent draft is extremely broad and vague, and is inconsistent with similar definitions of public funds already in use by the state of Oregon¹⁰. As a starting point, the Department should minimally consider striking “loaned or otherwise provided” from the definition.

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,

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¹⁰ ORS 295.001(16).