

November 29, 2018

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**RE: Pharmaceutical Research and Manufacturers of America Comments on the Third Draft HB 4005 Rules.**

Dear Mr. O'Brien:

Thank you for holding the Rules Advisory Committee (RAC) meetings and for distributing the third draft House Bill (HB) 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 five comment letters in which a number of concerns are highlighted, many of which remain unresolved. In this response, we focus on a subset of issues raised during the November RAC meeting.

**Protection of Trade Secret Information—Section 836-200-0540 of the Draft Rules**

PhRMA commends the Department for deleting the language in Section 836-200-0520 of the draft rules that would have made only certain of the "informational elements" listed in Section 836-200-0505 "eligible for conditional exemption from disclosure."

While PhRMA also commends the Department for providing a mechanism for manufacturers to appeal to the director a Department decision to disclose information designated as a trade secret, it is important as we have mentioned in our prior comment letters that the final rule also

provide a meaningful opportunity for judicial review. For example, under federal law, when an agency decides to disclose information designated as a trade secret, that agency must provide the holder of the trade secret with sufficient notice to seek judicial relief.<sup>1</sup> Similarly, as noted in PhRMA's prior comments, under Nevada's SB 539 implementing regulations, if a manufacturer initiates a challenge in court, the Department will not disclose the information until final resolution of the action, including any appeals.<sup>2</sup>

To provide a meaningful opportunity for judicial review, the Department should revise Section 836-200-0545 to read, "Notwithstanding subsections (1)-(4), if a manufacturer has made a trade secret claim, the information that is the subject of the trade secret claim will not be posted to the Department's website until a determination has been made by the Department or, in the case of a manufacturer's appeal, the director, as specified by 836-200-0540. If, within 60 days of the director's decision to disclose information designated as a trade secret, a manufacturer commences an action in a court of competent jurisdiction to enjoin the Department from disclosing such information, the Department will not disclose the information until final resolution of the action, including any appeals."

As it stands, the draft rule provides manufacturers only 15 days to review the director's decision, retain counsel, prepare the relevant legal filings, move for a temporary restraining order, and obtain a court ruling on the motion. This is simply unrealistic and not meaningful, especially given the complexity of trade-secret litigation. There is no need to place this burden on the courts that would have to hear and decide these emergency lawsuits, the Department that would have to defend them, and the manufacturers who would have to bring them. Instead, the Department should follow Nevada's lead and adopt the proposed revised language above so that any decision to disclose is stayed pending litigation.

### **Definition of "Net Yearly Increase"—Section 836-200-0505 of the Draft Rules**

During the November RAC meeting, considerable attention was paid to the definition of "Net Yearly Increase" when the Department put forward several potential definitions of how "net" could be defined. PhRMA believes the correct, and simplest, definition is in line with what the Department included in the "Second Draft HB 4005 Rules." This approach looks at the net price change over the course of the previous calendar year, where the numerator is determined by subtracting the price at the beginning of the year from the price at the end of the year, and the denominator is the price at the beginning of the year, and is similar to Option 1 in DCBS's "Definition Options Memo."

The price increase threshold established in Section 2(2)(b) of HB 4005 is indexed to the "previous calendar year," and under Oregon law, "calendar year" generally is understood to be the 12 months commencing January 1 and ending December 31.<sup>3</sup> Because HB 4005 was not effective

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<sup>1</sup> See FOIA Guide: "Reverse" FOIA, <https://www.justice.gov/oip/foia-guide-2004-edition-reverse-foia>.

<sup>2</sup> See Approved Regulation of the Department of Health and Human Services § 3(6)(b), 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).

<sup>3</sup> [https://www.oregonlaws.org/glossary/definition/calendar\\_year](https://www.oregonlaws.org/glossary/definition/calendar_year)

until March 2018, the first calendar year for which an increase could be calculated does not commence until January 2019, so the first reporting date based on a “calendar year” would not be possible until March 15, 2020. As a result, the first report should not be due until March 15, 2020. Requiring manufacturers to report on a calendar year prior to 2019 would cover actions taken prior to the enactment of HB 4005, which raises questions of due process. If the Department will not wait until March 2020 so that reporting can be based on the “previous calendar year,” as required by HB 4005, at a minimum, no price increases prior to the enactment date should contribute to the calculation of the 10% threshold established in Section 2(2)(b) of the bill.

### **Supplemental Documentation and Information Requests Under Section 2(7)(a) of HB 4005**

During the November RAC meeting, the Department discussed its current understanding of its authority to request supporting documentation or additional information concerning the report under Section 2(7)(a) of HB 4005 in a manner that allows the Department to ask for information beyond what is laid out in HB 4005. This interpretation exceeds the authority granted to the Department under Section 2(7)(a), which specifically states that any requested information must relate directly to the report, the components of which are delineated in Section 2(3), (5), and (6) of HB 4005. Section 2(7)(a) of the bill should not be interpreted so broadly as to allow information requests related to items not specifically called out in the bill as part of the report. Doing so would render meaningless the legislature’s express decision to limit such information to information “concerning the report.”

### **Patient Assistance Program Reporting—Section 836-200-0530(3) of the Draft Rules**

This section of the draft rules 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. As stated in RFI #5, PhRMA believes this goes beyond the clear scope and intent of HB 4005, where, in Section 2(5) of the bill, the type of patient assistance program reporting is limited to programs “offered by the manufacturer.” The current draft rule exceeds the authority granted to the Department in the bill by requiring manufacturer reporting related to patient assistance programs offered by “independent patient assistance programs.” Additionally, from a practical standpoint, this provision requires manufactures to report on information to which they do not have access. PhRMA believes this provision in subsection (3)(b) of the draft rule 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,<sup>4</sup> is not workable, creates unnecessary risk of penalties, and should, as a result, be removed.

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

In the event the Department insists on moving forward with subsection (3)(b) of the draft rule, then subsection (3)(c) of the draft rule should be amended with the following clarifying edits, which incorporate a reference to HHS OIG advisory opinions that are issued to charitable organizations to allow the operation of specific independent charity patient assistance programs designed to operate in compliance with OIG's guidance:

(c) Reporting manufacturers that provide funding for a bona fide independent charity patient assistance program designed in full compliance with (i) the guidance provided in the Department of Health and Human Services Office of the Inspector General's Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs (Federal Register / Vol. 79, No. 104 / Friday, May 30, 2014 / Notices), or (ii) an Advisory Opinion issued by the U.S. Department of Health and Human Services Office of the Inspector General, are not required to include information about the bona fide independent charity patient assistance program in any appendix required by this section.

### **Assessments Against Prescription Drug Manufacturers—Section 836-200-0555 of the Draft Rules**

The Department levied a fee against all manufacturers in the preliminary draft rules and continues to do so in the third draft. PhRMA has previously commented that the fee allowed in Section 2(12) of HB 4005, 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.

During the November RAC meeting, a suggestion was made that a larger fee be applied to those manufacturers who seek to protect trade secret information through an administrative and/or judicial process. PhRMA believes this would be an unnecessary and inadvisable direction for the Department to go. The Department already has full authority to collect fees for the purpose of paying *the full costs* associated with carrying out the provisions of Section 2 of HB 4005, so a larger fee is unnecessary. Such a fee would apportion the responsibilities for funding the Department's costs in a manner that penalizes and creates a disincentive for manufacturers to defend against the disclosure of their trade secrets. In addition, forcing manufacturers to pay a larger fee simply for taking action to protect their trade secret information as provided under federal law also would raise substantial constitutional concerns, including conflict preemption with the federal Defend Trade Secrets Act of 2016.

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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