

September 24, 2018

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**RE: HB 4005 Rulemaking Advisory Committee Request for Information Due by September 25, 2018**

Dear Mr. O'Brien:

Thank you again for holding the August 28, 2018 Rules Advisory Committee (RAC) meeting. The Pharmaceutical Research and Manufacturers of America (PhRMA) continues to appreciate the opportunity to participate in the RAC meetings and looks forward to working with you throughout the regulatory development process. House Bill 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 to comply with 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.

This letter addresses the request for information (RFI) following from the August 28, 2018 RAC meeting. As we expressed in our previous response, PhRMA would like to reiterate the importance of protecting against the disclosure of confidential trade secret information, as required by law.

- 1) What degree of specificity in the requirements for manufacturer reporting would be helpful to ensure the Department's ability to fulfil its statutory obligations and inform the public about the factors influencing rising drug costs while minimizing any unnecessary administrative burden on the Department and prescription drug manufacturers? Specific suggestions for rule language would be deeply appreciated.**

The PhRMA response to RFI #2<sup>1</sup> included a number of recommendations related to manufacturer reporting contained in Section 2(3), (4), (5), and (6) of House Bill 4005 (2018). The degree of specificity should be consistent with the language in the underlying statute.

- 2) **DCBS has suggested adopting a set of standards for prescription drug manufacturer filings, which would provide for a uniform reporting format and help clarify the Department's expectations. Similar to the product standards for health insurance filings, these standards could help provide additional guidance to reporting entities and could be altered to reflect changes in the industry without the need for additional rulemaking. The Department solicits feedback on this approach.**

PhRMA believes a uniform format for filing manufacturer reportable information, to the extent it provides a simple and consistent approach to submitting information, would be an acceptable approach and could, along with additional guidance, help clarify the Department's expectations. Departmental rules or regulations regarding the form should be consistent with the underlying statute, should be tight enough to provide clear direction and expectations, yet should be flexible enough to accommodate non-substantive changes as circumstances require in order to avoid unnecessary rulemaking.

- 3) **The Department solicits feedback on the best approach to interpret Section 2 (5) and the reporting requirements related to patient assistance programs. DCBS also requests any available information regarding the current landscape of patient assistance programs and the affiliations, if any, between existing patient assistance programs and prescription drug manufacturers.**

Consistent with PhRMA's previous comments<sup>2</sup> in this regard, PhRMA believes clarification should be provided in rule or regulation that the reporting requirements of Section 2(5), which pertain to patient assistance program reporting, are applicable only to programs run by pharmaceutical manufacturers themselves and are not applicable to programs offered by independent charitable organizations to which a manufacturer may contribute.

- 4) **The Department solicits any feedback on the best approach to conduct the public hearing required by Section 5 (2).**

Reiterating PhRMA's previous comments<sup>3</sup>, we believe the public hearing should be limited by administrative rule to the activities undertaken and reports received and filed by DCBS under Sections 2 and 5(1) during the preceding year. The scope of the hearing should be narrowly and specifically focused on these topics. The hearing must not include the presentation or discussion of information designated as proprietary and confidential trade secret information.

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<sup>1</sup> RFI response #2 (8.27.18) Section 1 and 2

<sup>2</sup> RFI response #2 (8.27.18) Section 1(c)

<sup>3</sup> RFI response #2 (8.27.18) Section 5

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

Sincerely,

*Linda Carroll-Shern*

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