

February 1, 2019

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Pharmaceutical Research and Manufacturers of America Comments on Final Draft Rule

Dear Mr. O'Brien:

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to participate on the Rules Advisory Committee (RAC) for HB 4005 and for the opportunity to comment on the Final Draft Rule. 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 PhRMA has explained in previous comment letters, the unprecedented breadth of HB 4005's disclosure obligations, as reflected in the proposed rules, presents serious constitutional concerns, including under the Takings Clause, the Dormant Commerce Clause, the Supremacy Clause, and the First Amendment. While this comment letter does not address all of these constitutional concerns, PhRMA would urge the Department and the Task Force on the Fair Pricing of Prescription Drugs to consider these issues, including in evaluating potential future legislative changes and proposed rules. If HB 4005 is implemented in the manner currently contemplated by the Final Draft Rule, 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 with nationwide applicability. Moreover, the required disclosures 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 drugs 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.

From a practical standpoint, many of the reporting requirements are not currently collected by manufacturers and will require implementation of new systems and methodologies in order to comply with the underlying statute and rule—all borne at a cost to the manufacturer and the health care system. It is therefore crucial that the requirements of HB 4005 and the rule are carried out in a manner that is as fair, predictable, and administratively simple as possible for both manufacturers and the state.

There remain a number of items in the Draft Rule we believe to be either inconsistent with the underlying statute or going beyond what the underlying statute allows. Many such examples can be found in our previous comments provided to the RAC. At a high level, issues that still need to be resolved include, but are not limited to: providing a meaningful opportunity for judicial review of a Department decision to disclose information designated as a trade secret; revising the definition of “Net Yearly Increase” so that it is consistent with the underlying statute; removing reporting requirements that go beyond what the underlying statute allows; revising the process by which the Department seeks supplemental documentation and information; and conforming the provisions related to patient assistance program reporting with the underlying statute.

1. Protection of Trade Secret Information—Section 836-200-0540

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 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 “[t]he fundamental requirement of due process”—“the opportunity to be heard at a meaningful time and in a meaningful manner.” *Mathews v. Eldridge*, 424 U.S. 319, 333 (1976).

PhRMA commends the Department for some of the changes that were made during the RAC process, including deletion of the language in Section 836-200-0520 in a previous draft that would have made only certain of the “informational elements” listed in Section 836-200-0505 “eligible for conditional exemption from disclosure,” and inclusion of a mechanism for manufacturers to submit a letter to the director to appeal a Department decision to disclose information designated as a trade secret. However, an opportunity to submit a letter to the director of the same agency that made the decision to disclose does not provide “meaningful” due process to manufacturers who risk having their valuable property rights destroyed by the

public disclosure of trade secrets. As we have mentioned in our prior comment letters submitted during the RAC process, it is imperative 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.¹ 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.²

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 the later of (i) a determination has been made by the Department, or (ii), in the case of a manufacturer's appeal, a determination has been made by the director, as specified by 836-200-0540, or (iii) 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 final resolution of the action, including any appeals."

As it stands, the Draft Rule provides manufacturers only 21 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.

Two recent cases in California demonstrate the inefficiency of the process contemplated by the Draft Rule.³ In those cases, pharmaceutical manufacturers received notices from state agencies indicating that the agencies had received public-records requests asking the agencies to disclose information that the manufacturers had submitted to the agencies pursuant to California's price-transparency law, SB 17. The manufacturers had designated the information as a trade secret and requested that the agencies treat it as confidential. Nevertheless, the agencies indicated that they intended to disclose the information to the requester within 14 days. Unlike Nevada, California did not provide for a stay of disclosure pending judicial review. As a result, the two manufacturers were forced to seek emergency temporary restraining orders in court. Although the courts were able to act quickly, grant the motions for temporary restraining orders, and enjoin the disclosure, this emergency litigation would not have been necessary if California had simply adopted Nevada's sensible framework for resolving manufacturers' claims that information should not be disclosed under a trade-secret exemption. The Department should

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

² 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).

³ *Amgen Inc. v. Cal. Corr. Health Care Servs.*, Case No. 18-stpc-03147 (Cal. Super. Ct.); *Ipsen Biopharmaceuticals, Inc. v. Cal. Pub. Emps. Ret. Sys.*, Case No. CPF-18-516445 (Cal. Super. Ct.).

follow Nevada’s lead and adopt the proposed revised language above so that any decision to disclose is stayed pending litigation.

Additionally, throughout the RAC process, PhRMA commented that the Department should take steps to ensure that information designated as proprietary and confidential trade secret information is protected from public disclosure. The Department 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 the Department clarifies that the “public interest” exception cannot swallow the rule that trade secrets must be exempted from public disclosure.

2. Definition of “Net Yearly Increase”—Section 836-200-0505

PhRMA believes the definition of “Net Yearly Increase” in the Draft Rule is inconsistent with the underlying statute. During the latter portion of the RAC process, considerable attention was paid to this definition when the Department put forward several potential options for 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 the Department’s “Definition Options Memo.”

An additional problem is that current definition is retroactive prior to the effective date of the bill. 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 31.⁴ Because HB 4005 was not effective until March 2018, the first calendar year for which an increase could be calculated does

⁴ https://www.oregonlaws.org/glossary/definition/calendar_year

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.

It should also be noted that the increase contemplated in this section as well as in HB 4005 does not include the significant rebates and discounts manufacturers pay and is not an accurate reflection of net spending or increase as a result.

3. Additional Requirements Not Authorized by Underlying Statute

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 several instances in the Draft Rule that potentially indicate manufacturers are required to report or give notice beyond what is required in HB 4005. As was expressed during the RAC process, PhRMA has concerns with recommendations related to manufacturer reporting contained in Section 2(3), (4), (5), and (6) of House Bill 4005. The Draft Rule inappropriately expands on some of these reporting items beyond what the underlying statute authorizes. In so doing, the Department has made more complex and burdensome an already extremely convoluted set of reporting requirements. The degree of specificity in the rule, and specifically throughout the reporting requirements found in 836-200-0530, should not expand beyond, but rather should be consistent with, the language in the underlying statute.

PhRMA commented previously that the definition of “new prescription drug” put forward in previous iterations of proposed draft rules was ambiguous and problematic, and that continues to be the case in the Draft Rule. Additionally, the Draft Rule is inconsistent with the underlying statute. The definition in 836-200-0505 notes that “A new prescription drug's introduction date is the date of its initial approval.” But Section 2 (6) of HB 4005 states, “Beginning March 15, 2019, 30 days or less after a manufacturer introduces a new prescription drug for sale in the United States at a price for a 30 day supply or for a course of treatment lasting less than one month that exceeds the threshold established by the Centers for Medicare and Medicaid Services for specialty drugs in the Medicare Part D program, the manufacturer must report to the department the information described in OAR 836-200- 0530 (4).” This creates a conflict because the date of approval and launch are not always the same, and HB 4005 clearly states that the introduction is tied to launch, not initial approval.

4. Supplemental Documentation and Information Requests—836-200-0535

HB 4005 requires the Department 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, the Department 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 in the underlying legislation, subsections 2(7)(a)(A) and 2(7)(a)(B). For the former, PhRMA responded during the RAC process that the Department should have 30 days to make an additional request. For the latter, PhRMA responded that manufacturers should have 90 days to respond. The Draft Rule allows 60 days in both instances with an additional 30 days if the manufacturer makes a request within the first 15 days after the manufacturer receives the Department's request. PhRMA believes manufacturers should be given a full 90 days to respond, or at least be given more time to request the 30-day extension as the need for an extension might not be realized until closer to the end of the originally allowed 60 days.

During the November RAC meeting, the Department also 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."

5. Patient Assistance Program Reporting—Section 836-200-0530(3)

This section of the Draft Rule 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 was stated during the RAC process, 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 manufacturers 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,⁵ is not workable, creates unnecessary risk of penalties, and should, as a result, be removed.

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 ~~operating 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.

6. Extend Account Generation Timeline—836-200-0510

The Draft Rule currently asks that reporting manufacturers create an online account for reporting by March 15, 2019 for reports that need to be filed by July 1, 2019. PhRMA requests that the Department extend the account registration deadline articulated in Section 836-200-0510(1) so that it is also "no later than 10 days prior to submitting the report", consistent with Section 836-200-0510(3) of the Draft Rule.

7. Assessments Against Prescription Drug Manufacturers—Section 836-200-0555

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. PhRMA requests that the Department revise the interest rate of nine percent per annum due on any late assessments to an interest rate equal to a lower amount, such as the Department's weighted average cost of capital. The Department should not use late assessments as a means to generate revenue.

Additionally, subsection (4) of this section should clarify that assessments imposed under the statute are due 30 days after the receipt of any assessment by the Department.

⁵ Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs (Federal Register /Vol. 79, No. 104/Friday, May 30, 2014/Notices)

8. Civil Penalties—836-200-0560

HB 4005 authorizes significant penalties on manufacturers in Section 3 and creates a complex tiering system that could prove difficult to fully understand. In previous comments submitted during the RAC process, PhRMA asserted that the civil penalties should be reasonable, fair, and clearly outlined in rule. PhRMA encourages the Department to work with manufacturers to understand and comply with the law so as to avoid incurring penalties due to ambiguity associated with this section.

* * * * *

PhRMA attended each meeting in-person, put forward a number of responses (all of which are attached), and engaged in earnest to make the rule as workable and administratively simple as possible for the industries involved and for the state. While some improvements were made along the way, there unfortunately remain many unresolved problems with the Draft Rule. PhRMA strongly urges the Department to consider the comments submitted during the RAC process, as well as these comments, and to incorporate them into the final rule. Thank you for the opportunity to submit these comments.

PhRMA looks forward to continuing to work with the Department on these important issues.

Sincerely,

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Appendix



August 17, 2018

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RE: HB 4005 Rulemaking Advisory Committee, July 31, 2018 Request for Information by close of business August 17, 2018

Dear Mr. O'Brien:

Thank you for holding the July 31, 2018 Rules Advisory Committee (RAC) meeting. The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates 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 specific request for information (RFI) issuing from the July 31 RAC with a requested response date of close of business on August 17.

1) The Definition of "new prescription drug" –Section 2(1)(f).

The RFI asks for a proposed definition of "new prescription drug" for the purpose of complying with Section 2(1)(f) of the bill. In the context of HB 4005, we interpret this term to refer to approval of novel drug products. Therefore, PhRMA recommends the following definition of new prescription drug:

“New prescription drug” means the first drug product to be approved under an original new drug application, under an abbreviated new drug application, or under a biologics license application.”

This definition ensures that changes to existing approved drugs, such as packaging changes, will be excluded, and prevents such changes from triggering the definition and consequent reporting requirements.

2) Timeframes for DCBS requests for additional information and manufacturer responses—Section 2(7)(a).

HB 4005 requires the Department of Consumer and Business Services (DCBS) to prescribe by rule the period of time in 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.

Additionally, there should be a process for manufacturers to indicate inability to comply with a departmental request due to the nonexistence, a deficiency, or unavailability of requested information. For example, a reporting entity may not have certain information for a product acquired after launch. This process should take the form of a written statement by the manufacturer to the department explaining their inability to comply with the supplemental request authorized in Section 2(7)(a)(B).

3) Establishing fees to be paid by manufacturers to pay DCBS costs –Section 2(12). Specifically, DCBS requests feedback on the merits of levying fees on all prescription drug manufacturers or only those that must file reports with the Department.

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.

4) Changes to health insurance rate review rules to implement Section 5 of HB 4005.

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. 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 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 initial comments. PhRMA looks forward to continuing to work with the DCBS throughout the RAC processes.

Sincerely,

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August 27, 2018

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RE: HB 4005 Rulemaking Advisory Committee, July 31, 2019 Request for Information by Noon August 27, 2018

Dear Mr. O'Brien:

Thank you again for holding the July 31, 2018 Rules Advisory Committee (RAC) meeting. The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates 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) from the July 31st RAC meeting with a requested response date of noon on August 27th, 2018.

1) Clarifying required content of reports and expectations for reporting manufacturers. Please provide detailed feedback on any additional clarifications that may be helpful to enable meaningful reporting on the data elements outlined in section 2 (3)-(6).

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.

The following are some of the areas in HB 4005 that require additional clarification:

a. Section 2(3)—Existing prescription drug price increase reporting

Section 2(3)(d)

PhRMA believes clarification should be provided in rule or regulation regarding the reporting requirement in subsection 2(3)(d), which provides that manufacturers must report “the name of any generic version of the prescription drug available on the market.” Specifically, any regulation or rule promulgated in relation to this requirement should specify that reporting is limited to only generic versions of the prescription drug that are known at the time of reporting.

Section 2(3)(f)

PhRMA believes clarification should be provided in rule or regulation regarding the reporting requirements in subsection 2(3)(f), which provides that manufacturers must report “direct costs incurred by the manufacturer” to manufacture, market, and distribute the prescription drug, and those incurred “for ongoing safety and effectiveness research associated with the prescription drug.” Specifically, any rule or regulation promulgated in relation to this requirement should provide a clear definition of “cost,” “market,” “distribute,” and “safety and effectiveness research.”

Section 2(3)(j)

PhRMA believes clarification should be provided in rule or regulation regarding the reporting requirements in subsection 2(3)(j), which provides that manufacturers must report the “ten highest prices paid for the prescription drug during the previous calendar year in any country other than the United States.” Specifically, any rule or regulation promulgated in relation to this requirement should specify that the prices reported pursuant to subsection 2(3)(j) are list prices and not prices representative of any available or provided rebate or discount.

b. Section 2(4)—Additional verification of manufacturer reporting under subsection (2) and (3)

Section 2(4) specifically calls for verification of “price increases reported.” Since “price” is narrowly defined in Section 2(1)(i), PhRMA believes additional verification should only pertain to WAC price guides or other publications.

c. Section 2(5)—Patient assistance program reporting

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.

d. Section 2(6)—New prescription drug reporting

Section 2(6)(a) and (b)

PhRMA requests clarification in rule or regulation that the information to be provided by pharmaceutical manufacturers pursuant to Sections 2(6)(a) and 2(6)(b) must be reported in a narrative manner, due to the wide range of factors and considerations taken into account by individual companies.

Section 2(6)(d)

PhRMA requests the phrase “not developed by the manufacturer” as used in Section 2(6)(d) to be defined to mean “did not fund in whole or in part Phase I, II, or III trials as defined in 21 CFR 312.21.”

2) In addition to general feedback on the implementation of these requirements, DCBS specifically requests stakeholder feedback on data that should be required under the following provisions:

a. For drug price increase reports, “factors that contribute to the price increase” – Section 2(3)(c)

Section 2(3)(c) requires reporting of the factors that contributed to the price increase for a prescription drug described in Section 2(2). PhRMA believes this should be a narrative description due to the wide range of factors and considerations taken into account by individual companies.

b. For new specialty drug reports, “The methodology used to establish the price of the new prescription drug”—Section 2(6)(b)

Section 2(6)(b) requires reporting of the methodology used to establish the price of a new prescription drug described in the first paragraph of subsection 6. PhRMA believes the rule should define “methodology” as the factors considered in establishing the price, and subsection (6)(b) should be interpreted to require a narrative description of these factors.

3) Clarifying the meaning of “timely,” “timely manner,” “inaccurate or incomplete” for the purpose of determining civil penalties –Section 2(8).

a. Clarifying Timely—Section 2(8)(a)

“Timely,” with respect to the reporting requirements listed in Sections 2(2) and 7(2), should be read to mean 11:59 PM on July 1, 2019, and 11:59 PM on March 15 respectively.

“Timely,” with respect to the notification requirements listed in Sections 2(6) and 6(6), should be read to mean 11:59 PM of the 30th day after introduction of a new prescription drug described in subsection (6).

“Timely,” with respect to the reporting requirements listed in Section 5(1) should be consistent with the rate filing timelines under ORS 743.018.

b. Clarifying Timely Manner—Section 2(8)(c)

“Timely manner” should be consistent with the department prescribed periods in Section 2(7)(a)(B) and incorporate departmental extensions listed in Section 7(b).

c. Clarifying Inaccurate or Incomplete—Section 2(8)(d)

“Inaccurate or Incomplete” information should be defined to be consistent with any rules addressing section 2(3)-(6) and (7), and should not include those instances where a manufacturer cannot produce the requested information¹.

4) Regarding the schedule of civil penalties required by Section 3, DCBS requests feedback on whether these penalties should be established by rule or through other guidance to drug manufacturers. We also request any feedback about how to vary the penalties “based on the severity of the violation.”

HB 4005 authorizes significant penalties on manufacturers in Section 3. PhRMA believes 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 information² or instances issuing from the extension authority granted the 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.

¹ See comments in RFI response #1 on section 2(7)(a)—The department should establish by rule a protocol for manufacturers to indicate an inability to provide specific information required/requested.)

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

- 5) Regarding the requirements for an annual public hearing—Section 5(2)—DCBS requests feedback on whether these requirements necessitate rulemaking, as well as any feedback on the format or structure of this hearing.**

PhRMA believes 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.

- 6) DCBS requests stakeholder feedback regarding any key rulemaking or operational considerations in the implementation of the trade secret disclosure exemption requirements in Section 2 (10).**

PhRMA believes 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. The “public interest” exception should not be interpreted so broadly that it nullifies the requirement that trade secrets be exempt from public disclosure by the State or otherwise conflicts with federal trade secret protections.

DCBS should develop a process that includes reasonable, confidential notice to manufacturers of potential disclosure by the state of trade secrets for manufacturers to defend their rights under applicable federal laws.

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

Sincerely,

Sheri Nelson

Sheri Nelson
Senior Director, State Advocacy
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September 24, 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: 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 #2¹ 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 comments² 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 comments³, 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.

¹ RFI response #2 (8.27.18) Section 1 and 2

² RFI response #2 (8.27.18) Section 1(c)

³ 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

Linda Carroll-Shern
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October 15, 2018

Jesse O'Brien
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Oregon Dept. of Consumer & Business Services, Division of Financial Regulation
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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

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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).

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.¹ 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.²

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 31.³ Because HB 4005 was not effective

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

² 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).

³ 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,⁴ is not workable, creates unnecessary risk of penalties, and should, as a result, be removed.

⁴ 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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