

October 15, 2018

TO:

Jesse O'Brien
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FROM:

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**BY Electronic Submission TO: Jesse.E.Obrien@Oregon.gov and
Karen.J.Winkel@oregon.gov**

**RE: HB 4005 Rulemaking Advisory Committee, Comments on Draft Rules Dated
September 24, 2018**

Dear Mr. O'Brien

Thank you for convening this Committee and providing the opportunity to give feedback on the implementation of 2018 HB 4005. I'm writing to give feedback from OSPIRG regarding the draft rules dated September 24, 2018 and the discussions of the last RAC meeting held on September 25, 2018. As a consumer advocacy organization with tens of thousands of citizen members throughout the state of Oregon, we are committed to help the Department of Consumer and Business Services ("DCBS") implement HB 4005 as it was intended, exposing valuable information about the factors influencing prescription drug pricing to public scrutiny.

While we generally view the current draft as faithful to the intent of HB 4005, there are several minor issues related to the treatment of trade secrets that could use greater clarity in the final rule. However, we're also concerned that the final rule could be weakened unnecessarily if certain elements of feedback from industry stakeholders on the RAC are given undue weight. We also believe that additional clarifications to the draft regulations regarding the universal registration of reporting manufacturers, the annual hearing required by HB 4005 Section 5, DCBS's treatment of "excessive or extraneous" submissions, and the definition of "public funds" would make the draft regulations more faithful to the purpose of HB 4005 and less vulnerable to misinterpretation.

I. Treatment of Information Claimed to be Trade Secret

We're glad to see that DCBS has chosen to follow the strong pro-transparency approach to trade secret protection set out in HB 4005 Section 2(10) in draft rule 836-200-0520. However, there is some room for additional clarification and improvement. Section 2(10) expressly indicates that information provided by reporting manufacturers that qualifies as a trade secret will be made publicly available, unless disclosure is not in the public interest.

In previous RAC meetings, we have advocated for a 2-part approach to the analysis required by Section 2(10): separately dealing with the questions of whether a piece of information is a trade secret and whether its disclosure is in the public interest. This is because the public interest analysis is probably more difficult than the trade secret analysis, and in most cases the problem may be easily avoided simply through a determination that the information is not a valid trade secret. For example, any piece of information that is publicly available cannot be claimed as a trade secret, and a failure to establish the secrecy of an item under proposed 836-200-0520(b)(2) would result in its publication by DCBS without requiring consideration of the public interest argument.

While the current rule could be interpreted as functioning in this way already, it should make its interpretation even clearer by expressly stating that information that is disclosed without establishing both trade secret protection and a public interest favoring non-disclosure will be published.

We would also like to preempt any argument that DCBS could violate Oregon's trade secret law by making required disclosures under HB 4005. Oregon's trade secret law, enacted at ORS 646.461 *et seq.* only applies liability to the "misappropriation" of trade secrets using "improper means." While publication of a trade secret can be "misappropriation," we do not think it is possible to interpret a disclosure by DCBS that is required by law can be an action performed through "improper means."

While DCBS is arguably an entity acquiring information through a mechanism that creates "a duty . . . to maintain its secrecy or limit its use," (ORS 646.661(2)(d)(C)) it receives that information from manufacturers who are aware that this information must be disclosed by DCBS unless the public interest weighs against disclosure. Any duty DCBS could conceivably owe to a reporting manufacturer will be limited accordingly. Further, ORS 646.473(3) grants limited immunity from trade secret law to "public bodies and officers . . . on the advice of any attorney authorized to advise the public body, its officers, employees or agents." Since DCBS is required to make trade secret information public when required by the public interest, the state

Department of Justice would surely support a decision to disclose submissions pursuant to HB 4005.

Since Federal trade secret law uses the same principles of common law regarding “misappropriation,” the same logic applies at a national level. Accordingly, it is not possible for DCBS to misappropriate a trade secret by publishing it as required by HB 4005 Section 2(10).

II. Universal Registration, Universal Reporting, Universal Fees

As currently drafted, the proposed rules create a definition for “reporting manufacturer” that extends to all entities that could be required to submit information under HB 4005, not limited to entities that actually trigger the reporting requirements of the statute by raising prices or introducing new specialty drugs. All reporting manufacturers are required to register with DCBS, make annual filings regardless of whether they have implemented any price increases that would trigger reporting.

At the September 25 hearing, several industry stakeholders expressed concern that some of these requirements went beyond the authority granted to DCBS in HB 4005, specifically: requiring all manufacturers to register, report, and pay annual fees.

This argument is clearly erroneous. DCBS is granted broad authority under HB 4005 Section 2(12) to “adopt rules as necessary for carrying out the provisions of this section, including but not limited to rules establishing fees to be paid by manufacturers to be used solely to pay the costs of the department in carrying out the provisions of this section.” DCBS has chosen to fund this program by requiring all manufacturers to pay an annual fee – spreading the cost burden throughout the industry and ensuring a stable stream of funding. Implementing an industry-wide fee structure like this clearly requires some form of universal registration and universal fee, and these choices are well within DCBS’s power under HB 4005.

III. Annual Hearing Under HB 4005 Section 5(2)

DCBS previously requested feedback on implementation of the annual public hearing required by HB 4005 Section 5(2), specifically: should the Department address this hearing in rulemaking, and what form should the hearing take. In previous meetings, DCBS indicated that it was leaning towards an interpretation of Section 5 that the hearing should be an industry facing event where it could receive feedback on the implementation of HB 4005.

This is much too limited of an interpretation. The hearing under Section 5(2) is an integral part of the public exposure of the information collected pursuant to HB 4005’s reporting procedures, alongside its web publication under HB 4005 Section 2(9) and the annual report required by

Section 2(13). At minimum, it should include a presentation of the findings in DCBS’s annual report in a format accessible to members of the media and public, with time allotted for public engagement. We don’t discount DCBS’s hope to use the forum as an opportunity to receive feedback on the reporting process, but limiting the event to that purpose alone would be a disservice to the transparency goals of HB 4005.

We recommend that DCBS specifically address the hearing requirement of Section 5 by rule through the addition of a new subsection to the draft rule 836-200-0530 that specifically delineates the minimum standards for a public hearing as we have laid out in this comment.

IV. “Extraneous or Excessive” Information – 836-200-505(2)(n)

There was some discussion at the September 25 meeting regarding new language in draft rule 836-200-505(2)(n), which generally deals with a reporting manufacturer’s voluntary disclosures of additional information as permitted by HB 4005 Section 2(2)(k). DCBS proposed that the Director would be empowered to deem “extraneous or excessive” information that is not “useful” to the review of a drug price increase “inaccurate”, and thus subject to civil penalties under HB 4005 Section 2(8)(d). This suggestion was founded on a valid concern that a reporting manufacturer could effectively filibuster DCBS by flooding it with documents. However, some industry stakeholders raised a concern that as written this clause leaves manufacturers stuck between a concern of penalties from both under-reporting and over-reporting under HB 4005.

In that meeting, we suggested that since this clause was drafted to apply to voluntary submissions pursuant to HB 4005 Section 2(2)(k), it mostly applies to information that a manufacturer believes deserves consideration even though its disclosure is not required. Accordingly, an adequate disincentive against a reporting manufacturer attempting to flood DCBS with documents is simply for DCBS to ignore the extraneous submissions. However, this backstop should also be extended to apply more generally to excess submissions purportedly responsive to required disclosures due to the valid concern about overburdening the agency’s capacity, as well as applying this standard to reports related to new specialty drugs.

We propose the following revisions: (1) breaking the second sentence of 836-200-0505(2)(n) out into its own lettered subsection, so it applies more generally; (2) adding a similar subsection to 836-200-0505(4); and (3) revising the relevant language as follows:

“Extraneous or excessive information that is not useful for the director’s review of a drug price increase may be deemed ~~inaccurate information~~ irrelevant at the discretion of the director, and disregarded in the Department’s analysis and reports.”

Our final comment on this issue is to recommend that if DCBS chooses to use this proposed framework for excessive submissions, the Department should also make clear by rule that all information submitted as part of this process will still be published on the Department website, even if the Director deems it to be irrelevant. Such information may still be of interest to the public and the media, despite not being useful to the Department's own review process.

V. "Public Funds" As Referenced in HB 4005 Section 2(2)(e) and Elsewhere

There was some discussion in the September 25 meeting regarding the term "public funds". In particular, there was some confusion about what sort of distinction, if any, should be made between foreign and domestic sources of public funding. Further, there seems to be some confusion whether "public funds" includes foreign sources of funding at all.

The draft rules as they currently exist do not address this issue consistently. 836-200-0500(5) defines "Public Funds" as including any funds provided from a "federal, state, or local government entity." The word Federal seems to imply an exclusion of non-domestic government entities, as many foreign governments cannot be characterized as "Federal". By contrast, proposed rules 836-200-0505(2)(g) and (4)(f) ask reporting manufacturers to "clearly indicate which public funds were provided by United States government entities and which were provided by foreign government entities." In the September meeting, this drew some criticism as arguably requiring a disclosure of information beyond what was authorized by HB 4005.

At minimum, the rule should be revised to eliminate this inconsistency. Further, we do not believe the distinction between foreign and domestic is necessary. The plain language of HB 4005 at Section 2(2)(e) and elsewhere requires disclosure of "The research and development costs associated with the prescription drug that were paid using public funds." This is clear statement by the statute that does not make a distinction between foreign and domestic government entities. "Public funds" clearly means public funds, without the need to add a restriction to domestic sources. Accordingly, we suggest that 836-200-0500(5) be revised as follows:

"Public Funds" means any funds granted, loaned or otherwise provided by a ~~federal~~ national, state, or local government entity."

This follows the clear intent of HB 4005 to require disclosure of all public funds supporting development of prescription drugs subject to the reporting requirement, and eliminates the inconsistency with other portions of the draft regulations. We also propose revision of 836-200-0505(2)(g) and 836-200-0505(4)(f) by eliminating the second sentence of both subsections. As an example, this would alter 505(2)(g) as follows:

~~“The research and development costs associated with the prescription drug that were paid using public funds, including all available information about the sources and uses of these public funds. If any portion of the research and development costs associated with the prescription drug were paid using foreign government funds, the manufacturers will clearly indicate which public funds were provided by United States government entities and which were provided by foreign government entities.”~~

This avoids the potential concern that this disclosure goes beyond the authorization of HB 4005. Furthermore, as the first clause still requires disclosure of “all available information about the sources and uses of these public funds,” it seems likely that most information related to foreign vs. domestic sourcing will still be included in these reports, except to the extent it could be protected under a valid trade secret exemption from disclosure.

Thank you for your time and consideration.

Respectfully submitted,

/s/

Mark O. Griffith