

To: 2018 HB 4005 Rulemaking Advisory Committee (“RAC”)

Jesse Ellis O’Brien

2018 HB 4005 RAC Members

By Email to: Jesse.E.OBrien@Oregon.gov

From: Mark O. Griffith, Health Care Advocate, OSPIRG

Re: July 31 RFI - Contents of Reports; Trade Secret Balancing

Dear Colleagues,

Thank you to Jesse for organizing this committee and providing the opportunity to give feedback on the implementation of Oregon 2018 HB 4005 (“4005”). I’m writing today on behalf of OSPIRG to provide responses to the Department of Consumer and Business Services’ (“DCBS”) request for information regarding the contents of reports and expectations for reporting manufacturers, and considerations related to implementation of the trade secret disclosure exemption under 4005 Section 2(10).

DCBS has also requested feedback related to the schedule of civil penalties under 4005 Section 3, definitions for “timely,” “timely manner,” and “inaccurate or incomplete,” and the annual public hearing required by 4005 Section 5(2). OSPIRG does not have any particular comments on those matters at this time.

Contents of Reports and Expectations for Reporting Manufacturers

With regard to the question of what manufacturers should be required to disclose under 4005 Section 2(3)(c), “The factors that contributed to the price increase,” we point to the proposed regulations implementing California’s 2017 SB 17 (“CA SB 17”). The relevant text is proposed to be implemented CCR Title 22, Division 7, Chapter 9.5, Article 1, §96070(9), and reads:

“A narrative description of the specific financial and nonfinancial factors used to make the decision to increase the wholesale acquisition cost of the drug product and to decide on the amount of the increase. The description shall include, but shall not be limited to, an explanation of how these factors explain the increase in the wholesale acquisition cost of the drug product.”

CA SB 17 shares many structural similarities to 4005 and reflects similar policy concerns. This particular language echoes the text of the relevant portion of CA SB 17 almost verbatim. In areas where CA SB 17 has similar provisions to 4005, but more precise language, as was the case here, California’s proposed regulations provide a good model for DCBS to follow. Where

there is not an adequate model under the California regulations, as is the case for 4005 Section 2(60)(b), we suggest that DCBS use analogous language to that quoted above.

Such draft language could read:

“A narrative description of the methodology used to establish the price of the new prescription drug. The description shall include, but shall not be limited to, a description of the methodology, the specific financial and nonfinancial factors considered under this methodology, and an explanation of how these factors explain the price set for the new prescription drug.”

In any reports submitted in compliance with 4005, manufacturers should also be expected to make a clear argument whenever they wish to exclude information from publication under 4005 Section 2(10), as discussed in greater detail below.

Trade Secret Disclosure Exemptions - 4005 Section 2(10)

While 4005 Section 2(9) requires DCBS to publish most of the information reported to it under 4005’s reporting regime, it is specifically barred in 4005 Section 2(10) from posting Trade Secret information if “(A) The information is conditionally exempt from disclosure under ORS 192.345 as a trade secret; and (B) the public interest does not require disclosure of the information.” Furthermore, if the department withholds any information on this basis, it is required to post “a report describing the nature of the information and the department’s basis for withholding the information from disclosure.”

The structure of the statute makes it absolutely clear that the default assumption should be in favor of disclosure: to be withheld, both aspects of 4005 2(10) must be satisfied, and DCBS must justify any decision to withhold in detail. This is in keeping with the public policy favoring disclosure which underlies Oregon’s strong Public Records statutes. ORS 192.411(1) likewise puts the burden on any agency subject to a public records request to defend a decision to withhold records. Oregon’s case-law also strongly supports a default of disclosure, as the Oregon Court of Appeals wrote in *Turner v. Reed*: “disclosure decisions should be based on balancing those public interest that favor disclosure of governmental records against those public interests that favor governmental disclosure, *with the presumption always being in favor of disclosure.*”¹

However, while the “public interest in disclosure” has been present as a balancing element in Oregon law under ORS 192.345 for decades, the statute never precisely defines the term. Courts

¹ 538 P.2d 373 (1975) (emphasis added).

interpreting the public record statute typically emphasize the public interest in the conduct of state business: “Members of the Public are entitled to information that will facilitate their understanding of how public business is conducted.”² Here, however, the interest in disclosure comes from a different source, that is, the public’s interest in understanding the drivers of rising prescription drug prices.

Since both aspects of 4005 Section 2(10) need to be satisfied to justify non-publication by DCBS, the Department should ensure that any items a manufacturer seeks to protect on the basis of Trade Secret actually qualifies as such under ORS 192.345(a) before proceeding to the public interest balancing test. Any information that is, for example, publicly available in another forum, or where the manufacturer cannot make a clear case for the business advantage conferred by maintaining confidentiality, is not a valid trade secret and should not be protected.

Accordingly, reporting manufacturers should be expected to provide a strong argument in their submission to DCBS for why any information they ask to be excluded from publication on these grounds is both a legitimate trade secret under ORS 192.345(a), and why the public interest in understanding the drivers behind rising prescription drug prices is outweighed by their corporate interest in non-disclosure. In the absence of such a robust argument by a reporting manufacturer, DCBS should be expected to publish the information, as 4005 favors disclosure by default and DCBS will be unable to articulate a reason for non-disclosure without such a submission by the manufacturer.

Thank you for your time and consideration.

Respectfully submitted,



Mark O. Griffith
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OSPIRG

² *Guard Publishing Co. v. Lane County School Dist.*, 96 Or App 463, see App. C (1989); *rev'd on other grounds* 310 Or 32 (1990).