OSPIRG
Standing Up
To Powerful Interests

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November 1, 2018

TO:
Jesse O'Brien
Senior Policy Analyst
Oregon Department of Consumer & Business Services
Division of Financial Regulation
350 Winter St. NE
Salem, OR 97301

FROM:
Mark O. Griffith
Health Care Advocate
OSPIRG

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 October 19, 2018

Dear Mr. O'Brien,

Thank you for convening this Committee and providing the opportunity to give input on the implementation of 2018 HB 4005. I'm writing to give feedback from OSPIRG regarding the draft rules dated October 19, 2018 and the discussions of the last RAC meeting held on October 22, 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.

I. Trade Secret Matters

We're glad to see that DCBS is following the intent of HB 4005's treatment of information claimed to be protected under trade secret law in draft rule 836-200-0520. We encourage DCBS to retain this approach in the final rules, including an interpretation of "public interest" that may sometimes permit publication of manufacturer disclosures even if they would normally be entitled to trade secret protection. Failure to do so, as has been urged by PhRMA, would effectively ignore Section 2(10) of HB 4005, which expressly directs DCBS to publish protected information when required by the public interest.

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Until the law is actually implemented, it is difficult to predict how often, if ever, the public interest test will be invoked by DCBS to require publication. As such, it would be inappropriate to deviate from the intent of HB 4005 by weakening these rules in fear of the largely untested legal theories advanced by PhRMA in their written comments from October.

We encourage DCBS to maintain an interpretation of Section 2(10) in the final rules that requires a robust review of whether the information reporting manufacturers seek to protect is actually entitled to trade secret protection, and leaves open the possibility of disclosing even protected information when it is required by the public interest.

II. Defining "Net Increase" in Price

The current definition of "Net Yearly Increase" in 836-200-0500(5) compares the WAC price for any given drug on January 1 and December 31 of the relevant year. As was pointed out by the AARP, this definition leaves open the possibility that significant price spikes within the calendar year will not be captured in HB 4005's reporting requirements if the price comes back down before December 31.

In order to define "Net Yearly Increase" in a way that accurately reflects annual price movements, and to foreclose any possibility of gamesmanship by reporting manufacturers, we encourage DCBS to compare the average WAC prices between each calendar year, instead of simply comparing two isolated points in time. Average WAC price could be easily calculated by averaging the publically available WAC price for each month across the relevant year. For established drugs, we would encourage a comparison between the average WAC price in the most recent calendar year versus the average WAC price for the preceding year. For new drugs, the average price could be compared against the WAC price on the drug's introduction date.

While it seems unlikely that a manufacturer would manipulate national prices merely to avoid the regulations of a single state with a modest population, making this change would still result in a more accurate read of overall price trends. Not only would it avoid the problem of mid-year price spikes escaping scrutiny, it would also appropriately smooth out the price curve if a drug's WAC price is abnormally high or low at the end of a year due to market conditions beyond the manufacturer's control.

III. Independent Patient Assistance Programs

HB 4005 Section 2(5) requires reporting manufacturers to submit information related to "each patient assistance program offered by the manufacturer." There has been some discussion in the RAC regarding the treatment of patient assistance programs that are funded by a manufacturer, but are operated by an independent third party. In particular, some RAC members have

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suggested that the information required by Section 2(5) will not be available when a patient assistance program is operated by an independent entity.

We believe that the current draft rule 836-200-0505(3) strikes the correct balance between requiring manufacturers to report on independent patient assistance programs, while acknowledging that some of the information listed in Section 2(5) will not be available to a manufacturer even with a good faith effort to secure the information.

It should be clear that an independent program funded by a manufacturer still falls under the definition of "offered by a manufacturer." To interpret the statute otherwise would permit reporting manufacturers to avoid the requirements of Section 2(5) by spinning off new entities to run their patient assistance programs, then claiming that these entities are entirely independent. Accordingly, we recommend that DCBS keep draft rule 836-200-0505(3) in its current form.

Thank you for your time and consideration.

Respectfully submitted,

Mark O. Griffith