



VIA ELECTRONIC DELIVERY

February 1, 2018

Ms. Karen Winkel
Rules Coordinator
Oregon Department of Consumer &
Business Services, Insurance Regulation
350 Winter St. NE
Salem, OR 9730

RE: HB 4005 Proposed Rules

Dear Ms. Winkel:

The Biotechnology Innovation Organization (BIO) and Oregon Bioscience Association welcome the opportunity to offer input on the proposed rules regarding implementation of HB 4005. While we acknowledge many improvements have been made in the proposed rules from the earlier drafts, we remained concerned that the overall approach will have a negative impact on the effective implementation of HB 4005.

The biopharmaceutical industry supports more than 18,500 jobs in the State of Oregon. The economic output stemming from the biopharmaceutical industry in Oregon totals more than \$4 billion.¹ Moreover, the industry has completed more than 2,300 clinical trials of new medicines in the state. Further, of the more than 2,300 clinical trials, 1,252 target debilitating, chronic diseases—asthma, cancer, diabetes, heart disease, mental illnesses and stroke. These clinical trials have been done in association with the state’s clinical research centers, university medical schools and hospitals.²

We are pleased that the Department has made significant improvements in the proposed rule since the preliminary draft of rules was released in 2018. In particular, we appreciate the recognition that in many cases the rules extended beyond the scope of the statute. Many of the improvements are consistent with our letter dated October 15, 2018, such as:

- References to funding from foreign government sources;
- Eliminating reference to the submission of “extraneous or excessive information”; and
- Removal of a requirement to attest for the information submitted.

Nevertheless, we remain concerned that the rule will erode trade secret protections and exceeds statutory authority in a number of areas. Our concerns are as follows:

¹ TEconomy Partners, LLC., “The Economic Impact of the Biopharmaceutical Industry: 2015 Estimates,” *Policy Impact Whitepaper*, October 2017. http://phrma-docs.phrma.org/files/dmfile/PhRMA_GoBoldly_Economic_Impact.pdf

² Research in Your Backyard, PhRMA. <https://www.phrma.org/research-in-your-backyard/research-in-oregon>

§836-200-0505 Definitions

We are deeply concerned that the definition of a “new prescription drug” does not accurately characterize the appropriate “introduction date,” which is defined as “the date of its initial approval.” We strongly believe this should be changed to “date of market entry.” Often times there is a lag from the time a prescription drug is approved and the time it enters the market. The date of market entry can occur from days to months after the approval date. For example, the FDA may approve a drug earlier than its expected action date if the data clearly indicates a positive outcome for patients. However, the company may not be prepared to launch at this earlier date, as the product may not yet be available due to resources and manufacturing considerations.

We are also concerned that the current definition of “net yearly increase”, when applied to the 2018 reporting period, would require companies to factor in prices in effect prior to the law being enacted. We do not believe the statute supports this interpretation. Moreover, such a retroactive look-back is not indicative of future pricing decisions.

§836-200-0505 Form and manner Requirements for Drug Pricing Reporting

Patient Assistance Programs

While we appreciate the modifications the Department made, we believe the requirements in this section exceed statutory authority. As we noted in our letter of October 15, 2018, there is no reference in statute to independent charitable organizations operating a patient assistance program. As the language in the proposed rule indicates, these are “independent” organizations. While there may be public information available to the manufacturer, it is unreasonable and onerous to expect the manufacturer to track down information to make a legal filing of information on behalf of a separate, wholly independent organization. Once again, we urge this part of the provision be stricken from the reporting requirements.

§836-200-0510, Information Claimed to be Trade Secret

We strongly believe this proposed rule weakens trade secret protections. The protection of trade secrets is essential to ensuring a competitive and innovative healthcare marketplace. Therefore, it is essential to implement trade secret protections in accordance with state and federal law. As we indicated in our October 15, 2018 letter, the language regarding trade secrets is not consistent with the federal Defend Trade Secrets Act (DTSA).³ In the DTSA, information is a trade secret if it has commercial value, and the company or person has taken reasonable steps to ensure its security. The DTSA gives the holder of trade secrets the power to implement strict policies maintaining confidentiality of trade secrets to prevent litigation.

Of great concern, the proposed regulations indicate that the state assumes the information is not protected unless the manufacturer requests it remain confidential and then must prove to the state that the information is worthy of that protection. Furthermore, the regulation makes no reference to state or federal law, ORS 192.345 and 18 U.S.C. § 1836, et seq., respectively. Under the DTSA, the manufacturer could let the courts decide the validity of a request for disclosure; one the reasons for this is to ensure those that are making disclosure decisions are free from political expediency and would not disclose the

³ 18 U.S.C. § 1836, et seq.

information haphazardly, regardless of the steps the manufacturer has taken to keep it confidential. Proposed regulations such as these undermine the very purpose of the federal DTSA, to ensure a competitive and innovative market ecosystem. We strongly believe that the regulations should be changed in a manner consistent with the DTSA, much in the same way the Nevada regulations were crafted during the implementation of SB 539. At the very least, the rules should recognize the importance of state and federal statute.

§836-200-0560 Civil Penalties

We believe varying civil penalties up to \$10,000 is excessive for non-compliance of an administrative rule. It extends well beyond the threshold for simple administrative fines that would be more appropriate. Our membership is comprised of small, emerging companies. Small and emerging companies are responsible for 70% of the global clinical pipeline and 84% of all orphan-designated programs. Many of these companies work for years without products on the market but continue investing millions upon millions in research and development. In fact, 92% of publicly traded biotech companies in the US operate on a negative net income.⁴

Thank you for the opportunity to comment on these proposed regulations regarding the implementation of HB 4005.

Sincerely,

/s/

Patrick Plues
Vice President
State Government Affairs
Biotechnology Innovation Organization

Julie Black
Interim Executive Director
Oregon Bioscience Association

⁴ Factset, BIO Industry Analysis, January 2016