



**VIA ELECTRONIC DELIVERY**

October 15, 2018

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Oregon Department of Consumer & Business Services,  
Division of Financial Regulation  
350 Winter St. NE  
Salem, OR 9730

**RE: HB 4005 Preliminary Draft Rules**

Dear Mr. O'Brien:

The Biotechnology Innovation Organization (BIO) and Oregon Bioscience Association welcomes the opportunity to offer input on the preliminary draft rules regarding implementation of HB 4005. We are pleased that the Regulatory Advisory Committee took several of our suggestions from our previous comments to the "request for information," but we continue to have concerns that we believe must be addressed to ensure effective implementation of HB 4005.

Our specific comments regarding the preliminary draft rules are as follows:

**General Comments**

Throughout the draft rules, references are made to "standards set forth on the department's website." Specifically, the following sections refer to these "standards on the website":

- §836-200-0501 Registration Requirement;
- §836-200-0502 Threshold for Reporting Drug Price Increase;
- §836-200-0505 Form and manner Requirements for Drug Pricing Reporting; and,
- §836-200-0520 Information Claimed to be Trade Secret.

We believe that referencing these standards that have yet to be posted does not provide enough specificity. It also leaves open questions as to whether those "standards" referred to throughout the document would be open to public comment and rulemaking. It is essential that these "standards" also be developed with public comment and under the administrative procedures of the state.

**§836-200-0500 Definitions**

We are pleased that the RAC agreed with the recommendation that the definition of a "new prescription drug" should be limited to describe only novel therapies.

"Reporting Manufacturer": We disagree that any manufacturer that engages in the manufacture of drugs or "sets" prices, should be required to report. See explanation below. Based on the plain reading of the statute as well as numerous discussions with the

sponsoring legislators, the bill was not intended to create a compliance burden for companies that do not meet the statutory threshold.

### **§836-200-0502 Threshold for Reporting Drug Price Increase**

We believe that the required attestation in this section for a manufacturer that does not need to report goes beyond statutory authority. The text of HB 4005 does not include any requirements for attestation by manufacturers who are registered in the state but not otherwise implicated by the law, and we believe such a requirement is overly burdensome and goes beyond the law's requirements. It is expected that all businesses operate in accordance with federal, state and local laws; therefore, a company should not need to attest or file an additional statement indicating they are indeed in compliance, nor pay the assessment under §836-200-0550. Further, manufacturers that are required to report under the statute, but fail to do so, are already subject to penalties.

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

#### **Research from Public Funds**

We believe this section of the draft rules would inappropriately exceed the statutory authority. HB 4005 simply requires reporting of "the research and development costs associated with the prescription drug that were paid using public funds." The statutory language does not call for the level of specificity that the draft rules would require. Indeed, we are very concerned that the draft regulations reflect a fundamental misunderstanding of the role of basic research versus research conducted by pharmaceutical companies.

While some drugs are developed on the basis of "basic research" supported by government grants and the National Institutes of Health (NIH), the vast majority of innovative research comes from the private sector. The percent of drugs approved from 1990 to 2007 that benefited from some amount of government research was estimated to be 9.3% to 21.1%.<sup>1</sup> In 2016, the NIH research budget was approximately \$30.5 billion, while the entire biopharmaceutical industry invested approximately \$90 billion in research and development.<sup>2</sup>

The government-funded research, primarily conducted by the NIH, generally focuses on basic research on biopharmaceuticals, while the biopharmaceutical industry conducts both basic and applied research and development. Applied research – the core focus of the biopharmaceutical industry – is what's critical for discovering and bringing new cures to market. Definitions produced by the National Science Foundation explain that basic research does not typically have any formal applications in mind for the research they are doing,<sup>3,4</sup> i.e., they do not know how they would apply their research or develop a compound into a possible biopharmaceutical therapy. While the NIH does conduct applied research in areas such as medical devices and prevention, it does not typically conduct applied research on

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<sup>1</sup> Stephens, Ashley J., et al., "The Role of Public-Sector Research in the Discovery of Drugs and Vaccines," *New England Journal of Medicine*, February 10, 2011.

<sup>2</sup> Research! America, U.S. Investments in Medical and Health Research and Development, 2013-2016, Arlington, VA, Fall 2017. [https://www.researchamerica.org/sites/default/files/RA-2017\\_InvestmentReport.pdf](https://www.researchamerica.org/sites/default/files/RA-2017_InvestmentReport.pdf)

<sup>3</sup> National Science Foundation, Definitions, <https://wayback.archive-it.org/5902/20160210164701/http://www.nsf.gov/statistics/randdef/fedgov.cfm>

"Basic research is defined as systematic study directed toward fuller knowledge or understanding of the fundamental aspects of phenomena and of observable facts without specific applications towards processes or products in mind."

<sup>4</sup> "Applied research is defined as systematic study to gain knowledge or understanding necessary to determine the means by which a recognized and specific need may be met."<sup>4</sup>

biopharmaceuticals.<sup>5</sup> Development costs are borne by the manufacturer themselves. The rare exception to this is when government funding is put toward development of a vaccine or immediate public health emergency, such as the development of an influenza, Zika, or Ebola vaccine.

Additionally, Section (g) calls for information that may not be available to the manufacturer setting or raising the price, as discussed during the RAC meeting, where the “public funds” that could be attributed to particular prescription drug were not borne by the reporting entity, or disclosed during or prior to the acquisition of the entity, technology, information or intellectual property that contributed to the eventual development of the prescription drug subject to the reporting requirement.

The average biopharmaceutical costs \$2.6 billion to bring from research and development to market.<sup>6</sup> This \$2.6 billion figure includes product failures. Out of thousands of compounds, only one will receive approval. The overall probability that a drug or compound that enters clinical testing, including those from public research, will be approved is estimated to be less than 12%.<sup>7</sup> These risks are undertaken by the biopharmaceutical industry, not the government.

Moreover, the statutory language does not make any reference to funding from foreign government sources. Indeed, this could be extremely difficult to quantify given the vast number of countries and the international nature of many studies. We believe this requirement should be taken out of the draft rules.

### **“Including but not limited to”**

These draft rules create a number of ambiguities in compliance. Particularly, all references (subsections “(e)” and “(h)B.” use the phrase “including but not limited to,” which not only expands the statutory authority, but creates an arbitrary and unclear legal and compliance burden for reporting entities and fails to give reporting entities adequate notice of the regulatory requirements. We request that all instances of the phrase “including but not limited to” in Section 836-200-0505 be stricken.

### **Extraneous or Excessive Information**

Subsection (n) creates a difficult compliance conundrum, but adding a potential penalty for the submission of “extraneous or excessive” information. This puts reporting entities at a potential risk of both “under-disclosure” or “over disclosure.” Aside from the lack of clear statutory authority to assess a penalty for submitting information the agency deems “extraneous”, this provision is also ambiguous, and fails to create a clear standard by which reporting entities may comply. We’d suggest as an alternative imposing a “good-faith” standard to protect against unnecessary and overly burdensome filings.

### **Patient Assistance Programs**

We believe this section also goes beyond the statutory limits. The statute makes no reference to charitable organizations that may operate an independent patient assistance program. If an organization that runs an independent patient assistance program receives

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<sup>5</sup> Chart Pack: Biopharmaceuticals in Perspective, Summer 2018, PhRMA. <https://www.phrma.org/report/chart-pack-biopharmaceuticals-in-perspective-summer-2018>

<sup>6</sup> DiMasi, JA, et al., Innovation in the pharmaceutical industry: New estimates of R&D costs. Journal of Health Economics. February 12, 2016.

<sup>7</sup> Biopharmaceutical Research and Development, The Process Behind New Medicines. PhRMA, 2015. [http://phrma-docs.phrma.org/sites/default/files/pdf/rd\\_brochure\\_022307.pdf](http://phrma-docs.phrma.org/sites/default/files/pdf/rd_brochure_022307.pdf)

funding from multiple organizations, it might be difficult for the manufacturer to know whether, as the draft provisions state, the company is providing the “majority of funding.” Moreover, many of these organizations or independent programs may provide discounts or co-insurance to a broad number of products, not just one individual company’s products. This part of the provision should be stricken from the reporting requirements. Specifically, the “majority of funding” standard is in direct conflict with the statutory limitation of patient assistance programs “offered by the manufacturer” in Section 2(5) of House Bill 4005.

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

We believe it is essential for the state to implement trade secret protections in accordance with state and federal law. The protection of trade secrets is essential to ensuring a competitive and innovative healthcare marketplace. The current section providing for some protections we do not believe is consistent with the federal Defend Trade Secrets Act (DTSA).<sup>8</sup> 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.

Nevertheless, one major concern with this preliminary draft or regulations, is 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. Under the DTSA, the manufacturer could let the courts decide the validity of a request for disclosure, but the information requested here being disclosed to the state based upon passage of the law, regardless of the steps the manufacturer has taken to keep it confidential. We believe this undermines 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.

### **§836-200-0510, Additional Information Requests**

We are pleased that the manufacturer is permitted to request an extension of the 60-day time period in which to respond to a request for additional information. While we continue to believe the original time-frame for a manufacturer to respond ought to be 90 days, 60 days with an extension of up to 30 days does provide for a possible 90-day period. Nevertheless, consistent with our previous comments, there could be unforeseen circumstances that might prevent a company from responding within this time period. We continue to believe it is important that the Department allow for additional extensions of this timeframe beyond 90 days on a case-by-case basis.

We also appreciate that the Department agreed with our recommendations to provide an avenue for manufacturers to indicate their inability to provide requested information due to the lack of availability of data. We believe having manufacturers provide a written statement outlining their reasons for the inability to complete the request is adequate.

### **§836-200-0550 Assessments Against Prescription Drug Manufacturers**

We strongly believe assessments should only be levied on manufacturers that are required to file a report. Many of BIO’s members are small and pre-revenue biotechnology companies with few or no products currently on the market. In fact, 92% of publicly traded

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<sup>8</sup> 18 U.S.C. § 1836, et seq.

biotech companies in the US operate on a negative net income.<sup>9</sup> These companies must use their limited resources as efficiently as possible in order to continue to supply the therapies that patients need and to invest in future innovation. As discussed above, we believe that requiring all manufacturers to report is beyond the statutory authority as well as the intent of the legislature (however, per well-established Oregon rules of construction, no inquiry is necessary if the plain language favors a particular reading).

Accordingly, subparagraph (1) should be modified to say "all reporting-eligible manufacturers, at the time of filing of a report pursuant to the statute and regulations, will be assessed an amount no more than \$X."

**§836-200-0560 Civil Penalties**

We understand the agency is still considering the level of civil penalties. In incorporating the comments above, the significance of penalties can magnify (or mitigate) some of the risks associated with the draft rules. We look forward to a fair discussion on appropriate penalties that considers the magnitude of potential risks on all reporting entities, whether large or small, public or private, and profitable or not.

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Thank you for the opportunity to comment on these preliminary draft regulations regarding the implementation of HB 4005. Should you have any questions regarding our comments, please do not hesitate to contact us.

Sincerely,

/s/

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/s/

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<sup>9</sup> Biopharmaceutical Research and Development, 2015.