



**VIA ELECTRONIC DELIVERY**

August 22, 2018

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

**RE: HB 4005 Rulemaking Advisory Committee, July 31, 2018 Request for Information**

Dear Mr. O'Brien:

We are writing on behalf of the Biotechnology Innovation Organization (BIO) and the Oregon Bioscience Association (OR Bio) to submit comments on the Rulemaking Advisory Committee's (RAC's) Request for Information (RFI) regarding implementation of HB 4005. We look forward to working with the RAC on developing regulations that balance the needs of transparency and that of the fragile innovative market ecosystem.

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than thirty other nations. BIO's members develop medical products and technologies to treat patients afflicted with serious diseases, to delay the onset of these diseases, or to prevent them in the first place. In that way, our members' novel therapeutics, vaccines, and diagnostics yield not only improved health outcomes, but also reduced health care expenditures due to fewer physician office visits, hospitalizations, and surgical interventions.

OR Bio, a state affiliate of BIO, represents biotech companies throughout Oregon developing critical lifesaving drugs, advanced health-care technologies, and cutting edge medical devices. Oregon Bio supports Oregon's bioscience community through networking, educational programs, enterprise support, advocacy, and the enhancement of research collaboration. We advocate for policies that foster innovation and work to ensure adequate access to health care products and services for all Oregonians, including those most vulnerable facing rare and orphan conditions searching for new treatments, therapies and cures.

We offer the following comments with respect to the questions posed in the RFI of July 31, 2018.

**Definition of "New Prescription Drug"**

We believe that the definition of a "new prescription drug" should be contained to a novel new drug. We offer the following definition, which is also supported by PhRMA:

“New prescription drug” means the first drug product to be approved under an original new drug application, under an abbreviated new drug application, or under a biologics license application.”

### **Timeframes for DCBS Requests for Additional Information and Manufacturer Responses Section 2(7)(a)**

**Section 2(7)(a)** of HB 4005 grants statutory authority to the Department of Consumer and Business Services (DCBS) to make a written request to manufacturers for additional information after the original report is filed. Additionally, the statute grants authority to DCBS to determine an acceptable period of time in which the Department may request additional information, as well as the amount of time the manufacturer can respond to these requests. BIO and OR Bio believes the Department should instate a 30-day period, following receipt of the original report, in which these requests may be made of manufacturers.

With regard to the time-period in which a manufacturer must respond to such requests made pursuant to Section 2(7)(a), BIO and OR Bio believes a minimum 90 days following receipt of the request would be an appropriate timeframe to allow manufacturers to gather the information necessary to provide a thorough response to any such requests. It is also important that the rule state clearly that the Department may extend this time period on a case-by-case basis. Further, the DCBS should provide an avenue for manufacturers to indicate inability to provide the requested information due to lack of available data. Such a process can allow for the manufacturer to provide a written statement outlining their inability to complete the request for additional information.

### **Establishment of Fees on Manufacturers**

The RFI asks whether fees should be levied only on manufacturers that are required to file a report or on all manufacturers. BIO and OR Bio strongly believes these fees should only be levied on manufacturers that are required to file a report. Many of BIO’s and OR Bio’s members are small and pre-revenue biotechnology companies with few or no products currently on the market. 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. In fact, 92% of publicly traded biotech companies in the US operate on a negative net income.<sup>1</sup>

Inappropriately accounting for the impact additional fees and regulatory burdens can upset the fragile innovative ecosystem. We therefore urge DCBS to only impose fees on those manufacturers who are required to file reports with the Department. There should be no attempt by the state to impose this regulatory scheme on manufacturers that do not meet the requirements of the statute.

### **Changes in the Health Insurance Rate Review Rules**

Pursuant to Section 5 in HB 4005, health insurance plans are required to report: (1) the 25 most frequently prescribed drugs; (2) the 25 most costly drugs as a portion of annual spending; (3) the 25 drugs that have caused the greatest increase in spending year over year; and (4) the impact of the cost of drugs on premium rates. In order to appropriately reflect and account for the impact that prescription drugs have on overall spending, cost must be defined as net of all rebates and discounts. According to a recent analysis, in 2017 biopharmaceutical manufacturers paid approximately \$44 billion in rebates to commercial

---

<sup>1</sup> Ibid.

August 22, 2018

Page **3** of **3**

health plans, and \$153 billion in rebates to all payers.<sup>2</sup> Given the significant amount of rebates that manufacturers pay to insurers every year, it is important to place these reported figures in the appropriate context.

\*\*\*

Thank you for the opportunity to comment in this process during the early stages of implementation of HB 4005. Should you have any questions regarding our comments, please do not hesitate to contact Jack Geisser at 202-962-9200.

Sincerely,

/s/

Jack Geisser  
Director, Healthcare Policy,  
Medicaid, and State  
Initiatives

Julie Black  
Interim Executive Director  
Oregon Bioscience  
Association

---

<sup>2</sup> "A World Without Rebates: Where Does the Money Go?", Nephron, August 16, 2018.