February 25, 2021

The Honorable Rachel Prusak, Chair
House Health Care Committee
State Capitol
900 Court St NE
Salem, OR 97301

Dear Representative Prusak:

The Oregon Bioscience Association (OR Bio) and the Biotechnology Innovation Organization (BIO) respectfully oppose HB 2044, which would make a number of changes to existing Prescription Drug Price Transparency program.

Our organizations have repeatedly expressed on our members' behalf an interest in working with the Department of Consumer and Business Services (DCBS) on good faith compliance with the Prescription Drug Price Transparency program. Yet instead of working collaboratively to resolve problems with existing law, DCBS has put forth HB 2044 to establish new and questionable requirements. For a more thorough explanation of our concerns, please see the attached letter, which was submitted to DCBS on the draft of this bill last fall.

If you have any questions, please do not hesitate to contact us to discuss this further.

Sincerely,

Liisa Bozinovic
Chief Executive Officer
Oregon Bioscience Association

Brian Warren
Director, State Government Affairs
Biotechnology Innovation Organization

cc: Members, House Health Care Committee

April 1, 2020

Andrew Stolfi, Administrator
Oregon Department of Business and Consumer Services
350 Winter St. NE
Salem, OR 97301-3881

Dear Mr. Stolfi,

Our organizations represent thousands of large and small biotech companies developing, manufacturing and/or selling innovative therapies to patients throughout the country - including in Oregon. As you may know, we were and continue to be heavily involved in the legislative conversations around drug price transparency, as well as participants in the rulemaking for the implementation of HB 4005. Since its implementation, we have received significant feedback from our members regarding the challenges in responding to follow-up requests for information under Oregon's drug pricing reporting laws. The purpose of this letter is to share those concerns and request further dialogue with the Department to better understand our issues, challenges and risks, and ideally find a process that works better for all involved.

First, some insight into our membership may be helpful in understanding the practical realities of compliance for biotech firms. The vast majority of our members are small companies that lack the internal compliance and legal mechanisms to adequately satisfy the compliance requirements of HB 4005 in their current form. Many of our larger member companies with significant gross revenues do not turn a profit, and focus their efforts on company viability so they can eventually be self-sufficient. Compliance for these companies is inherently cumbersome, and we would like to ensure that it is as easy as possible for them to meet the law's requirements. These are policy concerns we've voiced in the legislative, regulatory, and task force processes related to HB 4005, and are now being realized as companies are trying to comply with the law and rules.

In general, our members seek clarity on the parameters for follow-up requests for additional information. We suggest better "sideboards" to establish both the scope and timeline for the Department to follow-up on reports submitted by manufacturers; in the current environment there appears to be no clear end in the back-and-forth on requests for additional or new information. Additionally, it would be helpful for manufacturers to receive notification when the content of a report has been determined to be sufficient and or complete, and a timeframe to expect the Department to provide such notification.

The Department should consider additional rules establishing parameters for follow-up requests, and requiring specificity for the content the Department is seeking. This would allow our members' internal staff to assess when a reporting requirement has been satisfied. It does not appear in rule, or the intent of the statute, that the Department has unlimited ability to continue to send inquiries about information submitted by our members. We have been made aware of instances where a second set of follow-up questions from the Department are broader that the first set of response questions asked, or are related to aspects of a report that were not included in the first set of response questions. HB 4005 established a process for reasonable follow-up questions so that the Department can better

understand information reported by manufacturers, not for a prolonged written interrogation with few parameters. From a practical standpoint, and as a matter of fairness in process, follow-up requests should be limited only to the initial set of questions raised by the Department. Additionally, it would helpful to have acknowledgement back to the reporting manufacturer that reports have been received and accepted.

Substantively, we would like to work with the Department to develop and establish better procedures for the protection of trade secrets. While our members are careful not to share with us specific examples of requests related to proprietary data and trade secrets, we have continued to flag this is as the largest concern with the implementation of HB 4005. From a regulatory perspective, we believe the Department has the ability to limit its staff's pursuit of additional explanations as to why a reportable data point is a trade secret. The explanation themselves risk disclosing valuable information that could risk the viability of many of our members, their asset portfolios, and the continued innovation of new therapies and cures for Oregon patient populations.

We are committed to partnering with the Department to find practical, regulatory and, if necessary, statutory solutions to protect trade secrets. As noted in our comment letters on the implementing rules for HB 4005, we think this issue is not just a policy issue, but a matter of federal trade secret law. As we have noted and suggested publicly, our members have a heightened concern about the protection of trade secrets because HB 4005 does not contain protections enacted in other states, such as limiting the information reported to what is publicly available, or ensuring information submitted will not be made publicly available. Clear guidelines must be established about how information that includes trade secrets will be identified and protected by the Department.

Finally, in light of all these challenges, and the current COVID-19 crisis that is overwhelming resources at the state, as well as biotechnology companies that are working to develop treatments and vaccines, we ask the Department to temporarily suspend additional inquiries related to the last submission of drug pricing data. Following the state of emergency, we request that the Department hold a stakeholder meeting to explore if further rulemaking is needed to address these issues.

Our organizations and our members are committed to compliance with Oregon drug transparency laws and encourage continued dialogue to make the process clear, well-defined, and with minimal legal or financial risks to all organizations involved.

Sincerely,

Liisa Bozinovic
Chief Executive Officer
Oregon Bioscience Association

Brian Warren
Director, State Government Affairs
Biotechnology Innovation Organization

December 11, 2020

Cassie Soucy
Senior Policy Advisor
Division of Financial Regulation
Oregon Dept. of Consumer and Business Services
cassandra.soucy@oregon.gov

Comments re: LC 563 and Additional Considerations for Possible Legislation

Dear Ms. Soucy,

Thank you again for your continued engagement with our organizations regarding Oregon's Prescription Drug Price Transparency Program. As we have discussed, our members have had a myriad of challenges, which potentially mirror the difficulties the Division of Financial Regulation (DFR) staff is articulating through its call for comments and the LC draft. First and foremost, we believe those challenges, and other potential legal issues can be addressed (or solved?) with a clear definition and exemption of information properly deemed as trade secret. We would be happy to work with the DFR and legislators on that issue.

As to the existing draft and proposed additions to the programs, we offer the following comments, and the attached correspondence we've provided to the Division on these issues in the past.

Current Draft of LC 563
LC 563 appears to make policy changes beyond those that could be categorized as "technical fixes." Further, it is unclear how the additional requested information will help Oregon patients who benefit from such programs. Excluding the new provision related to patient assistant programs will address these potential problems related to reporting and disclosure. As raised on the stakeholder call, we have significant questions over the benefit to Oregon patients in reporting data regarding patient assistant programs for new therapies to market. This policy justification would be helpful in understanding the need for the additional language as well as the policy risks and costs.

As noted above, we also believe this issue implicates potential trade secrets and sensitive pricing information, that only risks exposure of our member's proprietary information, but in general, creates risk of anti-competitive behavior or allegations. The simple approach would be to exclude the language requiring disclosure of new patient assistant offerings from manufacturers. A stronger definition and process for identifying sensitive information and excluding trade secrets would also alleviate these concerns.

Additional Information Follow-up Requests
Our organizations strongly believe that the challenge DFR and our members are experiencing related to follow-up to additional information responses is a function of the lack of clear parameters for sensitive, proprietary information. This may be a structural problem that if addressed statutorily, and adopting other states' more explicit language

would both reduce follow-up requests and thereby save both staff and reporting companies' time and resource; ultimately benefiting Oregon consumers and patients.

Use of Aggregated Data
Once again, given the risks of disclosure of sensitive and proprietary data, we are concerned with any disclosure of such information, even if aggregated. Further, before DFR pursues additional authority to aggregate and share data, our members (and potentially the public) would like to understand policy justification and benefits of the aggregate information to both patients and consumers at-large.

For more information, please see attached our letter to DCBS dated April 1, 2020, and our comments to the HB 4005 Rulemaking Advisory Committee Dated October 15, 2018. We believe these letters also capture our ongoing concerns with the program.

We look forward to continuing these conversations.

Sincerely,

Liisa Bozinovic
Chief Executive Officer
Oregon Bioscience Association

Brian Warren
Director, State Government Affairs
Biotechnology Innovation Organization