March 20, 2019

The Honorable Laurie Monnes Anderson, Chair
Senate Health Care Committee
900 Court St NE
Salem, OR 97301

Dear Senator Monnes Anderson:

The Oregon Bioscience Association and Biotechnology Innovation Organization (BIO) write regarding SB 872. This bill would enact the recommendations published in the final report of the Joint Task Force on Fair Pricing of Prescription Drugs ("Task Force"). As you are aware, last year's HB 4005 established transparency reporting requirements for biopharmaceutical manufacturers and created the Task Force, which was charged with studying and issuing a report on how to lower prescription drug prices through additional transparency measures. We agree with the Task Force's focus on the entire pharmaceutical supply chain; transparency in prescription drug prices only provides an accurate picture when applied everywhere. Additionally, transparency should provide meaningful information and allow for reasonable protections for all parties to guard trade secrets.

While we agree with most of the recommendations in the Task Force's final report, we do have concerns with one area specifically: the proposal to require biopharmaceutical manufacturers to disclose the wholesale price of a prescription drug in any advertisements. This requirement would not provide consumers with meaningful information and we have concerns with this bill's attempt to regulate commercial speech.

The wholesale cost of a prescription drug does not provide meaningful information to most consumers. Task Force members know well that numerous transactions happen between the sale of a drug to a wholesaler and the receipt by a patient, in addition to a host of agreements between various middlemen. For this reason, wholesale price is a largely irrelevant number. As has been appropriately described by Alan Kirschenbaum in the FDA Law Blog: wholesale price, at best is "of modest relevance to some patients, is of no relevance to most patients, and is potentially confusing" to all patients.[1] Patients with health coverage pay out-of-pocket costs determined by their health insurer, which may be a set copayment or a percentage coinsurance. Providing a drug's wholesale price on advertisements could mislead many consumers into believing their costs are greater than reality.

We also believe this bill attempts an unlawful regulation of commercial free speech, protected by the US Constitution and upheld by the Courts time and again. Indeed, courts have held that compelled disclosures of even factual information raise First

[1] CMS Proposes to Require WAC Disclosure in TV Ads for Rx Drugs, FDA Law Blog, October 16, 2018, *available at:* http://www.fdalawblog.net/2018/10/cms-proposes-to-require-wac-disclosure-in-tv-ads-for-rx-drugs/

Amendment concerns when those facts relate to a controversial subject.[2] Here, the varying nature of insurance coverage in the United States, the fact that WAC is but a starting point for most PBM and insurer negotiations, and the fact that most consumers out of pocket expenses are not represented by WAC renders this individual metric at least controversial and more likely not factual.

Additionally, most advertisements are nationally produced and unable to be tailored to a single state law. **Regulation of prescription drug direct-to-consumer advertisements lies with the Federal government**. The Food Drug and Cosmetic Act provides authority to regulate advertisements to the federal Food and Drug Administration, and establishes a defined set of factors to be included within an advertisement to prevent misbranding claims. These factors are: "(1) the established name [of the advertised product], (2) the formula showing quantitatively each ingredient of [the advertised product], and (3) such other information in brief summary relating to side effects, contraindications, and effectiveness as shall be required in regulations which shall be issued by the Secretary."[3] Unambiguously absent from these factors is any mention of "price." FDA has acknowledged this limitation when it developed its regulations for "reminder advertisements," listing price as an optional element of such ads.[4]

The federal government's primacy in this area is also evident in the fact that the federal Centers for Medicare and Medicaid Services is currently in the final stages of the rulemaking process to require price disclosures in pharmaceutical advertising. While we have the same policy and legal concerns mentioned above, if this debate is to be had, it should be done at the federal level.

As the Senate Health Care Committee considers SB 872, we welcome the opportunity to discuss with you how this bill could be modified to provide meaningful transparency requirements to all participants in the prescription drug supply chain with reasonable protections for trade secrets.

Sincerely,

Julie Black
Interim Executive Director
Oregon Bioscience Association

Brian Warren
Director, Government Affairs
Biotechnology Innovation Organization

cc: Members, Senate Health Care Committee

[2] *See, e.g., Nat'l Inst. of Family & Life Advocates v. Becerra*, 138 S. Ct. 2361 (2018) (relating to the disclosure that crisis pregnancy centers were not licensed as factual but nonetheless controversial compelled speech.)
[3] 21 U.S.C. § 352(n) (emphasis added).
[4] 21 C.F.R. 202.1(i)