PhRMA
RESEARCH • PROGRESS • HOPE
1115 WEST BAY DRIVE NW, SUITE 205 • OLYMPIA, WA 98502 • 360-705-1276 • PhRMA.org

November 19, 2020

Cassandra Soucy
Senior Policy Analyst
Department of Consumer and Business Services
Division of Financial Regulation
350 Winter St. NE
P.O. Box 14480
Salem, OR 97309-0405

Electronically Submitted

RE: Draft LC 563

Dear Ms. Soucy:

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to provide comment on Draft LC 563, which expands pharmaceutical manufacturer reporting requirements under the previously enacted House Bill 4005. Given the existing manufacturer reporting requirements within the law and given that the existing law is subject to ongoing litigation, it is inappropriate to further expand these requirements in an unclear and impractical manner.

The following are PhRMA's comments related to Draft LC 563:

Expansion of Pharmaceutical Manufacturer Reporting Requirements

The changes proposed in section 2, subsection 5 of the draft would require manufacturers to submit additional information on patient assistance programs for qualifying drugs that are newly introduced to the market. This information, which is confidential and proprietary, may not be practically available to pharmaceutical manufacturers in the timeframe specified in Draft LC 563.

Enacted in 2018, House Bill 4005 requires pharmaceutical manufacturers to disclose to DCBS certain confidential and proprietary information related to drug manufacturing and pricing. The Department is required to then post the information provided by manufacturers to its website, even if the information is subject to trade-secret protection, unless the State determines that the "public interest does not require disclosure." 2018 Or. L. Ch. 7 § 2(9), (10)(a).

PhRMA has filed suit in Oregon, challenging the requirements placed on manufacturers under House Bill 4005 (and under 2019 follow-on legislation, House Bill 2658), as violating several provisions of federal law. As PhRMA has explained in its suit, much of the information that these Oregon laws require manufacturers to disclose is confidential and proprietary, deriving economic value by virtue of its confidential nature; publication would thus destroy its value. The information therefore constitutes trade secrets, both under state law and under the federal Defend Trade Secrets Act of 2016 (DTSA), 18 U.S.C. § 1836(b). Because House Bill 4005 permits the State to publicly disclose trade secrets whenever the State decides that publication would serve the "public interest," and provides manufacturers with no compensation for the destruction of this valuable intellectual property, House Bill 4005's public-interest exception violates the Takings Clause of the U.S. Constitution. House Bill

4005's public-interest exception also conflicts with—and therefore is preempted by—the DTSA because it systematically authorizes the misappropriation of manufacturers' trade secrets in direct violation of that federal statute. *See* 18 U.S.C. § 1836(a). In addition to authorizing the destruction of manufacturers' trade secrets in violation of federal law, House Bill 4005 violates the Commerce Clause of the U.S. Constitution, which prohibits states from regulating conduct outside their borders, because it ties its reporting requirements to increases in a drug's Wholesale Acquisition Cost, a list price that by law is uniform nationwide. And finally, House Bill 4005 violates the First Amendment because it requires drug manufacturers, and drug manufacturers alone, to provide narrative descriptions of their own internal decision-making regarding drug pricing decisions. PhRMA and the State have fully briefed these legal challenges to House Bill 4005 and the federal district court has scheduled oral argument for January 2021.

In addition to its legal deficiencies, House Bill 4005 provides manufacturers with insufficient protections to ensure that their trade secrets are not unlawfully disclosed: the law places the burden on a manufacturer to prove that the information is subject to trade-secret protection and fails to provide any concrete definition of the "public interest."

By expanding House Bill 4005's reporting requirements to cover additional proprietary and sensitive information, Draft LC 563 exacerbates these legal and practical concerns. In particular, Draft LC 563 would subject additional confidential information to public disclosure under House Bill 4005's vague public-interest exception, thereby increasing the likelihood that manufacturers' trade secrets will be destroyed in violation of the federal Constitution and the DTSA.

PhRMA understands the access and cost challenges faced by the people of Oregon. However, Draft LC 563 does not promote solutions to addressing affordability at the pharmacy counter. Requiring manufacturers to report patient assistance information for qualifying new drugs, including the total number of patients enrolled in their programs and total value of assistance provided, is confusing and premature, as much of that required information will not be available at the time the drug enters the market.

For the reasons noted above, PhRMA requests that DCBS remove the changes proposed in Section 2 from the draft and that any further amendments to the provisions of House Bill 4005 be delayed until PhRMA's pending lawsuit has been resolved.

Use of Information Found in the All Payer All Claims Database

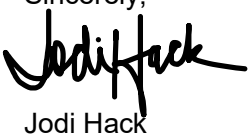
Section 1, subsection 10 of the draft will allow DCBS to access, use and disclose information submitted to Oregon's All Payer All Claims (APAC) database. PhRMA commends the State's effort to identify the causes of rising health care costs. National health spending is projected to grow at an average of 5.5% annually between 2018 and 2027 and is projected to reach nearly $6 trillion in that time.[1] Total spending growth for prescription drugs is projected to be just one-fifth of the growth for health care through the next decade.[2,3] PhRMA notes a few limitations related to the prescription drug data captured in the database that should be taken into consideration before this data is used broadly. First, pharmacy benefit managers (PBMs) and payers—which dictate the terms of coverage for medicines and the amount a patient ultimately pays—negotiate substantial rebates and discounts. In 2019, rebates and discounts paid to health plans, PBMs, the government and others totaled $175 billion. Claims data do not account for these rebates and discounts which, in 2019, reduced the price of brand

[1] Sisko, et al. National Health Expenditure Projections, 2018-27: Economic and Demographic Trends Drive Spending and Enrollment Growth.
[2] Altarum Institute. "Projections of the prescription drug share of national health expenditures including non-retail."
[3] Centers for Medicare & Medicaid Services (CMS). National health expenditure (NHE) data. NHE projections 2017-2026.

medicine by 45%, on average. In addition, hospitals mark up the cost of prescription medicines. On average, hospitals markup medicine prices nearly 500 percent.[4] This markup will be included in the claims data and may result in a significant difference between the Wholesale Acquisition Cost, the cost reported in the claims data, and the cost paid by the plan and consumer.

Thank you again for the opportunity to provide comment on LC 563. In light of the concerns expressed above, PhRMA urges the department to remove the amendments in Section 2 of the draft prior to proceeding with this legislation, and urges caution related to the use of information gather through the All Payer All Claims database. Please feel free to contact either Jodi Hack (503-508-5414) or Donna Steward (360-870-4434) should you have any questions regarding these comments.

Sincerely,



Jodi Hack
Senior Director, State Advocacy
PhRMA
Salem, OR

Donna Steward
Senior Director, State Policy
PhRMA
Olympia, WA

Joanne Chan
Assistant General Counsel, Law
PhRMA
Washington, DC

[4] The Moran Company. Hospital Charges and Reimbursement for Drugs: 2019 Update Analysis of Markups Relative to Acquisition Cost. http://www.themorancompany.com/wp-content/uploads/2019/07/Hospital-Charges-Report-July-2019.pdf.