



In Opposition to Oregon House Bill 2044 January 19, 2021

Position: The Pharmaceutical Research and Manufacturers of America opposes Oregon House Bill 2044, which would require drug manufacturer reporting of confidential and proprietary information for new drugs that may not practically be available to the manufacturer, and which is prematurely seeking to amend a law that is under ongoing litigation.

The changes proposed in section 2, subsection 5 of House Bill 2044 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 the bill. Manufacturers will have limited information available at the time these drugs are introduced to the market to complete the reports that would be required of them.

Of greater concern with this legislation is that the underlying law that would be amended by House Bill 2044 is the subject of ongoing litigation. Enacted in 2018, the Prescription Drug Price Transparency Act (2018 Or. L. Ch. 7, passed as House Bill 4005) requires pharmaceutical manufacturers to disclose to the Department of Consumer and Business Services (Department) 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 2018 Or. L. Ch. 7 (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 2018 Or. L. Ch. 7 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, 2018 Or. L. Ch. 7’s public-interest exception violates the Takings Clause of the U.S. Constitution.

It should also be noted that 2018 Or. L. Ch. 7’s public-interest exception 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, 2018 Or. L. Ch. 7 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, 2018 Or. L. Ch. 7 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.

In addition to its legal deficiencies, 2018 Or. L. Ch. 7 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 2018 Or. L. Ch. 7's reporting requirements to cover additional proprietary and sensitive information, House Bill 2044 exacerbates these legal and practical concerns. In particular, this bill would subject additional confidential information to public disclosure under 2018 Or. L. Ch. 7'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, House Bill 2044 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 may not be available at the time the drug enters the market.

For the reasons noted above, PhRMA requests that the changes to Section 2 subsection 5 be amended from HB 2044 and that no further changes be made to 2018 Or. L. Ch. 7 until PhRMA's pending lawsuit has been resolved.

PhRMA strongly opposes House Bill 2044 and urges your no vote on this legislation.

About

The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier and more productive lives. Since 2000, PhRMA member companies have invested more than \$900 billion in the search for new treatments and cures, including an estimated \$79.6 billion in 2018 alone.

PhRMA

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