STATEMENT

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Statement of the Pharmaceutical Research and Manufacturers of America (PhRMA)
In Opposition to Oregon Senate Bill 1535
January 30, 2020

Position: The Pharmaceutical Research and Manufacturers of America (PhRMA) strongly opposes Senate Bill 1535 which will require public disclosure of proprietary and confidential information and changes the calculation of the threshold for reporting which may have unintended consequences.

Senate Bill 1535 mandates disclosure of proprietary information by biopharmaceutical companies that will neither benefit patients nor decrease healthcare costs. PhRMA understands the access and cost challenges faced by the people of Oregon. PhRMA has been engaged on the implementation of House Bill 2658 which passed the legislature in 2019 and remain ready to work with the legislature to develop solutions that will truly help patients access their medicines. However, SB 1535 does not promote solutions to addressing affordability at the pharmacy counter. The approaches in this bill may also be unconstitutional and vulnerable to federal preemption.

Senate Bill 1535 fails to protect proprietary and confidential information and may be subject to constitutional challenge. Senate Bill 1535 purports to broadly immunize the Department of Consumer and Business Services and its officials from lawsuits based on their disclosure of trade secrets. Pharmaceutical manufacturers are already required to disclose to the Department sensitive business information under two existing Oregon laws, known as House Bill 4005 and House Bill 2658. The current attempt to immunize state officials threatens to further erode the insufficient existing protections under those laws for manufacturers' competitively sensitive, federally protected information.

Enacted in 2018, House Bill 4005 requires pharmaceutical manufacturers to disclose to the Department their confidential and proprietary information, including advertising, cost, marketing, pricing, and production information. And House Bill 2658, enacted in 2019, requires manufacturers to submit advance notices setting forth the timing of, and justification for, certain price increases. Under these laws, the Department publishes the manufacturer-provided information on its website, even if the information is subject to trade-secret protection, unless the State determines that the "public interest does not require disclosure."

PhRMA has initiated litigation challenging both HB 4005 and HB 2658 as inconsistent with the U.S. Constitution and federal statutory law. As PhRMA has explained in its suit, much of the information that Oregon requires 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). In addition to these deficiencies, House Bills 4005 and 2658 provide insufficient protection to ensure that trade secrets are not disclosed: They place the burden on a manufacturer to prove that the information is subject to trade-secret protection; they also fail to provide an adequate definition of the "public interest."

Senate Bill 1535 makes dramatically more acute the threat to trade secrets posed by these prior laws. By purporting to grant to the Department—and to all its officials—broad immunity from "any claims or action based on the disclosure of a trade secret," Section 14 of the bill attempts to eliminate an important deterrent to the publication of manufacturers' highly sensitive information. Notably, Section 14 is not by its terms limited to the disclosure of trade secrets made *in compliance with* Oregon law. Rather, the bill appears to confer blanket immunity for actions taken "[i]n good faith reliance on any order of disclosure issued pursuant to" the State's public records law, as well for acts taken "[o]n the advice of any [authorized] attorney." Section 14 could thus be read to leave manufacturers without a remedy for disclosure of their trade secrets, even if those disclosures are made *in violation of* Oregon law.

Moreover, by purporting to grant immunity for "*any claims or action* based on the disclosure of a trade secret," the bill threatens to violate the Supremacy Clause of the U.S. Constitution. As PhRMA has explained in its pending lawsuit, the public disclosure of trade secrets implicates rights created by the federal Constitution and under federal statute. It is well established that trade secrets are private property; as such, the Fifth Amendment to the U.S. Constitution prohibits the State from taking them without providing just compensation—in this case, by publishing them, thereby destroying their value.[1] The DTSA similarly prohibits the "misappropriation" of trade secrets and creates federal judicial remedies for such misappropriation.[2]

A key means for vindicating these federal rights are suits against state officials for injunctive relief. And in the DTSA, Congress expressly provided for civil damages actions against those who misappropriate trade secrets, including by disclosing confidential business information without permission. *See* 18 U.S.C. § 1836(b)(1), (3). In contrast to Senate Bill 1535's seemingly broad grant of immunity, the DTSA makes no exception for the unlawful action of state officials. Insofar as Senate Bill 1535 purports to immunize state officials who disclose protected information in violation of the DTSA or Oregon law, it conflicts with federal law and thus is subject to preemption.

Senate Bill 1535 changes the threshold for advance notice reporting which could have unintended consequences. This bill will require manufacturers to calculate the threshold for reporting price increases based on the lowest price for a drug at any point over an applicable 12-month period. This would require advance notice for products that may have experienced a cumulative decrease over the 12-month period. ORS 646A.689(2)(b)(A) states that advance notice reports are required for, "An increase in the price of a brand-name prescription drug for which there will be a net cumulative increase of 10 percent or more." SB 1535 revises this language to remove the focus on "net" increases and adds a new threshold for reporting when the price is at least 10 percent higher at any other time during the applicable 12-month period. This approach could lead to reporting when there is a cumulative decrease over the 12-month period, not a cumulative increase.

Senate Bill 1535 includes several vague references that will make it difficult for manufacturers to comply with the law. In particular, language in Section 3(8) of the bill provides authority to the Department of Consumer and Business Services to request "information from any manufacturer regarding any matter related to the administration of this section…" The section further requires manufacturers to "respond promptly and in the format requested by the department." Vague references to "any" information and the requirement to respond "promptly" place manufacturers in difficult positions when trying to comply.

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[1] *See, e.g.*, *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1002–04 (1984); *Phillip Morris, Inc. v. Reilly*, 312 F.3d 24, 41 (1st Cir. 2002) (en banc); *St. Michael's Convalescent Hosp. v. California*, 643 F.2d 1369, 1374 (9th Cir. 1981).

[2] *See* 18 U.S.C. § 1839(5)(B)(ii)(II) (defining "misappropriation" under the federal Defend Trade Secrets Act); *see also* Or. Rev. Stat. § 646.461(2)(D)(B) (defining "misappropriation" under the Oregon Uniform Trade Secrets Act).

This situation is further compounded by the requirement in Section 4(1) that establishes a penalty to be assessed against a manufacturer who does not respond "timely", which is different than the requirement to respond "promptly" included in Section 3(8). Rather than moving forward with vague language that stymies compliance efforts and potentially unfairly assesses penalties against manufacturers attempting to comply with the law, let the regulation process move forward on House Bill 2658 and after full implementation, identify whether there are gaps in the information provided which necessitates the collection of specific rather than vague information; and, if necessary, establish reporting standards that make sense to both manufacturers and the state.

PhRMA recognizes the access challenges faced by patients in Oregon concerned about high prescription drug costs. We stand ready to work with the Oregon legislature to develop market-based solutions that will bring greater affordability to patients. Unfortunately, this bill goes in the wrong direction and accordingly we strongly oppose the passage of SB 1535.

About PhRMA

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.

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