STATEMENT

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Statement of the Pharmaceutical Research and Manufacturers of America (PhRMA) In Opposition to Oregon A-Engrossed Senate Bill 1535
February 20, 2020

Position: The Pharmaceutical Research and Manufacturers of America (PhRMA) strongly opposes A-Engrossed 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.

A-Engrossed 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, ESB 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.

A-Engrossed Senate Bill 1535 fails to protect proprietary and confidential information and may be subject to constitutional challenge. ESB 1535 extends reporting requirements to manufacturers who do not have a requirement to report under existing advance notification laws. 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."

A-Engrossed 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." ESB 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.

A-Engrossed 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…" This language is extremely broad and fails to provide a sense of when such a request may move forward, the rationale for why the request has been made and the intended use of the information. This may lead to manufacturers being subject to unknown and unpredictable requests.

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.

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 ESB 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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