STATEMENT

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In Opposition to Oregon SB 763
February 24, 2021

Position: PhRMA respectfully opposes SB 763, which seeks to establish a registration mechanism for pharmaceutical representatives that is largely duplicative of federal reporting requirements and is administratively burdensome. This type of activity is heavily regulated at the federal level and a patchwork of state and local laws will create a complex regulatory structure unnecessarily.

PhRMA believes that ethical relationships with health care providers are critical to its mission of helping patients by developing and marketing new medicines. A cornerstone to achieving this mission is ensuring that health care providers have the latest, most accurate information available regarding prescription medicines, which plays an increasingly important role in patient health care.

This legislation largely ignores well-established federal requirements and industry codes of practice.

SB 763 is unnecessary as pharmaceutical representatives and marketing practices are broadly regulated by the federal government in a number of ways. Additionally, industry codes of practice and extensive training serve to further regulate interactions.

In addition to requiring duplicative reporting, this legislation places further administrative burdens on manufacturers and the state by requiring the population and maintenance of a fully-public list of pharmaceutical representatives as well as an annual report that is largely duplicative of information already available under the federal Sunshine Act.

- **The Physician Payments Sunshine Act, enacted as part of the Affordable Care Act, requires prescription drug manufacturers to annually report payments and transfers of value provided to physicians and teaching hospitals.** Reportable payments and transfers of value include meals, travel, and fee-for-service payments. The SUPPORT Act, which passed in October 2018, extended the Sunshine Act to non-physician prescribers beginning in 2021. Reported data are posted on a public website.
    - The Open Payments website (https://openpaymentsdata.cms.gov) is easily searchable and provides a wealth of information at the state/local, manufacturer and provider level.
    - Importantly, the Open Payments system permits physicians to review the data and dispute findings before it is publicly posted – something SB 763 does not contemplate.

- **The U.S. Food and Drug Administration (FDA) regulates all promotional labeling distributed about a prescription medicine.** Companies must submit promotional labeling to FDA at the time of initial dissemination, and for some medicines, labeling must be submitted to FDA prior to use. FDA guidance and regulations do not permit sales representatives to discuss information that is not consistent with the FDA-approved labeling for the product.

- **Pharmaceutical companies and their representatives are subject to criminal anti-kickback statutes and other federal criminal and civil laws (False Claims Act/Lanham Act Sunshine Act) that govern relationships with health care providers**. The U.S. Department of Health and Human Services (HHS) Office

of Inspector General has published detailed guidance for pharmaceutical manufacturers designed to deter violations of federal anti-kickback laws. These compliance guidelines prohibit *quid pro quos* between drug makers and health care providers.

- **The PhRMA Code on Interactions with Health Care Professionals offers guidance about appropriate interactions between pharmaceutical manufacturers and health care professionals.** Pharmaceutical manufacturers may offer items primarily for the education of patients or health care providers (items that are $100 or less). They may not provide items for health care providers use that do not advance disease or treatment education, even if they are practice-related items of minimal value.

- **Company representatives have extensive training about their company's medicines and the conditions that their medicines treat.** Pharmaceutical companies employ many physicians, pharmacists, and other scientists who work with others to create the information that is provided to health care providers. As a matter of course, promotional materials are approved by a cross-functional committee before deployed to the field.

SB 763 raises First Amendment Concerns and requires Pharmaceutical Representatives to provide potentially misleading information.

SB 763 raises serious concerns under the First Amendment because it regulates constitutionally protected speech between pharmaceutical representatives and health care providers by requiring a license before speaking and forcing specific speech.

This legislation requires a pharmaceutical representative to share with a health care provider the wholesale acquisition cost (WAC) of a pharmaceutical product or the availability of a generic alternative. Requiring a pharmaceutical representative to provide the WAC of a drug is unnecessary and provides little, if any, benefit to prescribers. The WAC or "list price" of a drug is widely reported and available through online tools and there are many available public databases where an individual may find a drug's WAC price. The WAC price does not define what a patient or an insurer pays for a drug and most importantly, could be misleading in identifying the least expensive drug for the patient and the healthcare system. The determinant factor for how much patients pay for a prescription is insurance benefit design, not the list price of a medicine.

Additionally, a pharmaceutical representative is subject to a penalty for failing to disclose the pricing information of a competitor to the health care provider.

There are no confidentiality protections for information submitted to the state.

SB 763 does not include sufficient protections for information submitted by a licensee. While the legislation does require the Director of the Department of Consumer and Business Services to redact any information that personally identifies a licensee, the required disclosures in the report may include sensitive or private information that could potentially be released to the detriment of the licensee or the health care providers.

For the above reasons, we respectfully urge Oregon legislators to oppose SB 763.

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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 $1 trillion in the search for new treatments and cures, including an estimated $83 billion in 2019 alone.