STATEMENT

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Statement of Opposition: Oregon HB 3486
March 16, 2015

Background: HB 3486 could threaten patient access to needed prescription medications, conflicts with several aspects of federal law related to Federal healthcare programs, may violate certain trade secret and other privacy protections, and could be applied in a way that violates the Anti-Discrimination protections of the Federal Affordable Care Act.

OR HB 3486 proposes to establish a Rules Advisory Committee to implement provisions of the bill by Jan 1, 2017 that would impact manufacturers who have a prescription drug with a wholesale acquisition cost (WAC) of $10,000 or more per cost of treatment and the manufacturer of the drug distributes the drug for sale in Oregon. Given the breadth of the pharmaceutical industry's innovative ecosystem in Oregon, along with the more than $43 million dollars of industry support through significant employment and the impact to the state's economy, certain aspects of this legislation raise grave concerns for patients as well as the industry moving forward. Specifically:

- It is important to keep in mind that the Affordable Care Act has significant safeguards in place for patients related to their out-of-pocket maximum exposure on a yearly basis due to medical bills. This provision, along with several other federal laws, is crafted to help protect patients while also facilitating their access to life-saving medicines and other medical interventions.
- It is unclear from the bill how publishing detailed cost for manufacturers in conducting business would help the general public understand and use that information for any type of decision making. In the healthcare space – Medicare and Medicaid principally – the federal and state governments oversee the administration of programs, along with the regulations surrounding pharmacy benefits and the public does not need access to specific itemized dollar amounts spent on patient assistance programs or clinical trials when looking for particular treatments.
- By singling out medications that cost $10,000 or more in the bill, particularly as applied to the Rules Advisory Committee, there is significant concern that any unintended effects of Committee decisions related to individuals needing these medications would unfairly discriminate against those individuals with regard to the administration of those patients' insurance benefits, which would, in turn, violate the anti-discrimination provisions of the Federal Affordable Care Act.
- Finally, the breadth of reporting required by manufacturers of these medicines could force companies to disclose otherwise protected trade secret or non-commercial information. This is clearly an unintended issue that must be re-visited prior to any enactment.

The vast majority of information sought to be collected, particularly financial data surrounding clinical trials, development and marketing costs, is considered protected confidential corporate information. Much of it, as well, falls into federal protections for trade secrets. This is important because substantial competitive information can be gleaned from costs associated with specific research and development information and sales and marketing information by marketplace competitors. This raises both practical and antitrust concerns. For this reason neither HHS nor FDA is permitted to disclose this type of information even if requested. In summary, these type of disclosures are limited due to confidentiality and proprietary reasons and therefore, this bill violates current business practices.

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The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading innovative biopharmaceutical research and biotechnology 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 $550 billion in the search for new treatments and cures, including an estimated $51.1 billion in 2013 alone.

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