STATEMENT

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In Opposition to Oregon SB 764-A
April 22, 2021

Position: The Pharmaceutical Research and Manufacturers of America (PhRMA) opposes SB 764-A, legislation to make certain patent settlement agreements presumptively anticompetitive.

Discussions about the cost and affordability of medicines are important. No patient should have to worry about whether they can afford the health care they need. SB 764-A seeks to inject state authority into patent settlement agreements, ignores the federal standard for evaluation of these agreements and may have the unintended consequence of delaying generic market entry. For the reasons detailed below, PhRMA urges legislators to oppose SB 764-A.

Patent settlements generally permit generic drugs and biosimilar products on the market earlier than patent expiration, generating significant savings for consumers. Patent settlements do not extend the patent term of an innovator's drug and therefore, do not lead to generic entry past patent expiry of the innovator's drug. According to one generic company's estimate, settlements on 10 products alone allowed generic launches an aggregate of 83.4 years before patent expiration, resulting in more than $67 billion in savings to consumers. Legislation restricting certain kinds of pharmaceutical patent settlements could prevent some pro-consumer settlements, reduce the value of patents, and reduce incentives for innovation.

SB 764-A displaces the Federal Trade Commission's (FTC) role in policing patent settlement agreements. As currently written, this bill is inconsistent with the approach of the U.S. Supreme Court in *FTC v. Actavis*, which established the standard under which the FTC and courts review patent settlement agreements. The FTC can review and take enforcement action against individual patent settlements under the U.S. Supreme Court's holding in Actavis, which provided for use of a "rule of reason" to determine whether a patent settlement agreement is anticompetitive. Since 2003, Congress has required pharmaceutical manufacturers to submit to the FTC certain agreements between manufacturers of new drugs and generic products, and Congress expanded this requirement in 2018, further enabling the FTC's review of these agreements. SB 764-A creates a different standard under Oregon law for assessing the appropriateness of settlement agreements. This inconsistency creates significant uncertainty for stakeholders and subverts the roles of the FTC and federal courts. In addition, SB 764-A limits the fact-finder with respect to the facts he/she can presume. The fact-finder in litigation should make appropriate determinations based on the circumstances of the case, consistent with U.S. Supreme Court precedent and longstanding antitrust law.

Modifying the standard for evaluation of patent settlement agreements could have a substantial chilling effect on procompetitive settlements that generate savings for consumers via earlier generic entry prior to patent expiration. Deterring procompetitive patent settlements could also lead to delayed generic entry by forcing generic companies to take complex patent challenges all the way to a court decision,

risking that the competing generic medicine remains off the market entirely until patent expiration.

Courts are charged with following the framework established by SB 764-A, but the Attorney General's Office will need to file litigation to initiate a court's review under that framework. Under Subsection (2) the bill states, "a court **before which the Attorney General brings an action** under this section shall presume that a resolution agreement … has anticompetitive effects and is a violation of this section if … an alleged infringer (a) Receives an item of value; or (b) Agrees to limit or stop researching, developing, manufacturing, marketing or selling a competing drug."

Based on this framework, the Attorney General's office will bear financial responsibility for bringing an action for the court's consideration and for litigating it. The framework set forth in SB 764-A for an action brought by the Attorney General mirrors that in California AB 824, which was estimated to have a significant fiscal impact. In California, the fiscal note was $901,000 in FY 2019-20, $1.6 million in FY 2020-21 and ongoing.

Finally, the bill is vulnerable to the same type of constitutional challenge that the Association for Accessible Medicines (AAM) brought against California's very similar law, AB 824, in which the district court observed that "if the Attorney General were to enforce the terms of AB 824 against two out of state parties that entered into a settlement agreement outside of California, having nothing to do with California, such conduct would likely violate the Dormant Commerce Clause."

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. PhRMA appreciates efforts to ensure access to medicines and is happy to be part of a conversation as to how best to serve patients; however, this bill has the potential to restrict earlier access to generic alternatives and is not consistent with U.S. Supreme Court precedent and for those reasons, **PhRMA urges Oregon legislators to oppose SB 764-A**.