STATEMENT

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In Opposition to Oregon's HB 2387
January 11, 2017

<u>Position:</u> The Pharmaceutical Research and Manufacturers of America (PhRMA) strongly opposes HB 2387 because it would negatively impact patients in Oregon and nationwide. In Oregon, brand and generic prescription drugs represent only 1.03% (net of rebates) of the total dollars spent on healthcare across Medicaid, state employees, and prisons by the State of Oregon[1]. While the bill as drafted promises limited cost savings to consumers, further inspection makes clear that the ultimate beneficiaries of this proposal are health insurers, who have stated that without the windfall they would receive under Section One, they could not support the remainder of the bill, which includes a cap on consumer out-of- pocket costs. Studies demonstrate that policies that decrease access to needed medicines can result in increased overall costs to the health care system. Therefore, the limited benefits that would apply to consumers are significantly outweighed by the dangerous implications of other provisions in this bill.

<u>HB 2387 would cap drug prices in Oregon by requiring manufacturers to reimburse payers for costs above an arbitrary threshold</u>.

Manufacturers already pay substantial rebates to health insurers and pharmacy benefit managers who use these rebates to subsidize other cost centers and reduce member premiums. A recent IMS report stated that the average rebate across all payers and supply chain entities is 38%[2]. This bill would replace existing, market-driven discounts and rebates with mandatory refunds to health insurers from manufacturers. The level of refund ("excess cost" in the bill language) would equal : (1) the difference between the drug's average wholesale price (AWP) and a specified "foreign price cap" and/or, (2) the difference between the consumers' prescription drug co-pay cost cap and the plan's out of pocket maximum. Again, it is important to recognize that the refunds would not flow directly to patients, but instead, to insurers. These standards would create arbitrary price caps at amounts so low they would undermine the entire pharmaceutical industry, stifling innovation simply for the purpose of putting money into insurance companies' pockets.

In 2015, pharmaceutical manufacturers paid $284 million in brand and generic rebates (mandatory and supplemental) on Oregon's Medicaid drug utilization alone. Oregon's share of those rebates, mandatory and supplemental, was $102 million and the federal government received $182 million[3]. These rebates are the product of a competitive market place that could vanish if the state eliminates incentives for negotiation, potentially resulting in greater costs to the state and the federal government. Researchers

[1] Menges Group, Prescription Drug Spending in State Medicaid Programs, Employee Health Plans, and State Prisons, issued May 2016.
[2] QuintilesIMS Institute. "Estimate of Medicare Part D Costs After Accounting for Manufacturer Rebates," October 2016.
[3] Centers for Medicare and Medicaid Services: 2015 CMS-64 reports.

who previously examined price control measures in other countries have noted they could lead to loss of other voluntary rebates.

The price control provisions in HB 2387 could negatively impact patients in Oregon and nationwide.

Numerous studies document the correlation between decreased access to medicines and poor health outcomes. Diminished access to medicines ultimately costs the healthcare system far more than any short-sighted, perceived savings on prescription medicines. Price controls in other countries have resulted in fewer medicines and treatments for patients as compared to those in the United States and other developed countries. From 2008-2012, the United States saw 104 new medicines came to market, in contrast to just 78 in the United Kingdom and 60 in Canada. Furthermore, the price cap /refund provisions set forth in this bill will chill innovation. This legislative proposal essentially could remove the economic incentive to develop new, lifesaving therapies for patients.

The manufacturer reporting requirements in the proposal are ill-conceived.

As drafted, manufacturers would be required to provide advance written notice to payers no less than 60 days prior to the effective date of an increase in the AWP of a drug, that results in a cumulative increase of more than 3.4 percent over the preceding 12-month period. Additionally, not later than 30 days following FDA approval to market a drug with an introductory average wholesale price of $10,000 or more per year, a manufacturer would be required to report significant data including a justification of the introductory price, expected marketing budget of the drug, and the amount paid for the drug if not developed by the reporting manufacturer. For drugs with an annual price increase of more than 3.4%, the manufacturer also must report the justification for the price increase. Yet, it is not clear how manufacturers could operationally provide such advance notice since AWP is not a number typically used or determined by manufacturers. Even if advance notice were workable, it would signal price increases to other manufacturers, wholesalers, and pharmacists, likely leading to adverse consequences, like stockpiling, drug shortages, and additional price increases.

Without question, HB 2387 could put medical research in jeopardy by placing arbitrary limits on innovative firms' ability to price their products, and mandating revenue transfers that would line health insurers' pockets. By drastically reducing payment to manufacturers for key innovations, many of which manufacturers research and develop over the course of decades, HB 2387 would ultimately result in fewer resources to fuel future research and development of life-changing drugs. It could result in decreased access to medicines, worse health outcomes, and a general decline in overall patient satisfaction.

The cost to bring a new drug to market today is roughly $2.6 billion with just a 1 in 10 chance of securing FDA approval. In 2015, biopharmaceutical companies invested more than $58.8 billion in research and development and in Oregon alone, jobs supported by the pharmaceutical sector paid over $199.2 million in state and federal tax revenue. Since 2000, more than 500 new medicines have been approved by the FDA, helping patients live longer, healthier lives. Medications are transforming many cancers into treatable conditions, reducing the impact of cardiovascular disease, offering new options for patients with hard-to-treat diseases like Alzheimer's and Parkinson's, and fighting even the rarest conditions.

Today, there are more than 7,000 drugs in development worldwide and many of these, if approved by FDA, would be first-in-class, meaning that they would treat disease in a way not yet available to patients.

When a government caps the amount that can be paid for a prescription drug, it essentially caps the resources available to fuel future innovation—which means patients lose.

While the proposed bill would introduce limited patient benefits, it fails to address the key ways in which payers limit patient access to important therapies – namely through adverse benefit design choices and utilization management strategies.

Co-pay caps, while supported by many, are flawed. The proposal would be far more effective if it focused on exploring solutions to the key drivers of increases in patients' out-of-pocket costs, including benefit designs that significantly limit coverage for the therapies that patients with chronic illnesses need most. For instance, patient protections such as co-pay caps will serve no purpose if insurers do not cover the medicines that patients need for treatment and well-being.

Importantly, the bill does not seek to promote transparency across broader health care costs and will not guarantee patient savings at the pharmacy counter. The proposal focuses myopically on drugs, which are only responsible for a limited share of premium costs.[4] And while it does attempt to provide some patient protections, it fails to address the practice of insurers imposing strict utilization management techniques and/or creating less robust formularies. Additionally, it does not provide patients with better information about: (i) their insurer's formularies, (ii) the evidence relied on by health plans in developing coverage rules, or (iii) strategies used by insurers to influence the medical care that patients receive.

The bill as proposed would redirect responsibility for managing risk away from the entities that are best suited and intended to manage that risk.

Health insurers are in the business of managing insurance risk, often receiving significant subsidies from state and federal taxpayers to support their operations – including tax exemptions, premium subsidies, and risk mitigation payments. Insurers collect premiums from patients in return for a commitment to cover needed medical care, prescription drugs, hospitalizations, and other services. HB 2387 would redirect responsibility for a portion of that commitment – prescription drug coverage – away from the state-regulated insurance industry, which is intended to manage that risk. This is irresponsible. To make matters worse, there is no requirement that insurers share the benefit of this windfall with patients.

For the above reasons, PhRMA opposes HB 2387 and urges legislators to oppose as well.

[4] In a recent study conducted by Avalere Health Consulting, prescription drugs only accounted for 13% of the premium increase in 2016 Silver Plans.