STATEMENT

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In Opposition to Oregon's HB 2387-3
April 17, 2017

Position: The Pharmaceutical Research and Manufacturers of America (PhRMA) strongly opposes HB 2387-3 because it would negatively impact patients in Oregon and nationwide. First, the Bill myopically and inappropriately focuses on prescription drug costs despite the fact that in Oregon, brand and generic prescription drugs represent only 1.03% (net of rebates) of the total dollars that the State spends on all state expenditures and only 4.15% of healthcare expenditures for Medicaid beneficiaries.[1] Next, the ultimate beneficiaries of this proposal appear to be health insurers. In fact, the latest amendments to the bill expressly acknowledge that a purpose of the program is to reduce the burden on insurers in this state of the excessive costs of prescription drugs through the Premium Protection Program. The amendments remove important patient protections from the earlier version of the bill, such as eliminating the requirement that insurers contact each enrollee in the course of treatment before removing his or her drug from the formulary. The amendments would also remove the requirement that various plan types offer at least one plan with no deductible or coinsurance for prescription drugs. PhRMA remains deeply concerned that insurers will be the primary group that benefits from this Bill, and patients, in turn, will be seriously harmed. Accordingly, we urge legislators to oppose the Bill.

HB 2387-3 would cap drug prices in Oregon by requiring manufacturers to reimburse payers for costs above an unreasonable cap. The price control provisions in HB 2387-3 could negatively impact patients in Oregon and nationwide.

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 state-mandated refunds from manufacturers to health insurers. The level of refund ("excess cost" in the bill language) would equal: (1) for certain brand drugs costing over $12,000 and a specified "foreign price cap", the difference between the drug's wholesale acquisition cost (WAC) and the "foreign price cap" and, (2) for generics, biosimilar, or off-patent drugs, the amount of any cumulative increase in WAC that exceeds 3.4% over a 12-month period. WAC does not reflect a significant number of prompt pay or other discounts, rebates or reductions in price across the supply chain, and hence the legislation and amendments impose refund requirements on the basis of misleading data that does not reflect actual prices in the competitive market. Furthermore, it is important to recognize that the refunds would flow directly to insurers, rather than patients.

[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.

The bill thus creates unfair price caps at amounts so low they would seriously damage the basic competitive marketplace for therapies and would threaten to undermine various rebates and negotiated discounts that are currently in place. 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 who previously examined price control measures in other countries have noted they could lead to loss of other voluntary rebates.

Additionally, 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. 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.

The manufacturer reporting requirements in the proposal are ill-conceived and unreasonable; they place medical research in jeopardy.

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 WAC of a drug, that results in a cumulative increase of more than 3.4 percent over the preceding 12-month period. Yet, it is not clear how manufacturers could operationally provide such advance notice; and 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.

Additionally, not later than 30 days following FDA approval to market a drug with an introductory WAC of $12,000 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. And, under the amendments, the manufacturer must report the 10 highest prices paid for the drug in the countries for which the foreign price cap is calculated. Such disclosure requirements are unreasonable and stand to seriously harm consumers in Oregon and beyond.

Without question, HB 2387-3 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 2387-3 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

[3] Centers for Medicare and Medicaid Services: 2015 CMS-64 reports.

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.

The amended bill makes certain changes to the prescription drug cost cap – adjusting the cap from $500 to $200 for bronze plan and from $250 to $100 for other plans. These thresholds are no longer per-year limits. Yet, the amended bill 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. The amendments continue to fail to address the practices of insurers imposing strict utilization management techniques and/or creating less robust formularies. 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 amended bill actually reduces transparency to consumers regarding their benefits. For example, the amendments delete the requirement that insurers offer enrollees the following: estimates regarding total out-of-pocket costs for formulary drugs, advance contact to enrollees in the course of treatment with a drug before removing that drug from the formulary, and a public posting during open enrollment period that highlights which drugs have been removed or will be removed from formulary.

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 2387-3 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 2387-3 and urges legislators to oppose as well.