STATEMENT

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In Opposition to Oregon Senate Bill 793 (SB 793)

March 7, 2017

Position: The Pharmaceutical Research and Manufacturers of America (PhRMA) opposes SB 793 which would arbitrarily cap the amount that a drug manufacturer can charge for a drug and would require justification for any price increase of more than 3.4% during a twelve month period. If the Department of Consumer and Business Services determines that the information provided to justify a price increase above 3.4% is insufficient, it will require the manufacturer to refund to the "purchaser" that portion of the price increase that the department finds to be excessive. Furthermore, the price definition in the bill, average manufacturer price (AMP), makes the bill unworkable.

Drug pricing and calculations vary and broad application could have unintended consequences.

Prices in the bill are based on the AMP which would not fully account for the significant rebates and discounts that manufacturers already pay to reduce insurer costs. Further, AMP is not an appropriate measure for tracking price growth. It is calculated on a retrospective basis and typically is lower than Wholesale Acquisition Cost (WAC), a measure frequently referred to as the "list price" for prescription medicines. By setting the maximum price increase threshold on AMP, which is a price negotiated between wholesalers and manufacturers, you are creating an unrealistic measure that does not reflect a significant number of other negotiated prices across the supply chain. Thus, the bill could have the unintended consequence of incentivizing higher list prices at the time of product launch, which could result in increased overall prescription drug spending.

SB 793 would cap drug prices in Oregon to benefit insurers and not patients.

The drug supply chain is complex and includes a variety of stakeholders. Supply chain entities are the beneficiaries of significant manufacturer rebates and discounts, while health insurers and other payers—not drug manufacturers—are responsible for the ultimate amount a patient pays for a drug. By not including these stakeholders in this legislation and by basing the price increase and reporting on AMP, the information that manufacturers would be required to provide would in no way reflect the actual competitive nature of the biopharmaceutical market and would create misleading data upon which the Department would base its decisions.

Today, manufacturers pay substantial rebates to health insurers and pharmacy benefit managers (PBMs) who use these rebates to subsidize other cost centers and reduce member premiums, but often do not use them to reduce a patient's deductible or co-insurance amount at point-of-sale. A 2017 report by the Berkeley Research Group indicates that while manufacturer rebates and discounts have grown over time, largely offsetting any increase in drug list prices, the amount that brand drug manufacturers realize has decreased, from 41% in 2013 to 39% in 2015. On the other hand, the amount realized by supply chain entities has increased from 38% to 42% during that same time. After manufacturer rebates and discounts have been

removed, the amount brand manufacturers retained represented only 7% of 2015 total US health care spending.

A February 2017 report from the CMS Office of the Actuary shows that since 2014—an anomaly year in which millions of uninsured patients gained coverage and a record number of new medicines were approved—prescription drug spending growth has fallen substantially. In fact, among all health care service categories, retail prescription drugs saw the largest decline in spending growth between 2015 and 2016. Spending for prescription drugs grew by 5% in 2016, in line with health care spending growth overall.

Pharmaceutical manufacturers, brand and generic, are the only part of the health care sector that pay to participate in the Medicaid program, thus reducing overall state health care costs. In 2015, pharmaceutical manufacturers paid $284 million in brand and generic rebates (mandatory and supplemental) on Oregon's Medicaid drug utilization. Oregon's share of those rebates, mandatory and supplemental, was $102 million and the federal government received $182 million[1]. These rebates are the product of a competitive market 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.

Finally, the bill would require a manufacturer to return any portion of a price increase deemed excessive back to the "purchaser," a term not defined in the legislation. The drug supply chain includes many purchasers - pharmacy benefit managers, wholesalers, insurers, pharmacies, and patients. As drafted, the intended beneficiary of this payment is unclear. The current system would make it virtually impossible for a patient to benefit from any payment established under this proposal.

SB 793 fails to address the access and affordability challenges that patients are facing with regard to their prescription medicines.

Today, it is common for a patient to pay the full list price for a medicine when in the deductible, even though the insurer receives a rebate from the manufacturer. By focusing myopically on manufacturers, the bill does not address any true patient access and affordability issues. This bill also does not take into account any medical benefit cost offsets that insurers received as a result of the benefits provided by prescription medicines. Studies have shown that proper adherence to prescription medicine therapy could reduce overall health care spending by $213 billion annually.

Payers use utilization management techniques to limit patient access to important therapies – namely through adverse benefit design choices and utilization management strategies. This bill fails to address insurer practices to restrict access and to create less robust formularies. Additionally, it would not require the reporting of information that is truly important to patients including: (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 price control provisions in SB 793 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

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

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 come 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.

Without question, SB 793 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 middlemen pockets. By drastically reducing payment to manufacturers for key innovations, many of which manufacturers research and develop over the course of decades, SB 793 could 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.

For the above reasons, PhRMA opposes SB 793 and urges legislators to oppose as well.