STATEMENT

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In Opposition to Oregon Senate Bill 793-1 (SB 793-1)

April 14, 2017

Position: The Pharmaceutical Research and Manufacturers of America (PhRMA) opposes SB 793-1 which would unreasonably cap the amount that a drug manufacturer can charge for a drug, and give the department unreasonable discretion to require the manufacturer to refund to the "purchaser" the portion of the price increase above the cap. The bill would also mandate certain disclosures for all price increases above the cap, even where those increases were determined to be fair and justified. Such price controls threaten patient access to drugs in Oregon and beyond, and they undermine the competitive landscape for innovation of new therapies. For these and various other reasons, the bill, as written, continues to be unreasonable and unworkable. The recently proposed amendments do nothing to cure these defects and, consequently, PhRMA strongly opposes this Bill.

The amendments to the bill continue to consider prices that do not reflect actual market circumstances; and mandating refunds based on these figures could have various harmful consequences for patients and other parties. As further detailed below, the bill amendments do not lessen the burden that the bill imposes on manufacturers and, in turn, patients. On the whole, the amended bill continues to place a burden on the manufacturers that ultimately detracts from innovation and research that is needed to help the patients of Oregon. It could have harmful consequences for patients and various other persons across the supply chain.

SB 793-1 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. The Bill amendments would consider wholesale acquisition cost (WAC) for both brand and generic drugs. This figure, as with the previously proposed figure, is unrealistic. WAC does not reflect a significant number of prompt pay or other discounts, rebates or reductions in price across the supply chain. By not including the various discounts, rebates, and other reductions in price paid out to these various stakeholders, the legislation does not take into account the actual competitive nature of the biopharmaceutical market and would create misleading data upon which the Department would base its decisions. Imposing a refund on the basis of such misleading data would unreasonably penalize manufacturers.

The bill amendments would also require manufacturers to provide notice of excessive price increases that will occur in the next 12 months. These increases would be calculated on the basis of this misleading data; moreover, requiring such advance notice would raise a host of anticompetitive concerns.

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.

The bill amendments also impose fees on manufacturers to help them effect this unreasonable regime. Specifically, the amendments would allow the Department to adopt via regulation a manufacturer fee to pay for the cost of reviewing justifications for excessive price increases and for the cost of any action by the department in response to excessive price increases. The fee would be an unspecified "base fee" plus an unspecified percentage of WAC of the drug under review.

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 793-1 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

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

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 793-1 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 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 793-1 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 793-1 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 793-1 and urges legislators to oppose as well.