Biotechnology Innovation Organization

March 8, 2017

The Honorable Laurie Monnes Anderson
Chair, Senate Health Care Committee
State Capitol
900 Court St NE
Salem, OR 97301

Dear Senator Monnes Anderson:

The Biotechnology Innovation Organization (BIO) respectfully opposes SB 793, which would require prescription drug manufacturers to report the price of drugs sold in Oregon and all price increases, and prohibit a price increase of greater than 3.4 percent unless approved by the Department of Consumer and Business Services. BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations.

BIO members research, develop and manufacture innovative therapies that provide unprecedented benefit to patients and bring value to the healthcare system. We strongly object to artificial price limitations imposed on innovative biopharmaceutical therapies. Such market manipulations will scare away investment, stifle future innovation and prevent us from delivering new cures to patients in need.

Of nearly 5,400 clinical programs currently underway globally, 70 percent are led by small companies. These start-ups and small research institutes are the engine of biotech innovation, and they rely heavily on investors to fund their research. With the high failure rate of potential new therapies, investing in the biopharmaceutical sector comes with substantial risk. Investors expect to recuperate losses and a reasonable return on investment, but these calculations are not performed on individual therapies in a vacuum—the ROI on successful therapies must make up for the failures as well. State regulation of drug prices will undoubtedly scare off investors and result in a devastating blow to small biotech companies' ability to secure funding for innovative research.

This bill also fails to take into account two very significant factors: the costs incurred by manufacturers in the research and development of therapies that do not make it to market and the value that our members' therapies bring to the healthcare system.

For every new medicine approved by the federal Food and Drug Administration, there are thousands of potential therapies that failed along the way. Researchers spend years in the drug discovery and pre-clinical stage, investigating broad categories of molecules in an attempt to separate those that might be fruitful from those that will not. Even for those that make it to the clinical trial stage, 90 percent of potential new treatments fail. Our members spend more money on research and development for products that do not make it to market than they do on products approved by the FDA. However, this bill only accounts for "the direct costs incurred by the manufacturer… [i]n the research and development of the prescription drug" facing a price increase.

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This bill also provides no consideration for the value that innovative therapies have to individual patients and to the healthcare system through decreased overall health costs. For example, a cancer medication may have a high cost but save even more money in avoided hospitalizations, surgeries, and other treatments. Innovative therapies developed by biopharmaceutical manufacturers have saved trillions in avoided health care costs, but SB 793 does not take this into account.

In addition to our broader concerns with price control legislation, we do have some specific concerns with various parts of this bill. SB 793 requires reporting of the Average Manufacturer Price (AMP) of a drug to the state and requires price justifications for specified increases of the AMP. However, AMP rates represent a specific pricing compendia used by the federal Centers for Medicare and Medicaid Services for calculating reimbursement to pharmacies and other providers for covered drugs dispensed to patients. AMP rates, by definition, are only for drugs in the retail pharmacy class of trade and specifically exclude drugs used in inpatient settings. The majority of biopharmaceutical therapies are not dispensed in the retail pharmacy class of trade and do not have an AMP calculated.

Even if a different pricing compendia were used, health plans and other payers do not pay the wholesale price or list price for prescription drugs, making it impossible to reflect a drug's true cost. According to IMS Health, list prices for brand-name drugs grew by 12.4 percent in 2015, while net prices after manufacturer rebates and discounts to payers grew by only 2.8 percent. So while a four percent increase would trigger a review under SB 793, the actual increase to a payer may be less than one percent.

Lastly, as part of this bill's proposed review process for price increases, SB 793 would compel biopharmaceutical manufacturers to report proprietary information on the costs to develop and sell innovative therapies. However, there is nothing in this bill that protects the confidentiality of this information.

BIO members are focused on comprehensive and sustainable solutions to improve patient access to medicines, while maintaining our steadfast commitment to investing in the hard work of innovation. We welcome a holistic debate about the value of innovative medicines, and are committed to exploring how value-based approaches to payment can facilitate smarter healthcare spending.

For these reasons, we respectfully urge your no vote on SB 793. If you have any questions, please do not hesitate to contact me at bwarren@bio.org or (916) 606-8016.

Sincerely,

Brian Warren
Director, State Government Affairs
Western Region

cc: Members, Senate Health Care Committee