STATEMENT

PhRMA
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In Opposition to Oregon HB 2308
Emergency Order – Goods Safety Requirement
March 11, 2021

Position: The Pharmaceutical Research and Manufacturers of America (PhRMA) respectfully opposes Oregon's House Bill (HB) 2308, which would authorize the Governor of Oregon, if necessitated by an emergency during a state of emergency, to "require" a "person" in the state to accept and fulfill orders for the manufacture, sale, and distribution of goods necessary to protect public safety, which could potentially include medications, during a stated emergency. In addition to raising constitutional concerns, this legislation could cause significant disruption in the supply chain that would negatively impact the production and distribution of other lifesaving medicines and treatments for patients.

PhRMA represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. Since 2000, PhRMA member companies have invested nearly $1 trillion in the search for new treatments and cures, including an estimated $83 billion in 2019 alone.

While the intent of this legislation may be to ensure access to goods needed to protect public health, the potential application of this authority to orders of treatments and vaccines could have the unintended consequences of disrupting the supply chain and could harm the research and development (R&D) of new treatments and cures for patients, especially at a time when medical innovation is needed to fight COVID-19 and other diseases. In addition to treatments and vaccines that are being researched to fight the pandemic, the biopharmaceutical industry is bringing revolutionary, innovative treatments to patients and families, changing and improving their lives for many different diseases and conditions.

Yet, our most pressing fight is against this deadly virus. Just four months after the pandemic was declared, scientists were able to decode the COVID-19 virus in record time (as compared to 20 months when SARS was eventually decoded) and to bring the first drug to clinical trial within four months. Now, less than one year after the pandemic was declared, three vaccines for COVID-19 have received emergency use authorization from the U.S. Food and Drug Administration (FDA) to help fight this deadly virus. FDA has also authorized a number of treatments and approved one treatment to aid in the battle against COVID-19. There is hope that we are turning the corner on this crisis as we continue to see more than 1, 772 vaccine and treatment candidates under investigation and making incredible progress, 13 of which are clinical trials in the State of Oregon.

This legislation would likely be preempted by the federal Defense Production Act and raises other constitutional concerns, such as under the Dormant Commerce Clause of the U.S. Constitution.

The President has authority under the federal Defense Production Act ("DPA") to require persons to accept and fulfill orders on a priority basis, where doing so is necessary for national security, such as for an issue of national defense or in response to a disaster. This bill attempts to provide similar authority to the Governor of Oregon and would likely conflict or interfere with the aims of the federal DPA and be

preempted. Any order by the Oregon Governor that, directly or indirectly, interfered with fulfilling an order issued pursuant to the federal DPA authority would likely be unenforceable.

In addition, HB 2308 could raise Dormant Commerce Clause concerns if products outside of the state are diverted to fulfill an order from the Oregon Governor.

This bill could disrupt the diverse pharmaceutical manufacturing supply chain, which is necessary during the ongoing COVID-19 pandemic.

HB 2308 could disrupt the supply chain for necessary medicines. Biopharmaceutical manufacturers are committed to ensuring a safe, stable, and secure supply chain, which requires a significant investment in time and resources to make sure that patients receive safe and effective medicines when they need them. As the R&D process progresses and researchers get closer to a potential successful treatment, companies must build the capacity to safely and efficiently manufacture sufficient quantities of that medicine for patients needing treatment, as well as developing plans for getting those medicines to patients. This includes, for example, contracting with various suppliers to ensure high-quality, reliable sourcing of certain materials used, ensuring the availability of the highly skilled labor force with the ability to manufacture the medicine, and maintaining the critical quality control and testing systems needed to protect patients.

At the same time, manufacturers have complex systems in place to avoid major disruptions in the supply chain. For example, they make sure they have back-up suppliers and facilities in different parts of the world in case of a natural disaster or emergency. That way if one facility experiences issues, another facility can quickly help and prevent any major or long-term disruptions in the supply chain.

Over decades, biopharmaceutical manufacturers have carefully built these robust global supply chains to ensure patients in the United States and around the world have ongoing access to medicines. Biopharmaceutical companies invest significantly in the design and ongoing maintenance and modernization of manufacturing facilities and their quality systems, and these efforts have been successful in avoiding any major disruptions due to the COVID-19 pandemic.

This legislation could reduce manufacturers' incentives to invest in Oregon with research and jobs, potentially negatively impacting the economy.

The biopharmaceutical industry is one of the most research-intensive industries in the U.S. In 2019, the biopharmaceutical sector invested about $83 billion in R&D, more than any other industry in the U.S. R&D is an expensive and risky undertaking with millions of patients benefiting from new cures and treatments. On average, it takes more than 10-12 years and $2.6 billion to bring a new medicine to market. Yet only 12% of drug candidates that enter clinical testing are eventually approved, meaning 88% will fail throughout the lengthy clinical trial process. Companies must continue to re-invest and attempt to recoup investments of failed clinical trials. However, policies such as HB 2308 may further strain and disincentivize biopharmaceutical companies to continue to push investments through the R&D process in Oregon.

Furthermore, policies like this could impact jobs in Oregon. The biopharmaceutical sector directly accounts for more than 4,183 jobs in Oregon and supports more than 17,306 jobs in Oregon totaling more than 21,000 jobs. These jobs generated over $3.9 billion in state and federal tax revenue for Oregon in 2019. This bill could place these jobs and tax revenue in jeopardy.

In summary, PhRMA stands ready to participate in the important discussions around access to medicines, but this legislation is not the answer. We stand ready to work with the legislature to develop solutions that would not interfere with or undermine federal efforts and that do not risk contributing to shortages of other lifesaving medicines and treatments.

PhRMA respectfully requests a NO vote on HB 2308.