June 15, 2021

The Honorable Charles Schumer
Majority Leader, U.S. Senate
322 Hart Senate Office Building
Washington, DC 20510

The Honorable Mitch McConnell
Republican Leader, U.S. Senate
317 Russell Senate Office Building
Washington, DC 20510

The Honorable Nancy Pelosi
Speaker
U.S. House of Representatives
235 Cannon House Office Building
Washington, DC 20515

The Honorable Kevin McCarthy
Republican Leader
U.S. House of Representatives
2468 Rayburn House Office Building
Washington, DC 20515

Dear Senate Majority Leader Schumer, Senate Republican Leader McConnell, House Speaker Pelosi, and House Republican Leader McCarthy:

The Council of State Bioscience Associations (CSBA) is an alliance of state-based, non-profit trade associations, each of which advocates for public policies that support responsible development and delivery of innovative life-enhancing and life-saving products. Most of our member companies are small-to-medium in size and most do not have products on the market. Yet, our member companies are leading the world in cutting edge research to develop new therapies and cures, including hundreds of potential vaccines and treatments for COVID-19. Scientists at these companies are providing hope for patients and their families and have moved with record speed to address the challenges brought forth by COVID-19.

The undersigned organizations write to express our strong concerns about H.R.3. This bill seeks to introduce international reference pricing and foreign price controls as a strategy to reduce prescription drug costs.

We appreciate the bipartisan and bicameral efforts underway to provide much needed financial relief for patients who cannot sustain high out-of-pocket costs for prescription drugs. This is a critical challenge for our nation, and we are committed to being part of the solution to address it, while also ensuring that we maintain the necessary incentive structure to foster future innovation.

Proposals like H.R.3, and similar bills that introduce price controls, particularly foreign reference pricing, into government and private healthcare programs will consequentially threaten patient access and choice, cede America's global leadership in biomedical innovation, and will have a disproportionately disastrous impact on small, emerging biotech companies.

These proposals are concerning for states and regions of the country with established life sciences communities, as well as for emerging biomedical

innovation ecosystems, working to attract capital investment and support entrepreneurship to build the companies and therapies of the future. Above all else, such proposals will quash the hopes of patients who are relying on this industry to develop next-generation cures and therapies for serious, life-threatening diseases.

By imposing artificial price controls tied to what other countries pay for their medicines, H.R.3 would significantly erode the U.S.-based biopharmaceutical economy. An analysis by the health economics firm Vital Transformation found that if H.R.3 had been in place during the last decade, it would have resulted in 61 fewer medicines, disproportionately impacting treatments for rare diseases, oncology, and neurology.[1]

In countries where reference pricing and price controls are already used, patients face limited access and significant wait times for those medicines that are approved. For example, 96 percent of new cancer drugs are available in the U.S., at an average delay of 0-2 months.[2] By comparison, Japanese patients have access to 59% of new medicines and wait on average 21 months. Even in Germany – the closest nation to the U.S. in terms of access – only 74% of new cancer medicines are available, with an average delay of 11 months. Should the U.S. implement foreign price controls, patient choice and access to the full range of life-saving therapies would undoubtedly be threatened.

Proposals to implement foreign price controls also put at risk the U.S.'s world-leading innovative biopharmaceutical sector that has created nearly one million jobs[3] across all 50 states and represents a large portion of our nation's Gross Domestic Product (GDP) - generating an economic output of approximately $1.3 trillion annually[4]. The sector already takes on extraordinary risks and makes significant investments in the hope that a few will eventually lead to the next generation of life-saving treatments for patients, and therefore, the looming potential of foreign price controls is truly an existential threat, and one that will undermine our ability to invest in future cures. Vital Transformation also found that along with the reduction in new medicines from small and emerging biotech companies, implementing H.R.3 would eliminate nearly 200,000 jobs in the biopharmaceutical sector, and nearly 1 million jobs across the country.[5]

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[1] H.R. 3 and Reference Pricing: Total Market Impact. Vital Transformation. March 2021. Available at: http://vitaltransformation.com/wp-content/uploads/2021/04/HR3_4.5.21_v10.1.pdf

[2] The United States vs. Other Countries: Availability of Cancer Medicines Varies. PhRMA Analysis of IQVIA Analytics Link and FDA, EMA and PMDA Data., Nov. 2020, https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/A-C/Comparison-of-Availability---New-Cancer-Meds---112520.pdf

[3] *The Economic Impact of the U.S. Biopharmaceutical Industry: 2015 National and State Estimates*. TEConomy Partners, LLC, Oct. 2017, https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/PhRMA_GoBoldly_Economic_Impact.pdf.

[4] *Ibid.*

[5] Vital Transformation. 2021.

It is also important to remember that the overwhelming majority – over 80 percent – of biopharmaceutical innovators in the US are small, start-up, pre-revenue companies without a single product yet on the market. A recent report by IQVIA showed that emerging biopharmaceutical (EBP) companies account for over 70 percent[6] of the total late-stage R&D pipeline and were responsible for almost two-thirds[7] of the patents for new drugs launched in 2018. These mostly pre-revenue companies without a product on the market are the ones most affected by fluctuations in investment caused by the political and public policy environment.

The recent actions taken by the Administration and Congress, including proposals like H.R.3, will significantly chill research and development, eliminate American jobs, and drive capital investment away from the life sciences and toward low risk sectors. Losing this pipeline of investment will significantly disrupt the existing pipeline of high-risk, potentially transformative treatments for genetic diseases, Sickle Cell Disease, Alzheimer's, ALS, and more. If price controls as proposed are implemented, it may reduce drug pricing in the short term, but it will certainly result in significantly reduced innovation and severely restricted access to life-saving medicines.

On behalf of the US's innovative life sciences community, we urge you to reject efforts to undermine America's global leadership in biomedical innovation by imposing foreign price controls on medicines in this country. Patients deserve hope and access to the life-saving therapies of today and tomorrow. As you move forward, we stand ready to work with you to consider alternative proposals that will propel American innovation forward and deliver affordable, accessible, and innovative therapies for patients who need them. Thank you for your consideration.

Please contact CSBA Executive Director, Michele Oshman at moshman@bio.org with any questions.

Respectfully,

Arizona BioIndustry Association, Inc
Bio Nebraska
BioAlabama
Biocom California
BioCT
BioFlorida
BioForward Wisconsin
BioKansas

[6] *The Changing Landscape of Research and Development*. IQVIA Institute for Human Data Sciences, 23 Apr. 2019, https://www.iqvia.com/insights/the-iqvia-institute/reports/the-changing-landscape-of-research-and-development.
[77] *Ibid.*

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Bioscience Association of Maine
Bioscience Association of West Virginia
BioUtah
California Life Sciences Association
Colorado BioScience Association
Delaware BioScience Association
Georgia Bio
Illinois Biotechnology Innovation Organization
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Michigan Biosciences Industry Association
Montana BioScience Alliance
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New Mexico Biotechnology & Biomedical Association
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