

United States Senate
WASHINGTON, DC 20510

February 9, 2021

The Honorable Charles Schumer
Senate Majority Leader
United States Senate
S-221 U.S. Capitol
Washington, D.C. 20510

The Honorable Nancy Pelosi
Speaker of the House
U.S. House of Representatives
H-232 U.S. Capitol
Washington, D.C. 20515

The Honorable Mitch McConnell
Senate Minority Leader
United States Senate
S-230 U.S. Capitol
Washington, D.C. 20510

The Honorable Kevin McCarthy
House Minority Leader
U.S. House of Representatives
H-204 U.S. Capitol
Washington, D.C. 20515

Dear Majority Leader Schumer, Minority Leader McConnell, Speaker Pelosi, and Minority Leader McCarthy

As Congress continues to negotiate the upcoming coronavirus disease 2019 (COVID-19) relief package, we urge you to include provisions that would boost our nation's capacity to domestically manufacture active pharmaceutical ingredients and drugs that are critical to national security and the public health. Specifically, we ask that you include portions of our *Pharmaceutical Supply Chain Defense and Enhancement Act*¹ in the package.

The COVID-19 pandemic has exposed America's overreliance on foreign sources for medical products. The bipartisan United States-China Economic and Security Review Commission estimates, for example, that the U.S. imports roughly 80 percent of all active pharmaceutical ingredients (the raw chemical components of drugs) used in domestically-manufactured generic

¹ S. 4175 (116th Congress).

drugs.² Meanwhile, recent analysis of the Department of Defense medical supply chain revealed that many pharmaceuticals used to protect servicemembers from nuclear, biological, and chemical threats were sourced outside of the U.S., raising significant national security concerns.³ Finally, the pandemic has made it impossible to ignore how global disruptions to medical supply chains can leave our domestic market facing shortages.

Given the importance of securing our nation's supply chain, we were pleased to see that President Biden's American Rescue Plan called "for an additional \$10 billion investment in expanding domestic manufacturing for pandemic supplies."⁴ This plan echoes President Biden's past commitments to "close critical U.S. supply chain gaps" by "leverag[ing] federal buying power and the full range of government authorities, including the Defense Production Act, BARDA, and federal procurements, to make sure that we make critical products in America."⁵

Fortunately, we have already written legislation that would accomplish President Biden's goals. The *Pharmaceutical Supply Chain Defense and Enhancement Act* would, among other provisions, invest \$5 billion in the Biomedical Advanced Research and Development Authority (BARDA) for the development of active pharmaceutical ingredients and finished drugs by private and nonprofit entities headquartered in the United States. As a condition for receiving BARDA funding, contractors would be required to maintain a stockpile of active pharmaceutical ingredients (thus mitigating potential shortages) and agree to sell taxpayer-funded drugs at reasonable prices. The bill would then use the procurement power of the Department of Defense (DoD), Bureau of Prisons, Department of Veterans Affairs, and Department of Health and Human Services (HHS) to shore up, in the short term, demand for domestically produced products. HHS, working with the DoD, would help identify which drugs BARDA should prioritize in its contracts.

We believe that this legislation, which was developed with input from national security experts, supply chain analysts, and domestic drug manufacturers, should be used as the starting point for House and Senate negotiations on relief package provisions related to domestic drug manufacturing. Specifically, we believe that the upcoming COVID-19 package should provide, at a minimum, \$5 billion to BARDA for domestic drug and API contracts and additional funding for agencies to purchase domestic drugs. To the extent feasible under reconciliation rules, we believe that the package should also specify that BARDA should (1) prioritize funding the development of "critical" drugs identified by HHS and DoD and (2) include reasonable price requirements in its contracts.

² United States-China Economic and Security Review Commission, "2019 Annual Report to Congress, Chapter 3, Section 3: Growing U.S. Reliance on China's Biotech and Pharmaceutical Products," November 2019, <https://www.uscc.gov/sites/default/files/2019-11/Chapter%203%20Section%203%20-%20Growing%20U.S.%20Reliance%20on%20China%E2%80%99s%20Biotech%20and%20Pharmaceutical%20Products.pdf>.

³ Id.

⁴ The White House, "President Biden Announces American Rescue Plan," January 20, 2021, <https://www.whitehouse.gov/briefing-room/legislation/2021/01/20/president-biden-announces-american-rescue-plan/>.

⁵ Joe Biden, "THE BIDEN PLAN TO ENSURE THE FUTURE IS "MADE IN ALL OF AMERICA" BY ALL OF AMERICA'S WORKERS," <https://joebiden.com/made-in-america/>.

Please do not hesitate to reach out to us or our staff with any questions about the *Pharmaceutical Supply Chain Defense and Enhancement Act*. We look forward to working with you as negotiations continue.

Sincerely,

/s/ Elizabeth Warren
Elizabeth Warren
United States Senator

/s/ Tina Smith
Tina Smith
United States Senator