

Congress of the United States
Washington, DC 20515

July 23, 2021

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Becerra:

As you may know, in October 2018 the Strategic National Stockpile (SNS) joined the Office of the Assistant Secretary for Preparedness and Response (ASPR) at the Department of Health and Human Services. The expectation of this move was to create better purchasing capability and more supply chain influence over the entire medical response framework.

However, the COVID-19 pandemic and the growing over-reliance of supply products from China now necessitates a thorough review of the SNS and consideration of leveraging new technologies to help domestically source active pharmaceutical ingredients (APIs) for the SNS inventory. Currently, many medical drug manufacturers lack plans to assess and address vulnerabilities in their manufacturing supply chain, putting them, and American patients at risk for drug supply disruptions.

For more than a decade, China has been the largest producer¹ of APIs in the world. It is estimated that Chinese manufacturers make around 40 percent² of all APIs used worldwide and that China and India are the source of 75-80 percent of the APIs imported to the United States³. In 2019, before the COVID-19 pandemic, a representative of the Defense Health Agency argued⁴ that “the national security risks of increased Chinese dominance of the global API market cannot be overstated”. This concern was unfortunately realized in March last year when India’s Ministry of Commerce and Industry announced restrictions on the export of 13 APIs, including: paracetamol, tinidazole, vitamin B1, B6 and B12, as well as any formulations made from those APIs.

The centralization of the global supply for essential ingredients for drugs in China and India makes it vulnerable to interruption, whether by mistake or design. If disruptions occur for an essential ingredient made in China, the United States will wait in line with other countries around the world to obtain it. This places the American patient at great risk.

In our view, through the SNS, ASPR needs to support domestic manufacturing capabilities by giving preference to domestically sourced APIs for any pharmaceutical products purchased for the SNS. The good news is new technology now enables manufacturers to unlock domestic supply chains. For example, advances in synthetic biology, genomics, and fermentation now allow the 40 percent of plant-

¹ “Chinese Manufacturers vie for piece of outsourcing pie.” Nature Biotechnology, December 2007. <https://www.nature.com/articles/nbt1207-1337>

² “Medicines and Healthcare Products Regulatory Agency.” United Kingdom Public Health, 2017. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/609425/Item_10_2017-OB-05_International_Strategy.pdf

³ “Active Pharmaceutical Ingredients (API) Market growth, trends, COVID-19 and Forecasts (2021-2026).” Mordor Intelligence, 2020. <https://www.mordorintelligence.com/industry-reports/global-active-pharmaceutical-ingredients-api-market>

⁴ “Pentagon Sees Security Threat in China’s Drug-Supply Dominance.” Bloomberg, August 5, 2019. <https://www.bloomberg.com/news/articles/2019-08-05/pentagon-sees-security-threat-in-china-s-drug-supply-dominance?>

based APIs to be produced in laboratories in the United States. These new manufacturing technologies can enable robust and agile supply of essential medicines. By giving the SNS purchasing preference to domestically sourced APIs, we can accelerate this transition and ensure we have adequate supplies of essential medicines.

We request a briefing from HHS, including appropriate officials from SNS and ASPR, before September 30th, on steps that are being taken by HHS to prioritize the purchase of APIs from domestic sources for the SNS.

The coronavirus pandemic has shined a light on our country's societal and economic vulnerabilities. Vulnerabilities in the supply chain and domestic manufacturing continue to challenge our ability to prevent or respond to public health emergencies. We must address issues with the Strategic National Stockpile, enhance medical supply chain manufacturing domestically and improve our national security.

Sincerely,



Bill Posey
Member of Congress



David Trone
Member of Congress



Ann Kuster
Member of Congress



Tim Ryan
Member of Congress



Brian Fitzpatrick
Member of Congress