

United States Senate

WASHINGTON, DC 20510

September 2, 2020

The Honorable Donald J. Trump
President
The White House
1600 Pennsylvania Avenue N.W.
Washington, D.C. 20500

Dear President Trump:

We write today to request additional information regarding your August 6, 2020 Executive Order to “ensur[e] essential medicines, medical countermeasures, and critical inputs are made in the United States.”¹ The coronavirus disease 2019 (COVID-19) pandemic has exposed the United States’ overreliance on foreign nations for critical pharmaceutical products, and it is imperative that the nation address this problem. However, your Executive Order will not meaningfully address the nation’s overreliance on foreign nations for key drug products. We have introduced legislation, the *U.S. Pharmaceutical Supply Chain Defense and Enhancement Act* that requires comprehensive action to revamp domestic manufacturing of critical drugs and their key starting materials and address vulnerabilities in our nation’s supply chain.² We hope you will work together with Congress in a bipartisan way to pass this legislation and eliminate this public health and national security gap.

The United States is heavily reliant on imports of the essential medicines (and their ingredients) that millions of Americans use each and every day.³ Last year, a bipartisan congressional commission released a report highlighting this problem and detailing the potential national security and public health concerns it poses.⁴ The commission estimated that the United States imports 80 percent of the active pharmaceutical ingredients (APIs), the raw chemical

¹ The White House, “Ensuring Essential Medicines, Medical Countermeasures, And Critical Inputs Are Made In The United States,” August 6, 2020, <https://www.whitehouse.gov/presidential-actions/executive-order-ensuring-essential-medicines-medical-countermeasures-critical-inputs-made-united-states/>.

² Office of Senator Elizabeth Warren, Warren, Smith Introduce Legislation to Boost U.S. Pharmaceutical Manufacturing Capacity and End Over-Reliance on Foreign Countries for Critical Drugs,” Press Release, July 2, 2020, <https://www.warren.senate.gov/newsroom/press-releases/warren-smith-introduce-legislation-to-boost-us-pharmaceutical-manufacturing-capacity-and-end-over-reliance-on-foreign-countries-for-critical-drugs>

³ 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%20Pr oducts.pdf>.

⁴ *Id.*

components of drugs that are required to manufacture pharmaceutical products, used in domestic production of generic drugs and warned of the dangers of this overreliance.⁵

Robust global supply chains are critical to ensuring the availability of pharmaceutical products, but overreliance on imports of pharmaceutical products and a lack of domestic manufacturing capacity pose several risks to the nation. First, without sufficient domestic capacity, the U.S. is vulnerable to supply chain interruptions. Disruptions, either accidental or by design, could result in drug shortages. Experts have warned that if imports of medicines or key materials were to be interrupted, “U.S. hospitals and military hospitals and clinics would cease to function within months if not days.”⁶ Second, overreliance on foreign materials poses public health concerns. Lax regulatory requirements abroad have allowed some low-quality and unsafe products to enter circulation in the United States. As a result, a number of U.S. and global drug scandals, including the 2008 heparin contamination scandal, in which over 240 people died—have been linked to drugs developed overseas.⁷ Third, U.S. reliance on foreign pharmaceutical ingredients poses national security concerns, as medication “can be weaponized,” withheld, or “sold without any real medicine” if developed by an adversary.⁸ This is particularly true of the Department of Defense (DoD) and the Department of Veterans Affairs (VA), which purchase drugs in bulk for military and veteran hospitals. Today, nearly roughly 25% of DoD pharmaceutical ingredients used in military hospitals originate from China.⁹

On August 6, 2020, you issued Executive Order 13944, “Combating Public Health Emergencies and Strengthening National Security by Ensuring Essential Medicines, Medical Countermeasures, and Critical Inputs Are Made in the United States.”¹⁰ The purported goal of this order is to “reduce our dependence on foreign manufacturers,” and “ensure sufficient and reliable long-term domestic production of these products, to minimize potential shortages, and to mobilize our Nation’s Public Health Industrial Base to respond to these threats.”¹¹ The Executive Order directs several federal agencies to prioritize the procurement of essential medicines and critical inputs from domestic manufacturers and to take whatever steps are necessary to promote

⁵ *Id.*

⁶ Testimony of Rosemary Gibson before the U.S.-China Economic and Security Review Commission, “Exploring the Growing U.S. Reliance on China’s Biotech and Pharmaceutical Products” July 31, 2019, <https://www.uscc.gov/sites/default/files/2019-10/July%2031,%202019%20Hearing%20Transcript.pdf>.

⁷ 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%20Pr oducts.pdf>.

⁸ Testimony of Rosemary Gibson before the Senate Committee on Small Business and Entrepreneurship,” March 12, 2020, https://www.sbc.senate.gov/public/_cache/files/1/c/1c39a1bc-f22c-4178-951e-29b92dcb2182/3AD9C94FB267763A83913E2303A6A772.gibson-testimony.pdf

⁹ 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%20Pr oducts.pdf>.

¹⁰ The White House, “Ensuring Essential Medicines, Medical Countermeasures, And Critical Inputs Are Made In The United States,” August 6, 2020, <https://www.whitehouse.gov/presidential-actions/executive-order-ensuring-essential-medicines-medical-countermeasures-critical-inputs-made-united-states/>.

¹¹ *Id.*

the manufacturing of these products in the United States. But the measures you have proposed fail to meaningfully guide federal agencies to address our overreliance on foreign pharmaceutical products and manufacturers.

This Executive Order fails to establish or even recommend the development of comprehensive guidelines for the list of essential medicines and key inputs the Food and Drug Administration (FDA) and the Department of Health and Human Services (HHS) have been tasked with creating. Your direction that the medicine and inputs be “medically necessary to have available at all times” falls well short of the specificity required to make this important list beneficial to the American public and secure essential medicines.¹² Additionally, the further deregulation of FDA and Environmental Protection Agency (EPA) regulations raises concerns as both agencies are responsible for ensuring manufacturers are producing safe and effective materials, and are doing so responsibly.¹³

Addressing the risks to national security and public health that overreliance on foreign pharmaceutical products poses will require more than a vague and inadequate Executive Order. Our legislation, the *U.S. Pharmaceutical Supply Chain Defense and Enhancement Act*, would take a series of steps that your Executive Order fails to put in place.¹⁴ It requires the Biomedical Advanced Research and Development Authority to issue contracts to U.S.-based companies capable of developing pharmaceutical products domestically. With these contracts, companies would commit to establishing manufacturing facilities or producing drugs from a comprehensive and well-vetted list of necessary drugs both safely and responsibly. It would also authorize additional funds for agencies to procure domestically produced drugs and key starting materials, leveraging the federal government’s buying power to create a robust and sustainable market. Our legislation would also increase transparency in the pharmaceutical supply chain by closing reporting requirement loopholes and providing additional resources to federal agencies so that they may compile and make sense of this huge amount of critical data. This will allow the federal government to be better equipped to address future challenges.

Absent these meaningful actions, your Executive Order will not help address this legitimate national security and public health problem. We ask that you work with us and with other members of Congress on a bipartisan basis to pass legislation to help rectify the failures of your Executive Order and address the public health and national security risks posed by our overreliance on foreign drug producers.

In addition, in order to better understand the steps the Administration plans to take to end the country’s overreliance on foreign pharmaceutical products in light of this Executive Order, we request answers to the following questions no later than September 16, 2020.

¹² The White House, “Ensuring Essential Medicines, Medical Countermeasures, And Critical Inputs Are Made In The United States,” August 6, 2020, <https://www.whitehouse.gov/presidential-actions/executive-order-ensuring-essential-medicines-medical-countermeasures-critical-inputs-made-united-states/>.

¹³ *Id.*

¹⁴ Office of Senator Elizabeth Warren, Warren, Smith Introduce Legislation to Boost U.S. Pharmaceutical Manufacturing Capacity and End Over-Reliance on Foreign Countries for Critical Drugs,” Press Release, July 2, 2020, <https://www.warren.senate.gov/newsroom/press-releases/warren-smith-introduce-legislation-to-boost-us-pharmaceutical-manufacturing-capacity-and-end-over-reliance-on-foreign-countries-for-critical-drugs>

1. Section 3 (iv)(c) of Executive Order 13944 directs the Food and Drug Administration (FDA) to “identify a list of Essential Medicines, Medical Countermeasures, and their Critical Inputs that are medically necessary to have available at all times in an amount adequate to serve patient needs and in the appropriate dosage forms.” The medicines on this list will be prioritized by federal agencies for U.S.-based procurement.
 - a. What factors will FDA use to determine an essential medicine appropriate for this list?
 - b. How does the Administration define “adequate to serve patient needs”?
2. The Executive Order also tasks the Department of Defense with producing a “defense-specific” list of essential medicines and critical inputs.
 - a. What factors will the DoD use to determine an essential medicine appropriate for this list?
 - b. Will this list be classified for national security purposes? If not, why not?
3. Section 3 (iv) directs the Department of Health and Human Services (HHS) and FDA to “[review] FDA regulations to determine whether any of those regulations may be a barrier to domestic production of Essential Medicines, Medical Countermeasures, and Critical Inputs, and by advising the President whether such regulations should be repealed or amended.” How does the Administration plan to ensure the preservation of FDA regulations that ensure the quality and safety of these essential medicines, as well as that of other products?
4. Section 4 directs the Environmental Protection Agency to “take all appropriate action to identify relevant requirements and guidance documents that can be streamlined to provide for the development of Advanced Manufacturing facilities and the expeditious domestic production of Critical Inputs, including by accelerating siting and permitting approvals.”
 - a. Please explain why expediting environmental and public health reviews and limiting public input is necessary to achieve the goals of this Executive Order.
 - b. Under the *National Environmental Policy Act* (NEPA), for certain activities, federal agencies must hold public hearings and comment periods, conduct environmental studies, and circulate environmental impact statements or environmental assessments. By “accelerating siting and permitting approvals,” what environmental and public health reviews or public input periods does the Administration seek to waive or expedite? Why is waiving or expediting these input periods necessary to achieve the goals of this Executive Order?
 - c. In developing this Executive Order, did the Administration consider the potential harms to the health and wellbeing of the American people that could stem from waiving or expediting existing environmental regulations? If not, why not?
5. Section 6 directs each federal agency to submit a report to the President detailing, amongst other details, “the sources of [Essential Medicines, Medical Countermeasures, and Critical Inputs].” The difficulties of such a requirement are well known, as materials may be produced in one location, altered in another, and then used as a final input in a third location. How does the Administration plan to support agencies in this reporting

requirement, given the well-documented difficulties in compiling this information from overseas manufacturers?

6. Section 2 (f) lists a number of circumstances that may exempt an essential medicine or critical input from the requirements of the Executive Order, including if, “their application would be inconsistent with the public interest; the relevant Essential Medicines, Medical Countermeasures, and Critical Inputs are not produced in the United States in sufficient and reasonably available commercial quantities and of a satisfactory quality; or their application would cause the cost of the procurement to increase by more than 25 percent.”
 - a. Has the Administration conducted any cost analysis to determine the potential increase in cost of procurement for these materials, including the likelihood that the cost of procurement will increase by more than 25 percent for certain essential medicines?
 - b. Has the Administration consulted with federal agencies, private industry, or experts to determine the potential increased cost of procurement for these materials?
 - c. How does the Administration define “inconsistent with the public interest”?

7. How much additional funding will agencies named in this Executive Order need as they attempt to fulfill its requirements?

We appreciate your attention to this matter.

Sincerely,



Elizabeth Warren
United States Senator



Tina Smith
United States Senator