

United States Senate
WASHINGTON, DC 20510

December 9, 2021

Mr. Gregory Kausner
Performing the Duties of Under Secretary of Defense for Acquisition and Sustainment
1000 Defense Pentagon
Washington, D.C., 20301

Dear Mr. Kausner:

We write to you regarding the nation's overreliance on foreign nations for critical pharmaceutical products, and the resulting risks that these vulnerable supply chains pose to the Department of Defense (DoD or the Department), our servicemembers and our national security. DoD's medical and pharmaceutical supply chain has a unique set of concerns and vulnerabilities that, if left unaddressed, represent a serious risk to national security. As our nation continues to confront challenges to our supply chains, we urge you to prioritize the challenges to the Department and the national security risks posed by overreliance on pharmaceuticals produced abroad.

Today, millions of Americans, including servicemembers and their families, rely on pharmaceutical drugs that are produced abroad, either in part or wholly, to treat chronic and severe illnesses and remain healthy. Reports have shown that less than a third of the facilities that manufacture the active pharmaceutical ingredients (APIs) in prescription drugs consumed by Americans are in the U.S.¹ In a 2019 hearing before the U.S.-China Economic and Security Review Commission, a witness testified that the U.S. has virtually no domestic manufacturing capability to make generic antibiotics, a class of drugs commonly prescribed to active-duty servicemembers.² The remainder are located abroad – particularly in China. APIs are the components of pharmaceutical drugs that “furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease,” and are necessary to manufacture pharmaceutical products such as generic drugs and vaccinations.³ Yet, only 28 percent of facilities manufacturing APIs used in drugs and 47 percent of facilities manufacturing finished dosage forms of drugs for the U.S. market are located domestically.⁴

¹ U.S.-China Economic and Security Review Commission, “2019 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>.

² Written testimony of Rosemary Gibson to the U.S.-China Economic and Security Review Commission, July 31, 2019, <https://www.uscc.gov/sites/default/files/RosemaryGibsonTestimonyUSCCJuly152019.pdf>.

³ 21 CFR 314.3.

⁴ Testimony of Janet Woodcock, Director of the Center for Drug Evaluation and Research at the FDA before the House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, December 10, 2019, <https://www.fda.gov/news-events/congressional-testimony/securing-us-drug-supply-chain-oversight-fdas-foreign-inspection-program-12102019>.

The risk of this overreliance on foreign API manufacturing—particularly for China—are serious, and the coronavirus disease 2019 (COVID-19) pandemic brought many of these vulnerabilities to light. Shortages in crucial medical supplies such as syringes, ventilators, personal protective equipment, and pharmaceuticals hampered the nation’s response to the pandemic in the early months.⁵ Any interruption to the supply of APIs or other pharmaceuticals from foreign manufacturers, either accidental or by design, would have similarly devastating consequences.

Numerous witnesses have appeared before Congress to warn of the potential consequences for DoD and national security in the event of disruption to the pharmaceutical supply chain. One expert, testified:

Medicines can be used as a weapon of war against the United States. In the hands of an adversary, they can be weaponized. Supplies can be withheld. Medicines can be made with lethal contaminants or sold without any real medicine in them, rendering them ineffective. These products can be distributed to specific targets. Detection is time-consuming at best, and virtually impossible at worst. The thousands of men and women on U.S. aircraft carriers in the South China Sea are dependent on the adversary for many of their essential medicines. Combat readiness and force protection are at risk with the military vulnerable to disruptions in supply and contaminated and toxic medicines.⁶

These concerns were corroborated by a recent DoD Office of the Inspector General’s report reviewing the federal government’s efforts to mitigate overreliance on foreign suppliers in the Department’s pharmaceutical supply chain.⁷ The report concluded that “DoD is dependent on the increasingly foreign sources used by the U.S. commercial pharmaceutical market,” due to a decline in domestic manufacturing capabilities for such materials. It warned that, “[a] disruption of the supply of foreign-made APIs to domestic manufacturers could cause a drug shortage that affects every level of the U.S. health care system,” and that, “these potential drug shortages could ultimately compromise the standard of care for Service members and DoD beneficiaries.”⁸ It also found that “the [Defense Logistics Agency] and the [Defense Health Agency] did not proactively assess and mitigate the risks of potential pharmaceutical supply chain disruptions.”⁹ This alarming report highlights a potentially dire situation facing the nation and DoD in particular. Mitigating the risks of disruption would represent a defensive capability that would significantly lower the national security and public health risks.

In your role as performing the duties of Acting Under Secretary of Defense for Acquisition and Sustainment, you are responsible for overseeing all matters relating to the procurement of goods for the Department and supply chain risk management, including that of APIs and other

⁵ Reuters, “COVID creates shortages of an array of U.S. medical supplies,” Timothy Aepfel, September 20, 2021, <https://www.reuters.com/world/the-great-reboot/covid-creates-shortages-an-array-us-medical-supplies-2021-09-20/>.

⁶Written testimony of Rosemary Gibson to the U.S.-China Economic and Security Review Commission, July 31, 2019, <https://www.uscc.gov/sites/default/files/RosemaryGibsonTestimonyUSCCJuly152019.pdf>.

⁷ U.S. Department of Defense, Office of the Inspector General, “Evaluation of the Department of Defense’s Mitigation of Foreign Suppliers in the Pharmaceutical Supply Chain,” September 20, 2021, https://media.defense.gov/2021/Sep/22/2002859154/-1/-1/1/DODIG-2021-126_REDACTED.PDF.

⁸ *Id.*


⁹ *Id.*

pharmaceutical products.¹⁰ While the Biden Administration issued a 100 Day Review on America’s supply chains on June 8, 2021, the review lacked any analysis of the specific and unique risk of pharmaceutical supply chain interruption to DoD, its servicemembers, and national security.¹¹ The Department must consider pharmaceuticals in its work to shore up vulnerable supply chains important to national security just as it does for semiconductors, microelectronics, and rare earth minerals. We urge you to focus on this important and consequential aspect of supply chain risk management.

Earlier this year, we reintroduced the bipartisan *U.S. Pharmaceutical Supply Chain Review Act* – legislation that takes much-needed steps to better oversee the nation’s pharmaceutical supply chain.¹² This legislation followed the publication of the U.S.-China Economic and Security Review Commission’s 2019 Annual Report that highlighted the nation’s “growing reliance” on products critical to the manufacturing of drugs, which are primarily made in China – a concern they reiterated in the following year’s report.¹³ This legislation would help address the national security risks of DoD’s pharmaceutical supply chain vulnerabilities and shed light on the nation’s overreliance on foreign countries for critical drugs used by millions of Americans. We have also introduced the *Strengthening Supply Chains for Servicemembers and Security Act* to require DoD to implement recommendations from the September 2021 DoD Office of the Inspector General report to protect its supply chains of pharmaceutical products.¹⁴ We urge you to consider them in your work addressing challenges to DoD’s supply chain.

We appreciate your attention to this matter.

Sincerely,



Elizabeth Warren
United States Senator



Marco Rubio
United States Senator

¹⁰ Department of Defense, “DOD DIRECTIVE 5135.02,” July 15, 2021, <https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodd/513502p.pdf?ver=2020-07-15-133537-053>

¹¹ The White House, “Building Resilient Supply Chains, Revitalizing American Manufacturing, And Fostering Broad-Based Growth,” June 2021, <https://www.whitehouse.gov/wp-content/uploads/2021/06/100-day-supply-chain-review-report.pdf>.

¹² Office of Senator Elizabeth Warren, “Warren, Rubio Reintroduce Bill to Assess Effects of America’s Overreliance on Foreign Countries in Pharmaceutical Supply Chain,” press release, April 22, 2021, <https://www.warren.senate.gov/newsroom/press-releases/warren-rubio-reintroduce-bill-to-assess-effects-of-americas-overreliance-on-foreign-countries-in-pharmaceutical-supply-chain>.

¹³ U.S.-China Economic and Security Review Commission, “2019 Report to Congress,” November 2019, <https://www.uscc.gov/sites/default/files/2019-11/2019%20Annual%20Report%20to%20Congress.pdf>; U.S.-China Economic and Security Review Commission, “2020 Report to Congress,” December 2020, [https://www.uscc.gov/sites/default/files/2020-12/2020 Annual Report to Congress.pdf](https://www.uscc.gov/sites/default/files/2020-12/2020%20Annual%20Report%20to%20Congress.pdf).

¹⁴ Office of Senator Marco Rubio, “Rubio, Warren Introduce Bill to Address U.S. Overreliance on Foreign Pharmaceuticals,” press release, November 4, 2021, <https://www.rubio.senate.gov/public/index.cfm/2021/11/rubio-warren-introduce-bill-to-address-u-s-overreliance-on-foreign-pharmaceuticals>; U.S. Department of Defense, Office of the Inspector General, “Evaluation of the Department of Defense’s Mitigation of Foreign Suppliers in the Pharmaceutical Supply Chain,” September 20, 2021, https://media.defense.gov/2021/Sep/22/2002859154/-1/-1/1/DODIG-2021-126_REDACTED.PDF.