

United States Senate

WASHINGTON, DC 20510

December 5, 2019

The Honorable Mark T. Esper
Secretary of Defense
United States Department of Defense
1000 Defense Pentagon
Washington, D.C., 20301

Dear Secretary Esper:

We write to request information regarding the national security risks posed by the role of foreign manufacturing in the pharmaceutical products supply chain. Millions of Americans, including servicemembers, rely on drugs to stay healthy—yet the United States imports a significant portion of these drugs' components from China.¹

In light of a recent report from the U.S.-China Economic and Security Review Commission (Commission) highlighting the nation's "growing reliance" on drug products made in China, it is critical that DoD, along with other key federal agencies, address the dangers posed by U.S. reliance on foreign drug makers.²

Last week, the Commission released a report highlighting the United States' growing reliance on Chinese-manufactured pharmaceuticals and China's role as a global "active pharmaceutical ingredient" producer.³ Active pharmaceutical ingredients (APIs) are the raw chemical components of drugs that "furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease."⁴ APIs are requisite to manufacture pharmaceutical products, including generic drugs and vaccinations. Despite the critical role of APIs in drug production an estimated 80 percent of APIs used in domestic pharmaceutical production originate in foreign nations—predominantly China.⁵

The Chinese government makes significant investments in its pharmaceuticals production and systematically undercuts market prices, forcing U.S., European, and Indian producers out of

¹ "U.S. Dependence on Pharmaceutical Products from China," The Council on Foreign Relations, Yanzhong Huang, August 14, 2019, <https://www.cfr.org/blog/us-dependence-pharmaceutical-products-china>; 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>

² U.S.-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>

³ *Ibid.*

⁴ World Health Organization, "Definition of Active Pharmaceutical Ingredients," July 2011, https://www.who.int/medicines/areas/quality_safety/quality_assurance/DefinitionAPI-QAS11-426Rev1-08082011.pdf

⁵ Politico, "China commission to ring the alarm on pharma imports," Doug Palmer, October 25, 2019, <https://www.politico.com/newsletters/morning-trade/2019/10/25/trumka-whats-the-rush-with-usmca-781528>

business.⁶ As a result, China is now the world's leading producer of APIs and accounts for more than 20 percent of total global output.⁷ More concerning, the U.S. relies on imports of general antibiotics from China – including penicillin, the most basic component of antibiotics – for diseases and infections across the spectrum.⁸ Hundreds of drugs Americans rely on to treat high blood pressure or heart or kidney conditions use APIs from China.⁹ Many Chinese-made APIs can be found in generic drugs, which account for 89 percent of U.S. prescriptions.¹⁰ Globally, the data is also alarming as India is fully dependent on APIs imported from China.¹¹

DoD is responsible for procuring pharmaceuticals and medical products used in military hospitals, which are required to be manufactured in countries that have signed on to the Trade Agreements Act of 1979 (TAA). China is not a signatory; however, the U.S. Defense Logistics Agency cites 25 percent of pharmaceutical ingredients in military hospitals are of Chinese origin, so China has effectively bypassed this requirement.¹²

DoD provides servicemembers and their families with drugs that can contain ingredients from China – the same drugs that have caused several public health crises in the United States and across the world. In 2018, the FDA found N-Nitrosodimethylamine, a known carcinogen, in the popular blood pressure medicine valsartan.¹³ The contaminant was traced back to one of China's largest pharmaceutical ingredient manufacturers, *after* the drug was sold to millions of people in twenty-three countries, including to U.S. servicemembers and their families.¹⁴ DoD was forced to recall the medicine without an adequate replacement after warning 31,000 military families they may have taken the contaminated drug.¹⁵ Furthermore, pharmaceuticals used by DoD to

⁶ New York Times, "Concerns grow in the U.S. over drugs made abroad," Gardiner Harris, January 20, 2009, <https://www.nytimes.com/2009/01/20/business/worldbusiness/20iht-drug.1.19514627.html>; 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>

⁷ World Health Organization, "China policies to promote local production of pharmaceutical products and protect public health," May 2017, <https://www.who.int/phi/publications/2081China020517.pdf>

⁸ Rosemary Gibson to the U.S.-China Economic and Security Review Commission, July 31, 2019, <https://www.uscc.gov/sites/default/files/RosemaryGibsonTestimonyUSCCJuly152019.pdf>

⁹ *Id.*

¹⁰ Stat News, "China has become the pharmacy to the world – and a national security risk for the U.S.," Ed Silverman, November 5, 2019, <https://www.statnews.com/pharmalot/2019/11/05/china-security-risk-gibson/>

¹¹ 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>

¹² "TAA Designated Countries," General Services Administration, <https://gsa.federalchedules.com/resources/taa-designated-countries/>; U.S.-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%20Prducts.pdf>

¹³ Bloomberg, "Pentagon Sees Security Threat in China's Drug-Supply Dominance," Anna Edney, August 5, 2019 <https://www.bloomberg.com/news/articles/2019-08-05/pentagon-sees-security-threat-in-china-s-drug-supply-dominance>

¹⁴ CNN, "FDA joins 22 countries' recall of common heart drug," Jen Christensen, July 16, 2018, <https://www.cnn.com/2018/07/13/health/valsartan-recall-fda-bn/index.html>; Military Health System, "Voluntary drug recall alert: Valsartan," September 14, 2018, <https://health.mil/News/Articles/2018/09/14/Voluntary-Drug-Recall-Alert-Valsartan>

¹⁵ Written testimony of Rosemary Gibson to the Health Subcommittee of the House Energy and Commerce Committee, October 30, 2019,

protect servicemembers from nuclear, biological and chemical threats are also sourced in China.¹⁶ An interruption in the supply of these products during an attack, either domestic or abroad, could have devastating consequences.

Specifically, overreliance on Chinese API exports raises the possibility that China could terminate or raise the cost of prescription drugs millions of Americans, including servicemembers, rely on every day in the event of escalating geopolitical tensions. This national security threat cannot be overstated. Should China seek to weaponize pharmaceuticals, by restricting exports to the United States, incorporating lethal ingredients in final products, or any other means, our domestic pharmaceutical industry is not prepared to handle mass shortages for domestic or military uses. Any interruption in the delivery of APIs or medicine would impact military readiness.

One expert summarized the concerns in testimony before Congress last month:

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.¹⁷

In addition to the national security concerns, there is evidence disputing the reliability of Chinese pharmaceutical products. More than 32 percent of FDA-inspected Chinese drug plants committed some sort of violation of agency standards, ranging from unprotected computer systems to outright fraud and data falsification.¹⁸ Yet, FDA reportedly lacks the resources for quality surveillance or to review data that may provide insights into product quality.¹⁹ Furthermore, FDA does not conduct tests to verify the contents or quality of imported drugs—though the one pharmacy evaluating drug efficacy found approximately 10 percent of tested products did not meet FDA’s standards.²⁰ Overall, there is a concerning lack of information surrounding the United States’ importation of APIs and critical drugs. With such gaps in

https://energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/documents/Testimony-Wessel-API_103019.pdf

¹⁶ Written testimony of Christopher Priest to the U.S.-China Economic and Security Review Commission, July 31, 2019, <https://www.uscc.gov/sites/default/files/Priest%20US-China%20Commission%20Statement.pdf>

¹⁷ Written testimony of Rosemary Gibson to the Health Subcommittee of the House Energy and Commerce Committee, October 30, 2019,

https://energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/documents/Testimony-Gibson-API_103019.pdf

¹⁸ U.S. Food and Drug Administration Office of Pharmaceutical Quality, “FDA Pharmaceutical Quality Oversight white paper,” 2015,

<https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/UCM442666.pdf>.

¹⁹ *Id.*

²⁰ Valisure, “Bad Batches,” <https://www.valisure.com/how-it-works/>

knowledge and understanding of our own supply chain, it is impossible to know the true extent of the problem and the risk posed to the United States.

DoD has already been called on to examine its procurement systems to ensure adequate domestic capacity, because reliance on a geopolitical rival for critical drugs presents a clear risk to our national security, even more so in a period of heightened tensions. It is essential the United States develop strategies to avoid over- or sole-reliance on China for its critical drugs and drug ingredients.

In order to better understand the potential national security risks posed by reliance on Chinese pharmaceutical products and DoD's role in addressing these risks, we respectfully request a staff level briefing and answers to the following questions no later than December 20, 2019.

1. Has DoD identified a list of drugs, APIs, or other pharmaceutical products that are needed to address readiness or national security risks and are vulnerable to foreign interference or interruption?
2. Has DoD conducted any assessment of DoD's and/or the United States' vulnerability to foreign interference or interruption in its drug supply line, and the potential readiness or national security threats from such actions? Has DoD consulted with FDA or any other agencies to assess the impact of this potential interference or interruption?
3. DoD relies on private entities—including via its prime vendor program—to streamline acquisition of various items, such as completed drugs, medical/surgical products, or pharmaceuticals. How does DoD determine which companies and vendors to rely on to procure drugs, APIs, and pharmaceutical products for use by servicemembers?
Specifically:
 - a. How does DoD decide which vendors to award these contracts to?
 - b. Does DoD perform any evaluations of the quality of the products they expect to receive from these prime vendors in advance of awarding a contract?
 - c. Does DoD perform any periodic evaluations of its prime vendors after the contract has been awarded, including an evaluation of whether these vendors procure drugs, APIs, and pharmaceutical products developed by Chinese manufacturers?
4. What actions, if any, has DoD taken to address any readiness or national security threats from dependence upon Chinese or other foreign manufacturers of drugs, APIs, or other pharmaceutical products?
5. What additional statutory authorities, if any, would be necessary to better enable DoD to procure drugs that meet FDA's quality standards and are not at risk of foreign interference, tampering, or interruption?

We appreciate your attention to this matter.

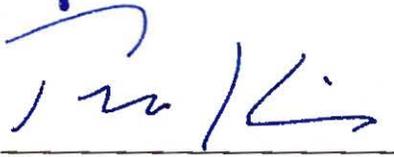
Sincerely,



Elizabeth Warren
United States Senator



Tom Cotton
United States Senator



Tim Kaine
United States Senator



Mitt Romney
United States Senator