

# United States Senate

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COMMITTEES:  
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RULES AND ADMINISTRATION

March 10, 2020

Secretary Alex Azar  
U.S. Department of Health and Human Services  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

Dear Secretary Azar:

As the novel coronavirus (COVID-19) continues to spread globally, I write to convey my significant alarm over American overreliance on Chinese – and foreign-manufactured pharmaceutical products and medical supplies and the consequent dangerous impacts – both for the health and well-being of Americans and for U.S. national security. I ask the Department of Health and Human Services to monitor the potential impact of this overreliance, and develop a strategy to ensure Americans have access to these medical products in the short-term while determining a longer-term plan to reduce U.S. reliance on foreign supply chains for these products.

As you are well aware, the COVID-19 was first detected in Wuhan, China and has now spread to more than 104 countries. There have been more than 109,000 cases confirmed and more than 3,800 deaths. For some time, experts both in and outside of the government have expressed serious concerns about the United States outsourcing medical products to foreign companies and the vulnerabilities resulting from this dependence. The outbreak of COVID-19 has put in stark relief the health, economic, and strategic risks of the current approach.

For millions of Americans, access to their drug supply can mean life or death. Yet increasingly, the United States produces very few of these products domestically. For example, the active ingredients for medicines treating breast and lung cancers and the antibiotic Vancomycin are made almost exclusively in China.<sup>1</sup> China is also the largest supplier of medical devices, such as MRI equipment, surgical gowns and other equipment that measures oxygen levels in the blood.<sup>2</sup>

During her October 30, 2019 testimony before the House Committee on Energy and Commerce, the Director of the Center for Drug Evaluation and Research, Janet Woodcock, asserted that the U.S. reliance on Chinese and other foreign sources of active pharmaceutical ingredients (APIs) was only growing. She described a set of startling statistics— while the United States has become a world leader in drug discovery and development over the past decade, it is no longer in the forefront of drug manufacturing. In particular, manufacturers of APIs, including statins and

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<sup>1</sup> <https://theconversation.com/the-silent-threat-of-the-coronavirus-americas-dependence-on-chinese-pharmaceuticals-130670>

<sup>2</sup> <https://theconversation.com/the-silent-threat-of-the-coronavirus-americas-dependence-on-chinese-pharmaceuticals-130670>

penicillin are increasingly foreign-made– with only 28 percent of the manufacturing facilities making APIs for the U.S. market in the United States; thirteen percent of these manufacturers are located in China.<sup>3</sup> The U.S. pharmaceutical sector relies on China for components, materials, and finished products.<sup>4</sup> In fact, three World Health Organization (WHO) “Essential Medicines” have API manufacturers that are based only in China.<sup>5</sup> For drugs used to combat biological threats, China has 37 API manufacturing facilities, while the U.S. has 19, compared to 117 facilities in the rest of the world.<sup>6</sup>

As the outbreak for COVID-19 has occurred, the risks of our dependence are growing. Our reliance on Chinese and other foreign API manufacturing facilities during this crisis is already beginning to compromise the U.S. drug supply, creating drug shortages and manufacturing quality problems. Some countries have increased restrictions on the export of their pharmaceuticals to the United States and other countries as they work to protect their own populations. For example, India recently decided to place restrictions on exporting Tylenol and the common antibiotic metronidazole to ensure Indian citizens have the pharmaceuticals they need.<sup>7</sup>

The nation’s dependence on foreign countries for medical products points to a much larger challenge that the United States must be prepared to address: China’s growing dominance in the health sector, including the biotechnology and pharmaceutical industries, and its collection of vast amounts of biomedical and other data, with potential long-term privacy risks for Americans.

It is essential that the United States develop strategies to reduce U.S. reliance on China and other countries for drugs critical to American patients. I appreciate your willingness to work with Congress to further strengthen our response capabilities and emergency preparedness. I respectfully request a briefing [and a written response] with answers to the following questions no later than March 23, 2020.

1. What actions has HHS taken to address the dependence on Chinese or other foreign manufacturers of drugs, APIs, or other pharmaceutical products and medical supplies and equipment since the outbreak of the COVID-19?
2. What is your strategy to ensure that Americans get the pharmaceuticals they need if significant shortages occur?
3. As the coronavirus continues to spread, what actions has HHS taken to ensure that patients can still access the drugs they need without access to drug components manufactured overseas?
4. What is your analysis of what drugs or ingredients cannot be made without supplies from China and other foreign countries?

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<sup>3</sup> <https://www.fda.gov/news-events/congressional-testimony/safeguarding-pharmaceutical-supply-chains-global-economy-10302019>

<sup>4</sup> <https://www.bis.doc.gov/index.php/documents/other-areas/642-department-of-homeland-security-dhs-assessment-impact-of-foreign-sourcing-on-health-related-infra/file>

<sup>5</sup> <https://www.fda.gov/news-events/congressional-testimony/safeguarding-pharmaceutical-supply-chains-global-economy-10302019>

<sup>6</sup> <https://www.fda.gov/news-events/congressional-testimony/safeguarding-pharmaceutical-supply-chains-global-economy-10302019>

<sup>7</sup> <https://www.nytimes.com/2020/03/03/business/coronavirus-india-drugs.html>

5. What is your plan to ensure that medical facilities, medical personnel and first responders have a reserve of necessary medical supplies and equipment as they continue to be on the front lines of efforts to prevent the spread of COVID-19?
6. Congress recently passed the Coronavirus Preparedness and Response Supplemental Appropriations Act, which includes more than \$2 billion for the Biomedical Advanced Research and Development Authority (BARDA) to invest in platform-based technologies with U.S.-based manufacturing for vaccines and therapeutics. How will HHS ensure these funds effectively reduce our short- and long-term reliance on foreign manufacturers of drugs, APIs, or other pharmaceutical products and medical supplies and equipment?

I appreciate your immediate attention to this matter. I look forward to working together on this critical issue moving forward.

Sincerely,

A handwritten signature in blue ink that reads "Mark R. Warner". The signature is written in a cursive style and is positioned above a horizontal line.

Mark R. Warner  
United States Senator

CC: Commissioner Stephen Hahn