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United States Senate

COMMITTEE ON
HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS

WASHINGTON, DC 20510-6250

February 27, 2020

GABRIELLE D'ADAMO SINGER, STAFF DIRECTOR
DAVID M. WEINBERG, MINORITY STAFF DIRECTOR

The Honorable Alex M. Azar II
Secretary
United States Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

The Honorable Chad F. Wolf
Acting Secretary
United States Department of Homeland Security
246 Murray Lane, S.W.
Washington, D.C. 20528

Dear Secretary Azar and Acting Secretary Wolf:

In our February 12th committee roundtable regarding the Coronavirus (COVID-19), some of the most disconcerting revelations involved the insecurity of our medical supply chain. Witnesses indicated that if the COVID-19 continues to spread, the United States medical supply chain will likely experience shortages of critical drugs and personal protective equipment (PPE).¹

According to previous studies, approximately 72 percent of the United States active pharmaceutical ingredient (API) supply relies on manufacturing outside the United States, with China accounting for 13 percent of that capacity.² This could strain supply during a Public Health Event of International Concern (PHEIC), a designation the World Health Organization gave to COVID-19 earlier this year.³ Additionally, it is critical that medical personnel have access to PPE when responding to an infectious respiratory disease outbreak. Experts estimate the United States would need 1.7 to 3.5 billion N95 respirators in a pandemic influenza response, but the United States produces only 1.5 billion respirators annually, a gap that could worsen a

¹ Homeland Security and Governmental Affairs Committee, *Roundtable on Are We Prepared? Protecting the U.S. from Global Pandemics*, 116th Cong. (Feb. 12, 2020); *Drugmakers braced for coronavirus disruption to China supplies*, Financial Times (Feb. 12, 2020).

² Janet Woodcock, M.D., Director – Center for Drug Evaluations and Research, U.S. Food & Drug Administration, Testimony before U.S. House of Representatives, Committee on Energy and Commerce, Subcommittee on Health (October 30, 2019), <https://www.fda.gov/news-events/congressional-testimony/safeguarding-pharmaceutical-supply-chains-global-economy-10302019>

³ *World Health Organization declares coronavirus a public health emergency of international concern*, CNN (January 30, 2020), <https://www.cnn.com/2020/01/30/health/coronavirus-who-public-health-emergency-international-concern-declaration/index.html>, Janet Woodcock, M.D., Director – Center for Drug Evaluations and Research, U.S. Food & Drug Administration, Testimony before U.S. House of Representatives, Committee on Energy and Commerce, Subcommittee on Health (October 30, 2019), <https://www.fda.gov/news-events/congressional-testimony/safeguarding-pharmaceutical-supply-chains-global-economy-10302019>.

potential shortage of necessary equipment.⁴ At a recent all member Senate briefing, Dr. Robert Kadlec, Assistant Secretary for Preparedness and Response at the United States Department of Health and Human Services (HHS), stated that the United States strategic stockpile of PPE should hold 300 million N95 respirators units, but is currently at only 10% of that level — 30 million units.⁵

In the short term, we are writing to obtain information regarding your Departments' assessments and planned actions designed to mitigate current and potential shortages of drugs and medical equipment that might be essential if COVID-19 becomes a significant problem in the United States.

To assess the health and safety implications of our nation's medical supply chain vulnerabilities in the event of a significant outbreak of COVID-19 in the United States, as well as the adequacy of the Departments' planned responses, we respectfully request that you provide the following information:

1. What specific vulnerabilities have you identified in the supply of APIs, finished drug products, and medical equipment, including PPE?
2. What actions have you taken, or plan to take, to address potential shortages?
3. What are the current versus scheduled inventory levels of drugs and medical supplies in the Strategic National Stockpile?
4. Availability of accurate COVID-19 testing kits will be crucial in mitigating a significant outbreak. What is the current best-case scenario for approval, and deployment of, a sufficient number of test kits?
5. What actions is the United States Department of Homeland Security (DHS) taking to secure land ports of entry against the spread of COVID-19?
6. What protective measures is DHS using to ensure that its workforce is protected from contracting COVID-19? Does DHS have access to sufficient numbers of PPE?
7. Please describe how the Federal Emergency Management Agency is preparing should COVID-19 become a pandemic in the United States.
8. Please describe the process used by DHS and HHS to collect and share information regarding passengers returning to the United States who you believe may be at risk of

⁴ National Center for Biotechnology Information, Personal Protective Equipment Supply Chain: Lessons Learned from Recent Public Health Emergency Responses (June 1, 2017), <https://www.ncbi.nlm.nih.gov/pubmed/28636443>.

⁵ Jenni Fink, *America Has 30 Million Masks, Needs 300 Million For Health Care Workers Fighting Coronavirus*, *HHS Secretary Says*, *Newsweek* (Feb. 25, 2020), <https://www.newsweek.com/alex-azar-coronavirus-masks-30-million-have-need-30-million-fight-america-senate-committee-1489058>

contracting COVID-19. How is that information used to identify and notify affected travelers?

We would appreciate your response to these questions as soon as possible, but no later than 5:00 pm on March 04, 2020. When you have the time after taking the necessary actions to address the current situation and have determined the COVID-19 outbreak has stabilized, we want to work with your Departments to assess what lessons have been learned and vulnerabilities have been exposed in order to be better prepared in the future.

Please note, the Committee on Homeland Security and Governmental Affairs is authorized by Rule XXV of the Standing Rules of the Senate to investigate “the efficiency, economy, and effectiveness of all agencies and departments of the Government.”⁶ Additionally, S. Res. 70 (116th Congress) authorizes the Committee to examine “the efficiency and economy of all branches of the Government including the possible existence of fraud, misfeasance, collusion, mismanagement, incompetence, corruption, or unethical practices”⁷

Sincerely,



Ron Johnson
Chairman



Gary C. Peters
Ranking Member

⁶ S. Rule XXV; *see also* S. Res. 445, 108th Cong. (2004).

⁷ S. Res. 70, 116th Cong. § 12(e)(1)(A) (2019).