

Congress of the United States
Washington, DC 20510

May 6, 2020

The Honorable Mike Pence
Vice President
White House
1600 Pennsylvania Avenue, NW
Washington DC 20500

The Honorable Mark T. Esper
Secretary
U.S. Department of Defense
1400 Defense Boulevard
Washington, DC 20301

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

Dear Vice President Pence, Secretary Azar, and Secretary Esper:

We write to you today to request information on the federal government’s capacity to develop and manufacture therapeutics and vaccines to combat the coronavirus disease 2019 (COVID-19) pandemic.

Starting in 2012, the Department of Health and Human Services (HHS) “established three new centers to develop and manufacture medical countermeasures, such as vaccines and medicines” in the event of infectious disease outbreaks or bioterrorist attacks.¹ The Centers for Innovation in Advanced Development and Manufacturing (CIADM) were intended to provide the United States with an infrastructure of “flexible, nimble, and modern vaccine manufacturing” capabilities—“the first major domestic infrastructure” of its kind. These centers operated in a public-private partnership model, “bringing together the innovative ideas of small biotech firms, the training expertise of academic institutions, and the development and manufacturing experience of large pharmaceutical companies.”²

To date, HHS and the Department of Defense have invested nearly \$670 million in four CIADM facilities,³ and have utilized these facilities in the nation’s Ebola and Zika outbreaks response.⁴

¹ Department of Health and Human Services, “HHS creates new centers to develop, manufacture medical countermeasures,” June 18, 2012, <https://wayback.archive-it.org/3926/20150121155406/http://www.hhs.gov/news/press/2012pres/06/20120618a.html>.

² *Id.*

³ Washington Post, “Federal vaccine development sites ill-suited to counter covid-19 epidemic,” David Willman, March 15, 2020, https://www.washingtonpost.com/investigations/federal-vaccine-development-sites-ill-suited-to-counter-covid-19-epidemic/2020/03/15/34e8586c-63c4-11ea-acca-80c22bbee96f_story.html.

⁴ U.S. Department of Health and Human Services, “National Health Security Strategy 2019-2022,” https://www.medicalcountermeasures.gov/media/37041/2019_ns.pdf.

This public manufacturing capacity could be critical in combatting COVID-19. However, according to reporting from *The Washington Post*, “none of the sites – in Florida, Maryland, North Carolina and Texas – have developed or are close to delivering medicines to counter the [COVID-19] outbreak.”⁵ Two of these sites are expected “to conduct small-scale testing of potential coronavirus vaccines,” while the other two sites are not expected to take a role at all in fighting COVID-19.⁶ Instead, without federal government manufacturing support, HHS’s solicitation proposals for the development of COVID-19 medical products have emphasized that the agency is “particularly interested” in products and technologies that already “have established domestic large-scale commercial...manufacturing capability.”⁷

Reportedly, in 2018, HHS Assistant Secretary for Preparedness and Response Robert Kadlec instructed a team of HHS and Pentagon officials to conduct a review of the CIADM sites. According to the review, “operational capability has not been adequately developed” and would need to be improved in order “to meet biodefense MCM [medical countermeasures] mission requirements.”⁸ Assistant Secretary Kadlec initiated another review by nonprofit Mitre Corporation, which reportedly found “similar deficiencies.”⁹

These reports, if true, represent the short sightedness and unwillingness to invest in the public alongside the private sector that has hamstrung the federal government’s public response to the COVID-19 pandemic. Now, the Administration is reportedly in the process of organizing a public-private partnership between pharmaceutical companies, executive agencies and the military called “Operation Warp Speed.” The project intends to speed the nation’s development of a COVID-19 vaccine with the goal of producing 300 million doses by next January 2021.¹⁰ The Administration appears to be relying on private sector actors to deliver on this promise.¹¹

We have proposed legislation, the *COVID–19 Emergency Manufacturing Act of 2020*, which would give the federal government authority to immediately manufacture and enter into contracts to manufacture various pharmaceutical drugs, medical devices, and other COVID-19 products to ensure that we can adequately meet the demands of the moment.¹²

⁵ Washington Post, “Federal vaccine development sites ill-suited to counter covid-19 epidemic,” David Willman, March 15, 2020, https://www.washingtonpost.com/investigations/federal-vaccine-development-sites-ill-suited-to-counter-covid-19-epidemic/2020/03/15/34e8586c-63c4-11ea-acc8-80c22bbee96f_story.html.

⁶ *Id.*

⁷ U.S. Department of Health and Human Services, “HHS Solicits Proposals for Development of Medical Products for Novel Coronavirus,” March 6, 2020, <https://www.hhs.gov/about/news/2020/03/06/hhs-solicits-proposals-for-development-of-medical-products-for-novel-coronavirus.html>.

⁸ Washington Post, “Federal vaccine development sites ill-suited to counter covid-19 epidemic,” David Willman, March 15, 2020, https://www.washingtonpost.com/investigations/federal-vaccine-development-sites-ill-suited-to-counter-covid-19-epidemic/2020/03/15/34e8586c-63c4-11ea-acc8-80c22bbee96f_story.html.

⁹ *Id.*

¹⁰ Bloomberg, “Trump’s ‘Operation Warp Speed’ Aims to Rush Coronavirus Vaccine,” Jennifer Jacobs and Drew Armstrong, April 29, 2020, <https://www.bloomberg.com/news/articles/2020-04-29/trump-s-operation-warp-speed-aims-to-rush-coronavirus-vaccine>.

¹¹ *Id.*

¹² “Warren, Schakowsky to Introduce Legislation to Publicly Manufacture Personal Protective Equipment, Prescription Drugs, Other Medical Supplies,” Press Release, April 30, 2020, <https://www.warren.senate.gov/newsroom/press-releases/warren-schakowsky-to-introduce-legislation-to-publicly-manufacture-personal-protective-equipment-prescription-drugs-other-medical-supplies>.

We intend to keep working to make that plan law. In the interim, however, the federal government should work expeditiously to coordinate its domestic manufacturing efforts for COVID-19 medical products. In order to better understand the status of CIADM facilities and other federal government manufacturing efforts, we request answers to the following questions by no later than May 20, 2020:

1. According to HHS's National Health Security Strategy 2019-2022, the United States increased "pre-pandemic vaccine antigen manufacturing capacity from 60 million doses to 600 million doses" after the 2009 H1N1 pandemic.¹³ Please provide a list of federal government facilities currently manufacturing products for COVID-19. What is the current output and maximum capacity of each of these facilities to manufacture medical countermeasure products, including each of the following:
 - a. Vaccines, including RNA vaccines, DNA vaccines, recombinant protein vaccines, viral vector-based vaccines, live attenuated vaccines, and inactivated vaccines;
 - b. Personal protective equipment, including surgical masks, surgical gowns, face shields, and N95 masks;
 - c. Testing materials, including chemical reagents, test swabs, and materials necessary to develop serological COVID-19 tests; and
 - d. Drugs and biological products that the Food and Drug Administration have reported to be in shortage.
2. Please provide a list of federal government facilities that could be rapidly re-tooled to manufacture the products listed above. What is the added capacity of each of these facilities for each of the subcategories listed above?
3. Please provide copies of reviews of CIADM conducted at the instruction of HHS in the past five years.
4. Please provide copies of contracts issued by the Biomedical Advanced Research and Development Authority (BARDA) and through "Operation Warp Speed" to private sector actors for the purposes of large-scale manufacturing.
5. Please describe the role of the newly formed National Biopharmaceutical Manufacturing Partnership between HHS and the Department of Defense to manage these centers.¹⁴

Thank you for your attention to this matter.

Sincerely,

/s/
Elizabeth Warren
United States Senator

/s/
Jan Schakowsky
Member of Congress

¹³ U.S. Department of Health and Human Services, "National Health Security Strategy 2019-2022," https://www.medicalcountermeasures.gov/media/37041/2019_ns.pdf.

¹⁴ *Id.*