Congress of the United States Mashington, DC 20510

June 18, 2020

The Honorable Mike Pence Vice President Eisenhower Executive Office Building 1650 Pennsylvania Ave NW Washington, D.C. 20502

Dear Vice President Pence:

We write to request information regarding reports and whistleblower complaints that the Trump Administration rejected an offer to build up domestic manufacturing capacity for N95 respirators just as the coronavirus disease 2019 (COVID-19) was first detected in the United States.¹ If these reports are accurate, they indicate that the Trump Administration's dismissal of an offer from a U.S.-based company to manufacture millions of N95 respirators and its failure to anticipate the immense need for masks has likely contributed to the chronic nationwide shortage of crucial protective equipment and the ongoing spread of the disease.

The Trump Administration's failure to properly prepare for a pandemic—and its lackadaisical response in the weeks between the first COVID-19 case being identified and the first American contracting the disease—left states and hospitals unprepared and under-resourced to combat the COVID-19 pandemic.² In just a matter of weeks, there were nationwide shortages of personal protective equipment (PPE) such as gowns, gloves, and masks and other face covers—equipment crucial to preventing the spread of the virus and protecting first responders and other health care professionals at the front lines.³ Hospitals, community health centers, nursing homes, and other health care providers were flooded with potential COVID-19 cases but forced to treat, test, or

https://www.washingtonpost.com/investigations/in-the-early-days-of-the-pandemic-the-us-government-turneddown-an-offer-to-manufacture-millions-of-n95-masks-in-america/2020/05/09/f76a821e-908a-11ea-a9c0-73b93422d691_story.html.

¹ The Washington Post, "In the early days of the pandemic, the U.S. government turned down an offer to manufacture millions of N95 masks in America," Aaron C. Davis, May 9, 2020,

² Associated Press, "State supply stocks sparse and dated before virus," David A. Lieb, Cuneyt Dil, April 23, 2020, https://apnews.com/1f123d323b4089a6f7b242abcceb6d08

³ Washington Post, "Shortages of face masks, swabs and basic supplies pose a new challenge to coronavirus testing," Carolyn Y. Johnson, March 18, 2020, <u>https://www.washingtonpost.com/climate-environment/2020/03/18/shortages-face-masks-cotton-swabs-basic-supplies-pose-new-challenge-coronavirus-testing/</u>

care for patients without adequate PPE, including masks.⁴ Dozens of reports surfaced of nurses and doctors using the same mask to treat several patients across multiple days, greatly increasing the chances of transmission.⁵ States were pitted against one another as they attempted to procure masks from an array of sources; even when they were seemingly successful, the federal government would often swoop in to outbid them at the last minute.⁶ Even as the shortage and its consequences became apparent, President Trump hesitated to use his powers under the Defense Production Act to direct manufacturers to produce masks.⁷

Today, health care professionals and first responders caring for COVID-19 positive patients are still being forced to reuse N95 respirators or use less effective surgical masks.⁸ Furthermore, reports from the Federal Emergency Management Agency (FEMA) indicate that domestic capacity to manufacture N95 respirators continues to lag behind of the 3.5 billion N95 respirators Department of Health and Human Services (HHS) Assistant Secretary for Preparedness and Response estimated we need to combat the pandemic.⁹ The ability to domestically manufacture N95 respirators could be critical in combatting COVID-19.

We are, therefore, concerned by reports that HHS officials refused to contract with Prestige Ameritech, "the largest domestic manufacturer of surgical masks and respirators in America,"¹⁰, after they offered to produce masks just one day after the first case of COVID-19 was confirmed in the U.S. ¹¹ In anticipation of extreme demand domestically, Prestige Ameritech contacted senior officials at HHS, writing "We still have four like-new N95 manufacturing lines... reactivating these machines would be very difficult and very expensive but could be achieved in a dire situation," and estimated that they would be able to produce nearly 1.7 million N95 respirators per week. ¹² However, HHS officials ultimately decided to not contract with Prestige Ameritech, responding, "I don't believe we as a government are anywhere near answering those questions for you yet"—a shocking admission on a date when there were already 581 cases worldwide and the Administration had been made aware of the potential for devastation several

⁴ Id.

⁵ Washington Post, "Shortages of face masks, swabs and basic supplies pose a new challenge to coronavirus testing," Carolyn Y. Johnson, March 18, 2020, <u>https://www.washingtonpost.com/climate-</u>

environment/2020/03/18/shortages-face-masks-cotton-swabs-basic-supplies-pose-new-challenge-coronavirustesting/.; Vox, "The mask shortage is forcing health workers to disregard basic coronavirus infection control," Lois Parhley, April 3, 2020, <u>https://www.vox.com/2020/4/3/21206726/coronavirus-masks-n95-hospitals-health-care-</u> doctors-ppe-shortage.

⁶ NPR, "A 'War' For Medical Supplies: States Say FEMA Wins By Poaching Orders," Joel Rose, April 15, 2020, https://www.npr.org/2020/04/15/835308133/governors-say-fema-is-outbidding-redirecting-or-poaching-theirmedical-supply-or

⁷ The Hill, "Trump rejects calls to directly use Defense Production Act," Peter Sullivan, March 22, 2020, https://thehill.com/policy/healthcare/488938-trump-rejects-calls-to-directly-use-defense-production-act

⁸ The Washington Post, "How far would a million N95 masks go? It's complicated, and this is why," Bonnie Berkowitz, May 19, 2020, <u>https://www.washingtonpost.com/graphics/2020/health/virus-masks-ppe/</u>.

⁹ <u>https://www.hassan.senate.gov/imo/media/doc/SCTF%20Demand%20PPE%20Chart.pdf</u>; The Washington Post, "How far would a million N95 masks go? It's complicated, and this is why," Bonnie Berkowitz, May 19, 2020, <u>https://www.washingtonpost.com/graphics/2020/health/virus-masks-ppe/</u>.

¹¹ Id.

¹¹ Id.

¹² Id.

weeks prior.¹³ In fact, just days after Prestige Ameritech originally contacted the Department, HHS Secretary Azar testified before the Senate Appropriations Committee that the United States had only 30 million masks but would need more than 300 million to combat the spread of COVID-19.

Despite HHS' initial rejection and high interest from overseas, Prestige Ameritech persisted, warning "U.S. mask supply is at imminent risk" and citing rising demand from China and Hong Kong.¹⁴ HHS continued to show little interest until two months later, on March 21, 2020, when the agency finally awarded contracts to six major medical equipment manufacturers to purchase approximately 600 million N95 respirators.¹⁵ On April 7, Prestige Ameritech was eventually awarded a \$9.5 million contract by FEMA for only 12 million masks, a small order the company has said they "could fulfill without activating its dormant manufacturing lines."¹⁶ Curiously, FEMA also awarded a contract for 10 million N95 respirators to a third-party distributor with "no history of procuring medical equipment" at a price per mask that was seven times higher than Prestige Ameritech offered in January.¹⁷

These reports are corroborated by Dr. Rick Bright, former Director of the Biomedical Advanced Research and Development Authority.¹⁸ According to Dr. Bright's May 2020 whistleblower complaint, in the days and weeks following Prestige Ameritech's initial contact, he repeatedly raised concerns within the Department and called on HHS to take up the company's offer. Yet his concerns reportedly "[fell] on deaf ears."¹⁹ Together, all the available evidence paints an alarming picture—that the Trump Administration failed to build up and invest in our country's

https://www.washingtonpost.com/investigations/in-the-early-days-of-the-pandemic-the-us-government-turneddown-an-offer-to-manufacture-millions-of-n95-masks-in-america/2020/05/09/f76a821e-908a-11ea-a9c0-73b93422d691 story.html; Johns Hopkins University, Coronavirus Resource Center,

https://www.washingtonpost.com/investigations/in-the-early-days-of-the-pandemic-the-us-government-turneddown-an-offer-to-manufacture-millions-of-n95-masks-in-america/2020/05/09/f76a821e-908a-11ea-a9c0-73b93422d691 story.html.

https://www.phe.gov/emergency/events/COVID19/SNS/Pages/procurement.aspx.

<u>73b93422d691_story.html.</u>; Vox, "The US was offered millions of masks in January. The Trump Administration turned the offer down," May 10, 2020, <u>https://www.vox.com/covid-19-coronavirus-us-response-trump/2020/5/10/21253689/covid-19-masks-trump-white-house-prestige-ameritech</u>

¹³ Washington Post, "In the early days of the pandemic, the U.S. government turned down an offer to manufacture millions of N95 masks in America," Aaron C. Davis, May 9, 2020,

https://coronavirus.jhu.edu/map.html; Axios, "10 times Trump and his administration were warned about coronavirus," Ursula Perano, April 12, 2020, <u>https://www.axios.com/trump-coronavirus-warnings-46ea8006-2e19-4810-82c1-0f10f4f9aa97.html</u>

¹⁴ Washington Post, "In the early days of the pandemic, the U.S. government turned down an offer to manufacture millions of N95 masks in America," Aaron C. Davis, May 9, 2020,

¹⁵ *Id.*; U.S. Department of Health and Human Services, Public Health Emergency, "Procurement of N95 Respirators: Response to the COVID-19 Pandemic,"

¹⁶ Washington Post, "In the early days of the pandemic, the U.S. government turned down an offer to manufacture millions of N95 masks in America," Aaron C. Davis, May 9, 2020,

https://www.washingtonpost.com/investigations/in-the-early-days-of-the-pandemic-the-us-government-turneddown-an-offer-to-manufacture-millions-of-n95-masks-in-america/2020/05/09/f76a821e-908a-11ea-a9co-

¹⁷ Id.

¹⁸ U.S. Office of Special Counsel, "Complaint and Disclosure Form," Dr. Rick Bright, February 29, 2020, <u>https://www.kmblegal.com/sites/default/files/NEW%20R.%20Bright%20OSC%20Complaint_Redacted.pdf?utm_so</u> <u>urce=newsletter&utm_medium=email&utm_campaign=newsletter_axiosvitals&stream=top</u> ¹⁹ *Id.*

domestic manufacturing capacity for crucial medical equipment and PPE even when the resources were made available to them. This inaction likely contributed to the spread of COVID-19 among health care workers and had devastating effects on our nation's health care workforce.

We have introduced legislation, the *COVID–19 Emergency Manufacturing Act of 2020*, which would give the federal government authority to immediately enter into contracts and manufacture medical devices, PPE, and other products to combat COVID-19 to ensure that we can adequately fight the pandemic.²⁰ We intend to keep working to make that plan law. In the interim, however, your Administration must work expeditiously to coordinate its domestic manufacturing efforts for COVID-19 medical products.

In order to better understand the federal government's refusal to procure N95 respirators from Prestige Ameritech and other potential untapped sources of PPE available to the federal government, we request answers to the following questions no later than July 2, 2020.

- 1. Please provide a list of all federal government contracts for manufacturing N95 respirators, including for each contract:
 - a. The total number of masks contracted;
 - b. The price per mask;
 - c. The manufacturer's current manufacturing capacity; and
 - d. The manufacturer's current domestic manufacturing capacity.
- 2. Why did the federal government initially turn down Prestige Ameritech's offers to domestically manufacture N95 respirators?
- 3. Why has the federal government not contracted with Prestige Ameritech for the production of N95 respirators using its dormant manufacturing lines?
- 4. Please provide a list of other manufacturing companies that domestically manufacture N95 respirators and the contracts that FEMA has awarded them.
- 5. Please provide a list of federal government facilities that could be rapidly re-tooled to manufacture N95 respirators and other PPE.
- 6. What is the federal government's acquisition goal for N95 respirators and other PPE to combat the COVID-19 pandemic?
- 7. What is the federal government's goal to replenish the Strategic National Stockpile with N95 respirators and other PPE?

We appreciate your attention to this matter.

²⁰ "Warren, Schakowsky to Introduce Legislation to Publicly Manufacture Personal Protective Equipment, Prescription Drugs, Other Medical Supplies," Press Release, April 30, 2020, <u>https://www.warren.senate.gov/newsroom/press-releases/warren-schakowsky-to-introduce-legislation-to-publicly-</u> manufacture-personal-protective-equipment-prescription-drugs-other-medical-supplies. Sincerely,

/s/ Elizabeth Warren Elizabeth Warren United States Senator /s/ Jan Schakowsky Jan Schakowsky Member of Congress