MEMORANDUM
To: Mr. Jeff Zients, Dr. Vivek Murthy, Dr. Marcella Nunez-Smith, and Dr. David Kessler
From: Senator Elizabeth Warren
Date: January 12, 2021
Re: COVID-19 Oversight Recommendations for the Biden-Harris COVID-19 Transition Team

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Congratulations on your appointments to serve as Coordinator of the COVID-19 Response and Co-chairs of the Biden-Harris Transition Team's COVID-19 Advisory Board. Your work is critical: the myriad failures of the Trump administration's response to the pandemic have resulted in an ongoing public health tragedy that grows worse daily in the absence of federal leadership. You have much work to do, and I am looking forward to working with you to protect public health, end the pandemic, and restore the economy. Since the beginning of the pandemic, I have been conducting extensive oversight of the Trump administration's public health failures, and based on this work, I have identified four key priorities for President-elect Biden and Vice President-elect Harris to address as soon as they take office:

I. **Improve transparency and encourage oversight of pandemic response efforts** to address questions about corporate profiteering and conflicts of interest;
II. **Address the pandemic's disproportionate impact on vulnerable populations**, especially communities of color, and individuals living and working in nursing homes, assisted living facilities, prisons, behavioral health facilities, and other congregate settings;
III. **Rectify supply chain challenges** that have hamstrung the nation's ability to control and mitigate the spread of the pandemic; and
IV. **Restore integrity to politicized pandemic response efforts** that have sidelined public health scientists and hampered the nation's pandemic recovery.

I have confidence in your and your teams' ability to respond to this crisis, and I look forward to working with you in the coming months to quickly put in place an effective response to the pandemic. I have provided additional details on my pandemic-related oversight work—and the recommendations that come from this work—below. The 13 recommendations below require no action by Congress: they can be put in place within days or weeks of the inauguration, and I hope you will do so. Please feel free to reach out to me or my staff if you have any questions about these urgent matters.

I. Lack of transparency in pandemic response efforts has left room for corporate profiteering and significant conflicts of interest, damaging the integrity of key administration efforts and reducing public confidence in the federal government's response.

The Trump administration has been rampant with cronyism and conflicts of interest since day one, and this corrupt behavior has included the administration's response to the COVID-19 pandemic. This corruption and lack of transparency saps public confidence in the response and results in substantial waste of time, money, and resources.

Earlier this year, for example, the former director of the Biomedical Advanced Research and Development Authority (BARDA), Dr. Rick Bright, filed a federal whistleblower complaint detailing pressure from the White House and administration officials to direct resources toward hydroxychloroquine, an unproven and ineffective treatment for COVID-19 that was championed by the

President's supporters.[1] Dr. Bright also alleged he witnessed senior U.S. Department of Health and Human Services (HHS) officials improperly steering taxpayer dollars toward "cronies" "for political purposes."[2] The head of Operation Warp Speed (OWS), Dr. Moncef Slaoui and other OWS officials,[3] have entered into a complicated contracting scheme that allows them to evade ethics laws and maintain investments in companies with a financial interest in OWS.[4] Dr. Slaoui continues to refuse to address these conflicts posed by his financial ties to companies with an interest in the outcome of OWS, even while acknowledging his financial dependence on these holdings.[5]

The Biden-Harris administration can and should address the Trump administration's behavior with regard to corruption and conflicts of interest, and its troubling lack of transparency about its COVID-19 pandemic response efforts. The Trump administration's failures in this area include:

- **Lack of Transparency of Federal Government COVID-19 Contracts with Private Companies.** To date, OWS has awarded over $13 billion in contracts to nearly 20 companies in pursuit of "substantial quantities of a safe and effective vaccine available for Americans by January 2021;"[6] the National Institutes of Health (NIH) has awarded over $1.8 billion to 975 recipients;[7] the Federal Emergency Management administration (FEMA) has spent billions to procure medical supplies; and BARDA, in conjunction with OWS, has spent nearly $14.5 billion to advance COVID-19 tests, treatments, and vaccines.[8] OWS deserves credit for what appears to be a successful effort to assist the private sector in unprecedently fast vaccine development. But the terms of many of OWS and other COVID-related contracts have been kept secret. The documents that have been released by the federal government in response to

[1] Science, "Emails offer look into whistleblower charges of cronyism behind potential COVID-19 drug," Jon Cohen, Charles Piller, May 13, 2020, https://www.sciencemag.org/news/2020/05/emails-offer-look-whistleblower-charges-cronyism-behind-potential-covid-19-drug; New York Times, "Health Dept. Official Says Doubts on Hydroxychloroquine Led to His Ouster," Michael D. Shear and Maggie Haberman, April 22, 2020; https://www.nytimes.com/2020/04/22/us/politics/rick-bright-trump-hydroxychloroquine-coronavirus.html; New York Times, "A Mad Scramble to Stock Millions of Malaria Pills, Likely for Nothing," Sheryl Gay Stolberg, June 16, 2020, https://www.nytimes.com/2020/06/16/us/politics/trump-hydroxychloroquine-coronavirus.html.

[2] *Id.*

[3] Kaiser Health News, "How Pharma Money Colors Operation Warp Speed's Quest to Defeat COVID," Rachana Pradhan, November 30, 2020, https://khn.org/news/article/how-pharma-money-colors-operation-warp-speeds-quest-to-defeat-covid/.

[4] Letter from Senator Elizabeth Warren, et al. to HHS Secretary Alex Azar, August 24, 2020, https://www.warren.senate.gov/imo/media/doc/2020.08.24%20Letter%20to%20HHS%20re%20Dr.%20Slaoui%202.0.pdf.

[5] New York Times, "The Man Behind America's Race for the Vaccine," Hosted by Kara Swisher, October 5, 2020, https://www.nytimes.com/2020/10/05/opinion/sway-kara-swisher-moncef-slaoui.html?showTranscript=1.

[6] U.S. Department of Defense, "Coronavirus: Operation Warp Speed Timeline," Accessed December 10, 2020, https://www.defense.gov/Explore/Spotlight/Coronavirus/Operation-Warp-Speed/Operation-Warp-Speed-Timeline/; US. Department of Health and Human Services, "Trump administration Announces Framework and Leadership for 'Operation Warp Speed'," press release, May 15, 2020, https://www.hhs.gov/about/news/2020/05/15/trump-administration-announces-framework-and-leadership-for-operation-warp-speed.html.

[7] HHS Tracking Accountability in Government Grants System, "HHS COVID-19 Funding," Accessed January 8, 2021, https://taggs.hhs.gov/Coronavirus.

[8] Public Citizen, "BARDA Funding Tracker," Last Updated November 2, 2020, https://www.citizen.org/article/barda-funding-tracker/; Letter from Senator Elizabeth Warren and Representative Katie Porter to HHS Secretary Azar, DoD Acting Secretary Miller, NIH Director Collins, BARDA Acting Director Disbrow, DHS Acting Secretary Wolf, and FEMA Administrator Gaynor, November 16, 2020, https://www.warren.senate.gov/imo/media/doc/2020.11.16%20Letter%20to%20HHS,%20NIH,%20DOD,%20BARDA%20re%20COVID-19%20Vaccines%20and%20Therapeutics%20Contracts.pdf.

Freedom of Information Act requests have been heavily redacted,[9] and one contract, Pfizer's $1.95 billion OWS contract, revealed that many taxpayer protections have indeed been written out.[10] There is no need for this secrecy and no benefit to opacity. To the contrary, absent transparency, it is impossible to trust whether conflicts of interest have tainted decisions and difficult to hold the federal government accountable for securing fair pricing and other consumer protections in the COVID-19 response.

- **Project Air Bridge Failures.** After multiple reports of seizures of COVID-19 medical supplies en route to states by federal officials, allegations of cronyism, and instances of price-gouging via third-party sellers, my staff opened an investigation into "Project Air Bridge," the Trump administration's medical supply chain management project.[11] The investigation revealed that Project Air Bridge—like the broader Trump administration response to the coronavirus—was marked by delays, incompetence, confusion, ethics questions, and secrecy across multiple federal agencies and in the White House.[12] The investigation found that Project Air Bridge was marred by an opaque and secretive chain of command, with Jared Kushner-connected private sector volunteers, rather than procurement experts within FEMA and HHS, running key parts of the response; and that, despite spending millions of taxpayer dollars, Project Air Bridge ultimately failed in its mission to provide much-needed supplies to the hardest-hit communities.[13] Information about how and why the Trump administration decided to use this approach remains unclear and raises a variety of ongoing ethics questions.[14]

- **Operation Warp Speed Conflicts of Interest.** OWS has contributed to the rapid development of multiple COVID-19 vaccines in mere months—a scientific achievement that is a testament to the hardworking scientists and researchers fighting COVID-19. The success of OWS, however, has been tarnished by the refusal of its chief scientific advisor, Dr. Moncef Slaoui, to resolve his financial conflicts of interest. Dr. Slaoui is a former GlaxoSmithKline (GSK) executive who still holds around $10 million of stock in the company—and OWS has provided

[9] NPR, "A Federal Coronavirus Vaccine Contract Released at Last, But Redactions Obscure Terms," Sydney Lupkin, October 24, 2020, https://www.npr.org/sections/health-shots/2020/10/24/927474041/a-federal-coronavirus-vaccine-contract-released-at-last-but-redactions-obscure-t.

[10] NPR, "Pfizer's Coronavirus Vaccine Supply Contract Excludes Many Taxpayer Protections," Sydney Lupkin, November 24, 2020, https://www.npr.org/sections/health-shots/2020/11/24/938591815/pfizers-coronavirus-vaccine-supply-contract-excludes-many-taxpayer-protections.

[11] "Warren, Schumer, Blumenthal Release New Findings and Documents from Investigation of Trump-Kushner 'Project Air Bridge' Coronavirus Response," press release, June 9, 2020, https://www.warren.senate.gov/oversight/letters/warren-schumer-blumenthal-release-new-findings-and-documents-from-investigation-of-trump-kushner-project-air-bridge-coronavirus-response.

[12] Letter from Senators Elizabeth Warren, Richard Blumenthal, and Charles Schumer to Pandemic Response Accountability Committee Acting Chair Horowitz, June 8, 2020, https://www.warren.senate.gov/imo/media/doc/Letter%20to%20PRAC%20re%20project%20airbridge%202020.06.pdf.

[13] *Id;* Washington Post, "Kushner coronavirus effort said to be hampered by inexperienced volunteers," Yasmeen Abutaleb and Ashley Parker, May 5, 2020, https://www.washingtonpost.com/politics/kushner-coronavirus-effort-said-to-be-hampered-by-inexperienced-volunteers/2020/05/05/6166ef0c-8e1c-11ea-9e23-6914ee410a5f_story.html; New York Times, "How Kushner's Volunteer Force Led a Fumbling Hunt for Medical Supplies," Nicholas Confessore, Andrew Jacobs, Jodi Kantor, Zolan Kanno-Youngs, and Luis Ferré-Sadurní, May 5, 2020, https://www.nytimes.com/2020/05/05/us/jared-kushner-fema-coronavirus.html.

[14] Washington Post, "Kushner coronavirus effort said to be hampered by inexperienced volunteers," Yasmeen Abutaleb and Ashley Parker, May 5, 2020, https://www.washingtonpost.com/politics/kushner-coronavirus-effort-said-to-be-hampered-by-inexperienced-volunteers/2020/05/05/6166ef0c-8e1c-11ea-9e23-6914ee410a5f_story.html.

GSK and its partner, Sanofi, with a $2 billion vaccine development grant.[15] The Trump administration allowed Dr. Slaoui to evade federal ethics laws by hiring him as a contractor rather than a federal employee—exempting him from conflict-of-interest laws that would have forced him to divest.[16] Dr. Slaoui continues to refuse to address these conflicts of interest, instead reaffirming his dependence on continuing GSK dividends with claims that he needs the payments for "my retirement."[17]

- **HHS Remdesivir Costs and Distribution Problems.** In July, HHS secretly negotiated with Gilead Sciences for a large supply of remdesivir,[18] ultimately allowing Gilead to charge American health insurers the highest price in the world for the drug[19]—representing windfall revenues of up to almost half a billion dollars for the company, paid for in whole or in part by increased insurance premiums for American families and higher taxpayer costs.[20] HHS made this deal despite having several other options available to expand remdesivir access in the United States[21] and despite the fact that American taxpayers spent over $70 million to help develop and test the drug.[22] Outside analysts concluded that the deal was "amazingly good for Gilead's executives and shareholders and amazingly bad for everyone else—bad for taxpayers, terrible for public health, and unethical."[23] In October, the FDA announced full approval of remdesivir,[24] making the antiviral the first approved COVID-19 treatment in the United States, raising more questions about remdesivir's pricing and accessibility. At the same time, the World Health Organization released a study indicating the drug provided no survival benefit

[15] U.S. Department of Health and Human Services, "HHS, DOD Partner With Sanofi and GSK on Commercial-Scale Manufacturing Demonstration Project to Produce Millions of COVID-19 Investigational Vaccine Doses," press release, July 31, 2020, https://www.hhs.gov/about/news/2020/07/31/hhs-dod-partner-sanofi-gsk-commercial-scale-manufacturing-demonstration-project-produce-millions-covid-19-investigational-vaccine-doses.html.
[16] Letter from Senators Elizabeth Warren and Richard Blumenthal and Rep. Pramila Jayapal to HHS Secretary Alex Azar, August 24, 2020, https://www.warren.senate.gov/imo/media/doc/2020.08.24%20Letter%20to%20HHS%20re%20Dr.%20Slaoui%202.0.pdf.
[17] New York Times, "The Man Behind America's Race for a Vaccine," Kara Swisher, October 5, 2020, https://www.nytimes.com/2020/10/05/opinion/sway-kara-swisher-moncef-slaoui.html.
[18] U.S. Department of Health and Human Services, "Trump administration Secures New Supplies of Remdesivir for the United States," press release, June 29, 2020, https://www.hhs.gov/about/news/2020/06/29/trump-administration-secures-new-supplies-remdesivir-united-states.html.
[19] Reuters, "Gilead's remdesivir could see $7 billion in annual sales on stockpiling boost: analyst," Saumya Joseph, June 3, 2020, https://www.reuters.com/article/us-health-coronavirus-remdesivir/gileads-remdesivir-could-see-7-billion-in-annual-sales-on-stockpiling-boost-analyst-idUSKBN23A2MN.
[20] This price represents the additional revenue generated from selling "more than 500,000 treatment courses" at "approximately $3,200 per treatment course," which is $860 above the "$2,340 per patient" price for patients in the rest of the world. U.S. Department of Health and Human Services, "Trump administration Secures New Supplies of Remdesivir for the United States," press release, June 29, 2020, https://www.hhs.gov/about/news/2020/06/29/trump-administration-secures-new-supplies-remdesivir-united-states.html; Gilead Sciences, Inc., "An Open Letter from Daniel O'Day, Chairman & CEO, Gilead Sciences," Daniel O'Day, June 29, 2020, https://stories.gilead.com/articles/an-open-letter-from-daniel-oday-june-29.
[21] Letter from Senator Warren et al. to HHS Secretary Alex Azar, July 16, 2020, https://www.warren.senate.gov/imo/media/doc/2020.07.16%20Letter%20to%20HHS%20re%20remdesivir%20pricing.pdf.
[22] Public Citizen, "The Real Story of Remdesivir," May 7, 2020, https://www.citizen.org/article/the-real-story-of-remdesivir/.
[23] STAT, "A powerful law gives HHS the right to take control of remdesivir manufacturing and distribution," Christopher Morten, Christian Urrutia, and James Krellenstein, July 2, 2020, https://www.statnews.com/2020/07/02/powerful-law-gives-hhs-right-to-control-remdesivir-manufacturing-distribution/.
[24] Politico, "FDA approves remdesivir as first coronavirus drug," Zachary Brennan, October 22, 2020, https://www.politico.com/news/2020/10/22/fda-approves-remdesivir-coronavirus-431336.

for COVID-19 patients in the study.[25] I have sent two letters to HHS requesting more information on the deal that HHS struck with Gilead and the agency has not clarified whether it will employ pricing protections and authorities available to the agency for ensuring the affordability and accessibility of the drug.[26]

Recommendations. President-elect Biden has committed to addressing conflicts of interest in the COVID-19 response with "strong, vigorously enforced protections against conflicts of interest, including transparency of personal finances;" closing loopholes and requiring "more extensive public reporting of all lobbying activity, such as disclosure of the materials that lobbyists now provide behind closed doors to public officials;" and increasing oversight, protecting whistleblowers, and appointing "an inspector general to review every coronavirus relief transaction currently evading serious scrutiny."[27] The Biden-Harris administration can address and rectify the problems caused by the Trump administration's corruption and lack of transparency, ethics, and oversight by taking the additional following actions:

1. **Establish and enforce strong conflict of interest policies for all administration officials.** The scientists and advisors guiding the federal government's COVID-19 efforts must be held to the highest ethical standards. The Biden-Harris administration must require that Dr. Slaoui and others working on the federal pandemic response, including any task force members or temporary advisors,[28] adhere to the same federal ethics standards as other federal employees. And the administration should voluntarily implement provisions of my *Coronavirus Oversight Recovery Ethics* (CORE) *Act* (S.3855), legislation that would address and eliminate conflicts arising in the selection or hiring of contractors or advisors; require White House task force members who work on pandemic response to file public reports detailing their financial interests; and ensure stronger oversight, accountability, and transparency in the federal government's response to COVID-19.

2. **Make contracts public and complete a thorough review of existing contracts to identify agreements that (1) have excluded common taxpayer protections from their terms and (2) appear to provide undue benefits to well-connected companies.** Given the massive taxpayer investment and the public health interest in COVID-19 therapeutics, vaccines, and other medical products, the American people deserve to know that the federal government is using their tax dollars to develop medical products at the best possible price for the public—not to line the pockets of wealthy companies by cutting corners in consumer protection, pricing, and quality. In order to ensure fair pricing, speed, effectiveness, and quality of COVID-19 medical products for the American people, the Biden-Harris administration should release all information and

[25] NBC News, "Massive WHO remdesivir study suggests no Covid-19 benefit. Doctors aren't so sure," Erika Edwards, October 16, 2020, https://www.nbcnews.com/health/health-news/massive-who-remdesivir-study-suggests-no-covid-19-benefit-doctors-n1243730.
[26] Letter from Senator Warren et al. to HHS Secretary Alex Azar, July 16, 2020, https://www.warren.senate.gov/imo/media/doc/2020.07.16%20Letter%20to%20HHS%20re%20remdesivir%20pricing.pdf; Letter from Senator Warren et al. to HHS Secretary Alex Azar, November 19, 2020, https://www.warren.senate.gov/imo/media/doc/2020.11.16.%20Letter%20to%20HHS%20re%20Remdesivir%20Pricing.pdf.
[27] Miami Herald Opinion Editorial, "Biden, Warren: There's no oversight of coronavirus relief — because that's what Trump wants," Joe Biden, Elizabeth Warren, May 3, 2020, https://www.miamiherald.com/article242350451.html.
[28] Kaiser Health News, "How Pharma Money Colors Operation Warp Speed's Quest to Defeat COVID," Rachana Pradhan, November 30, 2020, https://khn.org/news/article/how-pharma-money-colors-operation-warp-speeds-quest-to-defeat-covid/.

documents for federal contracts issued for the development, manufacture, and distribution of personal protective equipment, therapeutics, vaccines, diagnostics, and other medical products procured to identify, mitigate, treat, cure, and prevent the spread of COVID-19, including all contracts associated with OWS, BARDA, NIH, FEMA, HHS, and DOD. The Biden-Harris administration should also conduct a public review of these contracts to identify agreements that exclude common taxpayer protections, such as march-in rights, or appear to be giveaways to companies and individuals connected with the Trump administration. To the extent practical, the administration should identify and utilize its authority to re-negotiate flawed contracts.

3. **Use existing compulsory licensing and march-in authorities**. The Biden-Harris administration must aggressively use the federal government's march-in rights under the *Bayh-Dole Act,* which provide the federal government "with the ability to 'march in' and grant licenses for patents that result from publicly-funded R&D," allowing it to re-license the drug for production at a lower cost, "if necessary to alleviate health or safety needs" and under other circumstances.[29] The Biden-Harris administration should also employ the federal government's compulsory licensing authority. Under 28 U.S.C § 1498, the federal government can "use or acquire patented inventions" in exchange for providing "reasonable and entire compensation" to the patent holder.[30] The U.S. government has used this authority in the past to acquire lower-cost products and patented military equipment.[31] Using these authorities will ensure greater drug accessibility for the American public, fairly reward taxpayer investment, and protect against unfair and egregious profiteering off of this unprecedented health care crisis. Upon taking office, the Biden-Harris administration should conduct a review of COVID-19 and other pharmaceutical products and identify drugs that are in shortage, have experienced price gouging, or are critical to the treatment of common conditions—like diabetes, asthma, HIV/AIDS, and hepatitis C—but are too expensive for many patients. After conducting this review, the administration should utilize its compulsory licensing and march-in authorities (in conjunction with complementary authorities under the Defense Production Act) to award contracts to mitigate shortages and increase the supply of affordable drugs for millions of Americans.

4. **Release FDA data and improve EUA tracking and communication to providers and the public.** The Biden-Harris administration should prioritize increased transparency, data collection, and communication about the known and potential risks and benefits of drugs, devices, biological products, and vaccines authorized under Emergency Use Authorizations (EUAs). Since February 4, 2020, the FDA has issued 314 EUAs for COVID-19-related medical products, including tests, personal protective equipment, and ventilators.[32] This is an unprecedented expansion of EUAs—only 77 EUAs were issued between 2005 and 2018.[33] The seriousness of the COVID-19 pandemic warrants extraordinary measures, but it also places the

[29] Congressional Research Service, "March-In Rights Under the Bayh-Dole Act," John R. Thomas, August 22, 2016, https://crsreports.congress.gov/product/pdf/R/R44597.
[30] Yale Journal of Law and Technology, "A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health," Hannah Brennan, Amy Kapczynski, Christine H. Monahan, and Zain Rizvi, 2017, https://digitalcommons.law.yale.edu/cgi/viewcontent.cgi?article=1124&context=yjolt.
[31] *Id.*
[32] U.S. Food and Drug administration, "Coronavirus Disease 2019 (COVID-19) EUA Information," accessed January 8, 2021, https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#covid19euas.
[33] Science, "FDA – EUAs – current and past.xlsx." https://www.sciencemag.org/file/fda-euas-current-and-pastxlsx.

burden on the FDA to track the use of these newly-authorized products and quickly and clearly communicate EUA changes to providers and the public. This transparency is especially important in light of the Trump administration's heavy-handed political pressure that has been brought to bear on numerous agency decisions. I sent two letters to FDA Commissioner Hahn outlining these concerns and my recommendations on steps that the agency should take to address them.[34] Plans for distributing approved vaccines, including the role of key federal government agencies, and plans for prioritizing access for high-need groups, must also be made available to the public and incorporate input from representatives of underserved communities.

5. **Overhaul and facilitate oversight of the COVID-19 response**. President-elect Biden and I have written about President Trump's efforts to sideline and muzzle independent government watchdogs charged with overseeing the federal government's response to this pandemic.[35] President Trump has even appointed a partisan loyalist as the top watchdog for COVID-19 relief funds.[36] In contrast, President-elect Biden and I share a belief that inspectors general should be independent and shielded from removal except for "good cause;" whistleblowers must be protected; and the public must be granted extensive public reporting of all lobbying activity related to COVID-19, such as disclosure of the materials that lobbyists now provide behind closed doors to public officials. The Biden-Harris administration can rebuild public confidence in the pandemic response by honoring their commitment to "appoint an inspector general to review every coronavirus relief transaction currently evading serious scrutiny," and root out and undo "wasteful, corrupt deals and giveaways" through more transparency and lobbying disclosure.[37]

II. The COVID-19 pandemic is disproportionately affecting vulnerable populations, especially communities of color and individuals living and working in congregate settings.

The COVID-19 pandemic has exposed the systemic racism underlying America's health system and the inadequate protections for the most vulnerable members of our communities. Early in the course of the pandemic, it became clear that the public health emergency was disproportionately affecting individuals in nursing homes, prisons, and other congregate care settings, as well as communities of color. Because of historical and current inequities, communities of color are more likely to be impoverished, work essential jobs that can't be done remotely, live in overcrowded residences, rely on public transit to get to work, and have higher rates of pre-existing conditions that increase their COVID-19 risks—all of which

[34] Letter from Senators Elizabeth Warren and Patty Murray to FDA Commissioner Stephen Hahn, May 6, 2020, https://www.warren.senate.gov/imo/media/doc/2020.05.06%20Letter%20to%20FDA%20re%20data%20tracking.pdf; Letter from Senator Elizabeth Warren to FDA Commissioner Stephen Hahn, August 26, 2020, https://www.warren.senate.gov/imo/media/doc/2020.08.26%20Letter%20to%20FDA%20re%20communication%20about%20EUAs.pdf.

[35] Miami Herald Opinion Editorial, "Biden, Warren: There's no oversight of coronavirus relief — because that's what Trump wants," Joe Biden, Elizabeth Warren, May 3, 2020, https://www.miamiherald.com/article242350451.html.

[36] Letter from Senator Elizabeth Warren to Special Inspector General for Pandemic Recovery Brian Miller, November 9, 2020, https://www.warren.senate.gov/imo/media/doc/2020.11.09%20Letter%20to%20SIGPR%20Brian%20Miller%20about%20his%20refusal%20to%20investigate%20corruption.pdf.

[37] Miami Herald Opinion Editorial, "Biden, Warren: There's no oversight of coronavirus relief — because that's what Trump wants," Joe Biden, Elizabeth Warren, May 3, 2020, https://www.miamiherald.com/article242350451.html.

are resulting in disproportionately high rates of COVID-19 infection and death in these communities.[38] Similarly, residents of congregate care settings like nursing homes, assisted living facilities, behavioral health centers, and prisons are living in conditions that are inherently susceptible to the spread of COVID-19—while also being much more likely to be older and have pre-existing conditions that increase risks. My oversight work has revealed failures by the Trump administration in prioritizing these vulnerable communities.

- **Racial, Ethnic, and Other Demographic Data Collection.** I have been conducting oversight to help identify and address the disproportionate impacts of the pandemic on communities of color since March 2020.[39] While the CDC and its partner agencies have made progress in publishing COVID-19 data disaggregated by race and ethnicity, much more work remains. As of January 7, 2021 race and ethnicity information was not available for nearly half of COVID-19 cases.[40] In addition, my oversight work has revealed that CDC has been slow to provide full context on fatality rates by adjusting race and ethnicity rates for age, leading to the agency publishing misleading statistics that understate the risk to people of color (a problem that has been at least partially addressed after the agency made key changes to include this information in response to my requests).[41] Other information for individuals with COVID-19, such as disability status, gender identity, and sexual orientation, has not been consistently collected or published.

- **Individuals in Congregate Settings.** Congregate settings like nursing homes, assisted living facilities, and prisons and jails have been epicenters of the COVID-19 pandemic since the virus began to spread. My oversight has revealed the extent of these problems, and the gaps that are making outbreaks in these facilities so frequent and so severe. While nursing homes are regulated and monitored by federal regulators, for example, assisted living facilities are subject to little federal regulation or oversight. My staff's investigation of assisted living facilities found that these facilities have high rates of COVID-19 infections, hospitalizations, and deaths than average, but report limited COVID-19 data and have inadequate leave policies to protect workers and residents from harm.[42] Similarly, a recently released staff investigation of COVID-19 outbreaks in behavioral health facilities revealed that more than half of the surveyed programs had at least one case of COVID-19, but programs are not conducting routine testing of their staff and patients due to a lack of resources and slow turnaround times for tests.[43] Meanwhile, federal

[38] Centers for Disease Control and Prevention, "Health Equity Considerations & Racial & Ethnic Minority Groups," July 24, 2020, https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/race-ethnicity.html.
[39] U.S. Senator Elizabeth Warren, "Associated Press: Pressley and Warren Call for Racial Data in Coronavirus Testing," March 30, 2020, Press Release, https://www.warren.senate.gov/newsroom/news-coverage/associated-press-pressley-and-warren-call-for-racial-data-in-coronavirus-testing.
[40] CDC COVID Data Tracker, "Demographic Trends of COVID-19 cases and deaths in the US reported to the CDC," updated January 7, 2021, https://covid.cdc.gov/covid-data-tracker/#demographics.
[41] Letter from Senator Elizabeth Warren to CDC Director Robert Redfield, November 10, 2020, https://www.warren.senate.gov/imo/media/doc/2020.11.10%20Letter%20to%20CDC%20re%20Highlighting%20Interaction%20between%20Age%20and%20Race+Ethnicity%20in%20Publications.pdf. CDC resolved many of the concerns in this letter, posting updated on November 30, 2020.
[42] "COVID-19 in Assisted Living Facilities," Staff Report Prepared for Senator Elizabeth Warren, Senator Edward J. Markey, Rep. Carolyn Maloney, July 2020, https://www.warren.senate.gov/imo/media/doc/Assisted%20Living%20Facilities%20Staff%20Report.pdf.
[43] "COVID-19 in Behavioral Health & Addiction Treatment Programs," Staff report prepared for Senator Elizabeth Warren and Reps. Carolyn Maloney and Katie Porter, November 2020,

correctional facilities and state and local prisons and jails are not required to report sufficient demographic data to adequately track the spread of COVID-19. Oversight by my staff and others has revealed that there still continue to be substantial needs for testing and PPE at congregate care facilities.

Recommendations: To address and rectify these concerns, the Biden-Harris administration should quickly take the following actions:

1. **Improve demographic data collection and public reporting at CDC, CMS and other agencies responding to the pandemic.** CDC has a responsibility to work with its partner agencies, state and local health departments, and private actors such as laboratory companies to improve demographic data reporting. This may include improvements to technology that allow data to be shared across systems, enforcing existing data reporting requirements, and adding new standardized reporting fields to capture more nuanced data. CDC should also expand its data collection efforts to ensure that these efforts cover the expanded use of rapid antigen tests to the extent practicable. Additionally, CMS has access to detailed demographic data through Medicare claims that could be better leveraged to inform the pandemic response.[44] And HHS and FEMA should collect and publish more detailed information on how pandemic relief funds have been allocated at the community level and prioritize medically underserved communities in allocating future resources, including testing, provider relief payments, PPE, and vaccines.

2. **Improve data collection and public reporting & allocate resources to individuals in congregate facilities, including assisted living facilities, behavioral health facilities, and prisons.** The Biden-Harris administration must improve data collection and provide additional resources to protect individuals in congregate settings from the COVID-19 pandemic. My *Assisted Living Facility Coronavirus Reporting Act, Equitable Data Collection and Disclosure on COVID-19 Act, COVID-19 in Corrections Data Transparency Act, Expanding COVID-10 Testing Capacity Act,* and *Federal Correctional Facilities COVID-19 Response Act,* along with my oversight reports on assisted living facilities and behavioral health facilities, provide potential roadmaps for improvements. To address problems in these facilities, the administration must take action in its first 100 days to (1) improve data reporting so that public health professionals and the public can identify outbreaks and facilities in need of help; (2) provide resources so that congregate care facilities have ample testing and PPE; and (3) provide strong, science-based guidance on how these facilities can prevent outbreaks among staff and residents. Specifically, the administration should begin providing weekly (or at a frequency recommended by regional public health officials) COVID-19 diagnostic tests to individuals incarcerated in federal correctional facilities and should publish testing data (while protecting incarcerated individuals' privacy). The administration should also conduct a review of funds distributed to nursing homes, behavioral health facilities, and other congregate settings in 2020 to identify facilities that (1) have not received sufficient aid and (2) serve low-income and medically

https://www.warren.senate.gov/imo/media/doc/Behavioral%20Health%20Facilities%20COVID19%20Report%2011.30.20%20final.pdf.

[44] Letter to CMS Administrator Seema Verma from Senators Elizabeth Warren, Edward J. Markey, and Representative Ayanna Pressley, April 9, 2020, https://www.warren.senate.gov/imo/media/doc/2020.04.09%20Letter%20to%20CMS%20re%20COVID%20demographic%20data.pdf.

underserved populations in need of additional financial resources. The administration should prioritize directing financial support to help facilities increase staffing, conduct COVID-19 tests, and distribute vaccines.

III. Supply chain challenges have hamstrung the nation's ability to control and mitigate the spread of the pandemic and have yet to be rectified through federal government efforts.

The Trump administration's response to the COVID-19 pandemic has been marred by repeated supply chain challenges, including shortages of personal protective equipment, materials for COVID-19 diagnostic tests, and other critical products. And the pandemic has exposed our nation's overreliance on foreign sources for pharmaceutical products and active pharmaceutical ingredients, creating significant public health and national security threats—all while the Trump administration has refused to invoke the Defense Production Act to use the nation's manufacturing capacity to address chronic and life-threatening shortages.

- **Testing and Personal Protective Equipment (PPE) Availability.** The chronic lack of sufficient COVID-19 testing has severely hampered the nation's ability to mitigate the pandemic. Without a robust testing strategy that ensures all Americans have access to a diagnostic test and timely results, the United States is struggling to adequately track and combat COVID-19. My staff's investigation of lab companies that are conducting COVID-19 testing found that supply shortages for diagnostic tests continue to be a significant impediment to quickly processing and delivering the results of these tests to patients.[45] Throughout the pandemic, the Trump administration has refused to take steps to increase the availability of these materials to lab companies.[46] Meanwhile, my office has consistently heard from health care providers and essential workers about their difficulties accessing PPE, making it hard for them to keep patients, workers, and consumers safe.

- **Reliance on Foreign Sources for Key Pharmaceutical Products.** The United States is heavily dependent on foreign sources of pharmaceutical products such as active pharmaceutical ingredients (API) and their raw materials. Only 28% of facilities manufacturing APIs used in drugs and 47% of facilities manufacturing finished dosage forms of drugs for the U.S. market are located in the United States.[47] My oversight work has revealed that the COVID-19 pandemic has highlighted this overreliance, leaving materials needed for diagnostic testing in short supply and finding that an interruption to the supply of APIs and other pharmaceutical products could have

[45] Letter from Senators Elizabeth Warren and Tina Smith to HHS Secretary Alex Azar, December 7, 2020, https://www.warren.senate.gov/imo/media/doc/2020.12.07%20Letter%20to%20HHS%20re%20testing%20investigations_updated1.pdf.
[46] New York Times, "Virus Surge Brings Calls for Trump to Invoke Defense Production Act," Aishvarya Kavi, July 22, 2020, https://www.nytimes.com/2020/07/22/us/politics/coronavirus-defense-production-act.html.
[47] "Securing the U.S. Drug Supply Chain: Oversight of FDA's Foreign Inspection Program," December 10, 2019, Testimony of Janet Woodcock, Director, Center for Drug Evaluation and Research, FDA, https://www.fda.gov/news-events/congressional-testimony/securing-us-drug-supply-chain-oversight-fdas-foreign-inspection-program-12102019; Active pharmaceutical ingredients 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." (World Health Organization, "Definition of Active Pharmaceutical Ingredient," July 2011.)

severe public health and national security implications, and that the Trump administration has failed to adequately address this risk.[48]

Recommendations. To address and rectify these concerns, the incoming administration should take the following actions:

1. **Fully utilize the Defense Production Act.** The Biden-Harris administration must utilize its full authorities under the Defense Production Act to stabilize the supply chain of PPE, diagnostic tests, therapeutics, drugs, and other medical products needed to combat COVID-19. According to the White House, the Trump administration has "used the Defense Production Act 18 times in connection with Operation Warp Speed."[49] But these efforts have been piecemeal, not systemic, prompting alarm that the U.S. may face a "vaccine cliff" in the spring and illustrating that these isolated uses of the DPA are not enough to mitigate shortages of COVID-19 medical products.[50] With regard to securing the vaccine supply specifically, the Biden-Harris administration can start by using DPA's broad authorities provided under 50 U.S.C. § 4555 to require information disclosure from pharmaceutical companies. This would allow the administration to gain insight into and ascertain information regarding American pharmaceutical companies' capabilities and capacity. Using the DPA in this manner would allow the federal government to fully understand the capacity of American manufacturers to retool factories and production lines for all features of a vaccine, including glass, dry ice, vials, and packaging, distribution, and storage. President-elect Biden should also employ Title I of the DPA, which gives the President authority to require businesses to accept and prioritize contracts or orders and "allocate materials, services, and facilities to promote the national defense," in order to compel other pharmaceutical companies' involvement in vaccine production if such companies will not voluntarily do so.[51] This information and technology transfer, organized and authorized at the federal level, would ensure the mobilization of capacity to scale-out manufacturing across production sites.

2. **Invest in domestic drug manufacturers through BARDA**. The Biden-Harris administration should direct BARDA to contract with U.S.-based manufacturers of APIs, raw materials, and finished medicines to produce these materials domestically and protect against future interruptions to the pharmaceutical supply chain. My *U.S. Pharmaceutical Supply Chain Defense and Enhancement Act* would provide this funding while also providing the federal government with additional transparency into the flow of these products to the country.

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[48] Letter from Senator Elizabeth Warren et al. to Department of Defense, December 9, 2019, https://www.warren.senate.gov/oversight/letters/in-bipartisan-letter-warren-cotton-kaine-and-romney-warn-of-national-security-and-public-health-risks-posed-by-chinas-influence-over-drug-supply-chain; Letter from Senators Elizabeth Warren and Tina Smith to Food and Drug administration, November 10, 2020, https://www.warren.senate.gov/newsroom/press-releases/warren-and-smith-question-fda-on-resuming-safety-inspections-for-foreign-pharmaceuticals-entering-the-united-states.

[49] *Id.*

[50] New York Times, "States Complain of Smaller Vaccine Shipments Than Expected," Katie Thomas and Sharon LaFraniere, December 17, 2020, https://www.nytimes.com/2020/12/17/health/pfizer-covid-vaccine-doses.html; Politico, "U.S. could face months of vaccine shortages amid global competition," Sarah Owermohle, December 8, 2020, https://www.politico.com/news/2020/12/08/coronavirus-vaccine-shortage-443839.

[51] Federal Emergency Management Agency, "Defense Production Act Authorities," June 23, 2020, https://www.fema.gov/disasters/defense-production-act/dpa-authorities#:~:text=DPA%20Title%20I%20%2D%20Priorities%20and,to%20maximize%20domestic%20energy%20supplies.

3. **Build public manufacturing capacity to develop essential drugs and COVID-19 materials.** The Biden-Harris administration must build the nation's capacity to publicly manufacture critical medical products. First, the administration can direct HHS to identify and begin manufacturing a set of critical products—such as materials needed to conduct COVID-19 diagnostic tests and develop COVID-19 vaccines. HHS should also consider manufacturing off-patent drugs facing limited competition and price hikes, drugs ins shortage, and drugs used by millions of Americans, like insulin, with prohibitive prices. By utilizing the federal government's compulsory licensing and march-in authorities, along with identifying off-patent drugs and devices, the federal government could manufacture, or contract for the manufacture of, affordable medical products for millions of Americans—keeping prices down for critical drugs and ensuring widespread access to necessary care. The Trump administration has failed to utilize these authorities or invest in this public manufacturing capacity, hampering the nation's medical supply chain during the pandemic. My *Affordable Drug Manufacturing Act* and *COVID-19 Emergency Manufacturing Act* provide roadmaps for the advancement of public manufacturing.

IV. Politicized pandemic response efforts have sidelined public health scientists and hampered the country's pandemic recovery.

Finally, one of the root causes of the Trump administration's failure to effectively respond to the COVID-19 pandemic is its inability and unwillingness to develop and implement public health policies that are guided by science, facts, and public health principles rather than the ego and political whims of the President. The Trump administration's repeated politicization of decisions by the FDA, CDC, HHS, and other federal agencies has caused confusion and delay and undermined public faith in the federal government's ability to coordinate a pandemic response effort driven by science. This political interference permeated all aspects of the pandemic response effort, including in:

- **Medical Supply Distribution.** The Trump administration's distribution of medical supplies from the Strategic National Stockpile lacked transparency, failed to provide timely supplies to states and people in need, and appeared to be improperly influenced by political considerations.[52] The supply distribution failure was exacerbated by President Trump's public statements suggesting that governors' political support for his administration could influence how much support they received from the federal government and by evidence that President Trump was using his influence to deliver medical supplies as a way to support vulnerable Republican Senators up for re-election in the fall.[53]

- **Public Health Communication Through CDC.** President Trump and other administration officials have repeatedly and publicly pressured federal public health agencies to delay, weaken, or undermine public health rules, guidelines, and recommendations in order to support the administration's political goals.[54] Specifically, the CDC has modified or revoked guidance on

[52] Letter from Senator Warren et al. to DHS Inspector General and HHS Principal Deputy Inspector General, April 21, 2020, https://www.warren.senate.gov/imo/media/doc/2020.04.21%20Letter%20to%20FEMA%20and%20HHS%20OIG%20re%20Distribution%20of%20Medical%20Supplies.pdf.
[53] *Id.*
[54] Letter from Senators Elizabeth Warren, Richard Blumenthal, and Edward J. Markey to Inspector General Michael Horowitz, August 25, 2020,

cruise ships,[55] churches,[56] and schools,[57] in response to political pressure. These incidents have undermined public confidence in the CDC and contributed to public confusion about how to protect public health during this crisis.

- **Testing Strategy**. In a misguided effort to protect his political standing as he sought reelection, President Trump focused on minimizing testing to reduce the number of reported cases of COVID-19 throughout the pandemic, even as that resulted in broader community spread. In June 2020, he tweeted that increasing tests "makes us look bad"[58] and asked his administration to "slow the testing down, please."[59] A comprehensive national testing plan was reportedly shelved after White House officials, including those close to the President's son-in-law, Jared Kushner, concluded the pandemic was primarily affecting Democratic states, and therefore could be blamed on Democratic governors.[60] As a result, there is still no comprehensive national strategy to ensure that testing capacity is sufficient and appropriately targeted to the areas with the highest need.[61]

- **Drug Approvals Through FDA.** The FDA has, on several occasions, appeared to bend to the political will of the Trump administration by issuing Emergency Use Authorizations (EUAs) for treatments that have limited evidence of effectiveness, including hydroxychloroquine[62] and convalescent plasma.[63] These approvals, which came amid considerable political pressure from President Trump and other administration officials, have undermined the agency's credibility,

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https://www.warren.senate.gov/imo/media/doc/2020.08.25%20Letter%20to%20PRAC%20re%20politicization%20of%20COVID%20response.pdf.

[55] Elizabeth Warren, "Warren, Colleagues Urge Pence to Protect Federal COVID-19 Response from Political Interference," press release, March 13, 2020, https://www.warren.senate.gov/oversight/letters/warren-colleagues-urge-pence-to-protect-federal-covid-19-response-from-political-interference; USA Today, "White House task force quietly softened cruise ship no-sail restrictions after months of industry deference," Curtis Tate, Morgan Hines, Cara Kelly, and Brett Murphy, April 13, 2020, https://www.usatoday.com/story/travel/cruises/2020/04/13/coronavirus-cruise-ships-saw-red-flags-amid-chaotic-federal-response/2937001001/.

[56] Associated Press, "In reversal, White House tells CDC to post church guidance," Zeke Miller and Mike Stobbe, May 21, 2020, https://apnews.com/92a389588798ef5fec4a722d6d073955.

[57] Letter from Senator Elizabeth Warren and Representative Andy Levin to Education Secretary DeVos and CDC Director Redfield, July 28, 2020, https://www.warren.senate.gov/imo/media/doc/2020.07.28%20Letter%20to%20EDCDC%20re%20politicization%20of%20school%20reopening%20guidelines.pdf; NPR, "Trump Pledges to 'Pressure' Governors to Reopen Schools Despite Health Concerns," Barbara Sprunt, July 7, 2020, https://www.npr.org/2020/07/07/888157257/white-house-pushes-to-reopen-schools-despite-a-surge-in-coronavirus-cases.

[58] Donald J. Trump, June 15, 2020, https://twitter.com/realDonaldTrump/status/1272532925460905984.

[59] Stat News, "Trump says more Covid-19 testing 'creates more cases.' We did the math," Sharon Begley, July 20, 2020, https://www.statnews.com/2020/07/20/trump-said-more-covid19-testing-creates-more-cases-we-did-the-math/.

[60] Vanity Fair, "How Jared Kushner's Secret Testing Plan 'Went Poof Into Thin Air,'" Katherine Eban, July 30, 2020, https://www.vanityfair.com/news/2020/07/how-jared-kushners-secret-testing-plan-went-poof-into-thin-air.

[61] Letter from Senators Elizabeth Warren, Richard Blumenthal, and Edward J. Markey to Inspector General Michael Horowitz, August 25, 2020, https://www.warren.senate.gov/imo/media/doc/2020.08.25%20Letter%20to%20PRAC%20re%20politicization%20of%20COVID%20response.pdf.

[62] ABC News, "Timeline: Tracking Trump alongside scientific developments on hydroxychloroquine," Libby Cathey, August 8, 2020, https://abcnews.go.com/Health/timeline-tracking-trump-alongside-scientific-developments-hydroxychloroquine/story?id=72170553.

[63] Politico, "FDA authorizes plasma treatment despite scientists' objections," Zachary Brennan and Sara Owermohle, August 23, 2020, https://www.politico.com/news/2020/08/23/plasma-treatment-coronavirus-fda-trump-400390.

which may have contributed to public skepticism about a future vaccine; in May, only 49% of American adults, and only 25% of Black Americans, told pollsters that they planned to accept a COVID-19 vaccine.[64]

Recommendations. I look forward to working with you as you seek to prioritize science, improve transparency, and find ways to insulate our scientific public health agencies from political interference in the future, including by:

1. **Empower HHS, NIH, FDA, and CDC leadership to run their agencies without political interference.** Time and again, throughout the COVID-19 pandemic, heads of scientific and public health agencies have folded in response to President Trump's demands instead of following the science.[65] The Biden-Harris administration must appoint qualified and dedicated public servants to lead HHS, FDA, CDC, and other public health agencies, who will stand up for the agencies' scientists and public health experts. These individuals must be empowered to run the agencies without political interference and strengthen Scientific Integrity policies at their agencies to ensure that scientists are empowered to act on their findings.

2. **Pursue apolitical public health communications campaigns through CDC.** The Biden-Harris administration must strengthen public outreach efforts and allow public health professionals and the public to hear directly from CDC scientists, without censorship or filtering from political officials. As a result of the Trump administration's aversion to fact-based public messaging that would undermine President Trump's political agenda or image, political appointees have "intimidate[d] …[CDC] reports' authors and water[ed] down their communications to health professionals;"[66] the public knows little about concerning public health trends: for example, the alarming rates of excess mortality in the country[67] or the lasting, long-term impacts of COVID-19.[68] In addition to investing more research into these public health questions, the Biden-Harris administration must put in place stronger protections to allow officials at public health agencies to freely communicate their findings and recommendations.

3. **Use CDC's full legal authority to implement public health measures.** My oversight work has indicated that the CDC has expansive legal authority to implement and enforce public health measures, such as mask mandates, restrictions on gatherings, and reversing re-openings.[69] But

[64] Associated Press, "AP-NORC poll: Half of Americans would get a COVID-19 vaccine," Lauran Neergaard and Hannah Fingerhut, May 27, 2020, https://apnews.com/dacdc8bc428dd4df6511bfa259cfec44.
[65] Letter from Senators Elizabeth Warren, Gary Peters, and Patty Murray to GAO Comptroller Gene Dodaro, October 8, 2020, https://www.warren.senate.gov/imo/media/doc/2020.10.08%20Letter%20to%20GAO%20re%20Scientific%20Integrity%20and%20Independence%20at%20FDA%20and%20CDC.pdf.
[66] Politico, "Trump officials interfered with CDC reports on Covid-19," Dan Diamond, September 11, 2020, https://www.politico.com/news/2020/09/11/exclusive-trump-officials-interfered-with-cdc-reports-on-covid-19-412809.
[67] Letter from Senators Elizabeth Warren, Tammy Baldwin, and Tina Smith to HHS Secretary Alex Azar and CDC Director Robert Redfield, October 29, 2020, https://www.warren.senate.gov/newsroom/press-releases/warren-baldwin-smith-request-information-on-hhs-and-cdc-efforts-to-understand-and-respond-to-alarming-excess-mortality-amid-covid-19-pandemic.
[68] Letter from Senators Elizabeth Warren, Tammy Baldwin, Tina Smith, and Bernard Sanders to Vice President Mike Pence, July 23, 2020, https://www.warren.senate.gov/newsroom/press-releases/warren-colleagues-question-the-trump-administrations-efforts-to-understand-and-inform-americans-about-the-chronic-health-effects-of-covid-19.
[69] Letter from Senator Elizabeth Warren to CDC Director Robert Redfield, July 20, 2020, https://www.warren.senate.gov/imo/media/doc/2020.07.20%20Letter%20to%20CDC%20re%20quarantine%20and%20isolat

the agency has not used its full suite of tools, which have become heavily politicized as a result of the Trump administration's pandemic response. Section 361 of the Public Health Service Act (42 U.S. Code 264) authorizes the HHS Secretary to "take measures to prevent the entry and spread of communicable disease from foreign countries into the United States and between states."[70] The authorities under 42 CFR, Part 70 on Interstate Quarantine were delegated to the CDC to address significant public health threats that cross state and municipal borders and therefore cannot be controlled by a single state or community—such as the ongoing COVID-19 pandemic.[71]

Conclusion

The Trump administration's failed COVID-19 response has resulted in an ongoing national tragedy, with over 375,000 Americans killed by the disease, millions more seriously ill, and the economy in shambles.[72] You must act quickly to turn the federal government's response around and end this public health emergency. I look forward to working with you to do so, and I hope that these recommendations based on my oversight work over the last year assist your response.

ion%20authorities.pdf; Elizabeth Warren, "As COVID-19 Spreads Out of Control, CDC Declines to Use Authority to Stem the Surge," Press Release, August 14, 2020, https://www.warren.senate.gov/newsroom/press-releases/as-covid-19-spreads-out-of-control-cdc-declines-to-use-authority-to-stem-the-surge.

[70] Centers for Disease Control and Prevention, "Quarantine and Isolation Legal Authorities," https://www.cdc.gov/quarantine/aboutlawsregulationsquarntineisolation.html.

[71] Letter from Senator Elizabeth Warren to CDC Director Redfield, July 20, 2020, https://www.warren.senate.gov/imo/media/doc/2020.07.20%20Letter%20to%20CDC%20re%20quarantine%20and%20isolation%20authorities.pdf.

[72] Centers for Disease Control and Prevention, "United States COVID-19 Cases and Deaths by State," last updated January 12, 2021, https://covid.cdc.gov/covid-data-tracker/#cases_casesper100klast7days.