United States Senate Committee on
Homeland Security & Governmental Affairs
U.S. Senator Gary Peters | Ranking Member

ROAD TO RECOVERY:

ADMINISTRATION MUST BUILD PUBLIC TRUST AND ENSURE SAFE, EFFECTIVE, AND FREE CORONAVIRUS VACCINES

A HSGAC Minority Staff Report

Road to Recovery: Administration Must Build Trust and Ensure Safe, Effective, and Free Coronavirus Vaccines

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Executive Summary

Public health preparedness is an issue of national security. As of this report, the novel coronavirus (COVID-19) pandemic has infected more than 8 million Americans, and taken the lives of more than 220,000, leaving the United States to represent the highest number of cases and deaths in the world. The Trump Administration's failure to establish a comprehensive response that includes a surge in testing, contact tracing, and the availability of personal protective equipment (PPE), as well as the Administration's continued political interference in what should be a science-based public health response, has made combating this pandemic even harder.

A safe and effective vaccine that is free of charge and widely available to all Americans is an essential factor in reducing the spread of COVID-19. As of September 1, 2020, taxpayers have invested about $12.6 billion in vaccine development and manufacturing through Operation Warp Speed, a public-private partnership set up under the Department of Health and Human Services (HHS) to expedite the development and, once approved, widespread distribution of a vaccine. Operation Warp Speed aims to expedite what is ordinarily a lengthy, multi-year timeline by streamlining critical steps to accelerate the development, manufacture, and distribution of a potential vaccine. This program has set a goal of making an initial 300 million doses of COVID-19 vaccines available by January 2021. Despite these efforts, critical aspects of an effective vaccine development and distribution plan must still be addressed to fully prepare the U.S. to equitably deliver safe and effective COVID-19 vaccines to every American who wants one.

Although the federal government has significant experience mobilizing widespread vaccine campaigns, specifically with regard to influenza, the Trump Administration failed to release its vaccine distribution strategy until mid-September 2020. As part of this strategy, states were required to submit their own comprehensive immunization plans to the Centers for Disease Control and Prevention (CDC) by October 16, 2020 – a much too short timeframe of one month. Mass production and distribution of COVID-19 vaccines will be a novel and uncharted endeavor and the Trump Administration has not yet taken sufficient steps to prepare the American people for this effort. Repeated and sustained political interference in key scientific decisions, including the vaccine approval and authorization process, has further undermined the public confidence necessary to ensure Americans are willing to receive a COVID-19 vaccine.

This report, undertaken at the direction of U.S. Senator Gary Peters, Ranking Member of the Homeland Security and Governmental Affairs Committee, identifies critical gaps in the Administration's vaccine preparedness measures and recommends essential actions to strengthen our nation's response and speed the return to a post-pandemic world. More than nine months since President Trump learned about the severity and lethality of the coming COVID-19 pandemic, the United States still lacks a comprehensive national plan to combat the virus and continues to struggle securing N95 respirators and testing reagents, putting all Americans at increased risk.

To ensure the swift and equitable distribution of COVID-19 vaccines once available, the Administration must implement an inclusive and comprehensive vaccine strategy rooted in science and transparency. The Administration must also ensure pharmaceutical companies that have received billions in taxpayer funding to develop and manufacture vaccines are held accountable to the taxpayers, and that any vaccine is safe, free, and widely available to every American.

Findings of Fact and Recommendations

Findings of Fact

1. **The Trump Administration's politicization of the COVID-19 response and failure to provide clear, consistent, and evidence-based information has eroded public trust in any COVID-19 vaccine:** Americans' willingness to receive an eventual vaccine has fallen dramatically since the spring, as concerns about politicization have increased. Millions of Americans will need to be vaccinated to mitigate the spread of the virus.

2. **The Trump Administration has failed to provide states with sufficient amounts of critical supplies needed to combat COVID-19:** While the federal government has made progress in bolstering domestic production of critical ancillary supplies for vaccines, like needles and syringes, the U.S. is still facing shortages of PPE, including N95 respirators, that are critical to reducing the spread of COVID-19 and safely administering an eventual vaccine.

3. **COVID-19 has disproportionately affected communities of color, but the Administration's Playbook does not adequately account for these disparities:** Communities of color face double the risk of contracting and dying from COVID-19 compared to white communities. These disparities are due to a multitude of factors, including systemic health, economic, and social inequities that the Trump Administration has failed to take into account in its plans to distribute eventual COVID-19 vaccines.

4. **The Administration's Playbook does not sufficiently address how vaccine distribution will be funded:** Although the Administration has provided states, territories, and Tribes with guidance for vaccine distribution planning, these jurisdictions still need funding and additional resources to effectively carry out their plans. The Administration has not provided support for maintenance of adequate information technology systems, communications with the public, or vaccine administration. The CDC recently disbursed $200 million to states to prepare for vaccine distribution; however, according to CDC Director Redfield's September testimony before Congress, approximately $6 billion is still needed. Federal funding is critical to ensuring equitable and safe vaccine distribution.

5. **COVID-19 vaccines should be provided at no cost to all Americans; however, the Trump Administration has not been fully transparent about the eventual cost to individuals for a vaccine:** Although Congress and the Administration have taken steps to ensure that vaccines are widely available and covered with no out of pocket costs for consumers through most private insurance plans, Medicaid, and Medicare, potential coverage gaps remain, particularly for Medicare beneficiaries when a vaccine is provided under an Emergency Use Authorization (EUA), the uninsured, and the underinsured. Some pharmaceutical companies have pledged not to profit off their COVID-19 vaccines, while others have failed to definitively state they will not take advantage of this pandemic for profit.

Recommendations

1. **The Administration must immediately commit to and enact full transparency in the vaccine development, approval, and distribution processes:** Pharmaceutical companies should release, to the extent practicable, safety and effectiveness data from their clinical trials, once available; the Office of Management and Budget (OMB) should ensure transparency in the regulatory review process; the federal government should release more information regarding the terms of contracts and agreements with private industry for COVID-19 vaccines; and the CDC should publish its framework, once available, for determining distribution and allocation so the public can be assured that a vaccine is free, safe, effective, and equitably distributed.

2. **Science, not politics, must drive the release of a COVID-19 vaccine:** The White House must stop interfering in scientific decisions, including the Emergency Use Authorization (EUA) process, and public health experts must develop an evidence-based, transparent communications strategy on COVID-19 vaccines. Congress must pass the *Science and Transparency Over Politics Act*, S. 4638, cosponsored by Senator Peters, which would charge agency watchdogs with investigating political interference in the COVID-19 response – ensuring oversight and transparency. Congress should also combat vaccine misinformation and disinformation by passing Senator Peters' *COVID-19 Disinformation Task Force Act*, S. 4499, to inform the public about the risks of pandemic-related misinformation and disinformation.

3. **The CDC should release a detailed plan to address racial disparities in vaccine distribution:** For a vaccine to be effective, it must be widely distributed and accessible to all communities, especially those hardest hit by COVID-19. The Administration must articulate how vaccine distribution will address racial disparities and how the federal government will build trust with communities of color. This plan should include tracking demographic distribution data to ensure transparent and equitable distribution.

4. **The Trump Administration must ensure every community in the country has the resources needed for equitable vaccine distribution:** The Administration should ensure all states, Tribes, and territories have the resources they need to implement their plans in order to safely and equitably distribute COVID-19 vaccines and request additional appropriations from Congress to ensure this, if necessary.

5. **The Administration must take swift action to invest in the critical supplies necessary to combat COVID-19 and plan for longer-term investments in domestic advanced manufacturing of these supplies:** COVID-19 has exposed the many vulnerabilities of our medical supply chain. Throughout this pandemic, the Administration should ensure the availability of critical supplies through its authorities under the *Defense Production Act*. To be prepared for the next crisis, Congress must pass the *HOME Act*, S. 3780, introduced by Senator Peters, which would invest in domestic advanced manufacturing and encourage agencies to enter into long-term contracts for critical drugs and supplies.

6. **Congress and the Administration must ensure that a vaccine is available free of cost to every individual and that pharmaceutical companies are held accountable:** The Administration must commit to ensuring uninsured and underinsured Americans, as well as Medicare beneficiaries, have access to a vaccine free of charge. Pharmaceutical companies that received taxpayer funding for vaccine development and manufacturing should pledge not to profit off of a pandemic.

I. THE ADMINISTRATION MUST ENSURE SAFETY AND EFFICACY OF COVID-19 VACCINES AND BUILD PUBLIC TRUST

The Trump Administration's Strategy for Distributing a COVID-19 vaccine, released on September 16, 2020, set a goal of "ensuring that every American who wants to receive a COVID-19 vaccine can receive one."[1] As the pandemic spread across the U.S. in March 2020, President Trump made a similar, but unfulfilled, promise to the American people when he said, "anyone who wants a [COVID-19] test can get a test."[2] In order to achieve the Administration's goal that every American will have access to a COVID-19 vaccine, the Administration must ensure any vaccine adheres to stringent scientific standards to guarantee safety and effectiveness for eventual distribution. The federal government must also take all possible steps to build public trust by engaging in transparent and active communications with the public and key stakeholders in a consistent, evidence-based manner. Unfortunately, the opposite has occurred.

Public willingness to take a COVID-19 vaccine has fallen dramatically. Since April 2020, the percentage of U.S. adults who say they will get vaccinated for COVID-19 has decreased by 21 points, from 72% to 51%.[3] At the same time, nearly two-thirds of Americans are concerned that, due to political pressure from the Administration, the FDA will rush to approve a vaccine without first ensuring it is safe and effective.[4] People in Michigan report similar concerns, with a third of voters stating they would not get a COVID-19 vaccine, even if it was recommended by their doctor.[5] This shift in public opinion is in direct response to repeated and increasing revelations that top Trump Administration officials have taken actions that supersede scientific and expert recommendations for COVID-19 response efforts. Because of this extraordinary political interference, urgent action is now needed to safeguard the scientific process at our nation's public health agencies, ensure the development of a safe and effective vaccine, and rebuild the trust of the American people.

A. Vaccine Development Must Be Apolitical and Rooted in Science

To determine if a vaccine is safe and effective, it must first be evaluated through rigorous testing and clinical trials. As of September 23, 2020, four COVID-19 vaccine candidates supported by Operation Warp Speed are in Phase III clinical trials, the final stage before a vaccine is authorized for emergency use or licensed (i.e. approved) by the FDA if found adequately safe and effective.[6] To build public trust in the rigor of these trials, all four developers have released the clinical protocols for their studies.[7] All four clinical trials are also being

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[1] Department of Health and Human Services, *From the Factory to the Frontlines: The Operation Warp Speed Strategy for Distributing a COVID-19 Vaccine* (Sept. 16, 2020) (hereinafter "HHS OWS Distribution Strategy").

[2] *Anyone Who Wants a Coronavirus Test Can Have One, Trump Says. Not Quite, Says His Administration*, New York Times (Mar. 7, 2020) (https://www.nytimes.com/2020/03/07/us/politics/trump-coronavirus-messaging.html).

[3] *A Trend That Worries Health Experts: As U.S. Gets Closer to COVID-19 Vaccine, Fewer People Say They'd Get One*, Morning Consult (Sept. 11, 2020) (https://morningconsult.com/2020/09/11/vaccine-acceptance-public-poll/).

[4] Kaiser Family Foundation, *KFF Health Tracking Poll - September 2020: Top Issues in 2020 Election, The Role of Misinformation, and Views on A Potential Coronavirus Vaccine* (Sept. 10, 2020) (https://www.kff.org/coronavirus-covid-19/report/kff-health-tracking-poll-september-2020/).

[5] *More than a third of Michigan voters say they won't get vaccinated against COVID-19*, Detroit News (Oct. 6, 2020) (https://www.detroitnews.com/story/news/local/michigan/2020/10/07/one-third-michigan-voters-wont-get-fda-approved-covid-19-vaccine/5899708002/).

[6] National Institutes of Health, *Fourth large-scale COVID-19 vaccine trial begins in the United States* (Sept. 23, 2020).

[7] *AstraZeneca, Under Fire for Vaccine Safety, Releases Trial Blueprints*, New York Times (Sept. 19, 2020) (https://www.nytimes.com/2020/09/19/health/astrazeneca-vaccine-safety-blueprints.html); *Johnson & Johnson's Vaccine*

monitored by a Data and Safety Monitoring Board (DSMB), an independent group of experts who review clinical trial data for safety and scientific merit and make recommendations regarding the study.[8] DSMB panels have been described by one bioethicist as the "key guardians of science and safety."[9] Of the four vaccine candidates, AstraZeneca's U.S. clinical trials are currently on hold due to a suspected adverse reaction as the FDA investigates, and Johnson & Johnson has paused its clinical trial after one study participant experienced an unexplained illness.[10] Pauses in vaccine trials are not uncommon, according to experts such as Dr. Anthony Fauci, the Director of the National Institute of Allergy and Infectious Diseases.[11] Moderna and Pfizer's clinical trials continue.

In the United States, before a vaccine can be made available, it must first be licensed or authorized for emergency use by the FDA. During certain emergency circumstances, the FDA may issue an EUA, temporarily allowing the use of an unapproved medical product that, based on the available evidence, "may be effective" and whose "known and potential benefits" outweigh the "known and potential risks."[12] However, because the EUA process typically requires a lower burden of proof for effectiveness than the FDA's standard licensure process, public transparency and rigorous guidance for any EUA-authorized vaccine is critical. In an effort to ensure transparency, the FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) will meet publicly to discuss the "development, authorization, and/or licensure of vaccines to prevent COVID-19." Ultimately, before the FDA issues an EUA, it plans to hold a public meeting of its VRBPAC to "discuss whether the available safety and effectiveness data support authorization of an EUA for the specific request under review."[13]

The Administration's lack of transparency and political pressure in scientific processes has undermined the work of our public health experts, the global effort to identify safe and effective vaccines, and the public trust. Reports indicate the Administration has either altered or pressured the CDC into altering scientific reports and guidance for cruise ships, in-person learning at schools, and COVID-19 diagnostic testing.[14] One report indicated that the White

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Advances, Sparking Optimism in Race, New York Times (Sept. 23, 2020) (https://www.nytimes.com/2020/09/23/health/covid-19-vaccine-johnson-and-johnson.html).

[8] Food and Drug Administration, *Guidance for Clinical Trial Sponsors* (Mar. 2006) (https://www.fda.gov/media/75398/download).

[9] *The secretive group at the center of the nation's largest vaccine trials*, CNN Health (Oct. 3, 2020) (https://www.cnn.com/2020/10/03/health/dsmb-role-coronavirus-vaccine-trial/index.html). Moderna, AstraZeneca, and Johnson & Johnson all share the same DSMB because they are being funded by the federal government. Pfizer has a different DSMB because they are funding their own clinical trials.

[10] *As AstraZeneca's Covid-19 vaccine trial remains on hold in U.S., participants waiting on a second dose are in limbo*, STAT News (Oct. 6, 2020) (https://www.statnews.com/2020/10/06/astrazeneca-covid19-second-dose-trial-vaccine/); *Johnson & Johnson Covid-19 vaccine study paused due to unexplained illness in participant*, STAT News (Oct. 13, 2020) (https://www.statnews.com/2020/10/12/johnson-johnson-covid-19-vaccine-study-paused-due-to-unexplained-illness-in-participant/).

[11] *Fauci: Pausing vaccine trial for safety review is "not uncommon at all,"* Axios (Sept. 9. 2020) (https://www.axios.com/astrazeneca-vaccinie-phase-3-fauci-covid-45460394-aeb0-4608-a818-7f712c1706c3.html); *3 Covid-19 Trials Have Been Paused for Safety. That's a Good Thing*, New York Times (Oct. 14, 2020) (https://www.nytimes.com/2020/10/14/health/covid-clinical-trials.html).

[12] 21 U.S.C. § 360bbb-3(c).

[13] Food and Drug Administration, *Vaccines and Related Biological Products Advisory Committee* (accessed Oct. 13, 2020); Food and Drug Administration, *Emergency Use Authorization for Vaccines to Prevent COVID-19: Guidance for Industry* (Oct. 2020).

[14] *Scoop: CDC director overruled on cruise ship ban,* Axios (Sept. 29, 2020) (https://www.axios.com/scoop-white-house-overruled-cdc-cruise-ships-florida-91442136-1b8e-442e-a2a1-0b24e9a39fb6.html); *C.D.C. Testing Guidance Was Published Against Scientists' Objections,* New York Times, (Sept. 17, 2020) (https://www.nytimes.com/2020/09/17/health/coronavirus-

House entirely blocked CDC guidance that would have required face masks on public transportation.[15] Concerns of political interference also extend to the FDA, which issued EUAs for hydroxychloroquine and convalescent plasma as treatments for COVID-19 only after consistent pressure from the White House and the President. The FDA was forced to revoke the hydroxychloroquine EUA following mounting evidence of its potentially serious side effects and lack of effectiveness.[16]

Efforts by the FDA, CDC, and other public health agencies to address public concerns about vaccine safety and effectiveness have been repeatedly undermined by political officials, including the President himself, who has linked the timing of vaccine availability to the upcoming 2020 election.[17] After the FDA submitted draft guidance for COVID-19 vaccine EUA – with strict safety standards – for review by the Office of Management and Budget (OMB), a part of the Executive Office of the President, the Administration failed to include the guidance on its public tracking system (RegInfo.gov). The day after news of the guidance broke, the President threatened not to approve it. The White House has since approved the guidance, but only after it initially blocked the guidance entirely and the FDA released a version of the guidance on its own.[18] These types of actions increase politicization concerns in what should be an independent and scientifically rigorous process.

The FDA's COVID-19 EUA guidance requires all Phase III trials to provide data for a "median follow-up duration of at least two months after completion of the full vaccination regimen," so that FDA can thoroughly assess adverse events and other risk-benefit data.[19] Dr. Peter Marks, Director of the FDA Center for Biologics Evaluation and Research, explained that generally, when examining data on vaccination safety and effectiveness, the median timeframe when most adverse events occur is between two to three months. Dr. Marks described this

testing-cdc.html); *Behind the White House Effort to Pressure the C.D.C. on School Openings*, New York Times (Sept. 28, 2020) (https://www.nytimes.com/2020/09/28/us/politics/white-house-cdc-coronavirus-schools.html); Johnson & Johnson, *Political Appointees Meddled in CDC's 'Holiest of the Holy' Health Reports*, New York Times (Sept. 12, 2020) (https://www.nytimes.com/2020/09/12/us/politics/trump-coronavirus-politics-cdc.html).

[15] *White House Blocked C.D.C. From Requiring Masks on Public Transportation*, New York Times (Oct. 9, 2020) (https://www.nytimes.com/2020/10/09/health/coronavirus-covid-masks-cdc.html).

[16] *Trump Pressed for Plasma Therapy. Officials Worry, Is an Unvetted Vaccine Next?*, New York Times (Sept. 12, 2020) (https://www.nytimes.com/2020/09/12/us/politics/trump-coronavirus-treatment-vaccine.html); *Former FDA leaders decry emergency authorization of malaria drugs for coronavirus,* Science Magazine, (Apr. 7, 2020) (https://www.sciencemag.org/news/2020/04/former-fda-leaders-decry-emergency-authorization-malaria-drugs-coronavirus); Food and Drug Administration: *Coronavirus (COVID-19) Update: FDA Revokes Emergency Use Authorization for Chloroquine and Hydroxychloroquine* (June 15, 2020).

[17] *Trump claims White House can overrule FDA's attempt to toughen guidelines for coronavirus vaccine*, CNN (Sept. 24, 2020) (https://www.cnn.com/2020/09/23/politics/trump-fda-coronavirus-vaccine/index.html).

[18] *White House Blocks New Coronavirus Vaccine Guidelines*, New York Times (Oct. 5, 2020); (https://www.nytimes.com/2020/10/05/us/politics/coronavirus-vaccine-guidelines.html); *White House lifts block on FDA's stricter vaccine requirements*, Politico (Oct. 6, 2020) (https://www.politico.com/news/2020/10/06/fda-vaccine-guidelines-white-house-426764).

[19] Food and Drug Administration, *Emergency Use Authorization for Vaccines to Prevent COVID-19: Guidance for Industry* (Oct. 2020).

timeframe as "not too aggressive, [but] not too conservative."[20] Despite this evidence-based rationale, President Trump referred to the FDA's EUA guidance as "another political hit job."[21]

Transparency must also come from the pharmaceutical companies developing these vaccines. Clinical trials should be comprised of diverse populations, including representation from communities of color. The National Institutes of Health (NIH) have engaged in community outreach efforts to help ensure that "clinical trials include the racial and ethnic minority populations most affected by the pandemic," but the effectiveness of this effort is unclear.[22] Thus far, only Moderna and Johnson & Johnson discuss the need to proactively ensure adequate representation for racial and ethnic communities who have been disproportionately impacted by COVID-19 in their plans for Phase III clinical trials.[23] In early September, Moderna announced that it would slow down their enrollment to ensure diversity in its vaccine trials. As of August 28, 2020 only 24% of Moderna participants were from communities of color. As of October 9, 2020, only 34.5% of participants were from "diverse communities."[24] Pfizer reports similar representation, with only 29% of its participants having "diverse backgrounds." Of this number, only 10% are African-Americans and 13% are Hispanic/Latinx while 72% of participants are white.[25] Diverse representation in clinical trials is critical to ensuring vaccine efficacy for all Americans and building public trust in an eventual vaccine.

In addition, although there are over 200 vaccine candidates being tested worldwide, the Trump Administration has refused to participate in the COVID-19 Vaccines Global Access (COVAX) Facility, a global initiative to develop, manufacture, and equitably distribute a vaccine that has engaged over 170 countries.[26] By refusing to participate in COVAX, the Administration

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[20] Dr. Peter Marks, Food and Drug Administration, Director of the Center for Biologics Evaluation and Research, Remarks at Johns Hopkins University and University of Washington Vaccine Symposium, Panel on Regulatory Integrity and the Assessment of Vaccine Safety and Efficacy (Oct. 6, 2020); *FDA Sets Goals That May Put Vaccine Out of Reach Before Vote*, Bloomberg (Oct. 6, 2020) (https://www.bloomberg.com/news/articles/2020-10-06/fda-to-demand-two-months-safety-data-expert-review-for-vaccine).

[21] Donald Trump, Twitter post (Oct. 6, 2020, 9:09 pm) (https://twitter.com/realdonaldtrump/status/1313647605134614529).

[22] National Institutes of Health, *The Community Engagement Alliance (CEAL) Against COVID-19 Disparities* (accessed Oct. 7, 2020).

[23] AstraZeneca AB, *A Phase III Randomized, Double-blind, Placebo-controlled Multicenter Study in Adults to Determine the Safety, Efficacy, and Immunogenicity of AZD1222, a Non-replicating ChAdOx1 Vector Vaccine, for the Prevention of COVID-19* (Sept. 17, 2020) (IND 23522); Janssen Vaccines & Prevention B.V., *A Randomized, Double-blind, Placebo-controlled Phase 3 Study to Assess the Efficacy and Safety of Ad26.COV2.S for the Prevention of SARS-CoV-2-mediated COVID-19 in Adults Aged 18 Years and Older* (Sept. 15, 2020) (IND 22657); ModernaTX, Inc., *A Phase 3, Randomized, Stratified, Observer-Blind, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Immunogenicity of mRNA-1273 SARS-CoV-2 Vaccine in Adults Aged 18 Years and Older* (Aug. 20, 2020) (IND 19745); Pfizer, *A Phase 1/2/3 Study to Evaluate the Safety, Tolerability, Immunogenicity, and Efficacy of RNA Vaccine Candidates Against COVID-19 in Healthy Individuals* (IND 19736).

[24] *Moderna slows coronavirus vaccine trial enrollment to ensure minority representation, CEO says,* CNBC (Sept. 4, 2020) (https://www.cnbc.com/2020/09/04/moderna-slows-coronavirus-vaccine-trial-t-to-ensure-minority-representation-ceo-says.html); Moderna, *COVE Study: Participate to Make a World of Difference – Enrollment Updates* (accessed Oct. 13, 2020) (https://www.modernatx.com/cove-study).

[25] Pfizer, *Our Progress in Developing a Potential COVID-19 Vaccine* (accessed Oct. 13, 2020) (https://www.pfizer.com/science/coronavirus/vaccine); *Two Black university leaders urged their campuses to join a Covid-19 vaccine trial. The backlash was swift,* STAT News (Oct. 12, 2020) (https://www.statnews.com/2020/10/12/two-black-university-leaders-urged-their-campuses-to-join-a-covid-19-vaccine-trial-the-backlash-was-swift/?utm_source=STAT+Newsletters&utm_campaign=2d94c4eebf-Daily_Recap&utm_medium=email&utm_term=0_8cab1d7961-2d94c4eebf-151589117).

[26] Milken Institute, COVID-19 Treatment and Vaccine Tracker (https://covid-19tracker.milkeninstitute.org/) (accessed Sept. 23, 2020); *U.S. says it won't join WHO-linked effort to develop, distribute coronavirus vaccine*, Washington Post (Sept. 1, 2020) (https://www.washingtonpost.com/world/coronavirus-vaccine-trump/2020/09/01/b44b42be-e965-11ea-bf44-0d31c85838a5_story.html).

risks Americans not getting access to the first proven vaccines. Further, even if one of the U.S. funded vaccines is successful, not investing in our allied countries and allowing COVID-19 to spread abroad threatens American lives and would likely continue to depress the U.S. economy, which depends on international markets. As we have seen, viruses know no borders and can easily move from one part of the world to the next. Ensuring that a vaccine is available across the globe is a key aspect of overcoming this pandemic.

B. Clear and Consistent Communication Is Critical

Political interference continues to undermine public confidence in an eventual COVID-19 vaccine. In a public health crisis, an effective response hinges on the government's ability to provide clear and consistent information that the public trusts about what is known and not known.[27] The Trump Administration's communications about the COVID-19 pandemic have disrupted public health goals, caused significant confusion, and politicized evidence-based decisions made by career scientists. President Trump has made discredited and factually inaccurate statements about both the risks posed by the pandemic as well as potential treatments. He has also admitted knowingly misleading the public regarding his understanding of the deadliness of the virus.[28]

After a series of reports alleging political interference at the CDC and FDA, 78 health care stakeholders – including the American Medical Association, American Nurses Association, and others – signed a letter urging the federal government to make COVID-19 decisions based on evidence, not politics, and to clearly explain to the public the processes in place to ensure scientific rigor in vaccine development.[29] The New England Journal of Medicine, a preeminent nonpartisan medical journal, published an editorial – one of only four that has been signed by all of the editors in the Journal's 208-year history – expressing concern about the Administration's "dangerous incompetence" and noting that, despite its investments in vaccine development, the Administration's "rhetoric has politicized the development process and led to growing public distrust." As a result, "they have taken a crisis and turned it into a tragedy."[30]

Experience has shown that, even when a safe and effective vaccine is readily available, the public may be reluctant to take it, particularly in the midst of concerns about safety or politicization.[31] The Administration's strategic plan for vaccine distribution acknowledges the first step in any successful effort is communication with stakeholders and the public.[32] To be effective, these campaigns must be strategic, evidence-based, and grounded in research involving target populations. Any successful information campaign must also address misinformation and

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[27] Centers for Disease Control and Prevention, *Crisis & Emergency Risk Communication (CERC)* (accessed Oct. 7, 2020).

[28] *Woodward book: Trump says he knew coronavirus was 'deadly' and worse than the flu while intentionally misleading Americans*, The Washington Post (Sept. 9, 2020) (https://www.washingtonpost.com/politics/bob-woodward-rage-book-trump/2020/09/09/0368fe3c-efd2-11ea-b4bc-3a2098fc73d4_story.html).

[29] Alliance for Aging Research, *Science – Not Politics – Will Lead Us Out of COVID-19* (Sept. 22, 2020) (https://www.agingresearch.org/app/uploads/2020/09/Follow-the-Science-Group-Letter_FINAL.pdf).

[30] Eric J. Rubin, et al., *Dying in a Leadership Vacuum, New* England Journal of Medicine (Oct. 8, 2020); *In a First, New England Journal of Medicine Joins Never-Trumpers*, New York Times (Oct. 7, 2020) (https://www.nytimes.com/2020/10/07/health/new-england-journal-trump.html).

[31] *With Covid-19, Vaccine Messaging Faces an Unprecedented Test*, Undark Magazine (Sept. 23, 2020) (https://undark.org/2020/09/23/covid-19-vaccine-messaging/).

[32] HHS OWS Distribution Strategy, *supra* note 1.

disinformation about COVID-19, which has flourished online and on social media – prompting the World Health Organization to label the problem an "infodemic."[33]

The Administration has vowed that HHS will engage in an information campaign focused on vaccine safety and effectiveness, targeted to key populations and communities, developed in consultation with stakeholders, and based in research.[34] However, details of this campaign's development or timing are not readily available. Further, although the Administration has released a Vaccination Program Interim Playbook ("Playbook") for states, territories, Tribes, and localities with guidance on planning for a vaccine, including on how to engage in effective public communication, it is unclear if and when jurisdictions will receive the resources needed to run successful vaccination campaigns.[35] Meanwhile, the Administration has reportedly diverted $300 million to an advertising campaign spearheaded by political appointees, rather than public health experts, to "defeat despair" about COVID-19 in the lead-up to the November election.[36]

II. THE ADMINISTRATION MUST ADDRESS ONGOING SHORTAGES AND CONTINUE TO INVEST IN CRITICAL SUPPLIES

The COVID-19 pandemic has exposed the many vulnerabilities of our medical supply chain, from delivery models in which products are provided on an "as needed" basis to our overreliance on foreign sources for critical drugs and medical supplies. In December 2019, Ranking Member Peters released a Minority staff report that found the U.S. does not have the capability to independently manufacture the supplies necessary for administering a vaccine in the event of a pandemic.[37] As the report highlights, the former Director of HHS's Strategic National Stockpile (SNS) told Committee staff that, "[w]hile the SNS maintains ancillary supplies to administer countermeasures, the current manufacturing capability for licensed products cannot keep pace with predicted threats." With little visibility into the medical supply chain – both for pharmaceuticals and medical supplies – it is difficult to accurately assess the extent of U.S. reliance on foreign sources for critical products. Among U.S. top imports are medical supplies, surgical equipment, antibiotics, and active pharmaceutical ingredients (APIs).[38]

At the beginning of this pandemic, the federal government ignored critical warnings, sent millions of face masks to China, and scrambled to obtain sufficient supplies of testing kits and PPE for use in the U.S.[39] A former volunteer on Jared Kushner's COVID-19 Task Force

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[33] World Health Organization: *Managing the COVID-19 infodemic: Promoting healthy behaviours and mitigating the harm from misinformation and disinformation* (Sept. 23, 2020).

[34] HHS OWS Distribution Strategy, *supra* note 1.

[35] Centers for Disease Control and Prevention, *COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations* (Sept. 16, 2020) (hereinafter "CDC Vaccination Program Playbook").

[36] *'It's like every red flag': Trump-ordered HHS ad blitz raises alarms*, Politico (Sept. 25, 2020) (https://www.politico.com/news/2020/09/25/trump-hhs-ads-coronavirus-421957).

[37] Minority Staff, Senate Committee on Homeland Security and Governmental Affairs, *A Price Too High: Cost, Supply, and Security Threats to Affordable Prescription Drugs* (Dec. 6, 2019).

[38] Congressional Research Service, *COVID-19: China Medical Supply Chains and Broader Trade Issues* (R46304) (Apr. 6, 2020).

[39] *Ousted vaccine director files whistleblower complaint alleging coronavirus warnings were ignored*, CNN (May 5, 2020) (https://www.cnn.com/2020/05/05/politics/rick-bright-complaint/index.html); *U.S. sent millions of face masks to China early this year, ignoring pandemic warning signs*, Washington Post (Apr. 18, 2020) (https://www.washingtonpost.com/health/us-sent-millions-of-face-masks-to-china-early-this-year-ignoring-pandemic-warning-signs/2020/04/18/aaccf54a-7ff5-11ea-8013-1b6da0e4a2b7_story.html).

described the Administration's response as "a family office meets organized crime, melded with 'Lord of the Flies."[40] The federal government's failure to procure critical supplies directly and provide guidance to distributors left states to fend for themselves, oftentimes forcing states to engage in bidding wars against one another and the federal government. Widespread shortages permeated throughout the U.S. and were aggravated by China nationalizing its PPE supply and pandemic profiteering.[41] Without any comprehensive unified strategy, health care workers today continue to face shortages of N95 respirators and the reagents needed for testing.[42] Both of these materials are critical in mitigating the spread of COVID-19 and essential to ensuring the safe and widespread administration of an eventual vaccine.

Despite these catastrophic and avoidable missteps, the Administration recently released its vaccine distribution strategy, which recognizes the importance of centralized coordination: "[c]entralized jurisdiction allows the federal government full visibility, control, and ability to shift assets and use data to optimize vaccine uptake."[43] Unlike the Administration's response to widespread PPE and testing shortages, the implementation of Operation Warp Speed in May set up a coordinated private-public partnership with a unified goal "to produce and deliver 300 million doses of safe and effective vaccines with the initial doses available by January 2021."[44] Through Operation Warp Speed, vaccine manufacturing has occurred alongside vaccine development, shortening what is usually a lengthy, multi-year timeline. In tandem, the Trump Administration announced Project Jumpstart, another private-public partnership with the goal of producing 100 million syringes by the end of 2020 and another 500 million in 2021.[45]

The Biomedical Advanced Research and Development Authority (BARDA), a component of HHS, and the Department of Defense (DOD) have entered into contracts and agreements totaling more than $1.89 billion to increase manufacturing capacity to produce and deliver COVID-19 vaccines. Of this amount, approximately $815 million is dedicated to ramping up production of needles, syringes, and vials needed to safely administer a vaccine. *See* Figure 1. Although these contracts intend to ensure at least 234 million syringes by the end of 2020, and likely over a billion syringes by the end of next year, the delivery of these critical supplies is not guaranteed. In addition to these items, shortage concerns also extend to other supplies that are needed to safely distribute and administer a vaccine, including rubber stoppers, alcohol prep

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[40] A Young Kennedy, in Kushnerland, Turned Whistle-Blower, New Yorker (Sept. 21, 2020) (https://www.newyorker.com/magazine/2020/09/28/a-young-kennedy-in-kushnerland-turned-whistle-blower).

[41] Congressional Research Service, *COVID-19: China Medical Supply Chains and Broader Trade Issues* (R46304) (Apr. 6, 2020); *The World Needs Masks. China Makes Them, but Has Been Hoarding Them*, New York Times (Mar. 13, 2020) (https://www.nytimes.com/2020/03/13/business/masks-china-coronavirus.html); *It's Bedlam in the Mask Market, as Profiteers Out-Hustle Good Samaritans*, New York Times (Apr. 3, 2020) (https://www.nytimes.com/2020/04/03/technology/coronavirus-masks-shortage.html); *Late night deals, international holdups, and curious characters: Inside the state's quest for PPE*, Boston Globe (June 11, 2020) (https://www.bostonglobe.com/2020/06/11/nation/late-night-deals-international-hold-ups-curious-characters-inside-states-quest-ppe/).

[42] *The N95 shortage America Can't Seem to Fix*, Washington Post (Sept. 21, 2020) (https://www.washingtonpost.com/graphics/2020/local/news/n-95-shortage-covid/); *Covid-19 Testing Is Hampered by Shortages of Critical Ingredient*, Wall Street Journal (Sept. 22, 2020) (https://www.wsj.com/articles/covid-19-testing-is-hampered-by-shortages-of-critical-ingredient-11600772400).

[43] HHS OWS Distribution Strategy, *supra* note 1.

[44] Department of Health and Human Services, *Fact Sheet: Explaining Operation Warp Speed* (Sept. 24, 2020) (https://www.hhs.gov/coronavirus/explaining-operation-warp-speed/index.html).

[45] *Trump admin unveils plan to ramp up syringe production for future COVID-19 vaccine*, NBC News (May 12, 2020) (https://www.nbcnews.com/news/us-news/trump-admin-unveils-plan-ramp-syringe-production-future-covid-19-n1204436); Department of Defense: *DOD Awards $138 Million Contract Enabling Prefilled Syringes for Future COVID-19 Vaccine* (May 12, 2020).

pads, and PPE.[46] There could be interruptions in production due to unexpected manufacturing delays, a lack of raw materials, or a shortage of staff, for example. With some vaccines likely requiring two doses, continuity of production for these supplies is crucial.

Figure 1: U.S. Government Investments in Vaccine Manufacturing and Delivery as of Sept. 1, 2020[47]

Company	Amount	Date of Contract	Product
Marathon Medical Corp.	$27.5 million	May 1, 2020	320 million needles and syringes
Retractable Technologies, Inc.	$83.8 million		
ApiJect Systems America	$138 million	May 12, 2020	100 million prefilled syringes by 2020; 500 million prefilled syringes in 2021
Emergent Biosolutions (CIADM)	$628 million	May 30, 2020	Reserve and expand manufacturing capacity to produce and package vaccines for delivery
	$30 million	August 6, 2020	
SiO2 Materials Science	$143 million	June 5, 2020	Expand domestic manufacturing capacity for durable glass-equivalent vial production to produce 120 million vials by the end of 2020 and additional vials in 2021
Corning Pharmaceutical Technologies	$204 million	June 5, 2020	Expand domestic manufacturing capacity to produce an additional 164 million glass vials per year
Thermo Fisher Scientific	$49 million	June 13, 2020	Expand manufacturing capacity to package vaccines for delivery
Becton, Dickinson and Co.	$42 million	July 1, 2020	Expand manufacturing capacity for needles and syringes
Retractable Technologies, Inc.	$53.6 million	July 1, 2020	Expand manufacturing capacity for needles and syringes
Smiths Medical, Inc.	$20.6 million	July 11, 2020	Expand manufacturing capacity for needles and syringes
Texas A&M University System (CIADM)	$264 million	July 24, 2020	Reserve and expand manufacturing capacity to produce and package vaccines for delivery
Duopross Meditech Corp.	$48 million	August 5, 2020	500 million safety syringes (134 million by 2020)
Cardinal Health, Inc.	$15 million		
Gold Coast Medical Supply LP	$14 million		
HTLSTREFA, Inc.	$12 million		
Quality Impact, Inc.	$9 million		
Medline Industries, Inc.	$6 million		
Grand River Aseptic Manufacturing, Inc.	$1.6 million	August 6, 2020	Expand domestic manufacturing capacity to package vaccines for delivery
Ology Bioservices, Inc.	$106.3 million	August 17, 2020	Expand domestic manufacturing capacity to package vaccines for delivery

[46] *A race is on to make enough small glass vials to deliver coronavirus vaccine around the world*, Washington Post (Jul. 13, 2020) (https://www.washingtonpost.com/business/2020/07/13/coronavirus-vaccine-corning-glass/).

[47] This table includes relevant contracts based on BARDA's public announcements, U.S. government spending data, and public reporting.

Sources: Biomedical Advanced Research and Development Authority, BARDA's COVID-19 Domestic Manufacturing & Infrastructure Investments (accessed Oct. 20, 2020) (https://www.medicalcountermeasures.gov/barda/influenza-and-emerging-infectious-diseases/coronavirus/pharmaceutical-manufacturing-in-america/?filter=all); Government Spending Open Data, USAspending (accessed Oct. 20, 2020) (https://www.usaspending.gov/award/CONT_AWD_75A50120F33004_7505_75A50118D00013_7505); Government Spending Open Data, USAspending (accessed Oct. 20, 2020) (https://www.usaspending.gov/award/CONT_AWD_75A50120F33003_7505_75A50118D00012_7505); *Pandemic's Next Medical Shortage? Vaccine Needles, Syringes*, Bloomberg Law (May 7, 2020) (https://news.bloomberglaw.com/health-law-and-business/pandemics-next-medical-shortage-vaccine-needles-syringes); Department of Defense, DOD Awards $138 Million Contract Enabling Prefilled Syringes for Future COVID-19 Vaccine (May 12, 2020) (https://www.defense.gov/Newsroom/Releases/Release/Article/2184808/dod-awards-138-million-contract-enabling-prefilled-syringes-for-future-covid-19/source/GovDelivery/); Department of Defense, DOD Awards $104 Million for Procurement of Syringes in Support of U.S. COVID-19 Vaccination Campaign (Aug. 5, 2020) (https://www.defense.gov/Newsroom/Releases/Release/Article/2302139/dod-awards-104-million-for-procurement-of-syringes-in-support-of-us-covid-19-va/).

PPE is also essential for the safe administration of a vaccine, but the Administration has yet to put forth a centralized plan to address ongoing shortages. According to a recent GAO report, "[u]ntil HHS and [the Federal Emergency Management Agency (FEMA)] develop and communicate to stakeholders—such as state, local, tribal, and territorial governments—plans outlining specific actions the federal government will take to help mitigate remaining medical supply gaps, uncertainty will persist regarding whether the federal response will align with needs."[48] It is likely that the need for PPE will increase this fall with the influx of flu season in addition to COVID-19. CDC guidance reflects the limited PPE supply and advises health care workers on how to use PPE based on availability of the product. For example, in a crisis setting, CDC recommends using N95 respirators "beyond the manufacturer designated shelf life" and reusing N95s in certain situations.[49] Reports indicate that the Administration awarded questionable contracts to potentially unqualified companies, resulting in cancelled contracts and limited supply.[50] The Administration has failed to explain how it intends to address ongoing PPE shortages.

In addition to these ancillary supplies, cold storage containers will likely be high in demand.[51] The Playbook leaves the issue of cold chain storage up to the states, but advises states not to purchase ultra-cold storage equipment yet, noting that the vaccines requiring ultra-cold storage may be shipped from the manufacturer in coolers packed with dry ice.[52] A significant increase in demand can strain production for any product, and the federal government should be prepared to address potential cold storage supply chain issues that may arise.

In response to vaccine production delays experienced during the H1N1 influenza pandemic, HHS established three Centers for Innovation in Advanced Development and Manufacturing (CIADM) under BARDA. In 2012, BARDA awarded contracts to three Centers to increase domestic preparedness and support the development of medical countermeasures in

[48] Government Accountability Office, *COVID-19: Federal Efforts Could Be Strengthened by Timely and Concerted Actions* (GAO-20-701) (Sept. 21, 2020).

[49] Centers for Disease Control and Prevention, *Summary for Healthcare Facilities: Strategies for Optimizing the Supply of PPE during Shortages* (Updated July 16, 2020); *FEMA cancels $55 million contract for N95 masks*, CNN (May 14, 2020) (https://www.cnn.com/2020/05/13/politics/fema-ppe-contract-cancelled-coronavirus/index.html).

[50] *Feds Spend Billions On COVID-19 Contracts, Often Without Fully Competitive Bidding*, National Public Radio (June 9, 2020) (https://www.npr.org/2020/06/09/869052415/feds-spend-billions-on-covid-19-contracts-often-without-fully-competitive-biddin).

[51] *An unchartered situation for all of us': From shipping containers to security concerns, a Covid-19 vaccine supply chain takes shape*, STAT News (Sept. 8, 2020) (https://www.statnews.com/pharmalot/2020/09/08/covid19-vaccine-supply-chain-cold-chain/).

[52] CDC Vaccination Program Playbook, *supra* note 35.

response to bioterrorism threats, pandemic influenza, and other epidemics.[53] The Centers are intended to provide manufacturing surge capacity during a public health emergency.[54] According to CDC Director Redfield, the government would not be able to manufacture four of the vaccines currently being developed without these facilities.[55]

III. VACCINE DISTRIBUTION AND ALLOCATION MUST BE TRANSPARENT AND EQUITABLE

Although the U.S. has significant experience organizing large vaccine campaigns, including the annual influenza season and the 2009 H1N1 influenza pandemic, delivering COVID-19 vaccines will require significant resources and planning. The Administration's Playbook includes a high-level overview of how vaccines will be distributed and allocated once authorized or approved by the FDA. The CDC Director testified before Congress that it would likely cost between $5.5 and $6 billion to distribute COVID-19 vaccines.[56] The CDC has since announced the release of $200 million to jurisdictions to assist with vaccine preparedness, but it is unclear how much additional funding is needed to support vaccine distribution efforts.[57] The Playbook also leaves open how vaccine distribution will be funded. With many questions left unanswered, the National Governors Association has requested additional guidance on "the roles and expectations of states," including "the delineation of federal and state responsibilities; the funding needs associated with those responsibilities; and the planned supply chain management and vaccine allocation process."[58]

A. The Administration's Playbook Lacks Critical Distribution Details

Even with adequate preparation, mass distribution of COVID-19 vaccines – some of which require two doses and storage in ultra-cold conditions – and ancillary supplies present significant logistical challenges. Wholesale medical supplier McKesson, who handled the distribution of vaccines during the 2009-2010 H1N1 pandemic, will serve under CDC contract as the central distributor for both vaccine and ancillary supply kits.[59] States are responsible for ordering vaccines and the federal government, via McKesson and DOD, is responsible for distributing the products to states. A retrospective review of the H1N1 pandemic vaccine distribution strategy found that having the federal government purchase all available vaccines

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[53] Department of Health and Human Services Assistant Secretary for Preparedness and Response, *Centers for Innovation in Advanced Development and Manufacturing* (undated) (https://www.medicalcountermeasures.gov/media/8862/aspa_0420_20120615_aspr_pr_countermeasures_fact_sheet_combined508.pdf).

[54] Department of Health and Human Services' Centers for Innovation in Advanced Development and Manufacturing (https://www.medicalcountermeasures.gov/barda/core-services/ciadm/) (accessed Oct. 6, 2020).

[55] Senate Committee on Health, Education, Labor, and Pensions, *Hearing on COVID-19: An Update on the Federal Response*, 116th Cong. (Sept. 23, 2020).

[56] Senate Subcommittee on Labor, Health and Human Services, Education, and Related Agencies, *Hearing to Review Coronavirus Response Efforts*, 116th Cong. (Sept. 16, 2020).

[57] Centers for Disease Control and Prevention, *Administration Announces $200 million from CDC to Jurisdictions for COVID-19 Vaccine Preparedness* (Sept. 23, 2020).

[58] Letter from National Governors Association to President Donald J. Trump (Oct. 15, 2020).

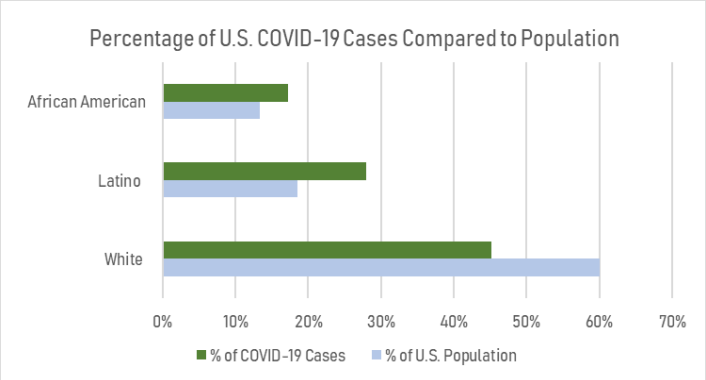
[59] *McKesson to Send Vaccine Needle, PPE Kits to Health Workers*, Bloomberg Law (Sept. 24, 2020) (https://news.bloomberglaw.com/health-law-and-business/mckesson-to-send-vaccine-needle-ppe-kits-to-health-workers); Department of Health and Human Services, *Operation Warp Speed – Kitting services of Government Furnished Material* (Sept. 23, 2020) (https://beta.sam.gov/opp/e11e349fcd6e4c968e9cf74724b0faad/view?index=opp&page=2&organization_id=100004222).

"provided greater control over vaccine distribution, necessary to ensure equity and helpful given the fluid nature of the public health response."[60] Communication with states on timing is essential to ensuring that states know when, and in what amount, to expect COVID-19 vaccines; however, this is not addressed in the Playbook.

A vaccine cannot be administered without the necessary supplies, like needles, syringes, and PPE. HHS intends to procure 6.6 million ancillary supply kits, with enough supplies to vaccinate 100 individuals each; however, PPE in each kit is limited to four surgical masks and two face shields, and disposal supplies will not be included.[61] States are responsible for obtaining their own "sharps" disposal containers, gloves, and bandages, which could lead to potential supply concerns. For example, the U.S. imports a significant portion of medical gloves from China, Malaysia, Thailand, and Vietnam and, according to FEMA, there is "no U.S. based manufacturing for nitrile gloves."[62] Certain types of examination gloves are currently listed on the FDA's Medical Device Shortage List."[63] The Playbook indicates that supply kits will be shipped separately from vaccines, but does not address how McKesson and DOD will coordinate the arrival of supplies and vaccines. The Playbook also does not set forth a specific formula for determining vaccine distribution to respective jurisdictions.

The effective distribution of vaccines and ancillary supplies to communities across the country will depend on the federal government and states maintaining up-to-date and interoperable information technology (IT) systems. These systems are critical in tracking (1) vaccine inventory (both at the state and federal level); (2) patient information (such as the timing and type of a second dose); (3) adverse event monitoring (if a patient experiences an adverse side effect as a result of the vaccine); and (4) administration costs (such as health insurance billing systems). While many of these systems will be maintained by the CDC, every state will need to ensure their own up-to-date IT systems. The CDC will also be the hub for national vaccination data and must have the capability to reliably track, sort, and analyze this information – whether addressing orders or analyzing demographic information of vaccine recipients.

Figure 2: Percentage of U.S. COVID-19 Cases Compared to Population



[60] Department of Health and Human Services, *An HHS Retrospective on the 2009 H1N1 Influenza Pandemic to Advance All Hazards Preparedness* (June 15, 2012) (https://www.phe.gov/Preparedness/mcm/h1n1-retrospective/Documents/h1n1-retrospective.pdf).

[61] CDC Vaccination Program Playbook, *supra* note 35; HHS OWS Distribution Strategy, *supra* note 1.

[62] White House COVID-19 Supply Chain Task Force, PowerPoint Slides by RADM John P. Polowczyk (undated) (https://www.hassan.senate.gov/imo/media/doc/SCTF%20Demand%20PPE%20Chart.pdf); United States International Trade Commission, *COVID-19 Related Goods: U.S. Imports and Tariffs* (5047) (Apr. 2020).

[63] Food and Drug Administration, Medical Device Shortage List (https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/medical-device-shortages-during-covid-19-public-health-emergency#shortage) (accessed Oct. 7, 2020).

Sources: Centers for Disease Control and Prevention, *CDC COVID Data Tracker* (accessed Oct. 20, 2020) (https://covid.cdc.gov/covid-data-tracker/?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fcases-updates%2Fcases-in-us.html#cases_casesinlast7days); U.S. Census Bureau, *Quick Facts* (accessed Oct. 20, 2020) (https://www.census.gov/quickfacts/fact/table/US/RHI225219).

The Playbook also lacks critical details on how it will address equitable distribution and racial disparities in vaccine delivery. Communities of color have been disproportionately affected by COVID-19 with double the risk of contracting and dying from the virus compared to white communities.[64] As shown in Figure 2, African American communities represent 17.2% of COVID-19 cases, but only 13.4% of the population; Latino communities represent 28% of COVID-19 cases, but only 18.5% of the population. These statistics are in stark comparison to white communities, who represent 45.2% of COVID-19 cases but account for 60% of the population. These disparities result from a multitude of factors, including systemic economic and social inequities.[65] HHS found that during the H1N1 pandemic, "racial and ethnic minorities were vaccinated at comparatively lower rates than other groups."[66]

B. Allocation Decisions Must Be Fair and Transparent

The Administration's strategic plan acknowledges that initial vaccine supply is likely to be limited, requiring the federal government, states, and localities to prioritize its distribution to certain at-risk groups.[67] As the vaccine supply increases, additional priority groups will be added, but access will likely remain limited to certain populations until enough is manufactured for the population at large.[68] A transparent, evidence-based process with clear criteria for prioritization is critical, and any such prioritization must take into account the workforce capacity of the health care system and other critical infrastructure, the risk of exposure to COVID-19, morbidity and mortality risks, and the results of vaccine trials in diverse groups. In addition, because of the disparate impact this virus has had on populations such as health care workers, older adults, nursing home residents, and people of color, any prioritization plan must be developed in consultation with experts in epidemiology, national security, civil rights, and other impacted groups.

Thus far, the Administration appears to be taking steps to ensure that allocation criteria are developed in a transparent, science-based manner. The Administration contracted with the National Academies of Sciences, Engineering, and Medicine and the National Academy of Medicine (NASEM) to develop a recommended framework for equitable draft allocation, which

[64] Kaiser Family Foundation, *COVID-19 Racial Disparities in Testing, Infection, Hospitalization, and Death: Analysis of Epic Patient Data* (Sept. 16, 2020) (https://www.kff.org/coronavirus-covid-19/issue-brief/covid-19-racial-disparities-testing-infection-hospitalization-death-analysis-epic-patient-data/); University of Minnesota, Center for Infectious Disease Research and Policy, *US blacks 3 times more likely than whites to get COVID-19* (Aug. 14, 2020) (https://www.cidrap.umn.edu/news-perspective/2020/08/us-blacks-3-times-more-likely-whites-get-covid-19).

[65] Centers for Disease Control and Prevention, *Disparities in Incidence of COVID-19 Among Underrepresented Racial/Ethnic Groups in Counties Identified as Hotspots During June 5–18, 2020 — 22 States, February–June 2020* (Aug. 21, 2020).

[66] Department of Health and Human Services, *An HHS Retrospective on the 2009 H1N1 Influenza Pandemic to Advance All Hazards Preparedness* (June 15. 2012) (https://www.phe.gov/Preparedness/mcm/h1n1-retrospective/Documents/h1n1-retrospective.pdf).

[67] HHS OWS Distribution Strategy, *supra* note 1.

[68] National Academies of Sciences, Engineering, Medicine, *Discussion Draft of the Preliminary Framework for Equitable Allocation of COVID-19 Vaccine* (Sept. 1, 2020) (https://www.nap.edu/resource/25917/25914.pdf).

was released on October 2, 2020.[69] This framework identifies tiers for vaccination prioritization, with frontline health care workers and the highest-risk individuals receiving top priority. The Playbook also describes groups that may be initially prioritized (e.g. the critical infrastructure workforce, including health care workers; people at increased risk of severe COVID-19; people in congregate settings), but does not prioritize among these groups.[70] The CDC's Advisory Committee on Immunization Practices (ACIP) is expected to review NASEM's framework, meet publicly to develop a prioritization strategy, and present that strategy to the CDC Director for adoption.[71] Because millions of Americans meet the Playbook criteria, federal guidance is needed quickly to help states determine how to allocate vaccines to those most in need.

IV. A COVID-19 VACCINE MUST BE FREE OF CHARGE AND ACCESSIBLE

The federal government has made substantial investments in the development, manufacture, and distribution of potential COVID-19 vaccines, a financial risk that is critical to the health and safety of millions of Americans. While the government's role to mobilize and provide federal funding during a crisis is critical, it is also important that private industry, including pharmaceutical companies, not use taxpayer dollars to profit off of a pandemic. A vaccine cannot be effective if it not affordable and widely available to all populations.

A. Vaccines Must Be Free to All Americans

In order for COVID-19 vaccines to turn the tide of the pandemic and allow more commercial activities to resume, they must be accessible to everyone. The Playbook commits that the federal government will provide COVID-19 vaccines and certain ancillary supplies "at no cost to enrolled COVID-19 vaccination providers" and, further, that the government will require that all providers "[a]dminister COVID-19 vaccine regardless of the vaccine recipient's ability to pay," a critical step in ensuring access.[72] However, any eventual cost presents a barrier to many individuals' ability to get a vaccine, and while Congress and the Administration have taken steps to ensure a vaccine is widely available free of charge to consumers, gaps remain.

In March 2020, Congress passed critical relief measures that have ensured large portions of the U.S. population will have access to a vaccine with no out of pocket costs. The *Families First Coronavirus Response Act* incentivized states to have Medicaid cover all COVID-19 vaccines without cost-sharing (e.g. co-pays or deductibles). Similarly, the *Coronavirus Aid, Relief, and Economic Security (CARES) Act* took steps to mandate Medicare coverage of COVID-19 vaccines and their administration without cost sharing.[73] However, the *CARES Act* language appears to apply only to vaccines licensed, not authorized for emergency use, by the FDA. As such, the Administration has raised concerns that Medicare may not cover costs for any vaccine administered under an EUA.[74]

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[69] National Academies of Sciences, Engineering, Medicine, *Framework for Equitable Allocation of COVID-19 Vaccine* (2020) (http://nap.edu/25917).

[70] CDC Vaccination Program Playbook, *supra* note 35.

[71] HHS OWS Distribution Strategy, *supra* note 1.

[72] CDC Vaccination Program Playbook, *supra* note 35.

[73] Coronavirus Aid, Relief, and Economic Security (CARES) Act, Pub. L. 116-136, Sec. 3713 (2020).

[74] *Medicare Wouldn't Cover Costs of Administering Coronavirus Vaccine Approved Under Emergency-Use Authorization*, Wall Street Journal (Sept. 23, 2020) (https://www.wsj.com/articles/medicare-wouldnt-cover-costs-of-administering-coronavirus-vaccine-approved-under-emergency-use-authorization-11600704447).

Most private health insurance plans are also expected to cover a COVID-19 vaccine due to the *Patient Protection and Affordable Care Act (ACA)* and the *CARES Act*. Under the ACA, most private health insurance carriers must cover, without cost sharing, immunizations that have been recommended by ACIP – the *CARES Act* ensures this coverage would occur within 15 days of ACIP's recommendation.[75] However, a gap may exist for short-term plans, otherwise known as "junk" plans, which are exempted from ACA requirements, including the requirement to cover immunizations.[76] The Trump Administration has consistently promoted consumer uptake of these plans, despite the fact that they do not guarantee adequate coverage.[77]

The Administration has failed to articulate a plan for how uninsured and underinsured individuals will be able to receive a vaccine free of charge. Although the *CARES Act* provides funding that could be used to support immunization for the uninsured and underinsured, the Administration has not adequately specified which funds will be used, whether additional funding is needed, or whether providers will be guaranteed reimbursement.[78] Even when the government has purchased the vaccine, it remains unclear, in some cases, who will pay for vaccine administration – the Playbook simply states, "CDC will share more information about reimbursement claims for administration fees as it becomes available."[79] While other government programs should make the vaccine accessible for uninsured children and many uninsured adults, the Administration's commitment to filling this gap remains unclear.[80]

B. Pharmaceutical Companies Should Not Be Allowed to Gouge Americans

Although the federal government has already purchased large quantities of potential COVID-19 vaccine doses, after the public health emergency, COVID-19 vaccines will eventually be purchased through regular commercial channels. The federal government has provided significant funding for the development, manufacture, purchase, and distribution of potential COVID-19 vaccines, but it appears to leave unaddressed pharmaceutical companies' – or other third parties' – ability to place an exorbitant price tag on a federally funded vaccine once it is available for purchase in the commercial market. Funding from both the *Coronavirus Preparedness Response Supplemental Appropriations Act* and the *CARES Act* have allowed BARDA to enter into agreements with pharmaceutical companies to invest in COVID-19 vaccines.[81]

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[75] 42 U.S.C. § 300gg-13.

[76] *Understanding Short-Term Limited Duration Health Insurance*, Kaiser Family Foundation (Apr. 23, 2018) (https://www.kff.org/health-reform/issue-brief/understanding-short-term-limited-duration-health-insurance/).

[77] *See*, e.g., *Trump administration allows ACA subsidies for leaner health plans*, Washington Post (Oct. 22, 2018) (https://www.washingtonpost.com/powerpost/trump-administration-allows-aca-subsidies-for-leaner-health-plans/2018/10/22/4b108d7a-d63b-11e8-83a2-d1c3da28d6b6_story.html).

[78] Coronavirus Aid, Relief, and Economic Security (CARES) Act, Pub. L. 116-136, Public Health and Social Services Emergency Fund.

[79] CDC Vaccination Program Playbook, *supra* note 35.

[80] In October, Pfizer received FDA approval to enroll children over the age of 12 in its Phase III trials, which previously only included participants aged 16 and older. The other Phase III vaccine trials under Operation Warp Speed do not involve individuals younger than 18 years old. The timeline for availability of a COVID-19 vaccine for children remains unclear.

[81] The Coronavirus Preparedness Response Supplemental Appropriations Act sets forth two affordability provisions on certain products purchased by the federal government, such as diagnostics, therapeutics, or vaccines. The first provision requires that purchases by the federal government are "in accordance with Federal Acquisition Regulation guidance on fair and reasonable pricing." The second provision grants the HHS Secretary authority to ensure COVID-19 vaccines, therapeutics, and diagnostics

As of September 1, 2020, the government has invested about $12.6 billion for the expedited development, manufacture, purchase, and distribution of anticipated COVID-19 vaccines.[82] *See* Figure 3. This amount also includes ancillary supplies, like needles and syringes, discussed in Section III, that are necessary to administer a vaccine and the expansion of manufacturing capacity needed to package vaccines for delivery. The contracts and agreements outlining the federal government's pricing parameters, however, are not public, making it difficult to assess the actual pricing of COVID-19 vaccines.

Figure 3: U.S. Government Investments in Vaccine Development or Doses as of Sept. 1, 2020

Company	Current Phase	Amount	Date of Contract	Doses
AstraZeneca / Oxford	Phase III	$1.2 billion	May 20, 2020	300 million
Janssen Pharmaceuticals, Inc. (Johnson & Johnson)	Phase III	$456 million	February 11, 2020	Development
		$1 billion	August 5, 2020	100 million
Moderna, Inc.	Phase III	$955 million	April, May, and July 2020	Development
		$1.5 billion	August 11, 2020	100 million
Pfizer, Inc. / BioNTech	Phase III	$1.95 billion	July 21, 2020	100 million
Sanofi / GSK	Phase I / II	$30.78 million	April 10, 2020	Development
		$2.04 billion	July 30, 2020	100 million
Novavax, Inc.	Phase I	$1.6 billion	July 6, 2020	100 million
Merck / IAVI	Phase I	$38 million	April 15, 2020	Development

Source: Biomedical Advanced Research and Development Authority, BARDA's Rapidly Expanding COVID-19 Medical Countermeasure Portfolio (accessed Oct. 20, 2020) (https://www.medicalcountermeasures.gov/app/barda/coronavirus/COVID19.aspx?filter=vaccine).

Recent reports indicate that DOD and BARDA have utilized "Other Transaction" authority to invest in the development and manufacture of a vaccine. This authority allows the government, in limited circumstances, to sidestep traditional contracting procedures, including certain intellectual property protections and other Federal Acquisition Regulation (FAR) requirements.[83] Although there can be benefits to utilizing Other Transaction authority when circumstances are appropriate, many questions remain about how BARDA and DOD have executed these agreements and what guardrails are in place to ensure affordable vaccine pricing. Furthermore, the manner in which Other Transaction authority is executed can make it more

developed using federal funds are "affordable in the commercial market," referring to the Secretary's ability to invoke certain authorities that would allow the federal government to issue a patent to a third party manufacturer in limited circumstances.

[82] Government Accountability Office, *COVID-19: Federal Efforts Could Be Strengthened by Timely and Concerted Actions* (GAO-20-701) (Sept. 21, 2020).

[83] *How Operation Warp Speed's Big Vaccine Contracts Could Stay Secret*, National Public Radio (Sept. 29, 2020) (https://www.npr.org/sections/health-shots/2020/09/29/917899357/how-operation-warp-speeds-big-vaccine-contracts-could-stay-secret).

difficult for the public to gain access to the terms of the agreements, further obscuring this information from the American people.

Despite significant funding from the federal government, only two pharmaceutical companies, AstraZeneca and Johnson & Johnson, have pledged not to profit off their COVID-19 vaccines.[84] BARDA's agreement with Pfizer is contingent upon Pfizer receiving an EUA or licensure. Currently, all doses of potential COVID-19 vaccines have been federally purchased and should be provided at no cost to providers or individuals, although, as discussed above, questions about the cost of administering these vaccines remain. Once America moves past this public health crisis, and the federal government is no longer the primary purchaser, vaccine pricing issues will likely emerge, especially when private and public payers must negotiate prices for COVID-19 vaccines.

CONCLUSION

The Trump Administration's failure to effectively mobilize a unified response to the COVID-19 pandemic through prompt action and consistent communication has hindered our nation's ability to effectively mitigate the spread of the virus and keep Americans safe. Widespread reports of political interference at our nation's leading scientific institutions continue to erode public confidence in an eventual COVID-19 vaccine. Although the development, manufacture, and distribution of a safe and effective vaccine are vital steps in returning to a post-pandemic world, a vaccine will not have any effect if the public does not trust it. To ensure the successful development, manufacture, distribution, and allocation of eventual COVID-19 vaccines, the Administration must:

- Ensure the vaccine development process is transparent, rooted in science, and representative of the American population.
- Fully utilize the authorities under the *Defense Production Act* and implement a strategic plan to acquire PPE and other critical medical supplies to prepare for the upcoming flu season, the ongoing pandemic, and the impending COVID-19 vaccination campaign.
- Publicly report the number of vaccines and supplies distributed to all states, Tribes, and territories on a daily basis and ensure these jurisdictions have the resources they need to equitably distribute, allocate, and track COVID-19 vaccines.
- Clarify how the Administration will ensure every individual can get a COVID-19 vaccine at no cost, promote pricing transparency for all federal COVID-19 vaccine agreements with pharmaceutical companies, and require pharmaceutical companies to pledge not to profit off of a pandemic.

[84] House Subcommittee on Oversight and Investigations, *Pathway to a Vaccine: Efforts to Develop a Safe, Effective and Accessible COVID-19 Vaccine*, 116th Cong. (July 21, 2020).