



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

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 219,000, 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.