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The Democratic COVID-19 Response: A Roadmap To Getting a Safe and Effective Vaccine To All

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THE DEMOCRATIC COVID-19 RESPONSE
A ROADMAP TO GETTING A SAFE AND EFFECTIVE VACCINE TO ALL
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July 13, 2020

COVID-19 poses an unprecedented threat to public health—in the mere months since SARS-CoV-2, the virus that causes COVID-19, was detected in the U.S., more than 3.2 million individuals have been diagnosed with COVID-19 and over 135,000 people have died in the United States.¹ According to CDC Director Dr. Robert Redfield, the actual case count is likely 10 times the confirmed case count.² The disease has pushed public health departments, health care facilities, communities, and families to their limits. And this public health crisis has brought with it educational, social, and economic challenges the nation must respond to as well.

Ultimately, vaccines that are safe and effective, produced at scale, equitably distributed, free and accessible to everyone, and widely taken up by the population are our best hope for ending this pandemic. Furthermore, neither U.S. health security nor economic security can be achieved unless markets around the world also recover, requiring vaccines be available and administered globally. We are not safe until all countries are safe. Achieving this goal is not just about doing things fast, it is about doing them right.

Unfortunately, the U.S. response to COVID-19 so far has been plagued by the Trump Administration’s track record of missteps and prioritization of politics over public health. Implementing an effective COVID-19 vaccination program will require a long-term, sustained effort that demands serious planning from the Trump Administration—planning it has refused to do in response to other challenges, such as ensuring a comprehensive nationwide, diagnostic testing system is in place. These failures, which range from a lack of centralized leadership to a refusal to leverage the full power of the federal government, resulted in chaotic communication with states and other partners, an absence of a clear strategy, and an inability to adequately mitigate the spread of the virus.³ When it comes to developing vaccines and making sure they reach every community, the nation needs a transparent, inclusive, and science-driven process.

This white paper lays out proposals from Senate Democrats to make sure COVID-19 vaccines are safe, effective, high quality, produced at scale, allocated in a manner that optimizes public health and reduces health disparities, free and accessible to everyone, widely embraced by the public, and set us on a path for economic recovery.

The Democratic proposal requires action in eight key areas:

1. Requiring the Administration Develop and Implement a Comprehensive Strategic Plan;
2. Providing \$25 billion in Emergency Funding for Vaccines and Vaccination Activities;
3. Ensuring COVID-19 Vaccines are Available at No Cost;
4. Setting Rigorous Standards for Vaccine Development and Scientific Review;

¹ <https://coronavirus.jhu.edu/map.html>

² <https://www.washingtonpost.com/health/2020/06/25/coronavirus-cases-10-times-larger/>

³ <https://www.help.senate.gov/imo/media/doc/HELP%20Committee%20Democratic%20Staff%20Testing%20Report%20FINAL.pdf>

5. Scaling Vaccine Manufacturing and Preventing Supply Chain Challenges;
6. Ensuring Equitable Distribution of Vaccines;
7. Preparing for and Implementing Widespread Vaccine Administration; and
8. Ensuring Post-Market Surveillance and Safety.

Requiring the Administration Develop and Implement a Comprehensive Strategic Plan

The rapid, efficient, and equitable development, manufacturing, review, allocation, distribution, and administration of one or more safe and effective COVID-19 vaccines presents a significant public health challenge. The federal government must develop, publish, and effectively implement a comprehensive national strategic plan that covers every phase of the vaccine enterprise and demonstrates how the federal government will lead this effort, in partnership with state, local, Tribal, and territorial leadership, industry, academia, and other stakeholders. This unprecedented effort must be developed, scaled up, and sustained in a manner that recognizes that the U.S. public health system is already under incredible strain.

This spring, the Administration announced the creation of Operation Warp Speed (OWS) to centralize the work of various federal departments and agencies across the full spectrum of the vaccine process. While this stands in contrast to the Administration's disorganized approach to testing, OWS must embrace clear, open communication with the public and essential stakeholders about the status of vaccine development, distribution, and administration efforts. Sustained, central, transparent leadership is required to avoid the failures of the diagnostic testing system. Finally, the nation must be able to trust that the person or entity leading these efforts is focused on public health and science and remains free from political influence or conflicts of interest.

A public strategic plan that lays out the Administration's approach to a COVID-19 vaccine or vaccines is the clearest way to accomplish these objectives—and this plan must be developed now. The initial plan should be released no later than August 7, 2020 and include detailed strategies, including specific timelines for completion, on how the Trump Administration will:

Clarify departmental and agency roles and coordination to ensure the federal government is leveraging its existing expertise, programs, and infrastructure, including maintaining the Center for Disease Control and Prevention's (CDC) public health leadership in vaccination campaigns and the role of existing federal advisory committees.

Conduct and support research and development to ensure one or more safe and effective vaccines, including specific plans to:

- Clarify the decision-making process for selecting which vaccine candidates receive federal support;
- Develop and publish post-marketing safety assessment plans;
- Publish data during trial stages and upon authorization or licensure of a vaccine;
- Conduct a publicly accessible meeting of the Food and Drug Administration's (FDA) Vaccines and Related Biological Products Advisory Committee (VRBPAC) for all vaccine candidates being considered for licensure or Emergency Use Authorization;
- Ensure clinical trial designs include demographically diverse participants;
- Transparently and rapidly share critical information about the research, development, and evaluation processes;

- Ensure continued investment in diverse vaccine development in case initial vaccine candidates are insufficient or not optimal to contain COVID-19; and
- Collaborate with the global scientific community, including the World Health Organization (WHO), the Coalition for Epidemic Preparedness Innovations (CEPI), and Gavi, the Vaccine Alliance.

Scale up necessary manufacturing, including specific plans to:

- Bring additional manufacturing capacity online, with a focus on fill and finish capacity for COVID-19 vaccines, and ancillary supplies such as vials, rubber stoppers, needles, and syringes, and personal protective equipment, with early engagement from FDA on regulatory expectations;
- Ensure high standards for manufacturing quality are maintained;
- Intervene in the supply chain when necessary to ensure a highly functional supply chain for all necessary elements;
- Balance the manufacturing needs for seasonal influenza vaccine, pandemic influenza vaccine, if necessary, and other vaccines; and
- Stockpile ancillary supplies to ensure a sufficient supply for both influenza and COVID-19 vaccination campaigns, as well as continuing routine immunizations.

Equitably allocate COVID-19 vaccines in a manner that optimizes public health and promotes equity by addressing health disparities, including specific plans to:

- Implement recommendations from the Advisory Committee for Immunization Practices (ACIP);
- Prioritize health outcomes for populations at higher risk for COVID-19 morbidity and mortality;
- Set and communicate clear expectations about who will be first in line to access a vaccine, why they have been prioritized, and when vaccines will be available for specific groups and for the general public; and
- Create accountability mechanisms that ensure vaccine allocation is science-driven and equitable.

Distribute COVID-19 vaccines to every community, including specific plans to:

- Build on the existing expertise and infrastructure of the CDC and state, local, Tribal, and territorial public health departments;
 - Ensure vaccines reach communities of color, people with disabilities, and other underserved communities;
 - Ensure an adequate workforce to distribute and administer COVID-19 vaccines;
 - Address logistical needs, including reaching rural communities, maintaining a cold chain logistics system, and overcoming other distribution obstacles;
 - Strengthen and expand data systems to support vaccine distribution and administration, and link them to a comprehensive system of vaccine safety monitoring systems; and
- Work multilaterally to ensure availability and global distribution of COVID-19 vaccines.

Administer a vaccine to hundreds of millions of people, including specific plans to:

- Strengthen vaccine confidence and combat misinformation using evidence-based approaches, including conducting necessary research to inform these approaches, engaging stakeholders, and developing and testing messaging regarding the benefits of eventual COVID-19 vaccines;
- Strengthen and expand existing immunization infrastructure, including information infrastructure, to be able to track every administered dose of vaccine in a manner that accounts for the possibility of multiple multi-dose vaccines being concurrently available, with a focus on uptake in communities of color and underserved populations;
- Ensure that all individuals will have access to eventual COVID-19 vaccines free of charge regardless of insurance type or insured status;
- Build on existing vaccine delivery infrastructure (e.g. doctors' offices, pharmacies, occupational health settings) and support the establishment and maintenance of supplemental vaccination sites, accounting for workforce needs and special populations (e.g., institutional housing, nursing homes, prisons); and
- Concurrently support an influenza vaccination campaign and the maintenance of routine vaccinations.

Strengthen existing vaccine safety monitoring systems to conduct post-market monitoring and active surveillance and commit to releasing relevant data.

Regularly update the national vaccines plan, to reflect new information about vaccine candidates, COVID-19, and other relevant factors.

Providing Emergency Funding for Vaccines and Vaccination Activities

Congress has already invested \$9.5 billion in vaccine research, development, and manufacturing. Given the scope of this crisis, however, more is needed, and the nation cannot afford to wait.⁴ In just 14 weeks, 47.1 million Americans filed for unemployment, a number that continues to rise.⁵ The U.S. economy is currently losing hundreds of billions of dollars each month, with the Congressional Budget Office (CBO) estimating that the economy will shrink 11 percent in the second quarter of 2020 and grow by three percent less over the next decade.^{6, 7} **Congress should provide \$25 billion in new emergency funding to support additional research and development, manufacturing, purchase, distribution, and administration of COVID-19 vaccines.**

The \$25 billion in new emergency funding and accompanying language should be dedicated to the following goals and objectives:

- Purchase vaccines for the U.S. population;
- Optimize the vaccine supply chain and address shortages of reagents and ancillary supplies by directly funding increased production and matching excess supplies or personnel with demand in other locations;
- Provide significant funding to the CDC to enhance and expand immunization infrastructure across the country, including funding for both the Section 317 program and the Vaccines for Children (VFC) program and immunization information systems (IIS) necessary for real time inventory management, distribution, uptake, and tracking during a mass vaccination campaign;
- Update and modernize public health data systems to gather robust data on who is getting vaccinated, including demographic factors, and information to support the vaccination of essential workers, such as first responders, health care providers, and grocery workers, and at risk populations, such as older adults, people with disabilities, patients in long-term care settings, and people with chronic health conditions;
- Recruit, train, and support the necessary additional workforce in collaboration with state, local, Tribal, and territorial health departments, primary care settings, and pharmacies, with special focus on communities of color and other vulnerable populations;
- Stand up federally-supported supplemental vaccination sites and promote new strategies for mass vaccination, such as drive through clinics and clinics in non-traditional locations that are easy to access and feel safe to attendees;
- Strengthen vaccine confidence and combat misinformation with federally supported communication, research, and outreach efforts;
- Develop and distribute tools and resources for health care providers prior to the administration of COVID-19 vaccines; and
- Concurrently support influenza vaccination campaigns and other routine immunizations.

⁴ Coronavirus Preparedness and Response Supplemental Appropriations Act; Coronavirus Aid, Relief, and Economic Security (CARES) Act; and Paycheck Protection Program and Health Care Enhancement Act.

⁵ <https://www.usatoday.com/story/money/2020/06/25/coronavirus-1-4-m-file-unemployment-benefits-amid-covid-19/3249252001/>

⁶ <https://www.cbo.gov/publication/56351>

⁷ <https://www.washingtonpost.com/business/2020/06/01/coronavirus-cbo-economic-impact/>

Ensuring COVID-19 Vaccines are Available at No Cost

In response to the H1N1 influenza pandemic of 2009, the federal government financed the development of a vaccine, purchased the vaccine, and provided it for free.⁸ The Trump Administration has not indicated it intends to purchase all necessary doses of COVID-19 vaccines and has said it will rely some on existing payment mechanisms (e.g., private insurance, Medicaid, Medicare).⁹

The federal government should use market commitments for vaccine purchase to foster innovation, provide a stock of vaccines that can be distributed to the population for free, incentivize manufacturers to produce at scale, and negotiate a fair price for a vaccine, given the government's purchasing power.¹⁰ This would also prevent pharmaceutical companies from reaping massive profits from taxpayer investments that largely insulate the companies from risk.

Furthermore, given the economic instability brought on by COVID-19, many people are experiencing significant changes to their incomes and health coverage – losing employer-sponsored coverage and changing income that affects eligibility for subsidized coverage like qualified health plans on the Affordable Care Act (ACA) exchange, Medicaid, and more.^{11, 12} The surest way to guarantee every person in this country gets vaccinated against COVID-19 free of charge is for the government to directly purchase the hundreds of millions of vaccines that will be necessary to immunize the U.S. population.

Congress should provide for the direct purchase of COVID-19 vaccines for the U.S. population, as it did in response to the 2009 H1N1 influenza pandemic.

Most patients and families have insurance that will cover the eventual COVID-19 vaccines. Congress took steps in the Coronavirus Aid, Relief, and Economic Security (CARES) Act to make COVID-19 vaccines free for Medicare beneficiaries and accelerate coverage without cost-sharing for enrollees in private health plans.¹³ That said, Congress needs to take additional steps to ensure that eventual COVID-19 vaccines are accessible and free for everyone.

Private Insurance

The ACA required all private insurance coverage offered in the individual and group market, including self-insured group health plans regulated under the Employee Retirement Income Security Act, to cover – without cost-sharing – immunizations that have a favorable recommendation from ACIP.¹⁴ The regulations implementing this patient protection require plans to begin covering ACIP-recommended immunizations in the plan year that begins on or after the date that is one year after the date ACIP makes its recommendation.¹⁵ In order to ensure

⁸ <https://www.gao.gov/new.items/d11632.pdf>

⁹ <https://apnews.com/b8bb6d9703c053cba098aa6b61392b5c>

¹⁰ <https://www.gavi.org/vaccineswork/what-advance-market-commitment-and-how-could-it-help-beat-covid-19>

¹¹ <https://www.kff.org/coronavirus-covid-19/issue-brief/eligibility-for-aca-health-coverage-following-job-loss/>

¹² <https://www.rwjf.org/en/library/research/2020/05/how-the-covid-19-recession-could-affect-health-insurance-coverage.html>

¹³ Sections 3713 and 3203 of the CARES Act

¹⁴ 42 USC 300gg-13

¹⁵ 45 CFR 147.130(b)

faster access to eventual COVID-19 vaccines, the CARES Act required plans to begin covering such a vaccine 15 business days after a favorable recommendation from ACIP.¹⁶ If successful, the Trump Administration-backed lawsuit to repeal the entire ACA would repeal this protection. This could have a serious impact on the approximately 76 million people who received expanded coverage of vaccines and preventive services because of the ACA.¹⁷

At this time, ACIP is scheduled to meet three times per year through 2023, and is already conducting analyses of the immunology of the SARS-CoV2 virus and epidemiology of COVID-19 to guide future work.¹⁸ The Heroes Act, which passed the House on May 15, requires ACIP to meet and issue a recommendation within 15 business days after a manufacturer receives a license to market a COVID-19 vaccine.¹⁹

VA Health and Military Health Coverage

The Veterans Health Administration covers immunizations against infectious diseases with no cost-sharing.²⁰ TRICARE covers immunizations without cost-sharing, although service members and their families may be charged a fee for the visit associated with receiving the vaccine.²¹

Medicare

The CARES Act also added eventual COVID-19 vaccines to the list of immunizations covered by Medicare Part B.²² Patients are not required to pay cost-sharing for Part B vaccines or services associated with administering them.²³

Medicaid

Coverage of eventual COVID-19 vaccines under Medicaid depends on the basis for which a beneficiary is eligible for Medicaid coverage. Generally, Medicaid covers ACIP-recommended vaccines for all beneficiaries up to age 21 under the program's EPSDT (Early and Periodic Screening, Diagnosis, and Treatment) benefit.²⁴ Children younger than 19 years of age on Medicaid have access to free vaccinations through the Vaccines for Children Program (this program also covers uninsured, underinsured, and American Indian and Alaska Native children).²⁵ Adult Medicaid beneficiaries covered under an Alternative Benefit Plan – including adults eligible through the Medicaid expansion – also receive coverage for ACIP-recommended vaccines with no cost-sharing.²⁶ For adults who receive traditional Medicaid coverage, states are not required to cover vaccines, though they have an incentive to do so: states that choose to cover all ACIP-recommended vaccines and preventive services recommended by the U.S. Preventive Services Task Force without cost-sharing for this population may receive an enhanced federal

¹⁶ Section 3203 of the CARES Act

¹⁷

<https://aspe.hhs.gov/system/files/pdf/139221/The%20Affordable%20Care%20Act%20is%20Improving%20Access%20to%20Preventive%20Services%20for%20Millions%20of%20Americans.pdf>

¹⁸ <https://www.cdc.gov/vaccines/acip/meetings/downloads/agenda-archive/agenda-2020-06-508.pdf>

¹⁹ Section 30302 of the Heroes Act

²⁰ <https://www.va.gov/health-care/copay-rates/>

²¹ <https://www.vaccines.gov/get-vaccinated/pay>

²² Section 3713 of the CARES Act

²³ https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/qr_immun_bill.pdf

²⁴ <https://www.medicaid.gov/medicaid/quality-of-care/quality-improvement-initiatives/quality-of-care-vaccines/index.html>

²⁵ <https://www.cdc.gov/vaccines/programs/vfc/about/index.html>

²⁶ <https://www.cdc.gov/nchhstp/preventionthroughhealthcare/healthdepartments/services.htm>

match for related expenditures; however, coverage gaps may remain.²⁷ While most states offer some coverage for adult immunizations, one review of all states and DC found that only 22 state Medicaid programs cover all 13 ACIP-recommended adult vaccines.²⁸

Uninsured

Additional resources are available to cover eventual COVID-19 vaccines for the uninsured, including funds made available in the CARES Act through the Public Health and Social Services Emergency Fund.²⁹ The federal government has also used authorities under section 317 of the Public Health Service Act to make vaccines available to uninsured adults.³⁰

If the federal government does not directly purchase enough COVID-19 vaccines for the full population, Congress must act to ensure that all individuals will have access to eventual COVID-19 vaccines free of charge regardless of insurance status, including for the uninsured, adult enrollees in traditional Medicaid who reside in states that do not yet require coverage for all ACIP-recommended adult vaccines, and others.

²⁷ <https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/downloads/SMD-13-002.pdf>

²⁸ <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2764807>

²⁹ Title VIII of the CARES Act states, “the Secretary of Health and Human Services shall purchase vaccines developed using funds made available under this paragraph in this Act to respond to an outbreak or pandemic related to coronavirus in quantities determined by the Secretary to be adequate to address the public health need:”

³⁰ <https://www.cdc.gov/vaccines/imz-managers/guides-pubs/qa-317-funds.html#Guidance>

Setting Rigorous Standards for Vaccine Development and Scientific Review

In developing COVID-19 vaccines, the U.S. government must protect the review process from political interference, require inclusive clinical trial designs, and engage with the international community. Agencies, researchers, and industry partners must be transparent about conflicts of interest and take the necessary steps to safeguard research integrity.

The global impact of COVID-19 has led to an unprecedented effort to quickly develop safe and effective vaccines. Currently, there are at least 192 vaccine candidates in development and several ongoing clinical trials being funded or run by the WHO, CEPI, and a growing list of nations including the United Kingdom, China, Russia, Australia, Germany, India, and Japan, among others.³¹ While any of these vaccine candidates and clinical trials may lead to the development of one or more safe and effective vaccines, translating and scaling those successes into vaccines that can be rapidly made available to the U.S. population and the global community will require coordination and collaboration with the international scientific community. This underscores the importance of the United States' engagement and leadership on these efforts. By not participating in global efforts to find a vaccine, the United States runs the risk of having limited access to successful candidates developed by one or more of these efforts.

The Administration should reverse its decision to withdraw from and freeze funding to the WHO and instead participate in the global effort to develop successful vaccines, including sharing insights from U.S. vaccine development that may inform the decisions of others.

Vaccine candidates should show safety and efficacy in protecting humans from COVID-19 through evidence generated from robust clinical trials that are randomized, double-blinded, and placebo controlled.³² Moreover, the clinical trials must prioritize inclusion of populations that are being disproportionately impacted by COVID-19, such as people of color,³³ pregnant and lactating women,³⁴ and people with comorbidities.³⁵ Understanding the safety and efficacy of potential COVID-19 vaccines for these populations is crucial to achieving community immunity. This effort will require targeted education and outreach, engagement with communities whose history with the health care system and biomedical research enterprise has led to mistrust, selection of trial sites in diverse and underserved areas, and flexibility and funding to make trials accessible to vulnerable populations.³⁶ Vaccine developers also should appropriately assess vaccine candidates for safety and efficacy in children and other populations who are often not included in clinical trials.³⁷

³¹ https://covid-19tracker.milkeninstitute.org/#vaccines_intro

³² <https://www.fda.gov/media/139638/download>

³³ <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/racial-ethnic-minorities.html>

³⁴ <https://www.cdc.gov/mmwr/volumes/69/wr/mm6925a1.htm>

³⁵ <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html>

³⁶ <https://www.ctti-clinicaltrials.org/briefing-room/webinars/engaging-racial-and-ethnic-minority-patient-populations-covid-19-clinical>

³⁷ <https://www.fda.gov/media/139638/download>

Ending the pandemic will require building public trust in COVID-19 vaccines to ensure the U.S. can reach the threshold of covering 70 percent to 85 percent population, which experts estimate is needed for community immunity.³⁸ The review process for vaccine candidates must be based on scientific evidence, not political or private interests.³⁹ FDA should not license or authorize for distribution any COVID-19 vaccine unless and until science-based evidence – including evidence generated from robust Phase III clinical trials – establishes these vaccines are safe and effective. In addition, it is critical FDA be fully transparent with regard to any decisions made to license or authorize a vaccine, including the prompt disclosure of data and information underlying the decision. To do this, FDA should convene a special meeting of its Vaccines and Related Biological Products Advisory Committee as part of its review of every vaccine candidate being considered for licensure and/or Emergency Use Authorization.

Finally, while the fastest way for the country to fully and safely re-open is through the rapid development and availability of COVID-19 vaccines, the federal government cannot cut corners in evaluating safety and efficacy. A rushed or incomplete process that ignores scientific principles, ethical research values, or regulatory safeguards could result in the licensure or authorization of vaccines that are ineffective or unsafe.⁴⁰ Vaccine applications must contain robust scientific support, including chemistry, manufacturing, control information, and nonclinical and clinical trial data, as recommended in FDA guidance, establishing that large-scale manufacturing can produce safe and effective vaccines.⁴¹ Innovations around expedited review of candidates and parallelization of clinical trials can speed up the process,⁴² but these measures are no substitute for robust safety and efficacy data, especially for vulnerable populations.⁴³ The Administration must weigh the relative efficacies of candidates, given the limited resources for manufacturing these vaccines at scale, to ensure a focus on vaccines that will serve all populations in real-world scenarios.

³⁸ <https://www.c-span.org/video/?c4891983/user-clip-herd-immunity>

³⁹ [https://www.thelancet.com/pdfs/journals/laninf/PIIS1473-3099\(20\)30496-5.pdf](https://www.thelancet.com/pdfs/journals/laninf/PIIS1473-3099(20)30496-5.pdf)

⁴⁰ https://jamanetwork.com/journals/jama/fullarticle/2766651?utm_campaign=articlePDF&utm_medium=articlePDFlink&utm_source=articlePDF&utm_content=jama.2020.8917

⁴¹ <https://www.fda.gov/media/139638/download>

⁴² <https://science.sciencemag.org/content/368/6494/948>

⁴³ <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-action-help-facilitate-timely-development-safe-effective-covid>

Congress should take steps to ensure the development and review of any COVID-19 vaccines meets certain standards. Specifically, Congress should:

- Ensure the U.S. is collaborating by appropriately exchanging scientific data with the international community;
- Promote the inclusion of demographically diverse participants in clinical trials for vaccines;
- Require U.S. membership in and support for the WHO and join other international efforts to develop vaccines, encourage COVID-19 vaccine developers to transfer their COVID-19 vaccine technology to other countries, and participate in the Access to COVID-19 Tools (ACT) Accelerator, CEPI, and other efforts;
- Ensure trial sponsors and FDA make clinical trial data and other relevant information about the vaccine candidates publicly available upon licensure or authorization; and
- Ensure FDA uses a fully transparent process that applies the appropriate standards for reviewing vaccine candidates to prevent political interference, including a meeting of VRBPAC.

Scaling Vaccine Manufacturing and Preventing Supply Chain Challenges

Even after a functional COVID-19 diagnostic test was developed, supply chain challenges, including shortages of some supplies and a lack of national level coordination to address shortages, hampered the nation’s ability to sufficiently scale testing for COVID-19.⁴⁴ To avoid the same mistakes, the federal government must carefully plan and coordinate the manufacturing of hundreds of millions of doses of high-quality vaccines, including scaled, coordinated production of often-used components such as syringe plungers and rubber stoppers to avoid the shortages in ancillary supplies the United States experienced with testing. It is critically important that these ancillary supplies are also high quality—as the nation saw with testing, quality issues with supplies can cause significant delays and require additional resources to use.⁴⁵

Manufacturing and supply efforts must account for increased demand for these supplies due to the likely overlap with flu season and the potential for concurrent need for influenza vaccines.⁴⁶ The Administration must have visibility into the entire supply chain, ensuring there is a “plan B” for vaccines and ancillary supplies. The Trump Administration has begun some of these efforts, announcing funding for increased advanced manufacturing capacity for vaccines and some ancillary supplies like vials and pre-filled syringes.^{47, 48, 49}

To achieve these goals, Congress must act to strengthen federal coordination of the vaccine supply chain and ensure sufficient increases in domestic production of necessary supplies.
Congress should:

- Allocate funding and authorize technical assistance, including requiring on-site presence for all manufacturing contracts, to scale up manufacturing capacity for vaccines and ancillary supplies, including vials, syringes, rubber stoppers, personal protective equipment, and adjuvants, that meet high standards of manufacturing quality;
- Ensure the federal government sufficiently leverages its coordination power to prevent and resolve supply chain challenges, including centrally procuring vaccines and issuing guaranteed contracts to manufacturers;
- Call for Presidential use of the Defense Production Act (DPA), when necessary, and require transparent communication from the Administration and manufacturers regarding any prioritization or allocation actions under the DPA; and
- Support the stockpiling of excess supplies in the Strategic National Stockpile.

⁴⁴ <https://oig.hhs.gov/oei/reports/oei-06-20-00300.pdf>

⁴⁵ <https://www.reuters.com/article/us-health-coronavirus-usa-testing/federal-covid-test-supplies-late-unsterile-washington-state-says-idUSKBN24403B>

⁴⁶ <https://jamanetwork.com/journals/jama/fullarticle/2767284>

⁴⁷ <https://www.hhs.gov/about/news/2020/06/01/hhs-adds-628-million-contract-emergent-biosolutions-secure-manufacturing-capacity-operation-warp-speed.html>

⁴⁸ <https://www.hhs.gov/about/news/2020/03/18/hhs-announces-new-public-private-partnership-to-develop-us-based-high-speed-emergency-drug-packaging-solutions.html>

⁴⁹ <https://www.hhs.gov/about/news/2020/06/11/operation-warp-speed-ramps-up-us-based-manufacturing-capacity-for-vials-for-covid-19-vaccines-and-treatments.html>

Ensuring Equitable Distribution of Vaccines

The federal government must carefully and thoroughly plan now to distribute vaccines to protect against COVID-19, even as such vaccines are in development. In doing so, the federal government must prioritize two critical issues: equitable distribution and sufficient immunization infrastructure.

Once an authorized or licensed vaccine is available, the federal government will need to prioritize high risk populations for early vaccination, because there will almost certainly not be enough doses to immediately vaccinate the full population. During the 2009 H1N1 influenza pandemic, states were advised to follow ACIP's recommendations for prioritizing vulnerable populations for vaccination, though states and localities were offered flexibility to define target populations themselves.^{50, 51} The Department of Health and Human Services has indicated that COVID-19 vaccine prioritization will "be adjusted based on experience during the first wave of the COVID-19 response, data on the virus and its impact on populations and the performance of each vaccine, and the needs of the essential workforce."⁵² A transparent process that includes a national conversation about vaccine prioritization should be undertaken so that all options are considered and all trade-offs clarified. This should inform guidance on state, local, Tribal, and territorial COVID-19 vaccine allocation decisions.

The Administration's prioritization plan must include concrete, tactical policies to ensure communities suffering disproportionately from COVID-19, including communities of color, older adults, people with disabilities, people with comorbidities, and essential workers, are prioritized for vaccination. The Administration should communicate directly to the public and to vaccine distribution stakeholders about vaccine prioritization to ensure there is a consistent, coherent message about who will receive vaccines first, and what the plans are to roll out vaccines to the rest of the public. The plan should also account for equitable and prompt distribution to medically underserved areas. Public health, not politics or corporate profits, must drive these critical decisions.

After determining prioritization, the federal government must ensure it can effectively distribute the vaccine—these efforts must be led by the CDC. While the Department of Defense, an active partner in Operation Warp Speed, clearly has extensive experience in logistics and operations that should be leveraged for the COVID-19 response, it is not a public health agency. In the United States, the role of supporting and overseeing immunization infrastructure and vaccination campaigns falls to the CDC due to its scientific expertise and longstanding relationships with public health departments. The CDC operates programs critical to our national vaccines distribution system: the Section 317 Immunization Program, which supports foundational immunization infrastructure across 64 jurisdictions, and the Vaccines for Children program, which purchases vaccines and provides them at no cost to children nationwide.^{53, 54} In 2009, the CDC distributed the pandemic H1N1 influenza vaccine to states through a centralized vaccine distributor built off of the VFC program.⁵⁵

⁵⁰ <https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5810a1.htm>

⁵¹ <https://www.ncbi.nlm.nih.gov/books/NBK54187/#ch4.s1>

⁵² <https://www.hhs.gov/about/news/2020/06/16/fact-sheet-explaining-operation-warp-speed.html>

⁵³ <https://astho.org/Programs/Immunization/Immunization-Infrastructure--The-Role-of-Section-317/>

⁵⁴ <https://www.cdc.gov/vaccines/programs/vfc/index.html>

⁵⁵ <https://www.cdc.gov/h1n1flu/cdcresponse.htm>

Distribution of eventual vaccines must account for logistics—particularly if, like many vaccines, COVID-19 vaccines require highly specific temperatures to remain stable and effective.⁵⁶ It will be essential to incorporate storage and transport capacity into any planning—including storage at manufacturing sites, capacity to distribute the vaccine safely without reducing its efficacy, and storage at the state, local, Tribal, and territorial level. This will be particularly important in rural and frontier areas and urban areas with limited access to health care facilities.

The federal government must also plan for global distribution of COVID-19 vaccines. Travel and international commerce are unlikely to fully resume without global control of COVID-19. “Vaccine nationalism” may pose serious problems to international collaboration to broadly administer COVID-19 vaccines globally, including to low income countries.⁵⁷ It also poses a significant health security risk to the United States. It is critical the U.S. collaborate with multilateral health organizations in global vaccine efforts.

To achieve these goals, Congress must act to expand existing immunization infrastructure and set parameters for equitable distribution of vaccines. Congress should:

- Require the federal government to incorporate equity into its plan to distribute COVID-19 vaccines, specifically to address disparities among communities of color, medically underserved communities, and low-income communities;
- Require the federal government to prioritize vaccine distribution in a manner that optimizes public health and is consistent with recommendations from ACIP, including protecting those at highest risk of severe illness, those at highest risk of infection due to occupation, place of residence, or other factors, and essential workers; and
- Establish and fund significant public private partnerships, including with chain drug stores, pharmacies, and third-party logistics companies, to expand vaccine distribution and ensure that every community has access to COVID-19 vaccines.

⁵⁶ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4743593/>

⁵⁷ <https://www.washingtonpost.com/health/2020/06/03/coronavirus-vaccine-global-race/>

Preparing for and Implementing Widespread Vaccine Administration

A successful vaccination campaign depends on the widespread administration of safe and effective vaccines to hundreds of millions of people across the country. This will be even more challenging given expectations that most COVID-19 vaccines in development will require more than one dose to achieve a protective effect.⁵⁸ Concurrently, the federal government must take every possible step to reduce the severity of the coming influenza season and to improve rates of routine immunizations that have decreased as a result of the COVID-19 pandemic.⁵⁹ As seasonal influenza vaccines are likely to arrive before COVID-19 vaccines, the upcoming influenza season provides an opportunity to test the future COVID-19 vaccination program to assess potential points of failure and to re-engineer a system to prevent transmission in immunization settings.

Furthermore, recent polls indicate that half of the U.S. population might not seek a COVID-19 vaccine.⁶⁰ It is therefore essential to use evidence-based communication and behavioral strategies to ensure high acceptance of COVID-19 vaccines. Coordination with state, local, Tribal, and territorial health departments, primary care physicians, pediatricians, obstetricians, nurses, pharmacists, and other health care providers on the front lines is essential, as is building on existing expertise, programs, and systems at the federal, state, and local level. In addition to traditional medical and public health stakeholders, such coordination should involve non-traditional partners including faith- and community-based organizations, businesses, unions, neighborhood associations, and others. The federal government must also track vaccine uptake by geographic area to ensure vaccine is reaching specific populations and monitor data to manage shortages and re-allocate doses as needed.

⁵⁸ <https://www.usatoday.com/story/news/health/2020/06/04/coronavirus-vaccine-may-require-two-shots-effective-heres-why/5309046002/>

⁵⁹ <https://www.statnews.com/2020/05/08/childhood-vaccinations-decline-coronavirus-pandemic/>

⁶⁰ <https://www.sciencemag.org/news/2020/06/just-50-americans-plan-get-covid-19-vaccine-here-s-how-win-over-rest>

To expand support for public health infrastructure and require the Executive Branch to communicate effectively to build vaccine confidence and combat misinformation, Congress should:

- Establish a core public health infrastructure fund that reaches \$4.5 billion annually to strengthen the public health system in the United States, bolstering the nation’s ability to effectively administer COVID-19 vaccines, along with the response more broadly;
- Strengthen the existing immunization infrastructure in the U.S., including through increased support for states, localities, Tribes, and territories to address gaps in capacity and capability;
 - Modernize and expand, with appropriate patient notification and appropriate privacy protections, immunization information systems, which help individuals and their health care providers track their vaccination history, provide information about missing and recommended vaccines, including for two-dose vaccines, identify gaps in immunization coverage, create reminders to ensure all doses are administered, and follow up on adverse events.
- Pass legislation to build vaccine confidence and combat misinformation, including the development of a national COVID-19 vaccine promotion plan, which could include a national communication campaign and a scale up plan for health care providers to effectively communicate about vaccines;
- Pass legislation to modernize public health data systems; and
- Communicate clearly and effectively to support strong uptake of a seasonal influenza vaccine and ongoing routine immunizations, starting immediately and continuing once COVID-19 vaccines are available.

Health care providers must have adequate and relevant information to relay to patients and families about any COVID-19 vaccine, including benefits, potential side effects, and other information typically included in a vaccine information statement.⁶¹ In addition, providers should have access to proper guidance outlining steps that can be taken to prevent the spread of COVID-19 during a vaccination campaign.⁶² Education and training are also important in promoting confidence in COVID-19 vaccines, as health care provider recommendations, presumptive communication, and motivational interviewing have been shown to influence acceptance of

⁶¹ <https://www.cdc.gov/vaccines/hcp/vis/about/facts-vis.html>

⁶² <https://www.cdc.gov/vaccines/pandemic-guidance/index.html>

vaccines.⁶³ For routine immunizations, the CDC offers vaccine education and training programs for various types of health care providers, tailored to match the recommendations of ACIP.⁶⁴

Additionally, the health care system must be prepared to administer safe and effective COVID-19 vaccines in a timely, efficient, and equitable manner. In order to achieve adequate population coverage, a robust, fully trained, and compensated workforce will be required to administer vaccines to all populations and in various settings across the country, including rural and underserved areas. One estimate suggests public health programs will need to triple the number of enrolled, licensed providers to ensure widespread vaccination, as was done during the 2009 H1N1 influenza pandemic.⁶⁵ In some cases, low provider reimbursement may also present a barrier to achieving adequate population coverage.

To ensure health care providers receive needed education and guidance and to support a sufficient workforce to administer vaccines, Congress should:

- Require the Administration to develop a set of robust tools and resources for providers as part of the COVID-19 vaccination campaign;
- Ensure the Administration widely distributes culturally and linguistically appropriate materials prior to the administration of COVID-19 vaccines;
- Require the federal government to assist states, localities, Tribes, and territories in strengthening and expanding the workforce needed to administer COVID-19 vaccines;
- Enact legislation to retain and recruit public health professionals who agree to serve in a state, local, Tribal, or territorial, health department through loan repayment;
- Ensure adequate reimbursement for administering vaccines, especially to underserved populations;
- Bolster the primary care workforce to ensure access to these vaccines for millions of individuals who rely on the health care safety net; and
- Provide temporary and targeted relief from licensing barriers that may impede the ability to fully and quickly scale the vaccine workforce, including relief from differing state scope of practice laws, which may affect which types of health care providers may administer eventual COVID-19 vaccines.⁶⁶

⁶³ <https://www.hhs.gov/sites/default/files/2017-vaccine-confidence-meeting-report.pdf>

⁶⁴ <https://www.cdc.gov/vaccines/ed/index.html>

⁶⁵ <https://www.healthaffairs.org/doi/10.1377/hblog20200418.799331/full/>

⁶⁶ <https://www.cdc.gov/phlp/publications/topic/vaccinationlaws.html>

Ensuring Post-Market Surveillance and Safety

As with any vaccine, safety issues may arise after licensure or authorization of COVID-19 vaccines. Given the speed of vaccine development and the likelihood that a very large number of people will receive a vaccine shortly after its FDA licensure or authorization, vaccine developers must conduct appropriate pharmacovigilance activities. As recommended in FDA guidance, developers should be planning for such activities at the time they submit their applications for approval.⁶⁷ Moreover, FDA should use its regulatory authority to require post-marketing studies when appropriate to continue to assess a vaccine's effectiveness when used in real world settings as well as known or potential risks posed by a vaccine. Study data should be reviewed and evaluated in publicly available settings, such as meetings of relevant federal advisory committees. The CDC and FDA should also strengthen existing vaccine safety monitoring systems, including the Vaccines Adverse Event Reporting System, the Vaccine Safety Datalink, and Sentinel to include COVID-19 vaccines.

Congress should ensure that FDA requires vaccine developers to submit and implement post-marketing pharmacovigilance plans and conduct any warranted post-marketing studies, and that FDA and the CDC conduct necessary active surveillance to assess and ensure vaccine safety.

⁶⁷ <https://www.fda.gov/media/139638/download>