

ONE HUNDRED SIXTEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
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May 21, 2020

The Honorable Deborah L. Birx, M.D.
Coronavirus Task Force Coordinator
White House
1600 Pennsylvania Ave NW
Washington, DC 20500

Dear Dr. Birx:

We write regarding the Trump Administration's planning efforts related to a future vaccine for coronavirus disease 2019 (COVID-19). Public health experts warn that a vaccination campaign will "require massive preparation and precise coordination."¹ As vaccine research and development progresses, we urge the Administration to develop and publicize to the greatest extent possible a national COVID-19 vaccine plan. Recognizing that our understanding of the virus changes by the day, such a plan should provide as much detail as possible on manufacturing capabilities and how they will be brought to necessary scale, recommendations for prioritization and allocation of vaccines to at-risk populations including health care workers and other first responders, guidance on provider training, and public education and outreach efforts, as well as coverage considerations in order to achieve the recommended utilization of a new vaccine in the United States once it is approved. While it will likely be at least several months until a safe and effective vaccine is approved for use in the United States, now is the time to prepare for a nationwide vaccine program.

To date, the Administration has not released a comprehensive COVID-19 vaccine plan. On May 15, the White House announced "Operation Warp Speed," a COVID-19 countermeasure development, manufacturing, and distribution framework with the aim "to have substantial quantities of a safe and effective vaccine available for Americans by January 2021."² According to the Administration, Operation Warp Speed will coordinate efforts across the federal government in order to develop vaccines, therapeutics, and diagnostics. For example, the National Institutes of Health (NIH) and numerous private sector partners are in the midst of

¹ *Good, a COVID-19 Vaccine is in Development – Will it Be Accessible to All Americans?*, Health Affairs (Apr. 20, 2020).

² U.S. Department of Health and Human Services, *Trump Administration Framework and Leadership for 'Operation Warp Speed,'* (May 15, 2020) (press release).

vaccine research and development. As of May 18, 2020, there are eight vaccines in clinical trials around the world, with three in clinical trials in the United States.³ Many more are in pre-clinical studies and expecting to move into clinical trials this year.

Given the unprecedented need for COVID-19 vaccines, collaboration in research and development is essential. To this end, NIH, the Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC), and Biomedical Advanced Research and Development Authority (BARDA), other U.S. governmental departments, the European Medicines Agency, and numerous academic, philanthropic, and private sector entities are collaborating on vaccine research and development through the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) public-private partnership, which will include harmonized efficacy trials, collaborating clinical trials networks, and more.⁴ The ACTIV partnership, along with other efforts, will reportedly be coordinated under Operation Warp Speed.⁵ While it is encouraging that these initiatives are underway, it is critical that these efforts be part of an overarching plan to bring vaccine and related supply manufacturing and distribution to scale once a COVID-19 vaccine is approved.

Just as collaboration on research and development is critical, so is collaboration and a comprehensive strategy on vaccine deployment. One key component of a comprehensive COVID-19 vaccine plan is ensuring the ability to bring manufacturing of the COVID-19 vaccine and ancillary supplies to scale before a vaccine is approved. Unfortunately, according to December 19, 2019, testimony from Dr. Robert Kadlec, the Department of Health and Human Services' (HHS) Assistant Secretary for Preparedness and Response (ASPR), before the Committee on Energy and Commerce's Oversight and Investigations Subcommittee, "The U.S. lacks sufficient domestic manufacturing capacity and/or raw materials" for medical countermeasures including vaccines.⁶ He further warned that, "in a pandemic, global manufacturing capacity will likely not be sufficient to meet demand, resulting in an inability to import adequate quantities of medical countermeasures."⁷ While Dr. Kadlec described several

³ Regulatory Affairs Professionals Society, *COVID-19 vaccine tracker*, Regulatory Focus (May 18, 2020).

⁴ Corey, Lawrence, et al, *A strategic approach to COVID-19 vaccine R&D*, Science (May 11, 2010).

⁵ U.S. Department of Health and Human Services, *Trump Administration Framework and Leadership for 'Operation Warp Speed,'* (May 15, 2020) (press release).

⁶ Written Testimony of Robert Kadlec, M.D., M.T.M&H, M.S. before the House Committee on Energy and Commerce Subcommittee on Oversight and Investigations, *Flu Season: U.S. Public Health Preparedness and Response* (Dec. 4, 2019).

⁷ *Id.*

initiatives that ASPR was taking to address these issues, they were not fully implemented before COVID-19 arrived in the United States.⁸

Since February, the Administration has announced several initiatives to address manufacturing capacity concerns for a COVID-19 vaccine. These range from identifying large-scale commercial manufacturing capabilities to initiatives intended to unify industry partnerships and speed up future manufacturing.⁹ For instance, BARDA has announced nearly \$1 billion worth of new investments to support development and scaled-up manufacturing for promising COVID-19 vaccines.¹⁰ And, last month, BARDA confirmed that contracts with a network of companies that could support vaccine production in the event of a pandemic were still in place, and that these companies “are prepared to begin manufacturing vaccine if needed.”¹¹

Last month, FDA Commissioner Stephen Hahn told members of the Committee that efforts were underway within the agency to assess and build production capabilities of vaccine-related supplies that will be necessary to administer a COVID-19 vaccine.¹² According to NIH Director Francis Collins, who also recently spoke with members of the Committee, the ability to bring production of a promising vaccine to scale is an important factor in determining whether to proceed with clinical trials.¹³ Dr. Collins indicated that research supported under the ACTIV public-private partnership will take these manufacturing needs into consideration.¹⁴ He also shared that NIH is working with both BARDA and FDA in preparation for production pipelines, cautioning that if we wait for proof of a vaccine’s effectiveness against COVID-19, we will have lost too much time to the virus.¹⁵

⁸ *Id.*

⁹ *Federal vaccine development sites ill-suited to counter covid-19 epidemic*, Washington Post (Mar. 15, 2020); *When coronavirus vaccine arrives, experts worry US not ready to mass produce*, ABC News (Apr. 16, 2020); *NIH announces strategy for developing COVID-19 drugs, vaccines*, Roll Call (Apr. 17, 2020).

¹⁰ *Special Report: Countries, companies risk billions in race for coronavirus vaccine*, Reuters (Apr. 25, 2020).

¹¹ *When coronavirus vaccine arrives, experts worry US not ready to mass produce*, ABC News (Apr. 16, 2020).

¹² Remarks by U.S. Food and Drug Administration Commissioner Stephen Hahn M.D. to members of the Committee on Energy and Commerce, Bipartisan briefing call (Apr. 22, 2020).

¹³ Remarks by U.S. National Institutes of Health Director Francis Collins, M.D., Ph.D., to members of the Committee on Energy and Commerce, Bipartisan briefing call (Apr. 30, 2020).

¹⁴ *Id.*; National Institutes of Health, *NIH to launch public-private partnership to speed COVID-19 vaccine and treatment options*, (April 17, 2020) (press release).

¹⁵ Remarks by U.S. National Institutes of Health Director Francis Collins, M.D., Ph.D., to members of the Committee on Energy and Commerce, Bipartisan briefing call (Apr. 30, 2020).

In addition to development, manufacturing, and distribution, a comprehensive COVID-19 vaccine plan must also take into account the decisions that will be necessary related to the allocation of a vaccine. According to former FDA Commissioner Scott Gottlieb, it will be “well into 2021 until anyone is going to have a vaccine available in the kinds of quantities that would be required to inoculate the entire United States[.]”¹⁶ Limited doses of a vaccine may be available as early as Fall 2020, and decisions will have to be made about how to prioritize those doses. Adult vaccination experts believe that this planning can begin now through existing public health infrastructure and must be based on Advisory Committee on Immunization Practices (ACIP) guidelines.¹⁷

Strategies for provider engagement and public education efforts will be similarly crucial to the success of a COVID-19 vaccine plan. Given that overall vaccination rates among adults are particularly low in the United States, and that marginalized communities are less likely to have access to vaccines, these efforts cannot begin soon enough.¹⁸ Stakeholders attribute low vaccination uptake and these disparities to a variety of factors, including lack of provider recommendations, access barriers and cost, as well as vaccine hesitancy and misinformation.¹⁹ Public health experts therefore believe that managing COVID-19 vaccination for adults will require “more staff, more resources, and additional IT capacity.”²⁰ They also point to the need for large-scale education efforts for both providers and consumers.²¹ Particularly in a broader environment of vaccine hesitancy, it will also be necessary to identify specific communities’ vaccine concerns and to create culturally sensitive materials and programming that comply with CDC recommendations to address their hesitations.²²

Considerations to address barriers related to patient vaccination costs will also need to be part of a comprehensive COVID-19 vaccine plan. Given the severe impact COVID-19 has had on unemployment and loss of insurance coverage in the United States, ensuring broad access to the COVID-19 vaccine will be critically important to our efforts to ensure access and uptake.²³ The recently enacted Coronavirus Aid, Relief, and Economic Security (CARES) Act took the

¹⁶ *Dr. Scott Gottlieb sees millions of coronavirus vaccine doses ready for testing this fall*, CNBC (Apr. 29, 2020).

¹⁷ Adult Vaccine Access Coalition, *Adult Vaccine Access Coalition’s Recommendations to Strengthen Immunization Infrastructure for COVID-19 Response* (Apr. 16, 2020).

¹⁸ *Vaccinate Your Family, 2020: State of the ImmUnion* (2020).

¹⁹ *Id.*

²⁰ *Good, a COVID-19 Vaccine is in Development – Will it Be Accessible to All Americans?* Health affairs (Apr. 20, 2020).

²¹ *Id.*

²² *Vaccinate Your Family, 2020: State of the ImmUnion* (2020).

²³ Kaiser Family Foundation, *Changes in Income and Health Coverage Eligibility After Job Loss Due to COVID-19* (Apr. 14, 2020).

first steps to address this issue. CARES expedited coverage of a future COVID-19 vaccine in private health plans by requiring coverage with no cost-sharing within 15 days of a recommendation from ACIP or the U.S. Preventative Services Task Force, and by ensuring coverage under Medicare Part B and Medicare Advantage without any cost-sharing.²⁴ However, while most Americans are guaranteed access to recommended immunizations at zero cost-sharing through their private health plans, some Americans could still face barriers to access because they are uninsured or because they have enrolled in health plans that do not offer the same level of immunization coverage.²⁵ Following the lead of the CARES Act, it will be vital for a COVID-19 vaccine plan to include coverage considerations and be transparent as to how cost barriers will be ameliorated for those who are uninsured and underinsured.

Finally, as the United States and the world respond to the COVID-19 pandemic, there are early warning signs to heed. Immunization rates for preventable infectious diseases, such as for measles, have recently decreased due in part to social distancing efforts.²⁶ Experts also caution that efforts to increase COVID-19 manufacturing may supplant production of other vaccines.²⁷ The development and implementation of a COVID-19 vaccine plan must also take these considerations into account.

Given the concerns above, we request a briefing on Operation Warp Speed and responses to the following requests by June 4, 2020:

1. Has the Administration developed, or does it intend to develop, a COVID-19 vaccine plan that includes strategies to support vaccine and ancillary supplies manufacturing and distribution needs, allocation decisions, provider engagement, patient education, and vaccine uptake goals? If so, please provide a copy of the plan, detailing who is or will be charged with the plan's coordination, as well as engagement efforts underway across the White House Coronavirus Task Force, U.S. Executive Branch Departments, state, local, territorial, and tribal health departments, and with health care, public health, and health information and reporting experts.
2. Does the Administration currently have a national strategy to bring the manufacturing of COVID-19 vaccine and ancillary supplies to scale once a COVID-19 vaccine is approved as safe and effective? If so, please detail who is coordinating the strategy and engagement efforts across the Administration and with the private sector. If not, please provide information regarding when such a strategy will be available.

²⁴ Coronavirus Aid, Relief, and Economic Security Act, P.L. 116-136.

²⁵ Vaccinate Your Family, 2020: *State of the ImmUnion* (2020).

²⁶ *Vaccine Rates Drop Dangerously as Parents Avoid Doctor's Visits*, *New York Times* (Apr. 23, 2020).

²⁷ *Id.*; *If a coronavirus vaccine arrives, can the world make enough?* *Nature* (Apr. 9, 2020).

3. Does the Administration currently have a national strategy to prepare the nation's immunization infrastructure to be able to allocate and distribute the COVID-19 vaccine once a safe and effective vaccine is approved? If so, please detail who is coordinating the strategy and engagement efforts across the Administration, with state, local, territorial, and tribal health departments, and with the private sector. If not, please provide information regarding when such a strategy will be available.
4. Does the Administration currently have a national strategy to support provider training and patient education and outreach to ensure the recommended uptake of the COVID-19 vaccine once approved for use? If so, please detail who is coordinating the strategy and engagement efforts with state, local, territorial, and tribal health departments, as well as with health care, public health, and health information and reporting experts. If not, please provide information regarding when such strategy will be available.
5. How will the Administration ensure equitable access to a COVID-19 vaccine, particularly among marginalized communities who have faced barriers to vaccinations in general and are more likely to be affected by COVID-19?
6. While the CARES Act ensures that a COVID-19 vaccine is available with no cost-sharing for patients in Medicare Part B, Medicare Advantage, and private health plans, there are still gaps in access. State Medicaid programs are not currently required to cover vaccines for adults, and as of the end of 2018 there were roughly 28 million uninsured individuals in the United States, a figure that has almost certainly grown during the current crisis. What steps will the Administration take to ensure that the COVID-19 vaccine will be available at no cost to those for whom it is indicated and who also do not receive coverage under Medicare Part B, Medicare Advantage or private health plans? More specifically, what steps will the Administration take to ensure a vaccine is available and accessible to those who receive coverage through Medicaid or are uninsured?
7. How will the Administration support existing immunization programs to prevent a further reduction in vaccination rates for non-COVID-19 infectious diseases?

The Honorable Deborah L. Birx, M.D.

May 21, 2020

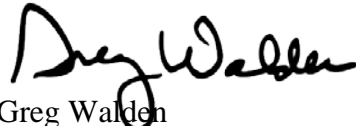
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Thank you for your attention to this matter. If you have any questions, and to schedule the requested briefing, please contact Jesseca Boyer of the Majority staff at (202) 225-2927 and Natalie Sohn of the Minority staff at (202) 225-3641.

Sincerely,



Frank Pallone, Jr.
Chairman



Greg Walden
Ranking Member



Diana DeGette
Chair
Subcommittee on Oversight
and Investigations



Brett Guthrie
Ranking Member
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