

United States Senate

WASHINGTON, DC 20510

May 7, 2020

Robert R. Redfield, MD
Director
Centers for Disease Control & Prevention
1600 Clifton Road
Atlanta, GA 30329

Robert Kadlec, MD
Assistant Secretary for Preparedness & Response
Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Dr. Redfield and Dr. Kadlec,

We write to request information about the Centers for Disease Control and Prevention (CDC) and Assistant Secretary for Preparedness and Response's (ASPR) plans for manufacturing, distributing, and administering a COVID-19 vaccine, or multiple COVID-19 vaccines once they are available, and your plans to prepare for and respond to vaccine supply and demand. The production and distribution of a successful COVID-19 vaccine or vaccines may be the most extensive and important public health undertaking of our lifetimes. We cannot afford to let the Administration delay it with additional missteps or leave it to chance or the whims of the market. This is a massive undertaking that requires careful planning, relentless attention to detail, and flawless execution of a national strategy, which must include making the vaccine available to all Americans for free.

Although a vaccine has not yet been developed, we are encouraged by the global race and clinical trials for developing a vaccine for COVID-19. However, we are concerned about the current capacity to produce, manufacture, and distribute a sufficient number of COVID-19 vaccines in addition to other vaccines, such as a seasonal influenza vaccine. A vaccine for COVID-19 is critical to protect the public health and truly get our country back up and running at full capacity once again. Given this reality, developing, producing, and administering a vaccine must be a top priority. We expect the Administration to take all necessary steps and make sound investments to ensure that anyone who is seeking or required to get a vaccine can do so immediately when a vaccine becomes available.

When it comes time to distribute a vaccine, the Administration must not repeat the missteps and medical product supply failures that have plagued the early response to COVID-19. While it will be many months before a vaccine is ready, it is critical your agencies use that time to take the steps necessary to ensure that once a vaccine is licensed or authorized, the nation has the production capacity, supply chains, and distribution networks ready to rapidly deploy the vaccine to hundreds of millions of Americans. **We therefore ask for a briefing on your vaccine production and distribution strategies to meet the goal of vaccinating as many Americans as possible once a vaccine is licensed or authorized, and that your briefing address the following questions.**

Vaccine Manufacturing and Supplies

- What is the status of the capacity of companies with vaccine candidates in development to manufacture the necessary number of doses for a COVID-19 vaccine? What surge vaccine production capacity is being developed by these companies, component manufacturers, and other public or private entities to meet the need of both COVID-19 and influenza vaccines?
- What additional "fill/finish" capacity is needed to rapidly fill vaccine vials and finish packaging vaccines in the necessary quantities?
- How are you working with companies developing vaccines, component manufacturers, and other public or private entities to secure sufficient supply of the necessary vials, syringes, needles, and other ancillary supplies or raw materials recovered to manufacture, store, distribute, and administer the necessary number of vaccine doses? What plans are in place to reach that capacity?
- What structures will be in place to detect potential bottlenecks early and to ensure that supply chain slowdowns or bottlenecks do not hinder vaccine manufacturing, distribution, and administration?

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- What monitoring is in place to track potential shortages of vials, needles, and syringes or any raw materials required to produce a COVID-19 vaccine and other injectable medications patients currently rely on? Are there control measures in place to maintain access to supplies for injectable medications?
- How will you protect the vaccine manufacturing and distribution process from undue political influence?

Vaccine Distribution and Surveillance

- Please describe any work to build and support a vaccine distribution system, specifically:
 - Will there be a single distributor or multiple distributors?
 - Will the distribution system be centralized (distributed to states) or decentralized (distributed to health systems, pharmacies, community health centers, etc.) and in what order of priority?
 - If centralized, how will local health departments be engaged to ensure that vaccine reaches people in local communities?
 - How will your agencies support the hiring and training of sufficient personnel to successfully distribute and administer a vaccine?
 - What will be the role of federal agencies to coordinate distribution and ensure that vaccines are equitably and freely distributed and reach every community, including ensuring equitable distribution of a vaccine for racial and ethnic groups that have been disproportionately affected by COVID-19?
 - How will you handle multiple vaccines with different characteristics, if necessary?
- Please describe the data and logistics system you will use to ensure there are not bottlenecks and maldistribution of vaccines.
- What additional capacity or resources does the CDC need to develop a surveillance system to track the number of COVID-19 vaccinations?
 - Will you track number of doses, state allocations, who receives vaccines, and number of vaccines that are not administered?
 - How will this tracking occur while monitoring postmarket adverse event reporting?
 - How will these activities proactively address and prevent health disparities?
- What work is underway to evaluate and enhance immunization registries (i.e. state Immunization Information Systems (IIS)) including to track who has received a dose or doses of the vaccine while protecting privacy?
 - Given that vaccines may be provided in non-traditional settings (e.g. pop-up sites or via ambulances), how do you intend to ensure that these facilities can access and use immunization registries?
 - How do you intend to ensure that immunization registries can communicate with one another so that data entered in one registry can be shared with the others when patients cross state or local boundaries?
 - How do you intend to support patient identification and matching in immunization registries?
 - How do you intend to leverage the demographic data elements identified by ONC as critical for data exchange to improve vaccine surveillance?
 - One way to improve patient matching is to standardize address information. The U.S. Postal Service (USPS) has a tool for standardizing addresses that it makes available for free to the shipping industry, but not health care. Have you worked with the USPS to minimize the inevitable patient matching challenges that will occur?

Vaccine Safety and Access

- Please provide a timeline for developing guidance on making fair allocations of a vaccine to states, tribes, local governments and territories.
- Which populations will be prioritized to get a vaccine first, and what are your plans are to ensure vaccines reach these populations?

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- What actions will CDC take to ensure the American people are confident about the safety and effectiveness of the vaccine, and that public communication about vaccine development is accurate and consistent with medical expertise?
- What actions will be taken to ensure communication to the public regarding access to and distribution of the vaccine?
- Will there be an independent monitor evaluating vaccine rollout?
- What steps are being taken to combat COVID-19 vaccine hesitancy and misinformation, including in advance of a vaccine becoming available?
- How will you address postmarketing reports of adverse events associated with the use of a COVID-19 vaccine? Will you commit to being fully transparent about these risks?
- Is the administration considering participating in an equitable global distribution system that prioritizes doses based on need in different priority groups such as health care and public safety workers?
- How will you work with global stakeholders to ensure a vaccine can be used to slow and stop the epidemic elsewhere?

We appreciate your attention to this endeavor and want to ensure that Congress is a strong partner. We ask for a response to this letter within 7 days with a timeline for development of a vaccine distribution strategy and a date by which you will provide the requested briefing. We would be pleased to have a preliminary phone call or virtual briefing if you think that would be constructive.

If you have any questions, please contact Elvia Montoya with Senator Merkley's staff at 202-510-8187 and Andi Lipstein Fristedt with Senator Murray's HELP Committee staff at 202-224-7675. Thank you for your attention to this matter, and we look forward to your response.

Sincerely,

/s/ Jeffrey A. Merkley
Jeffrey A. Merkley
United States Senator

/s/ Kirsten Gillibrand
Kirsten Gillibrand
United States Senator

/s/ Ron Wyden
Ron Wyden
United States Senator

/s/ Christopher S. Murphy
Christopher S. Murphy
United States Senator

/s/ Benjamin L. Cardin
Benjamin L. Cardin
United States Senator

/s/ Jeanne Shaheen
Jeanne Shaheen
United States Senator

/s/ Patty Murray
Patty Murray
United States Senator

/s/ Robert P. Casey, Jr.
Robert P. Casey, Jr.
United States Senator

/s/ Sheldon Whitehouse
Sheldon Whitehouse
United States Senator

/s/ Jack Reed
Jack Reed
United States Senator

/s/ Edward J. Markey
Edward J. Markey
United States Senator

/s/ Tammy Baldwin
Tammy Baldwin
United States Senator

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/s/ Chris Van Hollen
Chris Van Hollen
United States Senator

/s/ Tina Smith
Tina Smith
United States Senator

/s/ Michael F. Bennet
Michael F. Bennet
United States Senator

/s/ Kamala D. Harris
Kamala D. Harris
United States Senator

/s/ Richard Blumenthal
Richard Blumenthal
United States Senator

/s/ Tim Kaine
Tim Kaine
United States Senator

/s/ Sherrod Brown
Sherrod Brown
United States Senator

/s/ Elizabeth Warren
Elizabeth Warren
United States Senator

/s/ Bernard Sanders
Bernard Sanders
United States Senator

/s/ Mazie K. Hirono
Mazie K. Hirono
United States Senator

/s/ Amy Klobuchar
Amy Klobuchar
United States Senator

/s/ Dick Durbin
Richard J. Durbin
United States Senator