Congress of the United States
House of Representatives
Washington, DC 20515

August 6, 2020

The Honorable Mike Pence
Vice President of the United States
The White House
1600 Pennsylvania Avenue, N.W.
Washington, D.C. 20500

Dear Vice President Pence,

I write with grave concern regarding the Administration's COVID-19 Vaccine Manufacturing, Distribution, and Administration Plan. In light of July's highest number of new COVID-19 cases since the pandemic began, test positivity rates increasing in more than 30 States, record-high deaths and hospitalizations in multiple States, and ten days with more than one thousand COVID-19 death, the absence of a national plan to take control of the virus is troubling. Since Dr. Birx, member of the White House Task Force, recently stated that we are in a new phase of the pandemic, it is critical that the Administration provide answers regarding a successful COVID-19 vaccine campaign.

Furthermore, the Centers for Disease Control and Prevention (CDC) in past pandemics has been charged with leading the nation's vaccination campaign. Given the Administration's track record in responding to the pandemic and sidelining of CDC throughout the pandemic, Americans are waiting with bated breath regarding what and when to expect regarding the availability of the vaccine for themselves and their loved ones. With the pandemic continuing to explode across the country, I request answers to the following questions by Friday, August 14, 2020.

Development, Manufacturing, Production, and Procurement of Vaccines

1) Does the Administration plan to use FDA's gold standard of proven safety and efficacy?
2) What are the Administration's criteria for determining when to seek an EUA, if necessary?
3) What is the Administration's plan for ensuring equal representation of black, indigenous, and people of color in COVID-19 vaccine development?
4) Does the Administration have enough funding for manufacturing of vaccines, therapeutics, and diagnostics, and drug ingredients? If it, does not, please provide what additional resources are needed. Please provide a detailed spend plan, including how much money has already been spent and for what purposes, remaining funds and how the Administration plans to use them, and any additional funds the Administration is requesting and for what purposes.
5) Does the Administration have enough funding for the production of vaccines, therapeutics, and diagnostics, and drug ingredients? If not, please provide what additional resources are needed. Please provide a detailed spend plan, including how much money has already been spent and for what purposes, remaining funds and how the Administration plans to use them, and any additional funds the Administration is requesting and for what purposes.

6) How much funding is necessary for the purchase of vaccines, therapeutics, diagnostics, and drug ingredients? Please provide a detailed spend plan, including how much money has already been spent and for what purposes, remaining funds and how the Administration plans to use them, and any additional funds the Administration is requesting and for what purposes.
7) Please provide a list of purchase agreements the Secretary of HHS, including through BARDA, and the Secretary of Defense, through DARPA, have already entered into and the terms of those agreements, including price per dose, number of doses, expected delivery timeline, and how the doses will be distributed.
8) Please provide a list of research and development funding agreements the Secretary has entered into with manufacturers and the terms of those agreements, including any purchasing commitments, pricing requirements, and exclusive or nonexclusive licensing arrangements.
    a) What are the streamlined procedures followed in awarding contracts and how do they make sure essential protections are in place?
    b) How do the agreements prevent profiteering or self-dealing?
    c) What are the procedures for monitoring quality, progress, and capacity?
9) Has the Secretary established a formula for determining a reasonable price and planned to negotiate price with manufacturers of vaccines, diagnostics, and drugs? If yes, please include a detailed summary of the formula, how the Secretary will enforce this reasonable price, and to what extent it accounts for taxpayer investments made in the research, development, and manufacturing and production of the vaccine, diagnostics, or drug. If no, please provide an explanation for not negotiating a reasonable price and an explanation for how the Secretary will protect taxpayer investments and equitable access with fair and reasonable pricing.
10) Has the Secretary requested manufacturers submit their current manufacturing capacities for vaccines, diagnostics, and therapeutics? If he has not, when will he request this information? Please provide a detailed analysis on the current status of manufacturing capacities.
11) Has the Secretary requested manufacturers submit their projected manufacturing capacities for six and twelve months from the date of this letter? If he has not, when will he request this information? Please provide a detailed analysis for manufacturers including:
    a) pharmaceutical manufacturers,
    b) manufacturers that provide fill-finish services,
    c) manufacturers of brewing equipment, and
    d) the manufacturers of glass vials, syringes and needles, stoppers, and adjuvants.
12) Are multi-dose vials feasible for each vaccine candidate selected by Operation Warp Speed? Please provide a detailed analysis.
13) Have manufacturers submitted data on their Cost of Goods Sold? If they have not, when will the Secretary require manufacturers to submit data on their Cost of Goods Sold?
14) Are technology upgrades needed for the Vaccine Tracking System and Vaccine Adverse Event Reporting System? Please provide a detail analysis.
15) What are the Administration's plans for construction, renovation, or retrofitting of United States manufacturing facilities for vaccines and therapeutics respectively? Please include details on these plans for:
    a) new manufacturing facilities,
    b) fill-finish facilities
    c) facilities that manufacture brewing equipment, and
    d) facilities that manufacture glass vials, syringes and needles, stoppers, and adjuvants.

Distribution and Administration of a Vaccine

1) What is the Administration's plan to promote COVID-19 vaccine availability and encourage widespread vaccination?
2) What is the Administration's plan to distribute the COVID-19 vaccine? Please provide details for any criteria that will be used to determine groups of individuals that should receive priority in receiving a vaccine. Further, please provide a detailed timeline regarding vaccine distribution [once it has been approved for use].
3) What is the Administration's plan to distribute and administer vaccine doses nationally? Please provide the details of how the Administration is working with each State and Territory on their plans for distribution and administration.
4) What is the Administration's plan for monitoring and tracking vaccines around the country? What are the plans for engagement with States and Territories on monitoring and tracking?
5) What is the administration's plan for distributing and administering vaccines to uninsured individuals? Please provide details with respect to information campaigns, engagement and outreach with community leaders, and administration of vaccines?
6) What is the administration's plan for distributing and administering vaccines to communities of color? Please provide details with respect to information campaigns, and engagement and outreach with community leaders.
7) What is the administration's plan for distributing and administering vaccines to high-risk populations? Please provide details with respect to information campaigns, and engagement and outreach with community leaders.
8) What is the Administration's plan for providing culturally competent information regarding the availability and necessity of the COVID-19 vaccine?
9) How is the Administration engaging with global partners on the distribution and administration of a vaccine?

Given the urgent circumstances, I reiterate that a response to these questions is requested no later than Friday, August 14, 2020. As always, I stand ready to work with you to protect the health and safety of the American people, who deserve answers to these questions.

Sincerely,

Rosa L. DeLauro
Member of Congress

Lloyd Doggett
Member of Congress

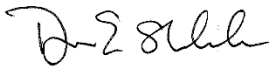
Jan Schakowsky
Member of Congress

Barbara Lee
Member of Congress

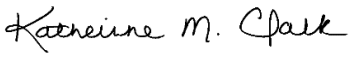
Lois Frankel
Member of Congress

Ro Khanna
Member of Congress

Katie Porter
Member of Congress



Donna E. Shalala
Member of Congress



Katherine Clark
Member of Congress

Peter A. DeFazio
Member of Congress

Mark Pocan
Member of Congress

Lucille Roybal-Allard
Member of Congress

Kim Schrier, M.D.
Member of Congress

CC: The Honorable Alex M. Azar II, Secretary of Health and Human Services
CC: Dr. Robert Redfield, Director of the Centers for Disease Control and Prevention