

Congress of the United States
Washington, DC 20515

September 8, 2020

The Honorable Alex M. Azar II
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Azar:

The Committee on Oversight and Reform and the Select Subcommittee on the Coronavirus Crisis seek information on the processes that will guide the Department of Health and Human Services (HHS) in determining the deployment and prioritization of any vaccines for COVID-19 and SARS-CoV-2 infection.

We all fully support the rapid development of a safe and effective vaccine. However, once one is approved for use, difficult decisions will follow. On day one, there will not be enough vaccine doses to administer immediately to everyone in America. It will take time to manufacture, distribute, and administer doses to hundreds of millions of people. Decisions will have to be made about who will get a vaccine first, whether particular groups will have priority for receiving a vaccine, and how to implement the determined order. As a vaccine is deployed, public health agencies will need to engage in ongoing surveillance for safety and effectiveness. These critical decisions must be made on the basis of science and our shared values—not politics.

Lack of preparation becomes more concerning each day, especially in light of recent statements by the Centers for Disease Control and Prevention (CDC) that early vaccine distribution to limited groups may begin as soon as late October or early November, with possible “large-scale distribution of the Covid-19 vaccines in the fall of 2020.”¹

Rapid Distribution and Deployment on a Massive Scale

Deploying a vaccine will be a sprawling and complicated endeavor. One or more vaccines will need to be manufactured in mass quantities, distributed nationwide, and administered at many thousands of points of care. Vaccines with more than one dose will further complicate the process. Some of the top vaccine candidates must be stored at very cold temperatures, requiring special logistics infrastructure for cold chain distribution.² It is essential that a plan is put in place that can be executed with all practicable speed and in an equitable and orderly manner.

¹ *CDC to States: Ready Vaccine Distribution for November*, Politico (Sept. 2, 2020) (online at www.politico.com/news/2020/09/02/cdc-states-vaccine-distribution-407783).

² *From ‘Freezer Farms’ to Jets, Logistics Operators Prepare for a Covid-19 Vaccine*, Wall Street Journal (Aug. 28, 2020) (online at www.wsj.com/articles/from-freezer-farms-to-jets-logistics-operators-prepare-for-a-covid-19-vaccine-11598639012).

It has been reported that nationwide distribution of a coronavirus vaccine, a responsibility that would typically be overseen by the CDC, will be a “joint venture” between CDC and the Department of Defense (DOD), with DOD handling logistics for manufacturing, kit compilation, and distribution, and CDC engaging with state and local public health organizations and conducting ongoing safety monitoring.³ We have questions about this deviation from existing vaccination systems, particularly since DOD will be engaged in an endeavor outside of its normal mission.

While at least some distribution will be supported by commercial partners with distribution experience, like McKesson Corporation, much of the responsibility for distribution appears to be delegated to the states, who have already been bearing much of the burden of the pandemic response even while facing declining resources.⁴ CDC has reportedly been urging some states and cities to draft plans on how to distribute a coronavirus vaccine, apparently hoping to use those as a guide for other states and cities. On August 27, 2020, CDC notified all states and five large cities to be prepared to distribute a vaccine to health care workers and other high-risk groups as soon as late October, apparently providing only three documents with 11 total pages to guide preparations.⁵

We are particularly concerned by reports that the Administration has not yet taken meaningful measures to engage with communities of color to ensure that the vaccination program will reach them.⁶

Achieving Fairness and Equity in Vaccine Prioritization and Targeting

To maximize public confidence and fairness in the vaccine distribution process, it will be essential to employ a transparent, science-driven approach, in full view of the American public, and to disclose the distribution plan well in advance of vaccine deployment.

Possible priority groups for a coronavirus vaccine include health care workers, high-risk populations, essential and critical infrastructure workers, older adults, racial and ethnic groups, those with underlying conditions, military service members, residents of high-infection regions, those who live in densely populated areas, and those who volunteered for clinical trials and

³ *Vaccine Distribution Will Be ‘Joint Venture’ Between CDC and Pentagon*, Politico (July 30, 2020) (online at www.politico.com/news/2020/07/30/coronavirus-vaccine-distribution-388904).

⁴ McKesson Corporation, *Press Release: McKesson to Distribute Future COVID-19 Vaccines in Support of Operation Warp Speed* (Aug. 14, 2020) (online at www.mckesson.com/About-McKesson/Newsroom/Press-Releases/2020/McKesson-Distribute-Future-COVID-19-Vaccines-Operation-Warp-Speed/).

⁵ *C.D.C. Tells States How to Prepare for Covid-19 Vaccine by Early November*, New York Times (Sept. 2, 2020) (online at www.nytimes.com/2020/09/02/health/covid-19-vaccine-cdc-plans.html).

⁶ *U.S. Lacks Plan for Getting Vaccine to Communities of Color Devastated by Virus*, Politico (Aug. 3, 2020) (online at www.politico.com/news/2020/08/03/vaccine-minority-communities-389878).

received a placebo.⁷ The World Health Organization has stated that healthcare workers, adults over 65, and adults with comorbidities should receive priority.⁸ Some experts have advocated for a weighted lottery system that would assign an order and give higher-priority individuals a higher likelihood of being selected earlier.⁹

Decisions on vaccine priority carry great weight and require sensitive judgments that must be made free from political considerations. To properly weigh all scientific, logistical, and ethical factors will require deliberation among independent experts in epidemiology, bioethics, economics, social justice, and other fields.

We are concerned that the Administration does not have a firm plan on how prioritization decisions will be made, since reports indicate that multiple bodies are deliberating on the issue, with little clarity on who is in charge or how contrasting recommendations will be reconciled.

Typically, the Advisory Committee on Immunization Practices (ACIP), which advises CDC, makes recommendations on appropriate uses of vaccines for different populations, as it did for the H1N1 influenza pandemic in 2009.¹⁰ During the coronavirus crisis, ACIP has already begun to discuss prioritization issues and has committed to listening to representatives of relevant communities during its deliberations.¹¹

Another committee was convened on an *ad hoc* basis to consider prioritization issues. On July 21, 2020, the National Academy of Medicine—reportedly at the request of National Institutes of Health (NIH) Director Francis Collins, but later formally requested by both NIH and CDC—named an expert panel to develop a framework on prioritization. On September 1, 2020, this panel released a draft framework for equitable allocation of a coronavirus vaccine that recommended an approach based on various risk factors.¹² We commend the panel for receiving public comments, including in a live virtual hearing, and look forward to seeing how its final

⁷ *Who Should Get a Coronavirus Vaccine First?*, Washington Post (July 29, 2020) (online at www.washingtonpost.com/health/2020/07/29/covid-vaccine-essential-workers-high-risk-populations/); Center for American Progress, *A Comprehensive COVID-19 Vaccine Plan* (July 28, 2020) (online at www.americanprogress.org/issues/healthcare/reports/2020/07/28/488196/comprehensive-covid-19-vaccine-plan/).

⁸ *WHO Sets Out Vaccine Allocation Plan*, Politico (June 23, 2020) (online at www.politico.com/news/2020/06/23/world-health-organization-vaccine-allocation-335469).

⁹ *Who Gets the Covid-19 Vaccine First? Here's One Idea*, New York Times (July 23, 2020) (online at www.nytimes.com/2020/07/23/health/coronavirus-vaccine-allocation.html).

¹⁰ Centers for Disease Control and Prevention, *2009 H1N1 Vaccination Recommendations* (Oct. 15, 2009) (online at www.cdc.gov/h1n1flu/vaccination/acip.htm).

¹¹ *Who Gets a Vaccine First? U.S. Considers Race in Coronavirus Plans*, New York Times (July 16, 2020) (online at www.nytimes.com/2020/07/09/us/coronavirus-vaccine.html).

¹² Committee on Equitable Allocation of Vaccine for the Novel Coronavirus, National Academies of Sciences, Engineering, and Medicine, *Discussion Draft of the Preliminary Framework for Equitable Allocation of COVID-19 Vaccine* (Sept. 1, 2020) (online at www.nationalacademies.org/news/2020/09/national-academies-release-draft-framework-for-equitable-allocation-of-a-covid-19-vaccine-see-public-comment).

report addresses some of the concerns and omissions raised, including the fact that the framework omitted any express consideration of race or ethnicity.¹³

While the National Academies committee crafts its recommendations, the path forward remains unclear. No announcement has been made on how ACIP will consider the panel's recommendations or how ACIP's recommendations will then be considered by CDC. The public is left wondering who will make final decisions on prioritization and whether it will be CDC, Operation Warp Speed, or the White House.¹⁴

The resulting confusion about who will make decisions on prioritization and the factors influencing those decisions risks undermining public confidence in the vaccine program. People will have more trust in the vaccine and the program when there is transparency and clarity on the process for deciding when and how they and their loved ones can expect to receive a vaccine.

Vaccine Safety Monitoring During and After Deployment

After the vaccine is deployed, it will be critical to monitor its safety and effectiveness on an ongoing basis. Guidance for industry issued by the Food and Drug Administration (FDA) recommended "early planning of pharmacovigilance activities before licensure" and a process for recording and identifying vaccines in health records.¹⁵ FDA will have an important, ongoing role in this effort.

The federal government should begin preparations for its role in this critical follow-through phase of execution now. There are already numerous national surveillance systems to monitor vaccines, including the Vaccine Safety Datalink and the Post-Licensure Rapid Immunization Safety Monitoring systems, each with their own benefits and limitations.¹⁶ We need to understand HHS's plans to use these existing systems or build new ones that are capable of supporting a vaccination program of the immense scale needed for the coronavirus.

Public transparency during post-vaccination safety monitoring will be essential, and we would like to understand HHS's plan to engage robust independent review through an open advisory committee. For example, for the H1N1 vaccine, the National Vaccine Advisory

¹³ *National Academies Gets Earful on Vaccine Framework*, BioWorld (Sept. 2, 2020) (online at www.bioworld.com/articles/497322-national-academies-gets-earful-on-vaccine-framework).

¹⁴ *U.S. Advisory Group Lays Out Detailed Recommendations on How to Prioritize Covid-19 Vaccine*, STAT (Sept. 1, 2020) (online at www.statnews.com/2020/09/01/u-s-advisory-group-lays-out-detailed-recommendations-on-how-to-prioritize-covid-19-vaccine/).

¹⁵ Food and Drug Administration, *Development and Licensure of Vaccines to Prevent COVID-19: Guidance for Industry* (June 2020) (online at www.fda.gov/regulatory-information/search-fda-guidance-documents/development-and-licensure-vaccines-prevent-covid-19).

¹⁶ Department of Health and Human Services, National Vaccine Program Office, *Overview of the U.S. Vaccine Safety Surveillance Systems & Ongoing Scientific Activities to Monitor Maternal Vaccine Safety* (Sept. 9, 2014) (online at www.hhs.gov/sites/default/files/nvpo/nvac/meetings/pastmeetings/2014/bok_maternalsafetyslides_septnvac2014.pdf).

Committee organized the H1N1 Vaccine Safety Risk Assessment Working Group, which met bi-weekly during the vaccination program's height to review safety data.¹⁷

We cannot wait to make decisions on these important issues. Vaccine development appears to be moving rapidly. On July 31, 2020, Dr. Anthony Fauci testified to the Select Subcommittee on the Coronavirus Crisis that he is "cautiously optimistic" that a coronavirus vaccine will be determined to be safe and effective by the end of this year. Dr. Fauci also acknowledged this determination is just the beginning of the process of providing a vaccine to all Americans who need it, noting, "I don't think that we will have everybody getting it immediately" and that Americans could expect to receive a vaccine "within the year 2021."¹⁸

Clear and open public communication about the government's efforts and decision-making about vaccine development, deployment, and safety monitoring are essential to building necessary trust in the vaccine project. Safely achieving the levels of immunity that will eliminate transmission will require a substantial portion of the population to get vaccinated. For that, we need public confidence in the vaccine and the vaccination process.

To assist the Committees in our oversight, please provide written answers to the following questions by September 22, 2020:

1. What are the federal government's current plans or frameworks for vaccine distribution and deployment, including prioritization?
2. What are the roles and responsibilities of HHS, CDC, FDA, NIH, DOD, and any other federal agency in distribution and deployment of a coronavirus vaccine, including which entity will be responsible for making final decisions on prioritization and post-vaccination safety monitoring?
3. What are the terms of McKesson's engagement? What other contractors have been engaged for vaccine distribution and deployment and on what terms?
4. What are the roles that ACIP, the National Academies, and any other independent advisory bodies will have in creating a national strategy for deployment and prioritization?
5. What are the federal government's plans to ensure public transparency on vaccine safety, efficacy, and prioritization?

¹⁷ National Vaccine Advisory Committee, *H1N1 Vaccine Safety Risk Assessment Working Group (VSRWAG)* (Jan. 31, 2012) (online at www.hhs.gov/sites/default/files/nvpo/nvac/reports/vsrawg_report_january_2012.pdf).

¹⁸ Select Subcommittee on the Coronavirus Crisis, Hybrid Hearing On "The Urgent Need for a National Plan to Contain the Coronavirus" (July 31, 2020).

6. What are the federal government's plans to increase vaccine confidence, including through public communications, community engagement and partnerships, and open advisory committee meetings?
7. What safeguards are in place to ensure vaccine decisions are made free from political considerations?
8. What are the federal government's plans for post-deployment monitoring of vaccine safety and effectiveness, including plans for existing and new vaccine safety surveillance systems and use of public advisory committees to assist in analysis and review?

In addition, we request a briefing for our staff on these issues by September 25, 2020.

The Committee on Oversight and Reform is the principal oversight committee of the House of Representatives and has broad authority to investigate "any matter" at "any time" under House Rule X. House Resolution 935 established the Select Subcommittee on the Coronavirus Crisis "to conduct a full and complete investigation" of "issues related to the coronavirus crisis," including the "preparedness for and response to the coronavirus crisis, including ... the development of vaccines and treatments."

If you have any questions regarding this request, please contact Committee staff at (202) 225-5051.

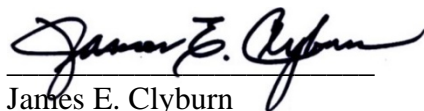
Sincerely,



Carolyn B. Maloney
Chairwoman
Committee on Oversight and Reform



Raja Krishnamoorthi
Chairman
Subcommittee on Economic and
Consumer Policy



James E. Clyburn
Chairman
Select Subcommittee on the Coronavirus Crisis

cc: The Honorable James Comer, Ranking Member
Committee on Oversight and Reform

The Honorable Michael Cloud, Ranking Member
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The Honorable Steve Scalise, Ranking Member
Select Subcommittee on the Coronavirus Crisis

The Honorable Stephen M. Hahn, M.D., Commissioner
Food and Drug Administration

The Honorable Francis S. Collins, M.D., Ph.D., Director
National Institutes of Health

The Honorable Robert R. Redfield, M.D., Director
Centers for Disease Control and Prevention

The Honorable Mark T. Esper, Secretary of Defense