

**Congress of the United States**  
**House of Representatives**

COMMITTEE ON OVERSIGHT AND REFORM

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June 18, 2020

The Honorable Dr. Stephen M. Hahn  
Commissioner  
Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

Dear Commissioner Hahn:

The Committee on Oversight and Reform seeks information on the processes that will guide the Food and Drug Administration (FDA) in its decisions about the development, review, and deployment of any eventual coronavirus vaccines.

Scientists are racing to create a coronavirus vaccine to protect us all. While they are engaged in their noble pursuit, we need to plan ahead. When a vaccine candidate is ready, it will be up to you, Dr. Hahn, to decide whether it is safe enough and effective enough to be given to the American people. We trust that you will make that decision in the best interest of the public health. And the best way to bolster that trust is to create transparency in how that decision will be made, how a vaccine arrives to that decision point, and how a vaccine will be deployed.

Vaccine development is, appropriately, happening faster than ever before. With that, the public has questions about whether corners are being cut. The title of Administration's vaccine plan, "Operation Warp Speed," did not help ease those concerns. We should start addressing questions now. If we wait until a vaccine candidate is in hand before announcing the rules by which it will be judged, people will not have faith in the process. We want the American public to be confident in the fact that FDA will not allow vaccine developers to cut corners, and that FDA will not approve coronavirus vaccines unless they are safe and effective.

Dr. Hahn, when you are presented with a promising vaccine candidate, you will face tremendous pressure to deploy it. For you, and for the confidence of the public, the rules must be laid out now, so that if you have to say no to deploying a vaccine, the public will understand why. And if you say yes, the public will trust that decision.

One simple step you could take today to ease the public's uncertainty would be declaring that any vaccine candidate will have to prove itself safe and effective in a complete Stage 3 clinical trial with at least 30,000 volunteers. National Institutes of Health (NIH) Director Francis Collins has already endorsed that 30,000-person floor, explaining that there is not "enough power in the analysis, to be able to document the vaccine works unless you get to roughly that

number.”<sup>1</sup> Beyond the 30,000-subject threshold, the design of clinical trials, including the demographics of the subjects, can ensure that FDA has the appropriate data to weigh the risks and benefits of an eventual vaccine candidate and how it might be deployed.

Transparency in review is going to be critical. Data about the vaccines’ safety and effectiveness should be available to independent scientists, like the Vaccine and Related Biological Products Advisory Committee (VRBPAC). Those scientists can distill the information and convey it to the public to boost confidence in the process. If you commit to involving VRBPAC in the decision-making process for every vaccine candidate, it will significantly increase public confidence in your future decisions.

Given that multiple agencies have responsibility in the process of developing and deploying a vaccine, interagency cooperation must be built into the process from the beginning. By bringing everyone to the table, a cooperative interagency consortium like the Public Health Emergency Medical Countermeasure Enterprise (PHEMCE) can ensure that all efforts are contributing to a successful vaccine program.

As other agencies contribute to the process, transparency and the quality of deliberations can be increased with the involvement of other advisory committees. For instance, clinical trial and design can be guided by technical and scientific peer review by the Vaccine Research Center Board of Scientific Counselors. In deciding difficult and sensitive questions of how to prioritize limited quantities of an approved vaccine—who is first in line—the participation of the expert National Vaccine Advisory Committee could prove invaluable and improve public cooperation with the program.

To assist the Committee in its oversight, please provide a briefing to our staff on the FDA’s policies and procedures for coronavirus vaccine development, trials, review, and deployment, including each of the following topics:

1. The decision-making process, the decision-makers and their roles, and the evaluation criteria that will be employed for vaccines applying for Emergency Use Authorization, and for any other FDA pathway through which vaccines are likely to enter the market;
2. The role that VRBPAC, and any other advisory committee, will have in the design of clinical trials, the review of safety and efficacy data of vaccine candidates, requesting more information from the makers of the vaccine candidates, authorizing a vaccine candidate for deployment, and planning deployment, including:
  - a. whether you will commit to submitting all vaccine candidates to VRBPAC and/or other advisory committees for review, and what FDA will do if

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<sup>1</sup> *Vaccine Experts Want the FDA to Commit to 30,000 People in COVID-19 Vaccine Trials*, CNN (June 12, 2020) (online at [www.cnn.com/2020/06/12/health/vaccine-trials-phase-3-covid-19/index.html](http://www.cnn.com/2020/06/12/health/vaccine-trials-phase-3-covid-19/index.html)).

- VRBPAC or another advisory committee recommends against deployment of a vaccine; and
- b. whether you will commit to submitting any plan for vaccine deployment, including production, distribution, and prioritization of recipients, to review by one or more advisory committees, and which ones they will be; and
  3. The categories and format of information FDA will require vaccine makers to submit for review, and when and how that information will be made available to VRBPAC and the public;
  4. The design of Stage III clinical trials, including whether you will commit to requiring a minimum number of subjects (e.g. 30,000);
  5. Deployment decisions, and post-deployment monitoring of vaccine outcomes; and
  6. The process for coordinating action among the relevant federal agencies with jurisdiction over vaccine development, review, approval, manufacture, and deployment, including NIH, the Biomedical Advanced Research and Development Authority, and the Centers for Disease Control and Prevention, and whether PHEMCE in particular has been engaged in the coronavirus vaccine initiative.

Please contact Committee staff by June 24, 2020, to confirm your agency's participation in a briefing to take place July 2, 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. If you have any questions regarding this request, please contact Committee staff at (202) 225-5051.

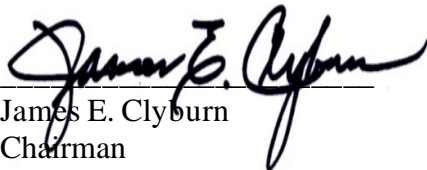
Sincerely,



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

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cc: The Honorable Jim Jordan, Ranking Member  
Committee on Oversight and Reform

The Honorable Michael Cloud, Ranking Member  
Subcommittee on Economic and Consumer Policy

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