

Congress of the United States

House of Representatives

COMMITTEE ON OVERSIGHT AND REFORM

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September 22, 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 Subcommittee on Economic and Consumer Policy seeks information on the safety and efficacy standards that the Food and Drug Administration (FDA) will use to issue an Emergency Use Authorization (EUA) for a COVID-19 vaccine. While the EUA process can offer a quicker pathway to approval for public use than FDA's licensing process, the tradeoff is less rigorous review and testing for safety and efficacy.

It is extremely important that FDA is transparent about its EUA guidelines in order to counteract the erosion of public confidence in the federal vaccine review process. Over three-quarters of Americans worry that that politics, not science or public health, is driving vaccine decision-making at FDA.¹ Over one-third of Americans say they would decline to take a COVID-19 vaccine approved by FDA right now.² Public mistrust is fueled in large part by President Trump, who has made a campaign promise of a vaccine before Election Day, over the public safety concerns of scientists and public health experts.³ For the benefit of the American public, the vaccination effort, and FDA's declining public confidence, you must release EUA guidelines as soon as possible, and far in advance of considering an EUA.

On June 30, 2020, FDA released a Guidance for Industry which recommended that vaccine developers utilize double-blinded, placebo-controlled studies and meet an efficacy standard of at least 50% more effective than a placebo in preventing infection or disease.⁴ At the time, this was a welcome gesture of transparency.

¹ *Poll: Most Americans Believe the COVID-19 Vaccine Approval Process Is Driven by Politics, Not Science*, STAT (Aug. 31, 2020) (online at www.statnews.com/pharmalot/2020/08/31/most-americans-believe-the-covid-19-vaccine-approval-process-is-driven-by-politics-not-science/).

² *One in Three Americans Would Not Get COVID-19 Vaccine*, Gallup (Aug. 7, 2020) (online at <https://news.gallup.com/poll/317018/one-three-americans-not-covid-vaccine.aspx>).

³ *Trump Scorns His Own Scientists over Virus Data*, New York Times (Sept. 17, 2020) (online at www.nytimes.com/2020/09/16/us/politics/trump-cdc-covid-vaccine.html).

⁴ *Guidance for Industry: Development and Licensure of Vaccines to Prevent COVID-19*, Food and Drug Administration (June 30, 2020) (online at www.fda.gov/regulatory-information/search-fda-guidance-documents/development-and-licensure-vaccines-prevent-covid-19).

In the nearly three months since issuance of that guidance, it has become increasingly clear that FDA intends to approve a COVID-19 vaccine for public use through the EUA process. Last month, you stated that FDA may even consider issuing an EUA before Phase 3 trials are complete.⁵ On September 16, the Centers for Disease Control and Prevention released a “COVID-19 Vaccination Program Interim Playbook” that sets out various scenarios involving FDA using the EUA process, with “Vaccine availability under EUA” as early as “End of Oct 2020.”⁶

But FDA has issued no details about the requirements that vaccine developers would need to meet or the degree of transparency that FDA itself would meet in awarding an EUA. FDA’s silence on these matters is not acceptable; I urge you to promptly make such standards available to the public in a comprehensive guidance document.

To assist the Committee in its oversight of FDA’s vaccine review and approval process, please provide written answers to the following questions by September 25, 2020:

1. Will FDA require that a vaccine candidate sponsor submit an application for EUA, or would FDA consider a request to issue an EUA from the White House, Operation Warp Speed, the Biomedical Advanced Research and Development Authority, or any other federal agency?
2. What scientific support for safety and effectiveness will FDA require for an EUA?
3. In considering an EUA, what is the minimum number of vaccinated study participants that FDA will require in a safety database for each sub-population? What characteristics will be required for a patient to be included in each such safety database?
4. In considering an EUA, will FDA require direct evidence of vaccine efficacy in protecting humans from SARS-CoV-2 infection and/or clinical disease, or will it accept surrogate markers of immune function as a predictor of protective immunity? If FDA accepts surrogate evidence, what scientific support will FDA require to justify the appropriateness of the surrogate marker as an indicator of immune status?
5. What is the minimum number of clinical endpoints in the placebo group that FDA would require for an EUA, and how might this number change depending on the nature or strength of an inferred response?

⁵ *FDA Leader Says Agency Could Consider Authorization for Covid-19 Vaccine Before Phase 3 Trials Are Complete*, *Financial Times Reports*, CNN (Aug. 30, 2020) (online at www.cnn.com/2020/08/30/health/fda-covid-19-vaccine-eua/index.html).

⁶ Centers for Disease Control and Prevention, *COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations* (Sept. 16, 2020) (online at www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf).

6. Will FDA require a floor of 50% efficacy for an EUA, as it recommended for a license under its June 30, 2020 Guidance for Industry? What lower bound of an appropriate confidence interval will FDA accept for an EUA? For what efficacy endpoints will this lower bound suffice, and is the lower bound higher for other efficacy endpoints?
7. Will FDA consider an EUA limited to certain defined sub-populations? If so, what factors will FDA use to determine the appropriate sub-populations, including the size of the sub-population, risks of transmission, and risks of severe disease?
8. Will FDA require informed consent, noting unapproved status, for patients receiving a COVID-19 vaccine made available under an EUA?
9. How will availability of vaccines in ready-to-deploy state factor into FDA's decisions to grant an EUA or determine which sub-populations should receive a limited EUA?
10. Will clinical trials be halted or modified based on the issuance of an EUA, and what considerations would guide that decision?
11. Will FDA commit to receiving recommendations on safety and efficacy from the Vaccines and Related Biological Products Advisory Committee in a meeting open to the public, prior to issuing any EUA?
12. What is FDA's plan to communicate to the public and patients the difference between an EUA and a full license, and what is known and not yet known about each vaccine's safety and effectiveness? How will FDA ensure that an EUA's issuance will not decrease confidence in COVID-19 vaccines?
13. Will you commit to publicly releasing a detailed guidance document on the standards that FDA will use in assessing an EUA for a COVID-19 vaccine?

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,



Raja Krishnamoorthi

Chairman

Subcommittee on Economic and Consumer Policy

cc: The Honorable Michael Cloud, Ranking Member