

ONE HUNDRED SIXTEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
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WASHINGTON, DC 20515-6115

Majority (202) 225-2927
Minority (202) 225-3641

September 15, 2020

Stéphane Bancel
Chief Executive Officer
Moderna, Inc.
200 Technology Square
Cambridge, MA 02139

Dear Mr. Bancel:

Pursuant to Rules X and XI of the U.S. House of Representatives, the Committee on Energy and Commerce is investigating the nation's response to the coronavirus disease of 2019 (COVID-19) pandemic. As part of this inquiry, we are examining efforts to develop a COVID-19 vaccine. We write today seeking further information about your COVID-19 vaccine research and development efforts and how you will ensure that only a safe and effective product will be made available to the public.

We appreciate your company's efforts to develop a COVID-19 vaccine and hope that a safe and effective vaccine can be made available to the public as quickly as possible. All COVID-19 vaccine candidates must be properly assessed based on rigorous science and their approval or authorization must be free from political pressure or other forms of outside interference. We remain concerned, however, that throughout the nation's COVID-19 pandemic response, the Trump Administration has demonstrated a disregard for science and public health in favor of political expediency.

If not carefully and objectively managed, we fear the same may prove true for a future COVID-19 vaccine. Dire consequences could result if any eventual authorization or approval of a vaccine is influenced by political pressure and is not based on sound science.

President Trump appears unable to keep himself from tying the timeline of the COVID-19 vaccine's availability to his own political needs. Over Labor Day weekend, the President again said that a COVID-19 vaccine would probably be available in October, and continued on by saying "maybe before a special date. You know what date I'm talking about," referring to

Election Day.¹ Two weeks earlier, the President referred to the U.S. Food and Drug Administration (FDA) and its career scientists who are responsible for reviewing and approving a vaccine as “the deep state,” and implied that FDA career staff are intentionally delaying a COVID-19 vaccine until after November 3, to hurt his reelection efforts.²

Unfortunately, the Trump Administration’s track-record of prioritizing politics over science and the President’s recent remarks appear to be eroding some of the public’s trust in a future vaccine. While one in three people indicated in July that they would get the vaccine when it became available, now just one in five people say they would get the vaccine once available.³ In addition to declining public confidence in a future COVID-19 vaccine, the American Medical Association has warned that physicians are growing increasingly concerned by the lack of information about the COVID-19 vaccine approval process.⁴ Further, public health experts caution that “public skepticism will be hard to overcome.”⁵

As an average of more than 38,000 new COVID-19 cases are diagnosed daily and more than 1,000 COVID-19 deaths occur each day in the United States,⁶ speed in the search for a COVID-19 vaccine is important, but safety, efficacy, and public trust must be priorities. Encouragingly, we heard from Moderna, Inc. (Moderna) during the Committee’s oversight hearing in July that the resources provided by Congress and the public-private partnerships underway have enabled a historically rapid pace of vaccine research and development that will not sacrifice safety or efficacy standards.

To that end, we applaud and appreciate that Moderna recently joined eight other pharmaceutical companies in signing a pledge committing “to developing and testing potential vaccines for COVID-19 in accordance with high ethical standards and sound scientific principles.”⁷ Among other commitments, your company pledged to submit a vaccine for emergency use authorization (EUA) or approval only “after demonstrating safety and efficacy through a Phase 3 clinical study.”⁸ While this announcement is to be commended, experts note

¹ *Vaccine makers promise safety amid shaky public confidence in Covid developments*, Politico (Sept. 8, 2020).

² *Trump wants FDA to ‘feel the heat,’ chief of staff says*, Politico (Aug. 23, 2020).

³ *Voters skeptical about potential COVID-19 vaccine and say that one this year would be rushed – CBS News poll*, CBS News (Sept. 6, 2020); *Vaccine makers promise safety amid shaky public confidence in Covid developments*, Politico (Sept. 8, 2020).

⁴ American Medical Association, *AMA strongly urges FDA transparency in COVID-19 vaccine development* (Aug. 26, 2020) (press release).

⁵ *Experts fear political pressure on COVID-19 vaccine*, The Hill (Aug. 2, 2020).

⁶ *Coronavirus in the U.S.: Latest Map and Case Count*, New York Times (Sept. 8, 2020); *Graphic: Coronavirus deaths in the U.S., per day*, NBC News (Sept. 10, 2020).

⁷ *Biopharma Leaders Unite to Stand with Science*, Businesswire (Sept. 8, 2020).

⁸ *Id.*

the absence of a commitment to transparency or other means of accountability in keeping this pledge.⁹

Since issuing guidance in June, FDA Commissioner Stephen Hahn has likewise indicated his commitment to uphold the scientific integrity of FDA and the vaccine review process.¹⁰ Testifying before the Committee, Dr. Hahn stated that FDA “will use the science and data that come to us, and we will use our high standards to assess the safety and efficacy of a vaccine.”¹¹ According to both the guidance and Dr. Hahn, a COVID-19 vaccine would have to show that it is at least 50 percent effective at preventing or decreasing the severity of the disease in a placebo-controlled randomized trial prior to an EUA or licensing approval by FDA.¹² Additionally, in response to concerns that FDA would be pressured by the Trump Administration to authorize a COVID-19 vaccine prior to the presidential election even if the data did not support the decision, Dr. Peter Marks, Director of FDA’s Center for Biologics Evaluation and Research, has “vowed to resign if the Trump administration approves a vaccine before it is shown to be safe and effective.”¹³

We appreciate your company’s efforts to develop a safe and effective COVID-19 vaccine and value the commitments your company and FDA leadership have made to uphold the scientific integrity of the approval process. While we look forward to the timely availability of a safe and effective COVID-19 vaccine that the public can trust, we are concerned that increasing political pressure threatens this achievement. We implore you to fulfill the commitments you made in your announcement to ensure science and safety drive the process. We also strongly encourage you to take steps to make the process more transparent in order to regain the trust and confidence of the American people in a future COVID-19 vaccine.

Given these concerns and growing mistrust that may hinder the nation’s ability to control the pandemic, please provide the following requested information by October 2, 2020.

⁹ *Pharma drew a line in the sand over Covid-19 vaccine readiness — because someone had to*, Stat News (Sept. 8, 2020); *Vaccine makers promise safety amid shaky public confidence in Covid developments*, Politico (Sept. 8, 2020).

¹⁰ Stephen Hahn, *FDA commissioner: No matter what, only a safe, effective vaccine will get our approval*, Washington Post (Aug. 5, 2020); Anand Shah, Peter Marks, and Stephen Hahn, *Ensuring the Safety and Effectiveness of a COVID-19 Vaccine*, Health Affairs (Aug. 18, 2020);

¹¹ House Committee on Energy and Commerce, Testimony of the Honorable Stephen M. Hahn, M.D., Commissioner, U.S. Food and Drug Administration, *Hearing on Oversight of the Trump Administration’s Response to the COVID-19 Pandemic*, 116th Cong. (June 23, 2020).

¹² Stephen Hahn, *FDA commissioner: No matter what, only a safe, effective vaccine will get our approval*, Washington Post (Aug. 5, 2020).

¹³ *Exclusive: Top FDA official says would resign if agency rubber-stamps an unproven COVID-19 vaccine*, Reuters (Aug. 20, 2020).

1. What is the current stage of development of Moderna's COVID-19 vaccine candidate(s)?
2. When does Moderna anticipate phase 3 clinical trial enrollment to be complete and further, what is the earliest you expect that phase 3 clinical trial participation will be complete?
3. Does Moderna intend to meet the safety and efficacy considerations included in FDA guidance? If not, please explain why and what thresholds Moderna intends to meet.
4. Would you object to a federal agency submitting an EUA request to FDA for your vaccine instead of or prior to your company submitting an EUA request? What course of action would Moderna take if a federal agency submitted an EUA request over Moderna's objections?
5. Will Moderna commit to making all clinical trial data publicly available at the conclusion of the trial? If not, please explain why and specify what information Moderna would be willing to make public to provide transparency and engender the trust of the American people.
6. What, if any, efforts has Moderna taken to date, or does it intend to take, to assure the public, health providers, and public health leaders that if made available for use your COVID-19 vaccine is both safe and effective?

Thank you for your attention to this matter. If you have any questions please contact Jesseca Boyer, Stephen Holland, and Peter Rechter of the Majority staff at (202) 225-2927.

Sincerely,



Frank Pallone, Jr.
Chairman



Anna G. Eshoo
Chairwoman
Subcommittee on Health



Diana DeGette
Chair
Subcommittee on Oversight
and Investigations