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COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY
COMMITTEE ON APPROPRIATIONS
COMMITTEE ON THE JUDICIARY
COMMITTEE ON RULES AND ADMINISTRATION

United States Senate
WASHINGTON, DC 20510-1304

September 3, 2020

Albert Bourla
Chairman and CEO
Pfizer, Inc.
235 East 42nd Street
New York, NY 10017

Dear Mr. Bourla:

As our nation confronts the health and economic toll of the COVID-19 pandemic, President Trump has clearly staked his campaign re-election strategy on the approval of a vaccine for this virus. At the Republican National Convention on August 27, President Trump stated that the United States, "will produce a vaccine before the end of the year, or maybe even sooner." This follows a response to an interview question on August 3 about whether a vaccine would be approved by Election Day in which he answered, "I think, in some cases, it's possible before … But right around that time. We have great companies."

As one of those companies participating in Operation Warp Speed, I commend your efforts and commitment to helping respond to the unprecedented challenge posed by this pandemic. Our nation desperately seeks a return to normalcy, which a safe and effective vaccine can provide, and I am encouraged by the development and progress made to date. However, we need to make certain that any eventual COVID-19 vaccine is one we can trust and is demonstrated to be safe and effective—not one that has corners cut or is rushed for political reasons. I write today to assess, in your important efforts to quickly bring a safe and effective vaccine to the public, how your company plans to maintain scientific and data-based standards in the face of White House political pressure regarding the approval process.

Despite President Trump's rosy outlook, our public health and biomedical experts have not projected such confidence in the timeline that the President seeks. National Institutes of Health (NIH) Director Dr. Francis Collins has stated that, "having a safe and effective vaccine distributed by the end of 2020 is a stretch goal". In a July interview, Food and Drug Administration (FDA) Commissioner Stephen Hahn stated, "I can't predict when a vaccine will be available." And National Institute of Allergy and Infectious Disease (NIAID) Director Dr. Tony Fauci has stated, "we should know by the end of December of this year, [or] the beginning of next year."

Recent public surveys have indicated alarming levels of skepticism among the American public about taking a coronavirus vaccine if shortcuts were taken or if the approval was motivated by politics rather than science. Only half of Black Americans report they would get a vaccine, which is particularly concerning given the disproportionate burden of COVID-19 cases and deaths among this population. It is essential that we boost confidence and vaccine uptake, and that stems from ensuring the integrity of the vaccine development and approval process.

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Unfortunately, the optics and political pressure from President Trump have only further undermined credibility in this process, following the President's tweets directed to the FDA urging the agency to speed regulatory reviews, which were followed only a day later by an emergency use authorization (EUA) for the therapeutic use of convalescent plasma. Additionally, the FDA's earlier controversy in issuing an EUA for hydroxychloroquine, following intensive pressure from President Trump—which was later rescinded—has further undermined confidence in the agency's science-based regulatory standards.

On July 2, in a Senate Appropriations Subcommittee hearing, NIH Director Collins, in addition to the heads of the Biomedical Advanced Research and Development Authority (BARDA) and Centers for Disease Control and Prevention (CDC), affirmed in response to my questioning that they had not, "felt any political pressure from the White House or other agencies in terms of the selection of the companies to develop a vaccine, the timing of the vaccine development, or the announcement of a vaccine."

Americans are eagerly seeking a safe and effective vaccine for COVID-19, and there has been significant and swift work to bring several vaccine candidates to clinical trials. To bolster public confidence in the integrity of the vaccine approval process, I request answers to the following questions from you by September 17, 2020:

1. How do you reconcile the inconsistency between the projected timeline promoted by President Trump and the timeline projected by our officials at NIH, BARDA, and FDA for a COVID-19 vaccine candidate?

2. Separate from your direct engagement with our federal health agencies (e.g. NIH, BARDA, FDA), have employees or representatives of the White House communicated with your company regarding your COVID-19 vaccine candidate? If so, please provide a copy of all such correspondence between employees or representatives of your company and the White House.
    a. Has your company received any political pressure or incentive, outside of your contract agreements, regarding your vaccine candidate?

3. In a recent interview with the Financial Times, FDA Commissioner Hahn stated, "it is up to the sponsor to apply for authorization or approval, and we make an adjudication of their application. If they do that before the end of Phase Three, we may find that appropriate."
    a. Is your company pursuing an application for approval or for emergency use authorization (EUA) of your COVID-19 vaccine candidate?
        i. If you are unable to answer by September 17, do you expect to have an answer to that question by October 1 or October 15?

4. In a recent interview with Reuters, NIAID Director Dr. Tony Fauci stated that, "The one thing that you would not want to see with a vaccine is getting an EUA before you have a signal of efficacy. One of the potential dangers if you prematurely let a vaccine out is that it would make it difficult, if not impossible, for the other vaccines to enroll people in their trial."

a. When did your vaccine candidate begin enrollment on its phase 3 trial in the United States?
b. When did, or when do you project, your vaccine candidate to reach 30,000 enrolled patients in its phase 3 trial in the United States?
c. When do you predict you will have a signal of efficacy from the phase 3 trial of your COVID-19 candidate in the United States?
d. Will your company cut any corners in adherence to the research, development, submission, or regulatory review process required under the Federal Food, Drug, and Cosmetic Act or Public Health Service Act for your vaccine candidate?
e. If the FDA issues an EUA for another COVID-19 vaccine candidate which is not your company's vaccine candidate, how would that impact your research, development, and approval process timeline?

5. A recent New York Times report indicated that Trump Administration officials told congressional leaders that they could give emergency approval to a coronavirus vaccine before the end of phase 3 clinical trials in the U.S., perhaps as early as late September.
    a. Are you aware of this potential timing?
    b. Would it be possible for the FDA to issue an EUA or approval based upon data from clinical trials in foreign countries? Do you support the inclusion of data from outside of the U.S. in the regulatory review of COVID-19 vaccines?

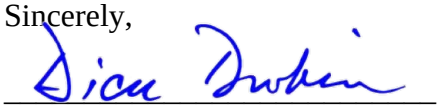
6. The FDA recently announced a convening of the Vaccine and Related Biological Products Advisory Committee on October 22. Does your company plan to present or directly participate in this event?

7. Are you concerned that the perception within certain populations of cutting corners or having political interference in the approval process will reduce vaccine uptake? If so, how can HHS bolster public confidence in the approval process?

8. Has federal funding contributed to the discovery, research, development, or production scaling of your vaccine candidate? If so, please provide a list of all such federal funding disaggregated by the specific patent and/or stage of the vaccine development process.
    a. If any patent related to your vaccine candidate is held by the federal government, please list the patent(s) and provide a copy of the licensing agreement.
    b. If any patent related to your vaccine candidate is held by the federal government, please explain how your company plans to make the benefit of the invention "available to the public on reasonable terms," as required by 35 USC 201.

Thank you for your efforts to bolster our nation's COVID-19 response through your vaccine research and development program. I look forward to receiving your response.

Sincerely,



Richard J. Durbin
United States Senator