Stephen Hahn
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
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Dear Dr. Hahn:

We are experts in virology, epidemiology, vaccinology, infectious disease, clinical care and public health. A vaccine(s) is needed to curtail the COVID-19 pandemic. We are committed to promoting the broad uptake of safe and effective COVID-19 vaccines. The need is urgent but all vaccines must be rigorously studied to determine whether their benefits exceed their risks.

For this reason, we urge that COVID-19 vaccines are made widely available only after the Food and Drug Administration (FDA) has been able to evaluate safety and efficacy data from completed Phase 3 clinical trials. The FDA's review must be as thorough as has been the case for previous vaccine candidates. As transparency will be critical for fostering public confidence and maximizing vaccine use, the open meetings of the FDA's Vaccines and Related Biologics Product Approval (VRBPAC) Committee must be an essential part of the authorization and approval processes.

Several COVID-19 vaccine candidates are now in Phase 3 trials. We hope one or more of them will soon prove to be both safe and effective. The decisions to fund and produce many millions of doses ahead of the trial results should save many months in providing approved vaccines to the American public. In short, productive collaborations between scientists, the pharmaceutical industry and the federal government may bring us to a remarkable and historic achievement – the creation of a vaccine within a year after this pandemic virus was first identified.

But an effective vaccine will only be truly useful if a large proportion of the public is willing to take it. Surveys have consistently shown that a significant fraction of Americans, from across the political spectrum, is reluctant to accept a COVID-19 vaccine. Some long-standing concerns about vaccine safety in general have no scientific foundation. However, more than 60% of US voters prefer that a COVID-19 vaccine be thoroughly evaluated before it is made available, even if doing so delays its roll-out. A particular concern applies to communities of color, where historical medical inequities are also likely to reduce vaccine uptake. Actively involving these and other communities that are at high risk of severe COVID-19 disease is essential to curtailing the pandemic. Similar considerations apply to vaccine distribution, which must not be determined by either an ability to pay or social influence.

The foundation of public confidence in vaccine safety has long been, and must remain, the well-established and trusted FDA approval procedures. The public is typically and rightly able to comment on vaccine approval. It is important that investigators share Phase 3 trial design details. For example, Data Safety Monitoring Boards apply predetermined "stopping rules" to decide whether a study should be terminated early based on the detection of early benefits, the

likelihood of no benefit, or the emergence of serious safety problems. These stopping rules should be publicly available. There must also be continuous monitoring for unexpected severe side effects that might only become apparent after large numbers of people are vaccinated.

To maximize the use of a COVID-19 vaccine(s) by the American people, it is therefore essential that the science and public health communities work with the federal government to increase public confidence in any approved or authorized product. However, we can only perform as advocates if we ourselves are persuaded that the vaccine(s) truly is safe and effective. We must be able to explain to the public what we know and what we don't know about these vaccines. For that to happen, we must be able to witness a transparent and rigorous FDA approval process that is devoid of political considerations. We ask that company executives and government officials take due note of these key points.

The COVID-19 virus has now killed more than 150,000 people in the USA alone. We need a safe and effective vaccine urgently, but any lack of trust in its properties could significantly compromise rollout. We look forward to the day when we can actively promote a safe and effective COVID-19 vaccine to the American people, based on our full confidence in its public health impact.

Signed,

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