October 6, 2020

Dr. Stephen M. Hahn
Commissioner
Food and Drug Administration

Dr. Peter W. Marks
Director
Center for Biologics Evaluation and Research
Food and Drug Administration

Dear Drs. Hahn and Marks:

As medical academics, scientists, and leaders, we believe the safety of a COVID-19 vaccine is paramount. As you know, a vaccine is given to healthy individuals and must adhere to the principle "first, do no harm." The Food and Drug Administration has a duty to protect those who are vaccinated from harm.

But the FDA's duty extends further. If the public does not have the utmost trust in the safety of the vaccine, the vaccination rate may not be sufficient to achieve herd immunity. In other words, the FDA's decision could alter the course of the pandemic.

This is why a rigorous safety standard is so essential—and why the FDA's standard is of grave concern. In a briefing document for the Vaccines and Related Biological Products Advisory Committee, the FDA indicated that it will require only a **median** of at least two months of safety observation of trial participants. Dr. Marks has explained that this standard is "not such a high bar" because it would allow for fewer than two months of observation of some trial participants.

We respectfully urge you to require a high bar for safety. The FDA should require a minimum of two months of safety observation for all trial participants. Trial participants are already a sample of the population; to diminish the weight of some trial participants does not make sense. Under the FDA's proposed lower bar, a vaccine could be authorized before many trial participants have been observed through the period when most adverse vaccine events occur.

There is too much at stake. Authorization of a vaccine before a high safety bar is met would severely erode public trust and set back efforts to achieve widespread vaccination. In short, premature authorization would prolong the pandemic, with disastrous consequences. The integrity of the Food and Drug Administration would be severely compromised, with long-term repercussions.

We stand ready to publicly verify the safety and efficacy of a vaccine if the science and scientific process support such a determination. In that case, we look forward to working with you to promote vaccination that will help bring this pandemic to an end.

cc: Members of the Vaccines and Related Biological Products Advisory Committee

Respectfully,

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