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September 4, 2020

Alex Azar  
Secretary  
Department of Health and Human Services  
200 Independence Ave. SW  
Washington, DC 20201

Dr. Stephen Hahn  
Commissioner  
Food and Drug Administration  
10903 New Hampshire Ave.  
Silver Spring, MD 20993

Dr. Robert Redfield  
Director  
Centers for Disease Control and Prevention  
395 E Street SW  
Suite 9100  
Washington, DC 20201

Moncef Slaoui  
Chief Advisor  
Operation Warp Speed  
Department of Health and Human Services  
200 Independence Ave. SW  
Washington, DC 20201

Dear Secretary Azar, Commissioner Hahn, Director Redfield, and Mr. Slaoui,

I write concerning the critical need for caution, transparency, and independent review of any potential COVID-19 vaccine. In recent days, several troubling announcements have been made that suggest regulatory approval of a vaccine will be expedited under political pressure. Though we all anxiously await a safe and effective vaccine, safety and efficacy cannot be spared in the process. Neither political nor economic pressure should determine regulatory approval—only scientific evidence and public health can guide this decision.

After several months of seemingly politically motivated emergency authorizations and loosening of regulations, Commissioner Hahn stated this week that he is considering emergency authorization of a COVID-19 vaccine before Phase 3 clinical trials are complete. These trials are necessary to prove the safety and efficacy of a vaccine. There are already reports that manufacturers are struggling to reach full enrollment of 30,000 participants and there continues

to be a lack of diversity. We should not skip additional steps by authorizing a vaccine before the results are in. Not only does this risk the safety of the American people, but as Dr. Anthony Fauci has noted, also reduces the likelihood that ongoing and future vaccine trials will be able to enroll eligible participants.

Last week, a participant in the Moderna trial came forward regarding Moderna's apparent decision to accelerate Phase 3 trials by setting a firm September 11 deadline for participants to receive their first vaccine dose. This particular participant was informed of the change in policy one day after Vice President Pence declared at the Republican National Convention that the U.S. was "on track" to have a COVID-19 vaccine during this year. Moderna has ignored inquiries from multiple media outlets concerning this decision and the trial participant still has not received an explanation for the expedited timeline.

Most notably, earlier this week, the CDC called upon all states to prepare for vaccine distribution by November 1<sup>st</sup>. States are now scrambling to recruit providers, establish additional vaccination sites, create public education campaigns, design vaccination tracking systems, and more—all while they do not know what vaccine they will receive, how it must be stored, how many doses will be required, or its safety and efficacy data, including how it affects different populations. I am deeply concerned that decisions are being rushed to meet President Trump's political goals rather than based on scientific evidence.

The FDA's June 30 guidance for vaccine approval already allows for a fairly ineffective vaccine to be approved. We should have greater assurance than a coin-toss in the efficacy of a vaccine for the worst health crisis we have faced in generations. According to Dr. Peter Marks, Director of the FDA's Center for Biologics Evaluation and Research, "we're going to need a vaccine that's probably in the order of 70% effective." Yet, the FDA is permitting vaccines with only 50% efficacy. In contrast, the polio vaccine is nearly 100% effective, and diphtheria, tetanus, and pertussis are 80-90% effective. To ensure this vaccine provides any meaningful utility, we need strong efficacy standards.

Further, an expedited timeline does not provide the data to understand how long immunity lasts or its strength of protection. As Dr. Marks noted, "we don't yet know that antibodies are the be-all-end-all of protecting against COVID-19." Some vaccines may decrease the chance of severe disease, but still permit infection and any established immunity may only extend for a short period. A late October or early November approval does not give our scientists enough time to assure immunity lasts; moving forward without these answers poses an imminent threat as Americans are misled into a false sense of security and stop social distancing, wearing masks, and following other public health guidelines.

To provide some assurance to the American people concerning the safety and efficacy of a COVID-19 vaccine, I strongly urge you to follow the expert counsel of the Infectious Diseases Society of America (IDSA) and use the full approval regulatory pathway and not issue any Emergency Use Authorizations for a COVID-19 vaccine. At a minimum, I strongly urge you to wait for complete Phase 3 trial data, including the safety monitoring phases after vaccination, and publicize this clinical data for independent experts to analyze prior to granting any authorization or approval. We should be following the advice of independent infectious disease

experts and providing ample time and transparency for them to review clinical data so they may provide a well-informed recommendation. Finally, I encourage you to amend the June 30 approval guidance to provide a more rigorous standard of efficacy.

Taxpayers have spent billions financing the research and development, as well as much of the manufacturing costs for COVID-19 vaccine candidates. In return, Americans should receive safe and effective vaccines and a stake in these products.

Sincerely,

A handwritten signature in black ink, appearing to read "Lloyd Doggett". The signature is written in a cursive, flowing style with a prominent horizontal line at the end.

Lloyd Doggett