Congress of the United States
Washington, DC 20515

February 26, 2021

Janet Woodcock, M.D.
Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Rochelle Walensky, MD, MPH
Director
Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, GA 30329

Dear Dr. Woodcock and Director Walensky,

Thank you both for your agencies' work on the COVID-19 vaccines and your continued commitment to ensuring science—not politics—guides decisions made by the Food & Drug Administration and the Centers for Disease Control and Prevention. We are writing today to urge you to continue this focus on evidence and science and look at real-world data coming out of the UK and other countries that are extending the time between doses in vaccines with two-dose series in order to give more individuals their first dose and consider, should there be an effectiveness and epidemiological benefit, updating Emergency Use Authorizations (EUAs) and incorporating flexibility for states and health care providers to extend the time between doses for less vulnerable populations in CDC vaccine recommendations.

As you both know, infectious diseases spread—and decline—exponentially. The faster we get vaccines out to the population, the faster we will end this pandemic. And we understand that FDA's commitment to basing EUA decisions on clinical trials is guided by the concern that any possible question about the science will be a cause for concern for those who are hesitant to take the vaccine. But the data that will be coming out of the UK and other allies whose data we can trust *is* science. We know the effectiveness of their strategy to delay the second dose—only delay, not remove it—will be one we can analyze scientifically. We will be able to see how successful this strategy will be to slow the spread. The FDA should have a plan to incorporate this real-world evidence and update EUAs so that CDC can work with state and local public health officials to determine if the spread in their communities would benefit from this strategy, too.

We know clinical trial efficacy doesn't mean the same as real-world effectiveness. For low-risk populations, any of the current FDA-authorized and other leading candidates with data seem to be effective for those who are already at low-risk. And it is not as though the first and second doses of currently-authorized vaccines provide equal protection; in the short-term, the first dose of the Pfizer/BioNTech vaccine provides 92.6% efficacy, and the second dose increases this to 94.8%. The potential for providing as many first doses as possible to dramatically reduce the spread of the virus in a community is monumental, and we believe it's critical that FDA and CDC continue to evaluate this.

Finally, many of these low-risk populations are appropriately being cautious, for themselves and others, and staying home as much as possible right now. But we have vaccines that can help reduce the amount of virus circulating, can save lives, and can permit a more rapid reopening of schools and our economy. Different populations have different needs, and CDC should have the flexibility to work with public health officials—again, based on scientific evidence—to weigh the public health benefits of delaying the second dose.

As the science and the virus quickly evolve, our policy must evolve, too. We urge FDA and CDC to continue your excellent work on the COVID-19 vaccines by carefully monitoring the data on longer-term effectiveness of the vaccines in countries that are adopting a strategy of delaying a second dose, and be prepared to take prompt action to incorporate this strategy should there be a public health benefit and get us closer to ending this pandemic.

Thank you for your consideration, and we look forward to your response.

Sincerely,

Ami Bera, M.D.
Member of Congress

Bill Foster
Member of Congress

Mark E. Green, M.D.
Member of Congress

cc: Jeff Zients, Coordinator of the COVID-19 Response and Counselor to the President