

July 23, 2020

Dear Dr. Wolfe and Mr. Annas:

Thank you for your recent letter advocating on behalf of volunteers participating in clinical trials to develop vaccines to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2. The Food and Drug Administration (FDA or Agency) recognizes the urgent need to develop safe and effective vaccines to prevent COVID-19 and is working collaboratively with industry, federal, domestic, and international partners, as well as other researchers, to accelerate this critical work.

There are various pathways that FDA is using to efficiently advance the development of safe and effective vaccines that will prevent COVID-19. For vaccine development, these pathways may vary depending on the vaccine candidate, but the pathways need to be carefully conceived and executed to ensure the development of safe and effective vaccines to address the current pandemic.

As FDA has publicly stated per a guidance for industry published on June 30, 2020, [Development and Licensure of Vaccines to Prevent COVID-19](#):

If it is no longer possible to demonstrate vaccine effectiveness by way of conducting clinical disease endpoint efficacy studies, the use of a controlled human infection model to obtain evidence to support vaccine efficacy may be considered. However, many issues, including logistical, human subject protection, ethical, and scientific issues, would need to be satisfactorily addressed. At this time no controlled human infection models for SARS-CoV-2 have been established or characterized.

We understand the concern that rapid progression through the usual phases of clinical development could be interpreted to mean that typical vaccine development steps are being skipped. Please know that FDA scientists will not “cut corners” in order to approve a vaccine. FDA will thoroughly evaluate the data submitted in support of a vaccine candidate’s safety and effectiveness and will only authorize or approve a vaccine for the prevention of SARS-CoV-2 infection and/or COVID-19 if the vaccine meets the Agency’s regulatory standards. FDA is committed to being as transparent as possible concerning the review process underlying the authorization or approval of a product in conformance with any applicable disclosure and regulatory regulations.

We appreciate your interest in this topic, as well as the opportunity to provide this information to you. Thank you for contacting FDA, and please feel free to contact us again if you have additional concerns.

Sincerely,



Stephen M. Hahn, M.D.
Commissioner of Food and Drugs