August 28, 2020

Dear Mr. Cronin, et. al.,

Thank you for your recent letter to Dr. Stephen Hahn, Commissioner of Food and Drugs, concerning the development of vaccines to prevent COVID-19. We appreciate your interest in this important topic.

FDA recognizes the urgent need to develop vaccines to prevent COVID-19, and we are working collaboratively with industry, federal, domestic, and international partners to accelerate this work. We also recognize that transparency around FDA's review, evaluation and decision-making with respect to COVID-19 vaccines is likely to impact public confidence in these vaccines.

As you are likely aware, on June 30, 2020, FDA published guidance with recommendations for those developing COVID-19 vaccines for the ultimate purpose of licensure. The guidance, entitled *Development and Licensure of Vaccines to Prevent COVID-19*, reflects the recommendations and assistance FDA has been providing over the past several months to companies, researchers and others. We believe that the guidance document provides transparency about FDA's current thinking about the scientific data needed to support approval of safe and effective COVID-19 vaccines. It helps the public understand FDA's process for evaluating the safety and effectiveness of COVID-19 vaccines and can build confidence that approved vaccines meet regulatory standards for safety and effectiveness. Please be assured that we are committed to principles of transparency, consistent with our statutory authority and regulations.

As part of FDA's evaluation of the safety and effectiveness of these vaccines, FDA will convene its Vaccines and Related Biological Products Advisory Committee (VRBPAC), a panel of outside, independent, technical experts from various scientific and public health disciplines that provide input on scientific data and its public health significance in a public forum. The VRBPAC is the most appropriate advisory committee for FDA to obtain input on scientific issues related to the development of vaccines to prevent SARS-CoV-2 infection and/or COVID-19. Given the widespread potential use of these vaccines, transparent discussion at VRBPAC will help ensure clear public understanding of the evidence supporting vaccine safety and effectiveness. FDA will carefully consider the scientific data as well as the input received at the VRBPAC meeting prior to the authorization or licensure of a vaccine to prevent COVID-19.

We will continue to explore additional mechanisms to be as transparent as possible about our decision-making and general thinking regarding vaccines to prevent SARS-CoV-2 infection and/or COVID-19 disease.

Thank you, again, for your concern and contacting us regarding this matter.

Sincerely,

Peter Marks, M.D., Ph.D.
Director
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