



August 27, 2020

Sidney M. Wolfe, M.D., Found and Senior Advisor
Michael A. Carome, M.D., Director
Public Citizen's Health Research Group
1600 20th Street, NW
Washington, D.C. 20009

Dear Drs. Wolfe and Carome,

Thank you for your recent letter related to the development and use of vaccines to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2.

The 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. There are various approaches that the FDA is using to efficiently advance the development of safe and effective vaccines intended to prevent COVID-19. The nature of a particular candidate vaccine and its intended use may impact the specific data required to advance through development and licensure. However, the goal of development programs is to demonstrate safety and effectiveness of a vaccine for the prevention of COVID-19.

The FDA's Center for Biologics Evaluation and Research (CBER) has oversight of vaccines used in the United States. When making decisions about Emergency Use Authorization (EUA) or licensure of COVID-19 vaccines, we will apply the relevant statutory and regulatory requirements in the Federal Food, Drug, and Cosmetic Act and the Public Health Service (PHS) Act. CBER staff involved in the evaluation of vaccines are highly qualified scientists and physicians who are knowledgeable about the complexity of vaccine development. The same CBER scientists and physicians who routinely advise sponsors on vaccine development programs, manufacturing considerations, and assessment of safety and effectiveness of all vaccines are the experts who are focused on the work related to COVID-19 vaccine development.

As with all vaccines, the FDA requires that vaccine developers provide sufficient data to the FDA to evaluate the safety and effectiveness of the vaccine for the intended use and population. The FDA is working with vaccine developers to help ensure that ongoing and planned clinical trials will provide sufficient data to support approval of safe and effective vaccines in the United States.

The FDA will only approve a Biologics License Application or issue an EUA for a COVID-19 vaccine after FDA has determined that the vaccine meets the relevant statutory standard. An EUA can be issued to facilitate the availability of an unapproved product only after several statutory criteria are met. Among these requirements is a determination by the FDA that the known and potential benefits of an unapproved product, when used to diagnose, prevent, or treat a serious or life-threatening disease or condition, outweigh the known and potential risks of the unapproved product.



After approval of a BLA or issuance of an EUA by the FDA, the safety of COVID-19 vaccines will continue to be closely monitored using various existing surveillance systems and in certain cases, the FDA may require the manufacturer to conduct post-marketing studies to further assess known or potential serious risks.

As you noted in your letter, FDA's guidance entitled, "[Development and Licensure of Vaccines to Prevent COVID-19](#)," addresses considerations regarding EUA of an investigational vaccine—and makes clear that an assessment regarding any potential EUA for a COVID-19 vaccine would be made on a case-by-case basis considering the target population and the totality of the relevant, available scientific evidence, including preclinical and human clinical study data of the product.

The guidance reflects the recommendations and assistance the FDA has been providing over the past several months to companies, researchers and others, and describes the Agency's current recommendations regarding the data needed to facilitate the manufacturing, nonclinical and clinical development, and approval of COVID-19 vaccines.

Additionally, the guidance provides an overview of key considerations to help manufacturers satisfy requirements for chemistry, manufacturing and controls, and nonclinical and clinical data needed for development and licensure, and for post-licensure safety evaluation of vaccines. The guidance explains that, given our current understanding of SARS-CoV-2 immunology, the goal of development programs at this time should be to support traditional FDA approval by conducting studies to directly evaluate the ability of the vaccine to protect humans from SARS-CoV-2 infection and/or disease.

We recognize that transparency around the FDA's decision-making with respect to COVID-19 vaccines is likely to impact public confidence in these vaccines. We believe that the guidance document provides transparency about the FDA's current thinking about the scientific data needed to support approval of safe and effective COVID-19 vaccines. It helps the public understand the FDA's process for evaluating the safety and effectiveness of new vaccines and can build confidence that these vaccines will meet regulatory standards for safety and effectiveness. Please be assured that we are committed to principles of transparency, consistent with statutory authority and regulations.

Also, as part of the FDA's evaluation of the safety and effectiveness of these vaccines, the FDA plans on convening, as necessary, 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. There are existing mechanisms in place applicable to VRBPAC for access to a range of expertise, transparency, and protections against conflicts of interest. The FDA regularly schedules VRBPAC meetings and currently there is one planned for this fall that could potentially include review of issues related to the development and licensure of vaccines to prevent COVID-19.



We sincerely appreciate your interest in this topic, as well as the opportunity to provide this information to you.

Sincerely,

Peter W. Marks

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