



September 28, 2020

The Honorable Alex Azar
 Secretary
 Department of Health and Human Services
 200 Independence Avenue SW, Washington, DC 20201

The Honorable Dr. Stephen M. Hahn
 Commissioner
 United States Food and Drug Administration
 10903 New Hampshire Avenue, Silver Spring, MD 20993

The Honorable Russell Vought
 Director
 The Office of Management and Budget
 724 17th Street NW, Washington, DC 20503

Dear Secretary Azar, Commissioner Hahn, and Director Vought:

As representatives of hundreds of thousands of scientists across the country, we write to urge you to adhere to stringent scientific and medical standards as the Food and Drug Administration (FDA) prepares to assess the safety and efficacy of vaccine candidates that are currently in phase III clinical trials.

The COVID-19 pandemic has created a tremendous burden for the American public and billions of others around the world. In this nation alone, we are approaching 7 million

infections and 200,000 deaths. Even in recovered patients, the long term consequences of the disease are not fully understood.

In the midst of this enormous crisis, we thank you for your leadership in your response to COVID-19 and are encouraged by the partnership between the government, academia, and private companies to bring one or more vaccines to the marketplace in record time through Operation Warp Speed.

However, as vaccine candidates move through phase III clinical trials, we urge you to exercise the independence and scientific rigor for which the FDA is known. Allowing a vaccine to enter the marketplace prior to a rigorous assessment of its safety and efficacy would undermine vaccine confidence in the nation, erode the public's trust in the agency, and risk the health of the American public.

The approval of a low-efficacy vaccine could lead to a false sense of protection, resulting in the easing of public health measures, and that will exacerbate the pandemic. Approving a vaccine without adequate testing could result in adverse impacts and worsen the already significant anti-vaccination sentiment.

For those reasons and more we believe that a full and thorough approval process for a vaccine is far better than the use of an Emergency Use Authorization (EUA). A thorough process will ensure safety and efficacy while giving the public the assurances it needs.

We do, however, recognize that the issuance of an EUA is within FDA's authority. Although we have yet to see the new standard communicated by the FDA to the White House for stricter emergency use authorization, in concept we support a very methodical and data-driven process to help ensure vaccine safety and effectiveness and also to restore public trust in the FDA and its decisions. As such, in the event that you decide to pursue an EUA, we urge you, at a minimum, to do the following:

1. Ensure that ample safety and efficacy data are available and have been reviewed by not just internal, but also independent, external experts.
2. Given the disproportionate burden of the disease on the elderly and communities of color, it's critical to ensure that data from phase III clinical trials reflects the diversity of the U.S. population and is powered by both communities of color and elder populations.
3. We live in a time of vaccine hesitancy and therefore believe more than ever that transparency in the review and assessment of the data by FDA's Vaccines and

Related Biological Products Advisory Committee is essential prior to any decision.

4. Commit to expanded and robust post-market surveillance to ensure that the safety, efficacy and quality of any vaccines approved through an EUA is closely monitored.

Lack of adherence to these principles will undermine the credibility of the agency, and the health of the American people.

We thank you for leadership and urge your vigilance against political interference in FDA's rigorous scientific decision-making process. Our scientists stand ready to work with you in this important endeavor.

Sincerely,

Federation of American Scientists
American Thoracic Society
Entomological Society of America
American Society of Tropical Medicine and Hygiene
American Association for Dental Research
American Institute for Medical and Biological Engineering
American Psychiatric Association
American Anthropological Association
Society of Vacuum Coaters
United States Pharmacopeia
American Association for Anatomy
American Institute of Biological Sciences
Biophysical Society
Society for Industrial and Applied Mathematics
Sigma Xi

cc:

Chairman Frank Pallone (D-NJ), House Committee on Energy and Commerce
Ranking Member Greg Walden (R-OR), House Committee on Energy and Commerce
Chairman Lamar Alexander (R-TN), Senate Committee on Health, Education, Labor, and Pensions
Ranking Member Patty Murray (D-WA), Senate Committee on Health, Education, Labor, and Pensions