



October 1, 2020

The Honorable Alex Azar
Secretary of U.S. Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Azar:

On behalf of the scientists and researchers the Biotechnology Innovation Organization (BIO) represents, I am writing to request that you publicly release all new guidance developed by the Food and Drug Administration (FDA) concerning emergency use authorization for vaccines to prevent the spread of COVID-19. The release of FDA guidance would provide scientists and researchers greater regulatory clarity and strengthen public confidence in any future vaccine that may be authorized or approved.

BIO member companies are leading a global effort to develop vaccines against COVID-19. In fact, more than 180 experimental vaccines for COVID-19 are currently in development, including 10 that now are in Phase 3 clinical trials. The scale and speed of the biopharmaceutical industry's response to the novel coronavirus are unprecedented. These efforts to bring a safe and effective vaccine to the public provide real hope that this pandemic will soon end, and our nation will begin to return to normal.

Our organization and member companies are working closely with FDA scientists and public health experts to achieve our shared commitment to testing and developing vaccines in strict accordance with sound scientific principles and with high ethical and safety standards.

That is why we were encouraged to learn the FDA has been finalizing new guidance to clarify what biopharmaceutical companies will need to demonstrate for safety and efficacy data in order to receive emergency use authorization for COVID-19 vaccines. Insight into FDA's views on clinical and scientific factors underlying emergency use authorization of COVID-19 vaccines would support ongoing research and development.

All new FDA guidance should be finalized and communicated with those on the frontlines developing potential vaccines. Just as importantly, it must also be shared more broadly with the American public. We cannot allow a lack of transparency to undermine confidence in the vaccine development process. The public must have full faith in the scientific process and the rigor of FDA's regulatory oversight if we are to end the pandemic. Releasing any additional guidance on granting emergency use authorization for a vaccine will go a long way in accomplishing this critical goal.



On behalf of BIO and its members, I am deeply grateful for the efforts of countless individuals across the federal government in response to this public health crisis. We look forward to continuing to work with key government partners to achieve our shared goal of ending the COVID-19 pandemic quickly and safely.

Best,

A handwritten signature in black ink, appearing to be "M. McMurry-Heath", written in a cursive style.

Dr. Michelle McMurry-Heath, Ph.D.
President and CEO