Congress of the United States
Washington, DC 20510

April 20, 2020

The Honorable Alex M. Azar II
Secretary
Department of Health and Human Services
200 Independence Avenue, Southwest
Washington, D.C. 20201

The Honorable Stephen Hahn, MD
Commissioner
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

Dear Secretary Azar and Commissioner Hahn,

We are writing to ask you to begin consideration of the conditions under which a COVID-19 vaccine might be approved and deployed more rapidly than under the usual approval process. This consideration must rest on a rational analysis of the risk/benefit ratio, based on the best available science, and be free of political interference.

For decades, the FDA and the public have been well served by a thoughtful drug approval process that appropriately balances the risks and benefits of early drug deployment. We recognize that there is an essential tradeoff between the benefits of having a new drug available quickly, the risks to human health of deploying a drug with effectiveness and side effects that are not fully known at the time of deployment, and the risks to test subjects in clinical trials. In the case of vaccines for normal diseases, this appropriately results in a typical approval time for vaccines of 18 months to several years.

However, the enormous human cost of the COVID-19 epidemic alters the optimization of the risk/benefit analysis in favor of more rapid approval and deployment. Every week of delay in the deployment of a vaccine to the seven billion humans on Earth will cost thousands of lives. Human misery also results from the economic damage caused by COVID-19 pandemic, and by the tragic psychological impact of social isolation on humans of all ages. Therefore, in addition to proceeding along the normal route for developing an approved vaccine for COVID-19, we urge you to consider adopting, in parallel, expedited procedures for testing, approval and use of COVID-19 vaccines.

As you know, rapid vaccine development balances risks to human health of voluntary test subjects in clinical trials, the risks of early deployment of a moderately tested vaccine to the general population, and the certainty of human suffering and death from delayed vaccine deployment. We write to assure you that Congress understands that a more risk-tolerant development process is likely appropriate in the case of a COVID-19 vaccine. In the case of accelerated human trials, justifiable risks may be taken by parallel testing of multiple dose levels, advancing more rapidly from phase to phase and potentially by challenge trials that involve

deliberately infecting volunteers who have received candidate vaccines or placebos to confirm the efficacy of those vaccines and are at very low risk of serious disease from the infection. [1] This could accelerate the emergency use and eventual licensure of vaccines that have also shown safety in larger groups by many months.[2] We urge you to consider these and other options, provided they proceed with the principle of informed consent of truly voluntary subjects and are backed by the best available science. Our situation in this pandemic is analogous to war, in which there is a long tradition of volunteers risking their health and lives on dangerous missions for which they understand the risks and are willing to do so in order to help save the lives of others.

Once approved, vaccines must be deployed as rapidly as possible to the full population of the world. Congress has given you clear direction and funding to invest in multiple routes to mass production for multiple plausible vaccine candidates, in advance of their testing and approval, with the acknowledgement that much of that capacity will likely go unused when the final set of vaccines is chosen for mass deployment. We reemphasize that direction from Congress and ask you to inform Congress immediately if it appears that mass production capabilities for significantly promising vaccine candidates are being delayed for economic reasons.

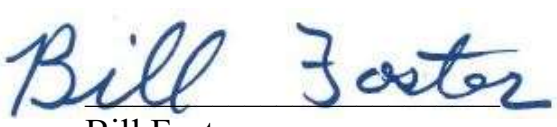
Plans for domestic production and deployment should be robust against potential export blockades by other countries, but equally we should not assume that US will go the route of hoarding either vaccines or the intellectual property they depend upon. Intellectual property must not be a roadblock, nor must the "not-invented-here" syndrome, nor should commercial considerations delay the delivery of best available vaccines to Americans and people throughout the world. We urge you to continue to stay current with international developments and to not fear to rely on the best available scientific data from transparent and trusted scientific collaborations from around the world. We urge you to continue to maintain close contact with vaccine developers and their regulators around the world so that if a better vaccine is developed, tested, and proven elsewhere in the world, we will be in a position to rapidly approve, procure, produce and deploy it.

We expect you to react flexibility to the situation as it evolves, follow the science as it develops, and adjust accordingly. We urge you to work closely with independent groups of experts such as the National Academy of Sciences, Engineering and Medicine's Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats to transparently make these decisions on the development, testing, and prioritization for deployment of potential vaccines among subpopulations, and to inform Congress and the public as these decisions are made. Finally, we reiterate that decisions about deployment of vaccines must be made by scientific and ethical experts, following legal principles defined by Congress, and be free of political interference.

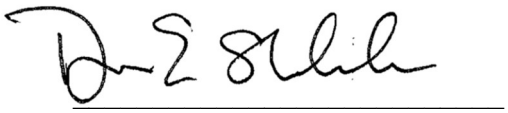
[1] https://academic.oup.com/jid/article/doi/10.1093/infdis/jiaa152/5814216
[2] https://science.sciencemag.org/content/368/6486/16

If you believe that additional legislation, or a clearer statement of congressional intent, is necessary or desirable for you to take the actions outlined above please let us know as soon as possible.

Respectfully,



Bill Foster
Member of Congress



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