Congress of the United States

Washington, DC 20515

May 3, 2023

Dr. Robert Califf
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Commissioner Califf,

We write to express our concern regarding the Food and Drug Administration's (FDA) pace for authorizing and approving updated COVID-19 therapeutics, learn more about the Administration's Project Next Gen, and inquire about a platform technology designation that was signed into law last Congress. As we enter the endemic phase of the outbreak, we should adapt our approach for addressing the worst health impacts of the virus.

Over the last three years, our country has seen variant after variant challenge health care providers' ability to stem the spread of the virus. Despite the great advances we have made in returning our world to its normal order, COVID-19 continues to be a concern for the most vulnerable populations in the U.S. – particularly immunocompromised Americans. With this in mind, we write regarding efforts to balance rigorous safety and efficacy evaluation with science-informed policies that move the next generation of countermeasures into pharmacies, hospitals, and other care delivery settings quickly. We must be focused on expanding treatment options that broaden protection for everyone.

While the FDA has modernized its process in the past for influenza vaccines and pioneered an unprecedented public-private partnership through the multi-agency Operation Warp Speed for COVID vaccines, we fear it has not provided the same attention to other interventions. Of particular interest are therapies that do not rely on the health of patient's immune system to provide benefit, such as oral antivirals, IV antivirals, and monoclonal antibody therapies (mAbs). Our foremost concern is that new variants are developing faster than current FDA emergency use authorization (EUA) reviews can be completed – all despite the continued innovation to update drugs and biologics for a changing virus. For example, the FDA pulled the last remaining mAb therapy from the market in January, because it was no longer effective against the new and dominant variants of the virus. It is imperative for the FDA to work closely with the private-sector to encourage the rapid development of new therapeutics that can both prevent and treat COVID-19.

A continuous stream of therapeutics for COVID-19 is essential because there is no silver bullet for every patient or for every variant. Many older adults and immunocompromised individuals, including cancer and transplant patients and those with immune system disorders, cannot rely on vaccines because their bodies are unable to mount an adequate response to immunization, and the waning effectiveness of vaccines as new variants emerge is a compounding challenge. Moreover, for vulnerable patients who

contract COVID-19, each therapy has limitations. For example, some treatments might not be an option because of drug-drug interactions with medications necessary to manage other conditions. With this in mind, it's critical the FDA consider how the authorization and approval timelines can be streamlined to support varied and updated medical countermeasures for new COVID-19 variants.

Key reforms to the FDA's authority and matters within FDA's jurisdiction permit that under certain circumstances, sponsors of applications and emergency use authorizations may also be permitted to leverage data related to previously submitted FDA platform technologies—to expedite the process. Strong consideration should be given to the accumulated knowledge of products from the past few years, and the favorable risk-benefit proposition for patients who have few or no alternative options. A platform approval methodology has worked in the past for other endemic, changing pathogens, most notably, an adjusted timeline for approving modified influenza vaccines annually. In learning from this approach, valuable time and resources could be spared, particularly when safety and efficacy data exist for predecessor therapies.

Please provide, in writing, answers to the below questions:

1. Will the FDA consider a platform approach for authorizing and approving updated mAbs or antivirals?

2. In the 117th Congress, language creating a platform designation program for technologies reviewed by the FDA was signed into law.

    - Is the FDA open to utilizing this directive for the review of products that treat and prevent COVID-19, including products previously under EUA?

3. While mAbs and antivirals are often prescribed to patients who are at high risk for hospitalization or death from COVID-19, there are still gaps in the availability of these drugs that contribute to poorer patient outcomes. How is the FDA currently working with health care providers to identify supply chain and delivery barriers and find solutions to them?

4. Does streamlining the clinical data package make sense for updated treatment and prevention options, particularly for targeted populations with unmet medical need and high risk of poor outcomes?

5. Recognizing that many of these therapeutics are aimed at a high-risk patient population with the highest likelihood of benefits, what recent changes have been made to expedite the authorization process?

We look forward to hearing from you on this important matter.

Sincerely,

Dan Crenshaw
Member of Congress

Lori Trahan
Member of Congress