

Dear Congress,

The undersigned organizations appreciate the Food and Drug Administration's (FDA) longstanding efforts to balance time to market for innovative treatments with rigorous safety standards. However, we write to express an urgent need for several improvements across the agency to increase efficiency to safely tackle current and future pandemics.

First, we note that holds on trials [increased by 66 percent at the Center for Biologics Evaluation and Research](#) (CBER) from 2014 to 2021. We urge you to conduct oversight, develop a process to lift holds more quickly, and push the FDA to work with stakeholders to solve any problems with trials on hold. While we understand that the FDA may have limited resources and a high demand for biologics review, we believe that Congress and the FDA should work together to streamline this process.

As Rep. Crenshaw (R-TX) [has also noted](#), while progress has been made on improving the timelines for vaccines, for therapeutics we believe that the pandemic approval pathway for treatments like monoclonal antibodies should be clarified and a process clearly delineated. For other endemic viruses, a platform approval methodology has proven successful and should be examined in this case. Additionally, for these kinds of therapeutics, with well-established safety profiles, we urge the reduction of safety database requirements. Establishing a more clear process for current and future pandemics and reducing the administrative burdens will help stakeholders get life saving treatments to people faster while maintaining product safety.

Finally, we note that COVID-19 test usability trials have been delayed and have increased costs in the U.S. as opposed to our counterparts in Europe. We believe that the Emergency Use Authorization process should account for time as a cost. Had these tests been available from June 1, 2020 through the end of 2020, research suggests [that](#) \$395 billion in GDP could have been saved and 117,000 deaths potentially avoided. Earlier and more widely-available tests could have also helped isolate infectious residents in [nursing homes](#), thereby reducing COVID's impact on vulnerable populations. While some argue that the U.S. has had a stronger focus on accuracy and safety than Europe, we note that Europe had more varieties of accurate tests quicker and at lower costs due to less onerous performance standards. The U.S. required [30,000 times](#) more sensitive screening than its United Kingdom counterparts for antigen tests.

Taken as a whole, it is clear that the Congress and the FDA should work to streamline some of its processes ahead of the next pandemic. COVID-19 was devastating as a national emergency but its lessons should strengthen our preparation and processes moving forward.

We hope that you will take these concerns into account as you consider how best to oversee and support the FDA's efforts to ensure that new treatments are timely, safe, and effective for all Americans.

Sincerely,



National Taxpayers Union



60 Plus Association



American Consumer Institute



Center for a Free Economy



Center of the American Experiment



Center for Individual Freedom



Center for Innovation and Free Enterprise



Pioneer Institute



Taxpayers Protection Alliance