Congress of the United States
Washington, DC 20515

April 11, 2022

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

Dear Commissioner Califf:

As the FDA continues to consider issues relating to the safety and efficacy of COVID-19 vaccines and therapeutics, Americans also continue to evaluate the benefits and risks associated with these vaccines and therapeutics in the midst of the changing dynamics of the pandemic. Nothing is more important to physicians, parents, patients, public health officials and elected officials than having access to as much information as possible when evaluating immediate and long-term responses to the pandemic.

Although we have been responding to the COVID-19 pandemic for two years, most of the information in the FDA's possession relating to EUA products, and now approved COVID-19 vaccines– including vaccines that have been mandated for tens of millions of Americans, has not been made available for independent review and evaluation. Broader access to this data early on in the pandemic could have been beneficial in making better public health decisions by enabling thousands of additional reviewers to evaluate the data and identify potential risks and risk factors. The fact that the data in the FDA's possession has remained behind an FDA firewall for more than 18 months is appalling.

There is absolutely no reason for failing to fully disclose pre- and post-EUA data in the FDA's possession for those products which have now been approved. We are extremely disappointed that Pfizer and the FDA used the courts to obstruct and delay the release of efficacy and safety information. The FDA even requested that the court to allow it to slowly release this information over a course of 75 years. Failure to be more forthcoming with this important safety and efficacy data undermines public confidence.

We write to request that the FDA immediately release all safety and efficacy data in its possession for EUA COVID-19 products which have now been approved by the FDA. This request applies to pre- and post-EUA approval data. We also request that all safety and efficacy data submitted to the FDA for future and ongoing evaluation of EUA, and subsequently approved, COVID-19 products be made publicly available within 14 days of the FDA receipt of such information. Delays in the release of efficacy and safety data of medical treatments fail to serve the public interest.

It is particularly noteworthy that the FDA already requires that most of this information be submitted by the manufacturers in redacted and releasable form, so as to protect manufacturer trade secrets and clinical trial participant information, according to §5.65 Exemption four, Federal Regulation 21 C.F.R. § 601.51(e), and 21 C.F.R § 20.63(b). Therefore, the FDA should have been preparing to immediately release data once licensure was granted, and should not have allowed vaccine mandates while the products were under EUA and the data remained unavailable to the public.

Lastly, the manufacturers of COVID-19 vaccines and other products have been granted immunity under the Public Readiness and Emergency Preparedness and Act (PREP) from liability for injuries caused by their products. Tens of billions of U.S. taxpayer dollars have been spent to purchase, distribute and administer these EUA COVID-19 products.

The "gold standard" for evaluating safety and effectiveness of medical treatments is rigorous independent review. To enable independent review, the FDA must allow for immediate release of this information.

Thank you for your immediate attention to this request and we look forward to hearing from you how the FDA will address this deficiency in a timely manner.

Sincerely,

Bill Posey
Member of Congress

Louie Gohmert
Member of Congress

Vicky Hartzler
Member of Congress

Thomas Massie
Member of Congress

Mo Brooks
Member of Congress

Ralph Norman
Member of Congress

Madison Cawthorn
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Mary E. Miller
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Clay Higgins
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Thomas P. Tiffany
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