Congress of the United States
Washington, DC 20515

August 25, 2020

The Honorable Dr. Stephen M. Hahn
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Hahn:

We are writing to request that the Food and Drug Administration ensure that the August 23, 2020 Emergency Use Authorization for COVID-19 convalescent plasma for the treatment of hospitalized patients with COVID-19 allow for the use of certain convalescent plasma products distributed prior to the EUA issuance. The unit labeling requirements for the EUA potentially limit the use of convalescent plasma collected and distributed prior to August 23 and could result in delays in treatment if not promptly addressed.

On August 23, 2020, the FDA issued an EUA to allow for wider use of convalescent plasma, based on "historical evidence using convalescent plasma in prior outbreaks of respiratory viruses, certain preclinical evidence, results from small clinical trials of convalescent plasma conducted during the current outbreak, and data obtained from the ongoing National Expanded Access Treatment Protocol (EAP) sponsored by the Mayo Clinic".[1] The EUA also mandates new labeling requirements on convalescent plasma, including information on the concentration of antibody titers.[2]

However, these labeling requirements differ substantially from those previous in use for the national Expanded Access Program for convalescent plasma led by the Mayo Clinic, which did not have titer indications labeled when distributed. This presents potentially significant barriers to access of convalescent plasma under the EUA, given the regulatory barriers and testing required to relabel units already distributed across the country. The resulting delays could have an impact on patient outcomes, with preprint data indicating that time to transfusion is a key factor correlated with lessening the severity or shortening the length of illness.[3]

---

[1] Fact Sheet for Health Care Providers: Emergency Use Authorization (EUA) of COVID-19 Convalescent Plasma for Treatment of COVID-19 in Hospitalized Patients. (2020, August 23). Retrieved from https://www.fda.gov/media/141478/download

[2] Ibid.

[3] Effect of Convalescent Plasma on Mortality among Hospitalized Patients with COVID-19: Initial Three-Month Experience. (2020, August 23). Retrieved from https://www.medrxiv.org/content/10.1101/2020.08.12.20169359v1

Given this unforeseen consequence, we are requesting that FDA take prompt action to ensure that these requirements do not unduly inhibit patient access to convalescent plasma. Thank you in advance for your attention to this request.

Sincerely,

Debbie Dingell
Member of Congress

Fred Upton
Member of Congress