Congress of the United States Washington, DC 20510

May 12, 2020

The Honorable Stephen Hahn Commissioner Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993 Robert R. Redfield, MD Director Centers for Disease Control and Prevention 1600 Clifton Road Atlanta, GA 30329

Dear Commissioner Hahn and Director Redfield,

We write to encourage the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) to take additional steps to increase public awareness of the importance and benefits of plasma donation as we respond to the coronavirus (COVID-19) pandemic.

Given the unprecedented scale and nature of this outbreak, is it critically important that we support the development of safe and science-based treatments. In some cases, clinicians and investigators rely on plasma donation by people who have recovered to develop these treatments.

As you are aware, the Mayo Clinic is leading a national Expanded Access Program that collaborates with the American Red Cross to coordinate the collection and distribution of convalescent plasma from patients who have recovered from COVID-19 to people in need across the country. This convalescent plasma contains antibodies that could help other patients struggling with the illness caused by the coronavirus. As of May 4, over 2,000 sites and 9,000 patients have participated in the Expanded Access Program. Johns Hopkins University is leading another investigational treatment using a biological product from convalescent plasma known as hyperimmune globulin to help reduce the severity of coronavirus infections.

Investigational therapies – which often lead to promising and even life-saving treatments – are being evaluated for their effectiveness in COVID-19 cases and rely on sufficient supplies of convalescent plasma from donors. Shortages of convalescent plasma have left some families in areas with fewer COVID-19 cases in search of possible donors on their own. Expanding the number of people who volunteer to donate plasma is especially important in light of recent accounts highlighting eligibility requirements and screening protocols that have reportedly limited the number of volunteers who actually qualify to donate.

² COVID-19 expanded access program (Accessed May 11, 2020). Uscovidplasma.org. Retrieved from https://www.uscovidplasma.org/#why

¹ Coronavirus (COVID-19) Update: FDA Coordinates National Effort to Develop Blood-Related Therapies for COVID-19. (April 3, 2020). Food and Drug Administration. Retrieved from https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-coordinates-national-effort-develop-blood-related-therapies-covid-19

³ Coronavirus (COVID-19) Update: FDA Coordinates National Effort to Develop Blood-Related Therapies for COVID-19.

⁴ Burch, Audra and Harmon, Amy. (April 30, 2020). 'Will You Help Save My Brother?': The Scramble to Find Covid-19 Plasma Donors. New York Times. Retrieved from https://www.nytimes.com/2020/04/29/us/coronavirus-plasma-donors.html

⁵ Harrison, Sara. (April 27, 2020). *The Race to Get Convalescent Plasma to Covid-19 Patients*. Wired. Retrieved from https://www.wired.com/story/the-race-to-get-convalescent-plasma-to-covid-19-patients/

We understand that FDA and CDC have taken initial steps to encourage plasma donation by partnering with outside organizations, issuing guidance on plasma collection, and developing an informational webpage. We encourage FDA and CDC to take additional steps to effectively share these resources with the public, people who have recovered from coronavirus, and hospitals and health systems caring for patients with the virus.

We also respectfully request your answers to the following questions:

- 1. How are patients who have recovered from COVID-19 and hospitals and health systems that treat COVID-19 patients made aware of the FDA and CDC's existing resources on plasma donation? Other than the efforts outlined above, are there additional ways in which the FDA and CDC have communicated the scientific importance and benefits of donating plasma?
- 2. Do the FDA and CDC have the authorities to widely publicize the need for plasma donation during this pandemic as part of, or in addition to, any existing partnerships through social media and other platforms?⁷
- 3. What additional resources or authorities do the FDA and CDC need from Congress to ensure that health professionals and the public are aware of the heightened importance of donating plasma during this time?

Thank you for your time and consideration of this important matter. We look forward to working with you to increase awareness of the importance of donating plasma to advance our understanding of the coronavirus pandemic.

Sincerely,

/S/ Amy Klobuchar/S/ Mario Diaz-Balart/S/ Joe CunninghamAmy KlobucharMario Diaz-BalartJoe CunninghamUnited States SenatorMember of CongressMember of Congress

⁷ Plasma Donations from Recovered COVID-19 Patients (Accessed on May 11, 2020).

⁶ Plasma Donations from Recovered COVID-19 Patients (Accessed on May 11, 2020). American Red Cross. Retrieved from https://www.redcrossblood.org/donate-blood/dlp/plasma-donations-from-recovered-covid-19-patients.html and Interim Infection Control Guidance on COVID-19 for Personnel at Blood and Plasma Collection Facilities (Accessed May 11, 2020). Centers for Disease Control and Prevention. Retrieved from https://www.cdc.gov/coronavirus/2019-ncov/hcp/blood-and-plasma-collection.html and