

Stephen Hahn, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

June 18, 2020

Dear Commissioner Hahn,

We write to request that the FDA create a temporary exception allowing for plasma donation by gay and bisexual men who have survived COVID-19 and do not maintain abstinence from sexual contact with other men. The current pandemic has created an urgent need for convalescent plasma from those who have developed antibodies to COVID-19, the most promising therapeutic treatment immediately available. Sexually active gay and bisexual men who can safely donate plasma could be identified—and all potential donors with COVID-19 antibodies who are qualified and willing to assist should be welcomed and encouraged to donate during this global public health emergency.

The undersigned organizations serve constituencies that include gay and bisexual men (or “men who have sex with men (MSM)” in the parlance of public health) and have a vested interest in ending policies that discriminate against them while simultaneously ensuring a safe and abundant blood supply. Many of the signatories have advocated on behalf of LGBT people for decades. Collectively and individually, we have submitted dozens of sets of comments regarding blood donation policies affecting LGBT people.

COVID-19 has spread across the globe and become a deadly pandemic of enormous scope at an unprecedented pace. In a little over three months since the first case of community spread in the United States was reported, approximately 2 million people have been diagnosed with COVID-19 in this country and over 113,000 people have died.^{1,2} No therapeutic treatments nor biomedical methods of prevention have yet been identified, and a vaccine is not likely to be widely available—if at all—until 2021.³

Although FDA has not approved any COVID-19 treatments, there are more than 25 clinical trials currently or preparing to recruit individuals for studies evaluating the efficacy of transfusing

¹ U.S. Center Disease Control, *CDC Confirms Possible Instance of Community Spread of COVID-19 in U.S* (Feb. 26, 2020), <https://www.cdc.gov/media/releases/2020/s0226-Covid-19-spread.html>; John Hopkins, *COVID-19 Dashboard by the Center for Systems Science and Engineering (CSSE)*, <https://coronavirus.jhu.edu/map.html>, (last visited Jun. 11, 2020).

² Because of the high percentage of asymptomatic cases, the actual number of people who have had COVID-19 in the United States is likely much higher. Aria Bendix, *To know the real number of coronavirus cases in the US, China or Italy, researchers say multiply by 10*, Business Insider, Apr. 19, 2020, <https://www.businessinsider.com/real-number-of-coronavirus-cases-underreported-us-china-italy-2020-4>; see also Pien Huang, *Fauci Says U.S. Death Toll Is Likely Higher. Other COVID-19 Stats Need Adjusting, Too*, NPR, May 13, 2020, <https://www.npr.org/sections/goatsandsoda/2020/05/13/854873605/fauci-says-u-s-death-toll-is-likely-higher-other-covid-stats-need-adjusting-too> (“Total number of confirmed cases: . . . The actual number of people with COVID-19 is probably much higher.”).

³ JAMA Network, *Coronavirus Q&A with Anthony Fauci, MD*, YouTube (Jun. 2, 2020), <https://www.youtube.com/watch?v=3MH-3ICY-N4&feature=youtu.be>.

antibody-rich plasma from patients who have recovered to treat current patients.⁴ These studies hypothesize that this antibody-rich plasma could be used to reduce the severity of disease progression and to potentially save lives. To further this research, FDA has been working with the American Red Cross to encourage people who have recovered from coronavirus to donate plasma.⁵

Gay and bisexual men who have survived COVID-19 could safely donate plasma as a part of the research protocols currently being conducted to determine the efficacy of convalescent plasma for people with active COVID-19. In April 2020, when blood supplies were running low in the wake of “shelter in place” orders across the country, the FDA recognized the exigency of the moment and accelerated its plans to reduce the deferral period for sexually active gay and bisexual men (MSM) from twelve months to three months.⁶ The FDA should recognize the exigency of this moment and allow gay and bisexual men who have survived COVID-19 to donate plasma in the context of a research protocol.

There are several safe options for using plasma donated by gay and bisexual men, including adding to the donor questionnaire a question about condom-less receptive anal sex in the past 6 weeks and deferring those who have engaged in this higher risk activity,⁷ but we suggest the following, which is uniquely available in the context of plasma donation. Because plasma has a shelf life allowing for its use a year or more after it is collected,⁸ all gay and bisexual men who have survived COVID-19 should be permitted to donate plasma within the context of a research protocol. The plasma collected on a particular date could be frozen and not released until the same donor returns to donate six weeks later and tests negative for HIV, HBV, and HCV on that day. This would ensure that the donor was not exposed to a transfusion transmissible infection within the window period, the pre-donation period of time during which a recent infection could go undiscovered by a nucleic acid test (NAT) conducted on the date of the original donation.⁹

As an additional benefit, this limited exception for gay and bisexual men who have survived COVID-19 to donate plasma would provide an opportunity to collect data that could inform future changes to the blood donation policy for gay and bisexual men. Though they would not affect the potential donor’s ability to have plasma collected on a particular day, questions could be posed as to the donor’s sexual and drug use activities over the previous three months. The answers to those questions could then be compared with future test results to determine which activities, if any, actually resulted in new infections. This information—like the information being

⁴ Search results for COVID-19 convalescent plasma studies recruiting participants, Nat’l Library Med., Nat’l Inst. Health, ClinicalTrials.gov, <https://tinyurl.com/ybbspfcq> (last visited Jun. 10, 2020).

⁵ *Plasma Donations from Recovered COVID-19 Patients*, Am. Red Cross, www.redcrossblood.org/donate-blood/dlp/plasma-donations-from-recovered-covid-19-patients.html, (last visited Jun. 11, 2020).

⁶ Ctr. Biologics Evaluation & Research, U.S. Dept. Health Human Serv., *Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products* (2020), <https://www.fda.gov/media/92490/download>

⁷ Ctr. Disease Control, *HIV Risk Behaviors* (2015) <https://www.cdc.gov/hiv/pdf/risk/estimates/cdc-hiv-risk-behaviors.pdf>.

⁸ University of Texas Medical Branch (UTMB Health), *Blood Transfusion Services*, www.utmb.edu, <https://tinyurl.com/yc9cpej5> (last visited Jun. 11, 2020).

⁹ Morris Humar, et al., *Nucleic Acid Testing (NAT) of Organ Donors: Is the ‘Best’ Test the Right Test? A Consensus Conference Report*, 10 *Am. J. of Transplantation* 889, 890 (Table 1) (2010), <https://onlinelibrary.wiley.com/doi/pdf/10.1111/j.1600-6143.2009.02992.x> (estimating the window periods for HIV, HCV and HBV as 5-6 days, 3-5 days, and 20-22 days, respectively).

collected through the current study of a donor questionnaire to assess individual risk for gay and bisexual men¹⁰—could be used to inform the creation of a nondiscriminatory blood donation policy.

As it did in March by reducing the deferral period for blood donation by gay and bisexual men to three months, the FDA should take the action necessary to marshal all available resources to meet the threats posed by COVID-19, including the gay and bisexual men who are willing and able to donate convalescent plasma. Failure to take this action could literally be the difference between life and death for some people who acquire COVID-19 over the next year or more. It would be inexcusable to fail these individuals in this way.

Should you have any questions regarding this request, please feel free to contact Scott Schoettes with Lambda Legal at SSchoettes@lambdalegal.org, or Andrea Levario with Human Rights Campaign at Andrea.Levario@hrc.org.

Sincerely,

Lambda Legal

Human Rights Campaign

AIDS United

GLAAD

GLMA: Health Professionals Advancing LGBTQ Equality

National Alliance of State and Territorial AIDS Directors

PFLAG National

The AIDS Institute

¹⁰ Ctr. Biological Evaluation & Research, *supra note 6*, at 7-8.