

# Congress of the United States

## House of Representatives

COMMITTEE ON OVERSIGHT AND REFORM

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<http://oversight.house.gov>

May 7, 2020

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

Dear Commissioner Hahn:

We urge the Food and Drug Administration (FDA) to immediately modify its donor deferral recommendations to allow all men who have sex with men (MSM) who have recovered from coronavirus and can safely donate plasma in support of treatment research efforts to do so. FDA's current policy—which recommends turning away all MSM if they have been sexually active in the past three months—stigmatizes gay and bisexual men and undermines critical research into potential coronavirus treatments.

On April 1, 2020, Chairwoman Carolyn B. Maloney and Representative Alexandria Ocasio-Cortez sent a letter urging you to revise FDA's donor deferral policy for MSM in light of the negative long-term impacts coronavirus will have on the United States blood supply.<sup>1</sup> The next day, FDA announced that it would shorten this deferral period from twelve months to three months.<sup>2</sup>

Shortening the MSM deferral period was a good first step. However, FDA's policy continues to exclude gay and bisexual men who can safely donate blood and blood products—including those who have recovered from coronavirus and can donate plasma to support treatment research efforts.

Although FDA has not approved any coronavirus treatments, there are currently more than a dozen ongoing clinical trials evaluating the efficacy of transfusing antibody-rich plasma

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<sup>1</sup> Letter from Chairwoman Carolyn B. Maloney, Committee on Oversight and Reform, and Rep. Alexandria Ocasio-Cortez to Commissioner Stephen M. Hahn, M.D., Food and Drug Administration (Apr. 1, 2020) (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/documents/2020-04-01.CBM%20AOC%20to%20Hahn-%20FDA%20re%20Blood%20Ban.pdf>).

<sup>2</sup> Food and Drug Administration, *Coronavirus (COVID-19) Update: FDA Provides Updated Guidance to Address the Urgent Need for Blood During the Pandemic* (Apr. 2, 2020) (online at [www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-provides-updated-guidance-address-urgent-need-blood-during-pandemic](http://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-provides-updated-guidance-address-urgent-need-blood-during-pandemic)).

from patients who have recovered to treat current patients.<sup>3</sup> To further this research, FDA has been working with the American Red Cross to encourage people who have recovered from coronavirus to donate plasma.<sup>4</sup>

FDA's current blanket deferral policy—which does not evaluate potential donors on the basis of individual risk—directly undermines critical efforts to develop an effective treatment for coronavirus. There is no scientific justification for denying MSM who have recovered from coronavirus the opportunity to safely donate plasma.<sup>5</sup> Yet, gay and bisexual men who have recovered from coronavirus and attempted to donate have been turned away in accordance with FDA's blanket deferral recommendation.<sup>6</sup>

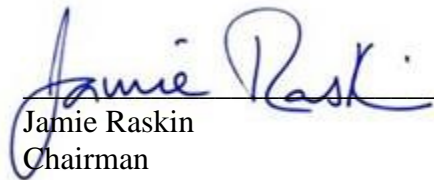
To ensure that efforts to develop an effective coronavirus treatment can proceed unhindered, we urge FDA to immediately modify its deferral recommendations so that all gay and bisexual men who have recovered from coronavirus and can safely donate plasma to support treatment research efforts are able to do so.

The Committee on Oversight and Reform is the principal oversight committee of the House of Representatives and has broad authority to investigate “any matter” at “any time” under House Rule X. If you have any questions regarding this request, please contact Committee staff at (202) 225-5051.

Sincerely,



Carolyn B. Maloney  
Chairwoman  
Committee on Oversight and Reform



Jamie Raskin  
Chairman  
Subcommittee on Civil Rights and  
Civil Liberties

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<sup>3</sup> Food and Drug Administration, *Fact Sheet for Patients and Parent/Caregivers Emergency Use Authorization (EUA) of Chloroquine Phosphate for Treatment of COVID-19 in Certain Hospitalized Patients* (Mar. 28, 2020) (online at [www.fda.gov/media/136536/download](http://www.fda.gov/media/136536/download)); National Library of Medicine, National Institutes of Health, *ClinicalTrials.gov* (online at [www.clinicaltrials.gov/](http://www.clinicaltrials.gov/)) (accessed May 7, 2020); Dr. Shen Chenguang et al., *Treatment of 5 Critically Ill Patients With COVID-19 With Convalescent Plasma*, *Journal of the American Medical Association* (Mar. 27, 2020) (online at [www.jamanetwork.com/journals/jama/fullarticle/2763983](http://www.jamanetwork.com/journals/jama/fullarticle/2763983)).

<sup>4</sup> American Red Cross, *Plasma Donations from Recovered COVID-19 Patients* (online at [www.redcrossblood.org/donate-blood/dlp/plasma-donations-from-recovered-covid-19-patients.html](http://www.redcrossblood.org/donate-blood/dlp/plasma-donations-from-recovered-covid-19-patients.html)).

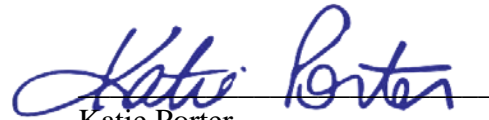
<sup>5</sup> J Weusten et al., *Refinement of a Viral Transmission Risk Model for Blood Donations in Seroconversion Window Phase Screened by Nucleic Acid Testing in Different Pool Sizes and Repeat Test Algorithms*, *Transfusion* (Jan. 2011) (online at [www.ncbi.nlm.nih.gov/pubmed/20707858](http://www.ncbi.nlm.nih.gov/pubmed/20707858)).

<sup>6</sup> *Doctors Can't Use COVID-19 Antibodies from Gay Men or Anyone Taking PrEP*, NBC News (Apr. 2, 2020) (online at [www.nbcnews.com/feature/nbc-out/doctors-can-t-use-covid-19-antibodies-gay-men-or-n1174341](http://www.nbcnews.com/feature/nbc-out/doctors-can-t-use-covid-19-antibodies-gay-men-or-n1174341)); *I Want to Donate Plasma for an Experimental Covid-19 Treatment. Because of Homophobia, I Can't*, Vox (Apr. 15, 2020) (online at [www.vox.com/2020/4/15/21222191/coronavirus-convalescent-plasma-donation-red-cross-homophobia](http://www.vox.com/2020/4/15/21222191/coronavirus-convalescent-plasma-donation-red-cross-homophobia)).

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Alexandria Ocasio-Cortez  
Member of Congress



Katie Porter  
Member of Congress



Deb Haaland  
Member of Congress

cc: The Honorable Jim Jordan, Ranking Member  
Committee on Oversight and Reform

The Honorable Chip Roy, Ranking Member  
Subcommittee on Civil Rights and Civil Liberties