

Congress of the United States

House of Representatives

COMMITTEE ON OVERSIGHT AND REFORM

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April 1, 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 you to immediately revise the Food and Drug Administration (FDA) recommendation that blood donation centers turn away men who have sex with men (MSM) who have been sexually active in the past 12 months. This antiquated policy is not based on current science, stigmatizes the LGBTQIA+ community, and undermines crucial efforts to increase the nation's blood supply as the United States grapples with the coronavirus crisis.

The coronavirus outbreak is almost certain to have significant, long-term impacts on the nation's blood supply. More than 4,000 blood drives across the United States have been canceled due to coronavirus, resulting in approximately 130,000 fewer donations.¹ The New York Blood Center alone reportedly had to cancel more than 600 blood drives, resulting in approximately 25,000 lost potential donations.² Numerous federal officials—including Surgeon General Dr. Jerome Adams and Department of Health and Human Services Assistant Secretary for Health Dr. Brett Giroir—have publicly encouraged people to donate blood.³

The current FDA policy unnecessarily restricts blood donations. According to one estimate, FDA's policy could prevent up to 4.5 million people from being eligible to donate

¹ Letter from Debra BenAvram, Chief Executive Officer, AABB, Kate Fry, Chief Executive Officer, America's Blood Centers, and J. Chris Hrouda, President, Biomedical Services, American Red Cross to The Honorable Stephen M. Hahn, MD, Commissioner, Food and Drug Administration (Mar. 20, 2020) (online at www.aabb.org/advocacy/correspondence/Documents/Joint-Letter-to-FDA-on-Blood-Supply-Chain.pdf).

² *COVID-19: Red Cross, New York Blood Center See Massive Shortage*, Montclair Local (Mar. 27, 2020) (online at www.montclairlocal.news/2020/03/27/montclair-covid-19-red-cross-new-york-blood-center-shortage/); *New York Blood Center Urgently Calls For Blood Donors*, Long Island Weekly (Mar. 31, 2020) (online at www.longislandweekly.com/new-york-blood-center-urgently-calls-for-blood-donors/).

³ The White House, *Tweet on Mar. 19, 2020, at 5:44pm* (Mar. 19, 2020) (online at www.twitter.com/WhiteHouse/status/1240756161437151234); "We Need People to Start Turning Out in Force to Give Blood": FDA Urging People to Donate Blood as Coronavirus Fears Intensify, America's Blood Centers (Mar. 12, 2020) (online at www.americasblood.org/news/fda-urging-people-to-donate-blood/).

blood. Revising the current restriction could result in as many as an estimated 615,000 additional pints of blood being donated each year.⁴

FDA's policy is not based on current science. According to the American Public Health Association, the FDA's policy "continues to prevent low-risk individuals from contributing to our blood supply" and "is not based in science but appears to be modeled after other countries' choices and fears."⁵

Similarly, according to the American Medical Association:

The ethical ideal for public policy in this area should be to transition away from policy that defers categories of persons based on attributing to all members risks associated with a population and toward policy that defers individual donors on grounds of evidence-based risk assessment.⁶

With the addition of an individualized risk assessment, the deferral period for all donors—including MSM—could be significantly shortened. The American Red Cross issued a statement last November calling on FDA to consider reducing the MSM deferral period from twelve to three months.⁷ Numerous other countries have already done so, including Canada, the United Kingdom, and France.⁸

FDA appears to be reevaluating its policy. In July 2016, FDA established a docket for public comment on its revised donor deferral recommendation.⁹ In March 2019, FDA asked its

⁴ UPDATE: *Effects of Lifting Blood Donation Bans on Men Who Have Sex with Men*, Williams Institute (Sept. 2014) (online at <https://williamsinstitute.law.ucla.edu/wp-content/uploads/Blood-Donation-Ban-MSM-Sep-2014.pdf>).

⁵ Letter from Georges C. Benjamin, M.D., Executive Director, American Public Health Association, to Food and Drug Administration (June 12, 2015) (online at www.regulations.gov/document?D=FDA-2015-D-1211-0053).

⁶ Letter from James L. Madara, M.D., Chief Executive Officer and Executive Vice President, American Medical Association, to Leslie Kux, J.D., Associate Commissioner for Policy, Food and Drug Administration (July 13, 2015) (online at www.regulations.gov/document?D=FDA-2015-D-1211-0063).

⁷ American Red Cross, *Press Release: American Red Cross Statement on FDA MSM Deferral Policy* (Nov. 21, 2019) (online at www.redcross.org/about-us/news-and-events/press-release/american-red-cross-statement-on-fda-msm-deferral-policy.html).

⁸ Daniel Grace et al., *Gay and Bisexual Men's Views on Reforming Blood Donation Policy in Canada: A Qualitative Study*, BMC Public Health (June 17, 2019) (online at <https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-019-7123-4>); M. Goldman et al., *Donor Deferral Policies for Men Who Have Sex with Men: Past, Present and Future*, Vox Sanguinis (Dec. 13, 2017) (online at www.onlinelibrary.wiley.com/doi/full/10.1111/vox.12623); Josiane Pillonel et al., *The Evolving Blood Donor Deferral Policy for Men Who Have Sex with Men: Impact on the Risk of HIV Transmission by Transfusion in France*, Transfusion (Feb. 6, 2020) (online at www.onlinelibrary.wiley.com/doi/abs/10.1111/trf.15677?af=R).

⁹ Food and Drug Administration, *Blood Donor Deferral Policy for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products; Establishment of a Public Docket; Request for Comments*, 81 Fed. Reg. 49673 (online at www.govinfo.gov/content/pkg/FR-2016-07-28/pdf/2016-17804.pdf).

Blood Products Advisory Committee to “consider the current 12-month MSM deferral policy and discuss the available scientific information regarding alternative procedures.”¹⁰

In light of the potential long-term impacts the coronavirus outbreak may have on the nation’s blood supply, we urge FDA to act swiftly in revising its policy so every person who can safely donate blood in the United States has the opportunity to do so.

We also request that FDA provide Committee staff with a briefing regarding its current policy, any plans to revise this policy, and efforts to ensure adequate supply as a result of the coronavirus crisis.

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



Alexandria Ocasio-Cortez
Member of Congress

¹⁰ Food and Drug Administration, *Blood Products Advisory Committee Meeting, FDA White Oak Campus, Silver Spring, MD, March 20-21, 2019* (online at www.fda.gov/media/120953/download).