

Congress of the United States
House of Representatives

COMMITTEE ON OVERSIGHT AND REFORM

2157 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515-6143

MAJORITY (202) 225-5051
MINORITY (202) 225-5074
<https://oversight.house.gov>

January 13, 2022

Dr. Janet Woodcock
Acting Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Woodcock:

We write to request that the Food and Drug Administration (FDA) take immediate action to reassess its current blood donation policy, which has had the discriminatory effect of preventing gay and bisexual men from safely donating blood. While FDA has made progress in updating this troubling policy, the existing recommendation that blood centers turn away men who have sex with men (MSM) who have been sexually active in the past three months continues to stigmatize gay and bisexual men and undermine crucial efforts to ensure an adequate and stable national blood supply.

On January 11, 2022, the American Red Cross declared its first-ever national blood crisis amid the surge of the Omicron coronavirus variant across the United States.¹ Since the beginning of the coronavirus pandemic, the Red Cross has seen a 10% decline in the number of people donating blood.² In 2021, the organization experienced a 34% decrease in new donors.³ In a joint statement with America's Blood Centers and the Association for the Advancement of Blood and Biotherapies, the Red Cross warned that "if the nation's blood supply does not stabilize soon, life-saving blood may not be available for some patients when it is needed."⁴

On April 1, 2020, as the coronavirus pandemic began to threaten America's national blood supply, Chairwoman Carolyn B. Maloney and Congresswoman Alexandria Ocasio-Cortez

¹ American Red Cross, *Red Cross Declares First-Ever Blood Crisis Amid Omicron Surge* (Jan. 11, 2022) (online at www.redcross.org/about-us/news-and-events/press-release/2022/blood-donors-needed-now-as-omicron-intensifies.html).

² *Id.*

³ *Red Cross Declares First-Ever National Blood Crisis*, CBS News (Jan. 11, 2022) (online at www.cbsnews.com/news/red-cross-blood-crises-united-states-covid-19/).

⁴ American Red Cross, America's Blood Centers, Association for the Advancement of Blood and Biotherapies, *Joint Statement: Blood Donors Urgently Needed During National Blood Donor Month and Throughout the Winter* (Jan. 10, 2022) (online at www.redcross.org/about-us/news-and-events/press-release/2022/joint-statement-blood-donors-urgently-needed.html).

wrote to then-Commissioner Dr. Stephen Hahn requesting that FDA immediately revise the year-long blanket deferral policy preventing gay and bisexual men from donating blood.⁵ Following their letter, FDA shortened the blanket deferral period from one year to three months.⁶

While FDA's 2020 revision was a step in the right direction, the three-month deferral period continues to prevent gay and bisexual men from safely donating blood. Since FDA last updated its blood donation recommendations, other countries have moved in the direction of individual risk-based assessment for potential donors. For example, in June 2021, England, Scotland, and Wales implemented an individual risk-based questionnaire that facilitates safe blood donations by sexually active gay and bisexual men.⁷

With the addition of an individualized risk-based assessment, the deferral period for all donors in the United States—including MSM—could potentially be eliminated. 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.⁸

In light of the urgent crisis facing America's blood supply, we urge FDA to take immediate action to reassess the existing three-month blanket deferral period for gay and bisexual men so that every person who can safely donate blood in the United States has the opportunity to do so.

We also request that FDA provide our staff with a briefing regarding its current blood donation policy, any plans to revise this policy, and FDA's efforts to ensure an adequate national blood supply amid the current public health crisis.

Thank you for your immediate attention to this matter.

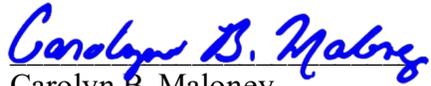
⁵ Letter from Chairwoman Carolyn B. Maloney, Committee on Oversight and Reform, and Rep. Alexandria Ocasio-Cortez to The Honorable Dr. Stephen M. Hahn, Commissioner, Food and Drug Administration (Apr. 1, 2020) (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/documents/2020-04-01.CBM%20AOC%20to%20Hahn-%20FDA%20re%20Blood%20Ban.pdf>).

⁶ 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).

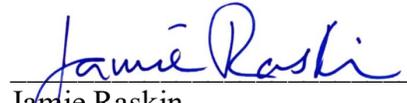
⁷ *Gay and Bisexual Men Are Now Allowed to Donate Blood in England, Scotland and Wales*, National Public Radio (June 16, 2021) (online at www.npr.org/2021/06/16/1007006637/gay-and-bisexual-men-are-now-allowed-to-donate-blood-in-england-scotland-and-wal).

⁸ 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).

Sincerely,



Carolyn B. Maloney
Chairwoman
Committee on Oversight and Reform



Jamie Raskin
Chairman
Subcommittee on Civil Rights and
Civil Liberties



Alexandria Ocasio-Cortez
Member of Congress



Katie Porter
Member of Congress

cc: The Honorable James Comer, Ranking Member
Committee on Oversight and Reform

The Honorable Nancy Mace, Ranking Member
Subcommittee on Civil Rights and Civil Liberties