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. Since the beginning of the coronavirus pandemic, the Red Cross has seen a 10% decline in the number of people donating blood. In 2021, the organization experienced a 34% decrease in new donors. 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.”

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

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2 Id.


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

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.

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.

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.

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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  Jamie Raskin
Chairwoman  Chairman
Committee on Oversight and Reform  Subcommittee on Civil Rights and Civil Liberties

Alexandria Ocasio-Cortez  Katie Porter
Member of Congress  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