

United States Senate  
WASHINGTON, DC 20510

January 13, 2022

The Honorable Xavier Becerra  
Secretary  
Department of Health and Human Services  
200 Independence Avenue SW  
Washington, DC 20201

The Honorable Janet Woodcock, MD  
Acting Commissioner  
Food and Drug Administration  
10903 New Hampshire Ave  
Silver Spring, MD 20993

Dear Secretary Becerra and Acting Commissioner Woodcock,

We write to express our alarm at the nationwide shortage of blood and blood products, which has placed patient care and safety at risk. For the first time, the nation's leading blood donation organizations, including the Red Cross, have declared a national blood supply crisis due to the continued impact of the COVID-19 pandemic. We urge the Food and Drug Administration (FDA) to quickly act on the best available science and update its outdated and discriminatory blood donor deferral policies for men who have sex with men (MSM), a long overdue step that would dramatically increase the eligible donor base.

It is critical that all patients have access to the health care services they need during this pandemic, and for many, the availability of blood and blood products is a necessary component of care. Unfortunately, a significant drop in the number of donations during the COVID-19 pandemic has resulted in a serious shortage of available blood. The Red Cross, America's Blood Centers, and AABB, formerly the American Association of Blood Banks, have declared a nationwide blood supply crisis for the first time, as the nation experiences its worst blood shortfall in over a decade.<sup>1</sup> In recent weeks, hospitals have had less than a single day's supply of critical blood products, and these organizations have had to limit distribution to health facilities in need. In fact, the Red Cross has reported that as much as one-quarter of hospital blood needs are not currently being met.<sup>2</sup>

While no single solution can fully solve these challenges, the FDA has the ability to take a simple and science-based step to dramatically increase the donor base and help address this crisis. In fact, the agency responded to our previous correspondence and took an encouraging step in the right direction during the early days of the pandemic, shortening the deferral period for MSM from 12 months down to three months in March of 2020.

However, any policy that continues to categorically single out the LGBTQ+ community is discriminatory and wrong. Given advances in blood screening and safety technology, a time-based policy for gay and bisexual men is not scientifically sound, continues to effectively exclude an entire group of people, and does not meet the urgent demands of the moment. And further, with increased uptake of Pre-Exposure Prophylaxis (PrEP), which significantly reduces the likelihood that an HIV-negative individual will acquire HIV, many more gay and bisexual men are aware of their HIV status and are taking steps to eliminate their personal risk. Instead of the current categorical deferral guidelines, we must adopt

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<sup>1</sup> <https://www.cbsnews.com/news/red-cross-blood-crises-united-states-covid-19/?intcid=CNI-00-10aaa3b>

<sup>2</sup> <https://www.redcross.org/about-us/news-and-events/press-release/2022/joint-statement-blood-donors-urgently-needed.html>

evidence-based policies focused on assessment of an individual's risk, not inaccurate and antiquated stereotypes.

All over the world, other countries have led on this issue by scrapping their discriminatory blood donation policies. In October of last year, Israel removed all restrictions on MSM blood donation.<sup>3</sup> And just last month, Canada's blood regulatory agency proposed removing all screening questions focused on gender and sexuality.<sup>4</sup> The tide is turning, and the data support this change.

In light of the nation's urgent blood supply crisis and to ensure that Americans have access to life-saving blood transfusions during the pandemic, we urge you to swiftly update your current blood donor deferral policies in favor of ones that are grounded in science, based on individualized risk factors, and allow all potentially eligible donors to do so free of stigma. We also request a briefing in the next 30 days on the agency's plan to update its MSM blood donation policies.

Thank you for your attention to this important issue.

Sincerely,

/s/ Tammy Baldwin  
Tammy Baldwin  
United States Senator

/s/ Elizabeth Warren  
Elizabeth Warren  
United States Senator

/s/ Edward J. Markey  
Edward J. Markey  
United States Senator

/s/ Robert P. Casey, Jr.  
Robert P. Casey, Jr.  
United States Senator

/s/ Tammy Duckworth  
Tammy Duckworth  
United States Senator

/s/ Richard Blumenthal  
Richard Blumenthal  
United States Senator

/s/ Sherrod Brown  
Sherrod Brown  
United States Senator

/s/ Cory A. Booker  
Cory A. Booker  
United States Senator

/s/ Bernard Sanders  
Bernard Sanders  
United States Senator

/s/ Christopher A. Coons  
Christopher A. Coons  
United States Senator

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<sup>3</sup> <https://www.timesofisrael.com/health-minister-announces-removal-of-all-blood-donation-restrictions-for-gay-men/>

<sup>4</sup> <https://www.cbc.ca/news/health/blood-service-recommends-ending-gay-blood-donation-ban-1.6286895>

/s/ Mazie K. Hirono  
Mazie K. Hirono  
United States Senator

/s/ Maria Cantwell  
Maria Cantwell  
United States Senator

/s/ Angus S. King, Jr.  
Angus S. King, Jr.  
United States Senator

/s/ Michael F. Bennet  
Michael F. Bennet  
United States Senator

/s/ Catherine Cortez Masto  
Catherine Cortez Masto  
United States Senator

/s/ Patrick Leahy  
Patrick Leahy  
United States Senator

/s/ Amy Klobuchar  
Amy Klobuchar  
United States Senator

/s/ Ron Wyden  
Ron Wyden  
United States Senator

/s/ Jeffrey A. Merkley  
Jeffrey A. Merkley  
United States Senator

/s/ Tina Smith  
Tina Smith  
United States Senator

/s/ Martin Heinrich  
Martin Heinrich  
United States Senator

/s/ Alex Padilla  
Alex Padilla  
United States Senator