

United States Senate
WASHINGTON, DC 20510

March 26, 2020

The Honorable Stephen M. Hahn, M.D.
Commissioner
United States Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

Dear Commissioner Hahn,

We write to express our concern with the Food and Drug Administration's (FDA) discriminatory blood donor deferral policy for men who have sex with men (MSM), particularly in the midst of a nationwide shortage of donated blood and blood products spurred by the COVID-19 pandemic. We must take every possible step to secure our nation's blood supply in this critical time, and in order to do so, we need to shift away from antiquated and stigmatizing donation policies to ones that are scientifically sound, based on individual risk, and inclusive of all potential healthy blood donors.

It is vital that all Americans have access to the health care services they need during this outbreak, and for many individuals, including accident and trauma victims, organ transplant recipients and cancer patients, blood transfusions remain a necessary component of care.¹ Unfortunately, our nation's blood supply has been severely constrained due to a decline in healthy donations. In fact, AABB, formerly known as the American Association of Blood Banks, has predicted 355,000 fewer blood donations as a result of the COVID-19 outbreak.²

During this crisis, Surgeon General Dr. Jerome Adams,³ Department of Health and Human Services (HHS) Assistant Secretary for Health Dr. Brett Giroir, and Dr. Peter Marks, head of the FDA's Center for Biologics Evaluation and Research (CBER), which oversees the safety of blood and blood products in the United States, have all expressed that blood donation for healthy individuals remains safe and is much needed.⁴ But while government health officials encourage every healthy individual to consider donating blood, the FDA continues to enforce a discriminatory donor deferral policy that effectively prohibits many healthy gay and bisexual men from doing so.

¹ <http://www.aabb.org/tm/Pages/bloodfaq.aspx#a2>

² <https://www.pbs.org/newshour/health/blood-donors-urgently-needed-to-avert-shortage-amid-outbreak>

³ https://www.cnn.com/world/live-news/coronavirus-outbreak-03-18-20-intl-hnk/h_b30dc266788f170714308fb4bda828fa

⁴ <https://www.redcross.org/about-us/news-and-events/press-release/2020/we-need-people-to-start-turning-out-in-force-to-give-blood.html>

We are steadfastly committed to ending this policy and encourage the FDA to shift to scientific practices that secure our nation's blood supply based on individual risk rather than the perpetuation of inaccurate stereotypes. We have written to your agency on this subject in the past and have appreciated the FDA's willingness to engage in discussions and make changes to the MSM deferral policy. In 2015, the agency took the important step of moving from a lifetime ban to a one-year deferral policy after last sexual contact.

However, with important advances in blood screening and safety technology, a time-based deferral policy is not scientifically sound, continues to effectively exclude many healthy gay and bisexual men, and does not meet the urgent demands of the moment.⁵ Further, with the increased uptake of Pre-Exposure Prophylaxis (PrEP), which reduces the likelihood that an HIV-negative individual will acquire HIV, many more gay and bisexual men are aware of their HIV-negative status and are taking steps to effectively eliminate their personal risk of HIV transmission.⁶ As such, it is imperative that we move away from discriminatory donor deferral policies that prohibit many healthy individuals from contributing much-needed blood and blood products.

In light of this shortage, we urge you to swiftly update blood donor deferral policies in favor of ones that are grounded in science, are based on individual risk factors, do not unfairly single out one group of individuals, and allow all healthy Americans to donate. We strongly encourage you to consider this critical solution as you work to develop a comprehensive response to the COVID-19 outbreak and ensure that Americans have access to life-saving blood transfusions.

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

/s/ Sherrod Brown
Sherrod Brown
United States Senator

⁵ <https://www.redcross.org/about-us/news-and-events/press-release/american-red-cross-statement-on-fda-msm-deferral-policy.html>

⁶ <https://www.cdc.gov/nchhstp/newsroom/docs/factsheets/cdc-msm-508.pdf>

/s/ Richard Blumenthal
Richard Blumenthal
United States Senator

/s/ Bernard Sanders
Bernard Sanders
United States Senator

/s/ Kamala D. Harris
Kamala D. Harris
United States Senator

/s/ Chris Van Hollen
Chris Van Hollen
United States Senator

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

/s/ Maria Cantwell
Maria Cantwell
United States Senator

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

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

/s/ Ron Wyden
Ron Wyden
United States Senator

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

/s/ Tammy Duckworth
Tammy Duckworth
United States Senator

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

/s/ Amy Klobuchar
Amy Klobuchar
United States Senator