

United States Senate
WASHINGTON, DC 20510

June 24, 2022

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

The Honorable Robert Califf, MD
Commissioner
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

Dear Secretary Becerra and Commissioner Califf,

We write to request an update on the Food and Drug Administration's (FDA) progress in modernizing its outdated and discriminatory blood donor deferral policies for men who have sex with men (MSM), a long overdue step that would dramatically increase the eligible donor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. We applaud the agency's responsiveness to our concerns in the early days of the pandemic when FDA shortened the deferral period for MSM from 12 months down to three months, however, given the ongoing nationwide shortage of blood and blood products, it is critical that FDA take further action. For nearly 40 years, sexually active MSM have not been allowed to donate blood. This must change.

On March 26, 2020, a group of Senators wrote to the FDA raising concerns with the agency's discriminatory blood donation deferral policy for men who have sex with men. Soon after, this policy was updated, and FDA shortened the deferral period. However, additional steps are needed to advance science and combat discrimination. We appreciate FDA's work on the Assessing Donor Variability And New Concepts in Eligibility (ADVANCE) study, which is focused on evaluating alternatives to the blood donor deferral policy for MSM. While no single action can fully address longstanding discrimination, we believe this study will serve as an important first step in making sure that any future donor policy is grounded in science. 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 from the donor base, 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.

It is time for the FDA to adopt evidence-based policies focused on assessment of an individual's risk, not inaccurate and antiquated stereotypes present in the current categorical deferral guidelines. With this shift, there will be a significant need for public outreach and education. As we look towards the completion of the ADVANCE study, we urge FDA to develop a strategic plan in concert with representatives of the LGBTQ+ community that will inform the public of its updated guidelines. Further, we strongly encourage the agency to prioritize outreach and

education to blood donation centers to expedite implementation of revisions to the blood donation guidelines.

In the midst of the ongoing blood shortage, it is absolutely essential for FDA to take steps to increase the availability of blood and blood products to prioritize patient care. Following the conclusion of the ADVANCE study, we expect that FDA will utilize this new evidence to work expeditiously and develop an evidence-informed policy based on individualized risk factors that meets the urgent demands of the moment.

The United States remains in a nationwide blood supply crisis for the first time. Now is the time for a new donor deferral policy that allows all potentially eligible donors to contribute free of stigma. Thank you for your attention to this important issue.

Sincerely,



Tammy Baldwin
United States Senator



Kirsten Gillibrand
United States Senator



Elizabeth Warren
United States Senator



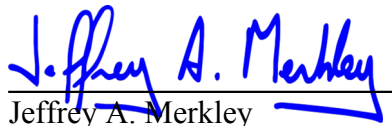
Bernard Sanders
United States Senator

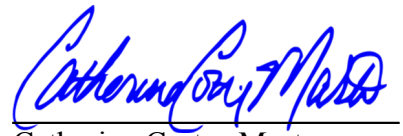



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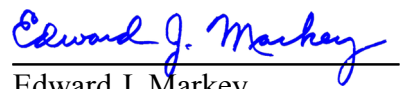

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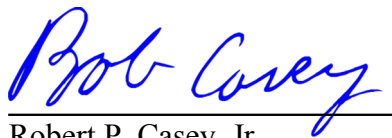

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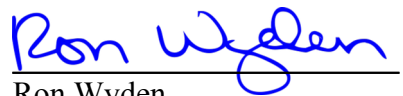

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United States Senator

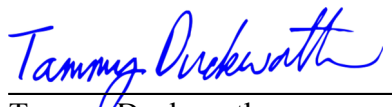

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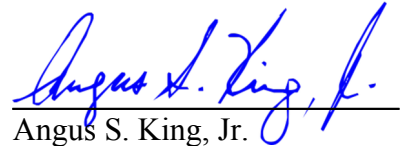

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Jacky Rosen
United States Senator



Tina Smith
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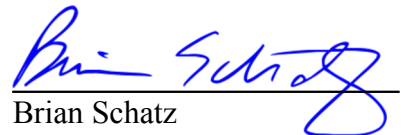
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