United States Senate
WASHINGTON, DC 20510

March 23, 2023

The Honorable Robert M. Califf, MD
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Califf,

We write to express strong support for the Food and Drug Administration's (FDA) recent proposal to assess blood donor eligibility using gender-inclusive, individual risk-based questions. This important change marks a critical step forward in removing discriminatory blood donor deferral policies for gay, bisexual, and other men who have sex with men (MSM), and will help ensure that those who need blood can get it. We encourage the agency to take thoughtful steps to promote responsible implementation of this policy, and continue to work with Congress to support scientific advancements that will further promote the safety of the blood supply.

On January 27, 2023, the FDA announced that it was proposing a change to eliminate time-based deferrals that had previously existed for MSM and women who have sex with MSM, marking an important shift to ensure that blood donation policy is better rooted in the most up-to-date science with a focus on individual risk factors, not outdated stigmas that effectively ban gay and bisexual men. This proposal, which is aligned with existing policies in countries like Canada and the United Kingdom, was based in part on the Assessing Donor Variability And New Concepts in Eligibility (ADVANCE) study, which focused on evaluating alternatives to the blood donor deferral policy for MSM at the FDA. We support the agency's careful review of the available data, and applaud this scientific advancement. Moving forward, we recommend that FDA continue studying how to improve existing blood donation policies to advance a safe and adequate supply of blood, while working to reduce stigma and increase transparency. Further, we encourage FDA to work closely with Congress to promote additional investments and scientific innovation in blood screening and safety technology. Now more than ever, we must support the development and adoption of technology that allow us to detect and respond to blood borne pathogens, and we look forward to collaborating with you on these efforts.

This proposal, and the scientific advancements it entails, must also be effectively communicated to the public and implemented in a thoughtful manner. FDA must work closely with the nation's blood collection establishments to ensure that they have the resources necessary to update their intake processes and adopt the new assessment tools. Blood collection establishments must also be educated and trained regarding these critical updates, and the agency must be cognizant of the need for gender inclusive language throughout. It is crucial that changes be closely monitored by the FDA, and that there be a structure in place for any necessary trouble-shooting as this policy is implemented. Finally, given that blood donation deferrals will remain in effect for people who rely on pre-exposure prophylaxis, or PrEP, FDA should strongly consider working closely with

members of the LGBTQ+ community to effectively convey the importance of PrEP and the scientific basis for this deferral. It is essential that those currently taking PrEP continue to receive treatment, and we stand ready to support FDA's efforts to track the latest data relevant to PrEP and blood donation.

For almost 40 years, most gay and bisexual men have been banned from donating blood. Over the past three years, we have made tremendous progress towards removing this ban, thanks in large part to the countless advocates who, even in the face of adversity, made sure we centered science and fought for the LGBTQ+ community. We encourage FDA to finalize its proposal to assess blood donor eligibility based on an individual risk assessment.

Sincerely,

Tammy Baldwin
United States Senator

Jeffrey A. Merkley
United States Senator

Sherrod Brown
United States Senator

Cory A. Booker
United States Senator

Robert P. Casey, Jr.
United States Senator

Richard Blumenthal
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Elizabeth Warren
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Peter Welch
United States Senator

Benjamin L. Cardin
United States Senator

Bernard Sanders
United States Senator

Maria Cantwell
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Ron Wyden
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United States Senator

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United States Senator

Michael F. Bennet
United States Senator

Tammy Duckworth
United States Senator

Tina Smith
United States Senator

United States Senate
WASHINGTON, DC 20510

Mazie K. Hirono
United States Senator

John Fetterman
United States Senator

Alex Padilla
United States Senator

Martin Heinrich
United States Senator

Robert Menendez
United States Senator