



STATE OF NORTH CAROLINA
DEPARTMENT OF HEALTH AND HUMAN SERVICES

ROY COOPER
GOVERNOR

KODY H. KINSLEY
SECRETARY

March 10, 2022

Robert Califf
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

FOR ELECTRONIC DELIVERY

Dear Commissioner Califf,

First, congratulations on your confirmation to serve once again as Commissioner of the FDA.

We write to express our concern for the nationwide shortage of blood and blood products, which is exacerbated by a discriminatory federal policy that places patient care and safety at risk. We join others, including the [American Medical Association](#), in urging the Food and Drug Administration (FDA) to remove its 90-day blood donor deferral policy for men who have sex with other men. This policy effectively bans gay and bisexual individuals from blood donation.

In the 40 years since the start of the U.S. HIV epidemic, there have been incredible advancements in both the development of highly sensitive HIV diagnostic platforms and our scientific understanding of HIV transmission. The FDA requires that all blood donations undergo nucleic acid testing for HIV, a test which can detect HIV within two weeks following infection. Consequently, the risk of HIV-infected blood entering donation pools is negligible. This diagnostic screening should be paired with an individual risk-based assessment based on our robust knowledge of how HIV is transmitted, and not discriminatorily applied to an entire group of individuals.

Other countries have led the way. Spain, Italy, England, Israel, and starting next week, France, have updated their blood donation processes to include individuals from the gay and bisexual community. Meanwhile the U.S. lags, clinging to a policy created in 1983.

There is no credible evidence that the 90-day MSM blood donation deferral period improves the safety of the nation's blood donation supply. And therefore, the continuation of this policy serves only to further stigmatize an already marginalized demographic group and unnecessarily restricts the eligible donor population during a time of extraordinary need in the US. The current policy is ineffective, unnecessary, and discriminatory.

Sincerely,

Kody H. Kinsley
Secretary
N.C. Department of Health and Human Services

Dr. Elizabeth Cuervo Tilson
State Health Director
N.C. Department of Health and Human Services

The undersigned join North Carolina in this request:

Mark Ghaly, MD, MPH
Secretary
California Health and Human Services Agency

Manisha Juthani, MD
Commissioner
Connecticut Department of Public Health

LaQuandra S. Nesbitt, MD, MPH
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