

Congress of the United States
Washington, DC 20515

June 10, 2021

Dr. Janet Woodcock, M.D.
Commissioner of Food and Drugs, Acting
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Dear Dr. Woodcock:

As we approach the five-year commemoration of the mass shooting at Pulse Nightclub in Orlando, Florida, we write to you in strong support of the Assessing Donor Variability and New Concepts in Eligibility (ADVANCE) Study.^[1] We believe this study will provide the data necessary for the Food and Drug Administration (FDA) to finally end the discriminatory blood donation deferral policy for men who have sex with men (MSM).

On June 12, 2016, 49 innocent men and women were murdered in a place of refuge for many in the LGBTQ+ and Latino communities, Pulse Nightclub. Through the grief and pain, thousands rallied to support the victims and survivors including blood donation. However, many gay and bisexual men were prohibited from donating desperately needed blood, compounding pain across the community.

For these reasons, we applaud the FDA's decision to launch a pilot study that will utilize an individual blood donation questionnaire to assess risk factors that could indicate possible infection with a transfusion transmissible infection, including HIV.

We appreciate that the FDA has been willing to engage in discussions specific to the MSM deferral policy and revise guidance following Pulse, which included modifying the blanket ban to 12-months and again to 3-months deferral periods. These are steps in the right direction, but ultimately reductions in the ban should not be tied specifically to sexual orientation or disaster-based supply issues. An individual's personal risk profile, regardless of sexual orientation and based on scientific and technological progress, should guide the policy.

Standard blood products donation organization practices include blood pool sample testing along with a donor screening questionnaire. Already, many countries including Argentina, Colombia, Italy, Mexico, Spain, and the United Kingdom as well as the European Union and World Health Organizations have adopted or recommended risk-based questionnaires over a universal ban based on sexual orientation.^{[2][3]}

Although the COVID-19 public health emergency has strained resources across federal, state, and local governments, we believe that the FDA's continued robust support for the ADVANCE Study is of significant interest to health security.

References

1. <https://advancestudy.org>
2. <https://www.nbcnews.com/feature/nbc-out/fda-considers-lifting-restrictions-blood-donations-gay-bi-men-n1252424>
3. https://apps.who.int/iris/bitstream/handle/10665/76724/9789241548519_eng.pdf

We appreciate your attention to this urgent matter and urge you to continue the FDA's support for the ADVANCE Study through its anticipated completion this year.

Sincerely,



Val B. Demings
Member of Congress




Mike Quigley
Member of Congress



Carolyn B. Maloney
Member of Congress



Adam B. Schiff
Member of Congress



Barbara Lee
Member of Congress



Ritchie Torres
Member of Congress