March 29, 2023

Submitted via www.regulations.gov[1]

Center for Biologics Evaluation and Research
ATTN: FDA-2015-D-1211-0152
Food and Drug Administration
Dept. of Health and Human Services
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: DOCKET ID FDA-2015-D-1211-0152, Recommendations for Evaluating Donor Eligibility Using Individual Risk-Based Questions to Reduce the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products

I am writing on behalf of Equitas Health, which is headquartered in Columbus, Ohio, to express comments and concerns with the rule proposed by the Food and Drug Administration (FDA) in regard to 1) blood donor eligibility and 2) the use of risk-based questions to reduce the risk of HIV transmission by blood and blood products. As such, Equitas Health is pleased to submit these comments in response to the Food and Drug Administration's (FDA or Agency's) Draft Guidance for Industry on Revised Recommendations for Evaluating Donor Eligibility Using Individual Risk-Based Questions to Reduce the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products.

Equitas Health is a federally designated community health center and one of the largest LGBTQ+ and HIV/AIDS serving healthcare organizations in the country. Each year, we serve tens of thousands of patients in Ohio, Texas, Kentucky, and West Virginia, and since 1984, we have been working to advance "care for all." Our mission is to be the gateway to good health for those at risk of or affected by HIV; for the lesbian, gay, bisexual, transgender, and queer/questioning (LGBTQ+) community; and for those seeking a welcoming healthcare home. In doing so, we offer primary and specialized medical care, pharmacy services, dentistry, mental health and recovery services, HIV/STI prevention and treatment services, Ryan White HIV case management, overall care navigation, and a number of community health initiatives.[2] Regarding this public comment, the non-discriminatory and evidence-based implementation of a blood donor eligibility rule is deeply important to our agency, our patients, and our broader community.

[1] Document prepared by Rhea Debussy, Ph.D. (she/her), Director of External Affairs with assistance from CenterLink: The Community of LGBTQ Centers. Document reviewed by Sam Brinker (he/him), General Counsel; Adrianna Udinwe (she/her), Associate General Counsel; and Sarah Green (they/she), Administrative Assistant – Advancement.
[2] https://equitashealth.com/about-us/

Recommendation 1: We strongly encourage the FDA to issue a non-discriminatory and evidence-based Final Guidance in relation to blood donor regulations this year.

We applaud the recently considered, evidence-based revisiting of the current blood donation deferral guidance, which unfairly discriminates against many members of the LGBTQ+ community in its current form. As you are aware, the FDA – in the early days of the HIV/AIDS epidemic – implemented a categorical ban on blood donations from men who have sex with men (MSM), which included gay, bisexual, queer, pansexual, questioning men and others. Additionally, this ban originally – by way of misgendering people – also actively impacted transgender women, trans-feminine people, and other gender expansive people who were assigned male at birth (AMAB).[3]

Beginning with the critiques of the AIDS Coalition to Unleash Power! (ACT UP!) in the 1980s and early 1990s, the broader LGBTQ+ community has widely viewed this ban as discriminatory in nature.[4] This is especially true, given the ongoing advancements for HIV prevention (i.e. pre-exposure prophylaxis or PrEP,[5] post-exposure prophylaxis or PEP,[6] and more[7]) and treatment (anti-retroviral therapy or ART[8]) efforts. As such, the LGBTQ+ community has been advocating for a more evidence-based approach, particularly given the high efficacy of PrEP, PEP, and ART. While there have been some positive changes to this guidance in the past decade,[9] the newly proposed guidelines, if implemented, would certainly expand the pool of eligible donors. This would ultimately strengthen our national blood supply, and there are many elements of this proposal that we support, while there are also areas that should be significantly improved upon.

We strongly support the newly proposed gender-neutral and behaviorally focused approach to evaluating the HIV risk of donors. In particular, the focus on the well-documented role that 1) new or multiple sexual partners and 2) anal sex have in assessing potential HIV transmission risk – in regards to the ability of current tests to yield reliable results – are important. And of course, this approach is certainly more favorable than an outright ban, which is the current guidance from the FDA. Given this, we applaud the removal of the previous time-based restrictions for men who have sex with men (MSM), which would include gay, bisexual, queer, pansexual, questioning men and others. And of course, many people who have previously been universally barred from donating blood will review the new guidance and welcome the opportunity to potentially donate blood. Given this reality, we strongly recommend the creation of and universal set of standard and culturally humble questions to determine if they can donate blood and blood products.

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[3] https://www.gmhc.org/gay-blood-ban/

[4] Gould, Deborah. 2009. *Moving Politics: Emotion and ACT UP's Fight Against AIDS.* Chicago: University of Chicago Press. *See also* Shilts, Randy. 1987. *And The Band Played On: Politics, People, and the AIDS Epidemic.* New York: ST. Martin's Press. & France, David. 2016. *How to Survive a Plague: The Story of How Activists and Scientists Tamed AIDS.* New York: Vintage Books.

[5] https://www.cdc.gov/hiv/basics/prep.html

[6] https://www.cdc.gov/hiv/risk/pep/index.html

[7] https://www.sfaf.org/resource-library/u-equals-u/

[8] https://www.cdc.gov/hiv/risk/art/index.html

[9] https://transequality.org/blog/fda-to-maintain-discriminatory-blood-ban-impact-on-trans-people-still-unclear; see also https://www.npr.org/sections/health-shots/2015/12/21/460580469/fda-lifts-ban-on-blood-donations-by-gay-and-bisexual-men

If made final, this revised guidance will expand the pool of eligible blood donors, and it will begin to correct a decades-long set of deferral policies that are not consistent with current evidence-based practices and science. More specifically, a 2014 report from the Williams Institute – a program at UCLA School of Law – found that by the FDA lifting donor bans for men who have sex with men (MSM) – which includes gay, bisexual, queer, pansexual, questioning men and others – the annual blood supply would increase by 2 to 4%, or 345,400 to 615,300 pints of blood annually.[10] Given demographic shifts in the broader LGBTQ+ community in the past decade, we expect those numbers to be even higher.[11]

Recommendation 2: We strongly encourage the FDA to review the administration's blood donor recommendations and deferral processes every 3 years to ensure that such recommendations reflect the current scientific and technological landscape.

Expanding the pool of eligible donors to the national blood supply is especially important given the impact that the COVID-19 pandemic has had on the national blood supply. Because of this impact from the COVID-19 pandemic, it is even more crucial that the FDA continue to review re-assess blood donor recommendations and deferral processes on a regular basis, and as noted above, we strongly recommend such re-assessment and review every 3 years. Given the continued impact of the COVID-19 pandemic on the national blood supply during the past 3 years, we strongly encourage this triennial review; this will help to ensure that the FDA's deferral processes are not turning away individuals, who would otherwise be able to donate blood or blood products.

As noted by the Mayo Clinic in March 2020, the COVID-19 pandemic had nearly immediate impacts on the national blood supply.[12] And as you may recall, the Red Cross, in January 2022, declared the first ever national blood supply crisis in the midst of the COVID-19 omicron surge.[13] At the time of this writing, there are roughly 150,000 active cases of COVID-19 and nearly 15,000 COVID-19-realted current hospitalizations in the country. Additionally, there have been nearly 104,000,000 total cases and over 1,100,000 total deaths in the country.[14] Given this information, the expansion of eligible donors – and the continued re-assessment and review of the FDA's blood donor recommendations and deferral processes on a regular basis – is crucial to providing necessary support to the national blood supply.

Recommendation 3 and 4: We strongly recommend the FDA to encourage more research on the interactions of PrEP, PEP, and ART in relation to HIV RNA detection. Further, we also strongly recommend the FDA to communicate clear, concise, and culturally humble information about the reasons for the on-going PrEP/PEP deferral in the currently proposed guidance.

In light of both 1) the minimal but present risk of breakthrough HIV infections and 2) the potential impact of the viral suppressive action of medications like PrEP, PEP, and ART on the ability of current testing technologies to reliably detect these infections, we understand the reasoning for deferral of

[10] https://williamsinstitute.law.ucla.edu/publications/blood-donation-ban-msm/
[11] https://news.gallup.com/poll/389792/lgbt-identification-ticks-up.aspx
[12] https://newsnetwork.mayoclinic.org/discussion/critical-blood-shortages-because-of-covid-19/
[13] https://www.redcross.org/about-us/news-and-events/press-release/2022/blood-donors-needed-now-as-omicron-intensifies.html
[14] https://covid.cdc.gov/covid-data-tracker/#datatracker-home

individuals taking PrEP, PEP, and ART. However, we adamantly encourage more research on the interaction of medications related to PrEP, PEP, and ART in relation to HIV RNA detection, so that this deferral can be immediately removed following the continued advancement of HIV detection technologies.

Similarly, we strongly urge the FDA – in coordination with the CDC and state/local public health authorities – to clearly, concisely, and publicly message the reasons for the PrEP, PEP, and ART deferral in this proposed rule. Communicating this information with accuracy and cultural humility is important to help reduce stigma against people living with HIV, in addition to PrEP/PEP users. And as such, this will help to strengthen public health interventions to reduce the number of new HIV infections annually, while also bolstering evidence-based conversations about safer sex practices and HIV prevention/treatment options. As inferred above, limiting and deferring people, who are being proactive in supporting their sexual health, leads to further stigmatization of both them and their communities. And of course, such misconceptions perpetuate the myth that PrEP/PEP users are promiscuous and/or have a higher risk of HIV infection, and as we know, such presumptions are plainly and categorically false.

As noted by the CDC and numerous studies over the past 20 years, PrEP has proven to effectively prevent HIV infection by 99% after 7 days of daily usage.[15] Therefore, the prohibition for blood donors who take PrEP is misguided, as the daily use of PrEP after 7 days is more effective in protecting blood products than from donors who are not taking PrEP regardless of sexuality. Similarly, the CDC notes that PEP, when taken within 72 hours of possible exposure to HIV, is highly effective.[16] Using similar logic as noted with the discussion of PrEP above, the prohibition of blood donors who take PEP is similarly misguided, given the high efficacy of this medical intervention in the prevention of a new HIV infection.

Recommendation 5: We strongly recommend the FDA to continue consulting with LGBTQ+ and HIV/AIDS focused community health centers and advocacy organizations when releasing proposed adjustments to blood donor regulations.

The recommendations above – including our final recommendation of consulting with LGBTQ+ and HIV/AIDS focused community health centers and advocacy organizations – are vital to the successful creation and implementation of a non-discriminatory and evidence-based policy on blood donor eligibility rules and related policies. As noted throughout this comment, the FDA must actively consult such organizations to ensure that these rules and related policies are informed by science not stigma. Such a goal requires the active assistance of LGBTQ+ and HIV/AIDS focused community health centers and advocacy organizations, given the decades-long discrimination that the broader LGBTQ+ community has faced from the FDA.

And to be clear, the FDA should be a leader – not a follower – in the international community, in regard to blood donor eligibility rules and related policies. However, it should be noted that such leadership requires a culturally humble, consistent, proactive, and community-invested review of agency recommendations for blood donor eligibility rules and related policies.

[15] Ibid *supra note* 4.
[16] Ibid *supra note* 5.

Concluding Remarks: To conclude, we strongly recommend that the FDA do the following:

1) To issue a non-discriminatory and evidence-based Final Guidance in relation to blood donor regulations this year, which will begin to correct the administration's decades-long discrimination against LGBTQ+ blood donors;

2) To review the administration's blood donor recommendations and deferral processes every 3 years to ensure that such recommendations reflect the current scientific and technological landscape, which will help to ensure that the rule accurately reflects our scientific reality;

3) To encourage more research on the interactions of PrEP, PEP, and ART in relation to HIV RNA detection, which will help to ensure that blood donation and deferral recommendations continue to be informed by science not stigma;

4) To communicate clear, concise, and culturally humble information about the reasons for the on-going PrEP/PEP deferral in the currently proposed guidance, which will help to decrease stigma against people living with HIV and PrEP/PEP users; and

5) To continue consulting with LGBTQ+ and HIV/AIDS focused community health centers and advocacy organizations when releasing proposed adjustments to blood donor regulations, which will help to ensure that proposed revisions to the administration's rules are crafted with culturally humility and community input.

Equitas Health would like to thank you for this opportunity to present comments on the proposed rule. And again, we are encouraged and supportive of these important updates to the FDA recommendations, and we are confident that these changes will increase the number of eligible blood donors, help to destigmatize LGBTQ+ individuals, and provide greater support to the availability of a safe national blood supply. Should you have any questions about our comments, please feel free to contact Dr. Rhea Debussy (she/her), Director of External Affairs at Equitas Health.