Evidence for Revision of 5-year MSM Tissue Donation Deferment Policy

Food and Drug Administration- Cellular, Tissue, and Gene Therapies Advisory Committee

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Pride & Plasma

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Contents

Letter

Dear Food and Drug Administration; Cellular, Tissue, and Genetic Therapies Advisory Committee,

Since 1994, the FDA has mandated the rejection of tissue donations from healthy queer men due to the MSM eligibility criteria under the Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) guidance[1]. Although this policy served the purpose of preventing widespread transmission of Human Immunodeficiency Virus through the nation's blood supply at a time when HIV was poorly understood and the methods of testing were both inadequate and potentially inaccurate, the state of HIV and AIDS in the United States is no longer that of the 1990s and the height of the epidemic. Thankfully, with advances in testing, prevention, and treatment, HIV is no longer at the same prevalence as it was 30 years ago. It is past time for the Tissue Donation Deferment Policy to match these changes and end the discriminatory practice of turning away sexually active queer men.

The FDA and other committees within the Center for Biologics Evaluation and Research, like the Blood Products Advisory Committee, have made previous steps towards ensuring equality in blood donation. The most recent revision to Recommendations for Evaluating Donor Eligibility Using Individual Risk-Based Questions to Reduce the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products[3] made headway by transitioning to an individual risk assessment. The stigma associated with biologics donation from LGBTQ+ individuals is not justified or beneficial to the nation's supply.

The FDA licenses nineteen tests for the use of detecting Hepatitis B and/or HIV in cadaveric tissue donors[2]. All nineteen of these tests are dually licensed or intended for the use of screening donors of blood products[2], which saw a removal of the blanket deferment policy for MSM donors on 5/11/2023[3]. If the tests are effective enough to assess for a virus in a living donor, for blood donation, they are effective enough to assess for the virus in a tissue donor. Further, all nineteen of the tests licensed for HIV and Hepatitis B testing in tissue donors received their first letters of approval after the policy's initial implementation in 1994[2]. Fifteen of the tests were approved after the 2004 final rule which expanded the policy to include anonymous sperm donation[2]. Eleven of the tests were approved after the last update in 2007[2]. The science has changed and the policy should as well.

At the time of the guidance's implementation, a lifetime deferment for MSM donors was the policy for blood donation, with the first reduction in deferment criteria taking place 21 years later, in 2015[3]. The sequential reductions to 3-months, and the current individual risk assessment have been implemented with no revisions to the tissue eligibility criteria. In this same time period, other countries have updated their tissue donor eligibility, most recently the United Kingdom- with Wales announcing a transition to an individual risk assessment (the same procedure as their blood donor screening) in September of 2023[86].

Compared to blood, procedures indicated for tissue grafts frequently have the option of synthetic products, both of which have advantages and disadvantages. The option of allographic cadaver tissue is an important option not only for patients who deserve autonomy, but also providers who deserve to practice and treat patients as they see fit.

This policy is also significantly more conservative than the organ donation procedure for MSM donors. The Department of Health and Human Services implements a labeling system for individuals who test negative but have a potential risk for transmittable infections through transplantation[4]. The act of labeling organs from MSM donors as "increased risk" is an option to allow these donations to be procured and once again ensuring that individual autonomy is enforced at all levels- both the donor, and the recipient. This policy was released on June 26, 2020[3]; almost 13 years since the previous update to the tissue eligibility policy.

The document has appeared on the Center for Biologics Evaluation and Research's *Guidance Agenda: Guidance Documents CBER is Planning to Publish During Calendar Year* for 2022[11], 2023[12], and 2024[95]. If the document is up for the first update in 17 years, this is a section worthy of review. With the previous draft agenda in 2024 separating eligibility determinations by infectious agent, we recommend releasing HIV and HBV policies together to ensure uniform criteria on risk factors.

We are not the first to present these arguments, but we hope to be one of the first to address all twelve tissues explicitly regulated by this policy, to show the comprehensive donors who have had their dying wishes taken away by the lack of action by the administration. Unlike with blood donation, tissue donors cannot advocate for themselves in the same way, and most individuals impacted by the policy are unaware of its impact. By the time the policy is applied- it is too late. We ask you to consider the public support and evidence that this discrimination is wrong, outdated, and ineffective at preventing high-risk donations from entering the national supply. The BPAC's guidance released on May 11th, 2023 makes great strides in removing another unjust MSM deferment policy. This policy is

in dire need of a revision- the science of the industry no longer mirrors the practice required by the FDA's guidance.

With the incoming presidential administration, with heightened urgency, we urge the committee and the FDA to consider the evidence and act swiftly to allow the right of tissue donations to individuals of all genders and sexualities. We would greatly appreciate the opportunity to share our work in a collaborative fashion. We thank the committee for their time and look forward to a decision.

Sincerely,

Pride & Plasma

Intended Oral Comment

Pride and Plasma initially requested to speak during the opportunity for public comment at the 11/24/2024 Cellular, Tissue, and Gene Therapies Advisory Committee Meeting- a request which was denied. We've attached the transcript of what would have been shared during the opportunity.

We, Pride and Plasma, and myself, Cole Williams, have no financial interests to disclose.

We understand that the committee did not intend to hear about the MSM tissue donation deferral policy today or at the previous meetings on 10/31/23 and 9/27/23, because of that, we thank you for the opportunity to share our public comment.

Since 1994, thousands of queer men have been denied their dying wishes of donating their tissues. The lack of scientific information of HIV/AIDs due to its novelty, as well as the previous blood donation policy, led the Public Health Service, and subsequently

the FDA to uphold a 5-year deferral. At inception, this policy was more progressive than the lifetime deferral for blood donors, and was synonymous with the organ donation eligibility criteria. Neither of those are the case at present.

With the scientific advancements, research and breakthroughs in the realm of HIV/AIDS, the 5-year deferment is no longer necessary, nor supported by science or other federal government policy. The implementation of Nucleic Acid Testing allows for HIV and Hepatitis B to be detected in a donor significantly sooner than five years, and was not nationally utilized at the time of the policy's creation in 1994.

Every donor is tested, and every donor has the potential to carry HIV and HBV, not just queer men. The current policy defers a queer man in a monogamous relationship, who is tested for STDs regularly, and only has safe sex. At the same time, heterosexual donors can have as many sexual partners as they wish, be unaware of their STD status, and never practice safe sex- but will still be permitted to donate. The policy is ineffective at stopping high-risk donors while simultaneously preventing low-risk donors from giving blood. Screening prior to donation should focus on high-risk activities, not a donor's sexuality. High-risk activities can be changed. Sexuality cannot.

Tissue donation is not seen as critical as organ donation, or even as necessary as blood donation. There are synthetic options for tissue grafts, or patients can elect to pursue xenografts or potentially autografts. These treatments do not exist in the realm of organ transplantation or transfusion medicine. However, tissue donations can ensure not only patient autonomy and choice, but access to treatments with reduced wait times. Ensuring a quality of life for a patient is still critical. As a registered nurse, I can testify to that.

The tissue eligibility criteria has not followed federal updates, or even FDA updates. The organ donation eligibility criteria was updated in 2013 to reduce the 5-year deferral to 12-months, and reduced again in 2020 to a 30-day period, at the recommendation of the CDC. The blood donation eligibility criteria was updated in 2015 to a 12-month deferral, a 3-month deferral in 2020, and an individual risk assessment in 2023. The CTGTAC should follow these policies and update the guidance and deferral criteria. The document has appeared on the Center for Biologics Evaluation and Research's *Guidance Agenda: Guidance Documents CBER is Planning to Publish During Calendar Year* for at least the past three years. If the document is up for the first update in 17 years, this is a section worthy of review.

The FDA has updated and approved many testing methods throughout the past 30 years, with a large number of new methods approved since the last update to the eligibility criteria. If there are improvements in infection detection, why has there not been a similar reduction in deferment out of the necessity for window periods?

Similar to how FDA blood donor policy followed similar updates in the United Kingdom and Canada (which were cited in the 5/11/2023 final guidance), the tissue donor policy should also follow the policy revisions from other countries. Significantly, the UK update from September 2023[86], which acknowledged that the risk of blood donation transmission and screening procedures could be applied to tissue donor screening.

Not all sexual contact carries the same risk. Oral sex does not carry the same risk as anal sex. However, the policy does not define what "sex" is criteria for deferment. Those in monogamous, long-term relationships are at a different risk than those who have multiple partners. The policy makes no exceptions for those at higher risk. The policy does not go far enough to identify and defer high-risk donors, and turns away healthy donors at the

same time. Although an end to the MSM deferral will not address all shortages, it will ensure healthy donors to replace high-risk donors that facilities are currently utilizing to meet demands.

This policy has turned away the donations from queer men for three decades. Those impacted by these policies cannot advocate for themselves, it is too late. We are here on their behalf, and the thousands more queer men who will continue to be labeled as “high-risk” for their sexuality until this policy is revised, removed, and an update is implemented.

If not in the interest of queer men who are being discriminated against, consider the patients who are having procedures delayed, tissue banks who are unable to meet the demands of their communities, and the medical facilities that are limited in caring for patients. If there is a more effective way to advocate for this change, we welcome it. We want to utilize both the committee and our team’s time in the most effective way possible.

Evidence

Literature Review

Minimal research has been published on tissue donation as a whole, with most research on human donation focusing on organ or blood. Further, there has been little research on the impact of the MSM deferral for tissue donation.

Overall, MSM may be more knowledgeable about health care treatments and their status. In a study of men's knowledge of Human Papilloma Virus, queer men were more knowledgeable about the risks both of the virus, as well as the effects of infection (ex. Increasing the risk of HIV/AIDS) compared to heterosexual men[5]. This is similar to the willingness to alter personal practices during the 2022 monkeypox (MPX) outbreak. In a survey, 48% of MSM "reported reducing their number of sex partners, 50% reported reducing one-time sexual encounters, and 50% reported reducing sex with partners met on dating apps or at sex venues since learning about the monkeypox outbreak"[6]. MSM identified that they were at risk and took action to limit it, just as they do with HBV vaccination and PrEP medication prescriptions.

60% of corneal donors are male[7], a trend that is similar to organ donors (59.7% of organ donors were male from 2005-2019[8]). Puente et al. state that with the advances in testing, HIV can be detected in 4-8 days when utilizing nucleic acid testing, and within 20-22 days for HBV NAT[7]. This contrasts the 6-month window that was necessary when the policy was implemented by the PHS. Additionally, the authors write that the United States is a large exporter of corneas, and therefore the MSM deferral impacts the ability to serve patients outside of the USA.

Leeies et al. researched the impact of deferrals on sexual orientation and gender identity diverse people, which include MSM. They write that these policies result in a smaller donor pool, and those impacted by the deferrals report them as harmful and stigmatizing. Specific harms caused by these policies include stigmatization and devaluation, bodily disrespect, mistrust, and disempowerment[9]. The deferral policies also do not specify if they are to be applied to transgender women and nonbinary individuals who were assigned male at birth. They state "the exclusion of such broad social identities from donation functionally stigmatizes 2S/GBTQþ persons and discriminates against many individuals who are not at increased likelihood of HIV and viral infection" (p. 9).

Disuniform policies across biologics eligibility can create confusion and ineffective usage of donations. In Canada, tissue and organ eligibility follows the same criteria and are based on the same infectious agents (p. 13)[90]. Besides screening for differing risk factors related to activity (ex. Sexual contact with another man), organ donor assessment does not recommend an anal or rectal exam unlike tissue donor assessment (p. 15)[90]. Additionally these policies are ineffective in organ donation, with the stigma associated with "increased risk donor" labeling practices being "associated with underuse of organs and nonuse of tissues" (p. 12)[90].

Moshirfar et al. summarize the issue when discussing non-cisgender individuals impacted by the policy; "we realize that transgender individuals make up only 0.6% (1.4 million) of the US population; however, with respect to ocular tissue donation, any possible donor needs to have proper consideration" (p. 220)[10]. Yes MSM and other individuals impacted by this policy are a small demographic. However, turning away healthy donors continues to harm patients in need. Allowing healthy MSM to donate tissues will not solve every graft shortage. It will not remedy diversity shortages among sperm donors. It will not

cure every cornea-blind individual in the world. But it will help. It will make a difference in every patient who receives a transplant that they were waiting on. It matters.

Blood and organ donation has followed the scientific process of research, policy revision, implementation, review of new data, and subsequent advances to both maintain safety of supply and promote maximum supply. Organ donation has gone as far as allowing HIV+ donor/HIV+ recipient transplantation[91]. Meanwhile, in tissue transplantation, procurement and transplant organizations have used donations from at-risk and infectious individuals. Eye banks in Indiana have received notice from the FDA for use of donations from five individuals with signs of sepsis[93], while one tissue bank's use of bone allograft from a donor with tuberculosis resulted in transplantation to 56 recipients[94]. If the eligibility criteria had been revised in the past 30 years, it is likely that these facilities would have had tissues from individuals who would not only be identified as lower risk, but truly hold lower risk in having their donations transplanted into these patients.

When current organ guidelines for limited acceptance of seronegative, but potential increased risk donors, the practices and procedures were revised and the data was reassessed. Additionally, when the deferment period for MSM organ donors was reduced from 12-months to 30-days, the percentage of IRD labeled donors decreased from 24.5% to 15.4% (1443)[92]. Patel, et al. write, "Since the 2013 guidelines, knowledge on the risk of transmission of HIV, HBV, and HCV has advanced, NAT has widely expanded, the undetectable window period has shortened, and treatments for HCV have increased in efficacy and availability." (1441)[92]. So, why has tissue eligibility criteria not followed suit?

2007 Sources

Thirty sources (no. 17-46 in the guidance) were cited for the 5-year men who have sex with men (MSM) deferral in the 2007 Food and Drug Administration (FDA) guidance, *Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps).* We have obtained copies of twenty-six of these sources. Of the sources we have not obtained, three (no. 20, 38, 41) were presentations at professional conferences. We do not know if these presentations were published, nor if they were peer reviewed. Source 35 utilized the same title as source 43, but the author listed did not publish any papers with that title.

These sources were specifically cited for the 5-year MSM deferral, not the general risk of Human Immunodeficiency Virus (HIV) and Hepatitis B Virus, (HIV and HBV are the two infections that were used as rational for the deferral). We have reviewed the twenty-six sources for relevancy, alignment with current best practices and scientific advancements, and applicability to the general MSM population in the United States in 2023.

When discussing the sources, “all sources” refers to the thirty sources cited for the MSM deferral (no. 17-46). “Non-conference sources” or “reviewed sources” refers to the twenty-six sources excluding the three sources that came from conference presentations that we were unable to verify, as well as source 35 (no. 17-19, 21-34, 36-37, 39-40, 42-46). As stated, we believe that source 35 was improperly cited.

No sources were published after 2001 across all groups. Similarly, the range for years of publication was 1992-2001 for all groups. The median year of publication for sources across all groups was 1998, nine years before the release of the eligibility criteria, and twenty-five years prior to this year (2023). 80% of all sources were published at least twenty-five years ago. The policy has remained in effect and its guidelines continue to be implemented. The sources rationalizing the ongoing deferral for MSM (and all groups) must

follow current scientific advances and recent publications in the literature. The best practices have likely seen significant changes as well as improved understanding of virology in the past quarter century.

However, the data utilized, published, and compiled in these sources are older than the years of publication share. Of the twenty-six sources we reviewed, twenty-two reported clear ranges for the data that was collected and/or utilized. (sources 19, 22-26, 28-30-34, 36-37, 39-40, and 42-46). This is a liberal review of the data, as some sources utilized data for only a few months (ex. No. 40, which collected data from 2/2/1987 through 4/30/1987). The data from these sources was from 1976-2000, with a median of 1991.

Some sources were not strictly research or articles. Source 17 was a transcript of a Blood Products Advisory Committee meeting where semen donation and risk factors were discussed. Source 18 was the initial 1994 Public Health Service Guideline that implemented a five-year deferral for MSM organ and tissue donors. Source 21 was a MMWR Report from the CDC, on guidelines for HIV surveillance. These sources did not share data on HIV, Hepatitis B, MSM, or related topics and were not included. Source 27 used over 350 documents, datasets, and additional information from public health personnel, but did not state the years of when the data was collected or compiled.

Twenty-five sources included research on HIV risk factors, prevalence, incidence, or other topics, while five sources focused on Hepatitis B, and two sources included research on both. We did not include sources 17 and 18, as these came from the FDA or PHS. Source 17 was a discussion on MSM deferral for semen donation, and 18 was the previous iteration of the eligibility criteria. These did not present new data or findings outside of the other twenty-eight sources.

Of these twenty-six reviewed sources, only fifteen identified men who have sex with men, or include male-male sex as criteria when researching HIV and Hepatitis B infection and transmission (sources 19, 21, 27, 29-34, 37, 40, 42, 44-46). Once again, these thirty sources were used to justify a five-year deferral for MSM donors, so the data backing up a policy should have been specific to that demographic.

Some of these twenty-eight sources (excluding sources 17 and 18) were from populations that MSM individuals could not be a part of. Source 24 not only does not mention MSM, the study population is child-bearing women from 1989-1994. This was not used for general HIV or Hepatitis B risk. Although it is possible for queer men to have sexual contact with women, that would likely be classified as heterosexual transmission rather than MSM.

Beginning in 1985, the FDA implemented a lifetime deferral for MSM blood donors who had been sexually active any time after 1977. Sources 20, 25, and 28 all focus on data obtained from blood donors. Any sexually active queer men would not have been eligible to donate blood and therefore not included in the study(ies). Source 25 only mentioned MSM individuals when sharing current ineligibility criteria.

Although the implementation of *Don't Ask Don't Tell* in 1994 replaced an outright prohibition on service of queer individuals, the new policy prevented service members from being open about their sexuality. If a service member is restricted to a naval ship, military base, or other location, they still are not able to be sexually active. If queer service members were having sex, they risked being discharged. Sources 23, 26, and 28, and 37 focused on data from the United States Armed Forces.

Source 23 assessed HIV infection incidence among members of the United States Army Reserve Components. The only demographics/risk factors identified were race, age,

marital status, income of residential area, and the incidence of AIDS infections in metropolitan areas of residence. The study itself acknowledged that the "RC population differs from the US population with regard to several important demographic factors", and therefore cannot be used when making generalizations about the national population. There is no way to know which of these infections, if any, were attributed to MSM contact, or any other activity deemed "high risk" as risk factors or causes for seroconversion were not identified or considered in the study. Further, this study was completed from 1985-1991, during the comprehensive ban on service by queer individuals.

Source 26 researched the risk factors for viral hepatitis among U.S. Navy servicemen while deployed on 6-month assignments on naval ships. This study was conducted during deployments from 1989-1991, while the comprehensive ban on service from queer individuals was in place, 3 years prior to the implementation of Don't Ask Don't Tell. It is understood that living in close contact with an individual that has Hepatitis B is a risk factor for infection, as written in the 2007 eligibility criteria:

> "E.9) Persons who have lived with (resided in the same dwelling) another person who has hepatitis B or clinically active (symptomatic) hepatitis C infection in the preceding 12 months (Ref. 69)."

Any individuals who were living within extremely close quarters on the ship were already at risk of Hepatitis infection, even if MSM individuals had been included in the study population, which they were not.

Source 28 researches risk factors for viral hepatitis and cytomegalovirus among volunteer blood donors at United States Navy facilities. The data was collected from 1990-1991, during the outright ban on queer military service, as well as the lifetime deferral for blood donation from queer men. There is no chance that MSM were in the sample. Three of the four blood donation facilities were in the contiguous United States, with the

fourth taking place in Okinawa, Japan. The only participants who were found to have an increased risk of HBV and CMV were those stationed in the Western Pacific.

As already confirmed by the eligibility criteria, close contact and residence with individuals who have an HBV infection are at higher risk. Service members stationed outside of the contiguous United States will be in significantly tighter quarters, and any infections are much more likely to spread. The study ends by stating “it should be noted that the overall prevalence of anti-HBc seropositivity prevalence (1.7%) in this military donor population is comparable to that in civilian blood donors”. Despite that no MSM are in the study, they aren’t in blood donors, so the generalizations and conclusions should not have been used to justify MSM deferral for tissue donation.

Source 37 looked into HIV seroconversion among young adults in the U.S. Army, specifically 1985-1993. The study mentioned MSM once when discussing findings from other studies, MSM and same-gender sexual contact was not identified within the sample (likely due to the prohibition on service from queer individuals). Any service members who answered yes to a question on same-gender sexual activity would have been at risk of discharge, there is no way to know how many, if any, of the HIV-1 seroconversions were attributed to MSM contact.

Many of these sources sampled populations that were already at increased risk due to behaviors or activities. Attributing the risk to an individual or participant’s sexuality rather than additional behaviors leads to inflated prevalence when the findings are applied to a national population. These studies utilized data from STD clinics, or completed interviews with individuals at clubs, bars, and other areas where individuals were having sexual contact with new, unknown individuals.

These locations and participants are established to be at a higher-risk for not only HIV and Hepatitis B infections, but all sexually transmitted infections. Individuals who frequent areas with individuals engaging with risky sex (including but not limited to, sex with a new partner, sex without knowing the partner's status, sexual activity while under the influence of drugs and/or alcohol), are at a higher risk. Individuals who are seeking repeat testing at STD clinics and HIV counseling centers are participating in activities that increase their risk for potential transmission. Although these locations are beneficial for collection of data on the topics of prevalence, incidence, as well as interventions, they can result in inflated conclusions, especially when forming generalizations to groups of individuals or geographical areas.

Source 19 recruited participants who had participated in at least one instance of high-risk sexual activity in the past twelve months. For the study, high-risk activity was initially defined as unprotected insertive or receptive anal sex or a diagnosis of syphilis, gonorrhea, or nongonococcal urethritis. Source 27 estimated the prevalence and incidence of HIV in large metropolitan areas. The studies reviewed for the study featured participants from STD clinics, counseling or testing sites, and drug treatment centers. Additionally, participants with multiple risk factors were categorized under only one risk type.

> "In the western and Pacific states of California, Oregon, Washington, Arizona, Colorado, Nevada, New Mexico, and Hawaii, in which HIV seroprevalence and risk of HIV are substantially higher among gay men than among injection drug users, gay and bisexual male injection drug users were considered in the risk category of men who have sex with men" (p. 643)

This practice resulted in an inflated incidence and prevalence for MSM individuals, and any generalizations to the entire MSM population would be further inflated considering that the study participants were from at-risk communities.

Source 30 assessed HIV prevalence and risk factors specifically among MSM in San Francisco. Participants were recruited from physical locations with MSM present. These

included “street locations, dance clubs, bars, businesses, and public venues''. These locations were selected because they were popular with MSM and had the potential for high-risk behaviors. The findings would have likely been significantly lower if the sampling occurred at LGBTQ+ bookstores, grocery stores in LGBTQ+ neighborhoods, or at other similar venues. Source 32 reviewed the ability of EIA tests to identify early HIV infection. The data and participants were from publicly-funded HIV testing sites.

Source 31 assessed the potential for enrollment of HIV vaccine trials in New York City. Although the study did focus on queer men (identified as gay or bisexual), the study themselves stated that they “elected not to use specific behavioral eligibility criteria” and that “The cohort was not intended to be a representative sample of gay or bisexual men in New York City”. The study sample was not sufficient to make conclusions about other future vaccine trials or enrollment for such trials, while the study itself was not representative enough to make national generalizations to MSM. Further, with data from 1993-1995, the landscape of infection education and risk prevention has changed to a point that sexual practices have also changed.

Source 33 estimated the seroprevalence of HIV infections among MSM in San Francisco using repeated, anonymous, HIV testing. Not only were these individuals pursuing testing, and had an indication for unknown status (like risky sex), the behaviors were repeated, leading to additional rounds of testing. Source 40 was one of the few publications to look into Hepatitis B (as well as Hepatitis C and HIV). However, as with similar studies, the participants sampled were from STD clinics. Additionally, the paper stated:

> “However, our findings must be confirmed in other studies, because condom use and the number of sex partners was queried for only the month before a patient’s visit, this information may not reflect sexual behavior months and years before this visit, when many of these infections were acquired.” (p. 994)

Source 36 looked at HIV infection rates in Miami from 1987-1992. However, the study was conducted using data from Miami STD clinics. These same clinics were responsible for the treatment of 98% of individuals with syphilis infections in the Miami area during that same time period. The study affirms this when writing “the number of persons who tested positive between 1988 and 1992 in Miami STD clinics is almost as large as the number of AIDS cases reported in Miami during that interval.” The sample is not just at a higher risk than the general population (residents of Miami), it seems to be that the sample comprises nearly all those at risk.

Source 42 assessed HIV seropositivity among individuals utilizing publicly funded counseling programs, as well as the potential routes for prevention strategies. Once again, although prevention strategies may be applicable to a general community, as all individuals have the potential for infection, those who pursue or are indicated for counseling and testing are at higher risk than the entire population. Source 44 looked at individuals accessing STD clinics. Source 45 features data on AIDS cases from 1996 to 2001, however, the 5-year MSM deferral criteria is rationalized due to a risk of HIV, and with advances in HIV treatment and accessibility, more patients are not advancing to a diagnosis of AIDS.

We understand why the FDA utilized data and studies from STD Clinics, counseling, and high-risk individuals, because that was available and published at the time. The specific topic of MSM and HIV and/or HBV was not heavily researched, and any data specifically on tissue donation was likely not comprehensive or in existence. However, that does not absolve the harm done to the LGBTQ+ community when generalizations from high-risk, and high-prevalence individuals are used to reject the donations and dying wishes of nearly 3-decades queer men have been subject to a 5-year deferral.

Numerous advances in testing, treatment, and understanding of HIV have come in the past 17 years. Significant changes in prevalence and incidence of HIV, both within the MSM population, and the country at large have changed the landscape of HIV. The reductions of deferral for MSM individuals in the policies of blood and organ donation eligibility in the USA should have triggered a review of relevant data since the 2007 guidance. They have not. Based on the sources used in the 2007 document, there are not sufficient studies on the general MSM population. The comparisons between those who have high-risk behaviors and those who do not cannot be made. If there is not sufficient literature to reach conclusions, the FDA should fund, support, and create new studies on relevant topics, as was done with the ADVANCE Study for blood donation.

Source 17 was a two hundred page transcript of the seventieth meeting of the Blood Products Advisory Committee. Many of the points of discussion at this meeting were not only unscientific and unfounded, but outright discriminatory. Here are a sample of the statements given:

> "The third area I want to talk about disclosure has to do with negotiated safety agreements. And so here we're in the realm of HIV-AIDS prevention. This is a strategy that's been used by some of the HIV-AIDS prevention campaigns for MSM to have them work out negotiated safety agreements with their partners if they're in steady relationships. Now steady does not necessarily mean ultimately monogamous. It just means that this is your main partner. // And so one prevention technique that's been used in prevention campaigns is to get MSM to work out negotiated safety agreements with their steady partners, and this would have to do with the fact that there would be an unambiguous agreement about sex, both within and outside the relationship.// And the agreement would have to do with unprotected sex within the relationship, that being both people are HIV tested, and safe sex if there's anything going on outside the relationship. That would either mean no anal sex with the outside, nonsteady partner or only protected anal sex with the outside, nonsteady partner or one-night stand or whatever it would be. // And so there have been four studies that I have found at this point that have delved into how good are people at keeping their negotiated safety agreements. And the situation is that negotiated safety agreements are set up, partners go into the negotiated safety agreement, and then one of the partners is reinterviewed afterwards to find out whether they keep to the negotiated safety agreement. What do you think they found? Well, I'll tell you. // There are four studies that I've found that have any sample size: Guzman, Wang, Davidovich, and Kippzax, and these are all published in the last few years. And they found when they asked men to set up negotiated safety agreements and then

> interviewed about compliance with the negotiated safety agreements, that the depending on the study and depending on the way it was done and where it was done, that compliance ranged from 60 to 94 percent, that men complied with their negotiated safety agreement. The low one was a 60-percent compliance in a study published in 2001, and the high one was 94-percent compliance in a study published in 1997." (pp. 73-74)

The idea that all MSM are at high-risk for sexually transmitted infections because even those who state that they are in monogamous relationships are cheating on their partners is incredibly bigoted.

Dr. Lachenbrach brought up the potential of inflated conclusions and data based on the frequency of studies that sampled and recruited at areas that were more likely to have high-risk individuals. The response was as follows:

> "We thought that this was a very important thing to do, to try to get the best estimate of HIV prevalence among this age group, and so we worked a long time trying to come up with the best design. And the best design that we could come up with was to sample young men who went out of their houses, out of their schools, and went to places where young men congregated with each other. // And so **this is not a survey of young men who don't go out; you know, who are staying home, who aren't sure of their sexual identity or who find partners at their high school and don't go out to places.** This is a survey of men who go out." (p. 90).

However, the generalizations from these studies are still being applied to all MSM, regardless of if they are "unsure of their identity", "found their partners in high school", or "stay home". Those individuals still are subject to the five-year deferral.

Source 19 looked into individuals interested in a vaccination for Human Immunodeficiency Virus, if one were to be approved at a later date. As of 2023, there still is not a vaccine for HIV, and while individuals who place trust in FDA and the vaccine authorization process may be willing to register as a tissue and organ donor, those similarities are correlation, and certainly not absolute. Further, the study was published in 1996, and with the increasing effectiveness of treatments and the longevity of individuals with an HIV infection, the sentiment and willingness to participate in a vaccination program

may have changed, regardless of the altered public mentality towards vaccination after the COVID-19 pandemic.

Source 34 researched the prevalence of Hepatitis B across the country. Although conclusions were determined for men who have sex with men, in the third National Health and Nutrition Examination Survey, only eighty of the 21,265 were MSM. A sample size of eighty individuals is not sufficient to make generalizations or conclusions on a national scale. Only 0.38% of participants in this study were MSM.

Source 35 looked at HIV among disenfranchised, 16-21 year old applicants to the U.S. Job Corps program. However, a group of 16-21 year olds are not applicable to the national population, especially considering the situations that these applicants came from. They were not enrolled in any school programs, but risk factors that contributed to an HIV infection were not researched. Applicants were grouped based on race, age, and hometown size/region. No questions or data were published on sexual partners, injection drug use, or other behaviors that may have led to an HIV infection.

Source 39 did not specify how study participants were recruited for the study, rather stating “In 1995, 587 HIV-negative MSM were recruited from the Seattle area using a variety of outreach methods” (p. 2042). However, individuals were likely recruited from STD clinics and treatment centers, as was the case in similar studies researching the same population. Although HIV-negative status was a requirement for inclusion, the study itself looked at any and all STD infection during the 12-month period, not specifically HIV. Only 1.3% of participants had an HIV-1 seroconversion during the year of follow-up (n= 5) compared to 5.7% for bacterial STIs (n=34). Although other STIs are curable, the treatment of HIV has seen significant progress in the previous 3 decades, to the point where the risk of transmission is incredibly low, when prescription regimens are adhered to.

Source 40 was a survey of HCV, HBV, and HIV infections among non-injection drug users in STD clinics. Despite the fact that all members of the sample were likely participating in unprotected sex, due to the indication and need for testing, The study found an HBV seroprevalence odds ratio of 4.4 for MSM activity, compared to a HBV seroprevalence 4.6 odds ratio for presence of HCV. The odds ratio of the number of male sexual partners was also not significant (p=.07). Although HCV is considered a risk factor for MSM organ donors, it is not for tissue donation and blood donation.

Source 42 wrote it best, stating “Other researchers have observed that individuals who continue to engage in risky sexual practices are likely to be repeatedly or regularly tested”, acknowledging that data compiled and collected from higher-risk populations would not be representative to the entire nation. This study focused on HIV positivity within publicly funded clinics and testing sites. The study identified and looked at a variety of risk factors, but combined all MSM and MSM injection drug users into one class- labeled MSM; “for analysis purposes, a single risk behavior (except for the combination of a man who has sex with men and uses injection drugs)”. The MSM data had two risk factors compared to every other class, resulting in inflated findings.

Source 44 identified varying risk factors other than those utilized by the FDA’s eligibility criteria, including cocaine use, but did not identify injection drug use as a risk factor for HIV. As the study participants were from STD clinics, unprotected sex (regardless of gender and/or gender of partner) is already an indicator for testing, one that likely will be seen by participants, rather than injection drug use. Additionally, the findings among MSM and heterosexual individuals were different, “among MSM, incidence declined with age; among heterosexuals, incidence increased with age” (p. 508). Organ and tissue donors may be more likely to be older individuals, and there is no limit on the age for donations. The

study found that in the older age group, incidence for heterosexuals was higher than that of MSM (the older age group was defined as individuals 40 and older).

Source 46 featured incredibly biased conclusions. Page 8 included the following:

> "**Men whose medical records indicated that they had ever had homosexual or bisexual contact were classified as MSM**. Men who were not classified as MSM and all women were classified as heterosexual. **It is important to recognize that misclassification of even a few MSM as heterosexual men would probably increase the observed prevalence among the men classified as heterosexual.**

To begin, all individuals hold the capacity for any infection, including HIV, not just MSM. Adding bisexual men who hadn't recently had sex with men, and instead had multiple contacts with women as MSM inflates any infections stemming from heterosexual intercourse by labeling them as the wrong risk factor. Additionally, the claim that closeted queer individuals are the cause of incidence rates amongst heterosexual populations is a complete double standard. The opposite belief, that miscategorization is necessary, was recognized in the same paragraph.

Despite practices that may have resulted in inflated findings for MSM populations, the researchers found the opposite- decreases in incidence within the MSM community.

> "Prevalence decreased among MSM who were 35 years of age or older, from 36% in 1993 to 26% in 1997, and decreased among those who were 25–34 years, from 34% in 1993 to 20% in 1997. Overall prevalence decreased from 16% in 1993 to 10% in 1997 among MSM who were under 25 years old." (p. 11)

Once again, the older individuals may be more likely to donate tissues and organs. Additionally, while not all data collected for the publication was from STD clinics, all MSM data was. Yes, individuals can contract any infection at any age, but if infection occurs more frequently at younger ages, older individuals are more likely to know their status, pursue treatment, and any chronic infection would be accessible through the patient's chart at the time of screening.

Other studies were not reciprocal to the tissue donation population. Although organ and tissue donation can occur at any age, it is more likely to occur at a later age. Most of these studies focused on individuals who are at a younger age, which correlates with a

greater likelihood of high-risk behavior. Only two sources looked at the nation as a whole- sources 22 and 34, both of which used data from the National Health and Nutrition Examination Surveys (NHANES).

Source 23 featured a sample with 95.9% of participants younger than 50 years old. 77% of source 25's members were under the age of 45. Source 26 had a mean age for participants of 24 years old and source 28 had a mean age of 25 as well. Some studies only included young participants, like source 30, which only enrolled those ages 17-22; or source 43, which limited eligibility to ages 16-21. 47% of those in source 31 were under the age of 30. 88% of those in source 32 were 40 years old or younger. 70% were 40 or younger in source 33. Source 37, which looked at the military, stated that 99.4% of those enlisted in the U.S. Army were under the age of 50.

Most research published on cadaveric donation focuses on organ donation, which we acknowledge has significantly more restrictions related to viability of procurement and donation compared to tissue donation. Because of this, the ages of organ donors may not be identical to the ages of tissue donors. However, they can get us closer to the general trends of donor demographics. In an analysis of organ donors from 2005-2019, the median age of donation was 42[8]. Additionally 59.7% of donors were male, despite the MSM deferral still in place. More men are being turned away when they are more likely to donate.

Regardless of the age at donation, the data confirms that individuals are more likely to participate in risky sex and therefore at a higher risk of infections like HBV and HIV at younger ages. The research, if it primarily focuses on that demographic, is going to have inflated results.

Approved Testing

Tests Approved for Screening Tissue Donors

Test	Agent [13]	Class [13]	Tissue Approval	Blood Approval
Abbott PRISM HBCore	Hepatitis B	ChLIA	10/13/05 [13]	10/13/05 [14]
Abbott PRISM HBsAG; Abbott PRISM HBsAG confirmatory	Hepatitis B	ChLIA, ChLIA specific antibody neutralization	7/18/06 [13]	7/18/06 [15]
Abbott Alinity S anti-HBC	Hepatitis B	CMIA	8/2/19 [13]	8/2/19 [16]
Abbott Alinity s HBsAG; and Alinity s HBSAg Confirmatory	Hepatitis B	CIMA	7/14/19 [13]	7/14/19 [47]
Genetic Systems HBsAg confirmatory assay 3.0	Hepatitis B	EIA	1/23/03 [13]	1/23/03 [48]
ORTHO HBc ELISA test system	Hepatitis B	ELISA	4/23/98 [13]	4/23/98 [49]
COBAS AmpliScreen HBV	Hepatitis B	PCR	8/2/05 [50]	4/21/05 [52]
Elecsys HBsAg II and Elecsys HBsAg II Auto Confirm	Hepatitis B	ECLIA	2/21/24[88]	2/27/24[88]
Elecsys Anti-HBc II	Hepatitis B	ECLIA	2/27/24[89]	2/28/24[89]
COBAS Ampliscreen HIV-1 test, ver. 1.5	HIV-1	Qualitative PCR	12/19/03 [52, 53]	12/20/02 [54]
Abbott Prism HIV O plus assay	HIV-1 & 2	ChLIA	9/18/09 [13, 55]	9/18/09 [55, 56]
Alinity s HIV Ag/AB Combo Reagent Kit	HIV-1, HIV-2	CIMA	7/23/19 [13]	7/23/19 [57]
Genetic Systems HIV-1/ HIV-2 Plus O	HIV-1 & 2	EIA	8/5/03 [13, 58]	8/5/03 [58]
Procleix ultrio assay	Hepatitis B & C, HIV-1	Nucleic Acid Test (TMA)	10/3/06 [13]	10/3/06 [59]
Procleix ultrio plus assay	Hepatitis B & C, HIV-1	Nucleic Acid Test (TMA)	5/25/12 [13]	5/25/12 [60]
Procleix ultrio elite assay	Hepatitis B & C, HIV-1 & 2	Nucleic Acid Test (TMA)	5/3/18	5/3/18 [61]
COBAS MPX test	Hepatitis B & C, HIV-1 & 2	PCR	1/17/20 [13]	10/20/16 [62, 63]
COBAS TaqScreen MPX Test	Hepatitis B & C, HIV-1 & 2	PCR	8/27/09 [13]	12/30/08 [64]
COBAS TaqScreen MPX Test 2.0	Hepatitis B & C, HIV-1 & 2	PCR	12/19/14 [13, 65]	12/19/14 [65]

Both the COBAS AmpliScreen HBV and COBAS AmpliScreen HIV-1 test (ver. 1.5) are not listed on "Testing Human Cells, Tissues, and Cellular and Tissue Based Product (HCT/P) Donors for Relevant Communicable Disease Agents and Diseases"[13]*. However, the package inserts for both indicate usage for screening of tissue donors. For the HBV test, The approval letter from 8/2/05 mentions usage for screening cadaveric donors, as well as a mention for organ donation approval in the 4/21/05 letter. For the HIV-1 test, the 12/19/03 approval letter lists usage for organ and other living donors, and the 3/5/09 letter includes testing of cadaveric donors.*

These 19 tests are approved by the FDA. Not only are the 19 tests approved for tissue donors, they are also approved for testing blood donors for the same infectious agents. Updated testing methods have resulted in a reduction from a lifetime policy to a 12-month policy, to a 3-month policy for blood donors. With the same tests used, these similar policies should see similar updates.

Of the 19 tests, all 19 were first approved after the 5-year deferral period was introduced by the Public Health Service in 1994. The length of the deferral period has not seen a chance despite these advances in testing. 9 of the 19 tests, nearly half, were approved after the previous revision in 2007. Given that the FDA is the same organization to approve the tests as the one which implements eligibility criteria, the effectiveness and risk of the testing methods should be known. If these tests are effective enough to earn the Administration's approval, and are effective enough to assess for infection in blood donors, why are they not effective enough to update the tissue donation eligibility criteria?

HIV and Hepatitis B from 1994 to 2023

HIV and HBV Infection Rates

Significant limitations were present while assessing changes in the incidence of HIV infections over the previous 3 decades. Many states did not track or publish data on infections, and many states prioritized AIDS infections over HIV. As treatments for HIV were developed, approved, and prescribed, the number of HIV+ individuals who progress to an AIDS diagnosis has dropped. This resulted in varied data, and some publications that were not specifically applicable to the risk of HIV transmission in tissue donation.

Estimated Incidence of Relevant Infections for MSM Deferment

Year	Estimated HIV Incidence	Rate of change (avg per year)	Estimated HBV Incidence	Rate of change (avg per year)
2007	56,000 [66]		43,000 [68]	
2015	37,800 [66]	-38.8% (-4.85%)	21,900 [69]	-65% (-8.1%)
2020	33,600 [67]	-11.8% (-2.36%)	14,000 [70]	-44% (-8.8%)

Estimated incidence for HIV infections were not available for 1985 and 1994, additionally, the reported infections came from less than two-thirds of states. In place of 2007, 2015, and 2020 were selected as the year the 5-year deferment was last implemented, the reduction of the lifetime blood donation deferment for MSM, and the reduction of the 12-month deferment for blood donation. However, in 1994, AIDS was the leading cause of death among those aged 25-44[71]. In 2023 it is not even in the top 10. The incidence of these infections has fallen, the prevalence has changed, and new treatments and prevention strategies have entered the market since the inception and continued implementation of the 5-year MSM deferral. The policy should follow these advances.

Hepatitis B Virus Vaccination

Unlike other relevant infectious agents for tissue donation, Hepatitis B has a vaccination, and has a vaccination that has been implemented widely during childhood vaccination series.

It wasn't until 1991 that the Advisory Committee on Immunization Practices recommended universal childhood vaccination[72], which was expanded to unvaccinated adolescents in 1995, and all of those under 19 in 1999. From 1993-2000, national HBV vaccination coverage increased from 16%-90% for those 19-35 months old, as well as an increase from near zero-67% for those 13-15 years old. The impact of this vaccination would not be seen immediately, and would not have been visible when the 5-year deferral was implemented.

Current efforts work to vaccinate MSM and other individuals at higher risk of HBV. Healthcare workers are also indicated for the vaccination series. Prior to the expansion of HBV vaccination efforts, 80% of those vaccinated were health care workers, while only making up 5% of HBV infections[72].

The acceptance of MSM for vaccinations have also likely changed due to recent events, such as the roll out and adherence with monkeypox virus vaccinations. The risk of HBV among MSM has likely decreased over the past 3 decades as the willingness to take preventative treatments has increased.

PrEP (Pre-Exposure Prophylaxis)

The first PrEP medication, Truvada, was approved by the FDA in 2012, 18 years after the 5-year deferral's implementation via the Public Health Service[73]. In 1994, use of HIV treatment as prescription prevention would have been unheard of. However, the treatment process was expanded with the approval of Descovy in 2019 and Apretude in 2022[73].

Significant advances in the fight against the HIV epidemic, without any revision or reduction to the deferral criteria for those deemed at-risk of the infection. The use of PrEP medications is affirmed and supported by the federal government, as seen by its prevalence in *Ending the HIV Epidemic in the U.S.* as well as the *HIV/AIDS Strategy for 2022-2005*.

PrEP is clinically effective at preventing HIV transmission when the prescription regimen is adhered to. However, even if a patient is not completely consistent, the risk of HIV transmission is still decreased. Siegler, et al. wrote that when taking the medications seven days a week, the risk of HIV transmission decreased by 99%, and risk decreased by 96% while taking the prescription 4 days a week. Kasaie, et al. reported that if 40% of HIV-MSM with more than 1 partner took PrEP 40% of the time, the national HIV incidence could decrease by 9.5% in 5 years[74]. The incidence could decrease by 43% if the sample and adherence grew to 80% each.

Not only are these medications on the market, they are seeing significant upticks in prescription. Siegler, et al. estimated that 118,249 individuals were on a PrEP prescription in the fourth quarter of 2017[75]. The study also noted that an increase in prescriptions had been seen every year since the drug's approval. Since that study, two more types of medications have been approved, insurance coverage has changed, and more patients have pursued treatment.

Not every individual indicated for a prescription, or who is at risk, takes PrEP, and not all of those with a prescription are adherent with the schedule and dosage. However, of the 1.2 million individuals who were identified as potential recipients by the CDC in 2015, less than half were MSM (492,000)[74]. MSM are the ones driving this change. HIV and how

we fight it has changed in the past 3 decades. The prevention strategies for HIV are vastly different to what was available two decades ago, or those ordered for other infections.

Even if a deferral is in place for PrEP medications due to the interference with accurate and effective testing, as was drafted for blood donation this year, the impact of the prescription on HIV infection among MSM should trigger a review, revision, and reduction to the 5-year deferral policy.

Economic Impact[76]

In 2021, the United States exported $236,000,000 worth of tissue, and was the fifth largest exporter of human tissue in the world. In that same year, we imported $399,000,000 worth of tissue. This resulted in a deficit of $136,000,000 in tissue spending. To decrease the imports and related costs, while also increasing exports, we should utilize all healthy donors. Economics is not the FDA's primary mission, and we understand that. It is not Pride and Plasma's either. However, when we work in and are forced to receive care in a cost-driven, profit-driven system, patients will pay the price, literally and figuratively for a decrease in domestic supply.

Similar Policies

In 2016, the FDA released "*Use of Nucleic Acid Tests to Reduce the Risk of Transmission of Hepatitis B Virus from Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products*"[77], which recommended the use of FDA approved NAT testing for tissue donors. This form of testing significantly decreases the detectability window for testing tissue donors, and should therefore also allow for shorter deferral periods for previous criteria put in place due to a risk of HBV. The guidance itself stated that the change in testing would

result in a "potential reduction of the infectious window period of up to 40 days depending on sensitivity of the HBsAg test" (p. 3). Additionally, this source was published nine years after the previous policy recommending the MSM deferral.

A May 2018 guidance, *Donor Screening Recommendations to Reduce the Risk of Transmission of Zika Virus by Human Cells, Tissues, and Cellular and Tissue-Based Products*,[78] recommended separate screening and testing procedures for living and cadaveric tissue donors. The screening questionnaire is far more accurate with living donors than with cadaveric donors, due to the possibility for follow-up questions and the ability to question the donor directly, rather than a relative or other individual. It is possible to implement separate MSM deferrals for living and cadaveric donors, if the FDA still felt that such criteria were necessary until additional studies and data could be collected. This would have significant implications for sperm donation, where living donors can undergo repeat rounds of testing, especially considering the shortage of viable sperm donors and the lack of diversity of available donations for those pursuing donor assisted reproduction.

The guidance, *Revised Recommendations for Determining Eligibility of Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products Who Have Received Human-Derived Clotting Factor Concentrates*[79], from November 2016 cited an update to blood donor eligibility as rationale for a similar update to tissue donation policy.

> **"In the document entitled "Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products; Guidance for Industry**" dated December 2015, FDA explains that, given the enhanced safety measures now used in the manufacture of clotting factor concentrates, **FDA does not consider the receipt of FDA licensed clotting factor concentrates or sex with a person who has received clotting factor concentrates to be a risk factor for HIV or hepatitis** (Ref. 11). Accordingly, FDA no longer recommends deferral for donors of blood and blood products who have had sex with an individual with hemophilia or related clotting factor deficiencies requiring treatment with clotting factor concentrates. Further, FDA has not recommended a deferral for the receipt of other FDA licensed plasma-derivatives because of HIV or hepatitis risks (Ref. 11)." (p. 2)

There have been 3 updates to MSM blood donor eligibility since the 2007 eligibility criteria's finalization- the twelve-month deferral in 2015, the three-month deferral in 2020, and the new individual risk assessment in 2023.

Similarly, there have been reductions in MSM eligibility in organ donation since the 2007 guidance. In 2013 the Department of Health and Human Services replaced the five-year deferral for organ donations with a labeling system for MSM donors who had been sexually active in the twelve months prior to donation. These organs were labeled as "increased risk donor" (IRD) and still offered to matched recipients after testing. The practice was revised to a thirty-day policy in 2020, where the IRD label was replaced with the specific risk factor, in this case, MSM.

In the 2023 blood donation eligibility update, *Recommendations for Evaluating Donor Eligibility Using Individual Risk-Based Questions to Reduce the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products*, updates to blood donor deferral criteria in other countries[3].

> "**FDA recognizes that other countries with similar HIV epidemiology as the U.S. have revised their donor eligibility criteria for MSM, based on risk assessments performed in these countries. Notably, the United Kingdom in 2021 and Canada in 2022 introduced a new approach for donor questioning based on individual risk factors** (Refs. 32-36). The approach is based on surveillance, epidemiology, and risk assessments that demonstrate that new or multiple sexual partners, and for those with new or multiple partners, anal sex, are the most significant risk factors that increase the likelihood of HIV infection (Refs. 32-37). Thus, the United Kingdom and Canada have adopted an individual risk-based approach that asks all presenting blood donors (regardless of sex or gender), if they have had a new sexual partner or more that one sexual partner in the last 3 months, and if so, they are asked if they had anal sex (Refs. 34, 38). Individuals who report having a new sexual partner and anal sex or having more than one sexual partner and anal sex in the last three months are deferred from blood donation. **To date, the United Kingdom and Canada have not reported safety concerns following the implementation of this individual risk-based deferral policy**." (p. 4)

If there is data available, from similar populations, it should be considered when reviewing the current practices and recommendations in our own country.

In September of 2023, The UK announced plans to implement the individual risk assessment for blood donors as a replacement for current tissue donor eligibility[86], based on recommendations submitted to the Advisory Committee on the Safety of Blood, Tissues, and Organs in May 2022. Looking at the safety, impact, and risk of the IRA implementation for blood donors, as well as the considerations of differences and similarities between blood and tissue samples and donors, the FAIR III working group determined that there would not be an increased risk upon recipients, nor would there be an additional burden upon donors and families participating in the screening process[85].

The FDA has cited other FDA tissue guidances, other FDA blood guidances, and other countries' policies when drafting updates to their own best practices. If these policies have been applied to similar documents, or even parts of the same 2007 eligibility criteria, why have they not been applied to the MSM deferral, considering that other nations, and other divisions within the FDA have taken the action to decrease the deferral of healthy donors?

Number of Donors Disqualified

Unlike with blood donation, most potential tissue donors are unaware that their donation has been rejected, for any reason. While a blood donor can have a conversation with the screening personnel, tissue donors do not. Additionally, not all tissue banks keep records of deferral rationales. If they do, they might not keep them indefinitely. There is no way to calculate how many MSM were impacted by this policy over the past 30 years.

Some groups have attempted to calculate the number of donors impacted. Puente et al., calculated that between 779-1,608 individuals were deferred every year[7]. This range was identified through a survey of eye banks, as well as a calculation of how many men were MSM and how many corneal donations were procured in 2018[7]. Given that the policy has remained the same length since implementation in 1994, we can calculate a very wide range of individuals potentially impacted by the deferral. Multiplying both ends of the range by 30 gives us 23,370-48,240 individuals deferred from donating.

However, that isn't the whole picture either. Unlike with blood donation, where most donors give one unit of blood, the number of recipients from a tissue donor is much greater. Donor Network West reports that each tissue donor can impact 75 recipients[80]. When we multiply the cumulative donor range by 75 potential recipients, we end up with 1,752,750-3,618,000 potential recipients over the past three decades.

Tissue donation is not always seen to be as critical as organ donation or as necessary as blood donation. However for cornea-blind patients who cannot see, for patients with decreased range of motion and reduced independence, for individuals waiting for heart valves, people who elect to pursue donor-assisted reproduction, these

donations are life-changing. Any increase in wait times, any decreases in availability, or just a limitation on patient choice and autonomy reduces quality of care. The deferral impacts not only healthy donors, but also potential recipients.

Findings from the FAIR III Working Group (UK SaBTO)[85]

The FAIR (For the Assessment of Individual Risk) steering group, was created in 2019 to assess the feasibility and accessibility of a transition to an individual risk assessment to replace the previous population-based deferment for MSM blood donors in the UK. The recommendations and findings were presented to the SaBTO (Advisory Committee on the Safety of Blood, Tissues and Organs) in October 2020 for implementation in Summer 2021. The third implementation of the FAIR (FAIR III) steering group looked to determine if the same, or similar Individual Risk Assessment for donors eligibility would be applicable to tissue donors. The working group initially determined that living donors could utilize the IRA process, but required more research into the feasibility of tissue donors (p. 2).

Separate screening for living and cadaveric donors was not determined to be a feasible option as it would have been inequitable, as would differential screening procedures between blood and tissue donors (p. 3). The final recommendation for deceased tissue donors was the implementation of the FAIR assessment with all questions about the number of partners, new partners, and anal sex (p. 4). The working group also identified the inherent difference among tissue and blood donation deferral, writing, “it was acknowledged that most tissue donors have only one opportunity to donate” (p. 11).

The working group similarly saw testing mechanisms for blood and tissue donor infection detection. “LSB and CB donors are tested to the same protocol as blood donors for hepatitis B surface antigen (HBsAg), antibodies to hepatitis C (anti-HCV), combined antibodies/antigen to human immunodeficiency virus (HIV) types 1 and 2 (anti-HIV), treponemal antibodies (syphilis) and antibodies to human T-lymphotropic virus (HTLV)

types 1 and 2 (anti-HTLV)" (p. 12). When different biologics are screened using the same methods, they should see similar methods for eligibility determination. Otherwise, there is inequitable treatment, and variations among the safety of these types of donations.

The working group also found that tissue donors were not identical to the general population, nor were they the same as blood donors. Of the LSB donors, 65% are over 65 years, indicating a predominately older population. The literature on the sexual behaviors in older aged populations was reviewed to help inform the discussions around risk both of acquiring infection from sexual behaviors but also potential impact on donor loss if they would be deferred under the FAIR criteria as used for blood donors" (p. 14-15). Therefore, if blood donors were able to be adequately assessed for risk of infectious agents, there would be a lower residual risk of undetected infection among tissue donors, who participated in high-risk activities at a lower rate. The group also found that 80% of tissue donors were 55 years or older- significantly older than blood donors.

In summary, the working group wrote:

> **"As noted above the most recent review of donor selection guidelines has recommended an approach based on epidemiological and behavioural evidence with a move away from population based criteria to a more individualised approach, looking at individual donor behaviours in the context of what is known to increase risk of infection. It is desirable to have similar donor selection guidelines for blood and tissue donors and to use similar questions in assessing cell donors hence this assessment of whether the blood donor FAIR work can be applied to tissue and cell donors" (p. 9).**

Other countries have taken the initiative to acknowledge that differential treatment amongst blood and tissue donors is unscientific, unnecessary, and results in variations in safety. We urge the FDA to follow in their footsteps, listen to your peers, and revise the current 5-year MSM deferment to a practice more in line with the current science. Tissue

donors only have one opportunity to give, please don't continue to take that away based on a donor's sexuality.

Press Releases and Statements on the MSM Deferment Policy

GLMA: Health Professionals Advancing LGBTQ+ Equality[87]

143-24-102. Revising Tissue Donation Eligibility Criteria to Ensure Equitable Donation Policies for LGBTQ+ Donors

GLMA urges the FDA to continue to encourage and monitor scientific advances in tissue testing methodology to enlarge the pool of potential safe eligible tissue donors as well as ensure equitable donation processes (e.g., inclusive gender markers for donors) for all donors regardless of sex assigned at birth, gender identity, and/or sexual orientation.

In 1994, the Public Health Service implemented a 5-year blanket deferral for any tissue donors who were MSM (men who have sex with men), a policy that has remained in effect since introduction.

GLMA: Health Professionals Advancing LGBTQ+ Equality urges the FDA to revise the Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) and the current 5-year blanket deferral for MSM (men who have sex with men). GLMA urges the American Association of Tissue Banks, as well as other regulatory bodies and tissue banks update their screening guidelines to transition to an individual risk assessment for all donors, not just MSM, as the FDA did with blood donation eligibility in May of 2023. These recommendations are also supported by the AMA, in their policy, Blood and Tissue Donor Deferral Criteria H-50.973.

Screening policies and regulations should reflect current scientific and medical knowledge, including a) advances in HIV screening; b) increased awareness and understanding concerning HIV transmission; c) increased access of Hepatitis B vaccines; and d) decreases in window periods of detection for infectious agents. Scientific and medical progress should trigger a revision in tissue donation eligibility, as the United Kingdom announced in 2023. These policies should be applied to all donors in the same way, regardless of sex, gender, and/or sexual orientation. Additionally, tissue procurement organizations should be able to utilize follow up questioning and testing of living donors (e.g sperm donation), which is not possible under the uniform eligibility criteria for living and deceased tissue donors. Further, GLMA encourages these regulatory bodies to adopt more inclusive language for all donors, including but not limited to MSM; gender-diverse; and LGBTQ+ donors."

American Medical Association (2022)[81]

Blood and Tissue Donor Deferral Criteria H-50.973

"Our AMA: (1) supports the use of rational, scientifically-based deferral periods for donation of blood, corneas, and other tissues that are fairly and consistently applied to donors according to their individual risk; (2) opposes all policies on deferral of blood and tissue donations that are not based on evidence; (3) supports a blood and tissue donation deferral period for those determined to be at risk for transmission of HIV that is representative of current HIV testing technology; (4) supports research into individual risk assessment criteria for blood and tissue donation; and (5) will continue to lobby the United States Food and Drug Administration to use modern medical knowledge to revise its decades-old deferral criteria for MSM (men who have sex with men) donors of corneas and other tissues."

United States Senate (11/29/2021)[82]

Senators Joe Neguse, Tammy Baldwin, David N. Cicilline, Michael F. Bennet, Mike Quigley, Elizabeth Warren, Sherrod Brown, Bernard Sanders, Robert P. Casey, Jr., Richard Blumenthal, Tina Smith, Cory A. Booker, Christopher A. Coons, Alex Padilla, Tammy Duckworth, Jeffrey A. Merkley, Martin Heinrich, Edward J. Markey, Amy Klobuchar
Representatives Carolyn B. Maloney, Katie Porter, Ann Kirkpatrick, Richie Torres, Nikema Williams, Paul Tonko, Ted. W. Lieu, James R. Langevin, Brian Higgins, Mark Pocan, Sara Jacobs, Raúl M. Grijalva, Theodore E. Deutch, Jamie Raskin, Scott H. Peters, Eleanor Holmes Norton, Sylvia R. Garcia, Suzane Bonamici, Jason Crow, James A. Himes, John yarmuth, Mark DeSaulnier, Mondaire Jones, Judy Chu, Linda T. Sánchez, Marie Newman, Barbara Lee, Pramila Jayapal, Mark Takano, Madeleine Dean, Nanette Diaz Barragán, Jan Schakowsky, Ro Khanna

"Dear Secretary Becerra and Acting Commissioner Woodcock:

We write to express our concern regarding the Food and Drug Administration's (FDA) policy
restricting the donation of tissues such as corneas, heart valves, skin, musculoskeletal tissue, and vascular tissue by men who have sex with men (MSM). We also call your attention to the broad consensus within the medical community indicating that the current scientific evidence does not support these restrictions. We have welcomed the FDA's recent steps in the right direction to address its discriminatory MSM blood donation policies and urge you to take similar actions to revise the agency's tissue donation criteria to align with current science so as not to unfairly stigmatize gay and bisexual men.

The FDA's restrictions on MSM tissue donation date back to 1994 Public Health Service guidance stating that any man who has "had sex with another man in the preceding five years" should be disqualified from tissue donation. This policy originated from the discriminatory notion that gay and bisexual men, by virtue of their sexuality, have HIV (human immunodeficiency virus). Unfortunately, the FDA continues to recommend that establishments making donor eligibility determinations disqualify men who have sex with another man in the preceding five years as potential donors of human cells, tissues, and cellular and tissue-based products, based on agency guidance issued in 2007, despite current science and the serious need for tissue donations.

In fact, a recent study in the medical journal JAMA Ophthalmology^1 estimated that between 1,558 and 3,217 corneal donations are turned away annually from otherwise eligible donors who are disqualified because of their sexual orientation, an unacceptable figure given widespread shortages of transplantable corneas. FDA policy should be derived from the best available science, not historic bias and prejudice. As with blood donation, we believe that any deferral policies should be based on individualized risk assessment rather than a categorical, time-based deferral that perpetuates stigma.

In addition to depriving patients of the opportunity to receive life-changing transplant surgeries, the current tissue donation policy unnecessarily stigmatizes and harms the LGBTQ+ community. For example, in July 2013, an Iowa teenager named Alexander "AJ" Betts took his own life after being relentlessly bullied by schoolmates and even teachers about being gay. Though he was allowed to donate his organs (including his heart, lungs, liver, and kidneys), his mother Sheryl Moore was told he was banned from donating his corneas exclusively because he was gay. He was tested for HIV and hepatitis before his organs were donated, and his organ donation saved the lives of six individuals, including another teenager. However, the outdated and discriminatory ban on MSM tissue donation meant that someone was deprived of visionrestoring surgery, while AJ's family suffered one more indignity due to anti-gay stigma.

The five-year deferral period for MSM tissue donors originated at a time when there were no reliable screening tests for HIV and other potentially transplantation-transmissible diseases. In 2021, all tissue donors are required to be screened for HIV and hepatitis using modern testing technology that is highly reliable within days to weeks of viral exposure. Scientific understanding of HIV, including our ability to test tissue donors for HIV, has advanced exponentially in the 27 years since 1994, and we would expect the FDA to update its policies accordingly.

There is broad consensus within the medical community urging the FDA to revise this outdated policy using current evidence. The American Medical Association's Policy H-50.973 states that the AMA "supports the use of rational, scientifically-based…tissue donation deferral periods" and "opposes all policies on deferral of… tissue donations that are not based on evidence." Furthermore, numerous medical organizations have taken the position that a five-year deferral period for MSM tissue donors is no longer evidence-based. These organizations, among others, include the American Academy of Ophthalmology, Eye Bank Association of America, American Association of Tissue Banks, American Society of Cataract and Refractive Surgery, American Academy of Dermatology, American Society of Transplant Surgeons, and Society of Critical Care Medicine, as well as a number of state medical societies.

It is imperative that we move away from discriminatory deferral policies that prohibit individuals from contributing much-needed tissue donations. The time is long overdue for the FDA to use modern evidence to revise its outdated restrictions on tissue donors, in addition to its recent and ongoing work to revise blood donation deferral policies. We ask that you provide us with a briefing in 30 days and a written update on the following:

(1) The FDA's progress in reassessing its policy that includes men who have had sex with another man in the preceding five years as a risk factor for HIV transmission through tissue donation; and

(2) An estimation of when recommendations for policy changes will be announced publicly and when these changes would take effect.

We appreciate your attention to this important issue and look forward to your timely response.

Sincerely,

1: Puente MA, Patnaik JL, Lynch AM, et al. Association of Federal Regulations in the United States and Canada With Potential Corneal Donation by Men Who Have Sex With Men. JAMA Ophthalmol. 2020;138(11):1143–1149. doi:10.1001/jamaophthalmol.2020.3630 "

Global Trends in MSM Tissue Donation Deferment

Similar to the procedures in the United States, most tissue donation occurs after death in other countries, resulting in a systemic lack of knowledge of deferral and eligibility criteria, including any policies that impact MSM. While Pride & Plasma prioritizes identifying global MSM deferment policies ourselves, many of the countries listed in the literature did not publicly release their donor eligibility criteria. If we were unable to obtain a copy of a country's policy, but found a publication that stated a less restrictive policy, that country is included with an asterisk.

Countries for Which We Obtained Documents

United Kingdom[83, 85]

- 2010: Working group reviewed ongoing deferral for MSM.
- 2013: Updated policy implemented a 12-month deferment for MSM
- 2017: Recommended a 3-month deferral (a reduction from the previous 12-month policy)
- 2023: Transition to individual risk assessment accepted.

Chile[84]

- 2018: Risky Sexual Behavior is identified as a new sexual partner in the past 12 months, no mentions of MSM or sexual orientation-based deferrals.

Countries Which We Communicated With*

Netherlands

- 4-month deferral policy for tissue donation

Countries Reported to have Shorter Deferral Policies for Cornea Donation by Puente et al.[7]*

Canada

- 12-month deferral for tissue donation from MSM

France

- 4-month deferral for MSM corneal donors

Countries With No MSM Deferral

- Spain
- Italy
- Mexico
- Chile
- Argentina

Petition Signatures

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Recommendations

1- Donor Eligibility

Route 1: Our Recommendation:

Our Recommendation (1/5): We recommend the removal of the 5-year deferral period for men who have sex with men. Five years is significantly longer than the necessary time period to ensure accurate testing of tissue donors, and the repeated deferral of MSM donors upholds the stigma that queer men are synonymous with HIV, infection, and illness.

Recommendation Cont. (2/5): We recommend a definition as to what "had sex" refers to. The varying routes of sexual contact (oral, vaginal, and anal intercourse) have different risks of all STI transmission, and should not be treated the same.

- We Recommend Specifying sexual activity to include vaginal and/or oral sexual activity.

Our Recommendation Cont. (3/5): We also recommend that the FDA include a line of recommendation to tissue banks to implement gender affirming practices. The 2020 blood donation guidance included:

> "*In the context of the donor history questionnaire, FDA recommends that male or female gender be taken to be self-identified and self-reported*".

This isn't perfect language, we would prefer to see inclusion for nonbinary and gender nonconforming donors, but it is a step in the right direction. The 2023 updated blood donation eligibility criteria removed this line. And while it was removed along with all gendered language, not every blood center (and tissue bank) is gender affirming. Federal policies that consider this and push to ensure equality and accessibility in a time where we frequently see shortages is critical. **We recommend including the following**:

- **"In the context of the family questionnaire, as well as donor screening and assessment, FDA recommends that donor gender identity (male, female, or other) be taken into account and applied accordingly"**

Recommendation Cont. (4/5): We recommend that along with the revision of the MSM criteria, the deferral criteria for any women who have had sexual contact with a MSM donor be removed.

Recommendation Cont. (5/5): Implement separate screening criteria and support a separate screening questionnaire for deceased and living donors. The ability for living donors (ex. sperm, oocyte) to speak with an employee greatly improves the accuracy of a screening questionnaire and allows for an individual risk assessment. Further, with sperm

and oocyte donation, living donors have the ability to go through repeat rounds of testing to ensure that a potential testing window does not lead to false negatives for infectious agents.

Route 2: Blood Donation

Our Recommendation (1/3): Follow the blood donation guidance. The FDA's Center for Biologics Evaluation and Research handles both blood donation and tissue donation policies. Rather than a 5-year deferment policy (and a 12-month deferment policy for women who have had sex with queer men) **we recommend replacing the text with the reciprocal text as the blood donation policy**:

- "from the most recent sexual contact, an individual who has had a new sexual partner in the past 3 months **and** who has had anal sex in the past 3 months."
- "from the most recent sexual contact, an individual who has had more than one sexual partner in the past 3 months **and** who has had anal sex in the past 3 months"

Recommendation Cont. (2/3): We also recommend that the FDA include a line of recommendation to tissue banks to implement gender affirming practices. The 2020 blood donation guidance included:

> "*In the context of the donor history questionnaire, FDA recommends that male or female gender be taken to be self-identified and self-reported*".

This isn't perfect language, we would prefer to see inclusion for nonbinary and gender nonconforming donors, but it is a step in the right direction. The 2023 updated blood donation eligibility criteria removed this line. And while it was removed along with all gendered language, not every blood center (and tissue bank) is gender affirming. Federal policies that consider this and push to ensure equality and accessibility in a time where we frequently see shortages is critical. **We recommend including the following**:

- **"In the context of the family questionnaire, as well as donor screening and assessment, FDA recommends that donor gender identity (male, female, or other) be taken into account and applied accordingly"**

Recommendation Cont. (3/3): We recommend that along with the revision of the MSM criteria, the deferral criteria for any women who have had sexual contact with a MSM donor be removed as well.

This is the same policy taken into effect by the United Kingdom in September of 2023, as recommended by the FAIR III Working Group.

Route 3: Organ Donation

Our Recommendation (1/5): Follow the Department of Health and Human Services' and Public Health Services' *Assessing Solid Organ Donors and Monitoring Transplant Recipients for Human Immunodeficiency Virus, Hepatitis B Virus, and Hepatitis C Virus Infection*"[1]. In 2020, a revision to the MSM organ donor eligibility was released. This policy reduced the former time frame from 12-months to 30-days, under the recommendation of the HHS Advisory Committee for Blood and Tissue Safety (a reduction to 3-months), followed by evidence from the CDC (30 days). The 2020 update included:

> *"Risk criteria (during the 30 days before organ procurement):"*
>
> > *"2. Man who has had sex with another man"*

We recommend usage of reciprocal language:

- **"Men who have had sex with another man in the preceding 30 days"**

Recommendation Cont. (2/5): We recommend that along with the reduction of the MSM time frame, the deferral criteria be replaced with a labeling system to replace a deferral questionnaire. Of "Increased risk donor", "high-risk donor", or "MSM donor." Although tissue donations are not frequently life-saving at the rate of which organ donations are, tissue donations have a potential to significantly alter a recipient's quality of life. Donors should have the opportunity to accept or decline an organ transplant, knowing the potential risks. This will ensure greater access to care and treatment, as well as faster treatment which will prevent the development and severity of complications and negative health outcomes.

Recommendation Cont. (3/5): We recommend that along with the revision of the MSM criteria, the 12-month deferral criteria for any women who have had sexual contact with a MSM donor be removed as well.

Recommendation Cont. (4/5): We recommend a definition as to what "had sex" refers to. The varying routes of sexual contact (oral, vaginal, and anal intercourse) have different risks of all STI transmission, and should not be treated the same.

- We Recommend Specifying sexual activity to include vaginal and/or oral sexual activity.

Recommendation Cont. (5/5): We include a statement to support gender-affirming practices for transgender and nonbinary donors. Similar to the 2020 Blood Donation Eligibility Criteria, we recommend including:

- **"In the context of the family questionnaire, as well as donor screening and assessment, FDA recommends that donor gender identity (male, female, or other) be taken into account and applied accordingly"**

2- Classification of Living vs Cadaveric Donors

Recommendation: We recommend revising the *Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)* into two separate guidances. The screening and testing capabilities of living donors and cadaveric donors are vastly different. Living donors are able to provide in-depth questionnaires directly. Create a separate set of policies for living donors in addition to the existing criteria for cadaveric donors.

Part 1: Quarantined Donations

Recommendation: We recommend removing deferral criteria related to infectious agents for quarantined donations that are repeatedly tested.

> *With sperm donation, potential donors are tested multiple times over a 3-month period, a 6-month period, or longer intervals. During this time, the initial and subsequent donations are held in quarantine. If a donor routinely tests negative for infectious agents, the initial donations are released for recipients. The window-period for effective testing is bypassed due to the repeat testing of donors.*

Part 2: Non-Quarantined Donations

Recommendation: We recommend introducing longer, more in-depth questionnaires for the donor, that assess number of sexual partners, the route of sexual activity performed, frequency, safe and safer sex methods, recent testing, and other risk factors that would not be effectively screened for when interviewing individuals other than the donor.

Citations

For clarity, the sources used in the 2007 guidance "Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)" for the 5-year MSM deferment are identified using the identical numbering. These are numbered 17-46 in both this document, and the eligibility criteria.

As sources 20, 38, and 41 were conference presentations, and were unable to be obtained, these numbers have been omitted from our citations list. Additionally, we believe that source 35 in the 2007 guidance was improperly cited, as the title was the same as source 43. For this reason, citation number 35 was also omitted.

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