

U.S. Sen. Baldwin, Colleagues: Push FDA to end discriminatory tissue donation policy

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Washington, D.C. – U.S. Senators Tammy Baldwin (D-WI), Michael Bennet (D-CO), Elizabeth Warren (D-MA), and Congressmen Joe Neguse (D-CO), David Cicilline (D-RI), and Mike Quigley (D-IL), are leading a bicameral effort in asking the U.S. Food and Drug Administration (FDA) to review and update its longstanding policy recommending the disqualification of men who have had sex with men (MSM) in the preceding 5 years as potential tissue donors for corneas, heart valves, skin, and musculoskeletal and vascular tissue.

These guidelines, which have not been significantly updated since 1994, have contributed to a significant shortage of needed tissue products nationwide, including most critically an acute need for donor corneas. 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. The broad consensus among the medical community indicates that the current scientific evidence does not support these discriminatory restrictions.

In a letter to Health and Human Services Secretary Xavier Becerra and Acting FDA Commissioner Janet Woodcock, the members of Congress wrote:

“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.”

“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,” **they continued.** “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.”

The group of members from the Senate and House requested a written update on the FDA’s progress in reassessing its policy. They also requested an estimate of when recommendations for policy changes would be announced publicly and when these changes would take effect.

“The discriminatory practice of focusing narrowly on men who have sex with men in determining who is allowed to donate certain tissues does not reflect current science, limits access to needed tissues, and continues to unfairly stigmatize one segment of society,” **said David Stacy, Government Affairs Director of the Human Rights Campaign.** “The FDA instead should focus its considerations for tissue donation deferrals on risky behavior by any potential donor, regardless of one’s sexual orientation. This would both advance equal rights and help maximize safe access to the nation’s supply of organ tissue.”

The letter was signed by Senators Tammy Duckworth (D-IL), Tina Smith (D-MN), Amy Klobuchar (D-MN), Sherrod Brown (D-OH), Bernard Sanders (I-VT), Richard Blumenthal (D-CT), Bob Casey (D-PA), Cory A. Booker (D-NJ), Chris Coons (D-DE), Alex Padilla (D-CA), Jeff Merkley (D-OR), Martin Heinrich (D-NM), Ed Markey (D-MA), and Amy Klobuchar (D-MN), and U.S. Representatives Carolyn B. Maloney (D-NY),

Katie Porter (D-CA), Ann Kirkpatrick (D-AZ), Ritchie Torres (D-NY), Nikema Williams (D-GA), Paul Tonko (D-NY), Ted W. Lieu (D-CA), James R. Langevin (D-RI), Brian Higgins (D-NY), Mark Pocan (D-WI), Sara Jacobs (D-CA), Raul Grijalva (D-AZ), Ted Deutch (D-FL), Scott Peters (D-CA), Eleanor Holmes Norton (D-DC), Jamie Raskin (D-MD), Sylvia R. Garcia (D-TX), Suzanne Bonamici (D-OR), Judy Chu (D-CA), Jason Crow (D-CO), Jim Himes (D-CT), John Yarmuth (D-KY), Mark DeSaulnier (D-CA), Mondaire Jones (D-NY), Linda T. Sánchez (D-CA), Marie Newman (D-IL), Barbara Lee (D-CA), Pramila Jayapal (D-WA), Mark Takano (D-CA), Madeline Dean (D-PA), Nanette Diaz Barragán (D-CA), Jan Schakowsky (D-IL), and Ro Khanna (D-CA).

A full version of this letter is available [here](#) and below.

An online version of this release is available [here](#).

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* 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 vision restoring 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.