



Congress of the United States

November 29, 2021

The Honorable Xavier Becerra
Secretary
Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Dr. Janet Woodcock
Acting Commissioner
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

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

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

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.


Sincerely,



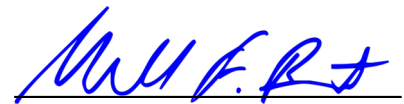
Joe Neguse
Member of Congress



Tammy Baldwin
United States Senator




David N. Cicilline
Member of Congress




Michael F. Bennet
United States Senator




Mike Quigley
Member of Congress



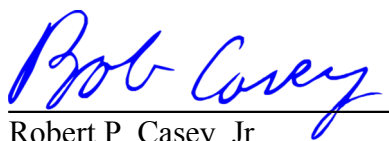
Elizabeth Warren
United States Senator




Sherrod Brown
United States Senator



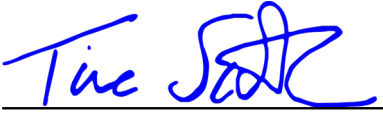
Bernard Sanders
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Robert P. Casey, Jr.
United States Senator



Richard Blumenthal
United States Senator



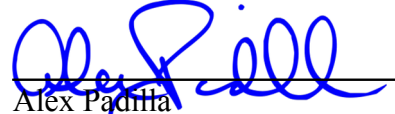
Tina Smith
United States Senator



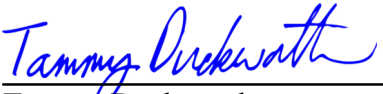
Cory A. Booker
United States Senator



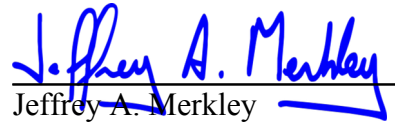
Christopher A. Coons
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Alex Padilla
United States Senator



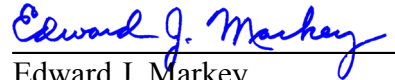
Tammy Duckworth
United States Senator



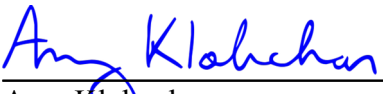
Jeffrey A. Merkley
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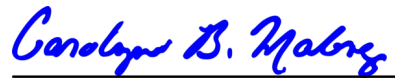
Martin Heinrich
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Edward J. Markey
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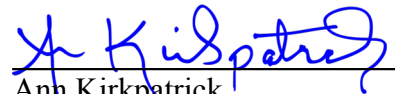
Amy Klobuchar
United States Senator



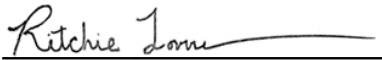
Carolyn B. Maloney
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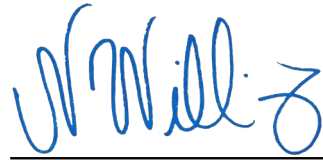
Katie Porter
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Ritchie Torres
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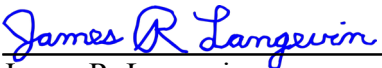
Nikema Williams
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Paul D. Tonko
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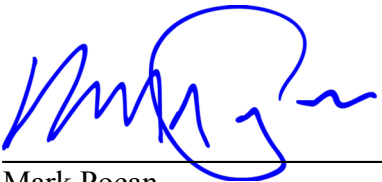
Ted W. Lieu
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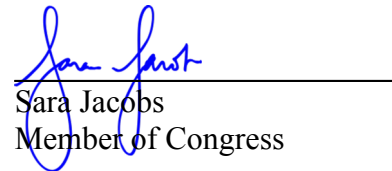
James R. Langevin
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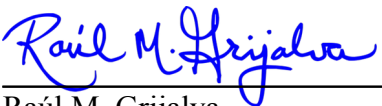
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Theodore E. Deutch
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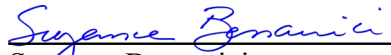
Scott H. Peters
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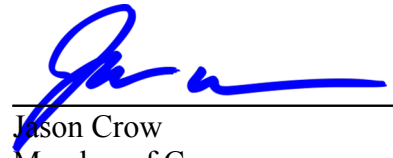
Eleanor Holmes Norton
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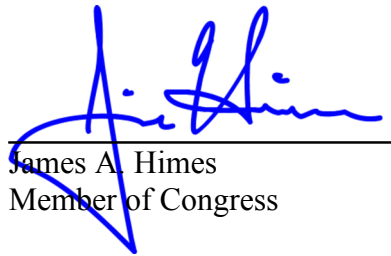
Sylvia R. Garcia
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Suzanne Bonamici
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James A. Himes
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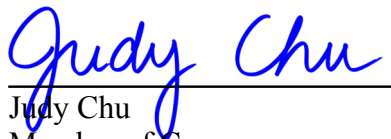
John Yarmuth
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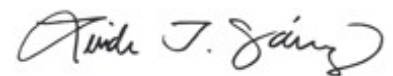
Mark DeSaulnier
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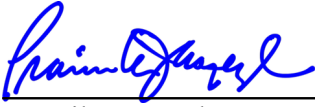
Linda T. Sánchez
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Marie Newman
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Barbara Lee
Member of Congress



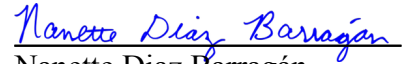
Pramila Jayapal
Member of Congress



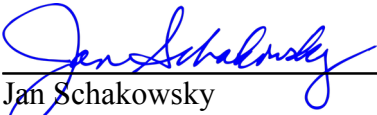
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