

Food And Drug Administration- Blood Products Advisory Committee

# Request for Revision of MSM Blood Donation Deferment Policy

11/28/2022

Pride and Plasma

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Letter

Dear Food and Drug Administration Blood Product Advisory Committee,

Since 1985, the FDA has turned away healthy queer men from donating blood due to the Blood Donation Deferment Policy.<sup>1</sup> Furthermore, the retroactive language of the policy impacted any man who was sexually active with another man since 1977.<sup>1</sup> 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 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 1980s at the height of the epidemic.<sup>1</sup> 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 Blood Donation Deferment Policy to match these changes and end the discriminatory practice of turning away sexually active queer men.

The FDA and Blood Products Advisory Committee has made previous steps towards ensuring equality in blood donations. The transition in 2015 from a lifetime deferment to a 12-month period was a step in the right direction. The transition in 2020 from a 12-month deferment to a 3-month period was a step in the right direction.<sup>1</sup> However, they still make judgments and assumptions based on an individual's sexuality, an unalterable trait. Asking queer men for celibacy while heterosexual individuals have no restrictions upon their sexual activity is a double standard. The policy also does not account for individual high-risk activities, such as sexual contact with multiple partners, methods of sexual activity, and participating in unprotected sex. The policy turns away healthy queer men with relatively low risk while allowing high-risk heterosexual donors to continue to donate. The policy is not effective in what it means to do-protect the blood supply.

However, advances in testing and diagnostic screenings of blood donations have ensured that the risk of transmission of HIV after testing is 1 in 1.5 million.<sup>2</sup> Nucleic Acid Testing was implemented on a national scale in 1999, 14 years after the implementation of the MSM Deferment Policy.<sup>3</sup> NAT is still the best practice utilized by blood donation facilities across the country. NAT allows for HIV to be detected in a blood donation within 10-33 days, significantly less than the current 3-month deferment period.<sup>4</sup>

There is no generic or synthetic replacement for donations of human blood products. This means that amid a critical national shortage of blood products, blood centers, medical facilities, healthcare providers, and patients cannot afford to turn away healthy donors. Blood banks have seen a low turnout of donors since August of 2021, with the Red Cross classifying the current shortage as the "worst blood shortage in over a decade" this year.<sup>5</sup> Addressing the shortage will require solutions from various areas, but allowing healthy queer men the right to donate could allow over 4.2 million new donors.<sup>6</sup> Testimony from blood centers on the impact of the current shortage is included in the brief. Facilities, providers, and patients are in dire need, and the FDA and BPAC have the authority and obligation to ensure they can assist those in need. The alterations to the policy, such as the reinstatement of donation privileges to those previously deferred under restrictions related to Creutzfeldt-Jakob Disease this year show an understanding of the need to ensure that all healthy donors can give blood.<sup>7</sup>

An Individual Risk Assessment is one potential transition from the blanket deferment policy for MSM donors. However, unless implemented for all donors, an IRA screening would be yet another hoop that queer men are forced to jump through while heterosexual individuals are deemed to have no risk of blood-borne diseases. All potential blood donors can transmit HIV and other blood-borne diseases. Screening every person who wishes to donate blood for high-risk

activities, and deferring those who pose a risk above a certain threshold, without holding those of a specific sexuality to a different standard, is a way to ensure equality and prevent discrimination within blood donations and health care at large. This is what the ADVANCE Study is working towards and researching, a project which we wholeheartedly support and an organization which we have been proud to partner with.

The United States prides itself on being a leader in various industries but has not followed the progress that many other nations have made in MSM blood donation deferment. Countries such as Canada<sup>8</sup>, France<sup>9</sup>, Israel<sup>10</sup>, Mexico<sup>11</sup>, Greece<sup>12</sup>, and more have zero restrictions based upon the sexuality of queer men; Germany<sup>13</sup>, the United Kingdom<sup>14</sup>, and others may provide deferment based upon high-risk activities such as multiple partners, but the language of these policies do not explicitly target queer men. We urge the Committee to follow the leadership and initiative of global leaders and restore the right to donate blood to queer men.

We have enlisted the support of the general public, LGBTQ community centers, medical and professional associations, and companies to help show support for a policy change. Their statements, comments, and names are listed in this brief. 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. We thank you for your time and look forward to your decision.

Sincerely,

Pride and Plasma

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*qui n'etait plus justifiee. #DonDeSang* [Tweet]. Twitter.

[https://twitter.com/olivierveran/status/1480918116880240643?ref\\_src=twsrc%5Etfw%7Ctwcamp%5Etweetembed%7Ctwterm%5E1480918116880240643%7Ctwgr%5E%7Ctwcon%5Es1 &ref\\_url=https%3A%2F%2Fwww.advocate.com%2Fworld%2F2022%2F1%2F12%2Ffrance-lifted-homophobic-blood-ban-men-who-have-sex-men-queer](https://twitter.com/olivierveran/status/1480918116880240643?ref_src=twsrc%5Etfw%7Ctwcamp%5Etweetembed%7Ctwterm%5E1480918116880240643%7Ctwgr%5E%7Ctwcon%5Es1&ref_url=https%3A%2F%2Fwww.advocate.com%2Fworld%2F2022%2F1%2F12%2Ffrance-lifted-homophobic-blood-ban-men-who-have-sex-men-queer)

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### Evidence

Blood donation is critical to providing care and performing life saving procedures for patients. The importance of maintaining a safe and secure national blood supply is necessary to prevent widespread transmission of blood-borne diseases and to ensure that treatments improve the health of patients, rather than worsening their conditions. Therefore, the FDA's deferment policy makes sense in theory, however certain deferral characteristics and their application unfairly discriminate against already marginalized populations- namely queer men, or as labeled by the scientific research and the policy itself- "men who have sex with men" or "MSM". This policy was implemented before the current advances in science and testing led to understanding of HIV and its transmission. While blood donation as a whole has followed the changes in science and advances in testing, the donation policy impacting MSM donors has not. It is past time for the FDA and the Blood Products Advisory Committee to end this policy's implementation- and far past time for queer men to have their right to donate blood returned.

The scope of HIV has changed drastically in the past 40 years. When HIV was first caught, it was associated with lung infections. Additionally, there were 270 cases and 120 deaths in 1981, the year with the first documentation, and the term AIDS wasn't used for another year, until 1982 (RED, 2018). By 1985 the crisis had reached a critical stage, with more cases that year than all the previous years combined (HIV.gov). The FDA needed to step in to prevent widespread transmission of the virus through blood donations. The deferment policies enacted in this period were necessary to prevent widespread transmission of HIV- they are no longer needed.

ELISA (enzyme-linked immunosorbent assay) was the first test approved to screen for HIV through blood, and wasn't approved until 1985 (HIV.gov). By that time there had been



7,669 cases documented of HIV, with 48% resulting in deaths of the patient (Center for Infectious Diseases, 1984). However, it wouldn't be until 1999 that Nucleic Acid Testing would be the national standard for HIV screening of blood donations (Kornman et. al., 1999). This was 14 years after the MSM deferral policy was implemented, and impacted queer men who had been sexually active within the past 22 years. The incidence of HIV in the United States had decreased 73% from 1985 to 2019 (Bosh et al., 2021).

With the transition and implementation of nucleic acid testing, the risk of HIV transmission has significantly decreased. The CDC reports that the risk of HIV transmission through blood products after screening is 1 in 1.5 million (Centers for Disease Control and Prevention, 2010). Additionally, the testing allows for detection of HIV within 10-33 days, significantly shorter than the current deferral period of 3 months (Centers for Disease Control and Prevention, 2022). The 3-month deferral period is longer than necessary to ensure accurate testing, a 1 month or even 45-day deferral policy for donors would be sufficient. However, singling out MSM donors is still a double standard. All donors can be hosts and incubators of HIV, so all donors should be subject to the same risk-based deferral policies, as all donations are tested the same.

Other deferral activities such as sharing needles, non-prescription drug injection, and contact with blood products of another individual all increase a potential donor's risk of HIV. Being queer does not, high risk sexual activity increases the risk of transmission of HIV and other sexually transmitted infections, but HIV is not a queer disease, anyone can transmit it. The policy is remnant of when HIV was both poorly understood and when testing was ineffective. This is no longer the case.

This stigma that HIV and AIDS are "gay diseases" is not only factually incorrect, but demonizes the LGBTQ community further when legislators and bigots already are constantly working to harm queer individuals. "36% of women and 44% of men 25-44 years old in the United States reporting ever having HAI [heterosexual anal intercourse] in their lifetime" (Hess et al., 2017, p. 5). If the deferment policy was for type of sex, these donors should also be deferred. However, with deferral still applied for oral sex, which has a significantly lower risk of HIV (National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, 2016). Without exceptions for protected sex, the policy's message is clear- queer men are held to a higher standard than their heterosexual counterparts.

The policy changes in 2015 and 2020 were steps in the right direction. Vitalant, one of the nation's largest blood centers, found that there was no increase in HIV through blood donations after the transition from the lifetime to the 12-month policy (Grebe, et al., 2020). However, they have not been enough. While we applaud the work of the ADVANCE Study and wholeheartedly support a transition to an Individual Risk Assessment, it is important to note that no new research was shared with the transitions from a lifetime deferral, nor from the 12-month to 3-month period. We are asking for equality. Queer men deserve the right to give blood just as everyone else- something all the more important during the current national blood shortage.

The Policy makes no exceptions for donors in monogamous relationships, those who practice safe sex, or who are tested on their own. Male condoms, when used correctly can reduce the risk of HIV by up to 90% (United States Agency of International Development, 2016). Queer men who take pre-exposure prophylaxis prescription lower that risk even further. The blanket deferment policy turns away men with low or negligible risk if they are queer, while allowing heterosexual individuals with high risk (multiple sexual partners, unprotected sex, and unknown

STI status) to donate. The policy is not only a double standard, but it is ineffective. High risk donors are allowed to give blood while low risk individuals are turned away based upon their sexuality. The national blood supply is still at risk.

The United States prides itself on being a leader in healthcare. We create new medications and treatments, have world-class medical facilities, but in blood donation equality, we lag behind. While MSM blood donation deferment policies are not exclusive to our country, many nations have revised their policies, but we have not. Although we did not research the blood donation policies of every nation, those we included show the vast difference in treatment of queer men in the medical sector.

On September 11, 2022, Canada revised their new blood donation deferment policy, now asking if they have had new or multiple sexual partners, and if the donor had anal sex with any of these partners. This allows for queer men who participate in other forms of sexual activity, or those in monogamous relationships to donate blood. Canada's MSM blood donation policy was also implemented in the 1980s, with a transition to a 5-10 year deferment period in 2011, a 5 year period in 2013, 3 months in 2019, prior to the new questions, which are set to be implemented on 12/4/2022 (Canadian Blood Services, 2022). There is no question that asks about the gender of the donor or any of their partners.

France currently has no deferral period for sexually active queer men who wish to donate. In 1983, France implemented a lifetime deferral for queer men, which was revised in July of 2016 to a 12-month period, followed by a 4-month period on 2/1/2020. The current policy was implemented on 3/16/2022. New questions include exposure to HIV with pre-exposure or post-exposure prophylaxis, as well as medications and prescriptions, but no questions ask the donor's sexuality (Association for the Advancement of Blood & Biotherapies, 2022).

Israel's procedure blood donation deferment is uniform for all donors regardless of gender or sexual orientation. If a donor participates in high-risk sexual activity, or has multiple partners, they are deferred for 3 months. There are no questions related to sexual orientation. This is after a research study where queer men who had been sexually active within the past 12 months donate a pint of blood, which was frozen for 4 months. After the 4 months, the donor attempted to donate again, if both donations are negative for HIV, plasma donations were accepted. From the 1980s to 2017 a lifetime deferment policy was in place. The new practice was announced on 8/19/2021 for implementation in the same year (Spiro, 2021).

Mexico has allowed queer men to donate blood if they practice safe sex through the use of condoms since 12/27/2012. In 1993, queer men were given a lifetime deferral. Additionally, Mexico was the first North American country to lift their practice of turning away queer men from donating (McAdam & Parker, 2014).

Greece implemented a lifetime deferment policy in the 1980s, similar to the United States. This policy was revised on 1/10/2022, with questions related to sexual orientation being removed. (Association for the Advancement of Blood & Biotherapies, 2022).

The United Kingdom currently allows queer men to donate if they have been in a monogamous relationship for greater than the previous 3 months. Deferral qualifications include anal sex with a new or multiple partner(s) within the past 3 months. These are revisions to the previous deferral criteria which included a 12-month period in 2011, a blanket 3-month period in November 2017, and 3-months with an exception for monogamous donors in June of 2021 (Blood and Transplant).

Germany requires queer men to wait 4 months to donate blood if they have a new or multiple sexual partner(s). Heterosexual donors with "frequently changing partners" are also

deferred. Men who are in monogamous relationships have no deferral requirements (Association for the Advancement of Blood and Biotherapies, 2021).

There have been numerous previous attempts to revise this policy. Most notable was the National Gay Blood Drive from 2013-2015, which was instrumental in revising the lifetime deferral policy. Representative Adam Schiff (CA-28) has introduced two House Resolutions (Expressing the sense of the House of Representatives that blood donation policies in the United States should be equitable and based on science, 2020) (Expressing the sense of the House of Representatives that blood donation policies in the United States should be equitable and based on science., 2021). Although these attempted to revise the policy, the Blood Products Advisory Committee has revised the policy without external pressure, as seen with the 2020 revision to 3-months and this year's revisions for deferral of donors related to Creutzfeldt-Jakob Disease. The FDA's updated guidance for blood pressure and pulse recommendations on 5/23/22 also expanded the pool of eligible donors. The ADVANCE Study has been working to determine the safety of a transition to an individual risk assessment, and we are proud to have partnered with them. Doing what is right should not take this many people working tirelessly for this many years.

The need for blood donations is more critical than ever, with the American Red Cross classifying the current shortage as the worst in decades (2022). In our partnerships with national and regional blood centers, testimony stated that facilities are unable to meet the demand. The end of the MSM deferral policy would have a strong impact upon the national blood supply. In Canada, 77% of MSM donors reported willingness to donate if given the ability (Grace et al., 2020). Similar numbers can be expected in the United States.

The Blood Product Advisory Committee's and FDA's own actions on updating deferment policies show an understanding of this shortage and the impact it has on patients. There is no replacement for human blood products. Facilities cannot function under current conditions and cannot afford to turn away healthy donors- especially for a reason as trivial as sexuality.

The blood products deferment policy for MSM donors is discriminatory. It turns away healthy donors for something that they cannot change, their sexuality. Turning away low-risk queer men while continually allowing high-risk heterosexual donors and queer women is a double standard. In the midst of the worst blood shortage in a decade, blood banks cannot afford to turn away healthy donors. We urge you to continue the revisions that have been made in the past years regarding MSM donors, as well as those made in past months regarding general eligibility. In the interests of patients losing access to care and procedures, blood banks suffering in a shortage, and queer men being discriminated against we ask you to reinstate the right to donate blood and save lives to MSM donors. We recommend a removal of the MSM deferment policy, and a transition to an individual risk assessment to all donors, regardless of gender or sexual orientation. We look forward to the results from the ADVANCE Study and to your decision.

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### Testimony on the Current Blood Products Shortage

#### **ImpactLife 8/8/2022**

"ImpactLife faces many challenges, as do other blood centers around the country, in meeting the demand for blood and blood products. These challenges have included impacts from COVID, staffing shortages, and schools and businesses cutting back on hosting drives. We have had to reduce our blood-collection capacity at many of our operations due to these challenges. ImpactLife strongly supports updating the deferral for men who have sex with men to an evidence-based deferral. For more information on ImpactLife's support of the LGBTQIA+ community, please follow <https://www.bloodcenter.org/about/initiatives/dei/pride/>."

#### **Carter BloodCare 8/8/2022**

"The need for blood is urgent and nonstop. We strongly support initiatives for donor-screening alternatives that are inclusive, safe, and not based on sexual or gender identity. We urge elected representatives to support change that reflects our entire community and provides everyone the equal opportunity to make a lifesaving difference."

#### **LifeStream Blood Bank 8/9/2022**

"LifeStream Blood Bank's supply levels for all blood types has been critically low for months due to the ongoing blood shortage. LifeStream serves over 80 hospitals in Southern California. We do not have enough blood on the shelf to meet all hospital patients' needs. We have consistently had under two days of total supply on hand, which threatens lifesaving treatments for the patients we serve. LifeStream supports efforts to encourage FDA modification of the guidance regarding gay men and blood donation."

#### **San Diego Blood Bank 11/28/2022**

"San Diego Blood Bank continues to face our worst shortage of donated blood in over a decade. While we have a long-standing and supportive community of donors that have answered the call to donate blood during the pandemic, we are constantly challenged to meet the demands of the hospitals which we support. On any given day, we may have less than one days' supply of certain blood components on-hand. This hardship is anticipated to continue or worsen in the upcoming respiratory virus season and over the course of the holidays."

Press Releases & Statements on the MSM Deferment Policy

**GLAAD 4/16/2020- "Open Letter to FDA from Medical Professionals"**

"We -- the undersigned infectious disease and HIV specialists, public health professionals, clinicians, healthcare administrators, trainees and researchers -- recommend an immediate reevaluation of the FDA's 2018 "Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products" and an overturning of the scientifically outdated ban against MSM blood donors.

As you well know, we are on the precipice of a critical nationwide shortage of blood products. On March 18, 2020, Surgeon General Jerome Adams pleaded with the American public for blood donations in the wake of an unprecedented number of blood drive cancellations due to the COVID-19 pandemic, resulting in an estimated 86,000 blood donations according to the American Red Cross. This severe shortage could be alleviated if antiquated restrictions lacking scientific data were responsibly lifted. According to a 2014 study by the Williams Institute at UCLA School of Law, eliminating the MSM ban would result in an estimated 360,600 MSM donors being able to donate an additional 615,300 pints of blood per year. Moreover, lifting the MSM ban would increase the number of convalescent plasma donors, a promising treatment for COVID-19.

We are collectively obligated to immediately create policies and promote public health interventions that effectively address the many downstream crises created by the COVID-19 pandemic.

Since the 1985 blood donation ban against MSM, the science of HIV testing -- particularly the use of pooled nucleic acid testing -- has revolutionized our capacity to identify individuals with HIV attempting to donate blood. HIV nucleic acid testing is nearly 100% sensitive and narrows the window period to a approximately 10 days from the time of infection. Banning men from blood donation for at least a year since their most recent sexual encounter with a man is unscientific and based on outdated antibody-based HIV testing algorithms. Fortunately, we can reliably test for HIV using antigen-based assays and maintain the safety of the U.S. blood supply.

While the FDA's recent decision to shorten the prohibition window to 3 months is a step in the right direction, it does not go far enough in reversing the unscientific ban.

A broad ban against MSM blood donors does not take into account the actual risk behavior in question that could jeopardize blood supply safety -- very recent condomless anal or vaginal intercourse with a partner with HIV viremia -- engaged by those regardless of sex, gender, and/or sexual orientation. Mexico, Russia, as well as several countries in Europe, Central America, South America, and Asia have no MSM ban on blood donation. Many countries, such as Italy and South Africa, have adopted a more rational, evidence-based, and effective risk-based assessment instead of blanket bans which only serve to stigmatize a group of potential donors and limit the pool of donors at this critical juncture in public health. A 2013 study found that after eliminating the MSM blood donation ban in Italy, there was no increase in the proportion of donors found to have HIV who were MSM versus non-MSM. Policies and protocols which focus on targeted screening for specific high-risk behaviors, regardless of sexual orientation, are a much more scientifically rigorous and non-discriminatory approach to maintaining a safe blood supply. In fact, MSM in monogamous relationships, those on Pre-exposure Prophylaxis, and those who consistently use condoms have a particularly low risk of HIV acquisition.

While changing policy and implementing such changes in the field are logistically challenging, the COVID-19 pandemic is asking us to step up and revise regulations that no longer serve the greater good. We are not advocating for relaxing standards that would compromise the safety of our blood supply. Instead, we advocate for scientifically-driven standards that uphold the utmost safety of the blood supply and simultaneously promote equity and reverse historical discrimination in blood donation.

As such, we recommend an immediate reevaluation of the FDA's 2018 "Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products" and an overturning of the scientifically outdated ban against MSM blood donors."

## **Association for Advancement of Blood & Biotherapies 10/18/2021- "What's Next for MSM Deferral Policies?"**

"Blood donation policies for men who have sex with men (MSM) have been the subject of much attention in recent years. Throughout the world, countries are reexamining their policies; many have reduced deferral times for MSM, while others have eliminated them altogether or implemented alternative policies to address infectious disease risk. In the United Kingdom, for example, a new donor eligibility process was implemented this summer in which all blood donors - regardless of gender - are asked about recent sexual activity. Similarly, in Italy and Spain, MSM are no longer addressed in deferral policies; instead, the deferral policies are based on alternative criteria.

In the United States, the MSM deferral was reduced from "if even one time since 1977" to 12 months in 2018; it was reduced further - to three months - last year. Currently in the United States, the Assessing Donor Variability And New Concepts in Eligibility (ADVANCE) study is ongoing and is designed to evaluate behavioral screening questions. The results will help determine if alternative deferral policies are feasible.

The 2021 AABB Annual Meeting session titled "Hot Topic: Men Who Have Sex with Men (MSM) - Movement Toward Individual Risk Assessment" provided updates on the latest news with MSM policies and the ADVANCE study. Sponsored by the AABB Donor History Task Force and the ISBT Transfusion Transmitted Infectious Diseases Working Party, the session also offered insight on MSM deferral policies throughout the world.

Brian Custer, PhD, MPH, vice president of research and scientific programs at Vitalant, discussed the evolution of MSM deferral policies in the United States in recent years before highlighting the ADVANCE study, for which he is the principal investigator. Custer noted that the study is funded by the FDA and was designed through a collaborative process called the Blood Equality Working Group.

"The ADVANCE study is designed to provide FDA with evidence by which to consider alternatives to the blood donor deferral policy for MSM while maintaining the safety of the blood supply," Custer said. "The study's primary objective is to conduct an initial assessment of the discriminant function of revised donor history questions for predicting recent infection with HIV in MSM who wish to donate blood." Custer noted that there are currently about 650 participants enrolled in the study out of a goal of 2,000.

Mindy Goldman, MD, medical director of donation policy and studies at Canadian Blood Services, offered insight about the Canadian experience with MSM deferral policies. "The Canadian federal government funded a MSM research program to inform the development of alternative screening approaches in February 2017," she said, "A second federally funded program focused on operational preparedness for implementation for source plasma began in August 2019."

She said these research programs led the way for a "successful implementation of progressively shorter time-based deferrals, with no change in HIV rates, risk per unit transfused, or compliance."

In addition, Health Canada is currently reviewing a proposed policy that would move to a gender-neutral, risk-based behavior criteria for all blood donors. Goldman said the policy must still undergo additional assessment, including a review of a risk model and a post-implementation surveillance plan. "The review will take several months and, if approval is received, implementation could occur in the first half of 2022," she said.

## **United States Senate 1/13/2022- "Senator Baldwin Calls on FDA to Change Discriminatory Blood Donation Policies to Address National Blood Supply Shortage"**

"WASHINGTON, D.C. - Today, U.S. Senator Tammy Baldwin led a group of Senators formally calling on Department of Health and Human Services (HHS) Secretary Becerra and Food and Drug Administration (FDA) Acting Commissioner Woodcock to act on the most up to date science and update its discriminatory blood donor deferral policies for men who have sex with men (MSM). With the Red Cross declaring its first-ever national blood shortage that is posing risks to patient care, with as much as one-quarter of hospital blood needs not currently being met, the FDA can take the long overdue step to remove the discriminatory practice, increasing the eligible blood donor base and helping address the crisis.

In addition to decreasing the eligible donor base and depriving patients of needed blood, the current three month donor deferral blood donation policy for MSM 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, and that a policy focused on individual risk assessment rather than an effective ban on gay and bisexual men would be far more appropriate.

"In light of the nation's urgent blood supply crisis and to ensure that Americans have access to life-saving blood transfusions during the pandemic, we urge you to swiftly update your current blood donor deferral policies in favor of ones that are grounded in science, based on individualized risk factors, and allow all potentially eligible donors to do so free of stigma. We also request a briefing in the next 30 days on the agency's plan to update its MSM blood donation policies," the Senators wrote.

"Every two seconds, someone in the U.S. needs a blood transfusion to survive. But right now, the FDA continues to use archaic, discriminatory criteria to determine an individual's eligibility to donate blood based solely on their sexual orientation - not their individual risk factors - which is not rooted in science, limits access to crucial blood products, and stigmatizes one segment of society," said David Stacy, Government Affairs Director of the Human Rights Campaign. "The FDA instead should focus its considerations for blood donor deferrals based on risky behavior by any potential donor, regardless of one's sexual orientation. This would both best ensure a safe blood supply and maximize the pool of blood donors. We thank Senator Baldwin and her colleagues for their leadership on this issue."

This letter is also signed by Senators Elizabeth Warren (D-MA), Ed Markey (D-MA), Bob Casey (D-PA), Tammy Duckworth (D-IL), Richard Blumenthal (D-CT), Sherrod Brown (D-OH), Bernie Sanders (I-VT), Chris Coons (D-DE), Mazie Hirono (D-HI), Maria Cantwell (D-WA), Angus King (I-ME), Cory Booker (D-NJ), Catherine Cortez Masto (D-NV), Patrick Leahy (D-VT), Amy Klobuchar (D-MN), Ron Wyden (D-OR), Jeff Merkley (D-OR), Michael Bennet (D-CO), Tina Smith (D-MN), Martin Heinrich (D-NM) and Alex Padilla (D-CA).

We write to express our alarm at the nationwide shortage of blood and blood products, which has placed patient care and safety at risk. For the first time, the nation's leading blood donation organizations, including the Red Cross, have declared a national blood supply crisis due to the continued impact of the COVID-19 pandemic. We urge the Food and Drug Administration (FDA) to quickly act on the best available science and update its outdated and discriminatory blood donor deferral policies for men who have sex with men (MSM), a long overdue step that would dramatically increase the eligible donor base.

It is critical that all patients have access to the health care services they need during this pandemic, and for many, the availability of blood and blood products is a necessary component of care. Unfortunately, a significant drop in the number of donations during the COVID-19 pandemic has resulted in a serious shortage of available blood. The Red Cross, America's Blood Centers, and AABB, formerly the American Association of Blood Banks, have declared a nationwide blood supply crisis for the first time, as the nation experiences its worst blood shortfall in over a decade. In recent weeks, hospitals have had less than a single day's supply of critical blood products, and these organizations have had to limit distribution to health facilities in need. In fact, the Red Cross has reported that as much as one-quarter of hospital blood needs are not currently being met.

While no single solution can fully solve these challenges, the FDA has the ability to take a simple and science-based step to dramatically increase the donor base and help address this crisis. In fact, the agency responded to our previous correspondence and took an encouraging step in the right direction during the early days of the pandemic, shortening the deferral period for MSM from 12 months down to three months in March of 2020.

However, any policy that continues to categorically single out the LGBTQ+ community is discriminatory and wrong. Given advances in blood screening and safety technology, a time-based policy for gay and bisexual men is

not scientifically sound, continues to effectively exclude an entire group of people, and does not meet the urgent demands of the moment. And further, with increased uptake of Pre-Exposure Prophylaxis (PrEP), which significantly reduces the likelihood that an HIV-negative individual will acquire HIV, many more gay and bisexual men are aware of their HIV status and are taking steps to eliminate their personal risk. Instead of the current categorical deferral guidelines, we must adopt evidence-based policies focused on an assessment of an individual's risk, not inaccurate and antiquated stereotypes.

All over the world, other countries have led on this issue by scrapping their discriminatory blood donation policies. In October of last year, Israel removed all restrictions on MSM blood donation. And just last month, Canada's blood regulatory agency proposed removing all screening questions focused on gender and sexuality. The tide is turning, and the data support this change.

In light of the nation's urgent blood supply crisis and to ensure that Americans have access to life-saving blood transfusions during the pandemic, we urge you to swiftly update your current blood donor deferral policies in favor of ones that are grounded in science, based on individualized risk factors, and allow all potentially eligible donors to do so free of stigma. We also request a briefing in the next 30 days on the agency's plan to update its MSM blood donation policies.

Thank you for your attention to this important issue."

### **American Medical Association 1/26/2022- "The FDA Must Lift It's Discriminatory Blood Donor Policy"**

"With the nation's blood supply at its lowest point in a decade, and the American Red Cross declaring its first-ever national blood crisis earlier this month, it is time for the Food and Drug Administration (FDA) to do something the AMA and others have urged for years: remove its discriminatory ban that prevents many gay and bisexual men from becoming blood donors.

The existing ban requires gay or bisexual men to abstain from sex for a minimum of three months before they can donate blood. This policy was established in April 2020, when the FDA shortened the deferral time from one year to 90 days in response to a drastic decline in blood donations as the COVID-19 pandemic took hold and thousands of blood drives were canceled.

The current three-month deferral period singles out and bans blood donors based on their inherent attributes rather than the risk factors they present. For example, a man who has protected sex with another man in the three months prior to a blood donation cannot be a donor, but a man or woman who has unprotected sex with multiple partners of the opposite sex over the same time period remains eligible.

The roots of limitations against gay and bisexual blood donors date back to the HIV/AIDS crisis of the 1980s. In 1985, the FDA established a lifetime ban on donations by men who have sex with men (MSM) that remained in place until 2015, when the one-year deferral took effect. In shortening that period to 90 days in 2020, the agency said it expected the change would remain in place after the pandemic ends.

While that was a welcome change, the fact remains that further changes-including the removal of all categorical restrictions on MSM blood donations-are needed. The lifetime ban was imposed in an era when HIV was poorly understood, and it persisted for decades even as blood-screening technology improved dramatically. Today, every unit of donated blood is rigorously tested to detect any trace of HIV, syphilis, hepatitis, West Nile virus or other blood-borne diseases.

Evaluate all donors equally

At issue is the need to evaluate all potential blood donors on an equal basis based on their individual risk factors and without regard to their sexual orientation or gender identity. The FDA's Center for Biologics Evaluation and Research, which develops and regulates the standards for the collection of blood and blood products, should proceed further down the path it has already set out upon by ensuring that blood donation criteria are applied equitably across all segments of our population, including the LGBTQ+ community, based on the latest scientific evidence.

The American Red Cross, which supplies an estimated 40% of the nation's supply of blood and blood products, has stated its belief that blood-donor eligibility should not be based on sexual orientation, and has committed to

achieving that goal. One effort that could speed that achievement is the ongoing Assessing Donor Variability And New Concepts in Eligibility (ADVANCE) Study.

This important research may help shape FDA donor-eligibility requirements by changing the donor-history questionnaire and determining whether research-informed questions that better determine individual risk are just as effective in reducing the risk of HIV in donated blood as the existing 90-day deferral period. Results should be available later this year.

AMA policy supports using a rational, scientifically based deferral period for human tissue donations as well. FDA policy now requires a five-year deferral period for MSM seeking to donate human cells, tissues, and cellular and tissue-based products such as corneas. We have asked the FDA to change its tissue-donation policy to provide the same 90-day deferral period that applies to blood donations by MSM, and to use the ADVANCE Study or similar research to adopt individual risk assessment for donors.

In the meantime, as a Gallon Donor myself, I strongly encourage everyone to respond to the pressing need for blood donations by visiting the American Red Cross website and finding a donation site or blood drive near you. Blood cannot be manufactured or stockpiled, and a suitable supply depends solely on the good will of donors. The COVID-19 pandemic has cast an uncomfortable spotlight on many longstanding and too-often discriminatory policies that exist within our health system-and placed a new responsibility on all of us to work quickly to correct them."

### **ImpactLife 2/2/2022- "ImpactLife Responds to Calls For Change to Donor Eligibility Criteria"**

"The American Medical Association has issued a statement asking the U.S. Food and Drug Administration to update its blood donor eligibility criteria that prevent many gay and bisexual men from becoming blood donors. The AMA statement of Jan. 26, 2022 has focused attention on the policy that defers men from giving blood if they have had sexual contact with another man in the previous 90 days.

**BACKGROUND:** The first cases of acquired immunodeficiency syndrome (AIDS) from blood transfusion and plasma derivatives were identified in 1982 and blood collection agencies began deferring men who have had sex with other men soon thereafter. What had long been an indefinite deferral from blood donation was reduced to a 12-month deferral in 2015 and a 90-day deferral in 2020. The policy is often incorrectly referred to as an LGBTQ+ "ban" on blood donation. (While the deferral has clear implications for sexually active gay and bisexual men, it does not apply to all members of the LGBTQ+ community.)

**WHAT'S NEXT:** As the final authority on criteria for donor eligibility, the U.S. Food and Drug Administration has provided funding for research, currently underway, that will help determine the feasibility of alternative deferral policies. The Assessing Donor Variability And New Concepts in Eligibility (ADVANCE) study is evaluating donor screening questions based on individual behavior and risk. The results will help determine how future changes to blood donor eligibility might be implemented. (See: "What's Next for MSM Deferral Policies?" on the AABB website - Association for the Advancement of Blood & Biotherapies.)

Pete Lux, RN, is our Vice President, Donor and Patient Services. His work on the AABB Donor History task force places him among a group of blood industry leaders who are sharing their perspective on this issue with FDA. "At ImpactLife, we join in the calls for FDA to update the donor eligibility criteria for men who have sexual contact with other men," said Lux. "We support evidence-based changes that focus on individual risk, not excluding entire groups of potential donors."

As a member of America's Blood Centers, ImpactLife is committed to maintaining a safe and available blood supply and treating all potential donors with fairness, equality, and respect. To that end, we strongly support ongoing research initiatives designed to determine if donor-screening alternatives based on individual behaviors, not based on sexual or gender identity, will provide equivalent or superior transfusion safety.

We encourage the Food and Drug Administration to continue its examination of deferral criteria for men who have had sex with men to ensure the use of rational, science-based deferral periods that are applied fairly and consistently among blood donors."

## **United States House of Representatives 2/25/2022- "Eshoo, Cicilline, Lee, Maloney Lead Colleagues in Urging FDA to End Homophobic Blood Donation Deferral Period"**

"PALO ALTO, CA - This week, Representatives Anna G. Eshoo (CA-18), David N. Cicilline (RI-01), Barbara Lee (CA-13), and Sean Patrick Maloney (NY-18) were joined by 142 of their colleagues in urging the Food and Drug Administration (FDA) to end the blanket three-month blood donation deferral period for men who have sex with men (MSM) and transition to an individual risk assessment to determine donor eligibility.

As they state in their letter, "The existence of any deferral period tied to MSM further stigmatizes HIV/AIDS as a 'gay disease' and members of the LGBTQI+ community as 'unclean.' Sexual contact between two men is not listed as a risk factor for HIV/AIDS by the Centers for Disease Control and Prevention or the World Health Organization, yet the FDA directs any male donors with a 'history in the past three months of sex with another man' to defer donation for three months. This policy uses sexual contact between two men as a proxy for unsafe sex that is likely to contaminate the blood supply. This inaccurate association contributes to homophobia, not a safe blood supply."

Joining Reps. Eshoo, Cicilline, Lee, and Maloney on the letter are Reps. Pete Aguilar, Colin Allred, Jake Auchincloss, Nannette Diaz Barragan, Karen Bass, Ami Bera, M.D., Earl Blumenauer, Suzanne Bonamici, Carolyn Bourdeaux, Jamaal Bowman, Ed.D., Brendan F. Boyle, Julia Brownley, Salud Carbajal, Tony Cardenas, Troy A. Carter, Sr., Ed Case, Sean Casten, Joaquin Castro, Judy Chu, Emanuel Cleaver, II, Steve Cohen, Gerald E. Connolly, Jim Cooper, Joe Courtney, Angie Craig, Charlie Crist, Jason Crow, Sharice L. Davids, Danny K. Davis, Madeleine Dean, Peter A. DeFazio, Diana DeGette, Rosa L. DeLauro, Suzan DelBene, Val B. Demings, Mark DeSaulnier, Ted Deutch, Debbie Dingell, Lloyd Doggett, Mike Doyle, Veronica Escobar, Adriano Espaillat, Dwight Evans, Lizzie Fletcher, Bill Foster, Lois Frankel, Ruben Gallego, Jesus G. "Chuy" Garcia, Jimmy Gomez, Al Green, Raul M. Grijalva, Brian Higgins, James A. Himes, Steven Horsford, Chrissy Houlahan, Jared Huffman, Sara Jacobs, Pramila Jayapal, Eddie Bernice Johnson, Henry C. "Hank" Johnson, Jr., Mondaire Jones, Kauli'i Kaha'ele, William R. Keating, Ro Khanna, Daniel T. Kildee, Derek Kilmer, Ann McLane Kuster, Conor Lamb, James R. Langevin, Rick Larsen, John B. Larson, Brenda L. Lawrence, Teresa Leger Fernandez, Andy Levin, Ted W. Lieu, Zoe Lofgren, Alan Lowenthal, Stephen F. Lynch, Kathy Manning, Doris Matsui, Lucy McBath, Betty McCollum, James P. McGovern, Grace Meng, Joseph D. Morelle, Seth Moulton, Jerrold Nadler, Grace F. Napolitano, Joe Neguse, Marie Newman, Donald Norcross, Eleanor Holmes Norton, Tom O'Halleran, Alexandria Ocasio-Cortez, Ilhan Omar, Jimmy Panetta, Chris Pappas, Donald M. Payne, Jr., Ed Perlmutter, Scott H. Peters, Chellie Pingree, Mark Pocan, Katie Porter, Ayanna Pressley, David Price, Mike Quigley, Jamie Raskin, C.A. Dutch Ruppersberger, Linda T. Sanchez, John P. Sarbanes, Mary Gay Scanlon, Jan Schakowsky, Adam B. Schiff, Bradley S. Schneider, Kim Schrier, M.D., Robert C. "Bobby" Scott, Terri A. Sewell, Elissa Slotkin, Adam Smith, Darren Soto, Abigail D. Spanberger, Jackie Speier, Marilyn Strickland, Thomas R. Suozzi, Eric Swalwell, Mark Takano, Dina Titus, Rashida Tlaib, Paul D. Tonko, Ritchie Torres, Lori Trahan, David Trone, Juan Vargas, Nydia M. Velazquez, Debbie Wasserman Schultz, Bonnie Watson Coleman, Peter Welch, Jennifer Wexton, Susan Wild, Nikema Williams, Frederica S. Wilson, John Yarmuth.

Dear Commissioner Califf,

We respectfully urge the Food and Drug Administration (FDA) to end the blanket three-month blood donation deferral period for men who have sex with men (MSM) and transition to an individual risk assessment to determine donor eligibility. The current policy is overly stringent given the scientific evidence, advanced testing methods, and safety and quality control measures within FDA-qualified blood donation centers; stigmatizes members of the LGBTQI+ community; and needlessly restricts the blood supply while our nation combats a critical blood shortage and the COVID-19 pandemic.

On January 11, 2022, the American Red Cross declared the first-ever national blood crisis amid the "worst blood shortage in over a decade.[1]" The COVID-19 pandemic and harsh winter weather have cut the number of blood drives and the number of people donating blood, resulting in some hospitals receiving less than a quarter of the blood requested. At a time when blood supply shortages are forcing hospitals to cancel surgeries and change treatment plans, the FDA's policy puts patients at risk.[2]



The existence of any deferral period tied to MSM further stigmatizes HIV/AIDS as a "gay disease" and members of the LGBTQI+ community as "unclean." Sexual contact between two men is not listed as a risk factor for HIV/AIDS by the Centers for Disease Control and Prevention or the World Health Organization, yet the FDA directs any male donors with a "history in the past three months of sex with another man" to defer donation for three months.[3] This policy uses sexual contact between two men as a proxy for unsafe sex that is likely to contaminate the blood supply. This inaccurate association contributes to homophobia, not a safe blood supply.

The medical community in the United States agrees that an individual risk assessment for all donors is the best way to protect our nation's blood supply. In fact, the American Medical Association supports "removing categorical restrictions for blood donations by MSM," and basing donation eligibility on "a person's individual risk.[4]" The FDA has made clear it will not consider these changes until the Assessing Donor Variability And New Concepts in Eligibility (ADVANCE) Study is completed. However, the results of the study have been delayed until mid-2022 due to difficulties recruiting participants and the COVID-19 pandemic. [5] What is the FDA doing to expedite recruitment and help meet the goal of 2,000 participants for the study?

At least 17 countries, including Spain, have no restrictions on MSM blood donation.[6] Additionally, in June 2021, the United Kingdom ended its three-month blood donation deferral period for MSM and implemented a donation eligibility policy based on individual risk.[7] These nations prove that an individual risk assessment that does not stigmatize members of the LGBTQI+ community is sufficient to screen blood donors and protect our nation's blood supply.

After celebrating National Blood Donor Month in January, we urge you to live up to your commitment to ensure blood donation policies are "based on science, not fiction or stigma.[8]" We urge the FDA to end the three-month blood donation deferral period for MSM and implement an individual risk assessment policy for blood donation. We thank you in advance for your timely consideration of this matter and look forward to your response."

### **Massachusetts Medical Society 3/23/2022- "Massachusetts Doctors Join Push for End of Blood Donation Ban for Gay and Bisexual Men"**

"As the nation faces its worst blood shortage in a decade, Massachusetts doctors are the latest to urge the Food and Drug Administration to end its 90-day blood donor deferral policy for men who have sex with men.

The Massachusetts Medical Society and The Fenway Institute on Wednesday called on the FDA to nix this blood donor policy affecting gay and bisexual men.

Banning gay and bisexual men from donating blood began at the start of the HIV epidemic about 40 years ago.

The FDA recently shortened the required period of sexual abstinence for men who have sex with men from one year to 90 days, but this blood donor policy is "discriminatory and not based in sound science," the health organizations said in a statement.

"The physicians of the Massachusetts Medical Society and The Fenway Institute urge the Food and Drug Administration to revoke its policy on unnecessary scrutiny and subsequent exclusion of men who have sex with men (MSM) from donating blood - a simple, safe step that will expand a blood supply that is perilously low across all health care settings," leaders of the groups added.

This push for local health organizations comes after top Massachusetts health officials – Marylou Sudders, secretary of the Massachusetts Executive Office of Health and Human Services, and Massachusetts Department of Public Health Commissioner Margaret Cooke - signed on to a letter to the FDA that called for the end of the 90-day blood donor deferral policy.

The nation's blood shortage poses "a serious health risk to our patients," according to the Massachusetts Medical Society and The Fenway Institute.

"Scientific advances have dramatically improved blood screening, and there remains no evidence to suggest that including MSM in the pool of available blood donors poses an increased risk of adverse outcomes to patients in need," the groups wrote.

"An immediate shift in policy will help us care for our patients and save lives, while reversing an arbitrary rule that does nothing to advance public health and exacerbates stigma against members of the LGBTQ community," they later added.

In a new study, the FDA is enrolling about 2,000 men who have sex with men who would possibly be willing to donate blood. The Assessing Donor Variability And New Concepts in Eligibility (ADVANCE) study is investigating whether or not donor deferral can be based on individual risk assessment, the feds said in a statement.

"Developing the scientific information that is needed to further change blood donor policies does take time and effort," an FDA spokesperson said. "The FDA has made forward progress in this regard and has been actively engaged in reexamining the issue of blood donor deferral for men who have sex with men, taking into account the current body of scientific information, and we are considering the possibility of pursuing alternative strategies that maintain blood safety."

### **America's Blood Centers 4/4/2022- "ABC Statement: On the FDA's Blood Donor Deferral Policy for Men Who Have Sex with Other Men (MSM) & the ADVANCE Study"**

"As the U.S. Food and Drug Administration's (FDA) landmark Assessing Donor Variability and New Concepts in Eligibility (ADVANCE) study passes 50 percent of planned enrollment, America's Blood Centers (ABC) today reiterated its call for a safe and available blood supply that treats all potential donors with fairness, equality, and respect.

ABC supported the FDA change in 2020 that reduced the donor deferral period from 12 to three months for men who have sex with other men (MSM). Important work is now occurring to collect the needed scientific evidence to further evaluate the current policy. ABC strongly supports this effort as a pathway to the establishment of donor-screening based on individual risk behaviors, not sexual or gender identity. The use of rational, science-based deferral periods must be applied fairly and consistently among blood donors.

The ADVANCE study is a pilot study funded by the FDA that focuses on the blood donor deferral policy for men who have sex with other men (MSM). Three blood collection organizations, including ABC-member's OneBlood and Vitalant, are currently collaborating with LGBTQ community centers and organizations in eight locations to enroll participants. The study seeks to determine if different eligibility criteria can be used at blood centers nationwide that focuses on each donor's individual risk behavior rather than their sexual orientation.

The FDA initially instituted a lifetime deferral on blood donations for MSM in 1983 to reduce the chance of HIV in the blood supply at a time when testing was limited or non-existent. In 2015, the FDA revised this policy and moved to a 12-month deferral in response to comprehensive testing and data demonstrating safety in shortened deferral. This policy was revised again in 2020 to the current 3-month deferral during the COVID-19 public health emergency.

Gay and bisexual men are being enrolled in the ADVANCE study to collect data on the performance in assessing risk of new questions that may be added to the donor history questionnaire in the future. The results, which are expected in late 2022, will be submitted to the FDA for review and the agency will then decide the next steps in this process, including how the data will be released to the public."

### **College of American Pathologists 4/5/2022- "College of American Pathologists Statement on Supporting Gender-Neutral Blood Donor Screening"**

"The College of American Pathologists (CAP) recognizes that the nation's blood supply must be both safe and sufficient to meet the needs of patients and ensure people are healthier because of excellence in laboratory medicine, including the blood banks which pathologists lead. The CAP strives for inclusivity and diversity in all our endeavors, and strongly supports gender-neutral blood donor screening based on individualized risk assessment for HIV infection instead of sexual identity.

In response to the impact of the COVID-19 pandemic on the blood supply shortage, in April 2020, the U.S. Food and Drug Administration (FDA)-the regulatory body that oversees the U.S. blood supply and blood

centers-shortened donor deferral periods from 12 months to 3 months. These measures update previous (December 2015) FDA recommendations for reducing the risk of blood transmission-related infections, including human immunodeficiency virus (HIV), that precluded men who have sex with men (MSM) from becoming donors. Despite these updates, the U.S. still faces a severe national blood shortage crisis-particularly with O negative and O positive typed red blood cells.

More inclusive and more objective blood donor screening may increase both the safety and the availability of the nation's blood supply.

Blood banks in several European countries and Israel already have instituted gender-neutral blood donor screening measures, and Health Canada is currently reviewing a similar recommendation from the Canadian Blood Services. Currently, the FDA and leading blood collection organizations are sponsoring the pilot ADVANCE (Assessing Donor Variability And New Concepts in Eligibility) Study to evaluate alternatives to its current deferral policy for MSM to examine if different questions could be used in the donor history questionnaire. Local blood centers are partnering with LGBTQ+ community centers in eight metropolitan cities across the country to help recruit study participants.

Blood donors take great pride in making irreplaceable contributions to the health of their communities. The CAP supports participation in the ADVANCE Study, and the ability of safe and eligible individuals, regardless of sexual identity, to give life-saving blood donations needed every day."

### **American Red Cross 10/24/2022- "American Red Cross Statement on FDA MSM Deferral Policy"**

"The American Red Cross issued the following statement regarding the U.S. Food and Drug Administration's guidance "Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products" which outlines the deferral criteria for men who have had sex with men (MSM):

The American Red Cross seeks to build an inclusive environment that embraces diversity for all those who engage with our lifesaving mission. As such the Red Cross believes blood donation eligibility should not be determined by methods that are based upon sexual orientation and is committed to working with partners toward achieving this goal.

In April 2020, the U.S. Food and Drug Administration-who determines blood donor eligibility-- reduced the deferral time for men who have sex with men (MSM) from 12 to three months. The Red Cross is encouraged by this action, which we view as an interim step to achieving our greater goal. But the Red Cross also recognizes that further progress is needed, and we continue to strongly support the expanded use of new research and technologies to work toward elimination of donor eligibility questions that would no longer be necessary.

Between December 2020 and September 2022, the Red Cross, along with One Blood, Vitalant and partner LGBTQ+ community organizations, participated in a years-long pilot study funded by the FDA in select cities that could potentially lead to changes to blood donor eligibility criteria for gay and bisexual men. The ADVANCE Study focused on evaluating alternatives to the FDA's MSM policy and serves as a first step in providing data that will help the FDA determine if a donor history questionnaire based on individual risk would be as effective as a time-based deferral related to MSM in reducing the risk of HIV in the blood supply. If the study's scientific evidence supports the use of the different eligibility questions, it could lead to further efforts to change the MSM eligibility criteria.

The ADVANCE Study concluded enrollment on Sept. 30, 2022. Researchers from the participating blood centers will complete their work by the end of 2022, which includes completing follow-up visits with participants into the fall, and then forward the information to the FDA to determine the next steps. We would like to extend a heartfelt thank you to the LGBTQ+ community partners, study participants, and all those who supported the groundbreaking ADVANCE Study as we all seek to make blood donation a more inclusive process while maintaining the safety of the blood supply.

The American Red Cross remains steadfast in our commitment to ensure that every blood recipient receives safe, lifesaving blood when needed. We ask advocates and stakeholders to join us in this important dialogue and pathways

toward achieving our goal, while recognizing the need to always maintain patient safety. Together, we will work toward an inclusive and equitable blood donation process that treats all potential donors with equality and respect, and ensures a safe, sufficient blood supply is readily available for patients in need."

Letters of Support**San Diego Blood Bank 11/28/2022**

Dear Food and Drug Administration & Blood Products Advisory Committee,

Since the 1980s, the FDA has placed restrictions on blood donations from queer men and other groups thought to be at higher risk for sexually transmitted infections. However, the face of medicine and testing for blood borne diseases has changed greatly in the past thirty years. With improvements in testing like Nucleic Acid Testing (NAT) of donations, the risk of HIV transfusion-transmitted infection has been reduced to an estimated 1 in 1.5 million. Nucleic acid testing and other measures have reduced the infectious window period (time from infection to test detection) from months to approximately 9 days, significantly less than the current 3-month deferral period.

Blood centers and medical facilities are facing the worst shortage of donations in over a decade, yet healthy donors with minimal risk of HIV infection are being turned away due to their sexuality. Blood centers do not need to turn away sexually active queer men from donating blood. Although the replacement of a lifetime deferral to a deferral period of 12 months in 2015 and a pandemic revision to 3 months in 2020 were steps in the right direction, they were not enough to enable an equal ability to donate blood. We believe potential donors should be screened based upon individual risk and risk-increasing behaviors, not sexuality. For instance, there are currently know considerations for safer sex practitioners, individuals in monogamous relationships, or the form of sexual activity in which a donor engages. A blanket deferral period for queer men endorses the idea that HIV and AIDS are "gay diseases," rather than infections that can be transmitted to anyone, regardless of sexual orientation.

We urge the FDA to implement recommendations and regulations for blood donation based on peer-reviewed clinical evidence which ensures the safety of the national blood supply, while not needlessly excluding already marginalized communities from the life-saving act of giving blood. In the interest of the queer men that are subjected to this discrimination and patients in dire need of safe blood products, we ask the FDA to revise their current policy.

Sincerely,

San Diego Blood Bank

## Global Trends in MSM Blood Donation Deferment

### Canada

- Mid 1980s: Canadian Red Cross Blood Transfusion Service enacts lifetime deferment policy for MSM donors who have had sex with another man since 1977
- 2007: After considering data, Canadian Blood Services chooses to continue lifetime deferment policy for MSM donors
- 2010: Ontario Superior Court rules that MSM blood donation deferment policy is not discriminatory
- 2011: Canadian Blood Services moves from a lifetime deferral period to a minimum of 5 years and a maximum of 10 years for MSM donors
- 2013: Health Canada sets a 5 year deferment policy for MSM donors
- 2016: Health Canada sets a 1 year deferment policy for MSM donors
- 2019: Health Canada sets a 3-month deferment policy for MSM donors
- 9/11/2022: Health Canada removes deferment questions related to donor sexual orientation
  - Current questions assess new anal sexual partner within 3 months, as well as removal of a plasma deferment policy
  - New questions are set to be enacted on 12/4/2022
- Canadian Blood Services (2022). *Sexual Behaviour-Based Screening*.  
<https://www.blood.ca/en/blood/am-i-eligible-donate-blood/sexual-behaviour-based-screening#:~:text=Health%20Canada%20approved%20the%20change,years%20since%20last%20sexual%20contact>

### France

- 1983: Lifetime deferral for MSM donors enacted
- 2016: 12-month deferment policy enacted for MSM donors
- 2019: 4-month deferral policy enacted for MSM donors
- 3/16/2022: deferral period for MSM donors ended.
  - Revised donor screening questionnaire questions use of pre and post-exposure prophylaxis.
- Association for the Advancement of Blood & Biotherapies (2022, January 13). *France, Greece Move to Allow Blood Donation from MSM*.  
<https://www.aabb.org/news-resources/news/article/2022/01/13/greece-moves-to-allow-blood-donation-from-msm#:~:text=Men%20who%20have%20sex%20with,eligibility%20processes%20in%20those%20countries>

### Israel

- 1980s: Lifetime deferral for MSM donors enacted
- 2017: 12-month deferral enacted for MSM donors

- 10/1/2021: All questions related to same-sex activity will be removed, enacting a 3-month deferral period for all high-risk donors or those with multiple partners.
- Spiro, A. (2021, August 19). *Health Minister Announces Removal of All Blood Donation Restrictions for Gay Men*. The Times of Israel.  
<https://www.timesofisrael.com/health-minister-announces-removal-of-all-blood-donation-restrictions-for-gay-men/>

### Mexico

- 1993: MSM donors not permitted to donate blood.
- 12/27/2012: MSM donors were permitted to give blood if they used condoms or barrier methods of contraception, the same as other countries.
- McAdam, C., Parker, L., (2014). An Antiquated Perspective: Lifetime ban for MSM blood donations no longer global norm. *DePaul Journal of Health Care Law*, 16(1), 21-65.

### Greece

- 1980s: Retroactive lifetime deferral for MSM donors who had been sexually active since 1977.
- 2011: 12-month deferral period enacted
- 2017: 3-month deferral period enacted
- 2022: Questions on sexual orientation removed.
  - New questions screen for donors who have had anal sex with new or multiple partners within the past 3 months.
- Association for the Advancement of Blood & Biotherapies (2022, January 13). *France, Greece Move to Allow Blood Donation from MSM*.  
<https://www.aabb.org/news-resources/news/article/2022/01/13/greece-moves-to-allow-blood-donation-from-msm#:~:text=Men%20who%20have%20sex%20with,eligibility%20processes%20in%20those%20countries>

### United Kingdom

- 1985: MSM donors receive permanent deferral from donating blood
- 2011: 12-month deferral period for MSM donors enacted
- November 2017: 3-month deferral period for MSM donors enacted
- June 2021: MSM donors who have been with the same partner for greater than the past 3 months are permitted to donate
- Association for the Advancement of Blood & Biotherapies (2020, December 14). *UK to Introduce New MSM Blood Donation Policy*  
<https://www.aabb.org/news-resources/news/article/2020/12/14/uk-to-introduce-new-msm-blood-donation-policy>

- Blood and Transplant. (n.d.). *Men Who Have Sex with Men (MSM)*. National Health Service. <https://www.blood.co.uk/who-can-give-blood/men-who-have-sex-with-men/>

### Germany

- 2017: 12-month deferral period enacted for MSM donors
- 6/24/2021: MSM Donors in monogamous relationships are able to donate. Donors with multiple partners or a new partner must wait for a 4-month deferral period, regardless of sexuality.
- Association for the Advancement of Blood and Biotherapies (2021, July 6). *Germany to Revise Blood Donor Eligibility Criteria*. <https://www.aabb.org/news-resources/news/article/2021/07/06/germany-to-revise-blood-donor-eligibility-criteria>

### Ireland

- January 2017: Lifetime deferral for MSM donors replaced with 12-month period
- March 2022: 4-month deferral for MSM donors enacted
- Individual Risk Assessment implemented at end of 2022 (all donors)
  - Donors with PrEP prescriptions receive a 4-month deferral (previous 12-month).
- Association for the Advancement of Blood and Biotherapies (2021, December 23). *Ireland to Ease Restrictions on Blood Donations from Gay, Bisexual Men*. <https://www.aabb.org/news-resources/news/article/2021/12/23/ireland-to-ease-restrictions-on-blood-donations-from-gay-bisexual-men>

### Italy & Spain

- No deferral specific for MSM sexual activity
  - Donors with high-risk activity may face deferral
- Association for the Advancement of Blood and Biotherapies (2021, October 18). *What's Next for MSM Deferral Policies*. <https://www.aabb.org/news-resources/news/article/2021/10/18/what-s-next-for-msm-deferral-policies>

### Lithuania

- 5/1/2022: MSM deferral lifted, all donors are asked the same questions, which cover unprotected sexual contact
- Lietuvos Nacionalinis Radijas Ir Televizija. (2022, May 2). *Lithuania Removes Homosexuality Question from Blood Donor Questionnaire*. <https://www.lrt.lt/en/news-in-english/19/1685569/lithuania-removes-homosexuality-question-from-blood-donor-questionnaire>

### Austria



- 5/20/2022: Transition from 12-month deferral period to individual risk assessment announced.
  - Greater than 3 sexual partners within 3 months will be deferred for 3 months.
- Association for the Advancement of Blood and Biotherapies (2022, May 23). *Austria to Introduce Individual Donor Risk Assessment*.  
<https://www.aabb.org/news-resources/news/article/2022/05/23/austria-to-introduce-individual-donor-risk-assessment>

### **Hungary**

- 1/1/2020: lifetime deferral for MSM donors ended.
- Hatter Society. (2020, May 6). *Lifelong Blood Donation Ban on Gay and Bisexual Men in Hungary Lifted*.  
<https://en.hatter.hu/news/lifelong-blood-donation-ban-on-gay-and-bisexual-men-in-hungary-lifted-0>

### **Malta**

- 2019: Lifetime deferral period for MSM donors replaced with 12-month period
- 2/2/2022: Individual Risk Assessment implemented for all donors regardless of sexual orientation
- Association for the Advancement of Blood and Biotherapies (2022, September 7). *Malta Introduces Individual Risk Assessment*  
<https://www.aabb.org/news-resources/news/article/2022/09/07/malta-introduces-individual-risk-assessment>

### **Netherlands**

- 9/1/2021: MSM donors who have been in a monogamous relationship for at least 12 months are permitted to donate.
  - MSM donors who are not in monogamous relationships for >12 months are required to adhere to a 4-month deferral period for sexual activity.
- Vanguard. (2021, September 2). *Netherlands Makes it Easier for Homosexual Men to Donate Blood*.  
<https://en.hatter.hu/news/lifelong-blood-donation-ban-on-gay-and-bisexual-men-in-hungary-lifted-0>

Petition Signatures

The following are 859 members of the public who have signed our petition. The petition language stated:

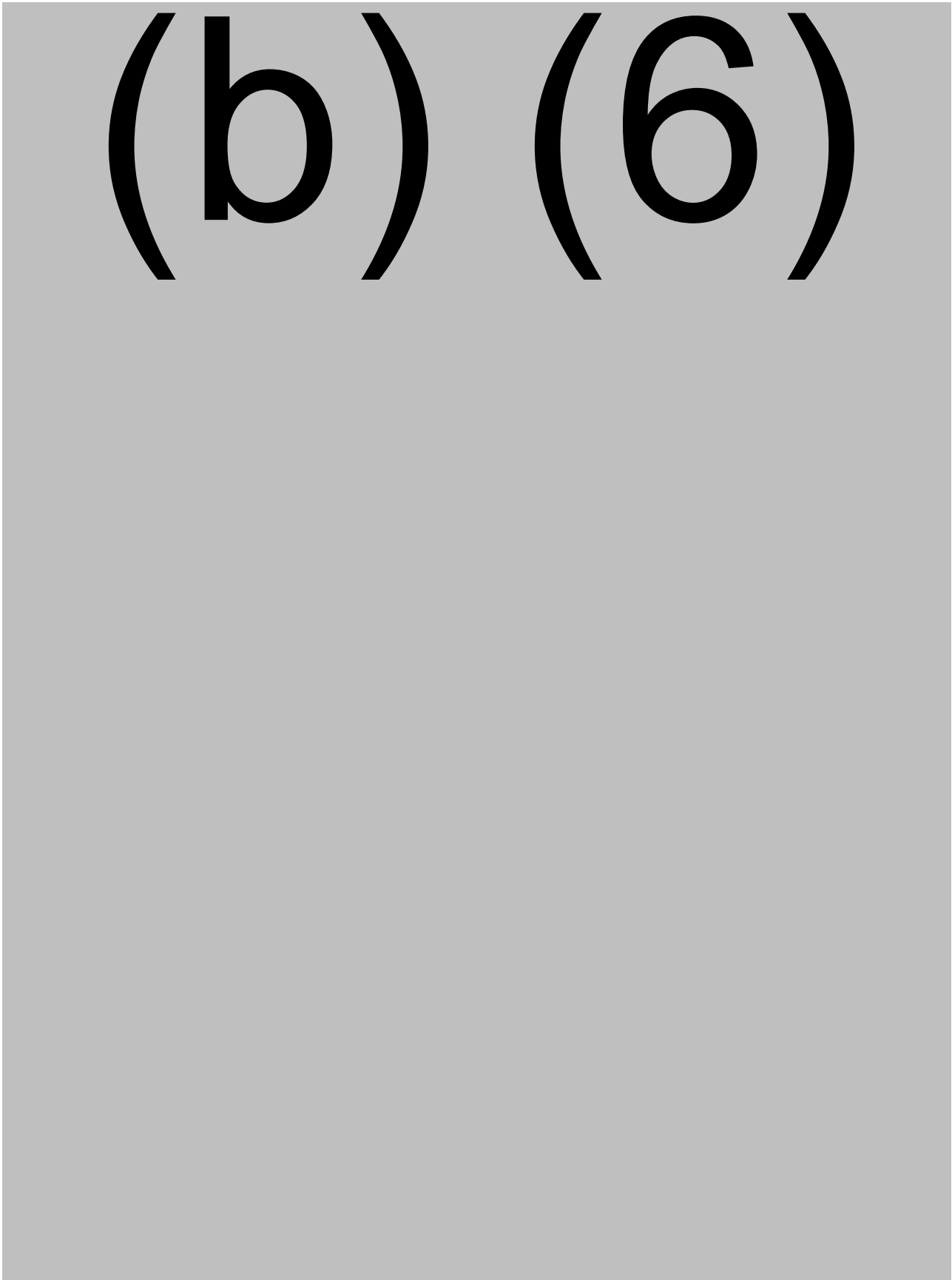
"Currently, sexually active queer men cannot donate blood if they've participated within the past 3 months. There are no exceptions for monogamous relationships, protected sex, or negative STI test results. Not only do current scientific findings reject these policies, but these regulations are not applied to heterosexual individuals in the same way. This policy is discriminatory and wrong, and we are working to bring bring it to an end."

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