TRANSCENDING SEX AND SEXUAL ORIENTATION: THE "TRANSGENDER APPLICATION" AND WHY THE MSM DEFERRAL POLICY SHOULD BE REPLACED WITH AN INDIVIDUALIZED RISK ASSESSMENT

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TRANSCENDING SEX AND SEXUAL ORIENTATION: THE "TRANSGENDER APPLICATION" AND WHY THE MSM DEFERRAL POLICY SHOULD BE REPLACED WITH AN INDIVIDUALIZED RISK ASSESSMENT

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Since 1983, the FDA has effectively banned men who have sex with men (MSM) from donating blood. What was once a lifetime ban is now a twelve-month deferral period from the point of an MSM's last sexual encounter. Despite outrage from LGBTQ advocates and advances in blood testing and storage that render a twelve-month deferral period unnecessary, the FDA has not abandoned its MSM deferral policy.

This Note takes a new approach to reform by highlighting a flaw in the MSM deferral policy in terms of its application to transgender individuals. This "Transgender Application" points out loopholes in the MSM deferral policy that are necessitated by the FDA's reliance on time-based deferrals that target donors based on sex and sexual orientation. This approach is likely to succeed because it shifts the focus away from the merits of the MSM deferral policy, instead drawing attention to the policy's misaligned goals and outcomes.

This Note offers a solution to the "Transgender Application" by proposing that the FDA replace its existing policy with an individualized risk assessment (IRA). Shifting to an IRA would increase the clarity of the deferral policy's language, decrease the blood shortage by expanding the number of eligible donors, and address concerns about the discriminatory effects of the current policy raised by LGBTQ advocates.

Though this Note attempts to persuade the FDA to re-evaluate its MSM deferral policy by focusing in on one problematic aspect of the policy, the solution alleviates many problems associated with the policy as a whole.

INTRODUCTION

SINCE 1983, the United States Food and Drug Administration (FDA), the federal agency responsible for regulating the nation's blood supply, has effectively banned men who have sex with men (MSM) from donating blood.1 Initially, the FDA placed a lifetime ban on blood donations from MSMs because agency officials believed that the

[1] U.S. FOOD & DRUG ADMIN., REVISED RECOMMENDATIONS FOR REDUCING THE RISK OF HUMAN IMMUNODEFICIENCY VIRUS TRANSMISSION BY BLOOD AND BLOOD PRODUCTS: GUIDANCE FOR INDUSTRY (2015).

HIV/AIDS virus was linked to the homosexual lifestyle.2 In December 2015, the FDA modified the blood donation guidelines to reduce the lifetime ban to a twelve-month deferral period for MSM donors.3 The FDA measures this period from the time of a potential blood donor's last male sexual contact to the time of his proposed blood donation.4

Despite scientific advances in blood donation testing and storage that render a twelve-month deferral period unnecessary,[5] the FDA has not updated the MSM deferral policy to align with modern science. Members of Congress and LGBTQ advocacy groups criticized the FDA's policy change for not going far enough, pointing out that the twelve-month deferral period for MSM donors is not scientifically warranted and continues to perpetuate the stigmas that homosexual sexual activity is a high risk behavior and that being homosexual is equated with having HIV/AIDS.[6] However, these advocates have failed to persuade the FDA to further alter the MSM deferral policy. Moreover, the FDA has refused to abandon time-based deferral periods for MSM donors.[7]

This Note argues that the FDA should once again re-evaluate its blood donation deferral policy and shift away from time-based deferral periods that target donors with a particular sex and sexual orientation. It

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[2] Christopher McAdam & Logan Parker, *An Antiquated Perspective: Lifetime Ban for MSM Blood Donations No Longer Global Norm*, 16 DEPAUL J. HEALTH CARE L. 21, 23 (2014) ("The fact that homosexual men constituted the initial population in which AIDS occurred in the United States led some to surmise that a homosexual lifestyle was specifically related to the disease.").

[3] U.S. FOOD & DRUG ADMIN., *supra* note 1.

[4] *Id.*

[5] McAdam & Parker, *supra* note 2, at 30 ("The success of testing and detecting HIV in blood has led many to question the appropriateness of the current MSM blood ban not only in the United States but internationally."); *Blood FAQ*, AMERICAN ASSOCIATION OF BLOOD BANKS, http://www.aabb.org/tm/Pages/bloodfaq.aspx#a10.

[6] Letter from Rep. Mike Quigley et al. to Robert M. Califf, Comm'r of the U.S. Food & Drug Admin. (Jun. 20, 2016) ("[W]e are concerned that the 12-month deferral policy, which suggests that the sexual relationships of MSM men and transgender women inherently pose a risk of HIV transmission, furthers a stigma that we have persistently fought to eliminate."); Press Release, Human Rights Campaign, FDA Blood Donation Ban Change Still Unacceptable (May 12, 2015) ("While the new policy is a step in the right direction toward an ideal policy that reflects the best scientific research, it still falls far short of a fully acceptable solution because it continues to stigmatize gay and bisexual men."); *New Blood Donation Policy Does Not Go Far Enough*, LAMBDA LEGAL BLOG (Dec. 21, 2015), http://www.lambdalegal.org/blog/201512221_hiv-policy-not-far-enough ("The guidance published today does not go far enough. An evidence-based policy would focus exclusively on the conduct of the potential donor, rather than the person's identity with regards to sexual orientation, gender identity or perceived risk factors based on the person's identity. Risk behaviors do not have a sexual orientation or gender identity.").

[7] U.S. FOOD & DRUG ADMIN., *supra* note 1.

does so by taking the new approach of highlighting a flaw in the MSM deferral policy in terms of its application to transgender individuals. This serves as an opportunity for the FDA to revisit the MSM deferral policy and assess the effectiveness of its current deferral period. This unique approach is likely to succeed because it shifts the focus away from the merits of the MSM deferral policy, instead drawing attention to the policy's misaligned goals and outcomes. The time is ripe for this argument because the FDA has indicated that it is open to reconsidering its policy, requesting comments on the topic as recently as July 2016.[8]

Part One of this Note describes the implementation of the MSM deferral policies, explains the rationales behind their enactment, demonstrates why the MSM deferral policy is no longer scientifically necessary, and argues that past attempts to overturn the FDA's policies have failed for not being mindful of the rationales behind the policies. Part Two takes a new approach to reform by examining the application of the MSM deferral policy to transgender individuals. This "Transgender Application" is the most recent example of how deferral periods based on a potential blood donor's sex and sexual orientation are both under- and overinclusive because the policy *does not* defer individuals who should be deferred and *does* defer others who should not be. Because it highlights how the FDA's policies no longer advance its stated rationales, the "Transgender Application" serves as a wedge to convince the FDA to open the door to reassessing the overall usefulness of deferral policies that are based on a potential blood donor's sex and sexual orientation. Part Three proposes that the FDA resolve the problem posed by the "Transgender Application" by replacing its existing blood donor eligibility guidelines with an individual risk assessment (IRA) instead of basing its deferral periods on a person's sex and sexual orientation.

I. THE MSM DEFERRAL POLICIES AND ATTEMPTS TO OVERTURN THEM

Before digging into the proposed reform to the MSM deferral policy, it is critical to understand the rationale behind the enactment of the policy, the science that makes the policy no longer justified, and why prior attempts to alter the policy have failed despite such scientific advancements. Section II.A of this Note details the MSM deferral policies, starting with the so-called "lifetime deferral period" for MSM donors up through the decision to shift to a twelve-month deferral period. Section II.B explains the rationales behind both the original enactment of the MSM deferral policy and the move to the twelve-month deferral period. Section II.C describes the advancements in blood donation testing and storage that make the FDA's twelve-month deferral period scientifically unnecessary. Section II.D shows how past attempts to overturn the

[8] Blood Donor Deferral Policy for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products, 81 Fed. Reg. 145 (July 28, 2016).

MSM deferral policies have failed despite such scientific advancements and argues that these attempts have proven unsuccessful because they were insensitive to the FDA's rationales for enacting the deferral policies in the first place.

A. Timeline of the MSM Deferral Policies

In the early 1980's, the first cases of what came to be known as AIDS were discovered in the United States.[9] Because homosexual men were the initial population in which AIDS was detected, it was believed that the disease was related to the homosexual lifestyle.[10] AIDS was commonly referred to as "the gay plague," "gay cancer," and "gay-related immune disorder."[11] Epidemiologists discovered that HIV leads to AIDS and that AIDS was transmissible through blood and sexual fluids.[12] This discovery caused scientists and public health policymakers to turn their attention to protecting the nation's blood supply from being contaminated with the HIV/AIDS virus.[13]

In July of 1982, the Centers for Disease Control and Prevention (CDC) hosted a meeting to discuss responses to the potential contamination of the blood supply.[14] At this meeting, CDC officials proposed the implementation of blood donor deferral guidelines.[15] These guidelines asked high risk groups, including gay men, to refrain from donating blood.[16] In March of 1983, the United States Public Health Service, which included the FDA and the CDC, "issued nonmandatory guidelines on the matter, urging members of groups at 'increased risk for AIDS' to refrain from donating plasma or blood."[17] At that time, the guidelines only included MSMs who "were currently sexually active with multiple partners, had 'overt symptoms of immune deficiency,' or had previously engaged in sexual relations with people who now did."[18]

In 1985, the FDA broadened the definition of groups at "increased risk for AIDS" to include all men who have had sex with another man, even once, since 1977.[19] This change, for the first time, expanded the

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[9] McAdam & Parker, *supra* note 2, at 22.

[10] *Id.* at 23.

[11] *Id.*

[12] Adam R. Pulver, *Gay Blood Revisionism: A Critical Analysis of Advocacy and the "Gay Blood Ban"*, 17 LAW & SEX. 107, 110 (2008).

[13] *Id.*

[14] *Id.* at 111.

[15] *Id.*

[16] *Id.*

[17] *Id.* at 115.

[18] *Id.*

[19] Joseph J. Wardenski, Michael E. McGovern, Alex Brohn & Deepika Bains, *A Drive for Change: Reforming U.S. Blood Donation Policies*, GAY MEN'S HEALTH CRISIS,

deferral policy to exclude monogamous male couples from donating blood.[20] In 1992, the FDA issued guidelines that made the 1985 policy that placed a lifetime ban on blood donations from all MSM donors mandatory.[21] In 2015, the FDA changed its guidelines to say that male donors would be deferred if they had "a history in the past [twelve] months of sex with another man."[22] This twelve-month deferral period for MSM donors remains the policy in effect today.

B. Rationales Behind the MSM Deferral Policies

The FDA's main objectives in implementing the MSM deferral policies were to safeguard the blood supply from HIV/AIDS and to minimize the risk of HIV/AIDS transmission during blood transfusions.[23] To accomplish these goals, the FDA determined that MSMs should be deferred from donating blood based on their perceived heightened risk of acquiring HIV/AIDS. For example, even though MSMs represent only 5% to 7% of the total male population in the United States, they represent about 51% of all HIV cases known throughout the country.[24] Furthermore, the FDA targeted MSM sexual conduct because a person is eighteen times more likely to contract HIV from unprotected anal sex than from unprotected vaginal sex.[25] The FDA claimed that these statistics supported an outright ban on blood donations from MSMs under the "precautionary principle," which "encourages policymakers to take the most cautious, risk-averse option whenever an activity potentially threatens harm to human health."[26] Assessing the evidence holistically, the FDA followed the precautionary principle and enacted a lifetime ban on all MSMs.

The FDA decided to consider alternatives to the lifetime ban as the rate of non-compliance with the policy increased.[27] In its industry guidance report, the FDA stated, "The rate of non-compliance of MSM under the indefinite deferral policy appears to be increasing because the percentage of male donors estimated to be MSM has risen from 0.6% in 1993, to 1.2% in 1998, and to 2.6% in 2013. Therefore, it is appropriate

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http://www.gmhc.org/files/editor/file/a_blood_ban_report2010.pdf (hereinafter A Drive For Change).

[20] *Id.*

[21] McAdam & Parker, *supra* note 2, at 24.

[22] U.S. FOOD & DRUG ADMIN., *supra* note 1.

[23] Pulver, *supra* note 12, at 127–28; U.S. FOOD & DRUG ADMIN., *supra* note 1.

[24] Pulver, *supra* note 12, at 126.

[25] *Three Reasons Gay Guys Are More Likely to Get HIV*, NEW ZEALAND AIDS FOUNDATION, https://www.nzaf.org.nz/getting-tested/testing-month/hiv-risk-for-gay-men/.

[26] Pulver, *supra* note 12, at 127–28.

[27] U.S. FOOD & DRUG ADMIN., *supra* note 1.

to consider alternatives."[28] In evaluating the policy alternatives, the FDA again looked to statistics about the rate of HIV infection and transmission for MSMs as a whole.[29] The FDA noted that in 2010, 63% of all "new HIV infections were attributed to male-to-male sexual contact."[30] Given the still high rate of HIV infection and transmission in MSMs, the FDA chose to adopt a twelve-month deferral period for MSMs to still allow for a latency period between the time of the potential HIV infection and the time of blood donations, but also to combat the decreased compliance with the lifetime deferral period.[31]

As part of its policy considerations, the FDA evaluated the possibility of implementing an individualized risk assessment (IRA), but ultimately concluded that IRAs were not a viable policy alternative to the lifetime ban.[32] The FDA stated that with "approximately 50,000 new HIV infections per year in the United States, conservative calculations performed by [the] FDA estimate that [shifting to IRAs] could potentially be associated with an approximately four-fold increase in HIV transmissions resulting from blood transfusions each year."[33] Furthermore, the FDA concluded that it could not rely on a potential blood donor's self-reported safe-sex practices because "the rate of partner infidelity in ostensibly monogamous heterosexual couples and same-sex male couples is estimated to be about 25%, and condom use is associated with a 1 to 2% failure rate per episode of anal intercourse."[34] Based on these figures, the FDA concluded that, "Such a policy, increasing the potential for the transmission of HIV infection, is not aligned with maintaining or improving the safety of the blood supply in the U.S."[35] Instead, the FDA chose to adopt the twelve-month deferral period for MSMs.[36]

The FDA's reliance on these statistics reveals that its deferral policies are grounded in the principle that deferring those who engage in male-to-male sexual conduct is the most effective way to safeguard the blood supply from HIV/AIDS and to minimize the risk of HIV/AIDS transmission during blood transfusions.[37] The FDA claims that time-based deferrals, such as the twelve-month deferral period for MSM donors, are the most appropriate policy option because male-to-male sexual

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[28] *Id.*
[29] *Id.*
[30] *Id.*
[31] *Id.*
[32] *Id.*
[33] *Id.*
[34] *Id.* The FDA stated that, "[e]ven if a potential donor is truthful in providing responses regarding his or her own behavior, the response may not be meaningful if a partner has not been monogamous." *Id.*
[35] *Id.*
[36] *Id.*
[37] *See* McAdam & Parker, *supra* note 2, at 24; U.S. FOOD & DRUG ADMIN., *supra* note 1.

conduct carries a heightened risk of exposure to HIVS/AIDS, and a person's blood needs an adequate window of time between the sexual contact and the donation to produce accurate results on an HIV test.[38]

C. Scientific Advancements in Blood Donation Testing and Storage Render the MSM Deferral Period Scientifically Unnecessary

At the beginning of the HIV/AIDS crisis, there were no testing procedures established to screen blood donations for HIV/AIDS, which helped the FDA justify the use of a time-based deferral period that targeted those at a heightened risk of contracting HIV/AIDS.[39] However, in 1985, the FDA adapted the enzyme-linked immunosorbent assay (ELISA) test to be used as a way of testing blood for HIV/AIDS.[40] Studies varied in their findings about the efficacy of the test, with results ranging from 68% to 100% effectiveness in identifying patients with AIDS.[41] In 1985, the FDA also adapted a test called the Western Blot due to the number of false-positives resulting from the use of the ELISA test alone in screening for HIV/AIDS.[42] From that point on, the ELISA test and the Western Blot were used in combination and had a higher success rate for detecting HIV in blood donations.[43] However, even the combination of these tests still required a latency period of several months between the point at which an individual was infected with HIV and the time that HIV could be detected in a potential donor's blood because a recently infected donor would not have developed the antibodies detected by the tests.[44]

In the early 2000s, scientists developed the nucleic acid test (NAT) to increase the accuracy of HIV detection and decrease the latency period needed for accurate results.[45] The NAT shortened the latency period for detecting HIV in a person's blood to between nine and eleven days.[46] This meant that the blood donation could accurately be tested for HIV in less than two weeks, which was a dramatic decrease from prior tests. The NAT has also increased the accuracy of HIV screenings, with one study finding that the NAT produces false-negatives only four times per ten million screenings for HIV, despite both human and technical error.[47] Today, the United States requires that all blood donations be subjected to

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[38] *See* McAdam & Parker, *supra* note 2, at 24.
[39] Pulver, *supra* note 12, at 117.
[40] *Id.*
[41] *Id.*
[42] McAdam & Parker, *supra* note 2, at 29.
[43] *Id.*
[44] *Id.*
[45] *Id.*
[46] *Id.* at 30.
[47] Meredith Ciufo, *Drawing Blood: Towards an EU Remedy for Blood Donation Rights*, 31 B.U. INT'L L.J. 341, 354–55 (2013).

the NAT.[48] The FDA mandates that a maximum of twenty-four samples be pooled and subjected to the NAT.[49] If the pool tests positive, each individual donation is subjected to repeat testing to identify and destroy the contaminated blood donation.[50] This means that at most, a two-week deferral period for potential blood donors could be scientifically justified by the FDA.

Coupled with the improvements in blood donation testing, scientific advancements in blood donation storage also make time-based deferral periods that target donors with a particular sex and sexual orientation unnecessary. While blood donations formerly had a shelf life of only twenty-one days, scientists have discovered ways to store blood donations for longer periods of time.[51] For example, scientists created safe, chemical additives to allow red blood cells to be refrigerated for up to forty-two days or frozen for up to ten years.[52] Similarly, plasma can be stored frozen for up to a year.[53]

Lengthening the time that blood donations can be stored allowed blood banks to quarantine blood donations for post-donation testing.[54] This means that after a blood donation is given, the unit of blood would be entered into a storage facility to conduct tests like the NAT.[55] This allows blood donations to be stored for the duration of the HIV/AIDS latency period and then subjected to testing so that the blood has had the requisite amount of time to develop the antibodies the NAT detects. This process ensures that the results of the NAT testing are more accurate. While blood donation storage technology at one time did not permit post-donation testing, scientific advancements now allow donations to be stored and used well past the latency period for detecting HIV/AIDS, making policy shifts away from the twelve-month deferral period for MSM donors viable.

D. Failed Attempts to Move Away from Time-Based Deferrals for MSM Donors

Members of Congress and LGBTQ advocacy groups have advocated for the FDA to shift its policies away from time-based deferrals for donors with a particular sex and sexual orientation.[56] These groups have

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[48] McAdam & Parker, *supra* note 2, at 49.

[49] *Id.*

[50] *Id.*

[51] *Blood FAQ*, *supra* note 5.

[52] *Id.*

[53] *Id.*

[54] Request for Information (RFI) on Design of a Pilot Operational Study To Assess Alternative Blood Donor Deferral Criteria for Men Who Have Had Sex With Other Men (MSM), 77 Fed. Reg. 49, 14802 (Mar. 13, 2012).

[55] *Id.* at 14804.

[56] Letter from Rep. Mike Quigley et al., *supra* note 6 ("[T]he FDA questionnaire should reflect risk-based behaviors as opposed to sexual orientation.");

mainly relied on arguments centered around the scientific advancements detailed in Section II.C and the harmful stigma that the MSM deferral policies place on homosexual and bisexual men.[57] For example, the National AIDS Forum—a convention that includes homosexual men and gay advocacy groups—issued a report, saying:

> The quarantine of blood is an ominous first step towards further social, political, economic and even physical quarantine of a community already denied many basic civil rights protection[s]. Stigmatizing the blood of an already disenfranchised segment of society may permit homophobic and racist forces to accomplish in the name of "science" what they thus far have been unable to fully accomplish politically.[58]

Similarly, the advocacy group Gay Men's Health Crisis released numerous statements opposing the FDA's twelve-month deferral period, saying, "[i]n practice, the new policy is still a continuation of the lifetime ban and ignores the modern science of HIV-testing technology while perpetuating the stereotype that all gay and bisexual men are inherently dangerous. Blood donation policies should be based on science, not stigma."[59] The group also cautioned, "[i]nstead of evaluating all potential donors to determine their actual risk to the blood supply, the FDA is telling the next generation of young gay and bisexual men that they are inherently diseased."[60]

While these arguments raise important points, they have not been persuasive enough to push the FDA to change its policies. For instance, in September of 2000, the FDA reconsidered the lifetime ban on MSM donors, noting that the policy "seemed discriminatory, lacked a firm foundation in science, and should be changed."[61] However, the FDA ultimately rejected a policy change due to "skepticism . . . fueled by the

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Press Release, Human Rights Campaign, *supra* note 6 ("While the new policy is a step in the right direction toward an ideal policy that reflects the best scientific research, it still falls far short of a fully acceptable solution because it continues to stigmatize gay and bisexual men."); *New Blood Donation Policy Does Not Go Far Enough*, *supra* note 6 ("The guidance published today does not go far enough. An evidence-based policy would focus exclusively on the conduct of the potential donor, rather than the person's identity with regards to sexual orientation, gender identity or perceived risk factors based on the person's identity. Risk behaviors do not have a sexual orientation or gender identity.").

[57] Pulver, *supra* note 12, at 114–15.

[58] *Id.* at 115.

[59] Press Release, Gay Men's Health Crisis, GMHC Responds To FDA's Discriminatory Blood Donor 12-Month Deferral Plan (Dec. 21, 2015).

[60] Press Release, Gay Men's Health Crisis, FDA Draft Guidance on Gay and Bisexual Male Blood Donors Is Discriminatory and Shameful (May 12, 2015).

[61] Pulver, *supra* note 12, at 118.

revelation that, by age 40, a full 1/3 of gay men in the United States are infected with human herpes virus-8, a virus used as an indicator of unprotected sexual activity trends."[62] Notably, the FDA only shifted from the lifetime ban to the twelve-month deferral period for MSM donors when it encountered increased non-compliance with the policy.[63] This reveals that arguments grounded in either scientific evidence or the discriminatory and stigmatic consequences of the MSM deferral policies are not persuasive to the FDA due to its continued cautiousness toward male-to-male sexual conduct.

II. HIGHLIGHTING THE PROBLEMATIC NATURE OF THE CURRENT MSM DEFERRAL POLICY THROUGH THE "TRANSGENDER TPPLICATION"

As discussed in Part One of this Note, the FDA emphasizes the increased risk of HIV/AIDS contraction and transmission that occurs in male-to-male sexual conduct in rationalizing its MSM deferral policies.[64] However, it is essential to understand that the FDA's position in reality rests on the view that sex between people with penises (PWPs)—not MSMs—is what presents a higher risk of HIV/AIDS infection and transmission than other types of sexual contact. Moreover, the category of PWP does not overlap entirely with the category of MSM, and the distinction between the two categories will become increasingly important as more individuals come out as transgender. Currently, there are an estimated 1.4 million transgender adults in the United States,[65] and many of those individuals may seek to donate blood. In order to understand why the MSM deferral policy is problematic, start by taking a look at how the FDA classifies a transgender donor's sex for blood donation purposes under deferral policies that depend on a potential blood donor's sex and sexual orientation.[66]

In 1980, the FDA adopted a policy that determined a potential blood donor's sex based on the sex he or she was assigned at birth.[67] This policy indicated that the sex a person identified as was not relevant for blood donation purposes, but only what sexual organs a person had at the time of his or her birth. In practice, this meant that a transgender woman was considered a male for blood donation purposes, and a transgender man was considered a female. In 2015, however, the FDA altered its

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[62] *Id.*

[63] U.S. FOOD & DRUG ADMIN., *supra* note 1.

[64] *See* McAdam & Parker, *supra* note 2, at 24; U.S. FOOD & DRUG ADMIN., *supra* note 1.

[65] Jan Hoffman, *Estimate of U.S. Transgender Population Doubles to 1.4 Million Adults*, THE NEW YORK TIMES (June 30, 2016), http://www.nytimes.com/2016/07/01/health/transgender-population.html.

[66] Nico Lang, *FDA's Blood Donation Rules Out Trans People*, THE DAILY BEAST (Sept. 6, 2016), http://www.thedailybeast.com/articles/2016/09/06/fda-s-blood-donation-rules-out-trans-people.html.

[67] *Id.*

policy to allow individuals to self-identify and self-report their sex so that their sex classification aligned with their identity.[68] This means that under the FDA's current policy, a person's sexual organs at the time of birth were no longer determinative of his or her sex for blood donation purposes. Instead, under the current FDA policy, a transgender woman is considered a female for blood donation purposes, and a transgender man is considered a male.

However, in the context of the MSM deferral policy, both systems of sex classification are flawed when applied to transgender individuals. This is because some of the individuals that the FDA intended to defer—namely PWPs who have sex with other PWPs—would fall outside the scope of the deferred individuals, while some non-PWPs would fall within the scope of the policy. This "Transgender Application" highlights the problematic nature of the MSM deferral policy because it reveals how the policy's reliance on sex and sexual orientation to defer potential blood donors creates loopholes in the policy. Furthermore, the "Transgender Application" shows how the MSM deferral policy does not serve the FDA's goal of deferring PWPs who have sex with other PWPs from donating blood.

A. Assessing the FDA's Classification by Self-Identified and Self-Reported Sex Policy

The FDA's current policy is both under- and overinclusive in the sense that it fails to capture some of the individuals it intended to defer from donating blood and captures some of the individuals it did not intend to defer. Table One demonstrates how this situation plays out with respect to transgender donors:

Table One: Under- and Overinclusivity of the FDA's current policy for classifying individuals based on their self-identified and self-reported sex.

	PWP	**Deferred**	**Intended to Defer if Having Sex with Another PWP**
Pre-Operation Transgender Woman	Yes	No	Yes
Post-Operation Transgender Woman	No	No	No
Pre-Operation Transgender Man	No	Yes	No
Post-Operation Transgender Man	Yes	Yes	Yes

[68] U.S. FOOD & DRUG ADMIN., *supra* note 1; Autumn Sandeen, *Transgender People and the FDA's New Blood Donation Guidelines*, LGBT WEEKLY (Dec. 24, 2015), http://lgbtweekly.com/2015/12/24/transgender-people-and-the-fdas-new-blood-donation-guidelines/.

As Table One shows, in two of the four situations, the FDA's current policy effectively captures the people it intends to defer from donating blood. This happens in the case of a transgender woman or a transgender man who has undergone sex reassignment surgery. The post-operation transgender woman would not be deferred from donating blood for having sex with a PWP because the FDA would consider this to be heterosexual contact. Likewise, the post-operation transgender man would be deferred from donating blood for having sex with another PWP, as the pair would be classified by the FDA as MSMs.

However, in the other two situations, the FDA's current policy is both under- and overinclusive. If a pre-operation transgender woman—who would be classified as a PWP—has sex with a PWP, she would not be deferred from donating blood even though the MSM deferral policy intends to defer individuals who engage in this type of sexual conduct. Similarly, if a pre-operation transgender man—who would not be classified as a PWP—has sex with a PWP, he would be deferred from donating blood despite the fact that the MSM deferral policy is not intended to cover heterosexual sex.

B. Assessing the FDA's Classification by Sex at Birth Policy

Switching back to the FDA's former policy of classifying the sex of potential blood donors based on the sex that the individual was assigned at birth does not resolve this problem, but rather reverses it. Table Two details this situation:

Table Two: Under- and Overinclusivity of classifying individuals based on their sex at birth.

	PWP	**Deferred**	**Intended to Defer if Having Sex with Another PWP**
Pre-Operation Transgender Woman	Yes	Yes	Yes
Post-Operation Transgender Woman	No	Yes	No
Pre-Operation Transgender Man	No	No	No
Post-Operation Transgender Man	Yes	No	Yes

As Table Two demonstrates, in two of the four scenarios the policy defers those that it was intended to defer from donating blood. This occurs in the situations before a transgender individual chooses to undergo sex reassignment surgery. A pre-operation transgender woman—who would be a PWP—would be deferred for having sex with another PWP,

which is the type of conduct the MSM deferral policy intended to defer. Analogously, a pre-operation transgender man—who would not be a PWP—would not be deferred from donating blood for having sex with another PWP since the MSM deferral policy does not intend to defer individuals based on their engagement in heterosexual sexual conduct.

Table Two also shows that in the other two scenarios there is a mismatch between those the MSM deferral policy intends to defer from donating blood and those it actually defers. If a post-operation transgender woman—who would not be a PWP—has sex with a PWP, she will be deferred from donating blood even though the MSM deferral policy was not meant to apply to this type of sexual conduct. Correspondingly, if a post-operation transgender man—who would be a PWP—has sex with a PWP, he would not be deferred from donating blood, although the MSM deferral policy aims to apply to that type of sexual conduct.

As seen in the comparison between Table One and Table Two, both sex classification policies create loopholes in the MSM deferral policy. The difference is that switching between policies reverses which groups are over-deferred and under-deferred from donating blood. In order to truly solve this problem, the FDA should shift away from time-based deferral periods that target donors with a particular sex and sexual orientation.

C. The "Transgender Application" is an Appropriate Vehicle to Advocate for a Shift Away from Time-Based Deferrals for Donors with a Particular Sex and Sexual Orientation

The loopholes created by the FDA's policies regarding the classification of a potential blood donor's sex are problematic because they showcase how the MSM deferral policy does not apply appropriately to all of the individuals it intended to defer. By over-deferring some PWPs and under-deferring other PWPs, the MSM deferral policy fails to achieve its goal of deferring PWPs who have had sex with other PWPs in the last twelve months from donating blood.

Unlike arguments that advocate for a shift in the FDA's policy based solely on the stigmatic and discriminatory effects of the MSM twelve-month deferral period, the "Transgender Application" should be persuasive, even compelling, to the FDA. This is because it shifts the focus away from the underlying merits of the MSM deferral policy and instead calls attention to the policy's misaligned goals and outcomes, pointing out that there are loopholes for PWPs in the deferral policy because it uses language that defers potential blood donors based on their sex and sexual orientation. After all, the FDA grounds the MSM deferral policy in the premise that sex between PWPs presents an increased risk of HIV/AIDS and therefore threatens the blood supply.[69]

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[69] *See* McAdam & Parker, *supra* note 2, at 24; U.S. FOOD & DRUG ADMIN., *supra* note 1.

By revealing that the MSM deferral policy does not apply to PWPs in the way it is intended, the "Transgender Application" should convince the FDA to re-evaluate the usefulness of basing deferral periods on a potential blood donor's sex and sexual orientation. The "Transgender Application" should persuade the FDA to change its policy to capture those engaging in high risk behaviors instead of allowing the loopholes under the policy's current language to persist. Just as the FDA changed course when it realized that there was increased non-compliance with the lifetime ban on blood donations from MSMs,[70] so too should it abandon deferral policies based on an individual's sex and sexual orientation when they do not and cannot be applied properly to an entire category of donors.

III. REPLACING DEFERRALS DASED ON A POTENTIAL BLOOD DONOR'S SEX AND SEXUAL ORIENTATION WITH INDIVIDUALIZED RISK ASSESSMENTS

This part proposes that the FDA should resolve the problem outlined in Part Two by replacing its existing blood donor eligibility guidelines with an individualized risk assessment (IRA). An IRA uses a set of questions about a potential blood donor's personal history to determine a his or her individual risk of being infected with HIV/AIDS.[71] Based on the potential blood donor's answers to the IRA, an organization hosting a blood drive would defer only those people who *actually* engage in the high-risk behaviors identified on the questionnaire. This solution would allow the FDA to defer donors whose individual behavior actually presents a risk to the blood supply instead of using a potential blood donor's sex and sexual orientation to create sweeping deferral policies that serve no purpose other than to stigmatize members of the LGBTQ community.

A. Describing Individualized Risk Assessments and How They Solve the "Transgender Application"

The current blood donor eligibility guidelines in the United States focus on deferring potential blood donors due to their membership in a certain group that the FDA has deemed to have a heightened risk of contracting and transmitting HIV/AIDS, such as MSMs. IRAs shift the focus from classifications based on statistics of the risk of the group *as a whole* to classifications based on a *specific* potential blood donor's high risk behavior.[72] IRAs ask potential blood donors about their engagement in high risk behavior, such as having sex with more than one partner whose sexual history is unknown, participating in prostitution, injecting

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[70] U.S. FOOD & DRUG ADMIN., *supra* note 1.

[71] Melissa Kong, *United States' Blood Donor Policy on Gay Men: Adopting an Italian Individual Risk Assessment Policy*, 23 ANNALS OF HEALTH L. ADVANCE DIRECTIVE 101, 102 (2014).

[72] *Id.* at 103.

intravenous drugs or sharing needles, or having sex with a partner who is known to have a communicable disease, such as HIV/AIDS.[73] Notably, while IRAs still ask a potential blood donor about his or her sexual behavior, they do not inquire about a person's sex or sexual orientation.

Shifting to an IRA would address the flaws revealed by the "Transgender Application" because it would close the loopholes in the current MSM deferral policy that allow potential blood donors to not comply with the policy's goals given the language of the FDA's sex classification policies. Instead of relying on classifications of a potential blood donor's sex and sexual orientation to determine his or her risk of HIV/AIDS, IRAs assess a potential blood donor's risk level based on his or her *actual* engagement in high risk behavior.[74] This system appropriately identifies high risk donors and defers them based on their behavior, as opposed to being both under- and overinclusive in deferring individuals with perceived risk based on their sex and sexual orientation.

B. Individualized Risk Assessments are a Safe and Viable Policy Alternative for the FDA to Pursue Due to the Scientific Advancements in Blood Donation Testing and Storage

When the FDA rejected shifting to an IRA in 2015, it stated that with "approximately 50,000 new HIV infections per year in the United States, conservative calculations performed by [the] FDA estimate that [shifting to an IRA] could potentially be associated with an approximately four-fold increase in HIV transmissions resulting from blood transfusions each year."[75] The FDA stated that such a policy was counter to its goals of protecting the nation's blood supply and preventing the transmission of HIV/AIDS through blood transfusions.[76] However, implementing an IRA is not counter to these goals—even assuming any projected increase in the number of HIV-positive blood donations is accurate—due to the continued scientific advancements in the testing and storage of blood donations detailed in Section II.C.

At the outset of the HIV/AIDS crisis, there were not testing procedures established to screen blood donations for HIV/AIDS.[77] However, in the early 2000s, scientists developed the nucleic acid test (NAT),[78] which shortened the latency period for detecting HIV in a person's blood to between nine and eleven days.[79] The NAT also increased the accuracy of HIV screenings, with one study finding that the NAT produces false-negatives only four times per ten million screens for HIV, despite

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[73] *Id.*
[74] *Id.*
[75] U.S. FOOD & DRUG ADMIN., *supra* note 1.
[76] *Id.*
[77] Pulver, *supra* note 12, at 117.
[78] McAdam & Parker, *supra* note 2, at 29.
[79] *Id.* at 30.

both human and technical error.[80] Today, the United States requires that all blood donations be subjected to the NAT.[81]

Even if at the outset of implementing an IRA there was an increase in the number of HIV-positive donations made,[82] the accuracy and across the board implementation of the NAT ensures that there would be no threat to the safety of the nation's blood supply because any contaminated donations would be promptly identified and destroyed.[83] This calls into question the accuracy of the FDA's projected four to five-fold increase in HIV transmissions through blood transfusions if the MSM deferral policy were lifted. One study found that the risk of transmitting HIV through a blood transfusion is one in two million in the United States.[84] Therefore, while time-based deferral periods for donors with a particular sex and sexual orientation may once have been scientifically justified, advancements in the testing of blood donations make such policies unwarranted and allow for the implementation of IRAs. Furthermore, as science continues to advance, IRA questionnaires can be updated to reflect new testing procedures and new information about HIV/AIDS contraction and transmission to more accurately identify and defer high risk donors.

Similarly, advancements in the storage of blood donations, especially when considered with the advancements in the testing of blood donations, support the implementation of an IRA as a low-risk policy option.[85] While blood donations formerly had a shelf life of only twenty-one days, scientists have discovered ways to store blood donations for longer periods of time.[86] Lengthening the time that blood donations can be stored allowed blood banks to quarantine donations for post-donation testing.[87] This means that after a blood donation is given, a unit of blood can now be entered into a storage facility and subjected to tests like the NAT.[88] This allows blood donations to be stored for the duration of the HIV/AIDS latency period and then subjected to testing so that the blood has had the requisite amount of time to develop the antibodies the NAT

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[80] Ciufo, *supra* note 47, at 355.

[81] McAdam & Parker, *supra* note 2, at 49.

[82] Ciufo, *supra* note 47, at 351 ("If the United States were to eliminate the lifetime ban researchers estimate in the first year of implementation an additional 322 HIV positive donations would be made under a five-year deferral policy, or 1,645 donations under a one-year deferral policy. After the first year, however, the increased risk from either deferral policy would likely decrease four to five fold.").

[83] *Id.*

[84] Kong, *supra* note 71, at 109.

[85] Ciufo, *supra* note 47, at 355.

[86] *Blood FAQ*, *supra* note 5.

[87] Request for Information (RFI) on Design of a Pilot Operational Study To Assess Alternative Blood Donor Deferral Criteria for Men Who Have Had Sex With Other Men (MSM), 77 Fed. Reg. 49, 14804 (Mar. 13, 2012).

[88] *Id.*

detects. This, in turn, leads to more accurate results and a safer blood supply. While blood donation storage technology at one time did not permit post-donation testing, scientific advancements allow donations to be stored and used well past the latency period for detecting HIV/AIDS, making IRAs a feasible and practical option.

C. Individualized Risk Assessments Have Been Successfully and Safely Implemented in Other Countries

In implementing an IRA, the United States can look to other countries to learn from their processes and adopt their best practices. Countries like Italy, Spain, and Mexico can serve as models for the United States in enacting IRAs.

1. Italy's Implementation of an IRA

In Italy, about 0.3% of the population is living with HIV/AIDS—a figure analogous to the United States.[89] Until 2001, Italy imposed a time-based deferral period on MSM blood donors "due to the belief that allowing MSM donors would pose a major risk of spreading HIV."[90] In 2001, Italy replaced its MSM deferral policy with an IRA.[91]

Italy's IRA screens its potential blood donors by asking questions about risky behaviors.[92] The policy distinguishes between behavior that poses a risk to the blood supply and behavior that poses a "high risk" to the blood supply.[93] Risky behavior includes "having a new sexual partner whose sexual behavior is unknown, having ever had one occasional sexual relationship with a person whose sexual behavior is unknown, [or] having had casual sex with an [HIV-infected] partner."[94] A blood donor who engaged in any "risky behavior" is deferred for four months from the incidence of such behavior.[95] Under Italy's policy, high risk behavior includes "usual/recurrent (occurring repeatedly) sex with more than one . . . partner whose sexual behavior is unknown, receiving or exchanging sex for money, use of injecting drugs, [and] usual/recurrent sex with a partner [who is] positive for . . . HIV . . . ."[96] Any potential

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[89] McAdam & Parker, *supra* note 2, at 40.

[90] *Id.*

[91] *Id.*

[92] *Id.*

[93] Barbara Suligoi et al., *Changing Blood Donor Screening Criteria from Permanent Deferral for Men Who Have Sex With Men to Individual Sexual Risk Assessment: No Evidence of a Significant Impact on the Human Immunodeficiency Virus Epidemic in Italy*, 11 BLOOD TRANSFUSION 441, 442 (2013), available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3729137/.

[94] *Id.*

[95] *Id.*

[96] *Id.*

blood donor who engages in these behaviors is permanently barred from donating blood.[97]

After Italy replaced its MSM deferral policy with an IRA, researchers conducted studies to track the prevalence of HIV-positive blood donations.[98] One study showed that "[f]or every 100,000 donations, 3.8 were HIV positive; for every 100,000 donations among repeat donors 2.4 were HIV positive; for every 100,000 donations among first-time donors 17.2 were HIV positive."[99] However, another study found that "the increase in HIV positive donations was caused not by MSM donors but heterosexual donors."[100]

Researchers also conducted studies in the Lombardy region of Italy, which has the highest incidence of HIV infection in Italy and accounts for twenty percent of the blood donations given in the country.[101] Researchers collected data from 1997 to 2005, which spans from the time Italy had its MSM deferral policy in place through after Italy implemented the IRA.[102] Out of all the blood donors during that time period, 130 were HIV positive.[103] Of the 130 donations, "risk factors associated with heterosexual intercourse accounted for 48% and male homosexual intercourse accounted for 12%."[104] The study concluded that while Italy did see an increase in the prevalence of HIV-positive donations, the risk factors associated with that increase were associated with "heterosexual promiscuity," not homosexual intercourse.[105]

While this Note does not advocate for introducing permanent deferrals for high risk behaviors like Italy's IRA policy currently employs, Italy's experiences show that removing classifications based on sex and sexual orientation does not necessitate an increased number of HIV-positive donations from MSM donors.[106] Italy's IRA policy provides a foundation, which coupled with scientific advances in blood testing and storage, could be a workable model for the United States in implementing an IRA.

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[97] *Id.*

[98] McAdam & Parker, *supra* note 2, at 40–41.

[99] *Id.* at 40.

[100] *Id.* at 51; Suligoi et al., *supra* note 93, at 445 ("[I]n 2010, MSM accounted for 40.3% and heterosexuals for 46.8% of new HIV diagnoses.").

[101] McAdam & Parker, *supra* note 2, at 41.

[102] *Id.*

[103] *Id.*

[104] *Id.* The remaining HIV transmissions were not caused by sexual activity. *Id.*; *see also supra* note 34.

[105] *Id.*

[106] *Id.*

2. Spain and Mexico's Implementation of an IRA

In 2005, Spain abolished its blood donor eligibility guidelines that deferred potential blood donors due to their sex and sexual orientation.[107] In its place, Spain implemented an IRA that asks potential blood donors questions about their personal and sexual history to gauge whether the potential blood donor has a high risk of HIV.[108] For example, "Spain now asks all blood donors if in the last six months they have had sex with more than one person, a person who is HIV-positive, a person with many different partners, . . . [or] a person who is an intravenous drug user."[109]

In 2012, Mexico overturned its ban on blood donations from MSMs.[110] In its place, Mexico adopted a "risky sexual practices" approach to blood donor eligibility.[111] Mexico defines "risky sexual practices" as "any sexual practice that may include 'contact or exchange of blood, sexual secretions or other bodily secretions between someone who might have a transmittable disease and areas of another person's body through which an infectious agent might be able to penetrate.'"[112] In Mexico, there have been no instances of transmission of HIV/AIDS through blood transfusions since 1999, a time before the IRA was enacted.[113]

Both Spain and Mexico's IRAs serve as possible templates for the United States in assessing alternative approaches and ultimately adopting an IRA. They also help ease the anxiety that increasing the possibility of HIV-positive donations entering the blood supply will lead to more HIV/AIDS transmissions through blood transfusions because this was not the case in Mexico.[114] In implementing an IRA of its own, the FDA should look to countries like Italy, Spain, and Mexico to determine what procedures produce the results best aligned with its goals of safeguarding the blood supply and reducing the transmission of HIV/AIDS through blood transfusions.

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[107] *Id.* at 39.

[108] *Id.*

[109] *A Drive for Change*, *supra* note 19, at 14–15 (quoting Ministerio de Sanidad y Política Social, Cuestionario Unifacado Para La Seleccion De Donates De Sangre y Componentes Sangueineos [Uniform Questionnaire for the Selection of Blood and Blood Component Donors], http://www.msps.es/profesionales/saludPublica/medicinaTransfusional/acuerdos/docs/cuestionarioUnificado.pdf).

[110] McAdam & Parker, *supra* note 2, at 44.

[111] *Id.*

[112] *Id.*

[113] *Id.* at 45.

[114] *Id.*

D. Tangential Benefits of Implementing an Individualized Risk Assessment

In addition to fixing the "Transgender Application," shifting to an IRA system would provide tangential benefits for blood drive administrators, LGBTQ advocates, and medical patients. The administrators of blood donation eligibility guidelines would benefit from this shift because it would increase the clarity of the language used in blood donor deferral policies.[115] LGBTQ advocates would benefit from shifting to an IRA because such a policy would reduce the stigma that is presently associated with the time-based deferrals for donors with a particular sex and sexual orientation.[116] Furthermore, this shift would reinforce educational efforts to prevent the infection and transmission of HIV/AIDS, regardless of a person's sex and sexual orientation.[117] Finally, medical patients would benefit because the increased number of eligible blood donors would lessen the current blood shortage facing the United States.[118] Each benefit is described in more detail below.

1. IRAs Lead to Increased Clarity in the Language of Blood Donor Deferral Policies

Under the current FDA policy, blood donation representatives must "[d]efer for 12 months from the most recent sexual contact, a man who has had sex with another man during the past 12 months."[119] Although the FDA guidelines state that "sex" means, "having anal, oral, or vaginal sex, regardless of whether or not a condom or other protection is used," not all blood donors interpret the meaning of sex that way.[120] Therefore, the potential blood donor is left to define the term for him or herself, possibly excluding oral sex or protected sex as part of the definition.[121] This confusion is compounded for those in relationships with intersex and transgender individuals because now they are asked to classify the sex of their partner, which may lead to inconsistent interpretations of and responses to the questionnaire. This uncertainty creates an inconsistency that is not in line with the goals of the policy.[122]

Shifting to an IRA would solve the problem by moving the questions away from classifications based on sex and sexual orientation and increasing the clarity of the language used in the questionnaire. Having

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[115] John G. Culhane, *Bad Science, Worse Policy: The Exclusion of Gay Males from Donor Pools*, 24 ST. LOUIS U. PUB. L. REV. 129, 136–37 (2005).

[116] Michael Christian Belli, *The Constitutionality of the "Men Who Have Sex with Men" Blood Donor Exclusion Policy*, 4 J.L. SOC'Y 315, 365 (2003).

[117] *A Drive for Change*, *supra* note 19, at 31.

[118] McAdam & Parker, *supra* note 2, at 63–64.

[119] U.S. FOOD & DRUG ADMIN., *supra* note 1.

[120] Culhane, *supra* note 115, at 136–37.

[121] *Id.*

[122] *Id.*

specific and clear questions about the potential blood donor's personal and sexual history helps to increase compliance with the policy due to the decreased risk of confusion or misinterpretation of the questionnaire.

2. IRAs Result in Reduced Stigma Associated with Time-Based Deferrals for Donors with a Particular Sex and Sexual Orientation

Although the FDA no longer places a lifetime ban on blood donations from MSMs, its twelve-month deferral policy retains the stigma associated with the lifetime ban.[123] When asked about his experience with the MSM deferral policies, one student activist said, "I have never been openly discriminated to my face like that before, and I have never cried as hard as I did when I returned to my room after trying to give blood."[124] Studies have shown that this student's feelings are widely held among the MSM community.[125] BloodDROPS, a project committed to learning about the effects of the MSM deferral policies, examined MSMs' views about and reactions to the FDA's policies and found that "individuals view the current policy as discriminatory and stigmatizing."[126]

Though the MSM deferral policies do not make sex between MSMs criminal, they do reinforce in official government policy the presumption that "'gay' is synonymous with HIV/AIDS"[127] or at least that "all gay men are guilty of risky behavior and communicable diseases."[128] The FDA's shift to the twelve-month deferral period did not solve this problem because the policy still effectively bans MSMs from being sexually active if they want to donate blood. Under the FDA's current policy, an MSM would have to choose between engaging in sexual activity for a year and donating blood. The Australian Red Cross stated that the choices MSM deferral policies pose "create[] a significant challenge to the donor's right to sexual preference."[129]

In addition to stigmatization, blood donation policies that classify donors and determine their eligibility based on their sex and sexual orientation have other destructive side effects. As one scholar noted:

> Laws prohibiting sexual activity between people of the same sex can create enormous obstacles for gays, lesbi-

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[123] Letter from Rep. Mike Quigley et al., *supra* note 6.

[124] Pulver, *supra* note 12, at 121.

[125] U.S. FOOD & DRUG ADMIN., *supra* note 1.

[126] *Id.*

[127] McAdam & Parker, *supra* note 2, at 58.

[128] *Id.*; Dwayne J. Bensing, *Science or Stigma: Potential Challenges to the FDA's Ben on Gay Blood*, 14 U. PA. J. CONST. L. 485, 499 (2011) ("The blood ban is distinguished in that it does not make MSM acts criminal. However, under the blanket ban, one is presumed guilty of risky behavior and communicable disease simply by being gay.").

[129] McAdam & Parker, *supra* note 2, at 52.

> ans, and bisexuals to come out, to meet potential partners, and to develop relationships. These laws create opportunities for blackmail and extortion, generate fear of exposure, promote the idea that anti-homosexual discrimination and violence is justified, and portray homosexuals as criminals.[130]

Furthermore, these policies "carry the serious risk of frightening some young people back into secrecy, abstinence, or solitude, with all kinds of risks for their emotional and physical wellbeing."[131] These policies also have negative effects on spreading awareness and information about HIV.[132] The stigma reinforced by the FDA's MSM deferral policies "undermines education to gay men about activities that decrease the likelihood of obtaining a sexually transmitted disease, such as engaging in protected sexual activity and maintaining monogamous, trusting relationships."[133] Furthermore, the policy frustrates efforts directed universally about the contraction and transmission of HIV/AIDS, giving heterosexual individuals the false impression that HIV/AIDS is only a worry for those who engage in homosexual sexual activity.[134]

By implementing an IRA in place of the current FDA policy that defers potential blood donors based on their sex and sexual orientation, the FDA would negate the presumption that MSMs likely have HIV/AIDS and engage in high risk behavior. Without the stigmatization of the current FDA policies, potential blood donors may be more likely to answer the questionnaire honestly and comply with any deferral period that is based on their specific answers to the questionnaire. This would help to screen out *actually* risky donors instead of relying on false assumptions that lead to both under- and overinclusivity in deferrals. While LGBTQ advocates have not been able to use this argument to persuade the FDA to change its twelve-month deferral policy for MSM blood donors, they would see the alleviation of this stigma and its side effects as a benefit of switching to an IRA.

Furthermore, implementing an IRA would help to reinforce educational efforts related to the infection and spread of HIV and to combat misconceptions about the virus.[135] By using "[a] screening procedure that distinguishes between low-risk and high-risk sexual practices by both MSM individuals and others, accompanied by materials explaining those risks and their relation to eligibility to donate blood[,]" enacting an IRA would educate all donors about HIV prevention, regardless of their

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[130] Kees Waaldijk, *The Right to Relate: A Lecture on the Importance of "Orientation" in Comparative Sexual Orientation Law*, 24 DUKE J. COMP. & INT'L L. 161, 187 (2013).

[131] *Id.* at 194.

[132] Bensing, *supra* note 128.

[133] *Id.*

[134] *Id.*

[135] *A Drive for Change*, *supra* note 19, at 31.

sex or sexual orientation.[136] According to Gay Men's Health Crisis, "[t]o the extent that exposure to such questions, informational materials, and pre-donation consultations encourages all individuals to engage in healthier, less risky practices, the policy will result in a safer donor pool overall. Such a policy would also fill the glaring hole remaining in any permanent or temporary deferral policy that implies, incorrectly, that a non-MSM individual is inherently safer from HIV and other transmissible diseases than an MSM individual, even if the former engages in high-risk behavior."[137]

3. Implementing an IRA Would Decrease the Blood Shortage by Increasing the Number of Eligible Blood Donors

Finally, implementing an IRA would decrease the shortage in the blood supply by increasing the number of eligible blood donors in the United States. There is a constant need for blood throughout the nation.[138] Every two seconds, a medical patient needs blood from the blood supply.[139] Over 44,000 blood donations are needed every day.[140] A single car accident can require around one hundred pints of blood.[141] In recent years, the demand for blood in the United States has been steadily increasing by about one percent each year.[142] Despite this continuous need, the number of blood donations has been decreasing in the past several years by about one percent per year,[143] leading to a shortage in the nation's blood supply.[144] In 2000, the shortage "was so critical that many hospitals throughout the United States had no choice but to cancel elective surgeries."[145] In 2012, the Red Cross said its national blood supply was at its "lowest level in [fifteen] years."[146]

Shifting to an IRA could help solve this problem because it would increase the number of individuals in the United States that are eligible to donate blood.[147] As Congress noted, "The current FDA deferral policy effectively leaves the majority of MSM ineligible to donate blood, as the [twelve]-month celibacy requirement is unrealistic for most healthy gay and bisexual men to meet."[148]

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[136] *Id.*
[137] *Id.*
[138] McAdam & Parker, *supra* note 2, at 62.
[139] *Id.*
[140] *Id.*
[141] *Id.*
[142] Belli, *supra* note 116, at 317.
[143] *Id.*
[144] *Id.*
[145] *Id.*
[146] McAdam & Parker, *supra* note 2, at 62.
[147] *Id.* at 63–64.
[148] Letter from Rep. Mike Quigley et al., *supra* note 6.

One study, by analyzing the survey data between 2000 and 2008 collected by the University of Chicago's General Social Survey, attempted to quantify the increase in eligible blood donors that would result from eliminating MSM deferral policies all together.[149] The study began by estimating the population of men over eighteen in the United States that would be currently barred from donating blood under the FDA's MSM deferral policy.[150] It found that 3.5% of adult men in the United States reported having sexual contact with a male partner in the past twelve months.[151] The study then applied this percentage to the overall population of adult men in the United States to estimate that there are about 3.9 million men in the United States that would be deferred from donating blood for having sex with a male partner in the past twelve months.[152] From that 3.9 million men, the study subtracted the number of MSM who are HIV-positive, as they would not be eligible blood donors even under an IRA.[153] Given that the CDC estimates that there are 532,000 HIV-positive MSMs in the United States, the number of eligible donors fell to roughly 3.85 million men.[154]

Next, the study applied figures from the American Red Cross about the percentage of the population that is eligible to donate blood and the number of people within that subgroup who actually donate blood.[155] Given that only a small percentage of the eligible blood donors actually donate blood each year, the study concluded that lifting the twelve-month deferral period for MSM donors would lead to an additional 53,269 annual blood donors.[156] The additional donors would be likely to donate 89,716 pints each year.[157] Since according to the American Red Cross one pint of blood can save up to three lives,[158] removing the twelve-month deferral period for blood donations from MSMs could save as many as 269,148 lives each year.

Last, it is noteworthy that replacing the twelve-month deferral period for blood donations from MSMs could lead to an increase in the number of blood donations from those who self-identify as straight.[159] According to a recent population-based health survey of men living in New

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[149] Naomi G. Goldberg and Gary J. Gates, *Effects of Lifting the Blood Donation Ban on Men Who Have Sex with Men*, 5 PITT. J. ENVTL. PUB. HEALTH L. 49, 49 (2011).

[150] *Id.* at 54.

[151] *Id.* at 55.

[152] *Id.*

[153] *Id.* at 54, 56.

[154] *Id.* at 56.

[155] *Id.* at 54, 56.

[156] *Id.* at 57.

[157] *Id.*

[158] AMERICAN RED CROSS, *Learn About Blood*, http://www.redcrossblood.org/learn-about-blood.

[159] Ryan H. Nelson, *An Indirect Challenge to the FDA's "Gay Blood Ban"*, 23 TUL. J.L. & SEXUALITY 1, 10 (2014).

York City, nearly ten percent of men surveyed who self-identified as straight had at least one sexual encounter with a male partner in the last twelve months.[160] While this figure may not be representative of the entire country, this survey is still useful in that it suggests that implementing an IRA could lead to a rise in eligible donors of all sexual orientations.[161]

CONCLUSION

The FDA currently places a twelve-month deferral period on MSM blood donors based on the idea that the MSM population has a heightened risk of contracting and transmitting HIV/AIDS. Given its dual goals of protecting the nation's blood supply and preventing the transmission of HIV/AIDS through blood transfusions, the FDA targets MSM blood donors by enacting policies that defer potential blood donors based on their sex and sexual orientation. However, the FDA's MSM deferral policy does not capture the donors it intended to, as seen by the "Transgender Application." This highlights the loopholes created by the FDA's sex-classification policies that allow some PWPs to not be deferred from donating blood while deferring some non-PWPs from donating.

To solve this problem and appropriately defer those with a heightened risk of contracting and transmitting HIV/AIDS from donating blood, the FDA should abandon its policies that defer potential blood donors based on classifications of their sex and sexual orientation and implement an individualized risk assessment (IRA). In shifting to an IRA, the FDA can look to other countries like Italy, Spain, and Mexico who have successfully and safely enacted IRAs and can learn from their best practices. Given the scientific advances in blood donation testing and storage, IRAs are a safe and reasonable policy option for the FDA to carry out. Implementing an IRA will increase the clarity of the policy's and the questionnaire's language, decrease the blood shortage by expanding the number of eligible blood donors, and address the concerns of LGBTQ advocacy groups who oppose the current MSM deferral policy due to its discriminatory and stigmatic effects.

By taking the new approach of focusing on the "Transgender Application" instead of criticizing the underlying merits of the MSM deferral policy itself, advocates are more likely to convince the FDA to shift away from time-based deferrals that target potential blood donors with a particular sex and sexual orientation and move toward the implementation of IRAs. Though this approach attempts to persuade the FDA to reevaluate its blood donor deferral policies by focusing in on one narrow problematic aspect of the MSM deferral policy, the solution alleviates the many problems associated with the policy as a whole.

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[160] *Id.*

[161] *Id.*

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