

United States' Blood Donor Policy on Gay Men:  
Adopting an Italian Individual Risk Assessment  
Policy

*Melissa Kong\**

I. INTRODUCTION

An estimated thirty-seven percent of the United States' population is eligible to donate blood, but less than ten percent of those eligible actually donate each year.<sup>1</sup> The small eligibility pool is due in part to restrictions placed upon potential donors.<sup>2</sup> One such restriction is a permanent ban from donating blood against men who had sexual contact with other men (MSM) at least once since 1977.<sup>3</sup> According to the United States Food & Drug Administration (FDA), MSM who donate blood pose an increased risk for the human immunodeficiency virus (HIV) and other infections to be transmitted by a blood transfusion.<sup>4</sup> Not all countries, however, prevent MSM from donating blood.<sup>5</sup> Italy does not prohibit blood donations from individuals

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\* Melissa Kong is a second-year student at Loyola University of Chicago School of Law who is pursuing a public interest certificate and a health certificate.

1. Vianca Diaz, *A Time for Change: Why the MSM Lifetime Deferral Policy Should be Amended*, 13 U. MD. L.J. RACE, RELIGION, GENDER & CLASS 134, 146 (2013); *Facts & Figures*, AM.'S BLOOD CTRS., <http://www.americasblood.org/about-blood/facts-figures.aspx> (last visited Mar. 7, 2014).

2. Diaz, *supra* note 1, at 146 (indicating one reason for the blood shortage is that only 37% of Americans are eligible to donate blood; if the United States amends its deferral policies then more willing and healthy citizens can donate).

3. Dwayne J. Bensing, *Science or Stigma: Potential Challenges to the FDA's Ban on Gay Blood*, 14 U. PA. J. CONST. L. 485, 486 (2011).

4. *Blood Donations from Men Who Have Sex with Other Men Questions and Answers*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/biologicsbloodvaccines/bloodbloodproducts/questionsaboutblood/ucm108186.htm> (last updated Aug. 19, 2013) [hereinafter FDA FAQ].

5. See Meredith Ciufo, *Drawing Blood: Towards an EU Remedy for Blood Donation Rights*, 31 B.U. INT'L L.J. 341, 344 (2013) (stating Spain and Italy do not have MSM restrictions in their blood donation qualifications).

based on their sexual orientation;<sup>6</sup> instead, Italy uses a process called an individual risk assessment (IRA).<sup>7</sup> If a person is deemed under an IRA to have high-risk behavior, he or she is not allowed to donate blood.<sup>8</sup>

This article argues the United States should emulate Italy's blood donation policy where an individual is assessed according to his or her own behavior, regardless of sexual orientation. Part II outlines the United States' MSM permanent deferral policy and Italy's IRA policy. Part III discusses the significant increase in the availability of scientific data in regards to HIV, which supports the fact that it is time to adopt an IRA policy in the United States. Part IV demonstrates other donors, outside of MSM donors, have the potential to be HIV-positive, further invalidating the United States' ban on MSM. Part V examines the advancements in technology that enables Italy to detect HIV-antibodies and that leads to virtually zero such infections entering the blood supply. Part VI will discuss the FDA's resistance to an IRA policy.

## II. BLOOD DONOR POLICIES

### A. United States' Blood Donor Policy

In the United States, the FDA requires that a blood donor is healthy, at least seventeen years old, and weighs a minimum of 110 pounds.<sup>9</sup> Moreover, a donor cannot fall into a deferral category.<sup>10</sup> A donor may receive a deferral for various reasons, including if an individual lived in certain coun-

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6. See *id.* (indicating Italy's blood donation qualifications are based on an individual analysis of high-risk behavior and MSM are not explicitly mentioned).

7. Barbara Suligo 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/>.

8. *Id.*

9. Whitney Larkin, *Discriminatory Policy: Denying Gay Men the Opportunity to Donate Blood*, 11 HOUS. J. HEALTH L. & POL'Y 121, 125 (2011) (stating in some states a blood donor may be 16 years old with parental consent).

10. *Id.*

tries, previously engaged in high-risk behavior, or possesses signs and symptoms of HIV.<sup>11</sup> There are two types of deferrals: temporary and permanent.<sup>12</sup> If a donor is issued a temporary deferral, a donor must wait for a specified period of time before giving blood.<sup>13</sup> If a donor is issued a permanent deferral, that individual is indefinitely banned from donating blood and subsequently placed on a national deferral registry.<sup>14</sup> The United States' current policy permanently defers MSM from donating blood.<sup>15</sup>

### *B. Italy's Blood Donor Policy*

Comparatively, Italy does not have a specific MSM deferral policy.<sup>16</sup> In 2001, Italy modified its blood-donor eligibility from a permanent deferral for MSM to an IRA, analyzing individuals based on his or her own at-risk behavior.<sup>17</sup> Instead, both males and females, heterosexuals and homosexuals, are permanently deferred if they engage in high-risk behavior.<sup>18</sup> A permanent deferral is issued if an individual engages in sex with more than one partner whose sexual behavior is unknown, participates in prostitution, injects drugs, or engages in sex with a partner who is known to have a communicable disease.<sup>19</sup> Sexual orientation, by itself, is not grounds for a permanent deferral.<sup>20</sup>

## III. INCREASED AWARENESS OF HIV

### *A. Scientific Knowledge Prior to the MSM Policy*

The FDA issued its MSM blood donation policy in 1985, at a time of un-

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11. *Id.*

12. *See id.* at 126 (discussing temporary and permanent deferrals).

13. *Id.*

14. *Id.*

15. Bensing, *supra* note 3, at 486.

16. *See Ciuffo, supra* note 5, at 344 (indicating that there is no mention of MSM in Italy's policy to qualify as a donor).

17. Suligoi et al., *supra* note 7, at 442.

18. *Id.*

19. *Id.*

20. *Id.*

certainty when tests could not accurately detect HIV-antibodies in blood and the cause of the virus was unknown.<sup>21</sup> In mid-1981, the first case of acquired immunodeficiency syndrome (AIDS) was characterized in homosexual men, but referred to as a rare lung disease.<sup>22</sup> Toward the end of the year, at least 270 homosexual men were diagnosed with what is now known as AIDS.<sup>23</sup> In response to this outbreak, in 1983, the FDA issued non-mandatory guidelines suggesting that at-risk groups refrain from donating blood.<sup>24</sup> One year later, scientists discovered HIV triggered the AIDS virus.<sup>25</sup> Throughout this time, HIV was most prevalent in sexually active MSM, and there was a general lack of scientific knowledge regarding the transmission of HIV.<sup>26</sup>

The AIDS outbreak transpired worldwide.<sup>27</sup> In Italy, the HIV epidemic began in 1982 and peaked in 1987.<sup>28</sup> Similar to the United States, there was a general lack of knowledge as to the cause of the AIDS outbreak.<sup>29</sup> Subsequently, Italy implemented a permanent deferral to MSM.<sup>30</sup> The FDA fur-

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21. See Larkin, *supra* note 9, at 121, 132.

22. See Kumanan Wilson et al., *Three Decades of MSM Donor Deferral policies. What Have we Learned?*, 18 INT'L J. OF INFECTIOUS DISEASES 1, 1 (2014), available at <http://download.journals.elsevierhealth.com/pdfs/journals/1201-9712/PIIS1201971213003081.pdf> (indicating in mid-1981 AIDS was characterized in homosexual men); Diaz, *supra* note 1, at 136 (indicating that on June 5, 1981, five gay men were found to have what is now known as AIDS; the United States Centers for Disease Control and Prevention published a report detailing the men with a rare lung infection).

23. Diaz, *supra* note 1, at 136.

24. See Bensing, *supra* note 3, at 491-92 (stating the Office of Biologics issued non-mandatory guidelines suggesting individuals that had an increased risk for AIDS should refrain from donating blood); *Vaccines, Blood, & Biologics*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/biologicsbloodvaccines/guidancecomplianceregulatoryinformation/ucm331317.htm> (last updated March 31, 2014) (indicating the Office of Compliance and Biologics is a division of the U.S. Food & Drug Administration).

25. Wilson, *supra* note 22, at 2.

26. See Larkin, *supra* note 9, at 121-22 (indicating at the time, AIDS was most prevalent in the MSM community and there was no test to accurately detect HIV antibodies).

27. See Wilson, *supra* note 22, at 1 (“In the early 1980s, several countries were confronted with the tragedy of HIV-contaminated blood”).

28. Suligoj et al., *supra* note 7, at 441.

29. See Wilson, *supra* note 22, at 1-2 (indicating in mid-1982, AIDS was primarily diagnosed in MSM and in response, blood operators worldwide issued blood donor deferrals from MSM; at the time, no blood test could detect the AIDS-causing agent).

30. Suligoj et al., *supra* note 7, at 442 (“[A]ny male who declared having ever had sex

ther revised its policy in 1985 to exclude MSM entirely and include language for a lifetime deferral, creating the United States' policy as it is today.<sup>31</sup> As scientific research improved, Italy adopted a new approach and the United States decided to stand by its MSM policy.<sup>32</sup>

### *B. Scientific Knowledge Post MSM Policy*

Increased awareness of HIV and its causes lead to policy changes worldwide.<sup>33</sup> In particular, Italy changed its policy to accept blood donations from healthy gay and bisexual individuals so long as they posed no high-risk behavior and their blood tested as safe.<sup>34</sup> The global community now knows that AIDS is a blood-borne disease and can be transferred through blood contact from one individual to another.<sup>35</sup> In the United States, in the time period after the FDA implemented the MSM policy, individuals began to practice safer sex, tests were developed to detect HIV antibodies, and the population better understood the disease.<sup>36</sup> Statistically, from the 1990s to the early 2000s, HIV rates decreased among gay men and increased among other groups.<sup>37</sup> However, the United States fails to react to

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with other men was systematically permanently deferred”).

31. See Larkin, *supra* note 9, at 134 (stating the FDA initially recommended to blood banks not to accept MSM blood but eventually MSMs were permanently barred from donating blood in 1985).

32. See Suligoi et al., *supra* note 7, at 442 (stating Italy adopted its new IRA policy in 2001); Larkin, *supra* note 9, at 121 (indicating scientists developed tests concluding sexual orientation has nothing to do with HIV); David Crary, *Gay Blood Donors Ban Endures In the U.S., Despite Lacking ‘Sound Science’*, HUFFINGTON POST (Sept. 15, 2013, 11:25 AM), [http://www.huffingtonpost.com/2013/09/15/gay-blood-donors-ban\\_n\\_3932001.html](http://www.huffingtonpost.com/2013/09/15/gay-blood-donors-ban_n_3932001.html) (indicating U.S. should adopt measures similar to Spain and Italy, where a ban on blood donations by MSM has been replaced by policies that ban donations to anyone who recently had unsafe sex).

33. See Ciuffo, *supra* note 5, at 352 (indicating Australia abandoned its five-year deferral for MSM and adopted a one-year deferral period); Ferbus Walsh, *Gay Men Blood Donor Ban Lifted*, BBC NEWS (Sept. 8, 2011), <http://www.bbc.co.uk/news/health-14844413?print=true> (indicating the U.K. lifted its permanent deferral on MSM in 2011).

34. Crary, *supra* note 32.

35. Larkin, *supra* note 9, at 121.

36. See *id.*

37. *Id.* at 139 (adding in 1999, blacks were twenty-five times more likely than whites to acquire HIV and women had a high likelihood of contracting HIV; among HIV-positive individuals between twenty and twenty-four years old, forty-four percent were women).

this new knowledge of information.<sup>38</sup>

The MSM policy unethically prohibits individuals from donating blood because of their sexual orientation, even though many of them are potential healthy donors.<sup>39</sup> The policy also sends a false message that MSM naturally participate in inherently risky activities, consequently undermining education that an individual can decrease the likelihood of contracting a sexually transmitted disease through protected sexual activity or involvement in a monogamous relationship.<sup>40</sup> It is an unjust system because heterosexual individuals engaging in risky behavior are only issued a temporary ban, whereas MSM are indefinitely banned.<sup>41</sup> Not only is the policy unjust to MSM, it is also inefficient in protecting the donated blood supply from infection.<sup>42</sup>

The policy is over-inclusive in permanently banning healthy MSM donors and under-inclusive in admitting risky non-MSM donors.<sup>43</sup> Given the new span of information regarding the causes of HIV, it would be reasonable to adopt Italy's IRA policy to ensure those engaging in the same level of risky behavior are treated fairly.

#### IV. AN ITALIAN STUDY: EXAMINING HIV-POSITIVE BLOOD DONORS

Italy's IRA policy demonstrates that MSM HIV-positive individuals do not outnumber HIV-positive individuals from other groups; rather, heterosexuals substantially contribute to new HIV diagnoses, which further indi-

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38. *See id.* at 127 (indicating blood drive questionnaires focus on a person's sexual orientation, asking, "From 1977 to present, have you [male donors] had sexual contact with another male, even once?").

39. *See* Diaz, *supra* note 1, at 135 (indicating the lifetime deferral policy prohibits those who are healthy and fit to donate).

40. Bensing, *supra* note 3, at 499.

41. *See* Larkin, *supra* note 9, at 129 (indicating the ban that applies to MSM does not apply to heterosexuals; heterosexuals who engage in similar risky sexual behavior have a temporary deferral for up to twelve-months).

42. *See id.* (indicating there is a flaw in a system that tolerates a wide range of risks associated with heterosexual sex but not MSM, even if MSM pose no risk through their individual behavior).

43. Bensing, *supra* note 3, at 501.

cates that the United States' permanent ban on MSM is unwarranted.<sup>44</sup> One study obtained data from the Italian blood donor surveillance system in order to compare data from 1999, when Italy had a permanent deferral on MSM, to data from 2009 and 2010, when Italy applied its IRA policy.<sup>45</sup> The study established that Italy did not see a significant impact from the IRA policy on the number of HIV-positive MSM donors.<sup>46</sup> Instead, the study found the number of HIV-positive MSM donors increased at a similar rate to the incidence of HIV-positive heterosexual donors.<sup>47</sup>

The study demonstrates there are other risks, besides allowing MSM to donate blood, that lead to an increase in HIV-positive blood donors.<sup>48</sup> Although the study did conclude that overall, Italy had a higher percentage of HIV-positive blood donors compared to other Western European countries,<sup>49</sup> there is no indication that there is a higher percentage of HIV-positive MSM donors.<sup>50</sup> In 2011, the World Health Organization found that 55.4% of HIV infections in Italy occurred through heterosexual contact, 38.1% occurred through MSM sexual contact, and 5.5% occurred through intravenous drug use.<sup>51</sup> These statistics suggest the greatest risk to donors is not the risk of allowing MSM donors, as the United States seems to think.<sup>52</sup>

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44. See Suligoi et al., *supra* note 7, at 445 (“[I]n 2010, MSM accounted for 40.3% and heterosexuals for 46.8% of new HIV diagnoses”).

45. *Id.* at 442-43.

46. *Id.* at 445.

47. *Id.*

48. See *id.* (demonstrating an increase in the number of new HIV-diagnoses in heterosexuals from 16% in 1999 to 46.8% in 2010 in comparison to MSM from 38.4% in 1999 to 40.3% in 2010; 2010 data reflects a lower percentage of new MSM HIV-diagnoses in comparison to new heterosexual HIV-diagnoses, MSM are not the sole cause of HIV-diagnoses and other factors may come into play).

49. *Id.*

50. See *id.* at 447 (indicating the IRA policy “did not significantly affect either the incidence or prevalence of HIV infection among blood donors or the distribution of MSM and heterosexuals among HIV antibody-positive blood donors”).

51. WORLD HEALTH ORG., KEY FACTS ON HIV EPIDEMIC IN ITALY AND PROGRESS IN 2011 (2013), available at [http://www.euro.who.int/\\_\\_data/assets/pdf\\_file/0019/191080/Italy-HIVAIDS-Country-Profile-2011-revision-2012-final.pdf](http://www.euro.who.int/__data/assets/pdf_file/0019/191080/Italy-HIVAIDS-Country-Profile-2011-revision-2012-final.pdf).

52. See *id.* (indicating heterosexuals have contracted HIV infections at a higher rate in comparison to MSM).

The United States is concerned that if we allow MSM to donate blood, there will be an increase in the number of MSM HIV-positive blood donors who will contaminate the blood bank, but this concern is not valid.<sup>53</sup> Even during the period that Italy's permanent deferral was in effect, Italy saw an increased prevalence of HIV-positive donors, indicating that other factors might be responsible for contaminating blood banks with HIV.<sup>54</sup> One factor may be the perceived low risk of acquiring HIV, a belief particularly prevalent among heterosexuals who have unprotected sex.<sup>55</sup> Moreover, a study conducted in Lombardy, Italy concluded that despite the increase in HIV-positive donors before and after Italy's 2001 change of policy, there was no significant increase in MSM HIV-positive donors.<sup>56</sup> In general, if the United States implements an IRA policy, it does not mean the number of MSM HIV-positive donors will increase.<sup>57</sup>

## V. ADVANCEMENTS IN BLOOD TESTING METHODS

### A. Nucleic Acid Testing in Italy

By adopting an IRA policy, Italy gives greater confidence to its donor screening procedures and its blood testing capabilities.<sup>58</sup> Shortly after implementation of the IRA policy, on June 28, 2002, Italy mandated nucleic acid testing (NAT) technology to screen blood donations.<sup>59</sup> This method en-

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53. See *id.* (indicating stating in 2011, Italy saw a higher percentage of heterosexual HIV infections than MSM HIV infections); FDA FAQ, *supra* note 4 (stating MSM have an increased risk for HIV); see also Suligoi et al., *supra* note 7, at 445 (stating in 2010, Italy had a higher percentage of new heterosexual HIV diagnoses in comparison to new MSM HIV diagnoses).

54. Barbara Suligoi et al., *Epidemiology of Human Immunodeficiency Virus Infection in Blood Donations in Europe and Italy*, 8 BLOOD TRANSFUSION 178, 183 (2010), available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2906188/>.

55. *Id.*

56. *Id.*

57. See *id.* (stating in Italy there was "no significant increase in the prevalence of HIV in blood donations from MSM before and after 2001").

58. Ciufo, *supra* note 5, at 356.

59. C. Velati et al., *Impact of Nucleic Acid Amplification Technology (NAT) in Italy in the Three Years Following Implementation (2001-2003)*, 10 EUROSURVEILLANCE 12, 12 (2005), available at <http://www.eurosurveillance.org/images/dynamic/EQ/v05n01/v05n01>.



sure detection of HIV-antibodies and helps improve detection of viral infections that are not detectable under other blood testing measures.<sup>60</sup> After an individual is infected with the HIV virus, he or she may not develop the antibodies for several months, so there may be a gap in time when the virus goes undetected by a blood test.<sup>61</sup> This gap in time, also known as the window period, is narrowed due to NAT.<sup>62</sup> NAT can detect infections at an early stage, approximately in four to seven days from when the donor was infected.<sup>63</sup> Although there is little data on the effectiveness of this type of blood testing in Italy, its effectiveness is proven to be very successful in other parts of the world.<sup>64</sup>

### B. Nucleic Acid Testing in the United States

With the advancements in today's technologies to detect infection, the blood testing process in the United States has virtually eliminated the possibility of infected blood entering the donated blood supply.<sup>65</sup> Today the risk of transmitting HIV through a blood transfusion is 1 in 2,000,000 in the United States.<sup>66</sup> The FDA invested many of its resources to test blood for HIV antibodies through NAT.<sup>67</sup> The technological advancement with NAT and its high level of accuracy calls into question the MSM lifetime deferral policies of the United States.<sup>68</sup> MSM should not be permanently deferred

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60. See Syria Laperche, *Blood Safety and Nucleic Acid Testing in Europe*, 10 *EUROSURVEILLANCE* 3, 3 (2005), available at <http://www.eurosurveillance.org/images/dynamic/EQ/v05n01/v05n01.pdf> (indicating NAT detects viral infections not detected by the serological screening methods).

61. Bensing, *supra* note 3, at 493.

62. See Larkin, *supra* note 9, at 137 (indicating that NAT can trim a few days off of the "window period").

63. Diaz, *supra* note 1, at 145-46.

64. Ciufo, *supra* note 5, at 356 (indicating effective blood tests have shown donors that they are HIV-positive when they were otherwise unaware).

65. Larkin, *supra* note 9, at 132.

66. *Blood Testing*, AM. RED CROSS, <http://www.redcrossblood.org/learn-about-blood/what-happens-donated-blood/blood-testing> (last visited Apr. 4, 2014).

67. Larkin, *supra* note 9, at 137.

68. Bensing, *supra* note 3, at 493.

when testing methods have drastically improved to detect viruses.<sup>69</sup>

#### VI. FDA'S RESISTANCE TO AN INDIVIDUAL RISK ASSESSMENT

Despite the success rate of NAT, the FDA still calls into question the small time frame in which HIV-antibodies cannot be detected.<sup>70</sup> The FDA argues individuals are less likely to unknowingly donate blood during the window period of infection if there is a permanent deferral in place on MSM.<sup>71</sup> This window period, however, applies to all high-risk groups; MSM do not pose a higher risk.<sup>72</sup> According to the FDA, there is not sufficient information to lift the ban, and there is a need for further evaluation.<sup>73</sup> The FDA emphasizes MSM have a higher risk than the general population of transmitting HIV and other infectious diseases.<sup>74</sup> The MSM policy ignores other groups that have a high prevalence of HIV.<sup>75</sup> Without justification, there is no reason to exclude one high-risk group and not the other.<sup>76</sup> Under the FDA's reasoning, it would make more sense to issue a permanent ban for all high-risk groups and include heterosexual donors who engage in unprotected, multiple-partner sex.<sup>77</sup> The FDA's policy is not in line with its stated goal to protect the donor pool.<sup>78</sup>

Moreover, the FDA argues there is a possibility once blood is stored for someone to accidentally give a patient untested blood or even blood that has

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69. *Id.*

70. FDA FAQ, *supra* note 4 (indicating the "window period" exists very early after infection and blood tests are unable to detect all infections).

71. Bensing, *supra* note 3, at 500.

72. *Id.* at 501.

73. See FDA FAQ, *supra* note 4 (stating that the highest increase in HIV-positive MSM was in ages 13 to 24 years, increasing twenty-two percent from 2008 to 2010 and that there needs to be further research because the younger generation is more likely to donate blood).

74. *Id.*

75. Bensing, *supra* note 3, at 501.

76. See *id.* (indicating the FDA does not provide a justifiable distinction between other groups with a high prevalence of HIV, such as African American females, and MSM).

77. *Id.*

78. *Id.*

tested positive for an infectious disease.<sup>79</sup> The FDA suggests even though medical errors are rare, they can occur due to the large number of donations, amounting to about 17 million each year.<sup>80</sup> The possibility that blood may be misplaced is an ever-present issue.<sup>81</sup> The sexual orientation of the donor does not matter; there is always the slight possibility of an accident occurring.<sup>82</sup> Regardless, the FDA intends to uphold its MSM policy until there is more scientific data validating that a change in policy would not present a significant risk to blood recipients.<sup>83</sup>

## VII. CONCLUSION

At the time the FDA implemented the United States' MSM policy, the nation took a precautionary approach to ensure the blood supply was free from pathogens;<sup>84</sup> however, with the evolution of science and the introduction of new technologies, it is time to lift the ban on MSM. Specifically, the United States should emulate Italy's IRA policy. By adopting Italy's IRA policy, the United States would ensure all high-risk behavior is deferred, regardless of one's sexual orientation.<sup>85</sup> Scientists uncovered the causes of HIV and determined it is not based on sexual orientation, but rather the transmission of blood or other bodily fluids, further indicating that it is time for a change.<sup>86</sup> Studies suggest there are several contributing factors that can account for high level of HIV-positive blood donors outside of MSM

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79. FDA FAQ, *supra* note 4.

80. *Id.*

81. Bensing, *supra* note 3, at 501.

82. *See id.* (indicating that the risk of blood accidentally being given to a patient in error is a threat that is always present).

83. FDA FAQ, *supra* note 4.

84. *See* Larkin, *supra* note 9, at 121 (indicating a permanent ban was issued against MSM donors in the absence of tests to detect HIV antibodies in blood and because of the past high prevalence of HIV in their community).

85. Suligoi et al., *supra* note 7, at 442 (stating Italy's IRA policy is applied to "all blood donors, both males and females, heterosexuals and MSM").

86. Larkin, *supra* note 9, at 121.

blood donations,<sup>87</sup> and this weakens the FDA's ban on MSM.<sup>88</sup> Advancements in technology virtually eliminate infected blood from entering the blood supply, undermining the United States' permanent deferral on MSM.<sup>89</sup> It is unethical for the United States to implement a permanent ban on MSM while only issuing a temporary ban on heterosexuals who engage in high-risk behavior.<sup>90</sup> The United States needs to take into account the fact that other groups, outside of MSM donors, pose a risk to the blood donor pool.<sup>91</sup> There is not a valid reason why one group should be permanently deferred over the other. It is time for the United States to adopt Italy's individual risk assessment blood donation policy.

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87. See Suligoi et al., *supra* note 7, at 446 (indicating Italian studies found no significant changes in the distribution of MSM and heterosexual HIV-positive blood donors before or after the country's IRA policy was implemented).

88. FDA FAQ, *supra* note 4.

89. Bensing, *supra* note 3, at 492.

90. Larkin, *supra* note 9, at 129.

91. See Diaz, *supra* note 1, at 140 (indicating the U.S. blood donation policy has several oversights including allowing donations from persons who had sex with a prostitute or women who had sex with HIV-positive males).