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October 2015

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### Recommended Citation

Christopher McAdam & Logan Parker, *An Antiquated Perspective: Lifetime Ban for MSM Blood Donations No Longer Global Norm*, 16 DePaul J. Health Care L. 21 (2014)

Available at: <https://via.library.depaul.edu/jhcl/vol16/iss1/3>

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# AN ANTIQUATED PERSPECTIVE: LIFETIME BAN FOR MSM BLOOD DONATIONS NO LONGER GLOBAL NORM

*Christopher McAdam*\*

*Logan Parker*\*\*

*But I know also, that laws and institutions must go hand in hand with the progress of the human mind. As that becomes more developed, more enlightened, as new discoveries are made, new truths disclosed, and manners and opinions change with the change of circumstances, institutions must advance also, and keep pace with the times.*

— Thomas Jefferson

## ABSTRACT

During the 1980's, the relatively unknown human immunodeficiency virus/acquired immunodeficiency syndrome ("HIV/AIDS") struck fear into the hearts of society and stigmatized the homosexual population as the root of the problem. In response to the threat posed by the disease and in an attempt to keep the nation's blood supply safe, the Food and Drug Administration ("FDA") imposed a lifetime ban on any man who has had sex with another man ("MSM") at any time, even once, since 1977 from donating blood. The United States still maintains the ban on gay blood donors while other nations have altered their regulations to reflect the science of today. In this article, we argue that the United States, and the

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FDA, have been unresponsive in assessing whether the MSM ban can be updated, and has largely ignored the global shift away from a lifetime ban. The basis that other countries have used to change their policies is applicable to the U.S., including the drastic reduction in detection time for HIV, and social, cultural, and legal changes. We argue the ban is discriminatory, bears no rational relationship to modern circumstances, and violates the constitution. Also, this policy is arbitrary and capricious for continued enforcement without consideration of current HIV transmission patterns. Further, we argue the MSM ban is against public policy. This article concludes by recommending the policy for blood donors take into account risk factors from all donors and that the deferral period for MSM donors be a maximum of six-months.

## I. INTRODUCTION

Five young men, all active homosexuals, were treated for *Pneumocystis carinii* pneumonia “in the period October 1980-May 1981.”<sup>1</sup> These five men were the first cases of acquired immunodeficiency syndrome (“AIDS”).<sup>2</sup> A few weeks later, a report by the Centers for Disease Control (“CDC”) found an additional twenty-six homosexual men with AIDS in the San Francisco and New York area.<sup>3</sup> By the fall of 1981, more than 100 AIDS cases had been reported to the CDC,<sup>4</sup> growing to 1000 cases by 1983.<sup>5</sup> Of those 1000 cases officially reported, 71% of them were cases of “men who have sex with men (“MSM”).”<sup>6</sup> Shortly thereafter, the disease was reported in every state in the country<sup>7</sup> and in other parts of the world.<sup>8</sup> In the first decade of the AIDS epidemic, death

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1. Centers for Disease Control, *Pneumocystic Pneumonia--Los Angeles*, 30 MORBIDITY AND MORTALITY WEEKLY REPORT 1, 1 (June 5, 1981) available at [http://www.cdc.gov/mmwr/preview/mmwrhtml/june\\_5.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/june_5.htm).

2. *Id.*; WORLD HEALTH ORGANIZATION, HIV/AIDS (Oct. 30, 2013), <http://www.who.int/features/qa/71/en/index.html>. (The human immunodeficiency virus (HIV) infects cells of the immune system, destroying or impairing their function. Infection with the virus results in the progressive deterioration of the immune system, leading to “immune deficiency.” The immune system is considered deficient when it can no longer fulfill its role of fighting infection and disease. Acquired immunodeficiency syndrome (AIDS) is the term that applies to the most advanced stages of HIV infection).

3. CENTERS FOR DISEASE CONTROL, *Kaposi's sarcoma and Pneumocystis pneumonia among homosexual men--New York City and California*, 30 MORBIDITY AND MORTALITY WEEKLY REPORT 1, 1 (July 3, 1981).

4. Dennis H. Osmond, *Epidemiology of HIV/AIDS in the United States*, UCSF HIV INSITE (Mar. 2003), <http://hivinsite.ucsf.edu/InSite?page=kb-01-03#S1.1X>.

5. *Id.*

6. Osmond, *supra* note 4.

7. *See id.*

8. *See History of AIDS Up to 1985*, AVERT, <http://www.avert.org/aids-hiv-epidemic.htm> (last visited Mar. 23, 2013).

was most often a certainty for those individuals who contracted the disease.<sup>9</sup>

Little was known about the disease when it was first discovered,<sup>10</sup> but it was later learned that it was both blood-borne and sexually transmitted.<sup>11</sup> “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.”<sup>12</sup> The disease was also referred to as “gay plague,” “gay cancer,” “gay-related immune disorder,” and even a bug that could be brought home to infect the family.<sup>13</sup>

Yet homosexual men were not the only subset of individuals contracting the disease.<sup>14</sup> By the summer of 1982, intravenous-drug users, Haitians, hemophiliacs, and recipients of blood transfusions who were not homosexuals, were showing the same signs of immune suppression and were developing the same unusual opportunistic infections that were first seen only in homosexual men.<sup>15</sup> Stemming from that, the CDC officially adopted “Acquired Disease Deficiency Syndrome” in July 1982 as the “official name of a mysterious organism that was believed to be causing homosexuals, hemophiliacs, Haitians, and intravenous drugs users to develop a variety of opportunistic infections.”<sup>16</sup>

With much of the nation still gripped in fear and ignorance, coupled with lack of scientific knowledge about HIV/AIDS, the government thought it imperative and necessary to take action and place appropriate procedures to control the spread of HIV/AIDS and keep the nation’s blood supply safe. The Food and Drug Administration (“FDA”) established regulations requiring standards to be established for screening blood and plasma donations for risk factors related to HIV and other infectious diseases.<sup>17</sup> To comply with the regulations, blood donation centers must

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9. *HIV/AIDS-30 Years Later*, CENTRAL COAST HIV AIDS SERVICES (2011), <http://www.cchas.org/Newsletters-PDFs/CCHAS-NL-Fall-2011-12.pdf>.

10. See AVERT, *supra* note 8.

11. See J. Sonnabend et al., *Acquired Immunodeficiency Syndrome, Opportunistic Infections, and Malignancies in Male Homosexuals: A Hypothesis of Etiologic Factors in Pathogenesis*, 249 JAMA 2370, 2371 (1983).

12. *The Relationship Between the Human Immunodeficiency Virus and Acquired Immunodeficiency Syndrome*, NIH: NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES (Mar. 23, 2010), <http://www.niaid.nih.gov/topics/hivaids/understanding/howhivcausesaids/pages/relationshiphivaids.aspx>.

13. See AVERT, *supra* note 8.

14. Michael Christian Belli, *The Constitutionality of the “Men Who Have Sex With Men” Blood Donor Exclusion Policy*, 4 J.L. SOC’Y 315, 330 (2003).

15. *Id.*

16. Belli, *supra* note 14, at 328.

17. See 21 C.F.R. §§ 640.3, 640.63 (2013).

assess a donor's medical history on the day of donation.<sup>18</sup> Generally, a donor must be healthy, at least seventeen years old, and weigh at least 110 pounds.<sup>19</sup> The regulations identify certain "high-risk" donors that are "deferred." The regulations did not stipulate MSM donors as high risk; instead the FDA issued guidance materials identifying MSM donors as high risk and not permitted to donate blood. The restrictions on MSM donors have evolved over the years,<sup>20</sup> and it was not until 1992 when the FDA released revised recommendations that officially required that "men who have had sex with another man even one time since 1977" should not donate.<sup>21</sup>

Today, the United States still maintains the almost three-decade old ban. This is despite other countries lifting or amending their bans recently,<sup>22</sup> advancements in testing technology since the ban was originally implemented,<sup>23</sup> the need for potential blood donors due to blood shortage,<sup>24</sup> growing pressure from political figures<sup>25</sup> and advocacy groups,<sup>26</sup> and petitions seeking to repeal and change the MSM blood ban.<sup>27</sup> The American Red Cross has even publicly requested this ban be changed.<sup>28</sup> However, the only steps towards revising this policy occurred

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18. See 21 C.F.R. § 640.3 (2013).

19. See *Eligibility Requirements*, AM. RED CROSS, <http://www.redcrossblood.org/donating-blood/eligibility-requirements> (last visited Mar. 23, 2013).

20. See *Revised Recommendations for the Prevention of Human Immunodeficiency Virus (HIV) Transmission by Blood and Blood Products*, U.S. DEP'T OF HEALTH & HUMAN SERVS. 2-3 (1992), available at <http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/OtherRecommendationsforManufacturers/MemorandumtoBloodEstablishments/UCM062834.pdf>.

21. *Id.*

22. See SABTO: ADVISORY COMMITTEE ON THE SAFETY OF BLOOD, TISSUES, AND ORGANS, *Donor Selection Criteria Review 32-34* (2011), available at [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/216109/dh\\_129909.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/216109/dh_129909.pdf).

23. See Neal Conan, *FDA Ban on Blood Donated By Gay Men Upheld*, NAT'L PUBL. RADIO (June 29, 2010), <http://www.npr.org/templates/story/story.php?storyId=128193248>.

24. See *US Faces Shortage of Donated Blood*, NEWS MEDICAL (Jan. 18, 2012), <http://www.news-medical.net/news/20120118/US-faces-shortage-of-donated-blood.aspx>.

25. See Kevin Robillard, *Hillary Clinton Announces Her Support for Gay Marriage*, POLITICO (Mar. 18, 2013), <http://www.politico.com/story/2013/03/hillary-clinton-gay-marriage-support-88988.html>; Mike Quigley, *Press Release: Lawmakers Call For FDA to Revise Blood Donation Policy As America Faces Summer Blood Shortage* (June 9, 2010), <http://quigley.house.gov/press-releases/lawmakers-call-for-fda-to-revise-blood-donation-policy-as-america-faces-summer-blood-shortage/>; Bill Mears, *Obama Views on Same-Sex Marriage Reflect Societal View*, CNN POLITICS (Mar. 23, 2013), <http://www.cnn.com/2013/03/22/politics/court-same-sex-obama/>.

26. Joseph J. Wardenski et. al., *A Drive For Change: Reforming U.S. Blood Donation Policies*, GAY MEN'S HEALTH CRISIS i-iii (2010), available at [http://www.gmhc.org/files/editor/file/a\\_blood\\_ban\\_report2010.pdf](http://www.gmhc.org/files/editor/file/a_blood_ban_report2010.pdf).

27. Michelle Castillo, *Students' Petition Calls on FDA to Change Ban on Gay Blood Donors*, CBS NEWS (Mar. 21, 2013), [http://www.cbsnews.com/8301-204\\_162-57575467/students-petition-calls-on-fda-to-change-ban-on-gay-blood-donors/](http://www.cbsnews.com/8301-204_162-57575467/students-petition-calls-on-fda-to-change-ban-on-gay-blood-donors/); see Michael Jones, *Urge the FDA to Overturn the Gay Blood Ban*, CHANGE.ORG, <http://www.change.org/petitions/urge-the-fda-to-overturn-the-gay-blood-ban>.

28. See Christen McCurdy, *Red Cross Favors Amending Blood Donation Policy by Gay and Bisexual Men*,

in February of 2012 when Health and Human Services asked for comments from the public regarding ideas on how to design a study to assess whether the policy can be changed.<sup>29</sup> No meeting or study has been conducted since this announcement.

This article draws attention to the increasingly irrelevant ban and addresses potential routes for challenging the MSM ban. The article ultimately argues that global policy changes are based on advanced science and sound policy. Global policy demonstrates that the U.S. is far behind, and we ought to look to it for guidance. Part II will discuss the history of the MSM ban and recent advancements in blood testing. Part III will look to the various countries around the world that have progressed beyond the United States in amending or lifting their MSM ban, and the international law argument to challenging the ban. Part IV will discuss whether the factors that lead other countries to revise their blood donation policies regarding MSM donors are applicable to the United States. Part V will focus on other possible challenges to the FDA's MSM ban: (1) the constitutional law argument; (2) the administrative law argument; and (3) the public policy argument. The conclusion of this article is that, by adopting the strategy of other countries, the United States can remove the ban on MSM donors and follow an individualized risk-based approach for deferring donors.

## II. THE MSM BAN

The U.S. Public Health Service ("PHS") is housed under the Department of Health and Human Services ("HHS").<sup>30</sup> The PHS is the umbrella agency that oversees the Food and Drug Administration.<sup>31</sup> The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation.<sup>32</sup> It is also responsible for protecting the nation's blood supply.<sup>33</sup> The FDA's authority to implement policies related to blood

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THE LUND REPORT (Aug. 10, 2012), [http://www.thelundreport.org/resource/red\\_cross\\_favors\\_amending\\_blood\\_donation\\_policy\\_by\\_gay\\_and\\_bisexual\\_men](http://www.thelundreport.org/resource/red_cross_favors_amending_blood_donation_policy_by_gay_and_bisexual_men).

29. 77 C.F.R. § 36.

30. James G. Hodge, Jr., *The Role of New Federalism and Public Health Law*, 12 J. L. & HEALTH 309, 337 (1997-98).

31. Shawn Carroll Casey, *Illicit Regulation: A Framework for Challenging the Procedural Validity of the "Gay Blood Ban,"* 66 FOOD & DRUG L. J. 551, 555 (2011).

32. *What We Do*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/WhatWeDo/default.htm> (last modified June, 19, 2012).

33. *What does FDA Regulate?*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194879.htm> (last modified June, 21, 2012).

comes from the re-delegation of the HHS statutory authority to uphold the public health.<sup>34</sup> HHS was granted this power from two statutes: the Public Health Service Act and the Food, Drug, and Cosmetics Act.<sup>35</sup> A subdivision of the FDA, the Center for Biologics Evaluation and Research (“CBER”), is entrusted with drafting regulations to ensure the quality and safety of the nation’s blood supply.<sup>36</sup> Together, the FDA and CBER are charged with licensing blood banks,<sup>37</sup> such as the American Red Cross, and creating safeguards to limit the risk of communicable diseases through blood donations.<sup>38</sup>

The FDA is entrusted with establishing requirements for blood testing prior to release to recipients,<sup>39</sup> and donor eligibility.<sup>40</sup> The FDA requires blood donation centers to evaluate individuals prior to testing based on medical, social, and sexual history.<sup>41</sup> Section 21 C.F.R. 640.3, issued by the FDA, establishes the suitability of a donor but does not speak to MSM donors as a high-risk group.<sup>42</sup>

Instead of promulgating a regulation about MSM deferrals, the FDA issued guidance materials in 1992 labeling MSM as a high-risk group that is excluded and unsuitable to donate blood.<sup>43</sup> Specifically, any man who has had sex with another man at any time, even once, since 1979, is indefinitely deferred.<sup>44</sup>

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34. See 21 C.F.R. § 5.10 (a)(3) (2013) (These functions are law enforcement functions of sort. They include among other subjects, blood and blood products).

35. 21 U.S.C §§ 301-309 (2013); 42 USC §§ 262-263 (2013).

36. 21 C.F.R. § 5.10 (a)(3) (2013).

37. 42 U.S.C § 262 (a) & (c) (2013); 21 U.S.C § 360 (b) (2013).

38. See *About CBER*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm123340.htm> (last modified Jan. 21, 2010).

39. 21 C.F.R. § 610.40 (2013).

40. 21 C.F.R. § 1271.50 (2013).

41. See 21 C.F.R. § 640.3 (a) (2013). (To be suitable to donate blood you must at least be 17 years old in most states (16 years old in some states with parental consents), and weigh at least 110 pounds, amongst other things.); See *Eligibility Requirements*, AM. RED CROSS, <http://www.redcrossblood.org/donating-blood/eligibility-requirements> (last visited April 12, 2013).

42. See 21 C.F.R. §§ 640.3 (b)–(f), 640.63 (c) (2013) (plasma donation information).

43. See *Revised Recommendations for the Prevention of Human Immunodeficiency Virus (HIV) Transmission by Blood and Blood Products*, U.S. DEP’T OF HEALTH & HUMAN SERVS. 2 (1992), available at <http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/OtherRecommendationsforManufacturers/MemorandumtoBloodEstablishments/UCM062834.pdf> (Gay plasma and sperm are treated similarly to gay blood and the FDA excludes them.); see 21 C.F.R. § 640.63(c) (2013); Luke A. Boso, Note, *The Unjust Exclusion of Gay Sperm Donors: Litigation to End Discrimination in the Gene Pool*, 110 W. VA. L. REV. 843, 845-46 (2008) (Yet, gay organs are not excluded, they merely have a five year deferral); Andrew Cray, *Discriminatory Donor Policies Substitute Stereotypes for Science*, CENTER FOR AMERICAN PROGRESS (Sept. 11, 2012), <http://www.americanprogress.org/issues/lgbt/news/2012/09/11/37294/discriminatory-donor-policies-substitute-stereotypes-for-science/>.

44. See Belli, *supra* note 14, at 339; see also Cray, *supra* note 43 (Other prospective donors that are permanently deferred: intravenous drug users; hemophiliacs; individuals who have ever had a positive antibody

### A. History of the MSM Ban

MSM were not always indefinitely deferred. The ban began in March 1983 when the Office of Biologics issued non-mandatory guidelines<sup>45</sup> recommending members of groups at “increased risk for AIDS” refrain from donating blood.<sup>46</sup> The first guidelines issued by the Office of Biologics only pertained to gays who were either currently sexually active with multiple partners, had “overt symptoms of immune deficiency,” or had previously engaged in sexual relations with people who had or exhibited such symptoms.<sup>47</sup>

The policy underwent numerous revisions since its introduction in 1983; such revisions allowed MSM to donate blood if they were not sexually active with multiple partners, did not have “overt symptoms of immune deficiency,” or had not previously engaged in sexual relations with people who now exhibited such symptoms.<sup>48</sup> The Office of Biologics issued biannual revisions to the original exclusion categories laid out in the 1983 non-mandatory guidelines from 1984 to 1996.<sup>49</sup> Beginning in 1986, the revised policy started excluding men who have had sex with another man, one or more times since 1977.<sup>50</sup> This revision amended the 1984 language that excluded males who have had sex with more than one male since 1979.<sup>51</sup> It wasn’t until 1992 that the FDA issued mandatory guidelines recommending a lifetime deferral for gay male donors.<sup>52</sup>

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test for HIV (AIDS virus); any man or woman who has had sex for money or drugs any time since 1977; anyone who has had hepatitis any time after their eleventh birthday; anyone who has had cancer; anyone taking insulin for diabetes; has multiple sclerosis; has heart disease; has had a stroke; Babesiosis or Chagas disease; Tegison for psoriasis; CDJ; and has traveled to or are from any Pattern II Country).

45. Memorandum from John C. Petricciani, Nat’l Ctr. For Drugs & Biologics, FDA, to All Establishments Collecting of Transmitting Acquired Immune Deficiency Syndrome (AIDS) from Blood Donors 1 (Mar. 22, 1983).

46. Ronald Bayer, PRIVATE ACTS, SOCIAL CONSEQUENCES: AIDS AND THE POLITICS OF PUBLIC HEALTH 85 (1989).

47. See generally Randy Shilts, AND THE BAND PLAYED ON: POLITICS, PEOPLE, AND THE AIDS EPIDEMIC (1988).

48. *Id.*

49. Dwayne J. Bensing, *Science or Stigma: Potential Challenges to the FDA’s Ban on Gay Blood*, 14 J. CON. L. 486, 492 (2012) (citing Memorandum from Elaine C. Esber, Ctr. for Drugs & Biologics, FDA, to All Registered Blood Establishments, Additional Recommendations for Reducing Further the Number of Units of Blood and Plasma Donated for Transfusion or for Further Manufacture by Persons at Increased Risk of HTLV-III/LAV Infection 1-2 (Oct. 30, 1986)).

50. *Id.*

51. Bensing, *supra* note 49, at 492 (citing Memorandum from Elaine C. Esber, M.D., Acting Dir., Office of Biologics Research & Review Ctr. for Drugs & Biologics, to All establishments Collecting Blood for Transfusion and All Source Plasma (Human) Establishments, Plasma Derived From Therapeutic Plasma Exchange (Dec. 14, 1984)).

52. See U.S. DEP’T OF HEALTH & HUMAN SERVS., *supra* note 43, at 7.



## B. The Ban At Work: Blood Donating & Testing Process

Every blood-testing center must evaluate the eligibility of a donor at the time of donation.<sup>53</sup> For an individual to be suitable to donate blood, the American Red Cross lists four steps that an individual must complete.<sup>54</sup> These steps are: (1) Registration; (2) Health History & Mini-Physical; (3) Donations; and (4) Refreshments.<sup>55</sup> Step one requires prospective donors to read education materials and then acknowledge in writing that they have read and understood these materials, have been given the opportunity to ask questions, and have provided accurate information.<sup>56</sup> Step three is where the donor, no longer prospective, donates blood, which takes eight to ten minutes.<sup>57</sup> Step four takes place after the donation, where a donor “should have a snack and something to drink in the refreshment area.”<sup>58</sup> Step two, which is the most relevant and pertinent to this article, can permanently defer a prospective donor based on a single question from the questionnaire.<sup>59</sup>

During step two of the blood donating process, a potential donor is faced with answering invasive and personal questions about health history.<sup>60</sup> The health history of a potential donor is assessed on a questionnaire or Health History Form (“HH Form”).<sup>61</sup> Many HH Forms are about fifty questions and start by asking preliminary questions about the donor’s perception of health, whether they have recently ingested medications on the medicine deferral list, and if they have donated blood recently.<sup>62</sup> The HH Form then moves into asking a donor about behavior that would elevate a donor’s risk of HIV or other diseases transmitted

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53. See 21 C.F.R. 640.3 (2013).

54. See *Donation Process*, AM. RED CROSS, <http://www.redcrossblood.org/donating-blood/donation-process> (last visited Mar. 24, 2013).

55. *Id.*

56. See *id.*

57. *Id.*

58. *Id.*

59. Belli, *supra* note 14, at 320-21; see *Full-Length Donor History Questionnaire*, AM. ASS’N OF BLOOD BANKS (May 2008), <http://www.fda.gov/downloads/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/LicensedProductsBLAs/BloodDonorScreening/UCM213552.pdf>.

60. See AM. RED CROSS, *supra* note 54.

61. Belli, *supra* note 14, at 321; see *Guidance for Industry: Implementation of Acceptable Full-Length Donor History Questionnaire and Accompanying Materials for Use in Screening Donors of Blood and Blood Components*, U.S. FOOD & DRUG ADMIN.: BLOOD & BIOLOGICS, <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM273685.pdf>.

(The stated purpose of the questionnaire is to “ensure the donor is in good health and the donation process is safe for the donor, and to identify risk factors for diseases transmissible by blood and blood components.”)

62. See *id.*

through the blood stream.<sup>63</sup> This includes “sexual contact” with a person with HIV, paying for sex or having sex with anyone who has paid for sex, or getting a tattoo.<sup>64</sup> The final set of questions could determine possible temporary or lifetime deferral donor status. A question presented on the HH Form explicitly asks, from 1977 to present, have “[male donors] had sexual contact with another male, even once?”<sup>65</sup> If a donor answers affirmatively to this question, the donor is automatically disqualified, categorically, from donating blood indefinitely;<sup>66</sup> no further evaluation, no more questions asked, and no mini-physical takes place.<sup>67</sup> Instead, that prospective donor is entered on a national ‘deferral’ database of people banned for life from donating.<sup>68</sup>

### C. Advancements in Testing

Many advancements in scientific technology have occurred in the years since the MSM blood ban was first instituted. The testing of blood for communicable diseases such as HIV has become more accurate and targeted. In 1985, blood banks were required to test blood donations<sup>69</sup> using an enzyme-linked immunosorbent assay test (“ELISA”).<sup>70</sup> The FDA created a new test, the Western Blot, in 1985 because the ELISA test was prone to false positives.<sup>71</sup> The two tests used in combination have a high rate of success for detecting HIV.<sup>72</sup> However, the latency period for HIV could be several months, thus rendering the tests useless because the person infected has not yet developed the antibodies detected by the tests.<sup>73</sup> Since the early 2000’s, the nucleic acid test (“NAT”) is another

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63. See *id.* (“Sexual contact” with a person with HIV or having paid for sex or had sex with anyone who has paid for sex will result in automatic deferral. The American Red Cross generally recommends that an individual wait 12 months to donate if they just got a tattoo); *Eligibility Criteria By Topic*, AM. RED CROSS, <http://www.redcrossblood.org/donating-blood/eligibility-requirements>.

64. See Blood Donor Screening and Testing, AM. ASS’N OF BLOOD BANKS, <https://www.aabb.org/resources/governmentregulatory/donoreligibility/Pages/default.aspx> (last visited Feb. 17, 2014).

65. *Full-Length Donor History Questionnaire*, *supra* note 59.

66. See Belli, *supra* note 15, at 327; See also John G. Culhane, *Bad Science, Worse Policy: The Exclusion of Gay Males from Donor Pools*, 24 ST. LOUIS PUBL. L. REV. 129, 136 (2005); Adrian Lomoga, *Are Men Who Have Sex with Men Safe Blood Donors?*, 12 APPEAL REV. CURRENT L. & L. REFORM 73, 78 (2007).

67. Belli, *supra* note 14, at 327.

68. *Id.*; Christopher Heredia, *Panel Upholds Ban on Gays Giving Blood: Advisors to FDA Call Risk of AIDS Too Great*, SAN FRANCISCO CHRONICLE, Sept. 15, 2000, at 1.

69. See Francine A. Hochberg, *HIV/AIDS and Blood Donation Policies: A Comparative Study of Public Health Policies and Individual Rights Norms*, 12 DUKE J. COMP. & INT’L L. 231, 231–32 (2002).

70. Belli, *supra* note 14, at 332–33 (ELISA detects human antibody produced in response to exposure to HIV).

71. *Id.* at 334.

72. *Kozup v. Georgetown Univ.*, 663 F. Supp. 1048, 1052–53 (D.D.C. 1987).

73. Belli, *supra* note 14, at 335–36.

widely used test.<sup>74</sup> NAT reduced the risk of transfusion transmission of HIV to about one unit per two million donations.<sup>75</sup> NAT detects the presence of HIV within nine to eleven days of infection.<sup>76</sup>

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.<sup>77</sup> The effectiveness of the testing has had no effect on the Blood Products Advisory Committee ("BPAC"). BPAC has refused time and time again to lift or even amend the MSM policy.<sup>78</sup>

This flies in the face of the success of HIV testing, shifting national public support for gay rights, and the nation's blood shortage crisis. Moreover, the decision of our country to maintain the ban, despite other countries with the same or lesser technology than the United States lifting or amending their ban, has sparked debate that the MSM blood ban is antiquated, not to mention discriminatory and stigmatizing.

### III. GLOBAL PERSPECTIVE ON MSM BLOOD DONOR POLICY

Every country in the world has specific challenges and history that require laws and regulations that would meet the needs of its particular citizenry. However, the research below reveals a clear pattern of several countries reevaluating their policies regarding MSM donations. Many countries recognize that deferral policies were enacted in the 1980's, during a time of confusion, stigma, and limited science. A rational evaluation of the current environment has led countries to repeal or modify

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74. See *Blood Testing*, AM. RED CROSS,

<http://www.redcrossblood.org/learn-about-blood/what-happens-donated-blood/blood-testing> (last visited Mar. 23, 2013); see also Christopher D. Pilcher et al., *Acute HIV Revisited: New Opportunities for Treatment and Prevention*, 113 J. CLINICAL INVESTIGATION 937, 937 (2004), available at <http://www.jci.org/cgi/reprint/113/7/937.pdf> ("While HIV nucleic acid amplification assays are now extremely sensitive and can reliably detect HIV by days 9–11 of infection . . . , they are vulnerable to false-positive rates as high as 1%. Such tests remain relatively expensive and have not traditionally been used for routine clinical HIV screening.")

75. See *id.*

76. *Guidance for Industry - Nucleic Acid Testing (NAT) for Human Immunodeficiency Virus Type 1 (HIV-1) and Hepatitis C Virus (HCV): Testing, Product Disposition, and Donor Deferral and Reentry*, U.S. FOOD & DRUG ADMIN. 3 (May 2010), available at <http://www.fda.gov/downloads/biologicsbloodvaccines/guidancecomplianceregulatoryinformation/guidances/blood/ucm210270.pdf>.

77. See generally SABTO, *supra* note 22, at 32-34.

78. The committee voted down any changes, including a comparable twelve-month deferral used for other high-risk groups for MSM in 2000, 2006, and 2010. *Transcript of Proceedings: 67th Meeting 201-02*, U.S. FOOD & DRUG ADMIN. BLOOD PRODS. ADVISORY COMM. (Sept. 15, 2000), available at <http://www.fda.gov/ohrms/dockets/ac/00/transcripts/3649t2.rtf>; *Transcript of Proceedings: 86th Meeting 60-61*, U.S. FOOD & DRUG ADMIN. BLOOD PRODS. ADVISORY COMM. (Mar. 9, 2006), available at <http://www.fda.gov/ohrms/dockets/ac/06/transcripts/2006-4206t2.pdf> (last visited Jan. 20, 2011); see *Charter of the Advisory Committee on Blood Safety and Availability*, U.S. DEP'T OF HEALTH & HUMAN SERVS. (Oct. 9, 2012), <http://www.hhs.gov/ash/bloodsafety/advisorycommittee/charter/charter.html>.

their policies regarding blood donations. The changes began as early as 2001 and have continued to the present day.

These countries have certainly not changed their policies lightly. In fact, many studies and press statements still emphasize that the safety of the blood supply is of the utmost importance. An important factor that all countries base their policies on is modern science. The implementation of NAT testing has drastically shortened the window period in which HIV might go undetected in a blood donation. Also, countries are reevaluating HIV infection trends in their population. A ban on MSM blood donations does not make sense if the primary vehicle of HIV infection is heterosexual intercourse, or intravenous drug use. Lastly, many countries have recognized the need for nondiscriminatory policies regarding blood donations. Nondiscriminatory laws are continually being extended to the LGBT community, and citizens are demanding equality for all.

### A. United Kingdom

The United Kingdom began permanently deferring blood donations from MSM in 1985 in response to the HIV/AIDS epidemic<sup>79</sup> and to protect against blood donors who were unaware of being HIV positive.<sup>80</sup> Disease testing of blood donations began in the 1960s and came under increased legal and medical scrutiny with the emergence of Hepatitis C and HIV in the 1970's and 1980's.<sup>81</sup> In the U.K., there has not been an HIV infection caused by a blood donation since 2002<sup>82</sup> (HIV infections between 1996 and 2002 were due to window period donations that did not test positive for HIV, and they were before the introduction of NAT testing).<sup>83</sup>

A study conducted in 2008 estimated 83,000 people were living with HIV in the U.K., of which 27% were unaware of their infection.<sup>84</sup> Of those infected, 61,213 cases received care, and of those receiving care, 50% of infections were caused by heterosexual intercourse, while 42% of those infections were caused by homosexual intercourse.<sup>85</sup> Of the HIV infections caused by heterosexual intercourse, 67% were caused by intercourse with

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79. SABTO, *supra* note 22, at 7.

80. *Id.* at 35.

81. *Id.* at 10.

82. *Press Release: Lifetime blood donation ban lifted for men who have had sex with men*, UNITED KINGDOM DEP'T OF HEALTH (Sept. 8, 2011), <https://www.gov.uk/government/news/lifetime-blood-donation-ban-lifted-for-men-who-have-had-sex-with-men>.

83. SABTO, *supra* note 22, at 40.

84. SABTO, *supra* note 22, at 19.

85. *Id.*

black Africans or caused while traveling abroad to sub-Saharan Africa.<sup>86</sup> A concentration of infections in urban areas is demonstrated by the fact that just over half of those infected with HIV in England live in London.<sup>87</sup>

The U.K. permanently defers donors who have ever had Syphilis, HIV, or Hepatitis C, those who have ever worked as a commercial sex worker, and those who have ever used intravenous drugs.<sup>88</sup> There is currently a twelve-month deferral period for those donors who have ever had sex with a commercial sex worker; had sex with someone who has used intravenous drugs; had sex with a man who has had sex with another man; or had sex with anyone who has been sexually active in parts of the world where HIV/AIDS is highly prevalent.<sup>89</sup>

The permanent deferral of MSM donors was reduced to twelve months, effective November 7, 2011.<sup>90</sup> A thorough review of MSM donor deferral policy and the related risks was published in April of 2011 by SaBTO, the Advisory Committee on the Safety of Blood, Tissues and Organs for the United Kingdom Department of Health.<sup>91</sup> From this report, the health ministers for the U.K. decided that having a deferral of twelve months for MSM would not create a greater risk of transmitting diseases via blood donations.<sup>92</sup>

The factors that the U.K. ministers took into consideration in reevaluating the policy for MSM blood donations included both technical and quality control advances, and social, cultural, and legal changes.<sup>93</sup> Perhaps among the most influential advances in technology is the reduction of the window period through the introduction of nucleic acid technology (NAT) testing.<sup>94</sup>

Significant legal changes include the passage of the Equality Act 2010.<sup>95</sup> This law “prohibits discrimination on grounds of sexual orientation by a public service provider.”<sup>96</sup> However, the law has an exception regarding the regulation of blood donations, stating that it is not

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86. *Id.*

87. *Id.*

88. See *Who Can't Give Blood*, UNITED KINGDOM NAT'L HEALTH SERV., <http://www.blood.co.U.K./can-i-give-blood/who-cant-give-blood/> (last visited Apr. 18, 2013).

89. *Id.*

90. *News Release: National Health Services Blood and Transplant*, NHS BLOOD & TRANSPLANT (Nov. 7, 2011), [http://www.nhsbt.nhs.uk/news-and-media/news-archive/news\\_2011\\_11\\_07.asp](http://www.nhsbt.nhs.uk/news-and-media/news-archive/news_2011_11_07.asp) (last visited Feb. 8, 2014).

91. See SABTO, *supra* note 22, at 1.

92. UNITED KINGDOM DEP'T OF HEALTH, *supra* note 82.

93. SABTO, *supra* note 22, at 8.

94. *Id.*

95. *Id.*

96. *Id.* at 43.

illegal for a blood service to deny a blood donation if the denial “is because of an assessment of the risk to the public, or to the individual, based on clinical, epidemiological or other data obtained from a source on which it is reasonable to rely . . .”<sup>97</sup>

The U.K. changed the deferral period for MSM donors despite the presence of a strict liability standard for the safety of blood donations. This strict liability standard is based on the “legitimate expectations of the public as to the safeness of the ‘product.’”<sup>98</sup> This standard was confirmed in a 2001 case, *A v. National Blood Authority*, in which 114 plaintiffs brought an action due to being infected with HCV via blood transfusions.<sup>99</sup> In this case, the High Court of England and Wales found that infected blood was defective under the Consumer Protections Act (CPA), and that there is a legal requirement to reduce the risk of infection and make the blood supply as safe as possible.<sup>100</sup>

The committee further recognized certain societal changes. Specifically, donating blood is “an important act of social responsibility and solidarity,” and that the exclusion of MSMs conveys “a marginalizing message at odds with the emphasis on the [LGBT] community being a fully accepted part of society.”<sup>101</sup>

Another factor that SaBTO considered was the international trend in changing deferral policies regarding MSM donations. Specifically, the study considered Spain and Italy’s risk-based approach, in which donors were considered for deferral based on behavior (having sex with HIV carriers, having more than one sexual partner at a time, or having sex with an occasional partner) over the previous twelve months.<sup>102</sup> The committee found that this approach, due to lack of adequate studies to document the impact on the safety of the blood supply, was not advisable.<sup>103</sup> The committee also looked to Australia’s change to a twelve-month deferral for MSMs and concluded that the slight increase in risk to the blood supply was due to non-compliance of donors rather than a failure of the deferral criteria.<sup>104</sup>

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97. *Id.*

98. *Id.*

99. *Id.* at 10.

100. SaBTO, *supra* note 22, at 10.

101. *Id.* at 43.

102. R. J. Benjamin et al., *Deferral of males who had sex with other males*, 101 VOX SANGUINIS 339, 362-63 (Issue 4, 2011); SaBTO, *supra* note 22, at 49.

103. *See id.*

104. *Id.* at 50.

The U.K. blood services uses a triple HIV/HCV/HBV NAT test on pools of samples.<sup>105</sup> Twenty-four samples are pooled together and subjected to NAT testing.<sup>106</sup> If the pool tests positive, it is then retested twice, and if it still tests positive, each sample is then tested individually.<sup>107</sup> The window period, the time between infection and detectable testing, is nine days for the NAT test.<sup>108</sup> Even within a pool of twenty-four samples, the viral load is high enough to result in a reactive test.<sup>109</sup> With the testing regimen in place, the estimated risk of receiving an HIV infected blood transfusion due to testing error is one in 5.8 million donations.<sup>110</sup> Further, an infection from a blood transfusion due to testing error has not occurred since 1996.<sup>111</sup> In the U.K., no infection via blood transfusion has ever been recorded due to testing that did not register an infected sample during a window period.<sup>112</sup>

In order to assess the prevalence of behavioral risk factors amongst blood donations that test positive for a disease, the donors whose donations test positive are contacted and asked standardized questions regarding their lifestyle.<sup>113</sup> Between 1996 and 2008, 356 of the donations tested positive for HIV and 44% of the donors reported heterosexual intercourse as the risk factor associated with their infection.<sup>114</sup> Of 356 donors, 29% reported as MSM.<sup>115</sup>

The U.K. study found that the window periods are the critical factor when setting appropriate deferral periods.<sup>116</sup> The window periods for NAT testing are on average 38.3 days for HBV, 4 days for HCV, and 9 days for HIV.<sup>117</sup> The study concluded that to account for the window period for HBV, not HIV, a twelve-month deferral was needed.<sup>118</sup>

The Committee found that a key risk to the safety of the blood supply, in regards to MSM donors, regardless of the deferral period, is that some donors simply will not comply with the rules and will donate blood

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105. *Id.* at 40.

106. *Id.*

107. SABTO, *supra* note 22 at 40-41.

108. *Id.*

109. *Id.* at 41.

110. *Id.* at 40.

111. *Id.*

112. *Id.* at 41.

113. *Id.* at 25.

114. *Id.* at 26.

115. *Id.*

116. *Id.* at 37.

117. *Id.* at 36.

118. *Id.* at 42.

when they should not.<sup>119</sup> A study was conducted that followed non-compliant donors to identify the reasons for their donations despite being barred.<sup>120</sup> The predominant reasons that non-compliers donate despite the deferral policy were “categorizing oneself as low risk, or discounting sexual experience that barred donation.”<sup>121</sup> Other factors that led to non-compliance included the belief that testing prevented spread of infection; misunderstanding the rule barring donation; the need for secrecy regarding sexual conduct; and resentment over the deferral policy.<sup>122</sup> However, a quarter of the non-compliers were not even aware that MSM conduct barred them from donation, and a third believed that only unprotected MSM conduct barred them from donation.<sup>123</sup> Almost all of the non-compliers that were interviewed regarding their non-compliance stated that they would comply with the deferral policy if they were adequately educated about the policy.<sup>124</sup>

The Committee presented the study to the ministers of health, and the recommended twelve-month deferral policy for MSM donors was adopted in September of 2011.<sup>125</sup> Due to the recent change in the policy, the U.K. has not released any information regarding whether the change in the deferral policy has resulted in any increased prevalence of HIV positive blood donations.

## B. Australia

Australia, like many countries, began deferring the blood donations of MSMs shortly after the outbreak of the HIV/AIDS epidemic in the early 1980's.<sup>126</sup> Approximately 3% of Australia's population (560,000 donors) donates blood each year, consisting of 1.3 million donations to meet a need of 1.4 million donations.<sup>127</sup> It was discovered in 1983 that a person could be infected with HIV via blood donation, and that men having sex

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119. See SABTO, *supra* note 22, at 50.

120. *Id.*

121. *Id.*

122. *Id.*

123. *Id.*

124. *Id.* at 51.

125. UNITED KINGDOM DEP'T OF HEALTH, *supra* note 82.

126. Clive R. Seed, et al., *No Evidence of a Significantly Increased Risk of Transfusion-Transmitted Human Immunodeficiency Virus Infection in Australia Subsequent to Implementing a 12-month Deferral for Men who have had Sex with Men*, 50 TRANSFUSION 2722 (2010).

127. *Review of Australian Blood Donor Deferrals Relating to Sexual Activity*, REVIEW COMMITTEE COMMISSIONED BY AUSTRALIAN RED CROSS 1 (2012), available at [http://www.bloodrulesreview.com.au/files/upload/blood\\_review\\_report\\_may\\_2012\\_electronic\\_version.pdf](http://www.bloodrulesreview.com.au/files/upload/blood_review_report_may_2012_electronic_version.pdf) [hereinafter AUSTRALIAN RED CROSS].



with men was an important mode of spreading the HIV virus.<sup>128</sup> At that time there was no screening method for HIV, and Australia began permanently deferring donors with a history of male-to-male sex.<sup>129</sup> Australia began implementing universal blood donor screening for HIV-1 antibodies when the test was discovered in 1985.<sup>130</sup> The last HIV infection caused by a blood transfusion occurred in 1998; the source was a female donor.<sup>131</sup>

From 2007-2011, the most predominant cause of HIV infection in Australia was sexual contact between two men.<sup>132</sup> The male-to-male contact was found to have caused 75% of infections while heterosexual encounters accounted for 16%.<sup>133</sup> Approximately 6% of reported cases of HIV infection were by persons with a history of injecting drugs.<sup>134</sup> Mathematical models identify MSM donors as the greatest risk of HIV infection via blood transfusions.<sup>135</sup>

Australia changed its deferral of MSM donors from permanent deferral to a twelve-month deferral period on October 9, 2000.<sup>136</sup> Australia applies the same twelve-month deferral period to heterosexual donors who also have risk-associated behaviors such as having sex for money, having sex with a partner infected with HIV, or having sex with a sex worker.<sup>137</sup> Donors are screened prior to donation by being asked whether “Within the last 12 months: [They] [h]ad male to male sex (that is, oral or anal sex) with or without a condom?”<sup>138</sup> Multiple partners or casual sex do not factor into the deferral criteria, nor does condom usage during sex.<sup>139</sup>

Due to improved testing capabilities, the window period for detecting HIV and other transfusion-transmissible infections has been greatly reduced.<sup>140</sup> The current deferral period is not based on the sexual practice of the donor, rather the prevalence of transfusion-transmissible infections among the donor’s sexual partner(s) (because although a donor may be

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128. Seed, *supra* note 126, at 2722-23.

129. *Id.* at 2723.

130. AUSTRALIAN RED CROSS, *supra* note 127, at 8.

131. *Id.*

132. *HIV, viral hepatitis and sexually transmissible infections in Australia Annual, Surveillance Report 2012*, THE KIRBY INSTITUTE FOR INFECTION AND IMMUNITY IN SOCIETY 20 (2012), available at <http://www.kirby.unsw.edu.au/surveillance/2012-annual-surveillance-report-hiv-viral-hepatitis-stis>.

133. *Id.*

134. KIRBY INSTITUTE, *supra* note 132, at 20.

135. Seed, *supra* note 126, at 2723.

136. *Id.* at 2724, Table 1.

137. Benjamin, *supra* note 102, at 343.

138. *Id.* at 347.

139. *Id.*

140. AUSTRALIAN RED CROSS, *supra* note 127, at 12, Table 1.

aware of his own potential risk, he never really knows for sure the sexual activity of his partner amongst a population with a high prevalence of HIV).<sup>141</sup> The twelve-month deferral for MSMs is thought to cover “the most conservative scenario for detecting an infection (i.e. double the length of time of the uppermost threshold for a testing window period or double the length of an incubation period for the appearance of symptoms).”<sup>142</sup> MSMs are singled out because over 80% of those infected with HIV report some kind of history with male-to-male sex.<sup>143</sup> Thus, a male who has had oral or anal sex with another male is at an increased risk of window period transmission and undetected HIV.<sup>144</sup>

Australia Blood Services (“ABS”) completed a study of blood donations containing HIV five years preceding (“Period 1”) and five years following (“Period 2”) the implementation of a twelve-month deferral period for MSMs.<sup>145</sup> This study included first testing donated blood for HIV, and when a donation tested positive for the virus, then ABS contacted the donor.<sup>146</sup> ABS asked the donor several questions on an anonymous basis to try and identify risk factors.<sup>147</sup> The number of times MSM was identified as a risk factor associated with a positive donation was compared before the deferral was changed to twelve months and after.<sup>148</sup>

The results of this study showed no significant effect on the number of HIV positive donations as a result of changing from a lifetime deferral to a twelve-month deferral.<sup>149</sup> In Period 1, ABS received 4,025,571 donations, of which twenty-four tested positive for HIV.<sup>150</sup> In Period 2, 4,964,628 donations were received, of which twenty-four tested positive for HIV.<sup>151</sup> Of the positive donations, sixteen were from male donors in Period 1, and thirteen were from male donors in Period 2.<sup>152</sup>

In Period 1, twenty of the twenty-four HIV positive donors consented to follow-up interviews, and fifteen donors disclosed risk factors.<sup>153</sup> Of

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141. *See id.* at 13.

142. *Id.*

143. *Id.* at 14.

144. *Id.*

145. Seed, *supra* note 126, at 2722.

146. *Id.* at 2724.

147. *Id.*

148. *See id.*

149. *See id.*

150. *Id.* at 2725.

151. *Id.*

152. *Id.*

153. Seed, *supra* note 126, at 2725.

those identifying risk factors, two of the donors disclosed themselves as MSM donors.<sup>154</sup> In Period 2, twenty of the donors conducted follow-up interviews, and sixteen of the donors disclosed HIV risk factors.<sup>155</sup> Of those sixteen donors, five were identified as MSM.<sup>156</sup> However, all five of the MSM donors, had male-to-male sexual conduct within twelve months of donating blood.<sup>157</sup> Thus, if they had disclosed this information during the pre-donation screening, they would not have been permitted to donate blood.<sup>158</sup> There was a non-significant increase in both male and female, and male-only HIV positive repeat donors from Period 1 to Period 2, but those repeated donations did not lead to positive recipients.<sup>159</sup> Further, this increase in HIV positive repeat donors came from one region of Australia where the number of new HIV infections increased by 20%.<sup>160</sup> In Period 2, the amount of newly reported HIV infections increased 41% nation-wide, but that increase was not reflected in the number of HIV positive donors.<sup>161</sup>

A recent review of the Australian blood donor deferral policy suggests that the twelve-month deferral for MSMs should be replaced by a six-month deferral policy because the change to twelve-month deferral did not result in increased risk to the blood supply.<sup>162</sup> A review of Australia's blood donor deferral policies was commissioned by the Australian Red Cross.<sup>163</sup> This study reviewed current deferral policies in light of modern testing practices.<sup>164</sup> The deferral policies are based on window periods where transfusion transmittable diseases can go undetected.<sup>165</sup> Window periods may vary depending on the infected person, thus deferral policies are based on the most conservative estimate of undetectable window periods.<sup>166</sup> Those window periods are then doubled to implement a safety

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154. *Id.* (Of the two donors considered MSM, one was confirmed as MSM and the other was highly suspected to be MSM due to a history of anal warts.)

155. *Id.*

156. *Id.*

157. *Id.* at 2726, Table 3.

158. *Id.* at 2726-27 (Exact reasons for the non-compliance of these MSM donors could not be ascertained. However, previous studies of blood donor non-compliance in Australia indicated reasons for non-compliance such as the temporal remoteness of the risk, a belief that testing of the blood made disclosure unnecessary, and a misunderstanding that the deferral did not apply to male-to-male sexual contact involving a condom).

159. *Id.* at 2726.

160. *Id.*

161. *Id.*

162. AUSTRALIAN RED CROSS, *supra* note 127, at 56.

163. AUSTRALIAN RED CROSS, *supra* note 127, at 1.

164. *Id.* at 12.

165. *Id.* at 13.

166. *Id.*

margin.<sup>167</sup> Out of the six transfusion transmissible infectious diseases (HIV, HAV, HBV, HCV, HTLV, Syphilis), HCV has the largest possible window period at 94 days.<sup>168</sup> Thus, the minimum deferral period with required safety margin is 188 days.<sup>169</sup> The commission concluded that the “deferral period of six months could be applied to the current sexual activity-related criteria without introducing an unacceptable risk to the blood supply.”<sup>170</sup>

### C. Spain

Approximately 1% of Spain’s population (from 15 to 49 years old) is living with HIV, as compared to approximately 12% of Spain’s MSM population.<sup>171</sup> However, Spain currently has no established deferral policy regarding MSM blood donors nor do blood centers ask donors questions regarding their sexual orientation.<sup>172</sup> The current laws regulating blood donations were passed in 2005.<sup>173</sup> Spain follows a risk-based assessment of each donor via their questionnaire, which includes questions that assess risks with a high prevalence of leading to HIV infection.<sup>174</sup> For instance, “blood donors who have had sex with HIV carriers/patients or IV drug users, sex with more than one partner at a time, either of the same or different gender, or sex with an occasional partner, are deferred for 12 months.”<sup>175</sup> Spain utilizes both NAT and Serology testing for HIV on blood donations.<sup>176</sup>

Increases of HIV infections in blood donations and in the general population may cause the Spanish government to pass new regulations regarding MSM blood donations.<sup>177</sup> The prevalence of HIV in blood

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167. *Id.*

168. *Id.* at 40 (HIV: Human Immunodeficiency Virus; HAV: Hepatitis A Virus; HBV: Hepatitis B Virus; HCV: Hepatitis C Virus; HTLV: Human T-Lymphotropic Virus).

169. *Id.*

170. *Id.* at 49.

171. *UNAIDS Report On The Global AIDS Epidemic*, UNAIDS 27 (2012), available at [http://www.unaids.org/en/media/unaids/contentassets/documents/epidemiology/2012/gr2012/20121120\\_UNAIDS\\_Global\\_Report\\_2012\\_with\\_annexes\\_en.pdf](http://www.unaids.org/en/media/unaids/contentassets/documents/epidemiology/2012/gr2012/20121120_UNAIDS_Global_Report_2012_with_annexes_en.pdf) (The sharpest declines in the numbers of people acquiring HIV infection since 2011 have occurred in the Caribbean (42%) and sub-Saharan Africa (25%). Globally, the number of people newly infected continues to fall: the number of people, adults and children, acquiring HIV infection in 2011 was 20% lower than in 2001 and the mortality rate from AIDS-related causes began to decline in the mid-2000’s because of the increase of technology, antiretroviral therapy, knowledge, and the steady decline in HIV incidence.).

172. Benjamin, *supra* note 102, at 364.

173. *Id.*

174. *Id.*

175. *Id.*

176. *See id.*

177. *Id.*

donations in Spain has been found to be one of the highest in Western European countries.<sup>178</sup> In fact, the influx of HIV in blood donations has been a rather recent event. In 2000, there were 4.5 HIV positive blood donations for every 100,000 donations; in 2009, that number had risen to 8.5 HIV positive blood donations for every 100,000 donations.<sup>179</sup> Of those donors who donated HIV positive blood, 88% were male and 74% of the donors disclosed MSM sexual behavior; compared to 22% promiscuous heterosexual behavior.<sup>180</sup> Blood donation officials in Spain believe that this increase is due to donors using blood donations as a way to discreetly take an HIV test.<sup>181</sup>

#### D. Italy

In Italy, an estimated 0.3% of the population is infected with HIV, with 150,000 citizens living with HIV/AIDS.<sup>182</sup> Approximately 10% of the MSM community is infected with HIV/AIDS.<sup>183</sup> Italy had a deferral for MSM donors until 2001 due to the belief that allowing MSM donors would pose a major risk of spreading HIV.<sup>184</sup> In 2001, Italy removed the question about male homosexual intercourse and replaced it with questions regarding risky sexual behaviors such as having multiple partners and unprotected sex.<sup>185</sup> Italy introduced NAT testing (which can test for HIV with an average window period of five days) for HIV in 2002.<sup>186</sup>

A 2009 study analyzed blood donations across Europe between 1995 and 2006.<sup>187</sup> This study found that Italy has the highest prevalence of HIV positive blood donations out of any other country in Western Europe.<sup>188</sup> For 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.<sup>189</sup> The incidence of HIV positive donations increased between 1995 and 2006

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178. *Id.*

179. *Id.*

180. *Id.*

181. *Id.*

182. UNAIDS, *supra* note 171, at A11.

183. *Id.* at A45.

184. C. Velati et al., *The Risk of HIV Transmission by Transfusion in Italy Does Not Increase After the Abolition of Ban on Blood Donations From Homosexual Men*, 93 VOX SANGUINIS 9, 9 (2007).

185. *Id.*

186. Seed, *supra* note 126, at 12; Barbara Suligoj et al., *Epidemiology of human immunodeficiency virus infection in blood donations in Europe and Italy*, 8 BLOOD TRANSFUSION 178, 178 (2010).

187. Suligoj, *supra* note 186, at 178.

188. *Id.* at 179.

189. *Id.* at 180.

while the prevalence of HIV among Italy's population generally has been stabilizing.<sup>190</sup> This study also showed that one-third of HIV positive persons in Italy were unaware of the source of infection and over half of those infected did not even suspect that they were infected.<sup>191</sup>

In 2007, a study was conducted to assess whether the risk of spreading HIV infection via blood transfusions had increased due to the complete removal of deferral based on male homosexual intercourse.<sup>192</sup> The study was conducted in the Lombardy region of Italy, which accounts for the highest incidence of HIV infection in Italy and accounts for 20% of blood donations in the country (about 500,000 donations per year).<sup>193</sup> Data was collected regarding HIV positive donations between 1997 and 2005.<sup>194</sup> Of the donors, 130 were found to be HIV positive. Of these 130 donations, risk factors associated with heterosexual intercourse accounted for 48% and male homosexual intercourse accounted for 12%.<sup>195</sup>

From 1997 to 2001, while MSMs were deferred, 87% of the HIV positive donations were associated with sexual risk factors, but only 18% of those HIV positive donations were associated with male homosexual intercourse.<sup>196</sup> From 2002 to 2005, 96% of the HIV positive donations were associated with sexual risk factors, and of those risk factors 22% were male homosexual intercourse.<sup>197</sup>

This study concluded that there was an increase in prevalence of HIV positive donations, but that the major risk factors associated with that increase was heterosexual promiscuity.<sup>198</sup> Further, HIV positive subjects with homosexual behaviors did not increase by a significant measure after ban on blood donations from MSMs was removed.<sup>199</sup>

### E. South Africa

In 2011, it was estimated that 5,600,000 people were living with HIV/AIDS in South Africa with 380,000 new infections per year.<sup>200</sup> The HIV positive population represents approximately 11% of the general

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190. *Id.* at 183.

191. *Id.* at 182-83.

192. Velati, *supra* note 184, at 9.

193. *Id.* at 9-10.

194. *Id.* at 10.

195. *Id.*

196. *Id.*

197. *Id.*

198. *Id.*

199. *Id.*

200. UNAIDS, *supra* note 171, at A10, A17.

population, while the prevalence of HIV in the MSM population is 10.4%.<sup>201</sup> South Africa saw a steady increase in the prevalence of HIV in the blood donor population between 1991 and 1998.<sup>202</sup> There were approximately two HIV infections per year caused by blood transfusion.<sup>203</sup>

The South African National Blood Service (“SANBS”) is responsible for blood donations throughout the country, and in 2005 they introduced individual donation NAT screening for HIV, HBV, and HCV.<sup>204</sup> In 2006, SANBS reviewed the deferral policy and found that based on internal reviews and the recently introduced individual NAT testing, the deferral period for MSMs could be changed from five years to six months.<sup>205</sup> Between 2005 and 2010, there have been no HIV infections caused by transfusion.<sup>206</sup> There has been an increase of HIV positive donors; however, this is attributed to heterosexual HIV positive donors coming from certain ethnic groups with a high prevalence of HIV.<sup>207</sup>

### F. Russia

Since 2001, HIV prevalence in Russia, Eastern Europe and Central Asia has increased by 250%, making the region home to the world’s most rapidly expanding epidemic.<sup>208</sup> However, the increase in HIV incidence in Russia is not due to homosexual sex between men.<sup>209</sup> Men who have sex with men comprise a relatively small proportion of total HIV cases in comparison to Western European and North American nations.<sup>210</sup> In 2012, unprotected male-to-male sex accounted for less than 1% of newly registered cases in Russia, whereas nearly 39% of new cases of HIV were transmitted via heterosexual sex.<sup>211</sup> New cases of HIV actually rose in 2012 by 12% with 200 new cases a day, yet sex between men was not the main cause.<sup>212</sup> In nearly 60% of new cases, drug injection with reused

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201. Benjamin, *supra* note 102, at 363.

202. Vermeulen et al., *Impact of Individual-donation nucleic acid testing on risk of human immunodeficiency virus, hepatitis B virus, and hepatitis C virus transmission by blood transfusion in South Africa*, 49 *TRANSFUSION* 1115, 1115 (2009).

203. Benjamin, *supra* note 102, at 345.

204. Vermeulen, *supra* note 202, at 1115.

205. Benjamin, *supra* note 102, at 345, 362.

206. *Id.*

207. *Id.* at 363.

208. *HIV and AIDS in Russia, Eastern Europe & Central Asia*, AVERT, <http://www.avert.org/aids-russia.htm> (last visited Feb. 27, 2013).

209. *Id.*

210. AVERT, *supra* note 208.

211. *Russia Reports 12% rise in HIV-200 New Cases a Day*, BBC NEWS EUROPE (Nov. 28, 2012), <http://www.bbc.co.U.K./news/world-europe-20526639>.

212. *Id.*

needles was the cause of the infection.<sup>213</sup> The highest-route of transmission in Russia involves blood transfusion,<sup>214</sup> and sadly children are the most susceptible to new infection.<sup>215</sup>

Russia has historical ill will toward the gay community. Article 121 of the Soviet Criminal Code prohibited consensual sexual relations between men, and sodomy was punishable by up to five years in prison.<sup>216</sup> In April 1993, the first part of Article 121, the act of men engaging in consensual homosexual acts, was decriminalized.<sup>217</sup> In 1999, Russia's authority on psychology decided that homosexuality was not classified as a mental illness.<sup>218</sup> Continuing with progress, on April 16, 2008, Russian Minister of Health and Social Development, Tatyana Golikova, signed a decree effectively repealing a six-year ban on gay blood donors on the basis of the ban being unconstitutional and discriminatory.<sup>219</sup> The lifting of the ban was a part of a campaign to build "the institution of blood donation" in Russia by the Ministry of Public Health.<sup>220</sup> This was a major win for LGBT human rights in Russia. "Russian legislation finally got rid of the last direct discriminatory provision against homosexual people."<sup>221</sup> However, Russia is returning to its old ways by introducing the "homosexual propaganda" ban.<sup>222</sup> The anti-gay bill is feared to make gay pride marches, demonstrations for gay rights, and public displays of affection by same-sex couples illegal.<sup>223</sup> The recent violence toward LGBT

213. *Id.*

214. Michael Mina, *HIV in Russia-Time for Action*, 86 U. TORONTO MED. J. 40, 40 (2009).

215. BBC NEWS EUROPE, *supra* note 211.

216. United States Bureau of Citizenship and Immigration Services, *Russia: Information on the Treatment of Homosexuals, Including Imprisonment and Involuntary Medical Treatment, and the Situation of HIV-Positive Citizens of Russia* (May 8, 1998), <http://www.unhcr.org/refworld/docid/3df0ba597.html>.

217. *Id.*

218. *Russia Ends Gay Blood-Donor Ban*, ASS'N OF DONOR RECRUITMENT PROF'LS,

<http://www.adrp.org/news-events-media/news/russia-ends-gay-blood-donor-ban> (last visited Feb. 17, 2014).

219. PDIMASO, *Russia Repeals Gay Blood Ban*, ADVOCATE.COM (May 27, 2008),

<http://www.advocate.com/health/health-news/2008/05/27/russia-repeals-gay-blood-ban>; *Russian Health Ministry Ends Ban on Blood Donations by Gays*, U.K.GAYNEWS (May 23, 2008), <http://www.ukgaynews.org.uk/Archive/08/May/2302.htm>.

220. *Building the Social Institution of Blood Donation in Russia*, THE HOLMES REPORT (Aug. 19, 2011), <http://www.holmesreport.com/casestudy-info/10785/Building-The-Social-Institution-Of-Blood-Donation-In-Russia.aspx> (An additional reason this campaign was set in motion was the lack of blood donors in Russia (12 per 1000 people in 2007-only 30% of the average European level)).

221. ADVOCATE.COM, *supra* note 219.

222. *See generally* Julia Ioffe, *Russia's Past is Ever Present: The "Homosexual Propaganda" Ban is Traditionalism at its Worst*, NEWS REPUBLIC (Feb. 3, 2013), *available at*

<http://www.newrepublic.com/article/112362/russias-gay-propaganda-ban-putin-brings-past-present>.

223. Kathy Lally, *Russian Anti-Gay Bill Sets Off Furor*, THE WASHINGTON POST (Jan. 29, 2013), *available at* [http://articles.washingtonpost.com/2013-01-29/world/36607984\\_1\\_anti-gay-bill-anti-gay-law-gay-propaganda](http://articles.washingtonpost.com/2013-01-29/world/36607984_1_anti-gay-bill-anti-gay-law-gay-propaganda).



persons in Russia and President Vladimir Putin's lack of willingness to stop such violence has sparked protests around the world and some are even calling for the boycott of the 2014 Winter Olympics.<sup>224</sup> However, even Russia has recognized that the gay blood ban needed to end.

### G. Mexico

On December 25, 2012, Mexico removed its ban on blood donations from gay and bisexual men.<sup>225</sup> NOM 003-SSA2, a regulation from 1993 that explicitly banned gay and bisexual men from donating blood based on their "practices" and their "increased probability of acquiring HIV or hepatitis infection," was effectively dissolved.<sup>226</sup> The new regulation NOM 253-SSA1 eliminates the systematic and categorical prohibition on gay male blood donations.<sup>227</sup> Instead, Mexico adopts a "risky sexual practices" based approach to blood donations, similar to Italy and Spain.<sup>228</sup> NOM 253-SSA1 defines these "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."<sup>229</sup>

Mexico, the first North American country to lift the ban on blood donations from gay and bisexual men, was applauded for the change.<sup>230</sup> A Mexican governmental body, the National Council to Prevent Discrimination, released a statement on December 26, 2012 stating that,

in making these discriminatory distinctions, the [previous] norm

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224. Slava Mogutin, *The Case for Boycotting the 2014*, THE HUFFINGTON POST (Aug. 20, 2013), [http://www.huffingtonpost.com/slava-mogutin/the-case-for-boycotting-the-2014-winter-olympics\\_b\\_3787006.html](http://www.huffingtonpost.com/slava-mogutin/the-case-for-boycotting-the-2014-winter-olympics_b_3787006.html).

225. Sunnive Brydum, *Mexico Lifts Blood Donation Ban for Gay and Bisexual Men*, ADVOCATE.COM (Dec. 20, 2012), <http://www.advocate.com/health/health-news/2012/12/28/mexico-lifts-blood-donation-ban-gay-and-bisexual-men>; *Mexico Lifting Gay Blood Donation Ban: Report*, THE HUFFINGTON POST (Dec. 27, 2012),

[http://www.huffingtonpost.com/2012/12/27/mexico-gay-blood-donation-ban-lift\\_n\\_2370570.html](http://www.huffingtonpost.com/2012/12/27/mexico-gay-blood-donation-ban-lift_n_2370570.html).

226. Andres Duque, *Mexico Lifts Gay and Bisexual Blood Donor Ban*, BLABBEANDO BLOGSPOT (Dec. 25, 2012, 6:45 PM),

<http://blabbeando.blogspot.com/2012/12/mexico-lifts-gay-and-bisexual-blood.html#.US2Cr448hqG> (referencing NOM 003-SSA2).

227. Norma Oficial Mexicana NOM-253-SSA1-2012, Para la disposicion de sangre humana y sus componentes con fines terapeuticos, 26 de Octubre de 2012, *available at* [http://www.colegiomedicohidalguense.org.mx/archivos2013/20121026\\_sangre.pdf](http://www.colegiomedicohidalguense.org.mx/archivos2013/20121026_sangre.pdf). [Mexican Ministry of Health Official Standard]; Brydum, *supra* note 225 (translating sections of NOM-253-SSA1).

228. Brydum, *supra* note 225.

229. *Id.*

230. Makini Brice, *Mexico Lifts Ban on Blood Donations from Gay Men*, MEDICAL DAILY (Dec. 27, 2012), <http://www.medicaldaily.com/mexico-lifts-ban-blood-donations-gay-men-244061>.

explicitly violated the prohibition against discrimination present in the Constitution and the Federal Law to Prevent and Eliminate Discrimination, as well as Article 24 of the American Convention on Human Rights and Article 26 of the International Civil and Political Rights Treat, among other international instruments of law, which establish that every person is equal before the law regardless of any condition.<sup>231</sup>

Prior to the new rule being promulgated, Mexico's incidence of new HIV infections decreased in a span of ten years by 29%.<sup>232</sup> There was also a noted shortage in the blood supply, and increased HIV testing technology produced no new cases of HIV/AIDS resulting from blood transfusions since 1999.<sup>233</sup> With the lifting of the gay blood ban in Mexico, an example may have been set for other North American countries to follow.

### H. Japan

Japan previously had a one-year deferral for MSM donors; however, this was updated to a six-month deferral policy in light of NAT testing, which greatly decreases the window period for detecting HIV.<sup>234</sup> Further, the Japanese blood donor questionnaire treats MSM behavior as an equally risky behavior as having a new heterosexual partner, which also requires a six-month deferral.<sup>235</sup> The questionnaire asks whether the donor has had a new heterosexual partner in the last six months, had sex with a man (if the donor is male), used illegal drugs, or had a sexual partner that meets any of the previous categories.<sup>236</sup> An affirmative answer to any of these questions results in disqualification from donating blood.<sup>237</sup>

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231. *Id.*; Consejo Nacional Para Prevenir La Discriminacion, *Celebra Conapred Entrada en Vigor de Norma de Donación de Sangre, Libre de Discriminación* (Dec. 26, 2012), [http://www.conapred.org.mx/index.php?contenido=noticias&id=3334&id\\_opcion=108&op=214](http://www.conapred.org.mx/index.php?contenido=noticias&id=3334&id_opcion=108&op=214).

232. *UNAIDS World AIDS Day Report 2012-Results*, UNAIDS 12 (2012), [http://www.unaids.org/en/media/unaids/contentassets/documents/epidemiology/2012/gr2012/JC2434\\_WorldAIDSday\\_results\\_en.pdf](http://www.unaids.org/en/media/unaids/contentassets/documents/epidemiology/2012/gr2012/JC2434_WorldAIDSday_results_en.pdf).

233. Monica Ortiz Uribe, *Blood Donors in Short Supply Amid Mexico Drug War*, NPR (May 5, 2011), <http://www.npr.org/2011/05/05/136023636/blood-donors-in-short-supply-amid-mexico-drug-war>; Carlos del Rio & Jaime Sepulveda, *AIDS in Mexico: Lessons Learned and Implications for Developing Countries*, 16 AIDS 1445, 1448 (2002), available at [http://www.hawaii.edu/hivandaids/AIDS\\_in\\_Mexico\\_Lessons\\_Learned\\_and\\_Implications\\_for\\_Developing\\_Countries.pdf](http://www.hawaii.edu/hivandaids/AIDS_in_Mexico_Lessons_Learned_and_Implications_for_Developing_Countries.pdf).

234. E-mail from Japanese Red Cross Society, BLOOD SERV. HEADQUARTERS (April 2, 2013) (on file with author).

235. *Id.*

236. *Id.*

237. *Id.*

## I. Canada

Canada, along with the United States, had a ban in place since the AIDS epidemic began.<sup>238</sup> The Canadian Blood Services (“CBS”), as mandated by its regulator, Health Canada, had placed a lifetime ban on blood donations from MSM anytime since 1977.<sup>239</sup> The policy stated that the ban is “based on current scientific knowledge and statistical information that shows that men who have had sex with other men are at greater risk for HIV/AIDS infection than other people.”<sup>240</sup> However, Canada recognized that the science of the 1970’s and 1980’s is outdated because there have been vast improvements to blood testing since then and the ban does not take into account safe sexual practices nor the fact that 94% of the homosexual and bisexual community in Canada is not HIV-positive.<sup>241</sup>

CBS acted to change this long-standing ban on MSM blood donations. CBS submitted a plan to Health Canada, to support a change from the lifetime ban on homosexuals to a deferral system.<sup>242</sup> A study created by the Canadian Medical Association determined that the benefits of a deferral system would offset the negative consequences.<sup>243</sup> The study revealed that changing the ban to a one-year deferral would result in a risk increment of one unit of blood for every eleven million units collected, a small potential hazard to those receiving blood donations.<sup>244</sup> The study argued that Canada was ripe for a change since “the current policy is counterproductive in terms of loss of donors, loss of good will, student protests, donor boycotts, lawsuits, and other negative effects.”<sup>245</sup>

Due to the efforts of CBS and other special interest groups, on May 22, 2013, Canada approved a proposal to change the lifetime ban on gay

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238. Matthew Coutts, *Canadian Blood Services Could Relax Donor Ban on Gay Men*, YAHOO! NEWS CANADA (Jan. 14, 2013), <http://ca.news.yahoo.com/blogs/dailybrew/canadian-blood-services-could-relax-donor-ban-gay-214133067.html>.

239. *Indefinite Deferrals*, CANADIAN BLOOD SERVS, [http://www.blood.ca/centreapps/internet/uw\\_v502\\_mainengine.nsf/page/Indefinite%20Deferral?OpenDocument](http://www.blood.ca/centreapps/internet/uw_v502_mainengine.nsf/page/Indefinite%20Deferral?OpenDocument) (last visited Mar. 11, 2014).

240. *Id.*

241. Coutts, *supra* note 238; see Mark A. Wainberg, et al., *Reconsidering the Lifetime Deferral of Blood Donation by Men Who Have Sex with Men*, 182 CANADIAN MED. ASS. J. 1321, 1322-24 (2010).

242. *Statement to Health Canada: Canadian Blood Services Policy on Excluding Men Who Have Had Sex with Men (MSM) from Donating Blood*, CANADA BLOOD SERVS. (Oct. 19, 2011), [http://www.blood.ca/CentreApps/Internet/UW\\_V502\\_MainEngine.nsf/printpageview/106904289370F312852579030075DFB3?OpenDocument](http://www.blood.ca/CentreApps/Internet/UW_V502_MainEngine.nsf/printpageview/106904289370F312852579030075DFB3?OpenDocument); Peter Baklinski, *Canada Poised to Partially Lift Ban on Gay Men Giving Blood*, LIFESITENEWS.COM (Nov. 28, 2012), <http://www.lifesitenews.com/news/canada-poised-to-partially-lift-ban-on-gay-men-giving-blood/>.

243. CANADIAN BLOOD SERVS., *supra* note 239, at 1323.

244. *Id.* at 1324.

245. *Id.*

blood donors to a deferral period of five years.<sup>246</sup> The new five-year deferral period means that men who have not had sex with men in the past five years are now eligible to donate blood in Canada.<sup>247</sup> The official announcement by Health Canada states that the improved screening and quick detection of HIV in blood within days, was a strong element in amending the ban.<sup>248</sup> This recent development puts additional pressure on the United States as its neighbors to the North and South have changed their gay blood policy. The deferral system is a step in the right direction; a step similar to recent changes in other industrialized countries.

### J. Other Countries

The foregoing countries are not isolated in their attempts and successes in advocating for the allowance of gay blood donations. Several other countries have recently modified their policy on allowing MSM blood donations. Sweden became one of the first European countries, along with Italy and Spain, to allow gay men to donate blood.<sup>249</sup> Even though the ban is not completely lifted, the lifetime deferral was exchanged for a year deferral period as of March 2010.<sup>250</sup> Moreover, although not completely analogous, China lifted its ban on lesbians donating blood on July 1, 2012.<sup>251</sup> Men who have sex with men are still prohibited.<sup>252</sup>

As of April 24, 2013, Chile lifted its ban on MSM donors after over a year of lobbying by LGBT groups, and now Chilean gay and lesbian individuals are allowed to donate blood if they meet certain criteria.<sup>253</sup> The change in the blood donation policy by the Chilean Health Ministry came

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246. *Health Canada Approves Proposals to Change Deferral Period for Certain Blood Donors – Regulatory Decision Will Not Compromise the Safety of Canada’s Blood System*, HEALTH CANADA (May 22, 2013), [http://www.hc-sc.gc.ca/ahc-asc/media/nr-cp/\\_2013/2013-65-eng.php](http://www.hc-sc.gc.ca/ahc-asc/media/nr-cp/_2013/2013-65-eng.php).

247. *Id.*

248. *Id.*

249. Jessica Geen, *Sweden to Lift Lifetime Blood Donation Ban for Gay Men*, PINKNEWS (Dec. 1, 2009), <http://www.pinknews.co.U.K./2009/12/01/sweden-to-lift-lifetime-blood-donation-ban-for-gay-men/>; *Gay Men May Donate Blood: Health Board*, THE LOCAL-SWEDEN’S NEWS IN ENGLISH (Dec. 1, 2009), <http://www.thelocal.se/23590/20091201/>.

250. *Id.*

251. Michael Evan, *Critics Question China’s Ban on Gay Blood Donors*, ASIAN CORRESPONDENT (July 27, 2012), <http://asiancorrespondent.com/86591/critics-question-chinas-ban-on-gay-blood-donors/>; Liu Meng, *Lesbian Blood Doan Lifted*, GLOBAL TIMES (Mar. 3, 2012), <http://www.globaltimes.cn/content/718593.shtml>.

252. *Id.*

253. Elizabeth Trovall, *Gays and Lesbians in Chile Now Allowed to Donate Blood*, THE SANTIAGO TIMES (Apr. 25 2013), <http://www.santiagotimes.cl/chile/health-and-environment/26066-gays-and-lesbians-in-chile-now-allowed-to-donate-blood>; see Nathan Simpson, *Chile Lifts Ban on Blood Donation for Gays and Lesbians*, QUEERLANDIA (Apr. 29, 2013), <http://queerlandia.com/2013/04/29/chile-lifts-ban-on-blood-donation-for-gays-and-lesbians/>.

less than a year after the country implemented a piece of anti-discriminatory legislation.<sup>254</sup> Potential gay and lesbian blood donors will no longer be denied outright, but instead will only be restricted based upon their answers to questions targeting those with a history of risky sexual behavior; a trend that most countries who recently lifted or amended gay blood donation policies are utilizing.<sup>255</sup> The deferral period in Chile is now twelve months.<sup>256</sup> Chilean Health Minister, Jaime Manalich, states that banning gay men from donating blood “made no sense from a scientific standpoint and even less when taking discrimination into consideration.”<sup>257</sup> An LGBT activist in Chile was quoted saying that, “As of today, sex between people of the same sex ceases to be considered a danger, disease or infection by the Health Ministry.”<sup>258</sup>

Many more countries are in a state of reevaluation. In Colombia, the Constitutional Court ruled against a blood clinic that asked about sexual orientation and turned gays away because they are perpetuating discrimination and the ban on gay blood donations was unnecessary because all blood centers are required to test blood donations for HIV.<sup>259</sup> Argentina is also one step closer to allowing gay men to donate blood as their Congress passed a bill that could ban clinics from asking blood donors about their sexual orientation.<sup>260</sup> The Senate sets the measure for debate sometime this year.<sup>261</sup>

#### IV. ARE GLOBAL LESSONS APPLICABLE TO THE UNITED STATES?

Every country in the world strives to maintain a healthy and ample blood supply for its citizens. The United States is not an outlier in regards to its testing procedures, its current HIV trends, or its need for additional blood supply. However, while the rest of the world is taking a critical and objective approach to its policies regarding blood donations, the United

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254. Simpson, *supra*.

255. *Id.*; See Parts C and D of Section III.

256. Simpson, *supra* note 253.

257. Andres Duque, *Chile, Columbia and Buenos Aires to Lift Gay Blood Donor Bans?*, BLABBEANDO BLOGSPOT (June 18, 2012 1:16 PM), <http://blabbeando.blogspot.com/2012/06/chile-colombia-and-buenos-aires-to-lift.html>.

258. Trovall, *supra* note 253.

259. *Ordenan revisar normatividad que impide que homosexuales donen sangre*, ELESPECTADOR.COM (May 28, 2012), <http://www.elespectador.com/noticias/judicial/articulo-349340-ordenan-revisar-normatividad-impide-homosexuales-donen-sangre>.

260. Jean Paul Zapata, *Argentina One Step Close to Allowing Gay Blood Donors*, GAYSTARNEWS (Nov. 20, 2012), <http://www.gaystarnews.com/article/argentina-one-step-closer-allowing-gay-blood-donors301112>. (The Bill is available at [http://www.noticiasurbanas.com.ar/info\\_item.shtml?x=107174](http://www.noticiasurbanas.com.ar/info_item.shtml?x=107174)).

261. *Id.*

States seems to be lagging behind global progress. The current steps towards evaluating the MSM ban in the United States pale in comparison to the extensive studies other countries have completed. Health and Human Services called for comments regarding the compliance of the MSM community to the regulations in February of 2012.<sup>262</sup> However, no meeting or study has been conducted since this announcement. HHS and the FDA have made it clear that revising this policy is not a priority, despite the requests of blood donation organizations for change.

A change to the deferral policy cannot be based merely on the desperate impact upon a subsection of our society. Rather, as many countries have pointed out, a change must stem from current scientific testing procedures, current trends in the growth of HIV, changing societal perception of the gay community, and current legal climate.

### A. Current Testing Procedures

The United States currently utilizes NAT testing for all blood donations, which can test for HIV between nine and eleven days after infection (window period).<sup>263</sup> The FDA requires blood donations to be pooled with a maximum of twenty-four samples and subjected to NAT testing.<sup>264</sup> If this pool tests positive, each donation is subjected to repeat testing on an individual basis.<sup>265</sup>

This testing process is similar to the testing process used by the countries that have changed their deferral policy for MSMs. The U.K. also pools donations in groups of twenty-four and performs NAT testing.<sup>266</sup> Australia, Spain, Italy, South Africa, Japan, Canada, and Mexico use NAT testing on their blood donations as well.<sup>267</sup> The U.S. was one of the earliest countries to utilize NAT testing in 1999.<sup>268</sup> As other countries have begun introducing NAT testing, they have modified their MSM deferral policies, because a lifetime deferral for an MSM does not scientifically make sense when the NAT test can reveal an HIV infection within nine to eleven days

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262. 77 C.F.R §36.

263. See SABTO, *supra* note 22.

264. *Guidance for Industry: Use of Nucleic Acid Tests on Pooled and Individual Samples from Donors of Whole Blood and Blood Components, including Source Plasma, to Reduce the Risk of Transmission of Hepatitis B Virus*, U.S. FOOD & DRUG ADMIN. 5 (2012) available at <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/ucm327850.htm>.

265. *Id.*

266. SABTO, *supra* note 22, at 41.

267. W. K. Roth et al., *International Survey on NAT Testing of Blood Donations: Expanding Implementation and Yield from 1999 to 2009*, 102 VOX SANGUINIS 82, 84 (2012).

268. *Id.*

after infection. South Africa introduced NAT testing in 2005, and changed its deferral policy to six months in 2006.<sup>269</sup> Australia adopted NAT testing in 2000 and changed its deferral policy to one year in 2000.<sup>270</sup> Japan changed its deferral period to a year in 2008, but when the NAT testing became even more advanced, it changed its deferral period to six-months in 2011.<sup>271</sup>

These countries almost immediately reevaluated their MSM deferral policies in response to the scientific advancement that NAT testing brought. However, the U.S. has failed to even seriously consider revising the policy that permanently defers a male who has had sex with another male in the past twenty-five years when the NAT test can identify HIV as early as five days. This policy simply can no longer be justified on scientific evidence.

### B. HIV Epidemiology Changes

New infections of HIV in the United States have been reduced by two-thirds since the height of the epidemic.<sup>272</sup> The term “Gay Plague” certainly no longer applies to HIV in the U.S. or the world. In the U.S., 25% of new HIV infections in 2010 were caused by heterosexual contact, while MSM accounted for 63%, and injected drug users accounted for 8%.<sup>273</sup>

A closer look at the statistics reveals that African Americans have a disproportionate representation in HIV infections. Although African Americans only account for 14% of the U.S. population, they account for 44% of new HIV infections.<sup>274</sup> Specifically, while African American males and white MSM infection rates are roughly equal, the infection rate of African American females is twenty times higher than white females, accounting for 13% of all new HIV infections.<sup>275</sup> It is estimated that 1 in 16 African American males, and 1 in 32 African American females will be infected with HIV at some point during their life.<sup>276</sup> New infections can be analyzed further by age groups. People aged 25-34 accounted for 31% of

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269. Benjamin, *supra* note 102, at 362.

270. Seed, *supra* note 126, at 2724, 2727.

271. BLOOD SERV. HEADQUARTERS, *supra* note 239.

272. CDC Fact Sheet: *New HIV Infections in The United States*, CTR. FOR DISEASE CONTROL & PREVENTION 5 (2012), available at <http://www.cdc.gov/nchhstp/newsroom/docs/2012/HIV-Infections-2007-2010.pdf>.

273. *Id.* at 2.

274. *Id.* at 3.

275. *Id.*

276. *HIV Among African Americans*, CTR. FOR DISEASE CONTROL & PREVENTION (2013), available at [http://www.cdc.gov/hiv/topics/aa/pdf/HIV\\_among\\_African\\_Americans\\_final.pdf](http://www.cdc.gov/hiv/topics/aa/pdf/HIV_among_African_Americans_final.pdf).

new infections, while those aged 13-24 accounted for 26% of new infections.<sup>277</sup> Yet, race, ethnicity, or age are nowhere on the blood donation questionnaire.

A continued rationale for permanently deferring MSM donors in the U.S. has been that the MSM population constitutes such a high risk of HIV prevalence within the community that allowing any of them to donate would constitute an unacceptable risk. However, in Australia, MSM constitutes 75% of HIV infections, a number even higher than in the U.S.<sup>278</sup> Despite this statistic, Australia changed its deferral period to twelve months, which resulted in no significant increase in the number of HIV positive donations.<sup>279</sup> In Italy, 10% of the MSM population has HIV (as compared to 0.3% of the general population), but when Italy changed to a risk-based questionnaire for donors, as opposed to a blanket deferral of MSM donors, the increase in HIV positive donations was caused not by MSM donors but heterosexual donors.<sup>280</sup> In the U.K., 42% of HIV infections are caused by MSM sexual activity, but the Ministry of Health determined that reducing the deferral period would not significantly increase risk to the blood supply.<sup>281</sup> In Japan, the MSM population has an HIV prevalence of approximately 5%, compared to less than 1% in the general population, and the deferral period was changed to six months in April of 2011.<sup>282</sup>

In almost every country around the world, the prevalence of HIV in the MSM population is higher than the general population. Countries have acknowledged that although this may be the case, scientific advances no longer warrant a lifetime deferral or disqualifying a specific segment of society from donating blood.

### C. Vanishing Stigma Towards the Gay Community

There was a time when the gay community was relegated to hiding their sexuality out of fear of scorn by greater society. However, time and activism have changed society's perception of the gay community. Around the world, countries are recognizing gay persons with antidiscrimination laws and recognizing same-sex relationships. In evaluating blood donor regulations, countries look to ethical considerations regarding treatment of

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277. CDC FACT SHEET, *supra* note 272, at 4.

278. AUSTRALIAN RED CROSS, *supra* note 127, at 2

279. Seed, *supra* note 126, at 2724.

280. UNAIDS, *supra* note 171, at A7, A45; C. Velati et al., *supra* note 184, at 2729.

281. SABTO, *supra* note 22, at 19; UNITED KINGDOM DEP'T OF HEALTH, *supra* note 82.

282. UNAIDS, *supra* note 171, at 26; BLOOD SERV. HEADQUARTERS, *supra* note 239.



MSM donors.<sup>283</sup> The U.K. recognized that “radical changes in both the legal and social consideration of same sex relationships reflect a society less accepting of perceived unfairness or discrimination.”<sup>284</sup> The recognition that the report speaks of is the Civil Partnership Act of December 5, 2005 that gave same-sex couples the right to civil unions, which carry the same legal rights as heterosexual unions.<sup>285</sup> The report went on further to consider that excluding MSMs creates a marginalizing effect that is at odds with the goal of making the LGBT community a fully accepted part of society.<sup>286</sup>

In Australia, the Australian Red Cross Blood Services recognized that the ban on MSM donors created a significant challenge to the donor’s right to sexual preference.<sup>287</sup> Society in Australia has embraced same-sex relationships, which are legal in five of the seven states, and by recognizing civil unions on the federal level with equal status to heterosexual unions.<sup>288</sup> Spain, which has no exclusion of MSM donors, recognized same-sex marriage in July of 2005.<sup>289</sup> Canada, which is considering revisions to their deferral policy of MSM donors, recognized same-sex marriages in July of 2005.<sup>290</sup> South Africa recognized same-sex marriage in 2006, the same year it changed its deferral policy for MSM donors to six-months.<sup>291</sup>

Society in the U.S. has also changed its perception of the LGBT community, which is evidenced in the changing perception of same-sex relationships. In the U.S., fifteen states and the District of Columbia allow same-sex marriages, ten states offer either civil unions or domestic partnerships in recognition of same-sex relationships, and two additional states recognize out-of-state marriages but do not offer it themselves.<sup>292</sup> This shift towards recognition began in the U.S. when Massachusetts became the first state to recognize same-sex marriages on May 17,

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283. See SABTO, *supra* note 22, at 52.

284. *Id.*

285. *Free guide to gay and lesbian couples considering a civil partnership*, <http://www.civilpartnershipinfo.co.U.K./> (last visited Apr. 24, 2013).

286. SABTO, *supra* note 22, at 43.

287. AUSTRALIAN RED CROSS, *supra* note 127, at 3.

288. *Australian Civil Unions*, AUSTRALIAN MARRIAGE EQUALITY, <http://www.australianmarriageequality.com/wp/australian-civil-unions/> (last visited Apr. 25, 2013).

289. *The Freedom to Marry Internationally*, FREEDOM TO MARRY, <http://www.freedomtomarry.org/landscape/entry/c/international> (last visited Sept. 25, 2013).

290. *Id.*

291. *Id.*; Benjamin, *supra* note 102, at 362.

292. *Winning the Freedom to Marry: Progress in the States*, FREEDOM TO MARRY, <http://www.freedomtomarry.org/states/> (last visited Sept. 25, 2013).

2004.<sup>293</sup> Currently, over 41% of the U.S. population lives in a state with marriage equality, civil unions, or domestic partnership recognition of same-sex relationships.<sup>294</sup> In the U.S., 53% of Americans support same-sex marriage.<sup>295</sup> Lawmakers have recognized this shift, as evident in a 2012 letter to Health and Human Services signed by 62 members of the House of Representatives and the Senate, including the current Secretary of State John Kerry, calling for HHS to revise the MSM ban.<sup>296</sup> Secretary Kerry, at the time a U.S. Senator, wrote that the regulation should rely “on the science of today and not the myths of twenty years ago.”<sup>297</sup> Further, a resolution<sup>298</sup> was recently introduced to the House of Representatives to update the blood donor criteria by U.S. Representatives and Senators.<sup>299</sup>

Indeed, the myths and stigma of twenty years ago have changed. The move towards recognizing LGBT relationships is evidence that society no longer views the gay community as a promiscuous and irresponsible subset of society. In relationship recognition, there is the recognition that the gay community in-fact has stable, long-term relationships, capable of lasting a lifetime and raising children. Thus, the rationale that MSM donors are all associated with risky behavior and that they are constantly in contact with HIV is no longer valid or supported. The U.S. should follow the lead of other countries and take the growing acceptance of the LGBT community into consideration when evaluating the current ban on MSM donors.

#### D. Current Legal Climate

Many countries have legal protections for the LGBT community in the form of anti-discrimination laws, which influence the evaluation of MSM donor regulations. With formalized anti-discrimination laws, countries have to evaluate whether banning MSM donors will be illegal, or even if legal, legally unadvisable.

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293. *Id.*

294. *Id.*

295. CBS NEWS, [http://www.cbsnews.com/8301-250\\_162-57576249/poll-53-of-americans-support-same-sex-marriage/](http://www.cbsnews.com/8301-250_162-57576249/poll-53-of-americans-support-same-sex-marriage/) (last visited Apr. 25, 2013) (Poll: 53% of Americans support same-sex marriage).

296. Quigley supports lifting gay blood donor ban, Windy City Media Group (June 8, 2012) <http://www.windycitymediagroup.com/APParticle.php?AID=38071&i=83&s=National> (last visited March 10, 2014).

297. *Id.*

298. House of Congress Resolution 80, 113th Congress 2d Session (January 29, 2014) available at [http://quigley.house.gov/uploads/HConRes\\_80.pdf](http://quigley.house.gov/uploads/HConRes_80.pdf)

299. Quigley Pushes Revising Discriminatory Blood Donation Policy During National Blood Donor Month (January 30, 2014) <http://quigley.house.gov/press-releases/quigley-pushes-revising-discriminatory-blood-donation-policy-during-national-blood-donor-month/> (last visited March 10, 2014).

In the U.K., the Equality Act of 2010 prohibits discrimination on grounds of sexual orientation by a public service provider.<sup>300</sup> Although the law has an exception for blood donations, the U.K. concluded that the MSM regulation must be read in light of the general prohibition of sexual orientation discrimination in the Equality Act of 2010.<sup>301</sup> Further, the Charter of Fundamental Rights of the European Union (“TEFU”) of 2000, prohibits discrimination based on sexual orientation.<sup>302</sup> Although Australia does not have an antidiscrimination law that includes sexual orientation as a protected class, the MSM deferral has been legally challenged three times as discriminatory on the basis of “sexuality and lawful sexual activity.”<sup>303</sup> When reviewing the deferral of MSM donors, the Australian Red Cross found that although those legal challenges were unsuccessful, it is the responsibility of government to regularly review the policy and ensure it is supported by scientific evidence and avoids violating the anti-discrimination laws of Australia.<sup>304</sup> South Africa passed the Promotion of Equality and Prevention of Unfair Discrimination Act in 2000, which made it illegal to discriminate against persons based on sexual orientation.<sup>305</sup>

Currently there is no federal law in the U.S. protecting LGBT citizens from discrimination, and it is perfectly legal to fire a LGBT employee on the basis of his or her sexuality in 29 states.<sup>306</sup> The Employment Non-Discrimination Act was reintroduced to the House of Representatives and the Senate on April 25, 2013, which would make it illegal to discriminate against an LGBT employee.<sup>307</sup> The U.S. has recognized the rights of LGBT persons when it signed the Joint Statement on the Rights of LGBT Persons at the Human Rights Council of the United Nations.<sup>308</sup>

In June of 2013, the United States Supreme Court announced its decision on the Constitutionality of the Defense of Marriage Act

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300. SABTO, *supra* note 22, at 43.

301. SABTO, *supra* note 22, at 43.

302. *European Union Directives on the Prohibition of Discrimination*, ICELANDIC HUMAN RIGHTS CENTRE, <http://www.humanrights.is/human-rights-and-iceland/equality--non-discrimination/> (last visited April 25, 2013).

303. AUSTRALIAN RED CROSS, *supra* note 127, at 4.

304. *Id.*

305. *Promotion of Equality and Prevention of Unfair Discrimination Act*, OFFICE OF THE PRESIDENCY (2000), available at <http://www.info.gov.za/view/DownloadFileAction?id=68207>.

306. *Congress Has Historic Opportunity to Take Action on Employment Discrimination*, HUMAN RIGHTS CAMPAIGN, <http://www.hrc.org/blog/entry/congress-has-historic-opportunity-to-take-action-on-employment-discrimination> (last visited Apr. 25, 2013).

307. *Id.*

308. *Joint Statement on the Rights of LGBT persons at the Human Rights Council*, U.S. DEP'T OF STATE (Mar. 22, 2011), <http://www.state.gov/r/pa/prs/ps/2011/03/158847.htm>.

(“DOMA”) in the landmark case of *United States v. Windsor*.<sup>309</sup> DOMA, the Federal law passed in 1996, defined marriage as between one man and one woman and applied this definition to over 1,000 federal statutes.<sup>310</sup> This law essentially blocked same-sex couples married under state law from being recognized by any federal statute. The majority opinion, written by Justice Kennedy, found that “DOMA seeks to injure the very class [states] seek to protect. By doing so it violates basic due process and equal protection principles applicable to the Federal Government.”<sup>311</sup> The opinion went on to find that DOMA “places same-sex couples in an unstable position of being in a second-tier marriage.”<sup>312</sup> DOMA was struck down as a violation of the Fifth Amendment, and now the barrier to the federal government recognizing state same-sex marriage licenses has been removed.<sup>313</sup>

Administrative agencies and departments in the U.S. government have begun recognizing LGBT rights. In 2010, President Obama signed legislation that began the repeal of Don’t Ask Don’t Tell, the military rule that barred known LGBT service members from serving in the military.<sup>314</sup> Regarded as one of the most discriminatory policies of the U.S. government, it was fully dismantled in September of 2011.<sup>315</sup> Further, in February of 2013, the military decided to extend federal benefits to the domestic partners of military personnel.<sup>316</sup> In June of 2009, the Department of State extended benefits to domestic partners of Foreign Service personnel.<sup>317</sup>

The legal climate is changing in the U.S.; adapting to the changes in society. In evaluating their MSM blood donation policies, other countries have had to consider whether the policy would be found to be illegal when faced with other laws of the nation. The U.S. should do the same. LGBT rights have been recognized on the state level, on the floor of the General Assembly of the U.N., in the military, and in the Department of State. The FDA must acknowledge these changes in law and policy and consider

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309. *United States v. Windsor*, 133 U.S. 2675 (2013).

310. *Id.* at 2690.

311. *Id.* at 2693.

312. *Id.* at 2694.

313. *Id.* at 2695.

314. *DADT Repeal*, NAVY PERSONNEL COMMAND, [http://www.public.navy.mil/bupers-npc/support/21st\\_Century\\_Sailor/dadt/Pages/default.aspx](http://www.public.navy.mil/bupers-npc/support/21st_Century_Sailor/dadt/Pages/default.aspx) (last visited Feb. 9, 2014).

315. *Id.*

316. *Memoranda for Secretaries of the Military Departments*, SEC’Y OF DEF. (2013), available at <http://www.defense.gov/news/same-sexbenefitsmemo.pdf>.

317. *Benefits for Same-Sex Domestic Partners of Foreign Service Personnel*, U.S. DEP’T OF STATE (2009), available at <http://www.state.gov/secretary/rm/2009a/06/125083.htm>.

making regulations for blood donations that are consistent with these changes.

## V. ADDITIONAL CHALLENGES

### A. Constitutional Law Argument

The FDA blood policy excluding gay men from donating blood treats gay donors and similarly situated straight donors differently. This unfair differentiation between gay and straight donors raises constitutional equal protection concerns.<sup>318</sup> This Part does not expand upon the arguments made by prior articles about the unconstitutionality of the MSM ban, but wishes to readdress the issue in light of a societal shift in the acceptance of gay marriage and the call for the MSM ban to be overturned in the United States and abroad.

When attempting to attack the MSM ban on constitutional grounds, the proper level of scrutiny needs to be determined. The Equal Protection Clause under the Fourteenth Amendment employs three tiers of judicial review.<sup>319</sup> The three levels of review are strict scrutiny, intermediate scrutiny, and rational basis.<sup>320</sup> The appropriate level of review employed by the judiciary depends upon a number of factors. These factors include the class involved, the particular rights infringed upon, a history of unequal treatment, and other variously weighed factors.<sup>321</sup>

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318. *Plyler v. Doe*, 457 U.S. 202, 216 (1982); *Plessy v. Ferguson*, 163 U.S. 537, 559 (1886) (Equal protection requires that "all persons similarly circumstanced shall be treated alike," as the Constitution "neither knows nor tolerates classes among citizens.").

319. See e.g., *City of Cleburne v. Cleburn Living Ctr., Inc.*, 473 U.S. 432, 440-42 (1985) (state legislation that distinguishes between the mentally retarded and others much be rationally related to a legitimate government interest).

320. If a classification implicates a suspect class, the classification is subject to strict scrutiny, requiring that the state demonstrate that the classification furthers a compelling governmental interest and is narrowly tailored to further that interest. Classifications based on race, national origin and ethnicity, and alienage have been treated as suspect. See e.g., *Loving v. Virginia*, 388 U.S. 1, 11 (1967) (Supreme Court invalidating a state law under strict scrutiny that prohibited interracial marriage); *Korematsu v. United States*, 323 U.S. 214, 216 (1944) (Supreme Court upholding the discrimination of Japanese Americans during World War II despite applying strict scrutiny to the government action). The Supreme Court has created a middle tier of review for classifications based on gender or illegitimacy commonly referred to as intermediate scrutiny. Classifications affecting such quasi-suspect groups must be substantially related to a sufficiently important governmental interest. See e.g., *Trimble v. Gordon*, 430 U.S. 762 (1977) (Supreme Court invalidating state law discriminating against illegitimate children under intermediate scrutiny). All other classifications are reviewed under the rational basis test, under which they are presumptively constitutional as long as they are rationally related to any conceivable, legitimate governmental interest, even if such interest is offered post hoc. See e.g., *Williamson v. Lee Optical of Okla., Inc.* 348 U.S. 483, 489 (1955) (Supreme Court applying a rational basis review to state law regulating a business).

321. *Cleburne*, 473 U.S. at 440.

Matters affecting individuals of a different sexual orientation have historically been reviewed under rational basis review.<sup>322</sup> However, in *Lawrence v. Texas*, a case challenging a Texas law that made consensual and private homosexual sex illegal, the Court departed from the rational basis review without formally committing to a higher level of scrutiny, and based its holding on the Due Process Clause, not the Equal Protection Clause.<sup>323</sup> A concurring Justice O'Connor based her opinion on equal protection grounds and argued for "a more searching form of rational basis" because the Texas sodomy law in question had a "desire to harm a politically unpopular group."<sup>324</sup> Further she wrote, "[m]oral disapproval of this group, like a bare desire to harm the group, is an interest that is insufficient to satisfy rational basis review under the Equal Protection Clause."<sup>325</sup> The court invalidated the Texas sodomy law because it targeted gay men, similar to the way that the MSM ban targets gay men. However, the Supreme Court does not recognize the "more searching form of rational basis" and explicitly claims to be applying standard rational basis in *Lawrence*.<sup>326</sup> The Supreme Court does not employ equal protection for invalidation nor has it increased the level of scrutiny with which to evaluate policies discriminating against gays.<sup>327</sup>

There is rapidly growing support for gay marriage and the full acceptance of LGBT rights in the U.S. as well as the rest of the world. President Obama has recently embraced a heightened level of scrutiny for statutes that single out LGBT people and gay marriage.<sup>328</sup> As noted above, the Supreme Court found that the Defense of Marriage Act violated the Fifth Amendment.<sup>329</sup> However, the Supreme Court did not outline a level of scrutiny by which to evaluate laws directed at the LGBT population. The Court did rely on precedent created in *Lawrence v. Texas*, as discussed above.<sup>330</sup>

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322. *Bowers v. Hardwick*, 478 U.S. 186, 186 (1986); *Romer v. Evans*, 517 U.S. 620, 631-33 (1996).

323. *Lawrence v. Texas*, 539 U.S. 558, 574-76 (2003) (Majority based its holding on the Due Process Clause and not the Equal Protection Clause).

324. Jeremy B. Smith, *The Flaws of Rational Basis with Bite: Why the Supreme Court Should Acknowledge Its Application of Heightened Scrutiny to Classification Based on Sexual Orientation*, 73 *FORDHAM L. REV.* 2769, 2784 (2005) (Also known as rational basis with a bite); *Lawrence*, 539 U.S. at 580.

325. *Lawrence*, 539 U.S. at 582.

326. Justin Reinheimer, *What Lawrence Should Have Said: Reconstruction an Equality Approach*, 96 *CALIF. L. REV.* 505, 514-515 (2008).

327. Arthur S. Leonard, *Lawrence v. Texas and the New Law of Gay Rights*, 30 *OHIO N.U. L. REV.* 189, 200 (2004).

328. *Windsor*, 133 S. Ct. at 2683.

329. *Id.* at 2696.

330. *See id.* at 2692, 2694.

The MSM ban fails a heightened level of rational basis review. Although the policy applies only to men who have had sex with men, “the conduct targeted . . . is conduct that is closely correlated with being homosexual. Under such circumstances . . . it is instead directed toward gay persons as a class.”<sup>331</sup> The MSM ban targets all gay men, even those who practice safe sex, get tested regularly, and do not have an HIV infection. The MSM ban creates a distinction between “gay men” and “men who have sex with men” without legal meaning. Moreover, there is no gay man that could pass the ban’s exclusion of a man who has had sex with a man since 1977.

The Court held in *Lawrence* that when the state makes conduct that defines a class as criminal, “that declaration in and of itself is an invitation to subject homosexual persons to discrimination both in the public and in the private spheres.”<sup>332</sup> The blood ban may not make MSM acts criminal, but it does presume all gay men are guilty of risky behavior and communicable diseases. This presumption is inherent in the MSM policy and continues the stigma that comes along with being a gay man. This sends a message to gay men that whatever they do, no matter how safe the sex they are having is, it does not matter because “gay” is synonymous with HIV/AIDS.

Furthermore, a person does not get HIV/AIDS because he is gay, nor does a person only get HIV by having sex with a man. A person contracts HIV by participating in risky behavior. It does not matter if that person is gay or straight. Instead of focusing on a category of people, the FDA blood policy should focus on the risky behaviors that increase the chances of spreading HIV/AIDS. The blood policies of other countries, the countries that have lifted or amended their bans on gay blood donations, consider risky behaviors. This is something that the U.S. has not done and is refusing to do.

The “precautionary principle,” which many defenders of the policy argue is the main reason for maintaining a ban on gay blood donors, does not serve its purpose because the FDA fails to apply the principle to all similarly situated people. The most cautious, risk-adverse option would be to ban blood from all high risk groups, including heterosexuals donors who engage in unprotected, multiple-partner, promiscuous sex regularly. While focusing on the high HIV prevalence in MSM, the FDA seems to ignore the high prevalence in other groups such as African American or young donors. There is not a justifiable distinction. While the MSM ban

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331. *Lawrence*, 539 U.S. at 583 (O’Connor, J., dissenting).

332. *Lawrence*, 539 U.S. at 575.

serves a broad exclusion with the purpose of protecting the blood supply, it does so by being both over-inclusive, by excluding healthy homosexual donors, and under-inclusive, by admitting risky heterosexual donors.

By categorically excluding gay men, the MSM policy is facially discriminatory. The ban does not apply to other high-risk groups, thus is not rationally related to its stated goal of protecting the nation's blood supply. A ban that discriminates against a suspect class without commendable rationalization violates the Equal Protection Clause and should be deemed unconstitutional.

## B. The Administrative Law Argument

The FDA is an administrative agency whose actions are governed by the Administrative Procedure Act ("APA") and reviewable by courts.<sup>333</sup> The APA governs the process by which federal agencies develop and issue regulations.<sup>334</sup> It includes requirements for publishing notices of proposed and final rulemaking in the Federal Register and provides opportunities for the public to comment on notices of proposed rulemaking.<sup>335</sup> The APA requires most rules to have a 30-day delayed effective date.<sup>336</sup> In addition to setting forth rulemaking procedures, the APA addresses other agency actions such as issuance of policy statements, licenses, and permits.<sup>337</sup> It also provides standards for judicial review if a person has been adversely affected or aggrieved by an agency action.<sup>338</sup> It is possible that a gay donor "suffering legal wrong because of an agency action, or adversely affected and aggrieved by agency action within the meaning of a relevant statute" can sue under the APA challenging the MSM policy.<sup>339</sup>

### 1. Final Action

A court must determine that an agency issued a "final action" for review to be possible. The FDA's ban on gay blood donations came through guidance documents that stated that MSM constitutes "high risk" for HIV/AIDS.<sup>340</sup> "Guidance documents do not themselves establish legally enforceable rights or responsibilities and are not legally binding on

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333. See *Abbott Labs. V. Gardner*, 387 U.S. 136, 140-50 (1967).

334. Administrative Procedure Act, 5 U.S.C. § 551 *et seq.*

335. *Id.*

336. *Id.*

337. *Id.*

338. *Id.*

339. 5 U.S.C. §§ 702, 706.

340. See *Eligibility Requirements*, *supra* note 20.



the public or the agency.”<sup>341</sup> However, if guidance has a “direct effect on . . . day-to-day business,” then it is possible for guidance to amount to a final rule.<sup>342</sup> The guidance documents used by the FDA prohibiting gay men from donating blood are final because they are relied upon by the industry.

The FDA did not itself make the arbitrary conclusions excluding gay men from donating blood. Instead, it relied upon the opinion of an advisory committee. This could be seen as an obstacle in an APA challenge to the MSM blood ban. Congress allows for the operation of “numerous committees, boards, commissions, counsels, and similar groups which have been established to advise officers and agencies in the executive branch of the Federal Government” under the Federal Advisory Committee Act in 1972 (“FACA”).<sup>343</sup> However, reliance on an advisory committee’s decision may constitute final agency action.<sup>344</sup> An Advisory committee producing these guidelines does not preclude the guidelines from being deemed an arbitrary and capricious FDA action in an APA challenge.

## 2. Formal and Informal Rulemaking

The FDA’s decision regarding MSM blood would be reviewed under a similar framework as an informal rulemaking in *Citizens to Preserve Overton Park, Inc. v. Volpe*.<sup>345</sup> In reviewing informal rulemaking, a “court must consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment. . . . Although this inquiry into the facts is to be searching and careful, the ultimate standard of review is a narrow one.”<sup>346</sup>

Courts will likely give a high degree of deference to agencies in informal agency actions. The scope of review for an agency action would be analogous to rational basis.<sup>347</sup> The review will be further limited by the fact that the FDA’s decision to ban gay blood donors is scientific and

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341. The Food and Drug Administration’s Development, Issuance, and Use of Guidance Documents, 62 Fed. Reg. 8961, 8967 (1997).

342. *Franklin v. Massachusetts*, 505 U.S. 788, 797 (1992); see *Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1021-24 (D.C. Cir. 2000); Todd D. Rakoff, *The Choice Between Formal and Informal Modes of Administrative Regulation*, 52 ADMIN. L. REV. 159, 167 (2000).

343. FACA utilizes procedural requirements on advisory committees similar to the judicial review provisions of the APA. Pub. L. No. 92-463, 86 Stat. 770 (1972).

344. See, e.g., *Int’l Brominated Solvents Ass’n v. Am. Conf. of Governmental Indus. Hygienists, Inc.*, 393 F. Supp. 2d 1262, 1381 (M.D. Ga. 2005).

345. *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 416 (1971).

346. *Id.*

347. See Merrick B. Garland, *Derregulation and Judicial Review*, 98 HARV. L. REV. 505, 532 (1985).

agencies like the FDA are deemed experts of highly technical issues.<sup>348</sup> Courts will set aside an agency action if the court finds that action to be arbitrary and capricious.<sup>349</sup> Arbitrariness is found when an agency offers “insufficient reasons for treating similar situations differently.”<sup>350</sup>

Here, the FDA provides no rational reasoning for continuing to bar MSM blood for a lifetime deferral, with the increasing technology, awareness, and better testing practices. Yet, they allow heterosexuals whom engage in high-risk sexual behavior, perhaps even riskier behavior than homosexuals, to donate and they are only deferred one year, if at all. The FDA’s MSM ban treats like situations differently. For instance, only a one-year deferral is applied to a heterosexual man who has had unsafe sex with an HIV positive prostitute, but a MSM in a monogamous relationship is banned from donating blood forever.<sup>351</sup> This cannot be held to be a rational distinction. Moreover, the distinction does not rationally relate to the prevention of disease transmission. In *State Farm*, the Court reasoned that agency actions are irrational if the agency “entirely failed to consider an important aspect of the problem . . .”<sup>352</sup> The FDA and the MSM fails to consider all of the new HIV transmissions resulting from heterosexuals. Rather than focus on the unsafe nature of sexual acts of homosexual men, the FDA should follow the lead of other countries that have updated their MSM donation policies by focusing on the unsafe nature and risky practices of any sexual act performed by any sexually active donor.<sup>353</sup> The FDA’s policy invents this distinction between MSM and heterosexual donors that is scientifically untenable; a gay man does not contract AIDS by being gay but by engaging in risky behavior, the same as heterosexuals. This risky behavior was taken into account in countries that recently changed their MSM blood donation stance. Accordingly, the FDA’s failure to consider this important health aspect renders its continued action of banning gay males from donating blood arbitrary and capricious.

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348. See generally JERRY L. MASHAW ET AL., ADMINISTRATIVE LAW: THE AMERICAN PUBLIC LAW SYSTEM CASES AND MATERIALS 868-92 (6th ed. 2003).

349. *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

350. *County of Los Angeles v. Shalala*, 192, F.3d 1005, 1022 (D.C. Cir. 1999).

351. AABB Donor History Task Force, *Guidance for Industry: Implementation of Acceptably Full-Length Donor History Questionnaire and Accompanying Materials for Use in Screening Donors of Blood and Blood Components*, June 2005, <http://www.fda.gov/downloads/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/LicensedProductsBLAs/BloodDonorScreening/UCM164193.pdf> (consists of a flow chart for each question asked on the HH form with corresponding deferral period).

352. *State Farm*, 463 U.S. at 43.

353. See *HIV Surveillance Report: Diagnosis of HIV Infection and AIDS in the United States and Dependent Areas, 2008*, 20 CENTERS FOR DISEASE CONTROL 7, 17-18 (2010).

### 3. Proper Notice & Comment

The APA requires an agency to allow the public to submit comments for thirty days on a proposed rule.<sup>354</sup> An agency can waive the notice and comment period if they have good cause.<sup>355</sup> The good cause exception is only available when the notice and comment period is impracticable, unnecessary, or contrary to the public interest.<sup>356</sup> When a regulation “has wide impact and is controversial,” an agency hoping to bypass the notice and comment requirement must provide a convincing argument for good cause.<sup>357</sup>

The FDA ban evolved over the years, however two central themes remain constant: (1) the ban categorically excludes MSM from donating blood; and (2) the changes to the ban all occurred without standard notice and comment procedures.<sup>358</sup> The FDA could have relied on the good cause exception on the basis of public interest when the HIV/AIDS epidemic first hit the U.S. in 1983, but the FDA never argued such a basis in its guidance. Continuing to argue the ban is in place to protect public interest is not convincing given technological and societal advancements. Although the policy originated out of an imperative to save lives, this alone cannot absolve the FDA’s failure to comply with notice and comment procedures.

### C. Matter of Public Policy

The need for blood is always in high demand. One donation can help save the lives of up to three people.<sup>359</sup> Every two seconds someone needs blood.<sup>360</sup> More than 44,000 blood donations are needed every day, and a single car accident can require as many as 100 pints of blood.<sup>361</sup>

Recent crises in the U.S. have increased the need for blood. In the summer of 2012, the Red Cross said that its national blood supply was at its lowest level in 15 years because of severe weather combined with a markedly slow summer of donations.<sup>362</sup> When Hurricane Sandy hit the

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354. 5 U.S.C. § 553.

355. 5 U.S.C. § 553 (b)(B).

356. *Id.*

357. See JEFFREY S. LUBBERS, A GUIDE TO FEDERAL AGENCY RULEMAKING 107 (4th ed. 2006).

358. See *Passim* Section II(A).

359. *Blood Facts and Statistics*, AMERICAN RED CROSS,

<http://www.redcrossblood.org/learn-about-blood/blood-facts-and-statistics> (last visited Apr. 27, 2013).

360. *Id.*

361. *Blood Facts and Statistics*, AMERICAN RED CROSS,

<http://www.redcrossblood.org/learn-about-blood/blood-facts-and-statistics> (last visited Apr. 27, 2013).

362. Natalie DiBlasio, *Red Cross Says Blood Supply at Lowest Level in 15 Years*, USA TODAY (July, 2012).

eastern coast of the U.S. in October 2012, more than 9,000 blood and platelet donations across 14 states were canceled and led to a long-term impact on blood shortages.<sup>363</sup> The flu season in early 2013 was particularly severe, as 48 states reported to have widespread influenza infections leading to the declaration of emergency blood shortages were declared because of the flu.<sup>364</sup>

Events abroad have also led to decreases in blood supply. The U.K. blood supplies were dangerously low after the Norovirus outbreak in early 2013.<sup>365</sup> Drug-related violence in Mexico attributed to the low blood supply in Mexico that was insufficient to meet the needs of more than one million individuals.<sup>366</sup> Japan's quadruple disaster—earthquake, tsunami, nuclear alert, and power shortages in March 2011—put substantial constraint on the nation's blood supply and led to the implementation of countermeasures in order to mitigate damage to the nation's blood supply in similar circumstances in future.<sup>367</sup> Perhaps what is more interesting is that Japan, Mexico, and similar countries revised their MSM ban in a short time period after these events and when blood shortages occurred.

One would assume with the great need for blood in the U.S. and around the globe donors would be stepping forward en masse to help their fellow man. However, that is not the case and the shortage of blood is still an issue. The two most common reasons cited by people who do not give blood are: "Never thought about it" and "I don't like needles."<sup>368</sup> However, the new reason should be "Can't, I'm gay." The MSM ban excludes a large donor base while exacerbating the nation's blood shortage. The MSM ban prevents more than seven million men—over 6.4% of the male population—from ever donating blood during their lifetimes.<sup>369</sup> Lifting the donation ban could increase the blood supply by

2012), <http://usatoday30.usatoday.com/news/health/story/2012-07-28/nationwide-blood-shortage/56545264/1>.

363. *Sandy Forces Cancellation of About 300 Blood Drives*, AMERICAN RED CROSS (Oct. 30, 2012), <http://www.redcross.org/news/article/Sandy-Forces-Cancellation-of-About-300-Blood-Drives>.

364. Michael Williams, *Flu Epidemic in USA Causes Blood Shortage*, BLOOD BANKER (Jan. 24, 2013), <http://bloodbanker.com/plasma/blood-donation-2/flu-epidemic-in-usa-causes-blood-shortage/>.

365. Emily Payne, *U.K. Blood Supplies Dangerously Low After Early Norovirus Outbreak Keeps Donors Away*, MAIL ONLINE (Jan. 3, 2013), <http://www.dailymail.co.U.K./health/article-2256707/Blood-stocks-running-low-festive-norovirus-outbreak-causes-shortage-donors.html>.

366. Less than 3% of Mexico's population donates blood voluntarily. Michael Williams, *Blood Donation in Mexico: What It's Like?*, BLOOD BANKER (October 23, 2013), <http://bloodbanker.com/plasma/plasma-donation/blood-donation-in-mexico-what-its-like/>.

367. K. Tadokoro, *Impact of the Great East Japan Earthquake/Tsunami on Blood Services and the Countermeasures Adopted*, 6 ISBT SCIENCE SERIES 354, 354 (2011).

368. AMERICAN RED CROSS, *supra* note 378.

369. N. Goldberg & G. Gates, *Effects of Lifting Blood Donation Bans on Men Who Have Sex With Men*, The Williams Institute (June 2010), available at <http://williamsinstitute.law.ucla.edu/wp->

more than enough to keep the blood supply out of critical shortage. That increase in donations would amount to 219,000 pints of blood, which could save over 657,000 lives annually.<sup>370</sup>

Although the need for blood will always be constant, the removal of the restriction on MSM donors would help to alleviate the constriction on the U.S. blood supply. In light of the recent blood shortages stemming from times of hardship and disaster, overturning the MSM ban has a compelling and imminent human element.

## VI. CONCLUSION

The most important factor in setting regulations regarding blood donations has been, and must continue to be, safety of the blood supply. However, threats to that safety must be continually reassessed based on current risks and current scientific advances that thwart those risks. The regulation must have a rational relationship to these factors and minimize any discriminatory effects.

The recommendation of this article, based on these factors, is that the FDA should change the blood donor policy to reflect an accurate risk assessment of the donor. This would mean the complete removal of any deferral for MSM donors. Instead of a blanket ban for an entire group, the policy must address risks of each individual donor. There is no rational basis for permanently deferring a MSM donor who had sexual activity associated with risk since 1977 while allowing a heterosexual donor who had sexual activity associated with risk the day before donating blood. Having a blanket allowance of heterosexual donors, despite possible risks that that promiscuous heterosexual practices carry, creates a risk of danger for the blood supply that is not currently being addressed. If a blood donor has had a change in sexual partners or engaged in unsafe sexual practices, regardless of whether they are heterosexual or an MSM, the donor should be deferred for no more than six-months.

NAT testing has revolutionized the testing of blood donations, yet the FDA seems intent on ignoring this scientific advancement. Countries mentioned in this article have taken a critical look at their policies, and the constant theme among all of them is that NAT testing has drastically reduced the window period in which HIV and other transfusion-transmissible infections can be detected in a donor blood supply. Window

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content/uploads/Gates-Goldberg-MSM-Blood-Ban-Jun-2010.pdf .

370. See Blood Facts and Statistics, American Red Cross,

<http://www.redcrossblood.org/learn-about-blood/blood-facts-and-statistics> (last visited February 19, 2014). One pint of blood can save up to three lives.

periods for detecting HIV ranging from five to ten days have led the United Kingdom and Australia to reduce their deferral period to twelve months, South Africa and Japan to reduce their deferral period to six months, and Spain, Italy, and Chile to assess donors on an individual basis with no blanket deferrals. The research mentioned in this article has confirmed that reducing the deferral periods, or abolishing them, have not led to a significant decrease in safety to the blood supply.

The United States' lifetime ban on MSM donors stands in stark contrast to the rest of the world. The reasons that this regulation was passed no longer exist, making it arbitrary and capricious. Citizens of the United States, all citizens, deserve regulations and policies that make this country safer and more equitable.

