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A TIME FOR CHANGE: WHY THE MSM LIFETIME DEFERRAL POLICY SHOULD BE AMENDED

Vianca Diaz^{*}

INTRODUCTION

"We live in a very different country than we did in 1983."¹ However, the men who have sex with men (MSM) lifetime deferral to blood donations enforced by the Food and Drug Administration (FDA) has been consistently upheld despite transformative medical advances and social movements over the last thirty years.² Also known as the "gay blood ban,"³ the current MSM deferral policy prohibits blood donations from men who have had sex with at least one other man since 1977.⁴ In 2012, the United States Department of Health and Human Services (HHS) issued an official notice announcing the request for information relevant to create a pilot study to review this policy, which was originally passed in response to the little information then known about the human immunodeficiency virus (HIV) and the acquired immune deficiency syndrome (AIDS).⁵

In 2010, the Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA or "Committee"), the lead federal agency committee that oversees the ban, upheld the MSM deferral policy de-

^{*} J.D. Candidate 2014, University of Maryland Francis King Carey School of Law. This Comment is dedicated to my two wonderful parents, Angel and Ernesto Diaz-Mangiafico, for their unwavering love and support. The love you both share for each other is one a person, gay or straight, may wait an entire lifetime to experience. I would also like to thank the staff of the *Maryland Law Journal of Race, Religion, Gender, and Class* for their help in making this publication a reality.

¹ Letter from Sen. Kerry et al., U.S. Senate, to the Hon. Margaret Hamburg, Comm'r., U.S. Food & Drug Admin. (Mar. 4, 2010), *available at* http://www.gmhc.org/files/editor/file/a_bb_18_Senators_FDA.pdf.

² See infra Part I.B; see also Vaccines, Blood & Biologics: Blood Donations from Men Who Have Sex with Other Men Questions and Answers, FDA.GOV, http://www.fda.gov/biologicsbloodvaccines/bloodbloodproducts/questionsaboutbloo d/ucm108186.htm (Jun. 18, 2009).

³ See Dwayne J. Bensing, Science or Stigma: Potential Challenges to the FDA's Ban on Gay Blood, 14 U. PA. CONST. L. 485, 486 n. 13 (2011).

⁴ Vaccines, Blood & Biologics, supra note 2.

⁵ Request for Information (RFI) on Design of a Pilot Operational Study to Assess Alternative Blood Donor Deferral Criteria for Men Who Have Sex with Other Men (MSM), 77 Fed. Reg. 14,801, 14,801 (Mar. 13, 2012).

spite its view that the ban was "suboptimal."⁶ The Committee found that further information was necessary to reevaluate the policy adequately and charged a working group to research the most current information about HIV and AIDS.⁷ In light of this research, ACBTSA will once again examine the policy and determine whether it should be lifted or altered.⁸

This Comment seeks to review the current policy within the current legal and cultural landscape. Part I discusses the history of the current ban on blood from MSM. Part II details the 2010 review of the policy and the steps that have led to the current review at focus in this Comment. Part III argues that the ban is unconstitutional with regard to lesbian, gay, bisexual, and transsexual (LGBT) rights jurisprudence and outdated given the current cultural climate, both nationally and internationally.

Ultimately, the FDA lifetime deferral policy unconstitutionally restricts an entire class of people from donating blood due to their sexual orientation as it irrationally prohibits those who are healthy and fit to donate. In so doing, the ban perpetuates the wrongful stereotype that all gay men are infected with AIDS and must be stopped from spreading the deadly disease. This is a time for change, a time when LGBT rights are at the forefront of the political and societal landscape and are gaining more support with each passing day.⁹ Echoing rights movements of the past:

⁶ HHS ADVISORY COMM. ON BLOOD SAFETY & AVAILABILITY, RECOMMENDATIONS 1 (JUNE 2010), *available at*

http://www.hhs.gov/ash/bloodsafety/advisorycommittee/recommendations/resolution s.htm.

⁷ *Id.* at 1-2

⁸ *Id.* at 1 (stating that "until further evaluation, the committee recommends that the current indefinite deferral for men who have had sex with another man even one time since 1977 not be changed at the present time"); *see also* Request for Information (RFI) on Design of a Pilot Operational Study to Assess Alternative Blood Donor Deferral Criteria for Men Who Have Sex with Other Men (MSM), *supra* note 5, at 14,801 ("The Advisory Committee . . . recommended that the policy should be retained pending the completion of targeted research studies that might support a safe alternative policy.").

⁹ See infra Part III.C.; see also Susan Page, Support Growing For Gay Marriage, DESERT SUN, Dec. 6, 2010, at A4 ("More than nine of 10 say people in their community have become more accepting in recent years.) "That feeling," Page notes, "is ratified in a nationwide USA Today poll of all Americans that finds broad acceptance of economic rights for same-sex couples and majority support for gay marriage and adoption." *Id.*

We, the people, declare today that the most evident of truths – that all of us are created equal – is the star that guides us still; just as it guided our forebears; just as it guided all those men and women, sung and unsung, who left footprints along this great Mall, to hear a preacher say that we cannot walk alone; to hear a King proclaim that our individual freedom is inextricably bound to the freedom of every soul on Earth. It is now our generation's task to carry on what those pioneers began. For our journey is not complete until . . . our gay brothers and sisters are treated like anyone else under the law.¹⁰

I. HISTORY OF THE GAY BLOOD BAN

A. The Emergence of AIDS

On June 5, 1981 the United States Centers for Disease Control and Prevention (CDC) published the first official report of what was latter dubbed AIDS, describing five cases of a rare lung infection among previously healthy gay men in Los Angeles, California.¹¹ Following this report, doctors from across the country submitted similar reports of opportunistic infections including rare types of cancers.¹² By the end of 1981, 270 severe immune deficiency cases among gay men had been documented in the United States, 121 of which resulted in death.¹³

On September 24, 1982 the CDC first used the term AIDS to describe a "disease at least moderately predictive of a defect in cellmediated immunity, occurring in a person with no known case for di-

http://abcnews.go.com/Politics/martin-luther-kings-speech-dream-full-

text/story?id=14358231&page=2.

¹⁰ President Barack Obama, Inauguration Address (Jan. 21, 2013), *available at* http://www.politico.com/story/2013/01/president-barack-obamas-2013-inaugural-address-full-text-86497.html; *see also* Dr. Martin Luther King, Jr., I Have A Dream

Speech at the Lincoln Memorial (Aug. 28, 1963), available at

¹¹ A Timeline of AIDS, 1981, AIDS.GOV, http://aids.gov/hiv-aids-basics/hiv-aids-101/aids-timeline/ (last visited May 15, 2013).

 $^{^{12}}$ Id.

¹³ Id.

minished resistance to that disease."¹⁴ The CDC found that most cases of AIDS were reported among homosexual men with multiple sexual partners,¹⁵ an observation that started the inevitable stigmatization of homosexual men as HIV/AIDS carriers that persists in part due to the continued upholding of the MSM policy.¹⁶

B. Lifetime Deferral of Blood Donations from Men Who Have Sex With Other Men

Housed within the FDA, the Center for Biologics Evaluation and Research (CBER) is responsible for the safety of blood products collected and distributed in the United States, including blood donations.¹⁷ In collaboration with other branches of the Public Health Service, CBER researches potential threats to the blood safety and develops standards to help mitigate them.¹⁸ Over a series of decades, the FDA has issued and implemented various recommendations to regulate the blood products in the United States, including the MSM deferral policy.¹⁹

The current MSM deferral policy is the result of several agency steps taken to ensure the safety of blood products in the country. On March 24, 1983 the FDA issued its first letters to all blood collection establishments, requiring them to:

> [P]rovide educational material to prospective donors, advising them to refrain from donating if they belong to a group that was at increased risk for AIDS, to re-educate donor screening personnel to recognize early signs and symptoms of AIDS, and to ask specific questions designed to detect possible AIDS symptoms or

¹⁴ A Timeline of AIDS, 1982, AIDS.GOV, http://aids.gov/hiv-aids-basics/hiv-aids-101/aids-timeline/ (last visited May 15, 2013).

¹⁵ A Timeline of AIDS, 1983, AIDS.GOV, http://aids.gov/hiv-aids-basics/hiv-aids-101/aids-timeline/ (last visited May 15, 2013).

¹⁶ See supra Part III.B; see also Shawn C. Casey, *Illicit Regulation: A Framework for Challenging the Procedural Validity of the "Gay Blood Ban,"* 66 FOOD & DRUG L.J. 552, 554 (2011) (discussing how the discriminatory effect of the policy was an issue from the initial forming stages).

¹⁷ Vaccines, Blood & Biologics: Blood & Blood Products, FDA.GOV, http://www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/default.htm (Jun. 19, 2012).

¹⁸ *Id*.

¹⁹ Id.

exposure, and to rewrite [standard operating procedures] to include appropriate handling and labeling of potentially infected units.²⁰

At the time, the regulations did not specifically discuss the gay community; instead, the guidelines sought to advise gay men who were "currently sexually active with multiple partners, had overt symptoms of immune deficiency, or had previously engaged in sexual relations with people who now exhibited such symptoms."²¹

These recommendations changed over the coming years, most notably in 1986 when the FDA recommended a policy "exclud[ing] men who have had sex with another man one or more times since 1977."²² In 1992, this policy included language that required a lifetime deferral.²³ Since its induction, the MSM policy has received immense criticism, mostly from the LGBT community, leading to reviews of the policy in 2000²⁴ and 2006.²⁵ However, neither of these reviews resulted in change, allowing thousands of units of healthy donated blood to go to waste and the stigmatization of gay men to continue.²⁶

II. CURRENT REVIEW

In February of 2010, the Gay Men's Health Crisis (GMHC) released a report called "A Drive for Change: Reforming U.S. Blood Donation Policies," which critically examined the MSM lifetime deferral policy in light of current scientific knowledge and societal

²⁰ Workshop on Streamlining the Blood Donor History Questionnaire 241 (2000), available at http://www.fda.gov/downloads/BiologicsBloodVaccines/News Events/WorkshopsMeetingsConferences/TranscriptsMinutes/UCM055357.pdf.

²¹ Bensing, *supra* note 3, at 492.

²² Id.

 $^{^{23}}$ See Bensing, supra note 3, at 492 (stating that one of the most significant changes was "in 1992, when the policy included language recommending a lifetime deferral for MSM.").

²⁴ See generally TRANSCRIPT OF PROCEEDINGS: BLOOD PRODUCTS ADVISORY COMMITTEE 67TH MEETING (2000), *available at*

http://www.fda.gov/ohrms/dockets/ac/cber00.htm#Blood%20Prducts.

²⁵ See generally TRANSCRIPT OF PROCEEDINGS: BLOOD PRODUCTS ADVISORY COMMITTEE 86TH MEETING (2006), *available at*

http://www.fda.gov/ohrms/dockets/ac/06/transcripts/2006-4206t1.pdf.

²⁶ See Naomi G. Goldberg & Gary J. Gates, *Effects of Lifting the Blood Donation Ban on Men Who Have Sex With Men*, 5 PITT. J. ENVTL. PUB. HEALTH L. 49, 57 (2011) (estimating the numbers of MSM that would likely donate: 130,150 if the ban was lifted completely, 53,269 if the ban was amended to a twelve-month deferral, and 42,286 if the ban was amended to a five-year deferral).

changes that show how current blood donation policies "reinforce[] incorrect and outdated information about the spread of HIV that serves to discriminate against and stigmatize gay and bisexual men."²⁷ A week after the report was released, the FDA received a letter from eighteen United States Senators expressing their concern over the current policy and requesting a reexamination of the deferral criteria for the MSM population.²⁸ That same day, the FDA released a statement to the press stating only that the ban "'[was] based on current science and data."²⁹ Senator Kerry, who signed the letter, called the response inadequate and pressed the FDA to "explain their defense of the law that bans gay men in America from donating blood."³⁰

With gay rights organizations, political figureheads, and blood establishments publically calling on the FDA for a change,³¹ HHS released a notice in the Federal Registrar of a meeting of ACBTSA.³² Established in 1997, the Committee has the authority *inter alia* to "advise, assist, consult with, and make policy recommendations to the Secretary and the Assistant Secretary for Health regarding . . . broad public health, ethical and legal issues related to transfusion and transplantation safety."³³ In June 2010, it met to consider whether "the current indefinite deferral for men who have had sex with another man

²⁷ See GAY MEN'S HEALTH CRISIS, A DRIVE FOR CHANGE: REFORMING U.S. BLOOD DONATION POLICIES iii (Sean Cahill, Nathan Schaefer, & John A. Guidry eds., 2010), *available at* http://www.gmhc.org/files/editor/file/a_bb_drivechangereport.pdf.

²⁸ See Letter from Sen. Kerry et al., *supra* note 1; see also Cheryl Wetzstein, Senators Ask FDA to Lift Gay Blood Donor Ban, Wash. Times (Mar. 5, 2010), http://www.washingtontimes.com/news/2010/mar/05/senators-ask-fda-to-lift-gayblood-donor-ban/?page=all.

²⁹ Press Release, Sen. John Kerry, Kerry Again Presses FDA on Blood Donation Ban on Gay Men (Mar. 9, 2010) *available at*

http://www.kerry.senate.gov/press/release/?id=cea319fc-c304-4f56-a484 d79584a06224.

³⁰ *Id*.

³¹ See id. ("The American Red Cross, America's Blood Centers, the AABB [formerly known as the American Association of Blood Banks], the American Medical Association, and many others have all publicly called on the FDA to modify the lifetime deferral policy for MSM, with the blood banks asserting that the current ban is 'medically and scientifically unwarranted.""); see also Wetzstein, supra note 28.

³² See Meeting of the Advisory Committee on Blood Safety and Availability, 75 Fed. Reg. 2,8619, 2,8619 (May 21, 2010).

³³ CHARTER: ADVISORY COMMITTEE ON BLOOD SAFETY AND AVAILABILITY 1 (2012), *available at* http://www.hhs.gov/ash/bloodsafety/advisorycommittee/charter/ charter_acbsa.pdf.

even one time since 1977 [should] be changed at the present time" ³⁴ in light of the "societal factors surrounding these issues as well as the science."³⁵

The meeting spanned two days and consisted of numerous presentations from blood transfusion experts, LGBT organizations, members of Congress, and public commentators.³⁶ Most notable was the joint statement submitted by American Association of Blood Banks, America's Blood Centers, and the American Red Cross reaffirming their 2006 position that the "current lifetime deferral for men who have had sex with other men is medically and scientifically unwarranted . . . [and should be] modified and made comparable with criteria for other groups at increased risk for sexual transmission of transfusion-transmitted infections."37 Additionally, these organizations, which "represent the blood banking and transfusion medicine community," recommended that the current lifetime deferral be amended to a twelve-month deferral.³⁸ Others in support of an amendment to the policy included forty-three members of the United States Congress who signed a letter stating that "[a]s the policy currently stands, a number of potential oversights and medically unjustifiable double standards seem apparent," including allowing donations from women who have had sex with HIV positive males or individuals who have paid prostitutes for sex.³⁹

 $^{^{34}}$ HHS ADVISORY COMM. ON BLOOD SAFETY & AVAILABILITY, supra note 6, at 1.

³⁵ Caption Notes for Advisory Committee on Blood and Tissue Safety, NIH.GOV, http://nih.granicus.com/TranscriptViewer.php?view_id=22&clip_id=45 (last visited May 22, 2013).

³⁶ See generally HHS ADVISORY COMM. ON BLOOD SAFETY & AVAILABILITY, 39TH MEETING MINUTES (2010), *available at*

http://www.hhs.gov/ash/bloodsafety/advisorycommittee/pastmeetings/acbsa2010-june-10-11mtg.pdf.

³⁷AM. ASS'N OF BLOOD BANKS, AM. BLOOD CTRS. & AM. RED CROSS, JOINT STATEMENT BEFORE THE ADVISORY COMMITTEE ON BLOOD SAFETY AND AVAILABILITY: DONOR DEFERRAL FOR MEN WHO HAVE HAD SEX WITH ANOTHER MAN (MSM) 1 (2010), *available at* http://www.hhs.gov/ash/bloodsafety/advisory committee/publiccomment/aabb 061110.pdf.

³⁸ Id.

³⁹ Letter from Sen. John Kerry et al., U.S. Congress, to the Advisory Comm. on Blood Safety & Availability (Jun. 9, 2010), *available at*

http://www.hhs.gov/ash/bloodsafety/advisorycommittee/publiccomment/43_congres smen_061110.PDF.

Despite believing that the current donor deferral policy was suboptimal, ACBTSA recommended that it not be changed.⁴⁰ In response to the committee's concerns, however, the Assistant Secretary for Health, Dr. Howard K. Koh, charged the Blood, Organ, and Tissue Safety Working Group ("Working Group") to develop an action plan to conduct the testing necessary to permit a further review of the policy.⁴¹

A. Working Group Action Plan

The Working Group Action Plan ("Action Plan") consists of four studies and one workshop, all of which are designed to determine if an alternative policy can be created to allow gay men with low-risk behaviors to donate safely.⁴² These studies were allotted twenty-four-to-thirty-six-months for completion.⁴³ According to an update presented on May 16, 2012, many aspects of the Action Plan have been initiated, but not yet completed.⁴⁴ After the first three studies have concluded, the Working Group will conduct a pilot study of alternate criteria created from the information collected that will allow a number of participating gay men to donate blood.⁴⁵ The results of this investigation will help determine whether the policy will be changed in a future ACBTSA meeting.

The first step in the Action Plan is part of the Retrovirus Epidemiology Virus Study II (REDS II) and seeks to determine the preva-

⁴⁰ HHS ADVISORY COMM. ON BLOOD SAFETY & AVAILABILITY, RECOMMENDATIONS, *supra* note 6, at 1.

⁴¹ HEALTH AND HUMAN SERVICES (HHS) ACTIVITIES AND RESPONSE TO MEN WHO HAVE HAD SEX WITH OTHER MEN (MSM) BLOOD DONOR DEFERRAL POLICY QUESTIONS 1 (July 22, 2011), *available at*

http://www.hhs.gov/ash/bloodsafety/advisorycommittee/recommendations/msm-deferral_qa_20110722-final.pdf.

⁴² See id.; see also Video: Blood Products Advisory Committee Day 2, (May 16, 2012), *available at* http://fda.yorkcast.com/webcast/Viewer/?peid=19caf 3c8c1624acdaab205ddde9c48581d (commencing at hour 5:43).

⁴³ HEALTH AND HUMAN SERVICES (HHS) ACTIVITIES AND RESPONSE TO MEN WHO HAVE HAD SEX WITH OTHER MEN (MSM) BLOOD DONOR DEFERRAL POLICY QUESTIONS, *supra* note 41, at 2.

⁴⁴ See Video: Blood Products Blood Products Advisory Committee Day 2, *supra* note 42.

⁴⁵ See HEALTH AND HUMAN SERVICES (HHS) ACTIVITIES AND RESPONSE TO MEN WHO HAVE HAD SEX WITH OTHER MEN (MSM) BLOOD DONOR DEFERRAL POLICY QUESTIONS, *supra* note 41 at 2; *see also* Request for Information (RFI) on Design of a Pilot Operational Study to Assess Alternative Blood Donor Deferral Criteria for Men Who Have Sex with Other Men (MSM), *supra* note 5, at 14,801.

lence of transfusion-transmitted diseases (TTDs) in the nation's blood supply and their association with infected donated blood.⁴⁶ The study aims to determine testing procedures that can be consistently used to test donated blood to reduce the risk of TTDs; specifically, it will identify donor risk factors that contribute to TTDs and how they can be targeted by updated blood screening procedures.⁴⁷

The second step in the Action Plan was a workshop that took place in September 2011.⁴⁸ Hosted by the FDA, it analyzed the causes of Quarantine Release Errors (QREs) that allow potentially unsafe blood to be released into the blood transfer system. QREs are defined as the "inadvertent release of a donated unit of blood (a) before all testing is known to be negative; (b) before other criteria affecting blood safety and quality are determined to have been met; or (c) despite a positive screening test or other finding of unsuitability."⁴⁹ According to the findings disseminated at the workshop, QREs are frequently due to human error.⁵⁰

The third step of the Action Plan is a two-part study that seeks to review the evaluation questionnaire provided to every donor prior to their physical donation. The first part of this study will evaluate the questions specifically.⁵¹ Various factors contribute to a person's understanding of the questions presented in these questionnaires, including "culture, social conditions, and language fluency."⁵² Thus, infected donors may answer questions incorrectly, allowing them to proceed with their donation and potentially contaminate the nation's blood supply. This component of the study seeks to determine how effective these questions actually are in stopping such consequences.⁵³

The most recent of the steps to be initiated is the second part of step three of the Action Plan. As part of the REDS III program, this component of the study seeks to determine the current levels of com-

⁴⁶ Request for Information (RFI) on Design of a Pilot Operational Study to Assess Alternative Blood Donor Deferral Criteria for Men Who Have Sex with Other Men (MSM), *supra* note 5, at 14,803; *see also* Video: Blood Products Blood Products Advisory Committee Day 2, *supra* note 42.

⁴⁷ Request for Information (RFI) on Design of a Pilot Operational Study to Assess Alternative Blood Donor Deferral Criteria for Men Who Have Sex with Other Men (MSM), *supra* note 5, at 14,803.

 $^{^{48}}$ *Id.*

 $^{^{49}}_{50}$ Id. at 14,802.

⁵⁰ *Id*.

⁵¹ *Id.* at 14,803.

⁵² *Id.*

⁵³ Id.

pliance and non-compliance of potential donors in admitting to behaviors that may cause such donors to be subject to the lifetime deferral.⁵⁴ As it relates to the male population, this study aims to determine how effective the deferral policy is in light of the reality that some individuals, especially straight men, continue to donate blood without disclosing their past MSM activity, which would have otherwise made them ineligible to donate.⁵⁵

B. MSM Review: Pilot Study to Determine Alternate Criteria

On March 13, 2012, HHS requested information and public comment as to the creation of a pilot study that will help determine alternate criteria for the MSM population that would allow some members of the population to donate.⁵⁶ Consistent with the recommendations proposed by ACBTSA in June 2010 and the Working Group Action Plan, the study will test what combination of pre-donation and post-donation testing will be adequate to promote safety.⁵⁷

There are several unanswered questions this study seeks to resolve, specifically: 1) the added costs of donor testing due to pre and post-screening policies and increases to quarantine inventories, 2) the added complexity of tracking blood testing, 3) the amount of time needed for a person to return after being deferred in the pre-screening stage and to release a blood donation after post-screening has deemed a blood sample safe, and 3) associated safety concerns.⁵⁸ Once these questions are answered, the MSM deferral policy will once again be reexamined to determine whether it should be amended to allow donations from gay men.⁵⁹

Numerous public comments were received as to the specific procedures implemented in the pilot study.⁶⁰ The American Red Cross

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⁵⁴ Request for Information (RFI) on Design of a Pilot Operational Study to Assess Alternative Blood Donor Deferral Criteria for Men Who Have Sex with Other Men (MSM), supra note 5, at 14,803.

⁵⁵ Id. ⁵⁶ Id. at 14,801.

⁵⁷ Id.

⁵⁸ *Id.* at 14,803–04.

⁵⁹ *Id.* at 14,801.

⁶⁰ See, e.g., Design of a Pilot Study to Assess Alternative Blood Donor Deferral Criteria for Men Who Have Had Sex With Other Men (MSM), REGULATIONS.GOV, http://www.regulations.gov/#!docketBrowser;rpp=25;po=0;dct= PS;D=HHS-OPHS-2012-0003 (last visited May 23, 2013) (showing ten public comments).

and American Association of Blood Banks, for example, both suggested the participants be MSM who have abstained from sex for one or more years.⁶¹ The FDA also received praise from civil rights organizations on the potential for the pilot study to change a policy that is "irrational and threatens the sustainability of the U.S. blood supply."⁶²

III. WHY THE LIFETIME GAY BLOOD BAN SHOULD BE AMENDED

In their future evaluation, public health entities should consider the advancements in blood testing and LGBT rights that make the current lifetime deferral archaic to today's notions of equality and justice. ACBTSA should recommend that the ban be lifted to allow blood donations from-low risk members of the gay male community. As the policy stands today, it not only violates the equal protection rights of the LGBT community but also fails to account for the advancements in HIV/AIDS testing. These advancements have increased the safety of blood products, making a lifetime ban on gay blood donations unnecessary to protect the safety of the nation's blood supply.

A. Policy Considerations in Support of Amending the Ban

Multiple policy considerations support an amendment to the ban that would allow low-risk donors from the gay and bisexual male community to donate blood.

First, there are "five overlapping layers" of safety precautions in place to ensure the safety of blood products distributed in our country.⁶³ Prior to the physical donation, all potential donors are provided educational materials and are asked specific questions as to their per-

⁶¹ See AM. RED CROSS, PILOT OPERATIONAL STUDY TO EVALUATE ALTERNATE BLOOD DONOR ACCEPTANCE CRITERIA FOR MSM 1 (2012), available at http://www.regulations.gov/#!documentDetail;D=HHS-OPHS-2012-0003-0003; AM. Ass'N OF BLOOD BANKS, COMMENT TO DESIGN OF A PILOT STUDY TO ASSESS ALTERNATIVE BLOOD DONOR DEFERRAL CRITERIA FOR MEN WHO HAVE HAD SEX WITH OTHER MEN (MSM) 2 (2012), available at

http://www.regulations.gov/#!documentDetail;D=HHS-OPHS-2012-0003-0002.

⁶² See, e.g., CTR. FOR AM. PROGRESS, COMMENT TO DESIGN OF A PILOT STUDY TO ASSESS ALTERNATIVE BLOOD DONOR DEFERRAL CRITERIA FOR MEN WHO HAVE HAD SEX WITH OTHER MEN (MSM) 2 (2012), available at

http://www.regulations.gov/#!docketBrowser;rpp=25;po=0;dct=PS;D=HHS-OPHS-2012-0003.

⁶³ Request for Information (RFI) on Design of a Pilot Operational Study to Assess Alternative Blood Donor Deferral Criteria for Men Who Have Sex with Other Men (MSM), *supra* note 5, at 14,802.

sonal and sexual health that may lead to a deferral.⁶⁴ All blood establishments, moreover, must keep a current list of those who are ineligible to donate,⁶⁵ and once blood has been donated, it is tested for any diseases and kept in quarantine until such tests are completed.⁶⁶ Finally, investigations are required if there are any reports or suspicions that blood establishments breach the above steps.⁶⁷

Second, there have been significant advancements in HIV testing that would allow many individuals deferred under the current policy to donate blood. In 1985, the FDA licensed the first commercial blood test that detected HIV antibodies in blood via enzyme-linked immunosorbent assay (ELISA).⁶⁸ Although this test was subsequently deemed inadequate due to its high rate of detecting false positives,⁶⁹ the FDA has approved a Western blot blood test kit, which is more precise in detecting HIV antibodies.⁷⁰ In combination, these tests are considered 100% effective.⁷¹ However, the window period for detection is up to several months because of the potentially underdeveloped state of antibodies in the body immediately following infection.⁷²

Significant steps have been made to ensure the availability of the most rapid and effective testing in the United States. In 2002, the FDA approved the first rapid HIV diagnostic test kit, which allows more widespread use of HIV testing.⁷³ Routine use of this nucleic acid testing, has closed the window period between infection and the detection of antibodies to approximately four-to-seven days.⁷⁴

Third, the deferral should be amended owing to the continued need for blood in the United States. According to the American Red Cross, more than 44,000 blood donations are needed every day, which

⁶⁴ Id.

⁶⁵ *Id*.

 $^{^{66}}$ *Id.*

⁶⁷ Id.

⁶⁸ A Timeline of AIDS, 1985, AIDS.GOV, http://aids.gov/hiv-aids-basics/hiv-aids-101/aids-timeline/ (last visited May 15, 2013).

⁶⁹ Bensing, *supra* note 3, at 493.

⁷⁰ Id.

 $^{^{71}}$ *Id*.

⁷² *Id.*

⁷³ A Timeline of AIDS, 2002, AIDS.GOV, http://aids.gov/hiv-aids-basics/hiv-aids-101/aids-timeline/ (last visited May 15, 2013).

⁷⁴ *Blood Testing*, AM. RED CROSS, http://www.redcrossblood.org/learn-aboutblood/what-happens-donated-blood/blood-testing (last visited May 23, 2013).

translates to over 16,060,000 blood donations needed every year.⁷⁵ However, only 16 million blood donations were received in 2006.⁷⁶ One account for this shortage is that only 37% of the U.S. population is eligible to donate and, out of that number, only 10% actually do.⁷⁷ Amending the deferral would allow more donations from willing and healthy citizens.

B. Unconstitutionality of the Gay Blood Ban

Fourth, the MSM lifetime ban should be amended because it runs afoul of LGBT equal protection jurisprudence

1. History of the Equal Protection Clause

Section One of the Fourteenth Amendment to the United States Constitution states that no state may "deprive any person of life, liberty, or property, without due process of law; nor deny to any person within its jurisdiction the equal protection of the laws."⁷⁸ The amendment was enacted in the aftermath of the Civil War to protect the rights of the newly freed slaves. The equality it affords has led to the abolishment of separate but equal policies in our schools⁷⁹ and provided protection to other minority groups, including the LGBT community.⁸⁰

The United States Supreme Court has established several tests to determine whether a state has created a law that violates this provision, known as the three tiers of scrutiny. The default standard is rational basis review, which requires a court to determine whether the law in question protects a legitimate government purpose and proposes means that are rationally in furtherance of that purpose.⁸¹ This standard of review is important for the purposes of this Comment because the LGBT community is not seen as a protected class, and the right to

⁷⁵ Blood Facts and Statistics, AM. RED CROSS,

http://www.redcrossblood.org/learn-about-blood/blood-facts-and-statistics (last visited May 15, 2013). ⁷⁶ *Id*.

⁷⁷ 56 Facts About Blood, AM. BLOOD CTRS.,

http://www.americasblood.org/go.cfm?do=Page.View&pid=12 (last visited May 15, 2013). ⁷⁸ U.S. CONST. amend. XIV, § 1.

⁷⁹ See Brown v. Bd. of Educ. of Topeka, Shawnee Cnty., Kan., 347 U.S. 483, 495 (1954).

⁸⁰ See Perry v. Brown, 671 F.3d 1052, 1096 (9th Cir. 2012), cert. granted, 133 S. Ct. 786 (2012).

⁸¹ See U.S. Dep't of Agric. v. Moreno, 413 U.S. 528, 533 (1973).

donate blood is not a fundamental right inherent to our citizenship. Thus:

[The] Fourteenth Amendment's promise that no person shall be denied the equal protection of the laws must coexist with the practical necessity that most legislation classifies for one purpose or another, with resulting disadvantage to various groups or persons. . . [I]f a law neither burdens a fundamental right nor targets a suspect class, we will uphold the legislative classification so long as it bears a rational relation to some legitimate end.⁸²

While almost any purpose not inherently discriminatory may be construed as legitimate, the Court has implemented important limitations on such findings.

2. Limitations on Permissible Government Purposes

In U.S. Department of Agriculture v. Moreno, the Court struck down a law that prohibited the distribution of food stamps to households inhabited by unrelated members.⁸³ It determined that the true purpose of the law was not legitimate because it sought to harm a politically unpopular group.⁸⁴ The Court subsequently reinforced this notion in *City of Cleburne v. Cleburne Living Ctr.*, striking down an ordinance that prohibited the construction of a mental disability home.⁸⁵ Justice White, writing for the majority, enumerated that irrational prejudice against mentally disabled groups is not a legitimate purpose for the state to create a law.⁸⁶

3. Extending These Principles to the LGBT Community

⁸² Romer v. Evans, 517 U.S. 620, 631 (1996).

⁸³ Moreno, 413 U.S. at 538.

⁸⁴ *Id.* at 534.

⁸⁵ 473 U.S. 432, 450 (1985).

⁸⁶ *Id.* at 446 ("The State may not rely on a classification whose relationship to an asserted goal is so attenuated as to render the distinction arbitrary or irrational."). Justice White further noted, "[S]ome objectives such as a bare . . . desire to harm a politically unpopular group . . . are not legitimate state interests." *Id.* at 446–47 (internal quotation marks and citations omitted).

In *Romer v. Evans*, the State of Colorado amended its constitution to prohibit homosexuality from being a protected class against discrimination.⁸⁷ Prior to the passing of Amendment Two, Colorado state and municipal public accommodation laws had included sexual orientation among a list of traits that could not be the basis for discrimination. Amendment Two invalidated the protections afforded this targeted class and prohibited future policies that sought to protect sexual minorities.⁸⁸

Writing for the majority, Justice Kennedy found that the amendment "impose[d] a special disability" upon the homosexual community in which they would not be protected from discrimination in a limitless number of transactions that "others enjoy or may seek without constraint."⁸⁹ Thus, the Court found that Amendment Two failed rational basis review because the "disadvantage imposed [was] born of animosity toward the class of persons affected: '[I]f the constitutional conception of equal protection of the laws means anything, it must at the very least mean that a bare . . . desire to harm a politically unpopular group cannot constitute a *legitimate* governmental interest.""⁹⁰ In so ruling, the Court upheld the long standing ideal that the "Constitution 'neither knows nor tolerates classes among citizens.""⁹¹

4. The Connection Between Equal Protection and Due Process

Although it may be argued that due process considerations are not within the realm of equal protection jurisprudence, the Supreme Court has found that the two may be linked to such a degree that a due process consideration may in fact enhance or hinder equal protection rights of a group. Justice Kennedy, writing for the Court *in Lawrence v. Texas*, found that "[i]f protected conduct is made criminal and the law which does so remains unexamined for its [due process] validity,

⁸⁷ 517 U.S. 620, 624 ("Amendment 2 repeals these ordinances to the extent they prohibit discrimination on the basis of homosexual, lesbian or bisexual orientation, conduct, practices or relationships.") (internal quotation marks omitted).

⁸⁸ *Id.* at 629.

⁸⁹ *Id.* at 631.

 $^{^{90}}$ Id. at 634 (quoting U.S. Dep't of Agric. v. Moreno, 413 U.S. 528, 534 (1973)) (emphasis in original).

⁹¹ *Id.* at 623 (quoting Plessy v. Ferguson, 163 U.S. 537, 559 (1896) (Harlan, J., dissenting).

its stigma might remain even if it were not enforceable as drawn for equal protection reasons."⁹²

In *Lawrence*, the Court found a Texas law criminalizing consensual sodomy between persons of the same sex unconstitutional under the Due Process Clause, overturning its decision in *Bowers v*. *Hardwick*.⁹³ Drawing from Justice Stevens's dissenting opinion in *Bowers*, Justice Kennedy stated:

> Our prior cases make two propositions abundantly clear. First, the fact that governing majority in a State has traditionally viewed a particular practice as immoral is not a sufficient reason for upholding a law prohibiting the practice... Second, individual decisions ... concerning the intimacies of their physical relationship ... are a form of liberty protected by the Due Process Clause of the Fourteenth Amendment.⁹⁴

The Court held that the statute furthered no legitimate state interest that allowed it to survive constitutional scrutiny.

5. Applying LGBT Case Law to the Current Ban on Gay Blood

The lifetime deferral is unconstitutional because it illegitimately discriminates against members of a politically unpopular group and would therefore fail to survive the lowest standard of rational basis review if challenged in the courts. As mentioned above, a law survives rational basis review if it protects a legitimate government purpose and proposes means that are rationally in furtherance of that purpose. Although the gay and bisexual male community is still one of the leading groups affected by the HIV/AIDS epidemic, the ban irrationally restricts healthy donors from donating blood due to their sexual orientation and fails to restrict others outside of sexual minorities that may be at high risk for spreading the disease.

⁹² 539 U.S. 558, 575 (2003).

⁹³ Id. at 578 ("Bowers was not correct when it was decided, and it is not correct today."). See 478 U.S. 186 (1986).

⁹⁴ *Lawrence*, 539 U.S. at 577–78 (quoting Bowers v. Hardwick, 478 U.S. 186, 216 (1986)).

a. The MSM Lifetime Deferral Fails to Protect a Legitimate **Governmental Interest**

When first enacted, the MSM lifetime deferral policy aimed to stem an unknown disease that had only been observed in the gay male community.95 At the time, the government had a legitimate interest in protecting the nation's blood supply by prohibiting any man who had had sex with another man since 1977, when AIDS was first documented, from giving blood donations.⁹⁶ Although the MSM community is still one of the leading groups affected by the HIV epidemic,⁹⁷ leading blood bank establishments have found that a lifetime deferral on gay blood is no longer necessary to protect the nation's blood supply.⁹⁸

Our increased understanding of the disease since 1977 has challenged the wrongful social stigma that gay men are inherently connected to HIV/AIDS.⁹⁹ The policy as it stands fails to account for the high prevalence of HIV among specific racial groups and heterosexuals, particularly heterosexual women.¹⁰⁰ As the policy is "predicated on assumptions about HIV/AIDS that are. . . based on mere stigma," it "provides false security to high-risk heterosexual donors."¹⁰¹ Donor deferral criteria should not focus on a person's sexual orientation but should rather focus on the sexual activity that can be risky and engaged in by any man, gay or straight, or woman. Ultimately, "[a] person is at risk of being infected with HIV . . . whether or not that person is gay, and whether or not that person is a man."¹⁰²

⁹⁵ See supra Part I.

⁹⁶ See Casey, supra note 16, at 555 ("By the end of 1983, most gay community groups accepted the enacted screening policies; [t]heir compliance stemmed in part from an understanding that deferral was a necessary, albeit temporary, precaution until a reliable test could be found.").

⁹⁷ HIV Among Gay and Bisexual Men, CDC.GOV (May 18, 2012), http://www.cdc.gov/hiv/topics/msm/index.htm.

⁹⁸ See supra Part II; see also Goldberg & Gates, supra note 26, at 52.

⁹⁹ See Bensing, supra note 3, at 499 ("The assumption inherent within the MSM policy is that all gay men are risky donors, enshrining the stigma of gay men in official government agency policy.").

¹⁰⁰ See Ctrs. for Disease Control & Prevention, CDC Fact Sheet: HIV AND AIDS AMONG GAY AND BISEXUAL MEN, 1 (2012), available at http://www.cdc.gov/nchhstp/newsroom/docs/2012/CDC-MSM-0612-508.pdf.

¹⁰¹ See Bensing, supra note 3, at 487-88; See also Michael C. Belli, The Constitutionality of the "Men Who Have Sex With Men" Donor Exclusion Policy, 4. J.L. SOC'Y 315, 364 (2003) ("To exclude gay men from the pool of eligible blood donors is not only discriminatory, but also creates a false sense of security amongst heterosexuals."). ¹⁰² See Bensing, supra note 3, at 499.

Amending the policy is the only way to ensure that all people, regardless of their sexual orientation, are treated equally in determining blood donor eligibility.¹⁰³

b. Preventing the Entire Gay Male Community from Donating Blood is Not a Means Rationally Related to Promote Safety of the Nation's Blood Supply.

Even if one finds the purpose of the ban legitimate, the ban would still fail the rational basis review standard as it fails to rationally further the government purpose of protecting the nation's blood supply from infection. As stated in *Moreno*, the law in place must be rationally related to further the purpose associated with it.¹⁰⁴ The ban fails this standard in two respects.

First, the MSM deferral policy is over-inclusive in that it prohibits potentially healthy donors from donating much needed blood, hindering a related governmental interest of stopping the blood shortage to save lives. As mentioned above, the American Red Cross estimates that thousands of needed blood donations fail to be filled each year, leaving many citizens without life saving blood.¹⁰⁵ Amending the life-time deferral to allow some within the gay population who are healthy and willing to donate will help bridge the gap between the needed number of blood donations and the numbers blood banks actually have thereby raising the amount of potential donors from a mere 37% of the population.¹⁰⁶

Second, the ban's narrow focus on the gay and bisexual male community makes it under-inclusive. The deferral as it currently stands allows many women and straight men who may be at a similar if not higher risk for HIV/AIDS due to their sexual behavior to donate potentially infected blood. Furthermore, the ban heavily depends upon self-deferrals in which the men themselves answer questions truthfully about their past sexual behavior at the pre-donation stage, knowing the answers to which will cause them to be deferred.

C. Cultural and Societal Context-National and

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¹⁰³ See id. at 501 (stating that "[t]he most cautious, risk-averse option would be to ban blood from all high risk groups, including heterosexual donors who engage in unprotected, multi-partner, sex.").

¹⁰⁴ See U.S. Dep't of Agric. v. Moreno, 413 U.S. 528, 533 (1973).

¹⁰⁵ See supra part III.A.

¹⁰⁶ See 56 Facts About Blood, supra note 77.

International Considerations

Newfound political and moral support for the LGBT community, both nationally and internationally, further supports altering the deferral policy.

1. National Considerations

The trend in the current case law regarding same-sex marriage rights shows increased support for same-sex marriage and equal marriage rights for the LGBT community. In February 2012, the United States Court of Appeals for the Ninth Circuit struck down a controversial law in California that prohibited marriage between members of the same sex. In a two-to-one decision, the court found that the law violated the Equal Protection Clause of the Fourteenth Amendment because it "serves no purpose, and has no effect, other than to lessen the status and human dignity of gay men and lesbians in California."¹⁰⁷ On October 18 of the same year, the United States Court of Appeals for the Second Circuit struck down the Defense of Marriage Act, which prohibits federal recognition of same-sex marriage, thereby limiting tax benefits to heterosexual married couples.¹⁰⁸ Both cases have since been granted certiorari by the Court on December 7, 2012, which is seen as a "milestone day for equal justice under the law and for millions of loving couples who want to make a lifelong commitment through marriage."¹⁰⁹

The political climate would also support an amended policy regarding limitations on gay blood donations. Numerous states have enacted same-sex marriage statutes, several of which passed this past fall. These states include Connecticut, Iowa, Maine, *Maryland*, Massachusetts, New Hampshire, New York, Vermont, Washington and the District of Columbia.¹¹⁰ Additionally, several states allow civil unions

¹⁰⁷ Perry v. Brown, 671 F.3d 1052, 1063 (9th Cir. 2012), *cert. granted*, 133 S. Ct. 786 (2012); *see also* Adam Nagourney, *California Ban on Gay Unions is Struck Down*, N.Y. TIMES, Feb. 8, 2012, at A1.

¹⁰⁸ See Windsor v. United States, 699 F.3d 169, 188 (2012), cert. granted, 133 S. Ct. 786 (2012); see also John Schwartz, U.S. Marriage Act is Unfair to Gays, Court Panel Says, N.Y. TIMES, Oct. 19, 2012, at A1.

¹⁰⁹ RICHARD WOLF, GAY RIGHTS PROPONENTS, OPPONENTS HERALD COURT ACTION, GANNETT NEWS SERV., DEC. 7, 2012, AT ARC.

¹¹⁰ See Defining Marriage: Defense of Marriage Acts and Same-Sex Marriage Laws, NCLS.ORG (Feb. 2013), http://www.ncsl.org/issues-research/human-services/same-sex-marriage-overview.aspx.

and provide state-level spousal rights to same-sex couples, including Delaware, Hawaii, Illinois, New Jersey, and Rhode Island.¹¹¹

Capitol Hill has also increased its support for gay rights. In 2011, President Obama overturned the long standing prohibition of outwardly gay members in the military known as Don't Ask Don't Tell, stating, "As of Sept. 20, service members will no longer be forced to hide who they are in order to serve our country."¹¹² The same year he also "direct[ed] all agencies engaged abroad to ensure that U.S. diplomacy and foreign assistance promote and protect the human rights of LGBT persons."¹¹³ Members of Congress have also publically urged a change in the MSM policy itself. In 2010, a letter was sent to ACBTSA prior to their meeting in June signed by Senator John F. Kerry, Congressman Mike Quigley, and other members of Congress urging efforts to modify the ban.¹¹⁴ Additionally, these same members of Congress are now voicing support of the pilot study that will use other criteria to allow gay men to donate blood that may lead to a lift of the life-time deferral.¹¹⁵

2. International Considerations

Gay rights are not only gaining increased support nationally. Many other countries have amended similar gay blood bans. In countries such as South Africa, Argentina, Australia, Hungary, and New Zealand government agencies have imposed time limits in which MSM's have to abstain from sexual activity for a certain time prior to

¹¹¹ *Id*.

¹¹² Elisabeth Bumiller, *A Final Phase for Ending 'Don't Ask, Don't Tell,* ' N.Y. TIMES, July 22, 2011, at A13.

¹¹³ Memorandum from President Barack Obama to the Heads of Exec. Dep'ts & Agencies (Dec. 6, 2011), *available at* http://www.whitehouse.gov/the-press-office/2011/12/06/presidential-memorandum-international-initiatives-advance-human-rights-l.

¹¹⁴ Letter from Congressman Brad Sherman to Dr. Arthur W. Bracey, Chair, Advisory Comm. on Blood & Tissue Safety & Availability (June 10, 2010), *available at* http://www.hhs.gov/ash/bloodsafety/advisorycommittee/publiccomment/ congressman_sherman_061110.pdf.

¹¹⁵ See supra Part II.

donating.¹¹⁶ Other countries, such as Russia, have completely lifted their equivalent ban.¹¹⁷

Most notably, the United Kingdom has become the first European country to lift its MSM blood ban, allowing men who have not had sex within the past twelve months to donate blood.¹¹⁸ Like the United States, most Europe countries have had a lifetime deferral on MSM donations since the 1980s.¹¹⁹ In 2011, however, the Advisory Committee on the Safety of Blood, Tissues and Organs (SABTO) recommended that health ministers in the United Kingdom change their policies after conducting an evidentiary review, which included data from studies concerning the "level of risk for infection transmitted in the donated blood, improvements in the testing of donated blood, and attitudes toward compliance with donor selection criteria."¹²⁰ SABTO concluded that no evidence supported the permanent exclusion of bisexual or gay men to donate blood" and that "the safety of the blood supply would not be affected by the change."¹²¹

CONCLUSION

As it stands, the MSM lifetime deferral policy permits a false stigma to persist by unconstitutionally targeting the LGBT community. The MSM lifetime deferral policy should be amended to correspond not only to advancements in testing and general knowledge as to what behaviors cause HIV but also to national and international movements to promote LGBT rights. This is a time for change. The time is right to change the laws based on outdated information and stereotypes and create a world where everyone, despite vast differences, are truly treated as equal.

¹¹⁶ *Revisit Blood Donor Ban for Gay Men: MDs*, CBC NEWS (May 25, 2010, 10:08 PM), http://www.cbc.ca/news/health/story/2010/05/25/blood-donation-ban-homosexual.html.

¹¹⁷ Russia Health Ministry Ends Ban on Gay Blood, PINK NEWS (May 27, 2008, 1:56 AM), http://www.pinknews.co.uk/2008/05/23/russian-health-ministry-ends-ban-on-gay-blood/.

¹¹⁸ UK Lifts Lifetime Ban on Gay Men's Blood Donations, INT'L BUS. TIMES NEWS (Sep. 9, 2011, 5:44 AM), http://www.ibtimes.com/uk-lifts-lifetime-ban-gay-mens-blood-donations-311236.

¹¹⁹ 1980 Gay Blood Ban Lifted in England, Scotland, and Wales, Digital J. (Sept. 9, 2011), http://digitaljournal.com/article/311304.

¹²⁰ Id.

¹²¹ Id.