DISCRIMINATORY POLICY: DENYING GAY MEN THE OPPORTUNITY TO DONATE BLOOD

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I. INTRODUCTION

It is imperative that the appropriate procedures are in place to control the spread of HIV/AIDS through blood transfusions. However, the twenty-five year old policy that denies men who have sex with men (MSMs) the opportunity to donate blood is a discriminatory policy that chooses to exclude someone based upon his sexual orientation and status as an MSM rather than risky encounters in which he has participated.

In the absence of a test that could accurately detect the HIV antibodies, it was understandable that the US Food and Drug Administration (FDA) implemented a permanent bar on MSMs because the disease was once most prevalent in their community. The onset of the policy brought awareness to their community, and they began practicing safe sex, thereby leading to the decline of AIDS within the community. Also, tests were developed to uncover the HIV antibodies, which allowed scientists to discover that sexual orientation had nothing to do with the disease, but rather that the disease was a blood-borne disease, or transferred through blood contact of one individual with the blood of another individual. At this point, though MSMs were the highest category of individuals

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being diagnosed with AIDS at the time, the policy should have been revoked after discovering that the disease was transferred through blood or other bodily fluids and not strictly sexual orientationrelated. Not revoking the policy goes against the original intent of the policy, which was to protect the blood supply from being tainted with HIV, and it also denies equal protection to MSMs.

This paper is divided into eleven sections. Part II explains the blood donation process and what steps are needed to actually succeed in donating blood in the United States. Part III talks about the eligibility requirements for donating blood and focuses on the factors that can exclude a person from donating blood. Part IV addresses the advertisements and societal perceptions towards donating blood. Part V discusses the regulatory procedures in place for blood banks. Part VI itemizes the tests used to detect viruses in the blood and their different benefits. Part VII discusses why MSMs are considered high-risk donors. Part VIII argues that MSMs should not be considered high-risk donors based upon the statistical breakdown that HIV/AIDS rates have actually been declining in their community. Part IX argues that by denying MSMs the opportunity to donate blood, they are being categorized as promiscuous and stigmatized as a disease-ridden community. It further argues that since all blood donations are tested, it is arbitrary to deny MSMs the right to donate blood. Part X discusses the different proposals that have been brought to the FDA to change the MSM exclusionary policy. Part XI concludes this article.

II. THE BLOOD DONATION PROCESS

When donating, there are four steps that a person must complete to have their blood considered for a blood donation.¹ The complete donation process takes about an hour.² At any time, an individual has the right to withdraw from the donation process.³ This withdrawal is

¹ See Donation Process, AMERICAN RED CROSS, http://www.redcrossblood.org/donatingblood/donation-process (last visited Sept. 30, 2010).

² Id.

³ Michael Christian Belli, The Constitutionality of the "Men Who Have Sex with Men" Blood

referred to as self-deferral.⁴ However, if at any time, one of the steps is not complete, the person will not be able to go through with the blood donation process.⁵

Education is the first step.⁶ In this step, the potential donor will sign-in with the staff or volunteer and go over basic eligibility requirements.⁷ Before being allowed to donate, potential donors "must read certain educational materials that 'contain information on the risks of infectious diseases transmitted by blood transfusion, including the signs and symptoms of AIDS.'"⁸ The individual will then be asked to "acknowledge in writing that they have read and understood these materials, has been given the opportunity to ask questions, and have provided accurate information."⁹ At that time, the potential donor "will be asked to show a donor card, a driver's license, or other form[s] of I.D. (identification)."¹⁰

After providing the blood bank volunteer or staff member with your identification, the potential donor then proceeds to step two: Health History and Mini-Physical.¹¹ In order to obtain the health history of the individual, a staff member will have the potential donor fill out a Health History Form [HH Form].¹² The health historian will conduct a private and confidential interview with the potential donor.¹³ The HH Form questions are designed to protect the health of the donor and the recipient.¹⁴ There are two main objectives that the HH Form seeks to find out: (1) if a potential donor has been exposed to any diseases that could taint the blood supply and (2) if a

⁶ See Belli, supra note 3, at 320.

- ⁸ See Belli, supra note 3, at 320.
- 9 Id. (internal quotations omitted).
- 10 Donation Process, supra note 1.
- 11 Id.
- 12 See Belli, supra note 3, at 321.
- 13 Id.
- 14 Id.

Donor Exclusion Policy, 4 J.L. SOC'Y 315, 320 (2003).

⁴ Id. at 320.

⁵ See Donation Process, supra note 1.

⁷ Donation Process, supra note 1.

donation would cause risk to the potential donor's health.¹⁵ "If a prospective donor responds positively to [either] of these questions, he or she will be deferred."¹⁶ Furthermore, the health history is also used to identify prospective donors who have been exposed to, or who may have diseases such as human immunodeficiency virus ('HIV'), hepatitis, or malaria."¹⁷ At this step, MSMs, if answering truthfully about sexual encounters with other men, are denied the opportunity to donate blood.¹⁸ The health historian's discretion in this process is extensive.¹⁹

After conducting the health history interview, the potential donor will then be subjected to a mini-physical.²⁰ This examination is used to determine if the donor has any pressing condition that would cause a life threatening issue for him or her while donating blood.²¹ During the mini-physical, the potential donor's "temperature, pulse, blood pressure, and hemoglobin level" are tested by drawing a current sample of blood.²² Any abnormalities found during this part of the examination may cause a patient to be deferred from donating blood.²³

If the patient successfully completes step two, then they are allowed to donate blood.²⁴ The actual blood donation process takes between eight to ten minutes.²⁵ After approximately a pint of blood is collected, the process is complete.²⁶ The collected blood is then sent to

19 Id. at 321.

¹⁵ Id.

¹⁶ Id. (internal quotations omitted).

¹⁷ Id. (internal footnotes and quotations omitted).

¹⁸ See Belli, supra note 3, at 322-24.

²⁰ Id.

²¹ Id. at 322.

²² Donation Process, supra note 1.

²³ See Belli, supra note 3, at 322 (citing Suitability of Donor, 21 C.F.R. § 640.63(d) (2001)).

²⁴ Id.

²⁵ Donation Process, supra note 1.

²⁶ Id.

the laboratory for "testing and component preparation."²⁷

After a donor has given blood, they are encouraged to enjoy refreshments provided at the site.²⁸ The donors can then leave the site after waiting ten to fifteen minutes.²⁹

III. WHO CAN ACTUALLY DONATE?

The FDA sets the medical guidelines for selecting blood donors.³⁰ A potential donor must meet the FDA's preliminary requirements in order to donate blood.³¹ In general, a blood donor must be "healthy, at least 17 years old in most states (16 years old in some states with parental consent), and weigh at least 110 pounds."³² In addition to these preliminary requirements, potential donors must acknowledge that they do not fall into "deferral categories."³³

These deferral categories are: "(i) people who engage in high risk behavior; (ii) people who have been incarcerated; (iii) people with signs and symptoms of HIV; (iv) people who were born, lived in or visited Pattern II countries; and (v) rape victims."³⁴ The high-risk behavior category is a category that includes, but is not limited to, the following: "past or present users of intravenous (IV) drugs; [a]ny man who has had sexual contact with another man [MSM] since 1977, even once; . . . [and] [m]en and women who have had sex for money

²⁷ See Belli, supra note 3, at 322 (citing Suitability of Donor, 21 C.F.R. § 640.63(d) (2001)).

²⁸ Donation Process, supra note 1.

²⁹ Id.

³⁰ Belli, *supra* note 3, at 322 (citing New York Blood Center Medical Guidelines, The Most Common Reasons for Not Being Able to Give Blood (Feb. 1996)).

³¹ Id.

³² Eligibility Requirements, AMERICAN RED CROSS, http://www.redcrossblood.org/donatingblood/eligibility-requirements (last visited Sept. 30, 2010).

³³ Belli, *supra* note 3, at 322. The requirements define healthy to mean "that you feel well and can perform normal activities." *ld*.

³⁴ Id. at 323 (citing Kathryn W. Pipelow, *AIDS, Blood Banks and the Courts: The Legal Response to Transfusion-Acquired Disease*, 38 S.D. L. REV. 609, 616 n.32; N.Y. BLOOD CTR., REGISTRATION/HEALTH HISTORY FORM (2000)).

or drugs since 1977."³⁵ The deferral categories are addressed by the questions in the HH Form.³⁶ A person should self-defer if they associate with any of these categories.³⁷

A. Temporary Versus Permanent Deferral

Temporary deferral is when a person can wait for a certain stipulated period of time and then donate blood after this time period elapses.³⁸ The duration for temporary deferral depends on the condition that causes the person to be in the deferral category.³⁹

Permanent deferral is when a person is permanently barred from donating blood based on a condition that he or she has or a behavior that he or she has engaged in; the blood center places the person on a national 'deferral' registry and never allows that person to donate blood.⁴⁰ Three main categories explain why a person is permanently deferred from donating blood.⁴¹ The first category is when someone has an experience or condition that puts the recipient or donor at a health risk as a result of blood donation.⁴² The second category is defined by the donor's behaviors that have put him or her at an increased risk for HIV or other serious diseases.⁴³ And the last

³⁵ Belli, supra note 3, at 323–24 (citing N.Y. BLOOD CTR, REGISTRATION/HEALTH HISTORY FORM (2000)). This article lists many of the categories that temporarily defer or permanently bar a person from donating blood. *Id.* at 323–27.

³⁶ See FULL-LENGTH DONOR HISTORY QUESTIONNAIRE, AM. ASS'N OF BLOOD BANKS, (rev. 1.3 May 2008), available at http://www.aabb.org/resources/donation/questionnaires/Documents/dhq/v1-3/Full-LengthDonorHistoryQuestionnairev1.3.pdf.

³⁷ See Belli, supra note 3, at 322-23.

³⁸ See Id., at 325, 327.

³⁹ Id. at 325-27.

⁴⁰ See Id. at 327-28.

⁴¹ Id. at 327. Charlene Galarneau, Blood Donation, Deferral, and Discrimination: FDA Donor Deferral Policy for Men Who Have Sex With Men, 10: 2 AM. J. BIOETHICS, Feb. 2010, at 29, 30,available at http://www.wellesley.edu/WomenSt/Galarneau,BloodDonation,AJOB2010. pdf.

⁴² Belli, *supra* note 3, at 327; *see also* Galarneau, *supra* note 41, at 30.

⁴³ Belli, *supra* note 3, at 327–28 (citing N.Y. BLOOD CTR. MEDICAL GUIDELINES, THE MOST COMMON REASONS FOR NOT BEING ABLE TO GIVE BLOOD (1996); *see also* Galarneau, *supra* note 41, at 30.

category is when a person has spent time in a particular geographic area that has a high incidence of HIV or other serious diseases.⁴⁴

B. Blood Drive Questionnaire

Many HH Forms have about fifty questions⁴⁵ and do not take very long to fill out. The preliminary questions ask about potential donors' perception of health, whether they have recently ingested medications on the medicine deferral list, and if they have donated blood recently.46 The next group of questions covers behavioral exclusions that would elevate a donor's risk for HIV or other diseases transmitted through the blood stream.⁴⁷ For example, these questions include whether a potential donor has ever had "sexual contact" with a person with HIV, ever been paid for sex or had sex with someone who has paid for sex, or ever had a tattoo.⁴⁸ The last set of questions deals with behaviors and experiences that temporarily or permanently bar blood donation.⁴⁹ The most relevant question to this article asks: "From 1977 to present, have you [male donors] had sexual contact with another male, even once?"50 It is the most prevalent because it is the only question that asks a person to disclose their sexual orientation. It is also notable that this exclusionary question does not concretely define sexual conduct.⁵¹

By not defining sexual conduct, two problems immediately arise. The first problem is that the prospective donor must define the term

46 Id.

47 Id.

48 Id.

49 Id.

⁴⁴ See Belli, supra note 3, at 328 (citing N.Y. BLOOD CTR MEDICAL GUIDELINES, THE MOST COMMON REASONS FOR NOT BEING ABLE TO GIVE BLOOD (1996); see also Galarneau, supra note 41, at 30.

⁴⁵ See, e.g., AM. ASS'N OF BLOOD BANKS, supra note 36.

⁵⁰ AM. ASS'N OF BLOOD BANKS, *supra* note 36.

⁵¹ See John G. Culhane, Bad Science, Worse Policy: The Exclusion of Gay Males from Donor Pools, 24 ST. LOUIS U. PUB. L. REV. 129, 136 (2005). Adrian Lomaga, Are Men Who Have Sex with Men Safe Blood Donors?, 12 APPEAL REV. CURRENT L. & L. REFORM 73, 83 (2007).

himself.⁵² By not defining the term, gay men could assume that this question is only focused on the "riskiest behavior: unprotected . . . anal intercourse."⁵³ The second problem arises because the undefined sex term "furthers the stereotypical image of gay men as dangerous just because of their 'gayness,' as opposed to any specifically highrisk behavior."⁵⁴ Though the term is ambiguous and undefined, "a man who answers yes is automatically barred from donating blood."⁵⁵ Celso Bianco, former executive vice president of America's Blood Centers, said that the question was counterproductive because "the question focuses attention on events that occurred more than twenty years ago instead of events that occurred within the currently known window period of days or weeks."⁵⁶ Another person commented that this question "tends to screen donors on the basis of sexual orientation rather than on the basis of relative risk."⁵⁷

C. Why the Exclusionary Policy on MSMs?

The justification for permanently excluding MSMs from the donor pool developed with the onset of AIDS in the United States, coupled with the lack of scientific knowledge about the incurable, thought-to-be sexually transmitted disease.⁵⁸ This policy is called the

⁵² Culhane, *supra* note 51, at 136.

⁵³ Id.

⁵⁴ Id. at 137.

⁵⁵ Equal Rights Panel Can't Fine Plasma Bank for Rejecting Gay Donor, AIDS POLICY & LAW, June 23, 2000, at 1; See Blood Donor Requirements, BLOODBOOK.COM, http://www.bloodbook.com/donr-requir.html (last visited Sept. 16, 2010).

⁵⁶ BOB ROEHR, THE GIFT OF LIFE: GAY MEN AND U.S. BLOOD DONATION POLICY (2000), available at http://www.libertyeducationforum.org/downloads/1h_whtpa_pbl00.pdf.

⁵⁷ Culhane, supra note 51, at 137 (quoting a letter from Jonathan Givner, Staff Attorney, Lambda Legal Defense and Education Fund, to Jill Warner, Regulatory Counsel to the Director, Center for Biologics Evaluation and Research (Dec. 22, 2003)).

⁵⁸ See A DRIVE FOR CHANGE: REFORMING U.S. BLOOD DONATION POLICIES, GAY MEN'S HEALTH CRISIS, http://www.gmhc.org/files/editor/file/a_blood_ban_report2010.pdf (last visited Sept. 29, 2010). A list of the permanently deferred categories is available at http://www.mdanderson.org/how-you-can-help/donate-blood/who-candonate/index.html.

"gay ban on blood donation."59

The gay blood ban differs from other permanent deferral policies in two distinct ways. First, it makes a man's status of identifying himself as a homosexual or bisexual the focal point of what puts him at risk of infection.⁶⁰ Second, the same standard does not apply to heterosexuals, whose similar risky sexual behavior only temporarily defers them as blood donors for up to twelve months.⁶¹ Thus, the gay ban on blood donation makes it impossible for gay men to ever donate blood, even though most are not infected with HIV.⁶² When Adrienne Smith was testifying on behalf of the Gay and Lesbian Medical Association, she said that "[t]his maxim exposes the central flaw in the current donor deferral policy which tolerates a wide range of risks associated with heterosexual sex while imposing a zero tolerance attitude towards MSMs [men having sex with men], regardless of the risk associated with individual behavior."⁶³

IV. WHY DONATE?

Winston Churchill once said, "We make a living by what we get, but we make a life by what we give."⁶⁴ For example, donating blood can help save the lives of accident victims and surgical patients.⁶⁵ Like many other American children, I was always taught that donating blood was a way of giving life to another person. My parents exemplified this belief, especially my father because his blood type is rare and thus in demand. Both of my parents became lifetime blood donors because of their consistent blood donations

According to the American Red Cross, there are eight main

⁵⁹ ROEHR, supra note 56.

⁶⁰ Id.

⁶¹ Id.

⁶² Equal Rights Panel Can't Fine Plasma Bank for Rejecting Gay Donor, supra note 55.

⁶³ ROEHR, *supra* note 56, at 4.

⁶⁴ Blood Tissue and Organ Donation Quotes, Sayings for Blood Drives and Organ Donors, THE QUOTE GARDEN, http://www.quotegarden.com/blood-organ-donation.html (last visited Sept. 16, 2010).

⁶⁵ Belli, supra note 3, at 315.

incentives to donate blood.⁶⁶ These incentives are beneficial to both the donor and the recipient.⁶⁷ The Red Cross lists on its website the following reasons to donate: (1) patients need your gift of life; (2) helps you learn your blood type; (3) donor gets a mini-physical; (4) great way to do volunteer work; (5) helps you to celebrate your good health; (6) helps to boost the donor's morale; (7) single donation can treat up to four different patients; and (8) donors help to support a multitude of special blood programs.⁶⁸

Four main lines of argument have developed in response to MSMs being forever denied the opportunity to donate blood.⁶⁹ First, one gay advocate argues that this ban allows people to assume that "all homosexual and bisexual men are [at] 'high risk' for HIV."⁷⁰ Second, there is an argument that this policy is homophobic and stigmatizes gay men.⁷¹ The third line of argument is that this policy erodes the self-esteem of homosexual and bisexual men and justifies other types of discrimination towards them.⁷² And lastly, there is a firm argument that the policy is so absurd that gay men who should self-defer may decide to ignore self-deferral in retaliation against the policy.⁷³

A. The Onset of AIDS and Development of MSM Discrimination

In the 1980s, the gay blood ban was introduced as a way to

- ⁷⁰ Johnson, *supra* note 69 (quoting Peter Tatchell).
- 71 See id.
- 72 Culhane, supra note 51, at 131.

73 Id.

 ⁶⁶ Why Donate Blood, AMERICAN RED CROSS, http://chapters.redcross.org/ca/norcal/donor/whydon.html (last visited Sept 16, 2010).
 ⁶⁷ See id.

⁶⁸ Id.

⁶⁹ See Ramon Johnson, Why Gay Men Can't Donate Blood, ABOUT.COM, http://gaylife.about.com/od/stdsgeneralhealth/a/blooddonation.htm (last visited Sept. 16, 2010); see also Culhane, supra note 51, at 131.

combat the newly discovered disease AIDS. ⁷⁴ During the beginning of the AIDS crisis, many ill-informed public health policies were created and upheld.⁷⁵ At the time, AIDS had a disproportionate effect on the gay community.⁷⁶ Because of this effect, the FDA "sought to permanently exclude all sexually active gay men from the blood donor pool."⁷⁷ The FDA also thought that AIDS was a sexually transmitted disease.⁷⁸ However, later research and testing found substantial evidence that this disease is blood-borne.⁷⁹

It is interesting to note that "[w]hile there have been occasional calls for the policy's repeal, no litigation has been filed and no national advocacy campaign has emerged."⁸⁰

B. How AIDS is transferred; Statistical Breakdown

AIDS is a blood-borne disease.⁸¹ It is transferred in three different ways.⁸² In 2000, 57% of U.S. HIV cases were transmitted via sexual relations, both homosexual and heterosexual.⁸³ An estimated 15 to 20% of infections were perinatal transmissions.⁸⁴ Perinatal transmissions occur when "women [transmit their] virus to their children either in pregnancy or in childbirth."⁸⁵ Approximately 25% of HIV infections were parenteral transmissions.⁸⁶ Parenteral

⁷⁴ See id. at 132.

⁷⁵ See id. at 131.

⁷⁶ Id. at 132.

⁷⁷ See Culhane, supra note 51, at 131.

⁷⁸ See Id. at 132.

⁷⁹ Derek Link, Should Gay Men be Allowed to Donate Blood?, THE BODY (NOV./DEC. 2000), http://www.thebody.com/content/art13321.html.

⁸⁰ Adam R. Pulver, *Gay Blood Revisionism: A Critical Analysis of Advocacy and the "Gay Blood Ban,"* 17 LAW & SEX 107, 108 (2008).

⁸¹ Link, supra note 79.

⁸² See Francine Hochberg, HIV/AIDS Blood Donation Policies: A Comparative Study of Public Health Policies and Individual Rights Norms, 17 DUKE J. COMP. & INT'L L. 231, 234–35 (2002).

⁸³ Id. at 234.

⁸⁴ Id. at 234–35.

⁸⁵ Id. at 234.

⁸⁶ Id. at 235.

transmissions are defined as "transmissions through blood transfusion, injection, or scarification."⁸⁷

V. IMPLEMENTED BLOOD SAFETY SYSTEM

In order to combat the transfer of AIDS, the FDA implemented a rigid system for testing a donor's blood.⁸⁸ This process is repetitive in order to make sure that tainted blood does not enter into the blood donor supply.⁸⁹ These tests have eliminated the risk of infected blood entering the blood supply to virtually zero.⁹⁰ Below is a discussion of the FDA's role in the process along with the actual testing procedures implemented by blood testing centers.

A. The Role of the FDA

The FDA has regulatory jurisdiction over blood, bodily organs, tissue, and fluids.⁹¹ The FDA is not allowed to consider financial matters when making policy decisions, but finances do sometimes play a major role in making a decision.⁹²

The FDA officially adopted the current policy of disallowing men who have had sex with men since 1977 to donate blood in 1985.⁹³ It was adopted in response to research findings that the newly discovered HIV virus was the virus that caused AIDS, the end stage disease of HIV.⁹⁴ The very specific date attached to the 1977 start date was chosen because it was thought that the virus was not very

93 Id. at 2.

94 Id.

⁸⁷ Hochberg, supra note 82, at 235.

⁸⁸ See Link, supra note 79, at 2.

⁸⁹ See id.

⁹⁰ *Kerry: Let Gay Men Give Blood*, THE BOSTONCHANNEL.COM (Mar. 4, 2010), http://www.thebostonchannel.com/health/22740841/detail.html.

⁹¹ Culhane, supra note 51, at 132.

⁹² ROEHR, *supra* note 56, at 5.

prevalent within the United States before 1977.95

B. Detailed History of the MSM exclusionary policy

In July of 1982, the Centers for Disease Control (CDC) adopted the name "Acquired Immune Deficiency Syndrome" (later referred to as "AIDS") to describe an organism that caused a certain group of the population to develop a wide variety of "opportunistic infections."⁹⁶ Opportunistic infections are defined as "infections [in people, caused] by organisms that don't [usually] cause disease in people with a healthy immune system."⁹⁷ These infections were found in homosexuals, hemophiliacs, Haitians, and intravenous drug users.⁹⁸ The first instance of AIDS was discovered in homosexual men in 1981.⁹⁹ The men found to have this disease were young and generally healthy until they developed AIDS.¹⁰⁰

At outset, experts were led to believe that this disease was associated with a particular group of people based on their lifestyle.¹⁰¹ Most of the disease's association was with homosexual men.¹⁰²

The federal government conducted a study in 1981 of 116 homosexual men with AIDS-like symptoms.¹⁰³ The symptoms for AIDS include, but are not limited to the following:

"extreme fatigue; rapid weight loss from an unknown cause (more than 10 lbs. in two months for no reason); appearance of swollen or tender glands in the neck, armpits or groin, for no apparent reason, lasting for more than four weeks; unexplained

98 Id.

103 Id. at 329.

⁹⁵ Id.

⁹⁶ Belli, *supra* note 3, at 328.

⁹⁷ Id. (internal citations omitted).

⁹⁹ Id.

¹⁰⁰ Id.

¹⁰¹ Belli, *supra* note 3, at 329.

¹⁰² Id. at 328–29 (quoting NAT'L INST. OF ALLERGY & INFECTIOUS DISEASES, NAT'L INSTS. OF HEALTH, THE RELATIONSHIP BETWEEN THE HUMAN IMMUNODEFICIENCY VIRUS AND ACQUIRED IMMUNODEFICIENCY SYNDROME (1995)).

shortness of breath, frequently accompanied by a dry cough, not due to allergies or smoking; persistent diarrhea; intermittent high fever or soaking night sweats of unknown origin; a marked change in an illness pattern, either in frequency, severity, or length of sickness; appearance of one or more purple spots on the surface of the skin, inside the mouth, anus or nasal passages; whitish coating on the tongue, throat or vagina; and forgetfulness, confusion and other signs of mental deterioration."¹⁰⁴

Of these 116 homosexual men, it was concluded that they had, on average, 1,100 sexual encounters.¹⁰⁵ Based on studies such as these, epidemiologists developed theories to explain why this particular group of people was seeing AIDS within their community.¹⁰⁶ These theories included: a repeated infection of an immune system by a sexually transmitted disease caused the system to break down, and an overexposure to many different sources' sperm caused an "immune suppressant effect."¹⁰⁷

The epidemiologists' newly-developed theories along with the uncertainties about AIDS propelled the FDA to eventually recommend that blood banks not accept donations from groups with a high HIV prevalence, including men who have sex with men, or MSMs.¹⁰⁸ At first, blood banks did not comply, as they found this policy as extremely discriminatory.¹⁰⁹ However, they eventually obliged, and MSMs were permanently barred from donating blood in 1985.¹¹⁰

¹⁰⁴ Health Encyclopedia – Diseases and Conditions, AIDS and HIV Infection – Symptoms, Treatment, and Prevention, HEALTHSCOUT.COM, http://www.healthscout.com/ency/68/101/main.html (last visited Sept. 29, 2010).

¹⁰⁵ Belli, *supra* note 3, at 329.

¹⁰⁶ Id.

¹⁰⁷ Id. at 330.

¹⁰⁸ See id. at 338-39.

¹⁰⁹ See Sherry Glied, Markets Matter: U. S. Responses to the HIV-Infected Blood Tragedy, 82 VA L. REV. 1493, 1496 (1996).

¹¹⁰ Andy Miller, Ban on Gay Donors Upheld, MSNBC.COM, http://www.msnbc.msn.com/id/37599992/ns/health-aids/ (last modified Jun.11, 2010).

VI. DEVELOPMENT OF BLOOD TESTS

In addition to permanently barring MSMs from donating blood, the FDA implemented the routine testing of donated blood.¹¹¹ With the development of routine blood testing, "[t]he risk of being infected with HIV through a [blood] transfusion fell from approximately 1 in 2500 to around 1 in 225,000."¹¹²

Safety regulation of the blood supply involves a thorough threestage process.¹¹³ First, there is donor deferral, which is where certain at-risk individuals are denied the opportunity to donate blood.¹¹⁴ The deferral system is established in conjunction with answers from the HH form.¹¹⁵ Each answer on the HH Form can yield a different restriction or outcome.¹¹⁶ Second, all blood is tested for infectious diseases and agents.¹¹⁷ Third, blood banks are regulated to ensure that they are properly implementing all FDA safety measures.¹¹⁸ The importance of overseeing blood banks is to identify HIV-infected units of blood and make sure that they do not enter into the blood supply.¹¹⁹

This section discusses the different tests that are used to keep infectious diseases out of the blood supply. The tests implemented try to address the "window period" problem.¹²⁰ The "window period" problem is where blood that is potentially affected by the HIV virus tests "HIV negative" due to the fact that recent HIV infections may not be detectable with the current technology.¹²¹

114 *Id.*115 *Id.*116 *Id.*117 *Id.*118 Link, *supra* note 79, at 3.
119 *Id.*120 *Id.* at 2.
121 *Id.*

¹¹¹ Belli, *supra* note 3, at 333.

¹¹² Steven Salbu, AIDS and the Blood Supply: An Analysis of Law, Regulation, and Public Policy, 74 WASH. U. L.Q. 913, 928 (1996).

¹¹³ Link, *supra* note 79, at 2.

A. The Enzyme-Linked Immunosorbent Assay (ELISA) and Western Blot Test

In 1985, the FDA approved the ELISA Test as the first HIV antibody blood test.¹²² The ELISA Test is fairly accurate, with an 17% false positive rate;¹²³ however, coupled with the Western Blot Test, the effectiveness increases to nearly 100%.¹²⁴ One disadvantage to the pairing of these two tests is the existence of a "window period" when the tests cannot accurately detect the development of HIV antibodies existing in the donor's blood.¹²⁵ Professor Gregory Gelles estimates that "the cost of preventing each direct infection ranges from \$36,300 to \$128,333."126 However, these costs are low in comparison to the cost of treatment that would be necessary if the test failed to detect and prevent the spreading of the HIV virus through blood donation.¹²⁷ The costs of failing to prevent an infection include: (i) patient treatment for life; (ii) pain and suffering of the patient; (iii) shorter lifespan due to HIV/AIDS; and (iv) the potential spreading to others through the recipient's blood.¹²⁸ This test on average can identify the presence of HIV antibodies twenty-five days after someone has been exposed to them.¹²⁹

B. Antigen Testing

Antigen Testing has recently created the most controversy in the testing of blood donations.¹³⁰ This test can detect HIV antibodies sooner than the ELISA test, thereby reducing the window period.¹³¹ However, the controversy in the medical field involves outweighing

122 Salbu, *supra* note 112, at 929.
123 Belli, *supra* note 3, at 334.
124 *Id.* at 335.
125 *Id.*126 Salbu, *supra* note 112, at 930.
127 *Id.*128 *Id.* at 930–31.
129 *Id.* at 931.
130 *Id.* at 933.
131 Salbu, *supra* note 112.

the cost of the test to the benefits that are available when using the test.¹³² Many investigators who have studied this test have found it ineffective and overly expensive,¹³³ stating that it "could negligibly reduce the number of infected units of blood that enter the blood supply."¹³⁴ Professor Gelles states that it costs on average about \$24 million per AIDS case prevented,¹³⁵ making the implementation of antigen testing "financially unrealistic."¹³⁶ In addition, this test is likely to only be able to "prevent approximately five to ten cases per year, [i.e.,] up to 25 percent of current cases of AIDS transmitted by transfusion."¹³⁷

C. Nucleic Acid Testing (NAT)

NAT is a new form of testing for HIV in which the FDA has invested many resources into developing.¹³⁸ Although NAT is not currently an implemented test and is rather in the later stages of evaluation, NAT has the ability to trim a few days off of the "window period" of discovering HIV within a donor's blood stream.¹³⁹ Currently, this test can "detect pieces of the virus's genetic material after [approximately] 20 days, [which is] a 50 percent reduction in the window period of HIV."¹⁴⁰ Testimony was introduced claiming that when NAT tests smaller pooled samples of blood, it can detect HIV within four to five days.¹⁴¹ Researchers are hoping that this particular test will completely eliminate the window period.¹⁴²

¹³² Id.

¹³³ Id.

¹³⁴ Id. at 933-34.

¹³⁵ *Id.* at 934.

¹³⁶ Salbu, supra note 112.

¹³⁷ Belli, *supra* note 3, at 336 (citation omitted).

¹³⁸ Link, supra note 79, at 2.

¹³⁹ Id. at 2–3.

¹⁴⁰ Belli, *supra* note 3, at 337 (citation omitted).

¹⁴¹ ROEHR, *supra* note 56, at 2.

¹⁴² Link, *supra* note 79, at 2–3.

D. HIV RNA Viral Load Testing

The HIV RNA Viral Load Testing is a type of test that quantifies the amount of HIV antibodies present in a person's blood.¹⁴³ It has the highest probability of detecting HIV sooner than any other technology currently available.¹⁴⁴ However, this technology has raised objections from blood industry specialists due to the cost and technological complexities associated with the testing.¹⁴⁵ RNA is also considered less cost efficient than both the ELISA and Western Blot Test combined.¹⁴⁶ This test costs about \$100 compared to \$20 for the ELISA and Western Blot Test.¹⁴⁷

VII. WHY MSMs ARE DEEMED HIGH-RISK DONORS

MSMs are deemed high-risk donors because since the onset of AIDS around the world and until a few years ago, MSMs were the largest category of individuals who were cumulatively diagnosed with AIDS.¹⁴⁸ Since 1979, about 70 percent of all reported AIDS cases were in MSMs.¹⁴⁹ In 2003, MSMs represented almost a third (34.6 percent) of all diagnosed AIDS cases, which was a drastic decrease from 78 percent.¹⁵⁰

VIII. MORE THAN MSMS

Other ethnic heterosexual minority groups are developing HIV and AIDS at a higher rate than MSMs.¹⁵¹ Originally, sexual

143 *Id.* at 3.
144 *Id.*145 *Id.*146 *Id.*147 Link, *supra* note 79, at 5.
148 Lomaga, *supra* note 51, at 80.
149 *Id.*150 *Id.*151 Belli, *supra* note 3, at 364.

orientation was thought to play a major role in the transmission of AIDS; it was later discovered that AIDS has nothing to do with sexual orientation but rather that it is transmitted through "blood or other bodily fluids."¹⁵²

Admittedly, in the beginning, many gay men died from AIDS related illnesses.¹⁵³ This attack on the gay community (the Community) raised awareness, and many gay men began practicing safe sex.¹⁵⁴ While gay men began practicing safe sex, heterosexuals took an immune attitude towards the fact that they could actually catch the disease. The numbers of heterosexuals contracting AIDS, due to their risky behavior, indicates their lax attitude.¹⁵⁵

From the 1990s into the early 2000s, statistics show that HIV rates among gay men were declining while they were rising in other groups.¹⁵⁶ The groups with the sharpest increases in HIV diagnoses were women and minorities.¹⁵⁷

In 1999, blacks donating blood were '25 times more likely than whites to have recently acquired HIV,' and of those between the ages of 20 and 24 who tested positive, 44 percent were women. Even more alarming, of those in the 13 to 19 year old age group diagnosed in 1999, 63 percent were female. According to researchers, these recent trends in HIV transmission 'indicate that AIDS is evolving from being largely an illness of white homosexuals to one of poor blacks [and women] who catch it through drug abuse and heterosexual encounters.'¹⁵⁸

The exclusion of gay men from the potential donor pool creates a false sense of security among heterosexuals¹⁵⁹ and further stigmatizes

152 Id. at 363.

153 *Id.*154 *Id.*155 *Id.* at 363–64.
156 Belli, supra note 3, at 364.
157 *Id.*158 *Id.*159 *Id.*

MSMs.¹⁶⁰ Heterosexuals are engaging in reckless behavior and contracting the opportunistic disease at a higher rate than gay men, who are permanently barred from giving blood.¹⁶¹ However, the blood banks refuse to adequately address the high-risk behaviors that heterosexuals are engaging in and instead use gay men as a mechanism to keep heterosexuals believing that they are immune to the disease.¹⁶² In addition, the "current blood screening policy tolerates 'considerable risks for heterosexuals but zero tolerance for gay men.'"¹⁶³ Heterosexuals' risky behavior has only been slightly addressed by temporarily barring them from donating blood, but not by permanently barring them and placing them on a 'deferral registry.'¹⁶⁴

IX. DENYING MSMS THE OPPORTUNITY TO DONATE BLOOD VIOLATES THEIR FOURTEENTH AMENDMENT RIGHTS

Gay men should be allowed to donate blood because the blood now goes through a stringent screening process that reduces the potential for contaminated blood entering into the blood stream to virtually zero.¹⁶⁵ Senator Kerry has "compared the effort to lift the blood donation ban to legislation he backed in 2008 to end the law banning people with HIV from travelling and immigrating to the United States. That [particular HIV travel ban] was lifted last year [in 2009]."¹⁶⁶

This particular section will discuss how to establish an equal protection claim and how the current MSM permanent deferral violates MSMs constitutional rights.

¹⁶⁰ Id. at 364-65.

¹⁶¹ Belli, *supra* note 3, at 363-64.

¹⁶² Id. at 364-66.

¹⁶³ Id. at 366.

¹⁶⁴ Id. at 366-67.

¹⁶⁵ Senators: Lift Ban on Gay Men Donating Blood, USA TODAY, http://www.usatoday.com/news/health/2010-03-05-gay-blood_N.htm (updated Mar. 5, 2010).

¹⁶⁶ Id.

A. How to Assert an Equal Protection Claim

In order to assert a claim of equal protection, the one who believes that they are being discriminated against must first establish discriminatory intent.¹⁶⁷ In order to establish discriminatory intent, the person must prove that the particular challenge "singled out a particular class of people for disadvantageous treatment and that such was motivated by a discriminatory purpose."¹⁶⁸ The Court looks at the legislative history or language of the particular policy and evaluates whether the policy "creates an irrational classification."¹⁶⁹

For the sake of argument, assuming that the plaintiff established that the policy had a discriminatory intent, the plaintiff must then prove that the policy is not "rationally related to a legitimate government purpose."¹⁷⁰ The Equal Protection Clause does not eliminate all discrimination, rather it justifies discrimination if it "is rationally related to a legitimate government interest and the classification utilized will be a rational means of pursuing that interest."¹⁷¹ The Court will look to a plethora of different factors in determining whether a policy is rational.¹⁷² The real issue in these cases is whether the policy or statute is related to the legislative classification.¹⁷³

B. How the MSM Exclusionary Policy Violates MSMs' Constitutional Rights

The current MSM policy, which imposes a permanent deferral on gay men from donating blood, violates their equal protection rights because it arbitrarily excludes them from the eligible blood donor pool.¹⁷⁴ The policy, which was implemented over twenty years ago

¹⁶⁷ Belli, *supra* note 3, at 348.
168 *Id.* at 348–49.
169 *Id.*170 *Id.* at 350.
171 *Id.*172 Belli, *supra* note 3, at 350.
173 *Id.* at 351.
174 *Id.* at 366.

when little was known about AIDS, was adopted in response to a crisis seen initially only in a particular class of individuals involved in a certain type of behavior.¹⁷⁵ Because of HIV's unknown cause and transmission mechanism,¹⁷⁶ the 1985 policy's permanent deferral of MSMs was understandable. It was also widely supported by the Community.¹⁷⁷ Currently, however, it is widely known and accepted that AIDS is a virus that is transmitted by blood or other bodily fluids,¹⁷⁸ so the initial reasons for the policy are now unfounded.¹⁷⁹ "Science has clearly proven that sexual orientation has nothing whatsoever to do with HIV transmission."¹⁸⁰

To exclude MSMs from the eligible pool of donors is discriminatory.¹⁸¹ Though it has been proven many times over that sexual orientation has nothing to do with contracting HIV/AIDS, the policy still remains unchanged.¹⁸² Leaving the MSM exclusionary policy in place creates a false sense of security among heterosexuals and allows a group of people to be discriminated against based on their sexual orientation.¹⁸³

Also, although all of the blood is tested, selective exclusion sheds further light on the idea that the policy is discriminatory.¹⁸⁴ All blood donations go through the same amount of FDA-regulated tests.¹⁸⁵ By denying MSMs the right to donate blood, it is associating a stigma with this particular group of people.¹⁸⁶ The stigma lies in the belief

178 Id. at 363.

¹⁷⁵ Id. at 363-64.

¹⁷⁶ See id. at 363.

¹⁷⁷ Belli, supra note 3, at 365.

¹⁷⁹ See id. at 365.

¹⁸⁰ Id. at 363 (quoting Gracie Bond Staples, Hearings to Decide if Gays Can Give Blood, COX NEWS SERVICE, Sept. 14, 2000, at 2 (quoting Jeff Graham, Executive Director of the AIDS Survival Project).

¹⁸¹ Id. at 364.

¹⁸² Belli, supra note 3, at 364.

¹⁸³ Id.

¹⁸⁴ Id. at 366.

¹⁸⁵ ROEHR, supra note 56, at 1.

¹⁸⁶ See Belli, supra note 3, at 365.

that the Community's promiscuity was the original reason for such a high number of AIDS-related deaths.¹⁸⁷ Continuing to uphold this policy allows heterosexuals who engage in high-risk behavior to continue to donate blood, even having their categories modified in order to reflect improved technology and increased accuracy in detecting HIV antibodies within the blood stream.¹⁸⁸

Selectively modifying the categories of heterosexuals engaging in high-risk activities and failing to modify that of MSMs, who do not all engage in risky activities, further demonstrates that the policy arbitrarily attaches to one group of individuals, holding them accountable for actions that they truly might not be engaged in.¹⁸⁹ Their sexual orientation automatically places them in a stigmatized class that has no way of redeeming itself.¹⁹⁰

X. PROPOSED RULES TO ACCEPT MSMS AS BLOOD DONORS

Though the policy violates MSMs Fourteenth Amendment rights and has remained unchanged, changes have been proposed.¹⁹¹ This section will discuss the different policy proposals and the motivations behind their continual rejections.

A. A Roadmap Through the Different Proposed Rules

Even though testing has improved for blood donations, the MSM policy has remained unchanged since its inception.¹⁹² In 1983, the Office of Biologics of the National Center for Drugs and Biologics (Office of Biologics) recommended an "interim measure" to prohibit high-risk groups, including MSMs, from donating blood.¹⁹³ This measure was recommended during a time when little was known

¹⁸⁷ See id. at 365.
188 See id. at 335, 367.
189 Id. at 367–68.
190 See id. at 364–65.
191 Belli, supra note 3, at 339 (quoting Salbu, supra note 112).
192 Id. at 338.

¹⁹³ Id. (quoting Salbu, supra note 112).

about HIV and AIDS.¹⁹⁴ In 1985, this recommendation became mandatory.¹⁹⁵ In 1986, a revision implemented procedures that maintained the confidentiality of exclusion, as well as implementing the written and signed acknowledgement that donors qualified under the new guidelines.¹⁹⁶ In 1988, the new guidelines expanded the list of emigrants who were barred from donating blood.¹⁹⁷ In 1990, recommendations expanded the ban on individuals excluded from donating blood.¹⁹⁸ These recommendations excluded potential donors who lived in or were from a particular geographic area or of a particular national origin.¹⁹⁹ At this time, the recommendations also "emphasized risky behaviors over status under the theory that the former provide a more accurate basis for excluding those at high risk."200 The policy further extended the deferral period to twelve months for people who engaged in sex with prostitutes within the past twelve months and people who had received a blood transfusion within the past twelve months.²⁰¹ In 1995, the Office of Biologics added inmates as a deferral category.²⁰² However, inmates were only temporarily deferred from donating, calculating the deferral period from their last day of incarceration.²⁰³

In 1997, the American Association of Blood Banks (AABB) and the FDA Blood Products Advisory Committee (BPAC) called for the removal of the permanent bar on MSMs trying to donate blood.²⁰⁴ During this meeting, AABB proposed that MSMs' deferral time period be reduced to a temporary deferral period of twelve months

¹⁹⁴ Id. at 363.

¹⁹⁵ See ROEHR, supra note 56, at 2.

¹⁹⁶ Belli, *supra* note 3, at 339 (quoting Salbu, *supra* note 112).

¹⁹⁷ Id. at 339-40 (quoting Salbu, supra note 112).

¹⁹⁸ Id. at 340 (quoting Salbu, supra note 112).

¹⁹⁹ Id.

²⁰⁰ Belli, supra note 3, at 340 (quoting Salbu, supra note 112).

²⁰¹ Id. at 340–341 (quoting Salbu, supra note 112).

²⁰² Id. at 341.

²⁰³ Id. at 342.

²⁰⁴ ROEHR, supra note 56, at 3.

"to make it 'consistent with those for other high risk sexual exposures."²⁰⁵ AABB has continued to hold this position.²⁰⁶

In September 2000, the BPAC proposed that the permanent bar against MSMs donating blood should be changed to a temporary bar of five years.²⁰⁷ Testimony stated that the increased risk of relaxing the standard would put about one infected unit of blood out of 750,000 units into the blood pool.²⁰⁸ When BPAC voted on this change, there was a seven to six vote not to change the policy.²⁰⁹ Five members were not present for the vote.²¹⁰

The American Red Cross continues to stand firm on its zero tolerance policy not to introduce any risk into the blood supply.²¹¹ However, there is "compelling research suggesting the risk was minimal and the change was desirable in terms of increasing the number of blood donors."²¹²

B. Motivations to Keep MSMs from Donating Blood

Because there is considerable research showing that allowing MSMs to donate blood would not increase the risk of tainted blood into the blood supply,²¹³ one then asks: Why are MSMs not allowed to donate?

The American Red Cross is one of the main opponents to changing the ban.²¹⁴ Much of its advertising focuses on the safety of its blood.²¹⁵ Additionally, the amount of money the American Red Cross raises and its sheer righteous attitude towards the whole

206 Id.

207 Id.

208 Id.

210 Id.

215 Id. at 3.

²⁰⁵ Id.

²⁰⁹ ROEHR, *supra* note 57, at 3.

²¹¹ Lomaga, supra note 51, at 80.

²¹² Id. (citing Dr. Farrugia, Australian Commonwealth Department of Health and Ageing).

²¹³ See id. (citing Dr. Farrugia, Australian Commonwealth Department of Health and Ageing).

²¹⁴ ROEHR, supra note 56, at 3-4.

system call into question the policy.²¹⁶

Some board members have even resigned, charging that the American Red Cross is homophobic because of its disregard of the overwhelming amount of research that supports a change to the MSM policy.²¹⁷ The Red Cross, of course, denies this allegation,²¹⁸ but the Red Cross still will not promote lifting the permanent deferral.²¹⁹

Though the Red Cross is a non-profit entity and enjoys the perks of a non-profit status, it likely wants to prohibit high-risk donations in order to reduce costs.²²⁰ Another advantage that the Red Cross could be seeking is a marketing advantage claiming that they have the "safest" blood.²²¹

XI. CONCLUSION

The permanent deferral of MSMs from donating blood is an arbitrary and irrational policy. Though no litigation over the issue exists, and the United States courts and legislatures have not recognized donating blood as a right, the argument can be made that the denial is infringing on MSMs' constitutional rights, considering heterosexuals are contracting HIV/AIDS at a higher rate than MSMs. This paper in no way argues that a right to donate blood exists; however, it does assert the claim that the opportunity to donate blood should exist for those who are being discriminated against based upon sexual orientation and status.

The FDA had reason to permanently bar all MSMs from donating blood at the onset of the disease. However, with technological advancements and the introduction of a policy that all blood is tested, it is arbitrary to impose a permanent bar on MSMs because science has repeatedly proven that sexual orientation has

- 217 Id.; See Lomaga, supra note 51, at 80.
- ²¹⁸ See ROEHR, supra note 56, at 3.
- 219 Id.
- 220 Id.
- 221 Id.

²¹⁶ Id.

nothing to do with contracting HIV/AIDS. Also, denying MSMs the opportunity to donate blood based on an outdated stigma limits the eligible blood donor pool.

If the FDA repeals the policy, a one-year deferral for MSMs should be implemented. This one-year temporary deferral period would be in line with that of other risky behavior groups. This temporary deferral would allow the blood supply donor pool to increase and take away the stigma associated with homosexuality.