DRAWING BLOOD: TOWARDS AN EU REMEDY FOR BLOOD DONATION RIGHTS

MEREDITH CIUFO*

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ABSTRACT

This Note considers the legality of European Union Member States' bans on blood donation by men who have sex with men (MSM), as well as available European legal mechanisms to challenge the bans. After the HIV/AIDS outbreak in the late 1970s, inadequate testing procedures led to

* J.D. Candidate, Boston University School of Law,. B.A., The George Washington University, 2010. I would like to thank Professor Lilian Faulhaber for her invaluable guidance, support and consistent enthusiasm throughout the writing process. A special thank you to family and friends for their support and encouragement, particularly my fiancé Daniel for agreeing to read my Note more than once.

blanket bans targeting perceived high-risk groups, such as intravenous drug users and MSM. Since then, Member States have developed more varied restrictions on MSM donations: automatic lifetime bans, time-based deferrals, and individualized risk assessments. Automatic lifetime bans, however, conflict with the fundamental freedom against discrimination based on sexual orientation. Furthermore, the bans are not justified by any quantitative risk. New screening technologies that allow for the reliable detection of HIV soon after infection eliminate the marginal safety benefit of lifetime bans over time-based deferrals or individual risk assessments.

Member State donation policies can be challenged through the European Court of Justice or the European Court of Human Rights. Though possible, a challenge in the European Court of Justice would be both procedurally and substantively difficult. Due to the availability of an individual cause of action and a strong anti-discrimination provision, the European Court of Human Rights provides the most appropriate forum.

INTRODUCTION

In September 2011, the United Kingdom announced it was removing its lifetime ban on blood donations from MSM in England, Scotland and Wales.[1] While the UK retains a one-year deferral, the policy change sparked renewed discussion of the European Union's position on MSM blood donation policies.[2] In an August 17, 2011 Parliamentary Question response the European Commission emphasized that EU Member States must implement Directives "in full respect of" the Charter of Fundamental Rights of the European Union ("the Charter"), which prohibits discrimination on the basis of sexual orientation.[3] Regardless, many Member States maintain a lifetime ban or time-based deferral on MSM donations.[4]

This Note examines the legality of these restrictions under European Union law, as well as the available European mechanisms to challenge them. Lifetime bans on MSM blood donations could be challenged through European judicial mechanisms as violating the fundamental freedom against discrimination based on sexual orientation. While the bans could be

[1] Press Release, U.K. Dep't of Health, Lifetime Blood Donation Ban Lifted for Men Who Have Had Sex with Men (Sept. 8, 2011), *available at* http://mediacentre.dh.gov.uk/2011/09/08/lifetime-blood-donation-ban-lifted-for-men-who-have-had-sex-with-men/.

[2] Answer from the Commission to Written Question E-006484/2011 , 2012 O.J. (C 128 E) 1, 56 (indicating only number, author, and subject), *full text available at* http://www.europarl.europa.eu/sides/getAllAnswers.do?reference=E-2011-006484&language=EN.

[3] *Id.*

[4] For a description of Member State laws *see* discussion *infra* Part I.A.

challenged through the European Court of Justice, the European Court of Human Rights would likely be the most appropriate and effective forum to initiate a claim.

Part I of this Note describes the historical and contemporary state of MSM donation policies, both at the Member State and European Union levels. Member State restrictions include lifetime bans, time-based deferral periods and individualized risk assessments. The EU provides a legal framework for regulating general public health issues as well as the specific authority to regulate blood donation policy at the European level. Under this authority the EU has adopted various positions on MSM donation regulation. The Note analyzes how Member State laws violate or contradict EU law. Additionally, this Note looks at the public health policy developments in reaction to the bovine spongiform encephalopathy / variant Creutzfeldt-Jakob disease outbreak (Mad Cow Disease) as a parallel example of competing Member State and EU public health policies involving discrimination claims.

Part II of this Note explores the social implications of MSM blood donation bans, both on international public health and on sexual orientation discrimination in Europe. The Note approaches the debate by surveying quantitative studies on the safety and privacy concerns involved. It then analyzes the discrimination issues raised by MSM bans and how challenging the bans fits into the equal rights movement in Europe.

Finally Part III of this Note explores the European legal mechanisms available to challenge Member State bans on MSM blood donations. It outlines the legal processes a party would use to challenge the laws through both the European Court of Justice and the European Court of Human Rights. The Note distinguishes the European Court of Human Rights as the best forum for challenging the Member State laws, offering better access to individuals and a stronger precedent for challenging sexual orientation discrimination.

Many authors have addressed the quantitative safety of MSM blood donation policies in the European Union,[5] and some have analyzed the balance between public health and individual rights. No author, however, has yet fully explored the validity of the various blood donation policies in terms of fundamental right infringements, or the possibility of using European judicial mechanisms to challenge the infringement. This Note provides an in-depth analysis of available European remedies, developing a European counterpart to the much-developed literature on challenging the United States' lifetime MSM blood donor ban.[6]

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[5] *See* discussion *infra* Part II.A.

[6] *See* Kevin Hopkins, *Blood, Sweat, and Tears: Toward a New Paradigm for Protecting Donor Privacy*, 7 VA. J. SOC. POL'Y & L. 141 (2000); Whitney Larkin, *Discriminatory*

I. HISTORICAL AND CONTEMPORARY BLOOD DONATION POLICIES

After the discovery of HIV/AIDS in the 1980s, widespread fear of transmission led to national and international efforts to protect the donated blood supply.[7] Policy-makers often targeted MSM as a high-risk group, and many countries imposed a lifetime ban on their blood donations.[8] Many countries still maintain these lifetime bans. Preventing MSM from donating blood based solely on their sexual orientation, however, is neither legal under European law nor justified by public health concerns.

A. Member State Restrictions

There are three types of MSM blood donation policies among the EU Member States: lifetime bans, time-based deferrals, and individual risk assessments. Most Member States ban MSM blood donation indefinitely, as of whenever MSM sexual contact begins.[9] This is similar to the United States' policy, which imposes a lifetime ban on all men who have had sexual contact with a male after 1977.[10] As an intermediate policy, the UK has lifted their lifetime ban and replaced it with a one-year deferral period after each MSM sexual contact.[11] While the deferral would allow men to donate blood after one year of abstinence, for most MSM the new law is effectively a lifetime ban. Alternatively, some Member States do not have any formal ban or deferral of MSM blood donations.[12] Spain and Italy, for example, do not mention MSM in their blood donation qualifications and restrictions and instead use an individual analysis based on high-risk behavior.[13] While individual assessment policies grant blood donation

Policy: Denying Gay Men the Opportunity to Donate Blood, 11 HOUS. J. HEALTH L. & POL'Y 121 (2011); Adam R. Pulver, *Gay Blood Revisionism: A Critical Analysis of Advocacy and the "Gay Blood Ban,"* 17 LAW & SEXUALITY 107 (2008).

[7] Francine A. Hochberg, *HIV/AIDS and Blood Donation Policies: A Comparative Study of Public Health Policies and Individual Rights Norms*, 12 DUKE J. COMP. & INT'L L. 231, 231-32 (2002).

[8] *Id.* at 232.

[9] R.J. Benjamin et al., *Deferral of Males Who Had Sex with Other Males*, 101 VOX SANGUINIS 339, 340 (2011). Table 1 lists France, Germany, Sweden, and Norway as examples of countries with indefinite MSM donation bans.

[10] *Id.* The lifetime ban has been challenged in the United States. Currently the Department of Health and Human Services (HHS) is conducting studies to reevaluate the current deferral policy. HHS RFI on Design of a Pilot Operational Study to Access Alternative Blood Donor Deferral Criteria for MSM, 77 Fed. Reg. 14,801 (Mar. 13, 2012).

[11] U.K. Dep't of Health, *supra* note 1.

[12] Benjamin, *supra* note 9, at 342. Table 2 lists Italy, Spain and Poland as countries without formal restrictions on MSM blood donation.

[13] *Id*. For example, in Spain, the blood center health professionals ask donors questions "related to the detection of risky activities . . . ." Blood donors in Spain are deferred

administrators the discretion whether to accept donations from self-identified MSM, MSM donations are not formally barred.[14]

B. EU Regulation of Food and Health Safety after BSE/nvCJD Scare as a Parallel Case Study

The Member State restrictions on MSM donations in response to HIV/AIDS discovery are similar to the restrictions on food and blood supplies in response to bovine spongiform encephalopathy (BSE) outbreak in the early 2000s. BSE was first diagnosed in the UK in 1986 and "reached epidemic proportions due to cattle being fed with processed animal protein, produced from ruminant carcasses, some of which were infected"[15] in 2000.[16] BSE is transmitted to humans orally, causing variant Creutzfeldt-Jacob Disease.[17] Fear of transmitting BSE via blood transfusions led many Member States to bar individuals from the UK from donating blood.[18] As a result of these restrictions, an EU Parliament member asked the European Commission in January 2001 whether the ban on UK blood donors was legal under EU law.[19] The Commission's answer included a plan to conduct scientific studies and recommend findings, rather than giving an opinion on the legality of the donation restrictions.[20] Since then, the Commission has continually researched and published findings on the status of the BSE epidemic in the EU.[21] The EU's response to the BSE outbreak was much more systematic and data driven than its response to HIV contamination of national blood supplies.[22] One reason

indefinitely if they have had sex for money, drugs or any compensation, have sex with more than one partner at a time, or intravenous use of illegal drugs. *Id*. at 364.

[14] ADVISORY COMM. ON THE SAFETY OF BLOOD, TISSUE & ORGANS, DONOR SELECTION CRITERIA REVIEW 49 (2011) (U.K.) [hereinafter SABTO REPORT].

[15] *Commission Staff Working Document Accompanying the Communication from the Commission to the European Parliament and the Council on the TSE Road Map 2*, at 4 (Annex I), SEC (2010) 899 final (July 16, 2010) [hereinafter Staff Document].

[16] Herbert Budka, Bart Goossens & Guiseppe Ru, *BSE and TSEs: Past, Present and Future*, 19 TRENDS IN FOOD SCI. & TECH. 34, 34-35 (2008).

[17] Staff Document, *supra* note 15, at 4.

[18] *CJD Fears Prompt Blood Donor Ban*, BBC NEWS (Mar. 16, 2004, 2:46 PM), http://news.bbc.co.uk/2/hi/health/3515358.stm.

[19] Written Question E-0096/01, 2001 O.J. (C 187 E) 181, 181, *available at* http://www.europarl.europa.eu/sides/getDoc.do?type=WQ&reference=E-2001-0096&language=EN.

[20] Answer from the Commission to Written Question E-0096/01, 2001 O.J. (C 187 E) 181, 182, *available at* http://www.europarl.europa.eu/sides/getAllAnswers.do?reference=E-2001-0096&language=EN.

[21] *Communication from the Commission to the European Parliament and the Council on the TSE Road Map 2*, at 4, COM (2010) 384 final (July 16, 2010).

[22] *See* discussion *infra* Part I.C regarding EU responses to Parliamentary Questions

for the more comprehensive EU response is that BSE involved food safety regulation, a more natural fit for EU regulation, as well as blood safety.[23] Another distinction is that BSE restrictions were not based on sexual orientation, but rather discriminated based on locality. Locality based discrimination is generally accepted in blood donation policy and is used by most countries to limit donations from individuals who spent time in countries with epidemic level HIV rates.

C. European Union Donation Policies

The European Union's power to regulate public health is based on Article 168 (formerly 152 EC) of the Treaty on the Functioning of the European Union.[24] On blood donation specifically, Article 168(4)(a) states that the Council shall adopt "measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives . . ." however, "these measures shall not prevent any Member State from maintaining or introducing more stringent protective measures."[25] A 2003 European Parliament and Council Directive adopted the Commission's proposed blood donation safety regulations.[26] While the Directive's requirements were fairly general and failed to specify any rules on donor eligibility, the Directive did require HIV testing of all whole blood and apheresis[27] donations.[28] Additionally, the Directive authorized the Commission to develop more technical regulations when warranted by "scientific and technical progress."[29] As in Article 168, the Council Directive permitted Member States to impose "more stringent protective

regarding MSM blood donation bans.

[23] TAMARA K. HERVEY & JEAN V. MCHALE, HEALTH LAW AND THE EUROPEAN UNION 351 (2004).

[24] Consolidated Version of Treaty on the Functioning of the European Union art. 168, Mar. 25, 2010, 2010 O.J. (C 83) 123 [hereinafter TFEU]; HERVEY & MCHALE, *supra* note 23, at 77. Article 152 EC (now Article 168) authorizes the Community to consider health interest in all policy and requires EU institutions to not just contribute, but to "ensure a high level of health protection in all Community activities." *Id*.

[25] TFEU art. 168.

[26] Directive 2002/98, of the European Parliament and of the Council of 27 January 2003 Setting Standards of Quality and Safety for the Collection, Testing, Processing, Storage and Distribution of Human Blood and Blood Components and Amending Directive 2001/83/EC, 2003 O.J. (L 33) 30.

[27] For an explanation of apheresis, or platelet donation, *see Platelet Donation*, AMERICAN RED CROSS, http://www.redcrossblood.org/donating-blood/types-donations/platelet-donation(last visited Dec. 4, 2012).

[28] Directive 2002/98, *supra* note 26, at 40 (Annex IV).

[29] *Id.* at 32 (¶ 26).

measures which comply with the provisions of the Treaty."[30]

The following year the Commission implemented their own Directive, detailing more technical standards for blood donation.[31] Unlike the Council, the Commission's Directive enumerated blood donor criterion and eligibility guidelines.[32] In Annex III 2.1, the Commission listed several criteria warranting permanent blood donor deferral.[33] Under the heading "sexual behavior," the Commission included "[p]ersons whose sexual behaviour puts them at high risk of acquiring severe infectious diseases that can be transmitted by blood."[34] Notably, the Commission did not specify MSM as high-risk sexual behavior, but instead left the category undefined.[35]

The Commission has since commented on the Directives on several occasions, reasserting that Member States must comply with the 2003 and 2004 guidelines.[36] In 2006, several European Parliament members wrote a Parliamentary Question to the Commission inquiring whether a Member State hospital's refusal "to accept blood from any and all gay, lesbian, and bisexual people on the sole grounds of their sexual orientation" violated Article 13 of the Treaty on European Union by assuming that such individuals are members of at-risk groups.[37] In response, the Commission emphasized that the "at-risk" lifetime ban is based on behavior, not sexual orientation.[38] Individual Member States can manage the at-risk criteria based on the specific circumstances of both their population and the individual donor to ensure the highest standards of blood safety and

[30] *Id.* at 33 (art. 4 ¶ 2).

[31] Directive 2004/33/EC, of the Commission of the European Communities of 22 March 2004 Implementing Directive 2002/98/EC of the European Parliament and of the Council as Regards Certain Technical Requirements for Blood and Blood Components, 2004 O.J. (L 91) 25.

[32] *Id.* at 31-34 (Annex III).

[33] *Id*. at 31-32.

[34] *Id.* at 32.

[35] *Id.*

[36] Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions on the Application of Directive 2002/98/EC, at 2, COM (2010) 3 final (Jan. 19, 2010) [hereinafter Communication from the Commission on the Application of Directive 2002/98/EC].

[37] Written Question E-4492/06, 2006 O.J. (C 329) 1, 145 (indicating only number, author, and subject), *full text available at* http://www.europarl.europa.eu/sides/getDoc.do?type=WQ&reference=E-2006-4492&language=EN.

[38] Answer from the Commission to Written Question E-4492/06, 2006 O.J. (C 329) 1, 145 (indicating only number, author, and subject), *full text available at* http://www.europarl.europa.eu/sides/getAllAnswers.do?reference=E-2006-4492&language=EN.

quality.[39] Therefore, the Commission acknowledged many member states excluded MSM donations under this category based on "national epidemiological situations which demonstrate higher HIV positive rates."[40] Throughout the answer the Commission reinforced that Member States could adapt the at-risk category to meet their population makeup, even if that included blanket characterizations of MSM.[41]

When proposals to change the lifetime MSM ban to a one-year deferral began to make progress in the UK in the summer of 2011, EU Parliament members again broached the subject in a question to the Commission.[42] They inquired whether banning gay and bisexual men from donating blood, even if they practice safe sex, violated Article 21 of the Charter of Fundamental Rights of the European Union.[43] In response the Commission noted, as it did in 2006, that "sexual behaviour is not identical with sexual orientation."[44] Unlike the 2006 answer, here the Commission emphasized that the "Member States are obliged to implement these Directives in full respect of EU Charter of Fundamental Rights, and notably of its Article 21 . . . They must do so also when maintaining or introducing more stringent protective measures under Article 4(2) of Directive 2002/98/EC."[45] The Commission's answer represented a policy change, shifting the balance in favor of the fundamental rights of the MSM community over the power of the Member States to exclude MSM from blood donations.

Soon after the Commission's answer was released and the UK lifetime ban was lifted, Lesbian, Gay, Bisexual and Transgender ("LGBT") rights organizations all around Europe called attention to the Commission's insistence that Member States respect Article 21.[46] Despite this attention,

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[39] *Id.*

[40] *Id.*

[41] *Id*.

[42] Written Question E-006484/2011, 2012 O.J. (C 128 E) 1, 56 (indicating only number, author, and subject), *full text available at* http://www.europarl.europa.eu/sides/getDoc.do?type=WQ&reference=E-2011-006484&language=EN.

[43] *Id.*

[44] Answer from the Commission to Written Question E-006484/2011, *supra* note 2.

[45] *Id.*

[46] Press Release, The Eur. Parliament's Intergroup on LGBT Rights, European Commission: Banning Gay Men from Donating Blood is Against EU Law (Sept. 8, 2011), *available at* http://www.lgbt-ep.eu/press-releases/european-commission-banning-gay-men-donating-blood-against-eu-law/; Justine Quinn, *European Commission States that Blanket Ban on Gay Blood is Contrary to EU Law*, EQUALJUS (Sept. 8, 2011, 1:10 PM), http://www.equal-jus.eu/node/631; Jessica Geen, *One-Year Blood Donation Deferral for UK Gay Men*, PINK NEWS (Sept. 8, 2011, 11:33 AM), http://www.pinknews.co.uk/2011/09/08/one-year-blood-donation-deferral-for-uk-gay-men/.

other Member States have not been quick to relax MSM donation restrictions. Even within the UK, Northern Ireland refused to remove their lifetime ban.[47] Due to the strong perceptions of HIV prevalence within the MSM community, it will likely take an effort at the EU-level to change Member State donation policies.

D. Compatibility of EU and Member State Donation Policies

The main conflict between Member State and EU law arises in the non-discrimination provision of the Charter of Fundamental Rights of the European Union ("the Charter"). Though the Charter began as a non-binding declaration, the Treaty of Lisbon made The Charter legally binding on Member States when implementing EU law in 2009.[48] The Charter's anti-discrimination policy, listed in Article 21, states "[a]ny discrimination based on any ground such as sex, race, colour, ethnic or social origin, genetic features, language, religion or belief, political or any other opinion, membership of a national minority, property, birth, disability, age or sexual orientation shall be prohibited."[49] Sexual orientation is defined as "each person's capacity for profound emotional, affectional and sexual attraction to, and intimate relations with, individuals of a different gender or the same gender or more than one gender."[50] A man's capacity for sexual attraction and intimate relations with another man falls under the sexual orientation definition and therefore under the Charter's protections.[51]

Member States that impose lifetime bans or time-based deferrals on MSM blood donations, do so on the basis of sexual orientation, in conflict with the letter and spirit of Article 21. While Member States remain free to restrict blood donation on the basis of high-risk sexual behavior, they cannot conflate sexual orientation with high-risk sexual behavior.[52] Bans and deferrals presume that all MSM sexual behavior is inherently risky, rather than examining individual safe sex practices. While a safe blood supply remains an important and necessary objective, it must be balanced against fundamental rights against discrimination.[53]

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[47] *Lifetime Ban on Gay Men Donating Blood is 'Prejudicial,'* BBC NEWS (Sept. 22, 2011, 6:38 AM), http://www.bbc.co.uk/news/uk-northern-ireland-15014823.

[48] EUROPEAN COURT OF HUMAN RIGHTS & EUROPEAN UNION AGENCY FOR FUNDAMENTAL RIGHTS, HANDBOOK ON EUROPEAN NON-DISCRIMINATION LAW 15 (2011) [hereinafter NON-DISCRIMINATION HANDBOOK].

[49] Charter of Fundamental Rights of the European Union, 2010 O.J. (C 83) 396 [hereinafter The Charter].

[50] NON-DISCRIMINATION HANDBOOK, *supra* note 48, at 97.

[51] *Id.*

[52] Answer from the Commission to Written Question E-006484/2011, *supra* note 2.

[53] While one could analyze the donation bans through the lens of a fundamental freedom of movement or as the right to donate blood as a right in and of itself, this Note will

II. BROADER IMPLICATIONS OF MSM BANS

MSM blood donation policies affect both public health and the broader equal rights movement in the European Union.[54] Many studies have analyzed the potential impact of lifting the current bans on MSM blood donations.[55] While there is no definitive consensus on the risks of eliminating all restrictions, there is ample evidence that a lifetime ban is unwarranted.[56] Furthermore, removing MSM lifetime bans would promote equal rights by reducing the stigma created by the bans and demonstrating a commitment to ending discrimination based on sexual orientation.[57]

A. Blood Donation Policy and International Public Health

The current rate of HIV infection in the European Union is 5.8 per 100,000 people.[58] In 2010 alone the World Health Organization reported 118,335 new cases of HIV infections in 51 of their 53 European Region countries.[59] In the EU specifically, heterosexual transmission accounted for the largest percentage of newly diagnosed cases.[60] Once adjusted to exclude individuals originating from countries with generalized HIV epidemics, however, heterosexuals' share is reduced to 24%.[61] Therefore MSM contact remained the predominant form of transmission in the EU, accounting for 38% of the new diagnoses in 2010.[62]

The purpose of exclusionary criterion for blood donation is to minimize blood infection and disease exposure risks to the lowest feasible levels.[63] MSM blood donations pose the greatest threat during the "window period," or the time between the initial infection and possible detection by screening mechanisms.[64] The recent availability of nucleic acid amplification tests

not address these lines of argument.

[54] *See generally* SABTO REPORT, *supra* note 14, at 40.

[55] *See* discussion *infra* Part III.A.

[56] *Id*.

[57] *See* SABTO REPORT, *supra* note 14, at 43.

[58] EUR. CTR. FOR DISEASE PREVENTION & CONTROL & WORLD HEALTH ORG. REG'L OFFICE FOR EUR., HIV/AIDS SURVEILLANCE IN EUROPE 2010, at 22 (2011).

[59] *Id.* at 1.

[60] *Id*. at 2.

[61] *Id*.

[62] *Id.*

[63] William Leiss, Michael Tyshenko, & Daniel Krewski, *Men Having Sex with Men Donor Deferral Risk Assessment: An Analysis Using Risk Management Principles*, 22 TRANSFUSION MED. R. 35, 38 (2008).

[64] Ana M. Sanchez et al., *The Impact of Male-to-Male Sexual Experience on Risk Profiles of Blood Donors*, 45 TRANSFUSION 404, 405 (2005).

(NATs) dramatically reduces this window period.[65] The window period remains whether an individual is prompted to test by the development of symptoms or an asymptomatic choice.[66]

One solution to the window period problem is deferral periods for MSM donations, similar to the 2011 UK policy. As an example, Australia launched a nationwide one-year deferral policy in 2000, in an attempt to harmonize the disclosure and exclusion restrictions for blood donation between homosexual high-risk conduct and heterosexual high-risk conduct.[67] A one-year deferral after MSM sexual conduct created a safety net, allowing time to either develop symptoms or obtain accurate test results.[68] Ten years later, there is no significant increase in HIV infections among blood donors in Australia.[69] While there was a non-significant increase in the proportion of HIV positive donors declaring MSM as a risk after the one-year deferral was implemented, this can at least in part be attributed to the policy change "attracting additional HIV positive donors."[70] Similarly, Italy experienced a non-significant increase in HIV positive donors when it removed its MSM lifetime ban.[71]

Any risk-benefit analysis must first establish the empirical risks associated with each blood donation policy. The various donation policies reflect the policy choices countries made according to their unique HIV epidemiology, and not all results can necessarily translate across borders. While HIV prevalence is not identical across the Member States, the following studies provide useful data and conclusions generally applicable to the European Union.

First, many studies examine the effects of a lifetime ban in non-European countries, particularly the United States. If the United States were to eliminate the lifetime ban researchers estimate in the first year of implementation an additional 322 HIV positive donations would be made under a five-year deferral policy, or 1,645 donations under a one-year

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[65] *Id*.

[66] *Id.*

[67] Clive R. Seed et al., *No Evidence of a Significantly Increased Risk of Transfusion-Transmitted Human Immunodeficiency Virus Infection in Australia Subsequent to Implementing a 12-Month Deferral for Men Who Have Had Sex with Men*, 50 TRANSFUSION 2722, 2723 (2010).

[68] *Id*. at 2727.

[69] *Id*. at 2726.

[70] *Id*. These additional HIV donors failed to disclose that their MSM contact occurred within twelve months of donation, which violated the one-year ban imposed by Australia. *Id.* Had the donors disclosed this risk they would have been barred from donating. *Id*.

[71] *Id*. (citing C. Velati et al., *The Risk of HIV Transmission by Transfusion in Italy Does Not Increase after the Abolition of Ban on Blood Donations from Homosexual Men*, 93 VOX SANGUINIS (SUPPL. 1) 3, 9 (2007)).

deferral policy.[72] After the first year, however, the increased risk from either deferral policy would likely decrease four to five fold.[73] Additionally, accurate donor screening and blood testing could help alleviate these risk increases.[74]

Since the HIV incidence is much higher in the United States than the European Union, 22.8 versus 5.8 out of 100,000 persons respectively,[75] the United States may require more stringent precautions. The rate of HIV prevalence in Canada is more similar to the European Union, reporting 8.6 adults infected per 100,000 persons in 2009.[76] Though the MSM community in Canada accounted for 51% of the HIV/AIDS infections at the end of 2005,[77] researchers do not expect a quantifiable increase in infections if the Canadian lifetime ban on MSM donations were removed or replaced with deferral.[78]

The increased risk resulting from replacing a five-year deferral with a one-year deferral proved insignificant in Australia.[79] In 2000-2001, the first year of the one-year deferral period, the HIV positive residual risk in the donor pool was 1 in 3.4 million.[80] For the next three-year period the risk reduced to 1 in 7.3 million.[81] The high level of blood safety was largely attributed to the efficacy of nucleic acid amplification tests, which can detect HIV between 10 and 21 days after the donor is exposed to the virus.[82] As HIV positive blood can be effectively screened within two to three weeks of infection, "there is no scientific reason to differentiate between individuals infected a few months or many years previously."[83] The one-year period proved more than sufficient to eliminate the risks of MSM donation in the window period. The UK modeling used by the SaBTO, the Advisory Committee on the Safety of Blood, Tissues and

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[72] Steven A. Anderson et al., *Quantitative Estimate of the Risks and Benefits of Possible Alternative Blood Donor Deferral Strategies for Men Who Have Had Sex with Men*, 49 TRANSFUSION 1102, 1109 (2009).

[73] *Id.* at 1111.

[74] *See* discussion *infra* Part II.B.

[75] H. Irene Hall et al., *Estimation of HIV Incidence in the United States*, 300 JAMA 520, 520 (2008).

[76] PUB. HEALTH AGENCY OF CAN., HIV AND AIDS IN CANADA SURVEILLANCE REPORT TO DECEMBER 31, 2009, at 2 (2010).

[77] Leiss, *supra* note 63, at 45.

[78] *Id*. at 48.

[79] Seed, *supra* note 67, at 2728.

[80] *Id.* at 2727 (noting the risk in 1994-1995 was 1 in 1.3 million in Victoria, and in 1997 was 1 in 4.6 million for repeat donors in several of Australia's jurisdictions).

[81] *Id.*

[82] *Id*.

[83] *Id.*

Organs, estimates that under the lifetime ban HIV infections occur in 1 per 4.4 million donations.[84] If non-compliance remained the same, the number of infections per donation is 1 per 4.39 million under a five-year deferral and 1 per 4.38 million under a one-year deferral.[85] The new potential risk amounts to one additional HIV infected donation by a newly eligible MSM donor every 455 years for five-year deferral or 21 years for a one-year deferral.[86] This means if a one-year deferral is in place, the likely frequency of an HIV positive donation entering the blood supply and infecting a recipient is once every 21 years.[87]

Finally, it is difficult to calculate the effects of Spain and Italy's choice to remove all MSM bans or deferrals. Neither country has a nationwide blood transfusion service, increasing the difficulty of acquiring accurate data.[88] One study estimates that the rate of donors with HIV positive blood is 3.8 and 6.0 per 100,000 donations in Spain and Italy, respectively.[89] While these rates are notably higher than those in countries with bans on MSM donations,[90] there are other contributing factors. In Italy, the occurrence of HIV positive donors increased before lifting the MSM ban in 2001.[91] Furthermore, the low perception of the risk of acquiring HIV, "even among repeat donors, who are traditionally more responsible with regards to ineffective risks," is likely much higher there than in other countries.[92] The misperception problem is particularly acute for heterosexual unprotected sexual activity in Italy, where the risk of HIV contraction is largely unknown despite the fact that this constitutes the most frequent transmission method.[93]

B. Blood Donation Policy and Equal Rights

Member States should balance the safety of potential blood recipients against the rights of donors to be free of unfair discrimination by blood donation exclusions.[94] One balancing scheme to determine whether a

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[84] SABTO REPORT, *supra* note 14, at 48 (Table 7).

[85] *Id.*

[86] *Id.* at 47.

[87] *Id*.

[88] *Id.* at 49.

[89] Barbara Suligoi et al., *Epidemiology of Human Immunodeficiency Virus Infection in Blood Donations in Europe and Italy*, 8 BLOOD TRANSFUSION 178, 181 (2010).

[90] *Id.* Noting the rate of HIV positive donations in other countries was 0.2 in Sweden, 1.1 in UK, and 1.3 in France per 100,000 donations. *Id.* All three countries had permanent deferrals at the time the study was conducted. *Id*.

[91] *Id.* at 183.

[92] *Id.*

[93] *Id.*

[94] SABTO REPORT, *supra* note 14, at 52 ("In addition to its duty of care to patients in

freedom restriction is reasonable or justified, is the Canadian "Oakes test."[95] Under the Oakes test, Member States consider (1) the sufficient importance of blood safety, (2) the rational connection between the denial of MSM donations and blood safety and the smallest degree of impairment necessary to protect blood safety, and (3) the proportionate effect of the risks on blood recipients compared with the benefit of allowing MSM donations.[96]

Another approach is a multi-factor test, taking into account (1) evidence of the risk of transmission from donated blood, (2) whether the risk is sufficient to justify treating donors differently, (3) the feasibility and resource demand of setting narrower parameters, and (4) whether there is another reason to treat donor groups differently.[97] While the multifactor test directly incorporates the empirical safety data and quantitative consequences on the blood recipients and blood collecting institutions, the test places less of an emphasis on the proportionate effects of the risk and benefits.[98] Therefore, this Note will analyze the various blood donation policies through a hybrid test, combining elements of the multifactor test and the Oakes proportionate effect test to determine the correct balance of interests for both deferral and no restriction policies.

The first factor is the empirical risk of HIV transmission from MSM donated blood.[99] Recalling the study results discussed in Section A, the risk of HIV infection from donated blood varies between policies of lifetime bans, deferral periods, and no MSM restrictions.[100] In general, the infection risk increase from implementing either a one or five-year deferral was non-significant.[101] The risk increase from eliminating the MSM ban in favor of a behavior-based exclusion has less concrete data.[102] While the rate of HIV positive donors was objectively higher in countries such as Italy and Spain, many other factors influence those numbers outside of MSM

need of blood products, the health service also has a moral obligation to those who wish to donate blood. This includes an obligation to protect donors from harm but also an obligation not to unfairly discriminate against them.")

[95] Leiss, *supra* note 63, at 40-41.

[96] *Id*. at 41.

[97] SABTO REPORT, *supra* note 14, at 53.

[98] *Id*. The SaBTO Report factors do not make a strong effort the look at the proportional benefit to the MSM donors and the possible risks to the future blood recipients.

[99] *Id.*

[100] *See* discussion *supra* Part II.A

[101] M. Germain, R.S. Remis & G. Delage, *The Risks and Benefits of Accepting Men Who Have Had Sex with Men as Blood Donors*, 43 TRANSFUSION 25, 29 (2003) (using the Quebec population as the risk pool).

[102] *See* SABTO REPORT, *supra* note 14, at 49.

blood donations.[103]

An important factor in quantifying the transmission risk is the availability and accuracy of testing mechanisms. In Australia, the implementation of NAT testing reduced the window period between infection and possible detection from 22 days to 9 days.[104] The American Red Cross's duplicate testing, using both NAT and serological methods, reduced the detection time of HIV positive donors to between 10 and 21 days from infection.[105] Despite susceptibility to technical and human error, one study found that false-negative errors occurred only four times per 10 million screens for HIV.[106] Since the implementation of NAT testing the risk of false-negative results has been further reduced, particularly during the window period.[107]

Furthermore, compliance with stated restrictions and honest responses to behavioral questions are another vital factor in blood safety and testing accuracy.[108] The leading causes of noncompliance with MSM restrictions are categorizing oneself as low risk, misunderstanding the rule, and privacy concerns regarding sexual history.[109] The UK SaBTO study also noted that non-compliers were more likely to self-identify as straight men and less likely to have engaged in anal or oral sex within the past year.[110] As blood testing and donor compliance can largely mitigate the risk of transmission, either a one-year deferral or individualized screenings are objectively safe options.

The second factor weighs the transmission risk against the fundamental freedom violation.[111] The advent of effective testing mechanisms and maintaining current compliance levels reduced the window period of infection uncertainty to less than three weeks.[112] In 2006 the average rate of HIV-positive first time donors in Western Europe was 6.3 per 100,000.[113] In countries with lifetime MSM donor bans the overall rate varied from 2.6 in Sweden to 14.1 per 100,000 first time donors in Switzerland.[114] The lifetime MSM ban did not reduce the HIV positive donor pool or even exclude HIV positive donors below the European

[103] *See* Suligoi, *supra* note 89, at 70.

[104] Seed, *supra* note 67, at 2727.

[105] *Id*.

[106] M.P. Busch et al., *False-Negative Testing Errors in Routine Viral Marker Screening of Blood Donors*, 40 TRANSFUSION 585, 588 (2000).

[107] Germain, *supra* note 101, at 29.

[108] SABTO REPORT, *supra* note 14, at 50.

[109] *Id*.

[110] *Id*.

[111] *Id.* at 53.

[112] *See* discussion in Part II.A.

[113] Suligoi, *supra* note 89, at 180.

[114] *Id*.

average. Therefore, the transmission risk does not support subjecting MSM donors to a lifetime ban.

Time-based deferrals strike a closer balance between the increased risk of transmission during the waiting period and the generalized discrimination of MSM. Requiring an entire year of abstinence before donor eligibility may be excessive considering the accuracy of the NAT tests to under a month from infection. The one-year deferral rate has proven to be a safe policy in other countries like Australia, where the transmission risk has not increased any significant amount.[115] Additionally, the deferral period policy still equates sexual orientation to high-risk sexual behavior.

A short deferral period may be justified in Member States in which MSM are much more likely than heterosexual members to be HIV positive or screening compliance is low. For example countries like Italy with no formal MSM restrictions and a high overall HIV-positive first-time donor rate of 17.2 per 100,000 may provide a stronger case for a time-based deferral.[116] In Member States with such disparate rates, the concern of false-negatives during a reasonable waiting period may outweigh the individual rights of MSM donors. The UK data, which estimated the risk of undetected HIV infectious blood donation during the window period to occur in 1 in 5.8 million donations under the current testing regime, may assuage the concerns of waiting period errors.[117] Thus, while a one-year deferral policy would not be justified, a shorter period might be depending on the availability of testing and reporting compliance.

Member States that replaced MSM bans with individual risk assessments have not simply given greater weight to eliminating discrimination, but instead rely on the effectiveness of testing and donor screening mechanisms. While the data is not definitive on the effectiveness of testing in Spain and Italy, testing mechanisms have proven effective elsewhere, even in cases where donors are unaware of their recent HIV infection.[118] Furthermore, empirical studies have shown no significant increase in HIV positive donations in Italy since removing the ban on MSM donors.[119]Fully balancing the relevant interests requires more data, but the current safety standards can justify replacing a lifetime ban or time-based deferral with a high-risk behavior assessment, at least as long as the HIV positive donor pool does not increase.

The third factor is the practicality and cost of implementing narrower,

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[115] Seed, *supra* note 67, at 2722 (24 out of 4,025,571 donors under five-year deferral; 24 out of 4,964,628 donors under one-year deferral—note that this is the overall donor pool, not the first-time donor pool).

[116] *Id.*

[117] SABTO REPORT, *supra* note 14, at 40.

[118] Germain, *supra* note 101, at 29

[119] Seed, *supra* note 67, at 2726.

more individualized assessments in lieu of bans.[120] The European Union requires testing for HIV infection for whole blood and plasma donations.[121] For blood donation systems not currently using NAT screenings, national health care systems would pay between $155 and $558 million dollars each year to implement the testing procedure.[122] While the cost of implementation remains high, most Member States have already introduced NAT testing to screen for HIV in blood donations.[123] Some Member States, such as the UK for example, went beyond the simple NAT test and implemented a triplex HIV/HCV/HBV NAT assay on blood donation samples.[124] Therefore, as most Member States already effectively safeguard the removal of MSM bans through NAT testing, a new donation policy would incur minimal additional costs or administration concerns.

Finally, the fourth factor is whether other reasons exist to treat the donor group differently.[125] The primary reason to treat MSM donors differently from other donor groups is the generally higher prevalence of HIV infection and the perception of higher risk sexual behavior within the MSM population.[126] The higher incidence of HIV does not justify the bans because, as discussed above, testing and donor screening can adequately accommodate this concern. MSM donors may fall into other categories that employ restrictions, such as travel history or infections from other diseases,[127] but those characteristics are unique to each individual and cannot be applied to the whole MSM community. Therefore, no other valid reason exists to discriminate against MSM donors.

In light of the four quantitative factors discussed above, an evaluation of the proportionate effect between the risks of increased MSM donations against the benefits from allowing the donations adds another dimension to

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[120] SABTO REPORT, *supra* note 14, at 53

[121] Directive 2002/98, *supra* note 26, at 40 (Annex IV).

[122] B.R. Jackson et al., *The Cost-Effectiveness of NAT for HIV, HCV, and HBV in Whole-Blood Donations*, 43 TRANSFUSION 721, 723 (2003) (discussing the price of implementation in the United States in 2003).

[123] W.K. Roth et al., *International Survey on NAT Testing of Blood Donations: Expanding Implementation and Yield From 1999 to 2009*, 102 VOX SANGUINIS 82, 84 (2012). Germany was the first country to implement NAT testing, followed by others. According to the Commission, in 2010 the following countries implemented NAT testing for HIV: Belgium, Denmark, Germany, Ireland, Greece, Spain, France, Italy, Latvia, Lithuania, Luxembourg, the Netherlands, Austria, Poland, Portugal, Slovenia and Finland. Communication from the Commission on the Application of Directive 2002/98/EC, *supra* note 36, at 7.

[124] SABTO REPORT, *supra* note 14, at 40.

[125] *Id*. at 53.

[126] HOMOSEXUALITY: A EUROPEAN COMMUNITY ISSUE 153 (Kees Waaldijk & Andrew Clapham, eds., 1993).

[127] *See generally* Benjamin, *supra* note 9.

the risk-benefit analysis. One important benefit of removing barriers to MSM donations is the increase in national blood supplies. For example in the United States, researchers estimate that changing from a lifetime ban to a one-year deferral would allow an additional 75,190 donors without HIV to contribute to the blood supply.[128] Another benefit is the reduction of the social stigma associated with MSM and HIV/AIDS.[129] In addition to benefiting the MSM community, the reduced stigma would benefit the entire European Union by eliminating unjust and unreasonable discrimination against specific groups within its society.[130] MSM participants in the UK study reinforced this notion, expressing a strong belief in the right to fair treatment for all donors, independent of considering blood donation as an important individual right.[131] The discussion above has analyzed the risks associated with changing the policy, as well as effective safeguards for those risks. Balancing the proportionate effects is difficult because the risks are largely quantifiable whereas the benefits are more intangible in nature. Considering the reduced risk of transmission that NATs and donor screening allow, the societal benefits of removing lifetime MSM donor bans outweigh the risks.

III. CHALLENGING MEMBER STATE MSM BANS THROUGH EU LEGAL MECHANISMS

Blood donation policy reform would have a positive effect on the LGBT community and could provide an important legal precedent for challenging Member State laws that infringe on the fundamental right against discrimination.[132] This section will outline the procedural requirements and potential effectiveness of challenging the Member State bans through European mechanisms.

A. Jurisdiction to Challenge Member States' MSM Bans

1. The European Court of Justice

The European Court of Justice ("ECJ") is bound to enforce the provisions of the Treaty on the Functioning of the European Union ("TFEU") and the Charter of Fundamental Rights of the European Union ("the Charter").[133] The relevant anti-discrimination provisions are Article

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[128] Anderson, *supra* note 72, at 1107.

[129] Liess, *supra* note 63, at 48.

[130] *Id.*

[131] SABTO REPORT, *supra* note 14, at 50.

[132] *Id.* at 43.

[133] EUROPEAN UNION NON-DISCRIMINATION LAW: COMPARATIVE PERSPECTIVES ON MULTIDIMENSIONAL EQUALITY LAW 33-35 (Dagmar Schiek & Victoria Chege eds., 2009).

19 of the TFEU[134] and Article 21 of the Charter.[135] Both provisions include sexual orientation as a protected class.[136]

The ECJ has "jurisdiction in actions brought by a Member State, the European Parliament, the Council or the Commission on grounds of lack of competence, infringement of an essential procedural requirement, infringement of the Treaties or of any rule of law relating to their application, or misuse of powers."[137] The TFEU does not support a private right of action for individuals to challenge national laws as violating European law.[138] An individual litigant can only use the direct effects doctrine, developed through ECJ jurisprudence, to raise a "Euro-defense" in a national court to incorporate EU law into their claim.[139] Once a litigant successfully raises a question to the ECJ,[140] the Court may determine that a Member State "has failed to fulfill an obligation under the Treaties" and require the State to comply with corrective measures applied in the judgment.[141]

The restriction on private causes of action greatly limits the ECJ as a forum for challenging Member States' blood donation policies. Despite this limitation, other avenues to reaching an ECJ decision may provide relief. The legal process and likelihood of success will be discussed in Part B.

2. The European Court of Human Rights

Article 14 of the European Convention on Human Rights ("ECHR") provides that "[t]he enjoyment of the rights and freedoms set forth in this Convention shall be secured without discrimination on any ground such as sex, race, colour, language, religion, political or other opinion, national or social origin, association with a national minority, property, birth or other status."[142] While Article 14 only includes 'sex' and not 'sexual

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[134] TFEU art. 19 ("Without prejudice to the other provisions of the Treaties and within the limits of the powers conferred by them upon the Union, the Council . . . may take appropriate action to combat discrimination based on sex, racial or ethnic origin, religion or belief, disability, age or sexual orientation.").

[135] *See* discussion *supra* Part I.D.

[136] *Id.*

[137] TFEU art. 263.

[138] RALPH H. FOLSOM, PRINCIPLES OF EUROPEAN LAW 76 (2nd ed. 2005) (citing Joined Cases 31 & 33/62, Wöhrmann v. Comm'n, 1962 E.C.R. 501 (holding "[t]he parties to an action pending before a national court or tribunal are not entitled to make a direct request to the Court of Justice for a preliminary ruling. . . .")).

[139] *Id.* at 76-77.

[140] *See* discussion *infra* Part IV.B.I.

[141] TFEU art. 249.

[142] Convention for the Protection of Human Rights and Fundamental Freedoms, as

orientation,' the European Court of Human Rights ("ECtHR") "has expressly stated that sexual orientation is included among 'other' grounds protected by Article 14 . . . ."[143] Therefore, Member State laws that discriminate on the basis of sexual orientation violate the ECHR.[144]

The ECtHR has jurisdiction to resolve all interpretation and application issues under the ECHR and subsequent Protocols.[145] Individual victims of a Member States' violation of the Convention have direct access to the ECtHR under Article 34 of the ECHR.[146] The Court has defined a "victim" as someone who has been personally or directly affected by the alleged Convention violation.[147] Although there is a high level of access for individual applicants the Court strictly enforces the admission rules, rejecting 96% of cases due to admissibility requirements in 2003.[148]

To be admissible, an individual applicant under Article 34 must not be anonymous or present an issue that the Court has substantially examined already.[149] Additionally, an applicant must exhaust all domestic remedies and apply to the Court within six months after the final domestic decision.[150] Protocol No. 14 introduced another hurdle, denying admission for Article 34 applications (1) if the "applicant has not suffered a significant disadvantage" (2) "unless respect for human rights . . . requires an examination of the application on the merits" and (3) "provided that no case may be rejected on this ground which has not been duly considered by a domestic tribunal."[151]

Article 34 provides an opportunity for an individual right of action. Thus, a private litigant challenging the Member State's blood donation policies has direct access to the ECtHR. The actual legal process and likelihood of success will be addressed in Section B below.

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amended by Protocols Nos. 11 & 14, Nov. 4, 1950, C.E.T.S. No. 5 [hereinafter ECHR].

[143] NON-DISCRIMINATION HANDBOOK, *supra* note 48, at 98.

[144] While the ECHR is not a legal mechanism of the European Union, all Member States are bound by the Convention and EU citizens can enforce their rights before the ECtHR. NON-DISCRIMINATION HANDBOOK, *supra* note 48, at 15.

[145] ECHR, *supra* note 142, at 20 (art. 32(1)).

[146] *Id*. at 21 (art. 34).

[147] PHILIP LEACH, TAKING A CASE TO THE EUROPEAN COURT OF HUMAN RIGHTS 124 (2nd ed. 2005).

[148] *Id*. at 21.

[149] ECHR, *supra* note 142, at 21 (art. 35(2)(a)-(b)).

[150] *Id*. (art. 35(1)).

[151] *Id*. at 22 (art. 35(3)(b)).

B. Legal Process to Challenge the MSM Bans

1. European Court of Justice

An individual can challenge the MSM donation bans in the ECJ three ways: a preliminary question ruling, institutional litigation, or a dispute between Member States. While each route presents benefits and challenges, none are ideal to challenge MSM donation bans.

The first option to challenge the MSM donation ban is through preliminary question jurisdiction under Article 267 of the TFEU (formerly Article 234 TEC).[152] When a Member State court faces a question regarding the interpretation of the EU treaty or the validity of an EU institutional body action, that court may request a preliminary ruling from the ECJ.[153] To challenge MSM donor bans, a claimant would question whether the Member State's bar based on sexual orientation is incompatible with the EU anti-discrimination laws. The preliminary question approach presents several logistical problems. The national court, rather than the claimant, makes the decision to refer the question to the ECJ.[154] The wide discrepancy of Member States' courts willingness to refer questions to the ECJ further complicates this problem.[155] For example, countries such as Ireland, Spain, Finland and Denmark have each made less than 200 preliminary question referrals between 1961 and 2004.[156] In contrast, Germany, France and Italy have made about 1,400, 700 and 850 referrals respectively in the same time period.[157] A claimant choosing the preliminary question route should carefully consider which Member States' national courts are more likely to refer the question, but even then, referral is unpredictable. Therefore, preliminary question referral is not the ideal path for successfully challenging the validity of the MSM bans due to the high level of unpredictability in getting the question referred to the ECJ.

The second route is through institutional litigation. The European Commission has the authority to deliver an opinion to a Member State that "has failed to fulfill an obligation under the Treaties."[158] If the Member State fails to comply with the opinion, Article 258 of the TFEU (former Article 226 of the TEC) authorizes the Commission to bring the case before

[152] TFEU art. 267.

[153] *Id*.

[154] Marlene Wind et al., *The Uneven Legal Push for Europe*, 10 EUR. UNION POL. 63, 64 (2009).

[155] *Id*. at 66 (Table 2).

[156] *Id.*

[157] *Id*.

[158] TFEU art. 258.

the ECJ.[159] If properly motivated, the Commission could issue an opinion to one or all Member States with discriminatory MSM bans alleging discrimination in violation of the TFEU and the Charter. States that did not reform their policies would be subject to ECJ litigation.[160] An individual or politically unconnected group will face difficulty convincing the Commission to issue an opinion, although the Commission has initiated thousands of infringement proceedings against Member States in the past.[161] More importantly, institutional litigation faces the same problem of indirectness as the preliminary question. The Commission, a disinterested third party, must decide whether to pursue the case. Institutional litigation does provide more flexible timing and the ability to multiple chances to bring attention to the violation, whereas one unsuccessful appeal to a Member State judge terminates the preliminary question route.

The third option is a dispute between two Member States. Article 273 of the TFEU (former Article 239 of the TEC) grants the ECJ jurisdiction to hear "any dispute between Member States which relates to the subject matter of the Treaties if the dispute is submitted to it under a special agreement between the parties."[162] Additionally, Article 259 (former Article 227 of the TEC) allows a "Member State which considers that another Member State has failed to fulfill an obligation under the Treaties" to bring the matter before the ECJ.[163] This route of ECJ jurisdiction also faces several challenges. Proceeding under Article 273 is particularly difficult because an individual or group must successfully convince one Member State to bring an action against another Member State, as well as convince both Member States to consent to a special agreement. Due to the high level of complexity involved in Article 273 cases, Article 259 is the preferable Member State conflict approach.

Under Article 259, a Member State must first allege that another State failed to fulfill an obligation under the Treaties in an action before the Commission.[164] Similar to the institutional approach, the Commission then delivers an opinion after each State presents its case.[165] If the Commission does not deliver an opinion within three months, the parties may bring the issue before the ECJ.[166] This route's major challenge is persuading a Member State to initiate a claim. On one hand, individuals looking to

[159] *Id*.

[160] *Id.*

[161] Folsom, *supra* note 138, at 98.

[162] TFEU art. 273.

[163] *Id*. at art. 259.

[164] *Id*.

[165] *Id*.

[166] *Id*.

challenge the MSM ban may have closer ties, and thus more influence, with their own Member State leaders than with the Commission. Member States, however, are reluctant to initiate claims against each other for diplomatic and institutional reasons.[167] Instead, Member States generally prefer to persuade the Commission to initiate institutional litigation.[168] As Member State disputes often lead to Commission intervention, a challenger ultimately has the same likelihood of success either way.

All three of these paths to ECJ litigation present significant procedural obstacles. Institutional litigation is probably the most feasible path for challengers of MSM donor restrictions, though this will depend on a challenger's resources and political connections.

2. European Court of Human Rights

An individual seeking to challenge a MSM donation ban as a violation of Article 14 of the ECHR has jurisdiction under Article 34.[169] The individual must still exhaust the remedies available at the Member State level.[170] The applicant may lodge a complaint simultaneously with both the domestic court and the ECtHR, and the ECtHR application process will open once the domestic litigation is complete.[171] To successfully arrive at the ECtHR, the applicant must not accept a settlement from domestic proceedings, as this may preclude an applicant from qualifying as a "victim" any longer.[172] Otherwise, a MSM applicant would be considered a victim under the Court's test because the discriminatory law directly affects him.[173] For the purposes of proving personal or direct effect, the MSM applicant should try to donate blood and maintain documentation of their rejection due to MSM status. In meeting the requirements under Article 35(3)(b), an MSM applicant would first argue that he suffered a significant disadvantage during his attempt at blood donation because he faced discrimination due to sexual orientation.[174] If the Court does not accept blood donation exclusion as a significant disadvantage because there is no fundamental right to donate blood, the applicant could alternatively argue that respect for human rights warrants an examination on the merits.[175] As the blanket bans on

[167] Folsom, *supra* note 138, at 98.

[168] *Id*.

[169] ECHR, *supra* note 142, at 21 (art. 34).

[170] *Id*.

[171] LEACH, *supra* note 147, at 22.

[172] *Id*. at 126 (citing Calvelli & Ciglio v. Italy, 2002-I Eur. Ct. H.R. 11).

[173] *Id*.

[174] ECHR, *supra* note 142, at 22 (art. 35).

[175] *Id*.

MSM donations are unquestionably discriminatory,[176] respect for human rights warrants at least an inquiry into the validity of the laws.

In considering the merits of a MSM donation ban challenge, the ECtHR would look at whether the individual faced discrimination and whether the differential treatment was proportional to the policy goals.[177] The Court's discrimination test determines whether the individual received different treatment from people in a similar situation for a prohibited reason, and whether that different treatment has a reasonable and objective justification.[178] For an MSM attempted donor who was rejected on the basis of his sexual orientation, the definition of "similar situation" is crucial to the outcome of the discrimination test. If "similar situation" is limited to other MSM applicants, then differential treatment is absent. Applying "similar situation" in this manner would render the discrimination test ineffective, because any restriction that targets an entire group could not meet the requirement. The more appropriate definition of "similar situation" includes all men with similar levels of risky behavior. Then, an MSM donor would meet the standard because he received different treatment than heterosexual men with similar behavior on the basis of a restricted ground.

The Court applies the second part of the discrimination test by considering whether the different treatment pursues a legitimate goal and is proportionate to the goal.[179] Safeguarding the blood supply is undeniably a legitimate goal, so the focus is whether the discrimination is proportionate. The Court balances the discriminatory law's benefits and harms and examines whether a "pressing social need" justifies the measure.[180] In the case of MSM donation exclusions, a legitimate aim (blood safety) is balanced against the harms of discrimination (reinforcing social stigma and violation of a fundamental right against discrimination). An applicant should argue that the accuracy of NAT testing and stable donor compliance has removed any pressing social need that might once have supported MSM donation bans. Therefore, a MSM applicant should be able to bring his claim to the ECtHR.

IV. CONCLUSION

This Note considers the legality of the Member States' MSM blood donation bans under European Union law, and explores the EU-level mechanisms available to challenge them. The lifetime bans on MSM

[176] Leiss, *supra* note 63, at 49.

[177] LEACH, *supra* note 147, at 349.

[178] *Id.*

[179] *Id.*

[180] *Id.* at 163.

donations violate the fundamental right of freedom from discrimination based on sexual orientation. The quantitative risks of removing the bans fail to justify the discriminatory law. A claimant may challenge a Member State's donation policies through either the European Court of Justice or the European Court of Human Rights legal framework. Due to the availability of an individual cause of action and a strong anti-discrimination provision, however, the European Court of Human Rights provides the most appropriate forum to challenge the discriminatory bans.