

Note

Bad Blood: An Examination of the Constitutional Deficiencies of the FDA’s “Gay Blood Ban”

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When twenty-six-year-old Evan Low was sworn in as the mayor of Campbell, California, he made headlines as the youngest Asian-American, openly gay mayor in the nation.¹ As a result of his dedication to civic engagement, government transparency, and fiscal responsibility, Mayor Low enjoyed popularity and respect as a public servant.² Mayor Low did not, however, receive similar treatment under the law as a gay man. Though Mayor Low now has access to rights that, until recently, were unavailable to him and other LGBT Americans, such as marriage and federal tax benefits, he is still barred from donating blood pursuant to federal policy which bans gay men from donating blood.³ Despite coordinating a blood drive

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1. Chris Vongsarath, *Campbell’s Evan Low Sworn in As Youngest Asian-American, Openly Gay Mayor in the Country*, SAN JOSE MERCURY NEWS (Dec. 2, 2009), http://www.mercurynews.com/breaking-news/ci_13909520.

2. *Id.*

3. Tracy Miller, *California Mayor Calls for End to FDA Ban on Gay Male Blood Donations*, DAILY NEWS (Aug. 21, 2013), <http://www.nydailynews.com/life-style/health/calif-mayor-calls-gay-blood-donor-ban-article-1.1433054>. The recent Supreme Court decision in *United States v. Windsor* furthered what many call the “gay rights” movement by striking down a key portion of the Defense of Marriage Act (DOMA), which discriminated against homosexuals as a class. Defense of Marriage Act, Pub. L. No. 104-199, § 3, 110 Stat. 2419, 2419 (1996), *invalidated by* *United States v. Windsor*, 133 S. Ct. 2675, 2695–96 (2013). Many states have also legalized gay marriage. Ryan L. Sievers, *Same-Sex Marriage Is Legal in 16 States, and This Is Good*, CHICAGONOW (Nov. 16, 2013, 12:41 AM), <http://www.chicagonow.com/art-of-business/2013/11/same-sex-marriage-is-good>.

with the American Red Cross, Mayor Low was not allowed to donate blood at the event.⁴ The ban, enacted in 1983, prohibits all men who have had sex with other men (MSM) since 1977 from donating blood, and is regarded by many as being unnecessarily discriminatory.⁵

Mayor Low is only the latest in an ever-increasing line of individuals who have been banned from donating blood since the guideline was implemented in 1983.⁶ The Food and Drug Administration (FDA) currently prohibits MSM from donating blood due to concerns that, as a population, MSM are at a higher risk for carrying HIV, hepatitis B, and other diseases that are transmittable via blood transfusions.⁷ The FDA's concern of assuring the safety of patients receiving blood was the primary impetus for the ban.⁸ The guideline was thus first implemented at the outset of the HIV/AIDS epidemic, when the disease was most rampant in the MSM community.⁹ Even as late as 2010, the MSM population accounted for 61% of new HIV infections, and 77% of male HIV infections were attributed to male-to-male sexual contact.¹⁰

Though the FDA currently cites statistics to justify its policies, many argue that the guidelines are now outdated and no longer based on "sound science."¹¹ Others contend that the ban is discriminatory and, as such, unconstitutional under U.S. law.¹² The FDA disagrees with both arguments and to this day maintains its "gay blood ban."¹³ Recent developments may see a

4. Miller, *supra* note 3.

5. *See id.*

6. *See id.*

7. *Blood Donations from Men Who Have Sex with Other Men Questions and Answers*, FDA, <http://www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/QuestionsaboutBlood/ucm108186.htm> (last updated Mar. 8, 2015) [hereinafter FDA Guidelines]. For the sake of consistency, this Note will refer to the FDA's policy as the "gay blood ban" throughout. Note that the FDA has recently indicated its willingness to alter the policy. *See infra* Part I.B. However, as this Note will discuss, this does not ameliorate the substantive problems of the current policy.

8. *See* FDA Guidelines, *supra* note 7.

9. *See id.*

10. *Id.*

11. Gillian Mohny, *FDA Ban on Gay Men as Blood Donors Opposed by American Medical Association*, ABC NEWS (June 20, 2013), <http://abcnews.go.com/Health/american-medical-association-opposes-fda-ban-gay-men/story?id=19436366> (quoting American Medical Association board member Dr. William Kobler).

12. *See* Miller, *supra* note 3.

13. *See* FDA Guidelines, *supra* note 7 (contending that the guideline "is not based on any judgment concerning the donor's sexual orientation," and

modified ban implemented in the near future, but as this Note will discuss, those changes are insufficient. Despite the FDA's attempts at justifying the ban, the fact remains that heterosexual individuals who engage in risky sexual behavior, gay women, and other populations with potential exposure to HIV and other diseases face no such ban.¹⁴

The gay blood ban raises several questions of law. This Note examines those issues and offers a solution that attempts to bridge the gap between the government's need to ensure the safety of the blood supply while also respecting the dignity of an oft-maligned population. Part I discusses the background and rationale for the original implementation of the gay blood ban, as well as recent developments in science, society, and law that affect the issue. Part II briefly analyzes legal and normative questions raised by the ban before delving into the most viable challenge to the ban, based on constitutional principles of equality. Part III offers a new framework by which the FDA can effectively and in a nondiscriminatory manner regulate the nation's blood supply.

I. DEVELOPMENT OF THE HIV EPIDEMIC AND SUBSEQUENT REGULATION

Though HIV and AIDS are understood in the scientific community today, this was not always the case.¹⁵ This Part examines both the history of the HIV/AIDS epidemic and the subsequent regulatory framework that arose as an attempt to protect the nation's blood supply. Section A briefly recounts the history of the HIV/AIDS epidemic in the context of its association as a "gay" disease as well as the developments in science and medicine that have led to current general knowledge of the virus. Section B discusses the history of the FDA's regulatory approach to the HIV virus in the context of blood donations.

A. HISTORY OF THE HIV/AIDS EPIDEMIC

The association between gay men and HIV, and the fears consequently produced by the connection, were justified at one point. The beginning years of the epidemic in the United States were filled with confusion and uncertainty. Cases were report-

that currently cited statistics are sufficient evidence for continuing the ban).

14. *Id.*

15. AIDS is the syndrome of medical complications arising from an HIV infection. See generally *What Is HIV/AIDS?*, AIDS.GOV, <http://www.aids.gov/hiv-aids-basics/hiv-aids-101/what-is-hiv-aids> (last updated Apr. 29, 2014) (explaining the relationship between HIV and AIDS).

ed as early as October of 1980, when an individual dubbed “Patient Zero” infected men at a New York City bath house with the virus that would eventually come to be known as HIV.¹⁶ The new disease was first acknowledged by the Centers for Disease Control (CDC) when it published reports of a rare lung infection, *Pneumocystis carinii pneumonia* (PCP), affecting several otherwise healthy young gay men in Los Angeles.¹⁷ Within days of the publication, doctors across the United States inundated the CDC with reports of similar infections in young gay men.¹⁸ Subsequent reports of diseases in the gay community were not confined to PCP. Other diseases that were reported included Kaposi’s Sarcoma, an unusually aggressive cancer that until then was a rare occurrence.¹⁹ The infections were exclusive to gay men at this point.²⁰

The still-unknown disease affecting men mostly in New York and California became so associated with homosexuals that it was initially called the “Gay-related immune disease,” and this name gained some popularity until the occurrence of infections in heterosexual Haitians.²¹ Though other populations, such as hemophiliacs,²² soon joined homosexuals and Haitians as groups associated with the disease, in the public’s eye the disease was largely a homosexual problem.²³ It was not until July of 1982 that the disease was officially renamed as “acquired immunodeficiency syndrome,” or AIDS.²⁴

When it became clear in 1982 that a new disease was rapidly spreading throughout the United States, several clinics and medical service organizations cropped up throughout the country, many emphasizing health services for gay men.²⁵ At

16. *AIDS in New York: A Biography*, N.Y. MAG., <http://nymag.com/news/features/17158> (last visited Apr. 20, 2015).

17. *A Timeline of AIDS*, AIDS.GOV, <http://aids.gov/hiv-aids-basics/hiv-aids-101/aids-timeline> (last visited Apr. 20, 2015).

18. *Id.*

19. *Id.*

20. *Id.*

21. *AIDS in New York*, *supra* note 16.

22. Hemophilia is a blood disorder that prevents blood from clotting properly in wounds. As a result, hemophiliacs bleed for longer periods of time, which is not a problem for cuts but can become life-threatening with larger injuries. *Hemophilia*, MAYO CLINIC (Sept. 26, 2014), <http://www.mayoclinic.org/diseases-conditions/hemophilia/basics/definition/con-20029824>.

23. *AIDS in New York*, *supra* note 16.

24. *Id.*

25. *A Timeline of AIDS*, *supra* note 17. A few examples include New York City’s Gay Men’s Health Crisis, the nation’s first community-based HIV/AIDS service provider, the San Francisco AIDS Foundation, and the first American

this time, little was known about the disease, and Congress passed reactive legislation to fund surveillance and AIDS research through the CDC and the National Institutes of Health.²⁶ In April of 1982, the first CDC estimate of the population affected by the disease numbered in the tens of thousands.²⁷ In late 1982, an AIDS infected donor transmitted the disease to an infant through a blood transfusion, causing the nation's first panic over the blood supply.²⁸

The final straw concerning blood donations was conclusive research indicating that AIDS was transmitted through sexual contact and, potentially, blood transfusions.²⁹ One 1983 Morbidity and Mortality Weekly Report indicated that the occurrence of AIDS cases paralleled that of another sexually transmitted disease, hepatitis B, and that "[t]he likelihood of blood transmission is supported by the occurrence of AIDS among IV drug abusers."³⁰ At this time, there was no way to detect AIDS in asymptomatic patients, and the precise cause was still unknown.³¹ Though the Report outlined some ways by which to reduce risk of infection, it conceded that, until AIDS was better understood by the medical community, the organization's ability to detect and prevent the disease was "somewhat compromised."³²

With widespread awareness of AIDS came concern over the nation's blood supply. Already fueled by cases of infection through blood transmission, the CDC initially recommended that all at-risk populations, such as intravenous drug users and MSM, refrain from donating blood or plasma.³³ According to the FDA, 1983 marked the first time that the MSM population was

AIDS clinic, established in San Francisco. *Id.*

26. *Id.*

27. *Id.*

28. *AIDS in New York*, *supra* note 16.

29. CDC, *Current Trends Prevention of Acquired Immune Deficiency Syndrome (AIDS)*, 32 MORBIDITY & MORTALITY WKLY. REP. 101 (Mar. 4, 1983), available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/00001257.htm>.

30. *Id.*

31. *Id.*

32. *Id.*

33. *Id.* Though blood donation guidelines had not yet been affected by concern for the blood supply, signs were already indicating that the FDA was preparing a guidelines overhaul. *Id.* ("The Food and Drug Administration (FDA) is preparing new recommendations for manufacturers of plasma derivatives and for establishments collecting plasma or blood. This is an interim measure to protect recipients of blood products and blood until specific laboratory tests are available.")

singled out and discouraged from donating,³⁴ though the ban would not become codified in FDA regulations until 1992.³⁵ Though undeveloped guidelines were implemented in 1983, the response of the FDA and the blood banking industry was highly criticized as “woefully inept” and ineffective at initially protecting the blood supply.³⁶ Given that the precise viral origin of AIDS was still unknown, there was no way to screen for infected blood, and so deferral³⁷ of the MSM population eventually gained traction as the next best viable option.³⁸

The “blood ban” did not originally apply to all individuals in the MSM population. Initially, the Public Health Service only identified homosexual and bisexual men who had multiple sex partners as one of the high-risk groups, and accordingly recommended that they defer from donating.³⁹ Though some groups argued that the recommendation went too far in discriminating against the gay male population, others criticized the ban for not going far enough.⁴⁰ Eventually, the FDA issued guidelines meant to serve as a temporary fix, and the gay community reluctantly acquiesced to the policy.⁴¹ In 1992, however, the ban became permanent, and the FDA instituted a lifetime blood donation ban on the MSM population without regard to other factors, such as number of sex partners or history of drug use.⁴² Given the ominous danger of infection through blood transfusions,⁴³ the subsequent public health concerns,

34. See Shawn Carroll Casey, *Illicit Regulation: A Framework for Challenging the Procedural Validity of the “Gay Blood Ban,”* 66 FOOD & DRUG L.J. 551, 551 (2011) (noting that, at first, the CDC only “recommended” that high risk groups, including MSM, be asked to defer from donating).

35. FDA Guidelines, *supra* note 7. As a federal agency, the FDA has the power to make rules. 5 U.S.C. § 553 (2012). Several laws give the FDA the authority to specifically regulate the nation’s blood supply. Food, Drug, and Cosmetics Act, 21 U.S.C. § 301 (2012); Public Health Service Act, 42 U.S.C. § 201 (2012); Biologics Act, 42 U.S.C. § 262 (2012).

36. See Linda M. Dorney, *Culpable Conduct with Impunity: The Blood Industry and the FDA’s Responsibility for the Spread of AIDS Through Blood Products*, 3 J. PHARMACY & L. 129, 130 (1994).

37. For the purposes of this Note, the “gay blood ban” refers to the FDA’s current policy, *supra* note 7, and a “deferral” refers to any period of time an MSM must abstain from having sexual relations in order to donate blood (for example, a one year period).

38. See Casey, *supra* note 34, at 554.

39. CDC, *supra* note 29.

40. Casey, *supra* note 34, at 554–56.

41. See *id.* at 555.

42. See FDA Guidelines, *supra* note 7.

43. See Francine A. Hochberg, *HIV/AIDS and Blood Donation Policies: A Comparative Study of Public Health Policies and Individual Rights Norms*, 12 DUKE J. COMP. & INT’L L. 231, 235 (2002) (“[T]he success of HIV transmission

and general ignorance of how the disease worked, as well as how to screen it, the ban, at the time it was implemented, was the best way to prevent the spread of AIDS.⁴⁴

B. A NEW REGULATORY REGIME: RESPONSES TO THE HIV/AIDS EPIDEMIC

As science and technology change, so do societal views. In some instances, the legal landscape reflects these alterations. Fifteen years ago, the concept of same-sex marriage was a novel idea and far from reality; today thirty-seven states and the District of Columbia have legalized same-sex marriage.⁴⁵ Similarly, the evolving landscape of medical knowledge, or the lack thereof, greatly impacted HIV/AIDS regulation across the board and continues to do so.⁴⁶ This Section recounts the history of the regulatory framework arising out of the HIV/AIDS epidemic. It also discusses the FDA's recent statements regarding a potential policy change—one that still raises the problems of the lifetime ban.

As AIDS became more widespread throughout the country, so did the impetus to understand the disease. It was no longer a mysterious illness affecting a small population, rather, “the greatest tragedy of the twentieth century.”⁴⁷ With the drive to understand the new killer disease came a wealth of scientific information and, eventually, the development of technologies that led to a better understanding of how AIDS worked and how to prevent its transmission.⁴⁸

is over 90% when infected blood is transfused to a formerly uninfected person.”) (citing BARRY D. SCHOUB, AIDS AND HIV IN PERSPECTIVE: A GUIDE TO UNDERSTANDING THE VIRUS AND ITS CONSEQUENCES 111, 114 (2d ed. 1999)).

44. See Mike Darling, *Banned for Life*, MEN'S HEALTH (2013), <http://www.menshealth.com/banned-for-life> (noting that there was no viable way of testing blood or plasma for HIV at the time the bans were implemented).

45. See *Same-Sex Marriage Laws*, NAT'L CONF. ST. LEGISLATURES (Feb. 19, 2015), <http://www.ncsl.org/research/human-services/same-sex-marriage-laws.aspx>. The issue of same-sex marriage continues to be in the spotlight, as the Sixth Circuit recently upheld bans against same-sex marriage, creating the first circuit split on the issue. *Id.*

46. For instance, current laws criminalizing knowing infection of sexual partners with HIV has in recent years been criticized as the landscape has shifted. See generally Kim Shayo Buchanan, *When Is HIV a Crime? Sexuality, Gender and Consent*, 99 MINN. L. REV. 1231 (2015) (arguing that decriminalization would best address the “discriminatory social meaning and effects of HIV criminalization”).

47. Muser Entertainment, *Madonna - In This Life (The Girlie Show)*, YOUTUBE (Mar. 7, 2009), <http://www.youtube.com/watch?v=7sBOxrsCmPo> (dedicating a song to her friends who died from AIDS).

48. See generally Mohny, *supra* note 11 (discussing the request of the

In 1985, shortly after acceptance of the MSM donor ban became mainstream, HIV was officially identified as the retrovirus responsible for AIDS.⁴⁹ Following this discovery, the FDA licensed a test for the purpose of detecting HIV's presence in donated blood and blood products, known as the enzyme-linked-immuno-sorbent-assay, or ELISA.⁵⁰ Though this test was a breakthrough, estimates indicated that adding the test to the blood collection process would be expensive.⁵¹ In the midst of this developing technology and increasing ability to test accurately for HIV/AIDS, the FDA tightened its donation policy in 1992.⁵² The resulting policy banned all men who had engaged in sexual activities with other men since 1977 from donating blood.⁵³ Though the ELISA test was the beginning, it certainly was not the most effective method of HIV detection.⁵⁴ As recently as 2012, a testing method known as Nucleic Acid Testing (NAT) has been offered as a more effective method of HIV detection.⁵⁵ It is more accurate and yields quicker results.⁵⁶ Instead of testing for HIV antibodies, NAT uses primers that identify RNA or DNA in blood samples as HIV-1 RNA, and is used for detecting other diseases as well.⁵⁷ Studies indicate that NAT testing has increased HIV detection yield by 23%.⁵⁸

With an ever-increasing body of knowledge and technology better equipped to test for the virus in blood samples, the gay

U.S. Department of Health and Human Services for "information from additional studies on the potential outcomes of changing the blood donation criteria").

49. Casey, *supra* note 34, at 556.

50. See *Doe v. Am. Nat'l Red Cross*, 866 F. Supp. 242, 244–45 (D. Md. 1994).

51. See *id.* at 245.

52. Casey, *supra* note 34, at 556.

53. *Id.*

54. See generally FDA, GUIDANCE FOR INDUSTRY USE OF NUCLEIC ACID TESTS ON POOLED AND INDIVIDUAL SAMPLES FROM DONORS OF WHOLE BLOOD AND BLOOD COMPONENTS, INCLUDING SOURCE PLASMA, TO REDUCE THE RISK OF TRANSMISSION OF HEPATITIS B VIRUS (2012), available at <http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/UCM327895.pdf>.

55. *Id.* Various iterations of the test were first licensed by the FDA for use beginning in 2006 or so, but the FDA began to encourage their use much later. *Id.*

56. See Debra Kain, *Adding Nucleic Acid Testing to HIV Screening May Help Identify More People with HIV*, UC SAN DIEGO NEWS CENTER (June 15, 2010), <http://ucsdnews.ucsd.edu/archive/newsrel/health/06-15TestingHIV.asp>.

57. FDA, *supra* note 54, at 2.

58. Kain, *supra* note 56.

blood ban is losing popularity in the medical community⁵⁹ and general population.⁶⁰ Other countries, which previously had followed the United States' lead in instituting lifetime bans, have now lifted those bans partially or entirely.⁶¹ As early as 1992, the Department of Health and Human Services indicated that HIV infections represented only a "minimal" risk to the blood supply.⁶² The Health and Human Service's Advisory Committee on Blood Safety and Availability (ACBSA) recently found that the current donation policies, while effective at excluding some high risk donors, also potentially excludes low risk donations, and as such has recommended a reevaluation of the current guideline.⁶³ The FDA ardently opposes updating its current policy, however, stating that it would "change this policy only if supported by scientific data showing that a change in policy would not present a significant and preventable risk to blood recipients."⁶⁴ The FDA maintains that there is no threat to the blood supply, that the MSM population remains the most high-

59. See Mohny, *supra* note 11 (noting that the American Medical Association now opposes the ban, arguing that "[t]he lifetime ban on blood donation for men who have sex with men is discriminatory and not based on sound science" (quoting AMA board member Dr. William Kobler)).

60. See Darling, *supra* note 44; Tyler Smith, *Gay Blood Considered Risk for Donation*, FOURTH EST. (Sept. 6, 2013), <http://www.fourthstatenewspaper.com/opinion/2013/09/06/gay-blood-considered-risk-for-donation>.

61. See generally Clive R. Seed et al., *No Evidence of a Significantly Increased Risk of Transfusion-Transmitted Human Immunodeficiency Virus in Australia Subsequent to Implementing a 12-Month Deferral for Men Who Have Had Sex with Men*, 50 TRANSFUSION 2722 (2010); Philip Caulfield, *Britain To Allow Gay Men To Donate Blood*, DAILY NEWS (Apr. 10, 2011, 11:46 AM), <http://www.nydailynews.com/news/world/Britain-gay-men-donate-blood-policy-step-u-s-ban-gay-donors-article-1.110214> (reporting that Britain will institute a ten-year deferral period in place of the previous lifetime ban); Scott Roberts, *Mexico Lifts Ban on Gay Men Donating Blood*, PINK NEWS (Dec. 27, 2012, 6:29 PM), <http://www.pinknews.co.uk/2012/12/27/mexico-lifts-ban-on-gay-men-donating-blood> ("Gay and bisexual men, who have a history of using condoms, who do not inject drugs, and are not sex workers can now donate."); Elizabeth Trovall, *Gays and Lesbians in Chile Now Allowed To Donate Blood*, SANTIAGO TIMES (Apr. 25, 2013), <http://www.archive.today/KNJUm> (reporting a lift of Chile's current ban with no time deferrals).

62. Memorandum from the Dir. of the Ctr. for Biologics Evaluation & Research to All Registered Blood Establishments, Revised Recommendations for the Prevention of Human Immunodeficiency Virus (HIV) Transmission by Blood and Blood Products (Apr. 23, 1992) (on file with the FDA), *available at* <http://www.fda.gov/downloads/UCM062834.pdf>.

63. FDA Guidelines, *supra* note 7.

64. *Id.* There was also considerable doubt as to whether the FDA could change this policy even if it had the desire to do so without going through the arduous notice and comment procedure. See *Paralyzed Veterans of Am. v. D.C. Arena L.P.*, 117 F.3d 579, 586 (D.C. Cir. 1997); *infra* Part II.B.2.

ly susceptible to HIV infection, and that testing technology is not adequate to justify a lift on the ban.⁶⁵

Though the FDA argues that the MSM population is still high risk to the point of justifying a ban, it has indicated a willingness to modify its policy. On December 23, 2014, the FDA issued a statement indicating that, in light of scientific data and the recommendations of advisory committees to the U.S. Department of Health and Human Services (HHS), it will soon consider altering the ban.⁶⁶ Specifically, the FDA is willing to “change . . . the blood donor deferral period for men who have sex with men from indefinite deferral to one year since the last sexual contact.”⁶⁷ Taking note of its prior error in implementing the lifetime ban, the FDA plans to initiate the appropriate notice and comment procedure.⁶⁸

Substantively, this development does little, if anything, to improve the current state of affairs for gay and bisexual men. The notice and comment procedure does not guarantee that the FDA will implement the new policy, only that it will *consider* its implementation. Further, the FDA will *not* consider lifting the ban in its entirety.⁶⁹ For some, this may appear to be progress. But this is the bottom line: the best case scenario sees the FDA implementing a one-year deferral period specifically addressing the MSM population; the worst case scenario sees no change in the policy if the notice and comment procedure results in enough opposition to the proposed change. Despite its

65. See *infra* Part II.B.2.

66. FDA Commissioner Margaret A. Hamburg’s Statement on FDA’s Blood Donor Deferral Policy for Men Who Have Sex with Men, FDA (Dec. 23, 2014), <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm427843.htm> [hereinafter *FDA Statement*].

67. *Id.*

68. *Id.* (“The FDA intends to issue a draft guidance recommending this proposed change in policy in 2015, which will also include an opportunity for public comment. We encourage all stakeholders to take this opportunity to provide any information the agency should consider, and look forward to receiving and reviewing these comments.”).

69. The FDA has already indicated an extreme reluctance in even altering the policy. See *FDA Panel Wary of Lifting Ban on Gay Blood Donors*, WTSP.COM (Dec. 3, 2014, 4:26 PM), <http://www.wtsp.com/story/news/health/2014/12/03/fda-panel-wary-of-lifting-ban-on-gay-blood-donors/19851057> (stating that the FDA’s experts did not embrace even the twelve-month deferral period proposal). One FDA official stated, “If I look at the science I would be very wary of a one-year deferral It sounds to me like we’re talking about policy and civil rights rather than our primary duty, which is transfusion safety.” *Id.* (quoting Dr. Susan Leitman).

willingness to consider a policy alteration, the FDA's position on HIV and the gay male population has not changed.⁷⁰

The FDA's assertions regarding HIV infections in the gay male population are not completely unfounded. Despite years of prevention and HIV awareness efforts and improved testing technology, the HIV infection rate in the U.S. has remained stable.⁷¹ In addition, early detection, which is critical to controlling the epidemic, is potentially challenging due to the window of time immediately following infection when testing accuracy is low.⁷² Perhaps the most unsettling fact is that young gay men are increasingly becoming infected with HIV, despite the fact that infection rates remain stable.⁷³ Of the 47,500 Americans who were infected with HIV in 2010, 26% were adolescents or young adults aged 13–24.⁷⁴ More disheartening is the fact that, from 2008 to 2011, young MSM (aged 13–24) accounted for the greatest percentage increase in diagnosed HIV infection.⁷⁵

The gay community also remains the predominant population affected by HIV/AIDS.⁷⁶ In 2010, the MSM population accounted for 63% of new infections, whereas the heterosexual population accounted for 25% and the intravenous drug using population accounted for 11%.⁷⁷ In 2010, the young MSM population experienced a 22% increase in the number of new HIV infections, which again was attributed to lack of understanding of the risk of HIV.⁷⁸ Still, though the FDA and blood banks remain responsible for maintaining the integrity of the blood supply,⁷⁹ a substantial portion of those in the medical⁸⁰ and legal⁸¹ communities maintain that the lifetime ban is now based

70. *Id.*

71. Kain, *supra* note 56.

72. *Id.*

73. NAT'L CTR. FOR HIV/AIDS, VIRAL HEPATITIS, STD, & TB PREVENTION, CDC, CS249858, HIV AND YOUNG MEN WHO HAVE SEX WITH MEN 1–2 (2010) [hereinafter HIV AND YOUNG MEN], available at http://www.cdc.gov/healthyyouth/sexualbehaviors/pdf/hiv_factsheet_ymsm.pdf (suggesting that this is a result of complacency in the younger generations).

74. *Id.*

75. *Id.* This amounts to around 12,000 young men each year. Further, 93% of HIV infections among males aged 13–19 are attributed to male-to-male sexual contact. *Id.*

76. CDC, NEW HIV INFECTIONS IN THE UNITED STATES 1 (2012).

77. *Id.* at 2.

78. *Id.*

79. See Jan M. Bennetts, *AIDS: Blood Bank Liability*, 27 WILLAMETTE L. REV. 355, 372 (1991); Dorney, *supra* note 36.

80. See, e.g., Mohny, *supra* note 11.

81. See, e.g., Casey, *supra* note 34.

on outdated science and old methods of determining one's HIV status, and is consequently bad law.⁸² This is relevant because in the past, courts have indicated that laws enacted when certain facts were relevant may be challenged by a showing that the facts no longer exist, a principle that could be applied to the FDA's ban.⁸³

The political climate, now more than ever, warrants that the policy be closely scrutinized. The FDA's policy on MSM donations has incited anger in the LGBT population, and has achieved a place in the national spotlight approaching that of the marriage equality discussion.⁸⁴ Furthermore, recent court decisions across the country have changed the legal landscape for sexual orientation-based laws and legal challenges.⁸⁵ Thus, the time is ripe (at least, politically) for doing away with the ban altogether.

Politics and policy aside, however, medical breakthroughs have vastly improved the landscape of HIV/AIDS treatment, detection, and prevention. The combination of several factors, such as a better understanding of HIV and HIV/AIDS detection, concerns for equal protection for LGBT citizens, and the harsh realities of the continuing HIV epidemic, produces a difficult legal and practical question. How do we protect the nation's blood supply, curb the spread of HIV, and still maintain the integrity and constitutional rights of the LGBT population? The following Part attempts to address this question and its implications.

II. ANALYSIS OF THE GAY BLOOD BAN

Though the FDA's blanket ban on MSM blood donations gained momentum as a viable way to keep the nation's blood supply "clean," the advent of technology and understanding of the disease has led to the regulation's growing unpopularity.⁸⁶ And though opposing the ban is a popular political position to

82. *Id.* at 553 (arguing for a one-year deferral period).

83. *See* *United States v. Carolene Prods. Co.*, 304 U.S. 144, 153 (1938) ("[T]he constitutionality of a statute predicated upon the existence of a particular state of facts may be challenged by showing to the court that those facts have ceased to exist." (citing *Chastleton Corp. v. Sinclair*, 264 U.S. 543, 548–49 (1924))).

84. *See, e.g.*, Alissa Scheller & Anna Almendrala, *Why Even a 12-Month Ban on Blood Donations from Gay Men Makes No Sense*, HUFFINGTON POST (Dec. 23, 2014, 9:33 PM EST), http://www.huffingtonpost.com/2014/12/23/gay-blood-ban-deferral_n_6374374.html.

85. *See infra* Part II.C.

86. *See supra* notes 59–60 and accompanying text.

take, there is a dearth of legal scholarship that meaningfully addresses the policy in light of modern case law pertaining to sexual orientation. However, that is not to say that legal challenges to the ban have not been contemplated by academics and practicing attorneys.⁸⁷

The normative arguments against the ban are much more cognizant of changing attitudes⁸⁸ and the need for a safe and adequate national blood supply. One source recently published a piece arguing for a complete lift of the ban, citing the “change in technology” as the primary evidence for its argument.⁸⁹ There is merit in this proposal. With new testing, it takes around ten days after unsafe sex to conclusively determine whether the individual has HIV—and thus whether the blood sample is viable or not.⁹⁰ Furthermore, within that ten-day window, the chances of a false negative are about one in two million.⁹¹ If every man who engaged in unsafe sex with another man were tested, it would make sense to change the ban to a deferral period of ten days after having engaged in unsafe sex.⁹² Regardless, much uncertainty has been removed from the blood screening process. Ultimately, it may be the normative arguments that help the hypothetical court in its decision.

87. The most recent piece regarding the gay blood ban inappropriately addresses the situation and, though well-intentioned, comes to an inadequate and perhaps incorrect conclusion. Ryan H. Nelson, *An Indirect Challenge to the FDA’s “Gay Blood Ban,”* 23 TUL. J.L. & SEXUALITY 1 (2014). Nelson offers what he calls a “weapon in the fight against the gay blood ban: an indirect, state-law challenge.” *Id.* at 3. His solution to the problem only involves indirect challenges on the state level on the basis of “places of public accommodation” discrimination, which even he admits is impractical unless undertaken in litigation nationwide. *Id.* at 16. Further, his vision of a “threat of such an unthinkable, catastrophic blood shortage” resulting from this litigation pressuring the FDA into changing its policies is somewhat disturbing. *Id.*

88. For example, many HIV-centric laws concern only gay men, including HIV criminalization crimes. *See, e.g.,* Buchanan, *supra* note 46, at 1240 (“[T]he seemingly arbitrary ways in which HIV crimes diverge from their public health rationale tend systematically to construct HIV as fairly benign when contained within stigmatized populations such as sex workers, intravenous drug users, and men who have sex with men. At the same time, these laws tend to criminalize the conduct of HIV-positive people when their behavior causes anxiety to more privileged heterosexuals, even when it poses no transmission risk.” (footnote omitted)).

89. Darling, *supra* note 44 (stating that inaccurate and slow testing processes are a thing of the past “thanks to a faster and far more accurate process called Nucleic Acid Testing—NAT, for short,” and that, “[u]nlike the EIA [enzyme immunoassays] test, the NAT can detect the amount of actual virus in the bloodstream, not just the antibodies produced to fight it”).

90. *Id.*

91. *Id.*

92. *Id.*

The most popular challenge to the ban is rooted in administrative procedure.⁹³ As an administrative agency, the FDA must follow certain rules in order for its regulations and guidelines to be binding on the public. Generally, to be binding, the agency must give notice of the proposed regulation and publish it in the Federal Register, including specific information for the public regarding the regulation, and may only circumvent the process in limited circumstances, as set forth in the Administrative Procedure Act (the APA).⁹⁴ Challengers argue that the MSM policy runs afoul of these procedural requirements.⁹⁵ However, the key piece is missing from these arguments: whether or not the FDA would even be able to change its policy or an interpretation of its own rule, without going through the arduous notice and comment procedure.⁹⁶ Both questions may be rendered moot by the FDA's willingness to proceed with the notice and comment process.

The FDA ban has also undergone criticism on the basis that it violates the federal Constitution's Equal Protection Clause.⁹⁷ There is little scholarship today that truly scrutinizes the policy adequately in light of recent developments in sexual orientation jurisprudence. Specifically, existing scholarship only analyzes the ban in light of *Lawrence v. Texas*,⁹⁸ a critical case that has since been superseded by subsequent case law that potentially expands its holding.⁹⁹ Given recent developments in civil rights jurisprudence, a constitutional challenge to the FDA gay blood ban is more viable than it was in years

93. For a general discussion on the binding effects of federal agency rules and guidelines, see generally Robert A. Anthony, *Interpretive Rules, Policy Statements, Guidances, Manuals, and the Like—Should Federal Agencies Use Them To Bind the Public?*, 41 DUKE L.J. 1311 (1992).

94. See 5 U.S.C. § 553 (2012).

95. See Casey, *supra* note 34, at 567.

96. There was previously a debate, to be discussed *infra* Part II.A, as to whether an administrative agency must alter its initial interpretation of a regulation by the same means of modifying the regulation itself, through the process of notice-and-comment rulemaking. See generally *Paralyzed Veterans of Am. v. D.C. Arena L.P.*, 117 F.3d 579, 586 (D.C. Cir. 1997) (holding that agencies must go through notice and comment to change their interpretations of regulations).

97. See Michael Christian Belli, *The Constitutionality of the "Men Who Have Sex with Men" Blood Donor Exclusion Policy*, 4 J.L. SOC'Y 315, 319 (2003).

98. 539 U.S. 558, 558 (2003) (holding, *inter alia*, that sexual conduct between two consenting adults is protected by the Fourteenth Amendment).

99. For a pre-*Lawrence* analysis of the ban, see generally Belli, *supra* note 97. See also *United States v. Windsor*, 133 S. Ct. 2675, 2695 (2013) (expanding on *Lawrence*).

past. In fact, the constitutional challenge to the ban is now the most important—and viable—challenge to the ban, and as such, this Section will focus on those arguments.

This Note will primarily address the constitutional problems with the ban—either in its current state or as it would exist in the form of a one-year deferral period. However, Section A addresses why the ban should be lifted from a normative standpoint. Section B briefly addresses the procedural challenge to the ban and its current (lack of) viability.¹⁰⁰ Section C delves into the larger constitutional issues of the policy, taking the analysis further than past scholarship in light of recent court decisions. This Part seeks to demonstrate conclusively that the legal justifications for ending the current policy should lead to a new regulatory framework that protects the interests of both the FDA and the MSM population.

A. THE NORMATIVE QUESTION: WHY BOTHER?

Before addressing how the ban might be challenged, it is important to understand why the ban should be lifted. This section seeks to answer that question. Why should we challenge a law that, from a lay perspective, inconveniences a minute portion of the population? The answer involves a balancing act the government should strive for: protecting the national blood supply while preserving the dignity of its citizens. Understanding why the ban should be lifted, as well as what an ideal policy might strive to accomplish, is crucial in understanding how to challenge it. Subsection 1 addresses the need to protect the blood supply and Subsection 2 addresses the protection of minority interests.

1. Protecting the Integrity of Our Blood Supply

Ideally, an FDA guideline regarding blood donor requirements would adequately preserve the integrity of the nation's blood supply. Protecting the blood supply has two components. First, ensuring an adequate supply must be accomplished through sensible donation policies that allow for as large a donation pool as possible. Second, the right steps must be put in place to ensure that the blood supply remains “clean.” This Subsection addresses each of these concerns in turn and determines that the current guideline fails to address them.

100. However, as the Note will discuss, many of the procedural problems with the current policy would be ameliorated if it is modified subject to a proper notice-and-comment rulemaking process.

Doubts abound as to whether the current law is too restrictive in its attempts to keep the blood supply “clean.” As established earlier, many in the medical profession no longer consider the ban to be based on sound science.¹⁰¹ Further, the FDA’s assertion concerning the adequacy of our nation’s blood supply may not be entirely accurate.¹⁰² Not all blood is created equal, and while asserting that in the aggregate no shortage exists, blood *type* shortages may still exist. Thus, the focus of expanding the pool of donors must address quality as well as quantity.

The rarest blood type, AB–, is represented in approximately 1.6% of our population.¹⁰³ While considered the “universal recipient” blood type, AB– is still a valuable potential source of blood donation, as are other rare types.¹⁰⁴ The MSM population contains individuals with rare blood types that are underrepresented in the aggregate blood supply.¹⁰⁵ Thus, though the quantitative supply may be adequate, that says nothing of rare blood, nor does the FDA address potential MSM donors with rare blood types that are not able to donate. Adding otherwise viable MSM to the pool of donors has the potential to significantly ameliorate blood shortage problems.¹⁰⁶

In addition to potentially curtailing the qualitative blood supply, the current policy also restricts the quantitative supply. As established before, the American Medical Association and the Red Cross report that the current ban is unwarranted, and

101. See Mohny, *supra* note 11.

102. See *supra* text accompanying note 65.

103. See *Blood Types*, AM. RED CROSS, <http://www.redcrossblood.org/learn-about-blood/blood-types> (last visited Apr. 20, 2015). That is a general estimate, and some sources put the actual number of AB– individuals much lower. See *Blood Type Chart*, NEW HEALTH GUIDE, <http://www.newhealthguide.org/Blood-Type-Chart.html> (last updated Apr. 20, 2015).

104. See *56 Facts About Blood and Blood Donation*, BLOOD CTRS. PAC., <http://www.bloodcenters.org/blood-donation/facts-about-blood-donation> (last visited Apr. 20, 2015).

105. There are, in fact, gay men with rare and useful blood types who would like to donate but nevertheless are barred from doing so. Interview with Michael Petre, Student, Univ. of Minn. Law Sch., in Minneapolis, Minn. (Mar. 30, 2014) (stating his blood type to be O–, a rare blood type usually in short supply and among the more useful blood types in donor compatibility). Some blood types, such as the type O–, are represented by minute portions of the population, and individuals with those blood types have very low odds of finding a compatible donor. See *Blood Type Chart*, *supra* note 103 (showing that Type O– individuals represent 6.5% of the population and have only a 7% chance of finding a compatible donor).

106. See NAOMI G. GOLDBERG & GARY J. GATES, WILLIAMS INST., EFFECTS OF LIFTING BLOOD DONATION BANS ON MEN WHO HAVE SEX WITH MEN 1–2 (2010), available at <http://williamsinstitute.law.ucla.edu/wp-content/uploads/Gates-Goldberg-MSM-Blood-Ban-Jun-2010.pdf>.

contributes to blood shortages.¹⁰⁷ Further, though the aggregate blood supply may generally be sufficient by some standards, the blood supply in certain markets experiences frequent shortages.¹⁰⁸

Moreover, recent studies indicate that, if the MSM lifetime were changed to a twelve-month deferral period, 53,269 additional MSM would likely donate, leading to approximately 89,716 extra pints of blood in the blood supply per year.¹⁰⁹ The number increases to 130,150 additional donors and 219,200 additional pints when the ban is lifted in its entirety.¹¹⁰ Using figures given by the American Red Cross as to how many lives one donor can potentially save, an additional 219,200 donated pints of blood translates to potentially 657,600 lives saved per year.¹¹¹ These numbers indicate that a *total* lift in the ban (not the FDA's proposed one-year deferral) would result in the national blood supply increasing by as much as 1.4%.¹¹² Such powerful statistics demonstrate that there is a clear and tangible benefit to allowing the MSM population to donate, without a restriction based on sexual orientation. Therefore, a better donor guideline would attempt to increase the donor pool, and one way to do that would be to lift the ban entirely.

That being said, the ideal policy would also protect the blood supply from contamination. Modern medical science indicates that the problem of contamination is not nearly as dire now as it was in the past.¹¹³ Further, medical technology has reached a point where the current FDA gay blood ban is “anti-

107. *Id.* at 1.

108. *See generally* Darling, *supra* note 44 (explaining that blood shortages in 2000 caused surgeries to be postponed in some major cities); *56 Facts About Blood and Blood Donation*, *supra* note 104 (noting that blood shortages “happen during the summer and winter holidays”).

109. GOLDBERG & GATES, *supra* note 106, at 2. Were the approximately 7.2 million men reporting having had another male sexual partner since the age of eighteen allowed to donate blood, the study demonstrates that the total donations would clearly increase even if only a fraction of these men chose to donate.

110. *Id.* at tbl.2.

111. According to the American Red Cross, a one pint donation can save up to three lives. *Blood Facts and Statistics*, AM. RED CROSS, <http://www.redcrossblood.org/learn-about-blood/blood-facts-and-statistics> (last visited Apr. 20, 2015).

112. *See* GOLDBERG & GATES, *supra* note 106, at 2 (“While these increases in the blood supply may seem modest, they would occur in an environment where blood supply shortages are common.”).

113. *See* Mohney, *supra* note 11 (arguing that the ban is “outdated in light of medical advances that can detect HIV in donated blood in *nearly all* blood donations” (emphasis added)).

quoted” and does little else than keep potential units of viable blood from entering the blood supply.¹¹⁴ While the FDA and blood banks had no way of detecting HIV in the blood prior to March of 1985, technology has advanced to the point where *all* blood is routinely screened for various diseases including HIV.¹¹⁵ Further, given the uses of the NAT test, ten days to two weeks is the approximate amount of time it takes to detect HIV in the blood following initial infection.¹¹⁶ Taking medical developments into account, the current policy is outdated and should be replaced by one that falls more in line with available technology.

2. Preserving the Dignity of All Citizens

Finally, the FDA should strive to protect the dignity of United States citizens, in this case, the gay male population. The word “dignity” should not only be taken to mean freedom from embarrassment in this circumstance, but should include acting on moral impulses that contribute to societal good. Take, for example, David Dassey, a healthy, HIV-negative 62-year-old gay man.¹¹⁷ Dassey experienced first-hand the Boston Marathon terrorist attacks as a participant in the race and, despite the dire circumstances, devastation, and loss of life, he was unable to donate blood to save lives in the midst of that crisis.¹¹⁸ The ban was enforced even in emergency circumstances. Experiences like Dassey’s are not uncommon. Whether out of a sense of duty or during times of crisis, gay men nationwide are being denied the chance to save lives due to a guideline the American Medical Association claims is “discriminatory.”¹¹⁹ Again, there are many gay men with useful and rare blood types who are not allowed to donate, despite being perfectly healthy.¹²⁰

Taken as a whole, the FDA’s gay blood ban is yet another policy that excludes a minority segment of the population from participating in activities based not on their illness or level of risky behavior, but rather on an inherent trait that exists independently of risk.¹²¹ Even the proposed one-year deferral would

114. *See id.*

115. *See Darling, supra* note 44.

116. *Id.*

117. *Id.*

118. *Id.*

119. *See Mohny, supra* note 11.

120. *See supra* note 105 and accompanying text.

121. Despite FDA statements to the contrary, *see FDA Guidelines, supra* note 7, the FDA ban excludes based on sexual orientation and not on the riskiness of sexual behavior. *See supra* note 5 and accompanying text.

have a similar effect.¹²² Therefore, the ideal policy would take into account the dignity of the MSM population while simultaneously ensuring an adequate, clean blood supply. Given the current state of medical technology, such a solution (that does not involve a qualification based on or affecting sexual orientation) is viable.

B. THE ADMINISTRATIVE PROCEDURE QUANDARY

Historically, the procedural challenge to the ban was the most popular.¹²³ Though the FDA has the power to regulate the nation's blood supply, all regulations must conform to federal guidelines on agency rulemaking governed by the APA.¹²⁴ In order for proposed rules to have a binding effect, general notice of the proposed rule must be published in the Federal Register, and must include specific information for disclosure to the public (this is widely known as notice-and-comment rulemaking).¹²⁵ Exceptions to this rule apply (1) when the agency intends the rule to be an interpretive rule, general statement of policy, or other policy that does not bind the public, or (2) if the agency for "good cause" finds that notice and comment procedures are impracticable or unnecessary.¹²⁶ The courts construe these exceptions narrowly and only recognize them reluctantly so as to preserve the public benefit of the statute.¹²⁷ Therefore, any federal agency rulemaking that fails to satisfy the notice-and-comment procedure and fails to satisfy either of the two exceptions—nonbinding intent or good cause—is not binding on the public.

Recent developments have prompted the FDA to consider altering, but not rescinding the ban, which renders a lengthy procedural discussion moot. However, this Note will briefly discuss prior scholarship to both give legal context to the old procedural argument, and to demonstrate *why* such a challenge would never have been a sufficient means by which to perma-

122. One medical expert states, "The one-year deferral notion constitutes symbolic progress, but is not any more warranted than a lifetime ban." Scheller & Almendrala, *supra* note 84.

123. See generally Casey, *supra* note 34 (challenging the procedural validity of the ban). That viability, however, has been severely undermined by the fact that the FDA has now initiated the notice-and-comment process in order to change the lifetime ban to a one-year deferral period. See *FDA Statement*, *supra* note 66.

124. See 5 U.S.C. § 553 (2012).

125. See *id.* § 553(b).

126. See *id.* § 553(b)(A)–(B).

127. Anthony, *supra* note 93, at 1323.

nently overturn the ban.¹²⁸ Subsection 1 briefly discusses the (now outdated) procedural attack on the ban, and Subsection 2 addresses the insufficiency of a procedural challenge alone.

1. A Now-Defunct Procedural Challenge

Many argue that the FDA did not properly publish the MSM guideline. The closest it has come to a formerly published regulation regarding MSM donors only applied to those who were free from “any disease transmissible by blood transfusion, *insofar as can be determined by history and examinations.*”¹²⁹ Other than this, no regulation conforming to the procedural guidelines of § 553 of the APA pertain to the exclusion of particular groups, including the MSM population.¹³⁰ Prior scholarship has established that the current policy was implemented without notice and comment, so it is not necessary to rehash in detail that which has already been established.¹³¹

Similarly, the old ban did not meet either exception. The regulation was never promulgated as a permanent one; it was accepted by the general population and blood banks with the assurance that it was only a temporary fix.¹³² Public discourse clearly accounted for very little in the events that led to institution of the permanent ban. Due to the controversial nature of the ban and the highly un-democratic manner in which it was enacted, the FDA likely has no defense for its guideline under the good cause exception. In addition, the FDA has never indicated that the policy is meant to be non-binding.¹³³ With no protection from either exception, the gay blood ban would have likely been struck down by the courts as an improperly implemented legislative rule if challenged before the FDA’s December 2014 announcement.¹³⁴

128. And, therefore, why any future challenge to the ban likely cannot rest on a procedural or administrative challenge alone, if at all.

129. Casey, *supra* note 34, at 562 (citing 21 C.F.R. § 640.3(b)(6) (2004)).

130. *See id.*

131. *See id.*

132. *See id.* at 555.

133. *See id.*

134. *See id.* at 567. Casey comes to the same conclusion, arguing that the rule “lacks a proper procedural foundation.” *Id.*

2. One Step Further¹³⁵

Proponents of the gay blood ban possibly have one weapon in their arsenal: the *Paralyzed Veterans* doctrine.¹³⁶ While the applicability of this doctrine to the FDA ban is only theoretical, it could potentially obfuscate any unilateral attempt by the FDA to alter or rescind the current ban. Having promulgated the gay blood ban pursuant to authority granted it by federal statute,¹³⁷ the FDA could, without interference by the courts, rescind the ban under the same authority. However, under *Paralyzed Veterans*, the FDA could only change its interpretation of its rule on who may donate blood “as it would formally modify the regulation itself: through the process of notice and comment rulemaking.”¹³⁸ This would be yet another obstacle to rescinding the ban, if the doctrine applied.¹³⁹

That would be a tenuous argument at best, since it would require a preliminary finding that the ban is an interpretative rule,¹⁴⁰ an unlikely outcome. Second, the doctrine will soon undergo scrutiny at the United States Supreme Court, since there is currently a circuit split on the matter.¹⁴¹ Ultimately, because a court would very likely find the gay blood ban to be legislative, the *Paralyzed Veterans* doctrine would have no applicability. Either way, supporters of the ban now only have the notice-and-comment rulemaking process as a means by which to try

135. Immediately prior to the publishing of this Note, the Supreme Court struck down the *Paralyzed Veterans* doctrine. See *Perez v. Mortgage Bankers Ass'n*, 135 S. Ct. 1199, 1206 (2015) (“The *Paralyzed Veterans* doctrine is contrary to the clear text of the APA’s rulemaking provisions, and it improperly imposes on agencies an obligation beyond the ‘maximum procedural requirements’ specified in the APA.” (emphasis in original) (citation omitted)). This decision does not meaningfully impact the formerly defective legitimacy of the ban, nor does it affect the ultimate analysis or proposal of this Note.

136. *Paralyzed Veterans of Am. v. D.C. Arena L.P.*, 117 F.3d 579, 586 (D.C. Cir. 1997) (holding that agencies must go through notice-and-comment to change their interpretations of regulations).

137. See *supra* note 35.

138. *Paralyzed Veterans*, 117 F.3d at 586.

139. Alternatively, an opponent of the ban could argue that the current policy is in violation of *Paralyzed Veterans* insofar as it adds the MSM population to existing rules on who can and cannot donate.

140. See *Paralyzed Veterans*, 117 F.3d at 586. If the Supreme Court were to uphold the doctrine, then interpretative rules would necessarily undergo formal notice-and-comment procedures every time an agency wished to change its interpretation of an already-implemented rule.

141. See Brief for Petitioners at i, *Nickols v. Mortgage Bankers Ass'n*, (No. 13-1052), 2014 WL 4181711, at *1, *petition for cert. granted*, No.13-1052, 2014 WL 834024 (June 16, 2014). For the D.C. Circuit opinion that was challenged and subsequently reversed, see *Mortgage Bankers Ass'n v. Harris*, 720 F.3d 966 (D.C. Cir. 2013).

and keep the ban in place. *Paralyzed Veterans* would likely not serve either opponents or proponents, given recent developments and the fact that the FDA will soon utilize the proper tools to potentially change the ban.

Prior scholarship does provide an argumentative framework by which the ban may be defeated in the courts,¹⁴² but the arguments, though persuasive, do not go far enough in addressing the underlying issues of the gay blood ban. At any rate, these arguments are more or less outdated in light of the FDA's decision to reconsider the lifetime ban.¹⁴³

While the procedural challenge to the FDA's ban is a significant step in the right direction, it does not take into account the underlying issue of constitutionality. Even if a court were to hold that the policy is non-binding on the public, this would speak nothing of whether the blood ban violates the federal Constitution.¹⁴⁴ As briefly discussed before, if the FDA ban were overturned on procedural grounds, that result alone would not speak to the law's substance, only the manner in which it was created.

Further, the FDA is now in the process of implementing a similar discriminatory policy following appropriate administrative procedure.¹⁴⁵ If the policy alteration is implemented properly, a procedural challenge to the new policy would be an exercise in futility. Therefore, a proper challenge to the blood ban must push any procedural arguments to the backburners, so to speak, in favor of an argument that speaks directly to the ban's validity—a constitutional challenge.

C. THE CONSTITUTIONAL INQUIRY

As the FDA's gay blood ban has not been formally challenged in court on constitutional grounds, there is no case law directly on point that may inform this analysis. Nevertheless, constitutional law is now the best and most viable option for having the current ban or proposed one-year deferral overturned.

142. See generally Casey, *supra* note 34 (challenging the procedural validity of the ban).

143. The premise of Casey's article does predict that the FDA could reduce the ban to a one-year deferral period. However, it fails to take into account any constitutional arguments in favor of overturning the ban. *Id.*

144. Specifically, the Fifth Amendment. U.S. CONST. amend. V. See discussion *infra* Part II.C.1.

145. See Scheller & Almendrala, *supra* note 84.

The FDA ban explicitly identifies and applies to a particular population—gay men—as a class.¹⁴⁶ To that effect, the Due Process Clause¹⁴⁷ and Equal Protection Clause¹⁴⁸ are each potentially relevant to the analysis, though pursuing one may yield more favorable results to litigants than the other. Ultimately, this Note seeks to conclude which of the two doctrines would better serve litigants seeking to invalidate the blood ban, and will follow the line of analysis best suited to overturning the ban on the basis of its unconstitutionality.

In the past, the Due Process Clause and the Equal Protection Clause were treated very differently, and courts emphasized that the Fifth Amendment contained no equal protection provision.¹⁴⁹ However, while courts still hold that the Fifth Amendment does not contain an Equal Protection Clause per se, current interpretation reflects otherwise.¹⁵⁰ The Supreme Court has gone as far as to state that “the concepts of equal protection and due process, both stemming from our American ideal of fairness, are not mutually exclusive . . . discrimination may be so unjustifiable as to be violative of due process.”¹⁵¹ Thus, either Equal Protection or Due Process can be used to challenge the FDA’s gay blood ban (or the potential one-year deferral).

Subsection 1 discusses a challenge under the federal Due Process Clause. Subsection 2 delves into the federal Equal Protection doctrine, which ultimately may be the better basis for a challenge to the ban. Subsection 3 brings the analysis to its conclusion, and ultimately, this Section concludes that the gay blood ban (and the proposed one-year deferral) is not constitutional as it applies to the MSM population.

1. Due Process

The Fifth Amendment’s Due Process Clause states that “No person shall . . . be deprived of life, liberty, or property, without due process of law”¹⁵² The Due Process Clause, un-

146. See FDA Guidelines, *supra* note 7 (noting that the ban applies to “men who have had sex with other men”).

147. U.S. CONST. amend. V (“No person shall be . . . deprived of life, liberty, or property, without due process of law . . .”).

148. U.S. CONST. amend. XIV, § 1 (“No State shall . . . deprive any person of life, liberty, or property, without due process of law, nor deny to any person within its jurisdiction the equal protection of the laws.”).

149. See *United States v. Carolene Products Co.*, 304 U.S. 144, 151 (1938).

150. See *Bolling v. Sharpe*, 347 U.S. 497, 499 (1954).

151. *Id.*

152. U.S. CONST. amend. V.

like the Fourteenth Amendment, applies to the federal government, so application to the FDA gay blood ban is appropriate without rehashing in detail the analysis in *Bolling v. Sharpe*.¹⁵³ Potentially discriminatory laws—those that curtail personal liberty of a class—are properly analyzed under the Fifth Amendment. Discrimination, if it is unjustifiable, may violate the Due Process Clause.¹⁵⁴ Specifically, the FDA ban, like any other potentially discriminatory law, would be challenged as violating *substantive* Due Process, as opposed to *procedural* Due Process.¹⁵⁵

A substantive Due Process challenge will stand if it affects or unduly burdens a property or liberty interest, but courts do not treat all interests the same.¹⁵⁶ If a law affects a fundamental liberty or right, then it will be subjected to strict scrutiny and upheld *only* if the law is necessary and narrowly tailored to achieve a compelling government interest.¹⁵⁷ Otherwise, the lesser “rational basis” standard would apply, and courts are very unwilling to disturb laws under this standard.¹⁵⁸ Thus, whether the gay blood ban or a one-year deferral would pass constitutional muster under a Due Process analysis depends on whether it affects a fundamental “liberty” or right.

153. *Bolling*, 347 U.S. at 497. The analysis in *Bolling* is more relevant to, and will be discussed in, the following section on Equal Protection. See discussion *infra* Part II.C.2. But for the purposes of Due Process, the Fifth Amendment’s Due Process Clause appropriately applies to the FDA’s regulation, being a creation of a federal agency.

154. *Bolling*, 347 U.S. at 499.

155. Substantive Due Process issues arise when the regulation or law *itself* deprives the individual of property or liberty interests. See generally *Lawrence v. Texas*, 539 U.S. 558 (2003) (discussing substantive Due Process). On the other hand, procedural Due Process requires that “an individual be given an opportunity for a hearing *before* he is deprived of any significant property interest.” *Cleveland Bd. of Educ. v. Loudermill*, 470 U.S. 532, 542 (1985). Thus, the issue in a procedural Due Process analysis is whether the victim was afforded the appropriate hearing or process due under the law. *Id.* And while, in theory, a procedural Due Process claim could have potentially been made against the FDA for the improperly implemented lifetime ban, *supra* Part II.B, such an argument is tenuous and likely irrelevant in light of recent developments.

156. See, e.g., *United States v. Windsor*, 133 S. Ct. 2675, 2695 (2013) (“The liberty protected by the Fifth Amendment’s Due Process Clause contains within it the prohibition against denying to any person the equal protection of the laws.”).

157. See *Planned Parenthood v. Casey*, 505 U.S. 833, 929 (1992).

158. See *Romer v. Evans*, 517 U.S. 620, 631 (1996) (“[I]f a law neither burdens a fundamental right nor targets a suspect class we will uphold the legislative classification so long as it bears a rational relation to some legitimate end.”).

The term liberty as it applies to the Due Process Clause enjoys a liberal interpretation, encompassing “the full range of conduct which the individual is free to pursue.”¹⁵⁹ Surely donating blood—contributing to the nation’s blood supply and thus national health—is more than a casual activity. For some, the act of donating blood is a serious moral obligation. At the very least, the act of donating contributes to a utilitarian “greater good,” that of keeping the nation’s blood supply at adequate levels.¹⁶⁰ Donating blood is a serious act of giving, even potentially life-saving, that requires a great deal of contemplation, and thus a court may reasonably find that donating blood may fall into the “full range” of personal conduct individuals are free to pursue.¹⁶¹

Assuming that donating blood is a liberty under the Due Process Clause, then no law may impede this liberty unless pursuant to a rational governmental objective.¹⁶² Further, if the law is restrictive, it must not be an “arbitrary deprivation.”¹⁶³ Because the FDA ban applies to MSM as a class, it would most likely be subjected to some form of heightened scrutiny in court.¹⁶⁴ The government interest is legitimate—the protection of our nation’s blood supply from HIV/AIDS was the genesis of the law—and for a while it was the best method of doing so.¹⁶⁵ However, the scientific and political landscape of our nation has changed since the regulation was implemented.¹⁶⁶ New methods of HIV detection are available, methods that are faster and more accurate than those available at the time of the ban.¹⁶⁷ Thus, the FDA’s regulation is not narrowly tailored to achieve what it sets out to do, but rather, only rests upon “hypothetical justifications” that are incorrect in light of current science and medicine.¹⁶⁸

159. *Bolling*, 347 U.S. at 499. This “free range” of conduct encompasses more than mere freedom from “bodily restraint.” It implicates the freedom from government interference in daily life, absent a proper governmental objective. *Id.* at 499–500.

160. This is especially so given recent concerns over blood shortages in major cities. *See infra* note 197.

161. *Bolling*, 347 U.S. at 499.

162. *See id.* at 499–500.

163. *See id.* at 500.

164. *See infra* note 211 and accompanying text.

165. *See supra* Part I.A.

166. *See supra* Part I.B.

167. *Darling*, *supra* note 44.

168. *See Bostic v. Schaefer*, 760 F.3d 352, 377 (4th Cir. 2014).

However, this brief analysis is contingent on the assumption that a court would view donating blood as either a property or liberty interest. Currently, no cases or legal authority speak to whether donating blood is a liberty or property interest. There is much less doubt as to whether donating blood is a *fundamental* right. And because a successful Due Process challenge hinges on the infringement of a *right*, this argument is likely the weaker one. And if a court wishes to avoid the arduous task of justifying a holding that donating blood is a fundamental right, it could merely bypass that inquiry by stating the FDA's policy doesn't even pass a rational basis test.

The Supreme Court has acknowledged that the Due Process Clause does not necessarily provide as much protection as Equal Protection.¹⁶⁹ As the Court has long held that the explicit guarantee of Equal Protection in federal law applies to the Fourteenth Amendment, and given that classifying blood donation is a tenuous argument, Due Process is likely the "lesser" of the two potential avenues by which to challenge the FDA's donation policy.

2. Equal Protection

In principle, the Equal Protection Clause speaks to the issue presented in the gay blood ban, that is, whether equity should limit the differential treatment gay and bisexual men receive based on their differences from heterosexual men.¹⁷⁰ It has been established that heterosexual women, gay women, and heterosexual men are not the target of the ban.¹⁷¹ The decision in *Bolling* and its progeny long ago established that there is an Equal Protection component incorporated into the Due Process Clause of the Fifth Amendment, thus affording citizens of the United States greater protection under federal law as well as state law.¹⁷²

169. *Adarand Constructors, Inc. v. Peña*, 515 U.S. 200, 213 (1995) ("Although this Court has always understood [the Due Process Clause] to provide some measure of protection against *arbitrary* treatment by the Federal Government, it is not as explicit a guarantee of *equal* treatment as the Fourteenth Amendment . . .").

170. See generally Derek W. Black, *The Constitutional Limit of Zero Tolerance in Schools*, 99 MINN. L. REV. 823, 868 (2015) ("[E]quity limits differential treatment based on immutable, illegitimate, or irrational differences between individuals.").

171. See *supra* Part I.B.

172. Specifically, the court in *Bolling* held that "the concepts of equal protection and due process, both stemming from our American ideal of fairness, are not mutually exclusive . . . [D]iscrimination may be so unjustifiable as to be violative of due process." *Bolling v. Sharpe*, 347 U.S. 497, 499 (1954). See

Since *Romer v. Evans*, courts generally accept the idea that homosexuals as a class fall under the protection of the Equal Protection Clause.¹⁷³ Since the decision in *Lawrence v. Texas*,¹⁷⁴ which struck down sodomy laws specifically targeted at same-sex couples,¹⁷⁵ courts have extended more protection to homosexuals as a class. This trend continued in the recent *United States v. Windsor* decision, in which the Supreme Court held that marriage laws defined exclusively in the context of heterosexual unions were unconstitutional.¹⁷⁶ It follows that *any* law that either facially discriminates against the LGBT population or has the effect of discriminating against them would be subject to an Equal Protection analysis.

The Equal Protection analysis is the more effective challenge to the FDA's gay blood ban, and this requires a deeper analysis. Subpart (a) will examine the discriminatory effect (if not purpose) the policy has on the MSM population. Subpart (b) will discuss how the overinclusiveness of the policy affects the effectiveness and legitimacy of the policy's goals. Finally, Subpart (c) discusses the appropriate level of scrutiny that would apply to the policy in an Equal Protection Challenge.

a. Whether the FDA's Policy Has a Discriminatory Effect on the MSM Population

The primary issue with using Equal Protection is that the FDA policy, either in its current form or its proposed form, does not specifically address homosexual or bisexual men.¹⁷⁷ Thus one may argue that, under *Romer*, the FDA's policy does not target a protected class. However, the analysis does not end there. Courts have widely held that facially neutral laws which have discriminatory *effects* or impacts on protected classes will also be subject to an Equal Protection analysis.¹⁷⁸ The FDA's blood ban, either in its current form or under the proposed one-year deferral, falls under the classification of laws that are not

also *Korematsu v. United States*, 323 U.S. 214, 235–36 (1944).

173. See *Romer v. Evans*, 517 U.S. 620, 631 (1996) (“[I]f a law neither burdens a fundamental right nor targets a suspect class, [the court] will uphold the legislative classification so long as it bears a rational relation to some legitimate end.”).

174. 539 U.S. 558 (2003).

175. *Id.* at 579.

176. See *United States v. Windsor*, 133 S. Ct. 2675, 2695 (2013).

177. See FDA Guidelines, *supra* note 7.

178. See, e.g., *Vill. of Arlington Heights v. Metro. Hous. Dev. Corp.*, 429 U.S. 252, 259 (1977).

facially discriminatory but which have a discriminatory effect.¹⁷⁹

The FDA policy explicitly prohibits men who have had sex with men since 1977 from donating blood.¹⁸⁰ In practical terms, this could cover heterosexual, bisexual, and homosexual men. However, the law largely impacts gay men, the very population that was associated with the HIV/AIDS epidemic.¹⁸¹ In addition, the FDA's MSM policy was specifically implemented to address concerns over HIV/AIDS.¹⁸² Gay and bisexual men inevitably represent a tremendous portion of the MSM population, and for all intents and purposes *define* the MSM population.

The law's discriminatory impact does not change even if the FDA's recommended one-year deferral period is implemented, because it also uses the MSM population as a starting point by which to weed out potential risky blood donors. For many gay men, the FDA's proposed new policy is just as prohibitive as the old one. To put it another way, "[t]he FDA has decided that the blood coursing through your veins isn't a lifetime threat to the American public—just a year-long threat."¹⁸³ The one-year deferral would do little to change that perception. In fact, maintaining a ban in some form effectively perpetuates negative stereotypes and stigmas attached to gay and bisexual men by basing donor guidelines on stereotypes, not science.¹⁸⁴

The discriminatory effect and intent are more pronounced when available science is taken into consideration.¹⁸⁵ The current ban and proposed one-year deferral are (and would be) written in such a way to suggest some discriminatory or sexual

179. These laws are also illegal. *See generally* Yick Wo v. Hopkins, 118 U.S. 356 (1886) (holding that a law, even if facially neutral, may impose purposeful discrimination if it is administered in a discriminatory way).

180. FDA Guidelines, *supra* note 7.

181. *See supra* Part I.A.

182. *See supra* Part I.B.

183. John Gallagher, *Nine Ways To Avoid Sex for the Next Year So You Can Donate a Pint of Blood*, QUEERTY (Dec. 31, 2014), <http://www.queerty.com/nine-ways-to-avoid-sex-for-the-next-year-so-you-can-donate-a-pint-of-blood-20141231> ("[T]o donate blood, you need to get ready now, which means giving up sex for a year.").

184. Andrew Cray, *Members of Congress Encourage End to Discriminatory Blood Donation Policy*, THINKPROGRESS (Aug. 5, 2013), <http://thinkprogress.org/lgbt%20/2013/08/05/2412721/msm-blood-donation>.

185. *Id.* ("The absence of a non-discriminatory rationale becomes even clearer in light of significant advancements in medical technology and developments in blood screening and record-keeping since the donation ban was put in place 30 years ago. In fact, current blood screening tests are so effective that the probability of HIV transmission through blood transfusion is one in 1.5 million, a significant decrease from risk levels in the mid-1990s.").

orientation-based animus. Further, the policies are part of larger fear-based policy-making in response to the HIV/AIDS epidemic.¹⁸⁶ The gay blood ban in any form does not likely fall under the type of laws that make classifications serving to protect legitimate interests, especially given the science that has developed since the ban was first implemented.¹⁸⁷

With all factors taken into consideration, including the history of the HIV/AIDS epidemic, the FDA's initial response by way of targeting homosexual men,¹⁸⁸ and this discussion, a court would very likely find both the gay blood ban and the proposed one-year deferral to have a discriminatory effect. Further, there is a reasonable chance that a court would find it (either the current ban or one-year proposal) to have a discriminatory intent, despite the wording of the policy.

b. Whether the FDA's Policy Is Overinclusive

Any time a law is challenged, the government may deflect the suit by proving the law is appropriately tailored to further some interest.¹⁸⁹ The FDA would likely argue that the gay blood ban meets that criterion under any level of scrutiny.¹⁹⁰ However, one crucial counterargument would be that the ban is overinclusive.

A law is overinclusive if it applies to all people who are similarly situated, but also people who should not be included; essentially, the law regulates more people than is necessary to achieve the government's purported interest.¹⁹¹ Under either a rational basis or strict scrutiny test,¹⁹² some laws are so underinclusive (not regulating enough individuals to accomplish government objective) or so overinclusive in their classification that the distinction "cannot be said" to rationally further the posited state interest.¹⁹³

186. *Id.*

187. *See Nordlinger v. Hahn*, 505 U.S. 1, 13 (1992).

188. *Casey*, *supra* note 34, at 554–56.

189. *See Ry. Express Agency, Inc. v. New York*, 336 U.S. 106, 112 (1949) (Jackson, J., concurring) ("The burden should rest heavily upon one who would persuade us to use the due process clause to strike down a substantive law or ordinance.").

190. *See infra* Part II.C.2.c for a discussion of the standards of scrutiny courts apply to these types of constitutional challenges.

191. *Equal Protection Definition*, LEGAL DICTIONARY, <http://legal-dictionary.thefreedictionary.com/Equal+Protection> (last visited Apr. 20, 2015).

192. *See Nordlinger*, 505 U.S. at 10 (discussing the rational basis and strict scrutiny standards).

193. *Id.* at 35 (Stevens, J., dissenting).

If a law is overinclusive, specifically, a court will invalidate it if it “sweeps too broadly and operates too indiscriminately” in furthering the state’s interest or objectives.¹⁹⁴ As Justice Stevens wrote, “[i]t is just short of absurd to conclude that the legitimate state interest in [regulating] a relatively small number” of risky individuals is rationally furthered by regulating a significantly wider population.¹⁹⁵

Blood banks’ opposition to the FDA’s gay blood ban illustrates this principle.¹⁹⁶ The American Red Cross, for example, has publicly argued against the lifetime ban on the grounds that it contributes to blood shortages.¹⁹⁷ The inability to collect the blood of millions of MSM, while not the sole cause of any blood shortage, is a contributing factor in the critical problem of the blood shortage.¹⁹⁸ As has already been discussed, while the blood supply in the aggregate is not in shortage, this speaks nothing of the potential for rare blood-type shortages.¹⁹⁹ Also recall that opening the pool of donors to gay men is estimated to save an upwards of 657,600 lives saved per year.²⁰⁰ All told, the ban *does* prevent a small portion of a high-risk population from donating, but also excludes thousands of otherwise viable, healthy donors.

The biggest factor in the ban’s overinclusiveness is developing technology. When the ban was first implemented, and little was known about HIV, that might have not been the case. But as science and society have evolved, the pool of donors at risk for HIV infection has narrowed.²⁰¹ The fact that thirty-seven states (and counting) now allow gay marriage²⁰² has significant-

194. *Id.*

195. *Id.* at 36–37 (drawing that conclusion as applied to property taxes in California).

196. It is estimated that, in any given year, more than seven million men are prohibited from ever donating blood. Casey, *supra* note 34, at 567. This is not surprising, however. As has been discussed, the concern over blood shortage has always been the primary objection of blood banks to the FDA policy. See Dorney, *supra* note 36, at 144.

197. See Darling, *supra* note 44 (“In 2000, [blood] shortages led to postponements of elective surgeries in Philadelphia, Atlanta, and Los Angeles. At the time, all hospitals combined needed about 80,000 units of blood daily, but the Red Cross could deliver only 36,000.”). *Id.*

198. *56 Facts About Blood and Blood Donation*, *supra* note 104 (“[I]f only one more percent of all Americans would give blood, blood shortages would disappear for the foreseeable future.”).

199. See *supra* Part II.A.1.

200. See *Blood Facts and Statistics*, *supra* note 111 (finding that a one pint donation can potentially save up to three lives a year).

201. See *supra* Part I.B.

202. See *States*, FREEDOM TO MARRY, <http://www.freedomtomarry.org/>

ly changed society's perception of the LGBT community. There is a discrete group of individuals whose behavior puts them at risk, including IV drug users and sharers and those who indiscriminately have unprotected sex.²⁰³ Those groups and the MSM population are not mutually inclusive, though the policy implications of the FDA's ban would seem to suggest otherwise.

Whether or not the FDA's gay blood ban is overinclusive is not wholly dispositive of the constitutional issue. Courts apply various standards of scrutiny when laws are challenged under the Equal Protection Clause, and under the same facts, one standard will yield more favorable results than the other. The overinclusiveness of the ban is thus tied closely with the standard of scrutiny that would likely apply.

c. The Appropriate Standard of Scrutiny

Though Equal Protection is likely the more effective of the two potential constitutional challenges, courts apply varying standards of scrutiny when analyzing such challenges and the outcome depends heavily on which standard the court chooses to use. Essentially, "unless a classification warrants some form of heightened review because it jeopardizes exercise of a fundamental right or categorizes on the basis of an inherently suspect characteristic, the Equal Protection Clause requires only that the classification rationally further a legitimate state interest."²⁰⁴

The least stringent level of scrutiny is known as rational basis, and a law challenged as violating the Equal Protection Clause will survive under an Equal Protection analysis if it is rationally tailored to further a legitimate state interest.²⁰⁵ This standard is more widely used, and will only be discarded for heightened scrutiny if a state-imposed classification "warrants some form of heightened review because it jeopardizes exercise of a fundamental right or categorizes on the basis of an inherently suspect characteristic."²⁰⁶

Strict, or heightened, scrutiny applies where courts find the question to be one of equal protection against infringement of fundamental rights or discrimination against suspect classes.²⁰⁷ Under the strict scrutiny standard, a law "may be justi-

states (last updated Mar. 4, 2015).

203. See *infra* Part III.B.

204. *Nordlinger v. Hahn*, 505 U.S. 1, 10 (1992).

205. *Id.*

206. *Id.*

207. See *generally* *United States v. Windsor*, 133 S. Ct. 2675, 2716–17

fied only by compelling state interests, and must be narrowly drawn to express only those interests.²⁰⁸ Further, the government bears the burden of satisfying the standard, and must rely on the law's actual purposes, rather than hypothetical justifications to prevail.²⁰⁹ Having historically been applied to cases of race and national origin discrimination,²¹⁰ the idea of subjecting classifications based on sexual orientation to strict scrutiny has grown popular in recent years.²¹¹

The Second Circuit explicitly endorsed this line of thought by applying strict scrutiny to classifications based on sexual orientation.²¹² When that decision made its way to the Supreme Court in *United States v. Windsor*, the Court flirted with the idea of applying strict scrutiny and, though it ultimately did not explicitly affirm the use of that standard, nevertheless affirmed the Second Circuit's ruling in its entirety.²¹³ The Fourth Circuit applied strict scrutiny recently to a same-sex marriage case, though the court did so because it held marriage to be a fundamental right.²¹⁴ Even though strict scrutiny was not applied on the basis of sexual orientation being a suspect class, the court nevertheless came close to doing so.²¹⁵ The Tenth Circuit has also applied strict scrutiny to cases involving same-sex couples.²¹⁶

The trend is clear: though the Supreme Court has not explicitly used a strict standard of review for classifications based on sexual orientation, its shifting attitude indicates that such a standard may become an eventuality, though not an inevitability. It is doubtful, though within the realm of possibility, that a federal court would decline to use at least *some* form of heightened scrutiny in analyzing a law such as the FDA's blood donation policy.

(2013) (discussing when strict scrutiny should apply).

208. *Bostic v. Schaefer*, 760 F.3d 352, 377 (4th Cir. 2014) (quoting *Carey v. Population Servs. Int'l*, 431 U.S. 678, 686 (1977)) (internal quotation marks omitted).

209. *Id.* (citing *Fisher v. Univ. of Tex. at Austin*, 133 S. Ct. 2411, 2420 (2013); *Shaw v. Hunt*, 517 U.S. 899, 908 n.4 (1996)).

210. *See, e.g., Adarand Constructors, Inc. v. Peña*, 515 U.S. 200, 222 (1995).

211. President Obama in particular is an advocate of applying the heightened scrutiny standard to cases involving sexual orientation discrimination. *See Windsor*, 133 S. Ct. at 2683.

212. *Id.* at 2684.

213. *Id.* at 2696.

214. *Bostic v. Schaefer*, 760 F.3d 352, 375 (4th Cir. 2014).

215. *Id.* at 375 n.6.

216. *See Kitchen v. Herbert*, 755 F.3d 1193, 1218 (10th Cir. 2014).

A strict-scrutiny analysis would very likely yield favorable results to those seeking to have the gay blood ban or one-year deferral overturned. The FDA may repeat its argument that the MSM population is more at risk of transmitting HIV/AIDS, but this argument would be unavailing, as the FDA “cannot rest upon a generalized assertion as to the classification’s relevance to its goals.”²¹⁷ In short, the “purpose of the narrow tailoring requirement [in a strict-scrutiny analysis] is to ensure that the means chosen fit the compelling goal so closely that there is little or no possibility that the motive for the classification was illegitimate.”²¹⁸

As already discussed, the FDA’s current gay blood ban and proposed one-year deferral are, as they relate to the goal of blood supply safety, impermissibly overinclusive. So under a strict-scrutiny analysis, the FDA would likely fail to persuade the court to uphold the constitutionality of the gay blood ban. If *any* viable and less discriminatory option for the FDA exists, then the court would especially look at the blood ban with a wary eye.

3. Constitutional Conclusions

The government objective of defending the blood supply must remain stalwart, yet this does not save the FDA’s gay blood ban or one-year deferral.²¹⁹ With the advent of new technologies and a greater understanding of HIV, the ban is no longer narrowly tailored to achieve a compelling government interest,²²⁰ but now is considered by many, including medical experts,²²¹ to be arbitrary and based on obsolete science.²²²

The landmark decision in *Windsor* struck down the most restrictive portion of DOMA.²²³ Gay marriage is now legal in

217. *Id.* (quoting *Richmond v. J.A. Croson Co.*, 488 U.S. 469, 500 (1989)) (internal quotation marks omitted).

218. *Id.* (quoting *Grutter v. Bollinger*, 539 U.S. 306, 333 (2003)) (internal quotation marks omitted); *see also id.* (stating that only “the most exact connection between justification and classification” would survive strict scrutiny (quoting *Gratz v. Bollinger*, 539 U.S. 244, 270 (2003)) (internal quotation marks omitted)).

219. This is especially true since the law is now based on scientific facts which have ceased to exist and have been replaced by newer understanding of the disease. *See Scheller & Almendrala, supra* note 84.

220. *See United States v. Windsor*, 133 S. Ct. 2675, 2717 (2013). The “narrowly tailored” law achieving a “compelling government interest” is the hallmark standard by which a law may survive the strict scrutiny standard. *Id.*

221. *See Mohnney, supra* note 11.

222. *See id.*

223. *See Windsor*, 133 S. Ct. at 2695–96.

thirty-seven states.²²⁴ That two men may legally marry yet be considered a high risk of HIV is not patently absurd, but the idea of monogamy between same-sex couples is now a socially (and in places, legally) recognized relationship, a far cry from the environment of the 1980's. The FDA blood ban (and potential deferral) does not address MSM who are in monogamous relationships and does not consider them to be low-risk individuals.²²⁵ With the changing attitudes towards homosexuality, same-sex marriage, and new technology, including the NAT and antibody tests,²²⁶ there is no justification, constitutional or otherwise, for maintaining the gay blood ban as it is.

Further, the guideline is likely violative of the federal Equal Protection Clause. While this Note cannot make a definitive conclusion as to the outcome of a constitutional challenge to the FDA's gay blood ban or one-year deferral, a successful challenge would very likely include arguments that the law, though facially neutral, has a discriminatory effect on gay and bisexual men as a protected class and is impermissibly overinclusive as to be violative of the Equal Protection Clause.

III. POTENTIAL EQUITABLE SOLUTIONS

The challenge to the FDA's gay blood ban set forth in this Note is a comprehensive, direct challenge to the ban. It proposes a method by which the ban may be properly challenged, directly in courts.²²⁷ By challenging the ban on the basis of its constitutional merits, this Note lays the groundwork for challenging the ban directly. An indirect challenge would not be sufficient, as it would not address the ban on its merits.²²⁸ Proving the unconstitutionality of the ban is, however, only one of this Note's ultimate goals. Pointing out the unconstitutionality of the current and future policy has little utility without suggesting an ideal policy that may be used instead. Section A briefly considers what other countries have implemented in terms of blood donation guidelines. Section B suggests an effective and equitable guideline.

224. See *States*, *supra* note 202.

225. FDA Guidelines, *supra* note 7.

226. See *Darling*, *supra* note 44.

227. See *supra* Part II (discussing constitutional challenges to the FDA's gay blood ban).

228. See *Nelson*, *supra* note 87, at 16.

A. COMPARATIVE APPROACH: WHAT OTHER COUNTRIES HAVE DONE

While maintaining the current gay blood ban cannot stand, as it most likely would not withstand constitutional muster, eliminating the ban entirely with no other guidelines may have troubling consequences.²²⁹ After all, the rate of HIV/AIDS infections in the young MSM population is on a steady rise.²³⁰ However, testing technology allows banks to determine whether blood is infected more inexpensively, more accurately, and more quickly.²³¹ Therefore, rather than eliminating the ban, a balance should be struck between preserving the integrity of the nation's blood supply and allowing certain MSM populations at low risk for HIV/AIDS infection to donate blood.²³²

One inquiry that may better inform the problem is a comparative approach—to look beyond the borders of the United States and evaluate how other countries with less restrictive guidelines on blood donations have handled the problem. Note that this comparative approach is not a basis for challenging the ban. It is a method by which to evaluate the effectiveness (or lack thereof) of blood donation policies from other nations.

Maintaining a deferral period of a year is a popular alternative to a lifetime bar, and many countries have done just that. Australia, for example, has a one-year ban in place.²³³ Studies have shown that, for men who are sexually inactive for a twelve-month period, there is no increased risk of transfusion-transmitted cases of HIV.²³⁴ However, while such deferrals are more progressive than the current United States regulation, they might lead to extended “dry spells”²³⁵ on any MSM

229. See FDA Guidelines, *supra* note 7. If anything, a questionnaire would be critical in ascertaining who may and who may not donate, so as to screen potentially high-risk donors.

230. HIV AND YOUNG MEN, *supra* note 73.

231. See Kain, *supra* note 56.

232. Low-risk sexual behavior as defined by the FDA (e.g., not having sex with prostitutes, not engaging in sexual activity involving intravenous drug use, etc.) should be applied to gay men as it is applied to heterosexual individuals. A low-risk MSM may be a gay man in a monogamous marriage, whereas a high-risk MSM may be a sex worker.

233. Seed et al., *supra* note 61, at 2722. A one-year deferral essentially allows gay men to donate blood if they have not had sex with other men within the past year.

234. See *id.*

235. The phrase “dry spell” is a common colloquialism meaning “to go for a period of time (usually longer than shorter) without something,” e.g., sex. *Dry Spell Definition*, URBAN DICTIONARY, <http://www.urbandictionary.com/define.php?term=dry%20spell> (last visited Apr. 20, 2015).

who ever hopes to donate blood.²³⁶ And this is the primary objection to the FDA's proposed one-year deferral period.

Other nations have implemented less restrictive laws. Declaring that "sex between people of the same sex ceases to be considered a danger, disease, or infection by the Health Ministry," Chile completely lifted the ban on gay and lesbian donors.²³⁷ Mexico has also lifted its ban entirely.²³⁸ Neither ban lifts are without qualification: Chile's new policy bans *all* people, regardless of sexual orientation, from donating blood if they have engaged in risky sexual behavior, which is defined as sex with more than one partner in the last twelve months.²³⁹ In Mexico, the focus is similarly on risky behavior rather than social groups.²⁴⁰ Gay and bisexual men who have a history of using condoms, who do not inject drugs, and who are not sex workers are eligible to donate blood under Mexico's new law.²⁴¹ Heterosexuals are subjected to the same standard,²⁴² an important distinction from the current United States guidelines.

In the countries that have lifted the ban, there is a clear shift in focus. Instead of identifying an individual's sexual orientation or a specific social group, the laws focus on risky behaviors.²⁴³ In the process of updating their laws, the countries with complete ban-lifts used compelling policy arguments in regards to ending discrimination.²⁴⁴ The countries that have ended their bans placed at least some emphasis on the rights of minority citizens. The FDA, on the other hand, makes little mention of whether its policy is discriminatory.²⁴⁵

236. Though a year-long deferral is clearly preferable to a lifetime ban, the practical consequences essentially restrict the sexual activity of the MSM population, especially considering that in some states, gay marriage is legal. The hypothetical one-year deferral would lead to an unusual situation for many MSM: abstain from sex (even if married) for a year, donate, and then resume sexual activity.

237. Trovall, *supra* note 61.

238. Roberts, *supra* note 61.

239. Trovall, *supra* note 61.

240. Roberts, *supra* note 61.

241. *Id.* It should also be noted that the new law is devoid of qualifications based on sexual identity. *See id.*

242. *See id.*

243. *See, e.g., id.*

244. *See* Sunnive Brydum, *Mexico Lifts Blood Donation Ban for Gay and Bisexual Men*, *ADVOCATE* (Dec. 28, 2012, 4:32 PM), <http://www.advocate.com/health/health-news/2012/12/28/mexico-lifts-blood-donation-ban-gay-and-bisexual-men>.

245. FDA Guidelines, *supra* note 7 ("FDA's deferral policy is based on the documented increased risk of certain transfusion transmissible infections, such as HIV, associated with male-to-male sex and is not based on any judg-

Excluding the policy justification from the discrimination-context cannot stand. As the previous section established, there are meritorious arguments addressing the discriminatory aspect of the FDA ban.²⁴⁶ Thus, for a truly equitable solution to emerge, evaluation of the ban must follow the model of countries such as Mexico and Chile and put more emphasis on eliminating discriminatory elements within any new guidelines.

B. A SAFE AND EQUITABLE POLICY SOLUTION

An ideal donation policy in the United States must maintain the integrity of the blood supply and provide equitable treatment to the MSM community. Above all, it may not apply in unqualified terms to one population or another in order to remain consistent with Due Process and Equal Protection.²⁴⁷ As such, this Note suggests a regulation that allows gay men who engage in non-risky sexual behavior to donate blood while maintaining safeguards in place to protect the blood supply.

First, the new regulation must apply to all individuals, men and women, regardless of their sexual orientation. Such a qualification is arbitrary and potentially unconstitutional, as discussed above.²⁴⁸ To create a law that is both effective and protects the constitutional interests of potential blood donors, the United States should look to solutions enacted by other countries, such as Chile and Mexico.²⁴⁹ Thus, the new guideline must shift the focus from sexual orientation to sexual behavior.²⁵⁰ The new regulation should take into account current medicine and current blood-testing technology.²⁵¹

Current technology allows for the detection of HIV immediately following infection at around ten days, and two weeks is considered a “safe” timeframe.²⁵² Because of the timeline in which HIV infection occurs and shows up in tests,²⁵³ all individ-

ment concerning the donor’s sexual orientation.”).

246. See *supra* Part II.C.

247. See *supra* Part II.C.

248. See *supra* Part II.C.

249. Roberts, *supra* note 61; Trovall, *supra* note 61.

250. For example, instead of focusing on gay men having sex, shift the focus to any individual who habitually uses intravenous drugs concurrently with sex.

251. See Darling, *supra* note 44.

252. *Id.*

253. *Id.* (“Within seven to 10 days, we can say with 99.9 percent accuracy whether or not a blood sample is HIV-positive. The chance of an HIV-positive blood sample testing negative after the 7 to-10-day window is about 1 in 2 million . . . [I]f you’ve had unsafe sex within the past 10 days, it might be reasonable for us to send you home. But a lifetime ban . . . is kind of ridiculous.”).

uals who have engaged in unsafe sex within fourteen days prior to attempted donation should be turned away. This will ensure that gay men engaging in “safe” sex, or those who have not, will still be eligible at some point in the foreseeable future to donate blood. Further, it should be emphasized that rejecting donations should be the exception: individuals who have a history of using condoms, engaging in safe sex, and who have not engaged in unsafe sex within the past fourteen days should be permitted to donate blood.²⁵⁴ This proposed process would impose no additional burden on blood banks, as they routinely pay for all blood screening, using the latest technology at their disposal.²⁵⁵

Defining what constitutes safe sexual activities is critical to developing a sound, effective guideline. For example, unsafe sex could constitute engaging in unprotected sex with one or multiple partners, having sexual relations of any sort with a sex worker, and engaging in sexual behavior in concurrence with drug use.²⁵⁶ However, stipulating the number of sexual partners one may have is, so to speak, another can of worms that this Note shall not open. Additionally, the definition may include stipulations regarding proper condom usage, regardless of the sexual partner(s) involved. Such a solution, with the fourteen-day deferral period, takes adequate steps to filter out high-risk donors and, with the elimination of the MSM designation, does not run afoul of the due process doctrine.

Such a new regulation should also follow the proper procedural guidelines for administrative rules, pursuant to the APA, so as to not make the same mistakes as the current guideline.²⁵⁷ Specifically, the notice-and-comment requirement, critical to preserving the public discourse on rules intended to be binding, should be respected in the interest of the democratic process.²⁵⁸

254. Either way, it would seem that the public health policy goals would still be maintained with this regulatory framework. The most critical objective now is to remove the stigma associated with HIV.

255. Blood banks do not only pay for HIV screening, they screen for a host of other ailments and viruses, including hepatitis B, hepatitis C, blood that is at risk for leukemia or neurological diseases, syphilis, West Nile Virus, and bacterial contamination. See *Donation FAQs*, AM. RED CROSS, <http://www.redcrossblood.org/donating-blood/donation-faqs> (last visited Apr. 20, 2015).

256. Such a definition for “unsafe” sexual activities may be taken from definitions provided in countries where the focus on donation restrictions is on behavior rather than sexual orientation, such as Chile. See *generally supra* Part III.A.

257. See *generally* 5 U.S.C. § 553 (2012) (articulating the rule-making procedures).

258. Cf. Anthony, *supra* note 93, at 1312 (“To use . . . nonlegislative documents to bind the public violates the Administrative Procedure Act . . . and

This proposed solution is the most equitable. By basing guidelines for who may donate on risky behavior rather than sexual orientation, the FDA can avoid claims of discriminatory policy-making.²⁵⁹ With clearly stipulated behaviors (proven to be high-risk) that would warrant a *temporary* deferral from donating blood, the FDA can achieve its goals of protecting and growing the national blood supply. The FDA would not only be acting pursuant to an unquestionably constitutional regulation, but one that increases the availability of blood and protects the dignity of the MSM population.

All of this being said, this Note includes a proposal for what a new blood donation guideline might contain. Currently, the language of the FDA's rule states that:

Men who have had sex with other men (MSM), at any time since 1977 (the beginning of the AIDS epidemic in the United States) are currently deferred as blood donors. This is because MSM are, as a group, at increased risk for HIV, hepatitis B and certain other infections that can be transmitted by transfusion.²⁶⁰

Even the new regulation, with its one-year deferral period, looks to contain the exact same language, which substantively changes nothing about the discriminatory impact on gay men.²⁶¹ This language must be eliminated in its entirety, as sexual orientation is an arbitrary method of determining risk.

Instead, the new regulation should begin with language such as: "Individuals who have engaged in sexual behavior characterized as risky, unsafe, or dangerous are currently deferred as blood donors." Removing a label regarding gender, sex, or sexual orientation is crucial in ensuring that the new rule applies equally to all citizens in accordance with federal Due Process and Equal Protection.²⁶²

Defining sexually unsafe or risky behavior, as explained above, is essential to forming the new rule in a way that best protects the nation's blood supply. Such language might say:

dishonors our system of limited government.").

259. One source points out that, though African-Americans account for a large portion of the HIV-positive population, there is no deferral for them and that, were such a deferral to be put in place, it would obviously be seen as racist. Smith, *supra* note 60.

260. FDA Guidelines, *supra* note 7.

261. *Donor Deferrals: The FDA's Blood Policy on Gay Men Falls Short*, PITTSBURGH POST-GAZETTE (Jan. 4, 2015, 12:00 AM), <http://www.post-gazette.com/opinion/editorials/2015/01/04/Donor-deferrals-The-FDA-s-blood-policy-on-gay-men-falls-short/stories/201501090002> (stating that under the potential new policy, "many gay men still won't be eligible to donate, and the nation's blood supply will continue to suffer for it").

262. See U.S. CONST. amend. V; U.S. CONST. amend. XIV, § 1.

“The FDA defines risky, unsafe, or dangerous sexual behavior as having engaged in any of the following activities within thirty days of donation: (1) engaging in unprotected sex with one or multiple partners; (2) engaging in protected or unprotected sex with a sex worker; (3) engaging in protected or unprotected sex in concurrence with intravenous or otherwise illegal drug use. ‘Unprotected’ sex is commonly understood to mean having sex without the use of a condom and/or a diaphragm.” This language is a more accurate representation of what populations present the most risk to the blood supply than does the current FDA rule. Adding sixteen days to the fourteen day “safety” window is designed to provide an extra level of reassurance that the screened blood is truly safe.²⁶³

The language contained within this proposed regulations accomplishes what the FDA should have set out to do when it first implemented the gay blood ban. It applies to individuals in a manner that is not discriminatory because it does not identify at-risk individuals by their sex, gender, sexual orientation, and so on. Second, it provides a more than adequate level of protection for the blood supply by clearly defining sexually risky behavior that is likely to result in an infection with HIV, hepatitis B, and other serious illnesses. With a blood donation guideline containing this language, the FDA would finally have a rule that is properly tailored to achieve its interests and the interests of the LGBT community.

CONCLUSION

The United States has a long and wearied history with the HIV/AIDS epidemic.²⁶⁴ The fight against the epidemic still continues, with the rates of young MSM infections on the rise and overall infection rates remaining stable.²⁶⁵ Nevertheless, the FDA’s current policy on blood donation, though implemented at a time when it was a logical solution, is no longer sensible.²⁶⁶ In fact, the policy, in light of technological developments,²⁶⁷ changing social attitudes, and increasing legal rights for the LGBT

263. And to an individual wishing to donate blood, this is a much less burdensome requirement. For example, a gay man wishing to donate under the current ban cannot if he has ever had sex. Under the proposed regulation, the burden would mean waiting a year. But if, for instance, this ideal regulation were implemented, a donor would have to wait a mere thirty days if he or she engaged in risky behavior.

264. See *A Timeline of AIDS*, *supra* note 17.

265. HIV AND YOUNG MEN, *supra* note 73.

266. See *supra* Part II.B.

267. See Mohny, *supra* note 11.

population²⁶⁸ is not only arbitrary, it may lead to ridiculous results.²⁶⁹

A sensible solution for the modern world would apply to all people regardless of sexual orientation, implement a reasonable deferral period for those who have engaged in unsafe sex, and take into account the current technology and attitudes of today. A new policy is clearly needed so that those individuals like Campbell, California Mayor Evan Low²⁷⁰ and other healthy gay men who would otherwise be perfect donors were it not for the capricious ban, may one day be allowed to participate in a system which saves lives on a daily basis.

268. See Sievers, *supra* note 3.

269. See, e.g., Darling, *supra* note 44.

270. Vongsarath, *supra* note 1.