

## COMMENTS

### SCIENCE OR STIGMA: POTENTIAL CHALLENGES TO THE FDA'S BAN ON GAY BLOOD

*Dwayne J. Bensing*\*

#### I. INTRODUCTION

There is a great need for blood in the United States.<sup>1</sup> Each year, 4.5 million Americans will need a blood transfusion.<sup>2</sup> The American Association of Blood Banks (AABB) estimates that 10.8 million volunteers donate blood each year, less than ten percent of the eligible donors.<sup>3</sup> The great need for blood, coupled with the small pool of donors, has resulted in blood shortages that jeopardize the execution of medical procedures.<sup>4</sup> The blood supply in the United States has reached a breaking point.<sup>5</sup>

---

\* J.D. Candidate, 2012, University of Pennsylvania Law School, B.A., 2007 University of Arkansas. Special thanks to Professor Sophia Z. Lee for her guidance in this process and to my partner, Christopher R. Howland, who provided feedback and encouragement.

1 See, e.g., *Blood FAQ*, AABB, <http://www.aabb.org/resources/bct/Pages/bloodfaq.aspx> (last visited Oct. 24, 2011) (“Every day in the U.S., approximately 44,000 units of blood are required in hospitals and emergency treatment facilities for patients with cancer and other diseases, for organ transplant recipients, and to help save the lives of accident/trauma victims. In 2008, more than twenty-three million blood components were transfused. And with an aging population and advances in medical treatments and procedures requiring blood transfusions, the demand for blood continues to increase.”).

2 *56 Facts About Blood*, AM.’S BLOOD CTRS., <http://www.americasblood.org/go.cfm?do=page.view&pid=12> (last visited Oct. 24, 2011).

3 See AABB, *supra* note 1 (stating that “AABB estimates that 10.8 million volunteers donate blood each year” and that “less than 10 percent” of the U.S. population “eligible to donate blood at any given time” actually do so).

4 See Ishani Ganguli, *Blood Shortage Puts Safety Measures in Question*, REUTERS (Sept. 10, 2007, 10:23 AM), <http://www.reuters.com/article/2007/09/10/us-usa-health-blood-idUSN064262220070910?pageNumber=1> (noting that “American blood banks experienced one of their driest summers in history” and that “[i]n Washington’s Georgetown University Hospital, officials came close to canceling nonemergency operations several times this summer”).

5 See *Red Cross Blood Supply Drops to Critically Low Levels*, AM. RED CROSS (July 11, 2011), <http://www.redcross.org/portal/site/en/menuitem.94aae335470e233f6cf911df43181aa0/?vgnnextoid=2b24ae4376d01310VgnVCM10000089f0870aRCRD> (stating that the American Red Cross “issued an appeal for blood donors to roll up a sleeve and address a critical shortage across the nation”).

FDA regulations require blood collection establishments, such as the American Red Cross, to screen potential blood and plasma donors for risk factors related to HIV and other infectious diseases.<sup>6</sup> To comply with the FDA's policy, on the date of the donation, blood donation centers are required to assess each prospective donor's medical history.<sup>7</sup> Generally, a donor must be healthy, be at least 17 years old, and weigh at least 110 lbs.<sup>8</sup> However, regulations identify certain "high-risk" donors that are "deferred."<sup>9</sup> Among the deferred groups that may not donate blood, the FDA guidance materials identify men who have had sexual contact with other men ("MSM"), even once, since 1977, as high-risk.<sup>10</sup> These men are given a lifetime deferral.<sup>11</sup>

In response to growing pressure from LGBT advocacy groups,<sup>12</sup> political figures,<sup>13</sup> and state<sup>14</sup> and local governments,<sup>15</sup> the U.S. De-

---

6 See 21 C.F.R. § 640.3(b)(6) (2011) (describing FDA qualifications of potential whole blood donors); 21 C.F.R. § 640.63(c)(9) (describing FDA qualifications of potential plasma donors).

7 See 21 C.F.R. § 640.3 (describing FDA requirements for determining the suitability of a potential donor of whole blood).

8 See *Eligibility Requirements*, AM. RED CROSS, <http://www.redcrossblood.org/donating-blood/eligibility-requirements> (last visited Oct. 24, 2011) (describing eligibility requirements for blood donors).

9 See U.S. DEP'T OF HEALTH & HUMAN SERVS., REVISED RECOMMENDATIONS FOR THE PREVENTION OF HUMAN IMMUNODEFICIENCY VIRUS (HIV) TRANSMISSION BY BLOOD AND BLOOD PRODUCTS 2 (1992), available at <http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/OtherRecommendationsforManufacturers/MemorandumtoBloodEstablishments/UCM062834.pdf> (explaining that the "implications for donors who have engaged in certain high-risk activities" may include a donor being considered "unsuitable," which may result in a "deferral").

10 See *id.* at 2–3 (including "[m]en who have had sex with another man even one time since 1977" under the "Criteria for the Exclusion of Unsuitable Donors Who Are at Increased Risk for HIV" section).

11 See *id.* at 3 (listing "[m]en who have had sex with another man even one time since 1977" as a group that "should not donate blood or blood components").

12 See, e.g., JOSEPH J. WARDENSKI ET AL., GAY MEN'S HEALTH CRISIS, A DRIVE FOR CHANGE: REFORMING U.S. BLOOD DONATION POLICIES i–iii (Sean Cahill et. al. eds., 2010), available at [http://www.gmhc.org/files/editor/file/a\\_blood\\_ban\\_report2010.pdf](http://www.gmhc.org/files/editor/file/a_blood_ban_report2010.pdf) (providing background on the development of the policy and arguing that the ban is outdated).

13 See Michelle Garcia, *Kerry Calls for Gay Blood Ban Repeal*, ADVOCATE.COM (July 26, 2010, 6:30 PM), [http://www.advocate.com/News/Daily\\_News/2010/07/26/Kerry\\_Calls\\_for\\_Gay\\_Blood\\_Ban\\_Repeal/](http://www.advocate.com/News/Daily_News/2010/07/26/Kerry_Calls_for_Gay_Blood_Ban_Repeal/) (describing Senator Kerry's "effort to get the U.S. Food and Drug Administration to revise its current policy barring all gay men from donating blood").

14 See Dan Aiello, *Ending the Federal Ban on Gay Blood Donations*, CAL. PROGRESS REP. (Aug. 19, 2009), <http://www.californiaprogressreport.com/site/node/252> (noting that "the Assembly Judiciary Committee [in California] passed AJR 13, the U.S. Blood Donor Nondiscrimination Resolution," which "call[ed] upon the nation's Food and Drug Administration to end its . . . ban on gay men donating blood to the nation's blood banks").

partment of Health and Human Services' Advisory Committee on Blood Safety and Availability met on June 11, 2010 to reconsider the MSM ban.<sup>16</sup>

Despite significant changes in testing since the ban was originally implemented,<sup>17</sup> the Committee decided to retain the twenty-five year old policy that bans blood donation by any man who has had sex with a man at any time, even once, since 1977.<sup>18</sup> In a 9-6 vote, the Committee cited a lack of research to support the notion that lifting the ban would not contaminate the blood supply.<sup>19</sup>

This FDA Policy raises questions of constitutionality and legality because it is predicated on assumptions about HIV/AIDS that are not based in fact or theory, but based on mere stigma.<sup>20</sup> The policy actually provides a one-two punch: at the same time as the policy reinforces negative stereotypes that gay men are carriers of communica-

- 
- 15 See ROBERT JACKSON, LEGISLATIVE AND COMMUNITY REPORT 2 (2010), *available at* [http://www.council.nyc.gov/d7/html/members/pdf/community\\_report\\_04.30.2010.pdf](http://www.council.nyc.gov/d7/html/members/pdf/community_report_04.30.2010.pdf) (explaining that “the [New York City] Council passed a resolution calling on the U.S. Food and Drug Administration (FDA) to eliminate its’ [sic] 30 year old prohibition on blood donation by gay and bisexual men” because the “ban was based on prejudice, a knee-jerk reaction, and misunderstandings about the HIV/AIDS disease” and because “[g]iven the constant need for blood, it [did] not make common sense to prohibit donations from an entire population”); *see also* Res. 18-486, 2010 Council of D.C (D.C. 2010), *available at* <http://www.dccouncil.washington.dc.us/images/00001/20100607125919.pdf> (explaining that on June 1, 2010 the Washington, D.C. Council passed a resolution calling on the FDA to “reverse the lifetime deferral of blood donations by men who have had sex with men since 1977 in favor of a policy that protects the safety and integrity of the blood supply that is based on an up-to-date scientific criteria [sic]”).
- 16 See HHS Advisory Committee on Blood Safety and Availability, U.S. DEP’T OF HEALTH & HUMAN SERVS., 1 (June 2010), [http://www.hhs.gov/ash/bloodsafety/advisorycommittee/recommendations/06112010\\_recommendations.pdf](http://www.hhs.gov/ash/bloodsafety/advisorycommittee/recommendations/06112010_recommendations.pdf) (voting on whether “current indefinite deferral for men who have had sex with another man even one time since 1977 [should] be changed”).
- 17 See Neal Conan, *FDA Ban On Blood Donated By Gay Men Upheld*, NAT’L PUB. RADIO (June 29, 2010), <http://www.npr.org/templates/story/story.php?storyId=128193248> (describing the improved method of testing blood that scientists have recently developed called “nucleic acid testing”).
- 18 See Jacqueline Mroz, *Gay Men Condemn Blood Ban as Biased*, N.Y. TIMES, Aug. 3, 2010, at D5 (describing the reaction of the gay community and others to the FDA’s decision to uphold the ban preventing gay men from donating blood).
- 19 See U.S. DEP’T OF HEALTH & HUMAN SERVS., *supra* note 16, at 1 (summarizing the HHS Advisory Committee on Blood Safety and Availability’s decision to continue the “indefinite deferral for men who have had sex with another man even one time since 1977”).
- 20 See Whitney Larkin, *Discriminatory Policy: Denying Gay Men the Opportunity to Donate Blood*, 11 HOUS. J. HEALTH L. & POL’Y 121 (2011) (arguing that the out-dated policy is discriminatory). *But see* Adam R. Pulver, *Gay Blood Revisionism: A Critical Analysis of Advocacy and the “Gay Blood Ban,”* 17 L. & SEXUALITY 107, 127–28 (2008) (arguing that there are legitimate public health justifications for preventing gay men from donating blood).

ble diseases just because of their orientation,<sup>21</sup> it undermines the FDA's need for potential blood donors by rejecting healthy gay donors.<sup>22</sup> The policy also provides false security to high-risk heterosexual donors because it ignores risky heterosexual behaviors, such as multiple partners and unprotected sex, which potentially endanger one's health and possibly the blood supply.<sup>23</sup>

This Comment will build upon the scholarly work that others have started<sup>24</sup> to address the various available legal avenues to challenge the FDA's MSM policy. Part II will briefly discuss the history leading to the current FDA Policy and the science that undermines the Advisory Committee's conclusions. Part III will address potential constitutional challenges to the FDA Policy and explain how recent Supreme Court decisions, and interpretations of those decisions, change the legal landscape in favor of repeal. Part IV provides a roadmap for APA challenges to the FDA Policy and explains how these challenges differ from constitutional claims, augmenting the available legal arguments against the policy. Finally, Part V will conclude by exploring the ways in which administrative constitutionalism could play a role in a successful challenge to the blood ban through the Administrative Process.

---

21 See SuchIsLifeVideos, *Bryan Fischer On Why GOProud Was Disinvited To CPAC 2012*, YOUTUBE (Aug. 4, 2011), [http://www.youtube.com/watch?feature=player\\_embedded&v=qXRrogq-FGg](http://www.youtube.com/watch?feature=player_embedded&v=qXRrogq-FGg) ("Now one of the reasons and I think this is where our argument[] [rejecting gays] [is] infallible . . . is the danger that homosexual contact imposes to human health . . . It's not a lifestyle. It is a death-style.").

22 See Zachary Roth, *Man Says He Was Rejected by Blood Bank for Seeming Gay*, YAHOO! NEWS (July 18, 2011), <http://news.yahoo.com/blogs/lookout/man-says-rejected-blood-bank-seeming-gay-151627659.html> ("[A] recent study found that the gay ban costs hospitals 219,000 pints of blood each year."); see also Naomi G. Goldberg & Gary J. Gates, *Effects of Lifting the Blood Donation Ban on Men Who Have Sex With Men*, 5 PITTSBURGH J. ENVTL. & PUB. HEALTH L. 49, 57 (2011) ("If the current MSM ban were completely lifted, we estimate that an additional 130,150 men would likely donate 219,200 additional pints of blood each year.").

23 See John G. Culhane, *Bad Science, Worse Policy: The Exclusion of Gay Males from Donor Pools*, 24 ST. LOUIS U. PUB. L. REV. 129, 130 (2005) (arguing that the blood ban is bad public health policy and harms the LGBT community).

24 See, e.g., Michael Christian Belli, *The Constitutionality of the "Men Who Have Sex With Men" Blood Donor Exclusion Policy*, 4 J.L. SOC'Y 315, 371-73 (2003) (posing equal protection challenges to the blood ban as applied to "Healthy Gay Men"). Note that this article was written prior to the *Lawrence v. Texas*, 539 U.S. 558 (2003), decision. See also Luke A. Boso, Note, *The Unjust Exclusion of Gay Sperm Donors: Litigation Strategies to End Discrimination in the Gene Pool*, 110 W. VA. L. REV. 843, 845-46 (2008) (explaining how the similar FDA ban on gay sperm is potentially challengeable under the Equal Protection Clause and the Administrative Procedure Act).

## II. THE MSM BAN

In July of 1982, Acquired Immune Deficiency Syndrome (“AIDS”) became the “official name of a mysterious organism that was believed to be causing homosexuals, hemophiliacs, Haitians, and intravenous drug users to develop a variety of opportunistic infections.”<sup>25</sup> Little was known about the disease, leaving the medical and LGBT communities utterly confused about an appropriate response.<sup>26</sup> The Centers for Disease Control (“CDC”)<sup>27</sup> proposed deferral guidelines—asking people in high-risk groups such as gay men, Haitians, and drug users to refrain from donating blood—at their summer 1982 meeting.<sup>28</sup> However, opposition to the CDC proposal was widespread, shared by the National Hemophilia Foundation and the LGBT community alike.<sup>29</sup> It became increasingly clear, though, both in the United States and abroad,<sup>30</sup> that a response to the threat of AIDS within the blood supply was necessary.<sup>31</sup> This Part provides the history and legal landscape of regulations promulgated for the purposes of securing the blood supply, and describes the technological ad-

25 See Belli, *supra* note 24, at 328 (chronicling “the AIDS crisis in the United States and HIV testing methods developed since its advent”).

26 See Linda Dorney, Book Note, *And The Band Played on Politics, People, and the AIDS Epidemic*, 3 J. PHARMACY & L. 55, 56 (1994) (reviewing RANDY SHILTS, *AND THE BAND PLAYED ON: POLITICS, PEOPLE, AND THE AIDS EPIDEMIC* (1988) (describing the initial confusion within the medical community regarding AIDS)).

27 See Sherry Glied, *Markets Matter: U.S. Responses to the HIV-Infected Blood Tragedy*, 82 VA. L. REV. 1493, 1495–96 (1996) (“The CDC has no direct regulatory power. It provides epidemiologic information and technical support to other regulatory agencies and information to medical providers and the public, but relies on the FDA and other Public Health Service agencies to implement its recommendations. It issued regular surveillance reports and initiated meetings of blood banks, manufacturers, and the FDA during the early 1980s, but its recommendations were often ignored in the face of opposition from powerful interest groups, especially blood bankers and gay rights activists.”).

28 See SHILTS, *supra* note 26 (describing the CDC’s proposed deferral guidelines).

29 See Pulver, *supra* note 20, at 111 (describing the negative reaction to the CDC proposal).

30 See Francine A. Hochberg, *HIV/AIDS and Blood Donation Policies: A Comparative Study of Public Health Policies and Individual Rights Norms*, 12 DUKE J. COMP. & INT’L L. 231, 231–32 (2002) (comparing the U.S. blood donation policy to five other countries that also ban “blood donations by MSM”); see also Rachael Lake, *MSM Blood Donation Ban: (In)Equality, Gay Rights and Discrimination Under the Charter*, 15 APPEAL 136, 136 (2010) (arguing that Canada’s ban on gay blood is discriminatory); Adrian Lomaga, *Are Men Who Have Sex With Men Safe Blood Donors?*, 12 APPEAL 73, 85–88 (2007) (arguing that the Canadian ban on gay blood is unconstitutional).

31 See Robin Marantz Henig, *AIDS: A New Disease’s Deadly Odyssey*, N.Y. TIMES, Feb. 6, 1983, at SM28 (describing the fear that many felt at the time regarding AIDS contamination in the nation’s blood supply and the “intensified” “efforts to find its cause and stop its spread”).

vancements that now make those policies both unresponsive to the goals they originally sought and legally problematic.

#### A. *History and Legal Landscape*

The U.S. Public Health Service (“PHS”), housed within the Department of Health and Human Services, is responsible for national public health.<sup>32</sup>

The specific responsibility for developing policies to ensure the quality and safety of the blood supply was delegated to the Center for Biologics Evaluation and Research (“CBER”) <sup>33</sup> under the guidance of the FDA.<sup>34</sup> The FDA implements policies related to blood and other bodily organs, tissues, and fluids; the policies are drafted by the CBER through federal regulations.<sup>35</sup> The FDA is charged with licensing blood banks,<sup>36</sup> and is therefore responsible for creating safeguards to

<sup>32</sup> See James G. Hodge, Jr., *The Role of New Federalism and Public Health Law*, 12 J. L. & HEALTH 309, 337 (1997–98) (“The United States Public Health Service, now a part of the Department of Health and Human Services, is the federal unit with primary responsibility for national public health.”). The PHS was originally the Marine Hospital Service; it was renamed in 1912. *Id.* at 331–32. Since that time, the PHS has grown from administering health services to marines to administering many of the operative agencies of the United States Department of Health and Human Services (“DHHS”), including the CDC, the National Institutes of Health (“NIH”), the Food and Drug Administration (FDA), and the Human Resources and Services Administration (HRSA). *Id.* at 337.

<sup>33</sup> The National Center for Drug and Biologics (“NCDB”) and its Office of Biologics were established as part of the FDA in 1982. See 47 Fed. Reg. 26913, 26913–14, 26919 (June 22, 1982). Both were reorganized two years later into the Center for Drugs and Biologics (“CDB”) and the Office of Biologics Research and Review, respectively. See 49 Fed. Reg. 10168, 10168, 10172–73 (Mar. 19, 1984). In 1987, the FDA established two centers to replace the CDB: the Center for Drug Evaluation and Research (“CDER”) and the Center for Biologics Evaluation and Research (“CBER”). See 52 Fed. Reg. 38275 (Oct. 15, 1987). In 1988, the Office of Biologics Research and Review—under the authority of the CBER—became the Office of Biologics Research. See 53 Fed. Reg. 8978, 8980 (Mar. 18, 1988). The Office of Biologics Research is under the umbrella of the Department of Health and Human Services (“HHS”) and “sends its memoranda out under the HHS heading of ‘Public Health Service, Food and Drug Administration.’” Steven R. Salbu, *AIDS and the Blood Supply: An Analysis of Law, Regulation, and Public Policy*, 74 WASH. U. L. Q. 913, 947 n.192 (1996).

<sup>34</sup> See 21 C.F.R. § 5.10(a)(1), 5.10(a)(4) (2004) (delegating to the FDA authority vested in the Secretary of DHHS under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 301–309 (2006)) and under sections 351 and 352 of the Public Health Service Act (relevant provisions codified at 42 U.S.C. §§ 262–263 (2006))).

<sup>35</sup> Authority vested in the Secretary of Health and Human Services under section 361 of the Public Health Service Act (codified at 42 U.S.C. § 264 (2006)) includes the law enforcement functions of the FDA. These functions concern, among other subjects, blood and blood products, and have been re-delegated by the Secretary to the Commissioner of Food and Drugs. 21 C.F.R. § 5.10(a)(3).

<sup>36</sup> See 42 U.S.C. § 262(a) (2006); see also 21 U.S.C. § 360(b) (2006) (requiring processing establishments, including blood banks, to register with the FDA); 42 U.S.C. § 262(c)

minimize the risk that blood infected with infectious diseases, such as AIDS, will make its way into the blood pool.<sup>37</sup>

To that end, the FDA has established requirements relating to the licensing of blood banks,<sup>38</sup> the testing of blood prior to its release,<sup>39</sup> and the eligibility of donors.<sup>40</sup> To comply with the FDA's policy, blood donation centers are required to assess each prospective donor's medical, social, and sexual history on the date of the donation.<sup>41</sup> Although these regulations do not specifically identify MSM donors as a high risk group,<sup>42</sup> the FDA has issued guidance materials identifying MSM individuals as among the high risk groups that may not donate blood.<sup>43</sup>

In the United States, blood donor restrictions have evolved through the years.<sup>44</sup> In March of 1983, the first non-mandatory guidelines were issued<sup>45</sup> by the Office of Biologics recommending members of groups at "increased risk for AIDS" to refrain from donating plas-

---

(2006) (allowing the FDA to inspect blood or blood product facilities that participate in interstate commerce); *Snyder v. Am. Ass'n of Blood Banks*, 676 A.2d 1036, 1039 (N.J. 1996) ("The Food and Drug Administration (FDA), an agency of the Public Health Service (PHS) in the United States Department of Health and Human Services (DHHS), inspects and licenses blood banks and other blood facilities.").

<sup>37</sup> See *About the Center for Biologics Evaluation and Research*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/cber/about.htm> (last modified Sept. 30, 2011) (explaining how CBER's responsibilities in this regard derive from the Public Health Service Act and from specific sections of the Food, Drug, and Cosmetic Act).

<sup>38</sup> See 42 U.S.C. § 262 (2006) (establishing licensure requirements for biological products introduced into interstate commerce); 21 C.F.R. § 606.100 (2010) (outlining standard operating procedures for collecting, processing, testing, storing, and distributing blood and blood components for transfusion and manufacturing purposes).

<sup>39</sup> See 21 C.F.R. § 610.40 (2010) (requiring blood collection establishments to test blood donations for evidence of infection at the time of collection); 21 C.F.R. § 640.5 (requiring lab tests of blood specimens to occur at the time of donation).

<sup>40</sup> See 21 C.F.R. § 1271.50 (2011) (requiring donors to be "free from risk factors for, and clinical evidence of, infection").

<sup>41</sup> See 21 C.F.R. § 640.3(a) (2010) (requiring that blood donation centers assess each prospective donor's medical history).

<sup>42</sup> See 21 C.F.R. § 640.3(b)-(f) (listing factors that disqualify individuals for whole blood donation); 21 C.F.R. § 640.63(c) (listing factors that disqualify individuals for plasma donation).

<sup>43</sup> See U.S. DEP'T OF HEALTH & HUMAN SERVS., *supra* note 9, at 3 (indicating that MSM should refrain from donating blood or blood components).

<sup>44</sup> Salbu, *supra* note 33, at 947 (describing the evolution of blood restrictions).

<sup>45</sup> Memorandum from John C. Petricciani, M.D., Dir., Office of Biologics, Nat'l Ctr. for Drugs & Biologics, FDA, to All Establishments Collecting Human Blood for Transfusion, Recommendations to Decrease the Risk of Transmitting Acquired Immune Deficiency Syndrome (AIDS) from Blood Donors 1 (Mar. 24, 1983), in *HIV AND THE BLOOD SUPPLY: AN ANALYSIS OF CRISIS DECISIONMAKING* 290-91 (Lauren B. Leveton et al. eds., 1995).

ma or blood.<sup>46</sup> At that time, however, the guidelines only included gays who were either currently sexually active with multiple partners, had “overt symptoms of immune deficiency,” or had previously engaged in sexual relations with people who now exhibited such symptoms.<sup>47</sup> Blood collection agencies were also asked to provide educational materials on AIDS to donors, and to educate staff about identifying early signs or symptoms of AIDS in potential donors.<sup>48</sup> Furthermore, physicians were encouraged to provide transfusions only when “medically necessary.”<sup>49</sup>

Between 1984 and 1996, the Office of Biologics issued biannual revisions of the exclusion categories originally set forth in the 1983 Memorandum.<sup>50</sup> For the purposes of this Comment, the most significant changes occurred in 1986, when the policy began excluding men who have had sex with another man one or more times since 1977<sup>51</sup> (amending the 1984 language excluding males who have had sex with *more than one male* since 1979)<sup>52</sup> and in 1992, when the policy included language recommending a lifetime deferral for MSM.<sup>53</sup>

### B. Technological Advancements

Since the ban on MSM blood was first instituted in 1983, there have been several significant technological advancements in the testing of blood for HIV that make more accurate and targeted screening possible. Beginning in 1985, blood banks initiated universal testing of blood donations.<sup>54</sup> The FDA’s first test, an enzyme-linked immu-

---

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

47 SHILTS, *supra* note 28, at 242.

48 Robert K. Jenner, *Chronology of AIDS*, in TRANSFUSION-ASSOCIATED AIDS 22 (Robert K. Jenner ed., 1995).

49 *Id.* at 23 (internal quotation marks omitted).

50 Belli, *supra* note 24, at 339.

51 Memorandum from Elaine C. Esber, M.D., Dir., Office of Biologics Research & Review (“OBRR”), Ctr. for Drugs & Biologics, FDA, to All Registered Blood Establishments, Additional Recommendations for Reducing Further the Number of Units of Blood and Plasma Donated for Transfusion or for Further Manufacture by Persons at Increased Risk of HTLV-III/LAV Infection 1–2 (Oct. 30, 1986).

52 Memorandum from Elaine C. Esber, M.D., Acting Dir., Office of Biologics Research & Review, Ctr. for Drugs & Biologics, to All Establishments Collecting Blood for Transfusion and All Source Plasma (Human) Establishments, Plasma Derived from Therapeutic Plasma Exchange (Dec. 14, 1984).

53 See U.S. DEP’T OF HEALTH & HUMAN SERVS., *supra* note 9, at 3.

54 Hochberg, *supra* note 30, at 246; see also *Blood Testing*, AM. RED CROSS, <http://www.redcrossblood.org/learn-about-blood/what-happens-donated-blood/blood-testing> (last visited Oct. 25, 2011) (describing the blood tests performed by the Red Cross).

nosorbent assay test (the “ELISA test”), was approved in 1985 and detected human antibody produced in response to exposure to HIV.<sup>55</sup> Because the ELISA test had a high rate of false positives (safe blood testing positive for HIV), the FDA approved the first confirmatory test, the Western Blot, in 1987.<sup>56</sup> In combination, the ELISA and the Western Blot tests are considered to be 100% effective for detecting HIV antibodies.<sup>57</sup> However, there is a latency period of up to several months in which a person infected with HIV has not yet developed the antibodies detected by these tests.<sup>58</sup> Since 2002, however, the routine use of nucleic acid testing (“NAT”) for the HIV virus itself (rather than its antibodies) has further reduced the risk of transfusion transmission of HIV to about one unit per two million donations.<sup>59</sup> Typically, the test will detect the presence of HIV within nine to eleven days of infection, providing a window period significantly shorter than the more common antibody test.<sup>60</sup>

These technological advancements have called into question the validity of lifetime deferral policies of MSM blood, both within the United States and abroad.<sup>61</sup> Despite these advancements, however, the Blood Products Advisory Committee (“BPAC”)<sup>62</sup> has refused to

---

55 Belli, *supra* note 24, at 332–33.

56 *Id.* at 334–35.

57 *Kozup v. Georgetown Univ.*, 663 F. Supp. 1048, 1053 (D.D.C. 1987).

58 *See* Belli, *supra* note 24, at 336.

59 *See Blood Testing*, *supra* note 54 (describing the blood tests performed by the Red Cross); *see also* Christopher D. Pilcher et al., *Acute HIV Revisited: New Opportunities for Treatment and Prevention*, 113 J. CLINICAL INVESTIGATION 937, 937 (2004), available at <http://www.jci.org/cgi/reprint/113/7/937.pdf>. Nonetheless, “[w]hile HIV nucleic acid amplification assays are now extremely sensitive and can reliably detect HIV by days 9–11 of infection . . . , they are vulnerable to false-positive rates as high as 1%. Such tests remain relatively expensive and have not traditionally been used for routine clinical HIV screening.” *Id.* The Red Cross tests “minipools” of sixteen units using NAT. *Blood Testing*, AM. RED CROSS, <http://www.redcrossblood.org/learn-about-blood/what-happens-donated-blood/blood-testing> (last visited Nov. 24, 2011).

60 *HIV Testing Basics for Consumers*, CTRS. FOR DISEASE CONTROL AND PREVENTION, [http://www.cdc.gov/hiv/topics/testing/resources/qa/be\\_tested.htm](http://www.cdc.gov/hiv/topics/testing/resources/qa/be_tested.htm) (last modified Apr. 9, 2010).

61 *See* James Gallagher, *Gay Men Blood Donor Ban to be Lifted*, BBC NEWS (Sept. 8, 2011), <http://www.bbc.co.uk/news/health-14824310> (discussing the lifting of the lifetime ban on blood donations of gay men in England, Scotland and Wales); Joanna Smith, *Blood Donor Agency Wants Lifetime Ban Lifted for Gay Men*, THESTAR.COM (Jan. 27, 2011), <http://www.thestar.com/news/canada/article/928904-blood-donor-agency-wants-lifetime-ban-lifted-for-gay-men> (discussing the Canadian Blood Services change in position to opposing the lifetime deferral).

62 BPAC, a standing advisory committee to the FDA’s Center for Biologics Evaluation and Research (“CBER”), is charged with “review[ing] and evaluat[ing] data concerning the safety, effectiveness, and appropriate use of blood, products . . . intended for use in the diagnosis, prevention, or treatment of human diseases.” *Charter of the Blood Products Advi-*

change the MSM policy. The committee voted down any changes, including a comparable twelve month deferral used for other high-risk groups for MSM, when advocates pressed for review of the policy in both 2000<sup>63</sup> and 2006.<sup>64</sup> An important difference between the 2000 and 2006 calls for repeal was that the Red Cross, which supplies more than forty percent of the nation's blood supply,<sup>65</sup> changed its position in favor of repealing the lifetime deferral policy.<sup>66</sup> Finally, in the summer of 2010, the Advisory Committee on Blood Safety and Availability<sup>67</sup> also refused to change the policy.<sup>68</sup> This most recent decision has reignited the debate and sparked protests from gay advocates<sup>69</sup> and scientists<sup>70</sup> that the policy is discriminatory and outdated.

---

sory Committee, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/BloodVaccinesandOtherBiologics/BloodProductsAdvisoryCommittee/ucm121602.htm> (last modified May 21, 2010). Among other things, BPAC advises the Commissioner of Food and Drugs (the "FDA Commissioner") "of its findings regarding the safety, effectiveness, screening and testing (to determine eligibility) of donors . . . and on the quality and relevance of FDA's research program which provides the scientific support for regulating [blood products]." *Id.*

63 FDA, TRANSCRIPT OF PROCEEDINGS, BLOOD PRODS. ADVISORY COMM. 67TH MEETING 201-02 (Sept. 14, 2000), available at <http://www.fda.gov/ohrms/dockets/ac/cber00.htm#Blood%20Prducts> (follow links for 9/14 and 9/15 transcripts under "Blood Products Advisory Committee" heading) (last visited Jan. 20, 2011).

64 FDA, TRANSCRIPT OF PROCEEDINGS, BLOOD PRODUCTS ADVISORY COMMITTEE 86TH MEETING 60-61 (Mar. 9, 2006), available at <http://www.fda.gov/ohrms/dockets/ac/06/transcripts/2006-4206t1.pdf> (last visited Jan. 20, 2011).

65 *Blood Facts and Statistics*, AM. RED CROSS, <http://www.redcrossblood.org/learn-about-blood/blood-facts-and-statistics> (last visited Sept. 18, 2011).

66 See *HHS Advisory Committee on Blood Safety and Availability Meets*, AM. RED CROSS (June 11, 2010), <http://www.redcross.org/portal/site/en/menuitem.1a019a978f421296e81ec89e43181aa0/?vgnnextoid=fce99570ba229210VgnVCM10000089f0870aRCRD> (recommending that the FDA "amend the indefinite deferral currently in place for a male who has had sex with another male since 177 to a 12-month deferral"); see also Rob Stein, *FDA To Review Ban on Gay Men Donating Blood*, WASH. POST, Mar. 18, 2006, at A06 (discussing the collective recommendation by the American Red Cross, American Association of Blood Banks, and America's Blood Centers to change the FDA policy permanently barring male blood donors who have had sex with another man as of 1977; the group argues that "current tests and screening methods have improved enough to protect transfusion recipients without the lifetime ban").

67 The Advisory Committee on Blood Safety and Availability was formed to find ways to encourage regular blood donors to donate blood more often than their average 1.5 times per year. *Charter of the Advisory Committee on Blood Safety and Availability*, U.S. DEP'T OF HEALTH & HUMAN SERVS. (Oct. 8, 2010), <http://www.hhs.gov/ash/bloodsafety/advisorycommittee/index.html>.

68 See *Caption Notes for Advisory Committee on Blood Safety and Availability Day 2*, U.S. DEP'T OF HEALTH & HUMAN SERVS. (June 11, 2010), <http://www.hhs.gov/ash/bloodsafety/advisorycommittee/pastmeetings/pastmeetings.html#jun10>.

69 See Mroz, *supra* note 18; *Gay Rights Petition to the FDA: Stop Preventing Gay Men from Donating Blood*, CHANGE.ORG, <http://www.change.org/petitions/fda-stop-preventing-gay-men->

### III. A CONSTITUTIONAL CHALLENGE: POST-LAWRENCE

The FDA blood policy treats gay men differently than similarly situated straight donors, thereby raising constitutional equal protection concerns. This Part expands upon arguments made by Michael Christian Belli in 2003<sup>71</sup> that the MSM ban is unconstitutional.<sup>72</sup> Since Belli's paper was written before *Lawrence v. Texas*,<sup>73</sup> as well as other relevant cases concerning gay rights, it is timely to readdress the issue of whether the MSM ban would withstand a constitutional challenge within today's jurisprudence. For the purposes of this Comment, rather than merely repeating the constitutional problems posed by the MSM policy, I focus on the Fifth Amendment Equal Protection arguments in a post-*Lawrence* world. Primarily, I address the level of scrutiny to which the ban might be subjected.<sup>74</sup>

Although Belli's article employs the rational basis review test when evaluating the Equal Protection Clause challenges to the MSM policy,<sup>75</sup> after *Lawrence*, one could argue that a stricter standard is appropriate when reviewing policies directed toward gays, and would therefore be appropriate when challenging the MSM policy.<sup>76</sup> The appropriate level of review employed by the judiciary depends upon a number of factors, such as (1) the class involved, (2) the particular rights infringed upon, (3) a history of unequal treatment, and (4) other variously weighted factors.<sup>77</sup> Belli bases his analysis upon the

---

from-donating-blood (last visited Oct. 24, 2011) (calling on members to sign a petition asking the FDA to stop discriminating against gay men).

<sup>70</sup> See, e.g., Conan, *supra* note 17.

<sup>71</sup> Belli, *supra* note 24, at 362–75.

<sup>72</sup> A similar argument was recently made in Canada, and failed. See Joe Fantauzzi, *Thornhill Gay Advocates Cry Foul Over Blood Ban Ruling*, AURORA BANNER (Ontario), Sept. 10, 2010, at 1 (discussing the Superior Court of Ontario's decision to uphold a ban on blood donations by gay men despite the plaintiff's argument that such a ban is unconstitutional).

<sup>73</sup> *Lawrence v. Texas*, 539 U.S. 558, 574–76 (2003) (discussing the link between equal protection and due process with respect to homosexual conduct, posing that to criminalize homosexual acts invites “subject[ing] homosexual persons to discrimination”).

<sup>74</sup> This Comment assumes success on technical issues, such as standing. For a discussion about stigma satisfying standing requirements, see Thomas Healy, *Stigmatic Harm and Standing*, 92 IOWA L. REV. 417, 488 (2007) (“[W]hen the government does stigmatize a group, members of that group should have standing to argue that the government's action is unlawful.”).

<sup>75</sup> Belli, *supra* note 24, at 347–51 (delineating the necessary elements to assert an Equal Protection claim, noting that countervailing factors relating to a legitimate state interest may dictate sustaining the challenged classification).

<sup>76</sup> GEOFFREY R. STONE ET AL., CONSTITUTIONAL LAW 664–86 (6th ed. 2009) (discussing whether sexual orientation is a suspect class).

<sup>77</sup> *City of Cleburne v. Cleburne Living Ctr., Inc.*, 473 U.S. 432, 440–42 (1985). Statutes that classify on the basis of race, alienage, or national origin, and laws that “impinge on personal rights protected by the Constitution,” are subjected to the highest standard of re-

fact that the Court in *Romer v. Evans*<sup>78</sup> used rational basis review. This Part, however, examines the possibility of strict scrutiny review and the MSM policy's viability when held to that standard.

Although the *Lawrence* majority decision was based in terms of due process, often due process claims are linked to equal protection claims.<sup>79</sup> The Court in *Lawrence* said "[e]quality of treatment and the due process right to demand respect for conduct protected by the substantive guarantee of liberty are linked in important respects, and a decision on the latter point advances both interests."<sup>80</sup> Concurring in the decision, Justice O'Connor explicitly based her opinion on equal protection grounds, instead of due process, explaining, "[m]oral disapproval of this group, like a bare desire to harm the group, is an interest that is insufficient to satisfy rational basis review under the Equal Protection Clause."<sup>81</sup> The Court's decision indicated that the Texas sodomy law was a violation of the law because it targeted gay men, similar to the way that the MSM ban targets gay men.

*Lawrence* was a game changing decision for the recognition of LGBT legal rights. In *Lawrence*, the Court departed from traditional rational basis review without committing to a higher level of scrutiny.<sup>82</sup> While Justices Kennedy and O'Connor claim to be applying ra-

view, strict scrutiny. *Id.* at 440. Such "will be sustained only if they are suitably tailored to serve a compelling state interest." *Id.* Legislative classifications based on gender or illegitimacy are also subject to a heightened level of review and will fail if, in the case of a gender, the classification is not "substantially related to a sufficiently important governmental interest," or in the case of illegitimacy, the classification is not "substantially related to a legitimate state interest." *Id.* at 441. All other classifications will be sustained if they pass the minimum standard of review, rational basis. *Id.* at 441-42.

78 517 U.S. 620, 631-33 (1996) (requiring rational basis review as the level of scrutiny for a Fourteenth Amendment equal protection matter concerning sexual orientation).

79 Laurence H. Tribe, *Lawrence v. Texas: The "Fundamental Right" that Dare Not Speak Its Name*, 117 HARV. L. REV. 1893, 1898 (2004) ("[D]ue process and equal protection, far from having separate missions and entailing different inquiries, are profoundly interlocked in a legal double helix.").

80 *Lawrence*, 539 U.S. at 575 ("If protected conduct is made criminal and the law which does so remains unexamined for its substantive validity, its stigma might remain even if it were not enforceable as drawn for equal protection reasons. When homosexual conduct is made criminal by the law of the State, that declaration in and of itself is an invitation to subject homosexual persons to discrimination both in the public and in the private spheres. The central holding of *Bowers* has been brought in question by this case, and it should be addressed. Its continuance as precedent demeans the lives of homosexual persons.").

81 *Id.* at 582 (O'Connor, J., concurring).

82 See Kristina Brittenham, Note, *Equal Protection Theory and the Harvey Milk High School: Why Anti-Subordination Alone is Not Enough*, 45 B.C. L. REV. 869, 889 (2004) ("In two relatively recent cases, *Romer v. Evans*, in 1996, and *Lawrence v. Texas*, in 2003, the Court suggested a move towards applying a heightened level of scrutiny when sexual orientation is a basis for discrimination.").

tional basis, they required more than the typical nominal justification of the anti-gay legislation when applying that review.<sup>83</sup> Anti-gay statutes now meet resistance in passing the rational basis review scrutiny, as can be seen in cases decided by lower courts on DOMA,<sup>84</sup> Don't Ask Don't Tell,<sup>85</sup> gay marriage,<sup>86</sup> and federal same-sex benefits.<sup>87</sup> Even state courts have looked to the *Lawrence* decision as an indicator of heightened scrutiny in dealing with anti-gay policies.<sup>88</sup> Indeed, post-*Lawrence* jurisprudence, at the least, must look more critically upon anti-gay policies.

On the other hand, the Court explicitly claims to be applying rational basis review in *Lawrence*, does not employ equal protection analysis,<sup>89</sup> and has failed to increase the level of scrutiny with which to evaluate policies discriminating against gays.<sup>90</sup> Furthermore, cases

---

83 See Toni Lester, *Adam and Steve vs. Adam and Eve: Will The New Supreme Court Grant Gays the Right to Marry?*, 14 AM. U. J. GENDER SOC. POL'Y & L. 253, 295–96 (2006) (discussing Justice Kennedy and Justice O'Connor's opinions in *Lawrence v. Texas*).

84 *Gill v. Office of Pers. Mgmt.*, 699 F. Supp. 2d 374, 389 n.114 (D. Mass. 2010) (citing *Lawrence* for the proposition “that the government cannot justify discrimination against same-sex couples based on traditional notions of morality alone”). The court therefore held Section 3 of DOMA, as applied to the plaintiffs, “violates the equal protection principles embodied in the Fifth Amendment” as “irrational prejudice plainly *never* constitutes a legitimate government interest.” *Id.* at 397.

85 *Log Cabin Republicans v. United States*, 716 F. Supp. 2d 884, 911 (C.D. Cal. 2010) (citing *Lawrence* in ruling that “Don't Ask Don't Tell constitutes an intrusion upon the personal and private lives of homosexuals, in a manner that implicates the rights identified in *Lawrence*, and is subject to heightened scrutiny” (internal citations omitted) (internal quotation marks omitted)).

86 *Perry v. Schwarzenegger*, 704 F. Supp. 2d 921, 996 (N.D. Cal. 2010) (ruling that Proposition 8 violated the Equal Protection Clause in excluding same-sex couples from marriage and was not rationally related to a legitimate state interest, and citing *Lawrence* as holding “homosexual conduct and attraction are constitutionally protected and integral parts of what makes someone gay or lesbian”).

87 *In re Levenson*, 587 F.3d 925, 931 (9th Cir. 2009) (“Because there is no rational basis for denying benefits to the same-sex spouses of [Office of Federal Public Defender] employees . . . the application of DOMA to the [Federal Employee Health Benefits Act] so as to reach that result is unconstitutional.”).

88 *Goodridge v. Dep't of Pub. Health*, 798 N.E.2d 941, 948, 953, 959 (Mass. 2003) (citing *Lawrence* as support in declaring the Massachusetts ban on same-sex marriage unconstitutional on state constitutional grounds).

89 Justin Reinheimer, *What Lawrence Should Have Said: Reconstructing an Equality Approach*, 96 CALIF. L. REV. 505, 515 (2008) (“Notably, the Court declined to invalidate the statute on equal protection grounds, although certiorari was granted on whether the Texas statute violated the Equal Protection Clause, and equality arguments were made during litigation.”). *But see* *Lawrence v. Texas*, 539 U.S. 558, 574 (2003) (noting that “the basis for declaring the Texas statute invalid under the Equal Protection Clause . . . is a *tenable argument*” (emphasis added)).

90 Arthur S. Leonard, *Lawrence v. Texas and the New Law of Gay Rights*, 30 OHIO N.U. L. REV. 189, 200 (2004) (“The *Romer* opinion never directly discussed whether sexual orientation

post-*Lawrence*, including decisions on adoption<sup>91</sup> and same sex marriage,<sup>92</sup> have failed to use a heightened level of scrutiny. Regardless, when addressing anti-gay policies, courts will inevitably be called upon to decide how *Lawrence* factors into the analysis.

Importantly, President Obama has recently embraced strict scrutiny of statutes aimed toward LGBT people. Indeed, “the President has concluded that given a number of factors, including a documented history of discrimination, classifications based on sexual orientation should be subject to a more heightened standard of scrutiny.”<sup>93</sup> Although the President’s view may not be immediately embraced or followed by the Court, it is important support for the position that laws and policies targeting gays should be evaluated under strict scrutiny, and indicates a shift in the legal analysis of policies and statutes directed toward LGBT people. It also supports the scrutiny with which the executive agencies, including the FDA, should review its own policies. Therefore, following the President’s order, the FDA, and the courts, should strictly scrutinize the MSM ban.

The MSM ban fails a heightened level of rational basis review. Even though the law applies only to conduct (men who have had sex with men), “the conduct targeted . . . is conduct that is closely corre-

---

discrimination claims would merit heightened scrutiny, or how such claims would fall along the equal protection scale between suspect and non-suspect classifications.”).

91 *Lofton v. Sec’y of the Dep’t of Children & Family Servs.*, 358 F.3d 804, 815–17, 826 (11th Cir. 2004) (holding that neither *Romer* nor *Lawrence* requires that the court use heightened scrutiny to strike down the Florida statute banning same-sex adoption).

92 *Citizens for Equal Prot. v. Bruning*, 455 F.3d 859, 866 (8th Cir. 2006) (“[T]he level of judicial scrutiny to be applied in determining the validity of state legislative and constitutional enactments under the Fourteenth Amendment is a subject of continuing debate and disagreement among the Justices. Though the most relevant precedents are murky we conclude . . . [the Oklahoma ban on same-sex marriage] should receive rational-basis review under the Equal Protection Clause, rather than a heightened level of judicial scrutiny.”); *Kern v. Taney*, 11 Pa. D. & C. 5th 558, 570 (Ct. Com. Pl. 2010) (“In *Lawrence*, the court expressly declined to extend its holding to governmental recognition or sanctioning of homosexual marriages. Therefore, under the current state of the law, we find that the right of consenting adults to engage in intimate conduct, without governmental interference, does not involve or guarantee the right to require a government to grant the parties a marriage.” (citation omitted)); *In re J.B.*, 326 S.W.3d 654, 674 (Tex. App. 2010) (“We conclude that homosexuals are not a suspect class, that persons who choose to marry persons of the same sex are not a suspect class, and that the Texas law [limiting marriage to opposite-sex couples] . . . does not discriminate against a suspect class.”). *But see* Mary M. Kellerman, *Citizens for Equal Protection v. Bruning: Why the Eighth Circuit Wrongly Upheld Nebraska’s § 29 in the Face of an Equal Protection Challenge*, 30 *HAMLIN L. REV.* 373, 407 (2007) (noting that Section 29 “fails even the lenient rational basis analysis”).

93 Press Release, Dep’t of Justice, Office of Pub. Affairs, Statement of the Attorney General on Litigation Involving the Defense of Marriage Act (Feb. 23, 2011), available at <http://www.justice.gov/opa/pr/2011/February/11-ag-222.html>.

lated with being homosexual. Under such circumstances . . . [i]t is instead directed toward gay persons as a class.”<sup>94</sup> While not targeting “gay men,” but only “men who have sex with men,” the policy creates a distinction without legal meaning. “After all, there can hardly be more palpable discrimination against a class than making the conduct that defines the class criminal.”<sup>95</sup> The MSM ban targets all gay men, even those who have no chance of an HIV infection. There is no sexually active gay man that could pass the ban’s exclusion of a man who has had sex with a man since 1977.

As explained above, making broad, meritless, class distinctions that exclude an unpopular group for the sole purpose of excluding that group is unconstitutional. The Court held in *Lawrence* that when the state makes conduct that defines a class as criminal, “that declaration in and of itself is an invitation to subject homosexual persons to discrimination both in the public and in the private spheres.”<sup>96</sup> The blood ban is distinguished in that it does not make MSM acts criminal. However, under the blanket ban, one is presumed guilty of risky behavior and communicable disease simply by being gay.<sup>97</sup>

The assumption inherent within the MSM policy is that all gay men are risky donors, enshrining the stigma of gay men in official government agency policy. This stigmatization is directed to gay men and everyone else: the ban on MSM blood sends the message to gay men that they are, by nature, automatically involved in risky sexual activities. This message undermines education to gay men about activities that decrease the likelihood of obtaining a sexually transmitted disease, such as engaging in protected sexual activity and maintaining monogamous, trusting relationships. The ban also supports other’s stigmatization of gay men in infusing the idea that being gay includes having HIV/AIDS. This stigmatization undermines efforts to decrease the spread of disease and works to disadvantage gay men.<sup>98</sup> To be clear, a person does not get HIV because he is gay, nor

---

<sup>94</sup> *Lawrence*, 539 U.S. at 583 (O’Connor, J., concurring).

<sup>95</sup> *Id.* (quoting *Romer v. Evans*, 517 U.S. 620, 641 (1996) (Scalia, J., dissenting)) (internal quotation marks omitted).

<sup>96</sup> *Lawrence*, 539 U.S. at 575.

<sup>97</sup> SuchIsLifeVideos, *supra* note 21 (“[The FDA] cannot afford to play Russian Roulette with the nation’s blood supply . . . . Now notice, [the MSM ban] does not have anything to do with bigotry [or] hatred. This is purely a matter of science, biology, and human health . . .”).

<sup>98</sup> See Deborah L. Brimlow, Jennifer S. Cook & Richard Seaton, *Stigma and HIV/AIDS: A Review of the Literature* 3 (May 2003) (unpublished manuscript), available at [http://test.stigmaactionnetwork.org/atomicDocuments/SANDocuments/20110330164904-HRSA\\_2003\\_Stigma%20and%20HIV-AIDS%20-%20A%20Review%20of%20the%20](http://test.stigmaactionnetwork.org/atomicDocuments/SANDocuments/20110330164904-HRSA_2003_Stigma%20and%20HIV-AIDS%20-%20A%20Review%20of%20the%20)

does a person get HIV by having sex with a man. A person is at risk of being infected with HIV if infected body fluids enter that person's body,<sup>99</sup> whether or not that person is gay, and whether or not that person is a man.

Defenders of the policy argue its merits, which range from highlighting the risk of MSM blood to the deficiencies in current testing for transmittable infections. These defenders argue that the MSM policy is rational under the "precautionary principle."<sup>100</sup> The FDA defends the policy by stating the high HIV prevalence (and other infections) in MSM men.<sup>101</sup> Because blood donor testing does not yet detect all infected donors, the argument goes, undetected infected donors would slip through the cracks if the ban were lifted.<sup>102</sup> The FDA also argues that the MSM policy reduces the likelihood that a person would unknowingly donate blood during the "window period" of infection.<sup>103</sup> Furthermore, they argue that excluding MSM decreases risk of blood accidentally given to a patient in error either before testing is completed or following a positive test.<sup>104</sup> Lastly, the FDA claims that there is no alternate set of donor eligibility criteria found to reliably identify MSM who are not at increased risk for HIV or certain other transfusion transmissible infections.<sup>105</sup>

The defenses articulated by the FDA do not withstand scrutiny. Without exploring the weaknesses of the precautionary principle it-

---

Literature.pdf (noting that "[s]igma against HIV/AIDS is often related to the stigma of homosexuality").

99 See *How Do You Get HIV or AIDS?*, DEP'T OF HEALTH & HUMAN SERVS., <http://aids.gov/hiv-aids-basics/hiv-aids-101/overview/how-you-get-hiv-aids/> (last revised June 20, 2011); see also NAT'L CTR. FOR HIV/AIDS, VIRAL HEPATITIS, STD & TB PREVENTION, HIV AND AIDS: ARE YOU AT RISK? (2007), available at <http://www.cdc.gov/hiv/resources/brochures/at-risk.htm> (listing ways a person may get HIV, all of which include activity with "someone with HIV infection").

100 Pulver, *supra* note 20, at 127–28 ("The precautionary principle encourages policymakers to take the most cautious, risk-averse option whenever an activity potentially threatens harm to human health.").

101 See NAT'L CTR. FOR HIV/AIDS, HEPATITIS, STD, AND TB PREVENTION, HIV AMONG GAY, BISEXUAL AND OTHER MEN WHO HAVE SEX WITH MEN (MSM) (2010), available at <http://www.cdc.gov/hiv/topics/msm/index.htm> (noting that gay, bisexual, and other MSM account for over half of all new HIV infections in the United States in 2006).

102 *Blood Donations from Men Who Have Sex with Other Men Questions and Answers*, U.S. FOOD & DRUG ADMIN. (June 18, 2009), <http://www.fda.gov/biologicsbloodvaccines/bloodbloodproducts/questionsaboutblood/ucm108186.htm> (explaining the rationale and parameters defining the FDA's MSM policy).

103 *Id.*

104 *Id.*

105 *Id.*

self,<sup>106</sup> the MSM policy fails to rationally apply that principle. The most cautious, risk-averse option would be to ban blood from all high risk groups, including heterosexual donors who engage in unprotected, multiple-partner, sex. The high HIV prevalence in MSM ignores the high prevalence in other groups (or subgroups, such as young, black MSM<sup>107</sup>), such as African American females,<sup>108</sup> and does not serve as a justifiable distinction.

That blood donor testing does not yet detect all infected donors or that donors may give during the “window period” applies equally to all donors, with no higher risk posed by MSM. Similarly, the risk of blood accidentally given to a patient in error either before testing, is completed or following a positive test is always present, regardless of whom the donors are. Alternate donor eligibility criteria could target behaviors that make potential donors an increased risk for HIV or certain other transfusion transmissible infections and have been extensively researched and suggested.<sup>109</sup> While the MSM ban serves as a broad exclusion with the purpose of protecting the blood supply, it does so by being both over-inclusive in excluding healthy gay donors, and under-inclusive in admitting risky non-gay donors.

By singling out one group, gay men, the policy is facially discriminatory; moreover, it is not rationally related to its stated goal of protecting the donor pools, insofar as it does not apply to other high-risk groups. A ban that discriminates against a marginalized group without meritorious justification violates the Equal Protection Clause of the Fifth Amendment and should be deemed unconstitutional.

#### IV. AN ADMINISTRATIVE PROCEDURES ACT CHALLENGE

Not only is the MSM ban unconstitutional, it is also illegal by violating the protections ensured by the Administrative Procedures Act (“APA”). Because the FDA is an Administrative Agency, the APA go-

---

<sup>106</sup> See Cass R. Sunstein, *Beyond the Precautionary Principle*, 151 U. PA. L. REV. 1003 (2003) (discussing why the precautionary principle should be rejected).

<sup>107</sup> See Press Release, Nat’l Ctr. for HIV/AIDS, Viral Hepatitis, STD, & TB Prevention, New Multi-Year Data Show Annual HIV Infections in United States Relatively Stable (Aug. 3, 2011), available at <http://www.cdc.gov/nchhstp/newsroom/HIVIncidencePressRelease.html> (“[B]lack MSM were the only group to experience a statistically significant increase in new infections over the four-year time period studied.”).

<sup>108</sup> See *Minority Women's Health*, WOMENSHEALTH.GOV (May 18, 2010), <http://www.womenshealth.gov/minority/africanamerican/hiv.cfm> (“[W]omen account for more than 1 in 4 new HIV/AIDS cases in the United States. Of these newly infected women, about 2 in 3 are African-American.”).

<sup>109</sup> See WARDENSKI ET AL., *supra* note 12.

verns it and its actions are reviewable by the courts.<sup>110</sup> Under the APA, “[a] person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof.”<sup>111</sup> Once a court finds that the agency’s action is final, it may then consider six factors to determine whether that action is unlawful: (1) is it arbitrary or capricious; (2) is it unconstitutional; (3) is it outside of the agency’s jurisdiction; (4) did the agency fail to follow statutory procedures; (5) is it unsupported by substantial evidence; or (6) is it unwarranted by the facts?<sup>112</sup> Therefore, it is possible that a gay donor could bring suit under the APA challenging the MSM policy.

An APA challenge is potentially even more advantageous here because it allows avenues for a court to rule that the MSM policy is illegal, without ruling on its constitutionality.<sup>113</sup> Similar arguments have been made about potential challenges of the FDA’s ban on gay sperm.<sup>114</sup> Like the MSM ban, the FDA also categorically excludes men who have had sex with men from sperm donor pools.<sup>115</sup> Rather than repeat those arguments here, this Part demonstrates how an APA challenge is similarly applicable to the MSM ban. This Part outlines the necessary components to an APA challenge, and discusses the possible drawbacks of this approach. Although other potential APA challenges are available, this Comment focuses on the claim that the FDA’s MSM ban is arbitrary and capricious.

The first question in an APA challenge is whether the agency decision constitutes “final action.”<sup>116</sup> The FDA’s action here is through

110 See *Abbott Labs. v. Gardner*, 387 U.S. 136, 140–50 (1967) (discussing when agency action is judicially reviewable).

111 See Administrative Procedure Act, 5 U.S.C. § 702 (2006).

112 *Id.* § 706.

113 See Carmel Shachar, *Administrative Law v. Constitutional Law: The Correct Decision on FDA’s Treatment of Plan B*, 37 J.L. MED. & ETHICS 523, 526 (2009) (explaining that APA challenges to Plan B regulations were more persuasive than Constitutional challenges); see also *Tummino v. Torti*, 603 F. Supp. 2d 519, 550 (E.D.N.Y. 2009) (ruling based on APA challenge to FDA’s course of conduct regarding the emergency contraceptive rather than constitutional challenge).

114 See Boso, *supra* note 24, at 853 (explaining how the similar FDA ban on gay sperm is potentially challengeable under the APA); see also Letter from John Givner, Staff Attorney, Lambda Legal, to Div. of Dockets Mgm’t, Food & Drug Admin. 1, 3–4 & 4 n.4 (Aug. 23, 2004), available at <http://www.fda.gov/OHRMS/DOCKETS/dailys/04/aug04/083004/04d-0193-c00017-voll.pdf> (arguing that the ban on sperm donation is arbitrary and capricious).

115 See Letter from John Givner, *supra* note 114, at 3–4 & 4 n.4.

116 See *Franklin v. Massachusetts*, 505 U.S. 788, 797 (1992) (“[T]o determine when an agency action is final, [the Court] ha[s] looked to, among other things, whether its impact is sufficiently direct and immediate and has a direct effect on . . . day-to-day business.” (internal quotation marks omitted)).

guidance documents, stating that MSM constitutes “high risk.”<sup>117</sup> “Guidance documents do not themselves establish legally enforceable rights or responsibilities and are not legally binding on the public or the agency.”<sup>118</sup> However, the courts have ruled that a guidance may amount to a final rule when its impact “is sufficiently direct and immediate and has a direct effect on . . . day-to-day business.”<sup>119</sup> Because the guidance materials here are final to the same extent that guidance documents banning gay sperm are final, namely that gay men are prohibited from donating in either sphere, those arguments equally apply here.<sup>120</sup>

An obstacle in an APA challenge to the MSM blood ban is that the FDA is following the opinion of an advisory committee, rather than making the arbitrary conclusions itself. Congress enacted the Federal Advisory Committee Act in 1972 to control the growth and ensure the open operation of the “numerous committees, boards, commissions, councils, and similar groups which have been established to advise officers and agencies in the executive branch of the Federal Government.”<sup>121</sup> To achieve these objectives, the FACA places a number of procedural restrictions on those bodies that constitute “advisory committees.”<sup>122</sup> Although courts have held that Congress did not in-

117 See *Eligibility Requirements*, *supra* note 8.

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

119 *Franklin*, 505 U.S. at 797; see also *Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1021–24 (D.C. Cir. 2000) (discussing when agency action constitutes final action); Todd D. Rakoff, *The Choice Between Formal and Informal Modes of Administrative Regulation*, 52 ADMIN. L. REV. 159, 167 (2000) (discussing the legal effect of guidelines generated without promulgating a “nominally-legally-binding regulation”).

120 See *Boso* *supra* note 24, at 854–58 (“[T]he FDA’s recommendations have a direct and immediate impact on the . . . industry, and second, the industry relies on those recommendations.”).

121 See Pub. L. No. 92-463, § 2(a), 86 Stat. 770, 770 (1972) (codified at 5 U.S.C. app. 2 § 2(a) (2006)) (defining an advisory committee as “any committee, board, commission, council, conference, panel, task force, or other similar group, or any subcommittee or other subgroup thereof” that is “established or utilized” by the President or an agency “in the interest of obtaining advice or recommendations for the President or one or more agencies or officers of the Federal Government”); see also *Grigsby Brandford & Co. v. United States*, 869 F. Supp. 984, 1001 (D.D.C. 1994) (defining an Advisory Committee as “any committee, board, commission, council, conference, panel, task force, or other similar group, or any subcommittee or other subgroup thereof, which is established . . . for the purpose of obtaining advice or recommendations on issues or policies which are within the scope of his or her responsibilities” (internal quotations omitted)). See generally *Pub. Citizen v. U.S. Dep’t of Justice*, 491 U.S. 438, 466 (1989) (finding that public interest groups had standing to bring suit under FACA).

122 See *NRDC v. Abraham*, 223 F. Supp. 2d 162, 175 (D.D.C. 2002) (explaining the Federal Advisory Committee Act).

tend for FACA to be enforced through a private right of action,<sup>123</sup> plaintiffs are nevertheless entitled to enforce FACA's substantive requirements through the judicial review provisions of the APA.<sup>124</sup> The APA and constitutional requirements of the FDA, however, are not shielded from challenge by the FACA, because reliance on an advisory committee's decision may constitute final agency action.<sup>125</sup> Therefore, that an advisory committee produces the guidelines does not protect the FDA's promulgation of an arbitrary and capricious policy from an APA challenge.

To determine the scope of review for the FDA's final decision banning MSM blood, a court must determine whether the decision was reached through formal or informal rulemaking.<sup>126</sup> As outlined above,<sup>127</sup> the FDA solicited comments regarding its guidance documents rather than following the formal procedures of formal rulemaking, and, therefore, its decision regarding MSM blood would probably be reviewed within a similar framework as an informal rulemaking.<sup>128</sup> The court explained in *Citizens to Preserve Overton Park, Inc. v. Volpe* that in reviewing informal rulemaking,

[T]he court must consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error

123 See, e.g., *Int'l Brominated Solvents Ass'n v. Am. Conf. of Governmental Indus. Hygienists, Inc.*, 393 F. Supp. 2d 1362, 1376 (M.D. Ga. 2005) (citing awareness of only two decisions in which FACA has been considered in light of the Supreme Court's decision in *Alexander v. Sandoval*, 532 U.S. 275 (2001), which held that there is no implied private right of action without basis in statutory text). "In each case, the result was the same: Congress did not intend for FACA to be permit a private right of action." *Int'l Brominated Solvents Ass'n*, 393 F. Supp. 2d at 1376.

124 See *id.* at 1320 ("Although Plaintiffs do not have a cause of action that arises under FACA, they are nevertheless entitled to enforce FACA's substantive requirements through the judicial review provisions of the APA.").

125 See *id.* at 1381 (noting that reliance on an advisory committee's recommendation could be considered to meet the Supreme Court's definition of "action" because it is one "manner in which an agency may exercise its power. . . . Moreover, it can be considered final for purposes of the APA because using . . . [those recommendations] represents the consummation of . . . [the advisory committee's] decision-making process and imposes certain obligations from which legal consequences flow." (citations omitted) (internal quotation marks omitted)).

126 *Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402, 414–15 (1971) (stating that "[r]eview under the substantial-evidence test is authorized only when the agency action is taken pursuant to a rulemaking provision of the Administrative Procedure Act itself," and that de novo review of whether the action was "unwarranted by the facts" is authorized only when the action is adjudicatory in nature (internal quotation marks omitted)).

127 See *supra* notes 59–60, 62.

128 See 2 AM. JUR. 2D *Administrative Law* § 159 (2007) ("In the case of informal rulemaking under the Federal Administrative Procedure Act, an agency must give interested persons an opportunity to participate in the rule-making process through submission of written data, views, or arguments with or without the opportunity for an oral presentation.").

of judgment. . . . Although this inquiry into the facts is to be searching and careful, the ultimate standard of review is a narrow one. The court is not empowered to substitute its judgment for that of the agency.<sup>129</sup>

This review is analogous to the limited rational basis review.<sup>130</sup> The review is furthermore limited by the fact that the agency's decision is science-based.<sup>131</sup> Because agencies are deemed experts of highly technical issues, courts are not viewed as the proper venue for most policy decisions. However, if the court finds that an agency action is arbitrary and capricious, the action is set aside.<sup>132</sup>

Courts generally give informal agency action a high degree of deference; that deference, however, is not a rubber stamp. In some instances, the Court has found an agency action to be arbitrary.<sup>133</sup> Agency action is arbitrary when an agency offers "insufficient reasons for treating similar situations differently."<sup>134</sup> Applying the standard set in *Volpe*, a searching and careful inquiry into the facts reveals that the MSM ban is facially irrational. As explained above, the FDA provides no rational reasoning for why MSM blood is barred for a lifetime deferral, yet, heterosexual donors engaged in similarly high-risk, or riskier behavior, are only deferred one year, if at all. "[O]nly [in] the most extreme cases do antibodies manifest later than six months following transmission," regardless of sexual orientation or sexual practice.<sup>135</sup> Indeed, "all testing is prone to error, human and other-

<sup>129</sup> 401 U.S. at 416 (citations omitted).

<sup>130</sup> See Merrick B. Garland, *Deregulation and Judicial Review*, 98 HARV. L. REV. 505, 532 (1985) (finding that courts afford agencies' "findings of fact great deference" under the minimum rationality or rational basis test).

<sup>131</sup> See JERRY L. MASHAW ET AL., ADMINISTRATIVE LAW: THE AMERICAN PUBLIC LAW SYSTEM CASES AND MATERIALS 868–92 (6th ed. 2003) (discussing judicial review of science-based decisions); see also *Baltimore Gas & Elec. Co. v. NRDC*, 462 U.S. 87, 103 (1983) ("When examining this kind of scientific determination, as opposed to simple findings of fact, a reviewing court must generally be at its most deferential."); *Fed. Power Comm'n v. Fla. Power & Light Co.*, 404 U.S. 453, 463 (1972) ("[W]hen resolution of that question depends on 'engineering and scientific' considerations, we recognize the relevant agency's technical expertise and experience, and defer to its analysis unless it is without substantial basis in fact."); *Browning-Ferris Indus. of S. Jersey v. Muszynski*, 899 F.2d 151, 160 (2d Cir. 1990) ("Courts should be particularly reluctant to second-guess agency choices involving scientific disputes that are in the agency's province of expertise.").

<sup>132</sup> See *Pub. Citizen v. Barshefsky*, 939 F. Supp. 31, 37 (D.D.C. 1996) ("The APA requires the court to set aside agency actions that are 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.'" (quoting 5 U.S.C. § 706(2)(A) (2006))).

<sup>133</sup> See, e.g., *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) ("Normally, an agency rule would be arbitrary and capricious if the agency has . . . entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to . . . the product of agency expertise.").

<sup>134</sup> See *Transactive Corp. v. United States*, 91 F.3d 232, 237 (D.C. Cir. 1996).

<sup>135</sup> Boso, *supra* note 24, at 863.

wise, but” the FDA does not provide facts that suggest that the rate of error diminishes after a year for heterosexual donors, but not for gay men.<sup>136</sup> Thus, the FDA’s MSM ban treats similar situations differently,<sup>137</sup> and it is irrational in light of the FDA’s interest in protecting public health. “Under these rules, a heterosexual man who had unprotected sex with HIV-positive [female] prostitutes would be OK as a donor one year later, but a gay man in a monogamous, safe-sex relationship is not.”<sup>138</sup> Such a distinction cannot be held to be rational.

The distinction between MSMs and men who have sex with women, without more, is not rationally related to the prevention of disease transmission. In *Motor Vehicle*, the Court reasoned that agency actions are irrational if the agency “fail[s] to consider an important aspect of the problem.”<sup>139</sup> In this case, an important aspect of the problem is unquestionably the growing number of new HIV transmissions resulting from non-MSM activity, and that, of those diagnosed with HIV, almost half transmitted the disease through means other than MSM contact.<sup>140</sup> Rather than focus on the unsafe nature of *any* sexual act performed by *any* sexually active person, the FDA focuses on the class of the parties engaged in sexual acts (gay men), and ignores the reality of disease transmission. Accordingly, under *Motor Vehicle*, the FDA’s failure to consider this important health aspect renders its action arbitrary and capricious.<sup>141</sup>

---

<sup>136</sup> *Id.*

<sup>137</sup> *See Transactive Corp.*, 91 F.3d at 237 (“[A]gency action is arbitrary when the agency offered insufficient reasons for treating similar situations differently.”).

<sup>138</sup> *See Boso*, *supra* note 24, at 863 (internal quotation marks omitted).

<sup>139</sup> *See Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (emphasis added).

<sup>140</sup> *See Centers for Disease Control, Diagnoses of HIV Infection and AIDS in the United States and Dependent Areas, 2008*, 20 HIV SURVEILLANCE REP., 7, 17–18 (2010), available at <http://www.cdc.gov/hiv/surveillance/resources/reports/2008report> (“Estimat[ing] rates of diagnoses of HIV infections among adults and adolescents, by sex and race/ethnicity” and showing the number of HIV diagnoses increased among male and female adults and adolescents exposed through heterosexual contact).

<sup>141</sup> *See Motor Vehicle*, 463 U.S. at 43 (finding an agency decision “arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise”). For decisions holding as arbitrary agency action based on scientific determinations, see *Association of Irrigated Residents v. EPA*, 632 F.3d 584, 593 (9th Cir. 2011) (finding the EPA’s failure to act in light of the strong evidence indicating inadequacies in current plan arbitrary and capricious); *Midwater Trawlers Cooperative v. Department of Commerce*, 282 F.3d 710, 720–21 (9th Cir. 2002) (suggesting that an agency decision was arbitrary where it was demonstrated that the rule was a “product of pure political compromise, not reasoned scientific endeavor”); *Estate of Aitken v. Shalala*, 986 F. Supp. 57, 61–62, 64 (D. Mass. 1997) (finding

The APA challenge of the MSM policy is by no means a slam-dunk. Courts are very reluctant to overturn administrative agencies' decisions generally,<sup>142</sup> and even more so when those decisions involve scientific determinations.<sup>143</sup> Here, however, is a case in which the agency decision that is arbitrary and capricious is not based upon conflicting scientific evidence nor differences in opinion about what constitutes high-risk conduct. Indeed, there is no technical subject for the court to address. Rather, the policy is arbitrary on its face because it treats all members of a class as though they are engaged in high-risk behavior, while ignoring those in that class who are not,<sup>144</sup> and those of other classes who are similarly engaged in high-risk behavior. The FDA policy invents a distinction between MSM and heterosexual donors that is scientifically untenable; a gay man does not contract AIDS by being gay, but by engaging in risky behavior, the same as heterosexuals.<sup>145</sup> The FDA policy does nothing to address the risky heterosexual behavior, and, instead, treats *all* gay men as dangerously sexually active.

#### V. ADMINISTRATIVE CONSTITUTIONALISM

As shown above, neither the constitutional equal protection arguments, nor the APA arbitrary and capricious challenge, are guaran-

---

grounds for agency decision to be considered arbitrary where the explanation currently offered by HCFA for its decision ran counter to the evidence before the agency).

142 See, e.g., *Schering Corp. v. FDA*, 51 F.3d 390, 399 (3d Cir. 1995) (finding that FDA's "judgments as to what is required to ascertain the safety and efficacy of drugs fall squarely within the ambit of the FDA's expertise and merit deference from us"); see also *Arkansas v. Oklahoma*, 503 U.S. 91, 113 (1992) (declaring ruling by Tenth Circuit an unauthorized "policy choice," and explaining that "[t]he court should not supplant the agency's findings merely by identifying alternative findings that could be supported by substantial evidence"); *Henley v. FDA*, 77 F.3d 616, 621 (2d Cir. 1996) (holding that although plaintiff's arguments were "sound and cogent," and the Court itself "might not have chosen the FDA's course had it been [theirs] to chart," the APA precludes courts for substituting their judgment for that of an agency).

143 See *NRDC v. Fox*, 93 F. Supp. 2d 531, 552 (S.D.N.Y. 2000) ("In the face of conflicting evidence at the frontiers of science, courts' deference to expert determinations should be at its greatest.") (quoting *Cellular Phone Taskforce v. FCC*, 205 F.3d 82, 90 (2d Cir. 2000) (internal quotation marks omitted)); see also *NRDC v. EPA*, 16 F.3d 1395, 1404 (4th Cir. 1993) (holding where record supported both water quality standard urged by plaintiffs and one chosen by EPA, "the best course of action is to leave this debate to the world of science to ultimately be resolved by those with specialized training in this field").

144 And, sadly, even persons who are not gay, but appear to be gay, making blood bank nurses the sexual-orientation police. See Roth, *supra* note 22.

145 See Naomi G. Goldberg & Gary J. Gates, *Effects of Lifting the Blood Donation Ban on Men Who Have Sex with Men*, 5 PITTSBURGH J. ENVTL. & PUB. HEALTH L. 49, 57 (2011) ("If the current MSM ban were completely lifted, we estimate that an additional 130,150 men would likely donate 219,200 additional pints of blood each year.").

teed to persuade a court to overturn this discriminatory MSM policy. A third approach, however, may hold promise. This Part suggests that the FDA, as an administrative body, has a role in determining whether its own policies are constitutional, and, therefore, could be persuaded to change the MSM policy, not based upon scientific evidence, but rather based upon its understanding of what the Equal Protection Clause requires; namely, that gay men, as a class, be treated equally to other similarly situated donors.

This Part seeks to expand upon arguments proposed by Gillian Metzger<sup>146</sup> and apply them to the role the FDA plays in constitutional decision-making. She explains, “constitutional law and ordinary administrative law are inextricably linked: Statutory and regulatory measures are created to address constitutional requirements . . . and agencies are encouraged to take constitutional concerns seriously in their decisionmaking.”<sup>147</sup> The indeterminacy of constitutional meanings opens a wide door for agency interpretation.<sup>148</sup> Because of this, agencies continually consider constitutional boundaries in making their policy.<sup>149</sup> Agencies are uniquely accountable and accessible to the public, and therefore may better reflect constitutional norms of the community.<sup>150</sup> Indeed, constitutional questions such as whether gay men should be a protected class can be decided at the agency level,<sup>151</sup> and possibly should be decided by agencies.<sup>152</sup>

---

146 Gillian E. Metzger, *Ordinary Administrative Law as Constitutional Common Law*, 110 COLUM. L. REV. 479 (2010).

147 *Id.* at 484.

148 See Richard H. Fallon, Jr., *The Supreme Court, 1996 Term: Foreword: Implementing the Constitution*, 111 HARV. L. REV. 54, 58 (1997) (“[R]easonable citizens, lawyers, and judges differ widely about what methodology should be used to interpret the Constitution, about which substantive principles the Constitution embodies, and about how, in more practical terms, constitutional norms should be protected by doctrine.”).

149 See Reuel E. Schiller, *Free Speech and Expertise: Administrative Censorship and the Birth of the Modern First Amendment*, 86 VA. L. REV. 1, 2–3 (2000) (explaining that administrators originally interpreted the First Amendment and constitutionality of police power limitations on free speech); see also Hiroshi Motomura, *Immigration Law After a Century of Plenary Power: Phantom Constitutional Norms and Statutory Interpretation*, 100 YALE L.J. 545, 564–75, 580–600 (1990) (arguing that “phantom constitutional norms”—norms rooted in due process, equal protection, and the First Amendment, but fundamentally at odds with plenary power doctrine—underlie many immigration decisions).

150 See generally Metzger, *supra* note 146, at 502 (“Congress and the President frequently impose statutory and regulatory restrictions on administrative decisionmaking that reflect their desire for agencies to attend to constitutional concerns.”).

151 See Reva B. Siegel, *Constitutional Culture, Social Movement Conflict and Constitutional Change: The Case of the de facto ERA*, 94 CALIF. L. REV. 1323, 1323–25 (2006) (arguing expansion of the Fourteenth Amendment’s Equal Protection Clause to cover sex discrimination “was forged in the Equal Rights Amendment’s defeat”).

Agencies have been called upon to determine the scope of the Equal Protection Clause before,<sup>153</sup> and should do so when their policies clearly animate concerns of class discrimination. Arthur Caplan, former chair of the Advisory Committee on Blood Safety and Availability, said the MSM policy “doesn’t make any sense, except as a matter of discrimination, to exclude one risk group completely and let others sort of go with abandon, if you will.”<sup>154</sup> Although new Advisory Committee members are sworn to “support and defend the constitution of the United States against all enemies; foreign and domestic,”<sup>155</sup> neither the minutes from the 2000 or 2006 meeting,<sup>156</sup> nor the recommendations offered after the 2010 meeting,<sup>157</sup> refer to the Constitution at all. Indeed, the committee was apprised of the constitutional issues presented by the discriminatory MSM policy.<sup>158</sup> The Committee should be called upon to align its MSM policy with the constitutional mandates of the Equal Protection Clause. Just as the Obama administration has decided that laws targeting the LGBT community should be under strict scrutiny,<sup>159</sup> branches of the government other than the courts are at liberty to come to more expansive readings of the Constitution. The FDA, charged with maintaining the public health, has an interest in securing its reputation as an agency dedicated to scientific conclusions rather than policies based on discriminatory stigma.

---

152 See generally Metzger, *supra* note 146, at 486 (“Agencies are not only well positioned to enforce constitutional norms effectively, but they are also better able than courts to determine how to incorporate constitutional concerns into a given regulatory scheme with the least disruption.”).

153 Sophia Z. Lee, *Race, Sex, and Rulemaking: Administrative Constitutionalism and the Workplace, 1960 to the Present*, 96 VA. L. REV. 799, 800–01 (2010) (describing FCC rulemaking interpreting the scope of the Equal Protection Clause).

154 Conan, *supra* note 17.

155 See DEP’T OF HEALTH & HUMAN SERVS., SUMMARY: ADVISORY COMMITTEE ON BLOOD SAFETY AND AVAILABILITY DEPARTMENT OF HEALTH AND HUMAN SERVICES 3 (2007), available at [www.hhs.gov/ash/bloodsafety/advisorycommittee/minutes/may2007.pdf](http://www.hhs.gov/ash/bloodsafety/advisorycommittee/minutes/may2007.pdf) (“Dr. Bracey invited the new members to come to the fore and Dr. Agwunobi swore them in.”).

156 See *supra* notes 63 and 64.

157 See *supra* note 68.

158 See Letter from Laura W. Murphy, Dir., A.C.L.U. Wash. Legislative Office & James Esseks, Dir., A.C.L.U. Lesbian Gay Bisexual Transgender & AIDS Project, to Jerry A. Holmberg, Advisory Comm. on Blood Safety & Availability (June 8, 2010), available at [www.aclu.org/files/assets/fdabloodban\\_comments\\_20100610.pdf](http://www.aclu.org/files/assets/fdabloodban_comments_20100610.pdf).

159 See Press Release, *supra* note 93.

## VI. CONCLUSION

This Comment is not intended to distract from or minimize the dangerous infection rates among MSM men.<sup>160</sup> Indeed, this author believes that the alarming figures of HIV infection among gay men should serve to increase awareness among the gay community and spark public policy that serves to decrease the rates of new infections by increasing the availability and commonality of testing and treatment. Nonetheless, the FDA's MSM policy is unconstitutional, arbitrary and capricious, and discriminatory against gay men in a way that should violate administrative understanding of the Equal Protection Clause. This Comment has sought to build upon the claims made by others so that this twenty-six year old ban may finally be lifted. As a result, not only will the blood supply benefit, but also the stigma attached to the blanket ban on gay men will no longer be legitimized.

---

<sup>160</sup> See Donald G. McNeil, *New H.I.V. Cases Remain Steady Over a Decade*, N.Y. TIMES, Aug. 4, 2011, at A16 (explaining that the HIV epidemic "is still concentrated primarily in gay men").