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# SOME MSM BLOOD DONORS MOVE FROM A LIFETIME DEFERRAL TO A ONE-YEAR BAN . . . “FINALLY” OR “NOT GOOD ENOUGH?”\*

HEATHER PRINTZ\*\*

## INTRODUCTION

*It feels good to give.*<sup>1</sup> *Find the hero in you.*<sup>2</sup> Blood banks choose these words carefully to inspire people to donate. The language is intended to create a desire to give and for good reason: *every two seconds someone needs blood!*<sup>3</sup> But, it also sends an implicit message about heroism and morality; if heroes give blood then those who do not must be morally corrupt.<sup>4</sup> It's a logical fallacy, especially because some choose not to donate while others are prohibited from doing so, but words impact society's perceptions and opinions.<sup>5</sup> This unintended

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\*The Journal of Health Care Law and Policy originally received this piece for publication in late 2015. At that time, publication delays prevented the timely release of this comment. Both the Author and the Journal of Health Care Law and Policy recognize that since the original submission, the FDA may have offered further clarification.

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1. *Give Blood*, AM. RED CROSS, [www.redcrossblood.org/](http://www.redcrossblood.org/) (last visited Sept. 17, 2015).
2. UNITED BLOOD SERVS., [www.unitedbloodservices.org/](http://www.unitedbloodservices.org/) (last visited Sept. 17, 2015).
3. AMERICA'S BLOOD CNTRS. [www.americasblood.org/](http://www.americasblood.org/) (last visited Sept. 17, 2015).
4. See Craig M. Klugman, *Blood Donation and Its Metaphors*, 10 AM. J. OF BIOETHICS 46, 46–7 (2010) (explaining that “[b]y creating a message that it is heroic and moral to donate blood, there is a tacit judgment that those who cannot give blood not only are impure, but also that they cannot do the right thing”); See also *id.* at 46 (supporting the idea that the industry has created a metaphor about the relationship between donating blood and being moral).

5. *Id.*

message creates a feeling of “otherness” or marginalization for those who are different, for people who *cannot* give blood.<sup>6</sup>

Blood banks are directed to follow deferral guidelines which, until recently, grouped “men who have had sex with another man even one time since 1977” (“MSM”) with prostitutes and intravenous drug users as permanently ineligible for blood donation, perpetuating a stigma about what it means to be a homosexual man.<sup>7</sup> In December 2015, the Food and Drug Administration (“FDA”) updated its 32-year-old guideline and now recommends blood banks “[d]efer for 12 months from the most recent sexual contact, a man who has had sex with another man in the past 12 months.”<sup>8</sup> Six months earlier, the Supreme Court ruled same-sex couples have the right to marry, specifically enumerating the ways in which they are equal to heterosexual couples, overturning decades of precedent and potentially blazing a trail for lesbian, gay, bisexual, transgender, and queer (“LGBTQ”) rights in the courts.<sup>9</sup> Yet in its latest guideline, the FDA clings to this archaic distinction between MSM and every other sexually active blood donor to defer most homosexual men from donating blood, implying: if you’re a sexually active homosexual male then you’re probably not a hero.

The roots of characterization run deep. In the 1980s, a mysterious epidemic swept the nation.<sup>10</sup> No one could pinpoint its cause or origin, creating a public health crisis but eliciting few ideas for an appropriate response.<sup>11</sup> Initially, the group of infections later known as Human Immunodeficiency Virus (“HIV”) were thought to be transmitted exclusively by men having intercourse with other

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6. See Christopher Fisher & Tony Schonfeld, *Sex and Blood: A Deeper Exploration of Discrimination in the FDA Blood Donor Policy*, 10 AM. J. OF BIOETHICS 40, 40–41 (2010) (describing the concept of “otherness”). Memorandum from Dir., 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), available at <http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/OtherRecommendationsforManufacturers/MemorandumtoBloodEstablishments/UCM062834.pdf> (providing the exact language of the group in question).

7. See *Eligibility Criteria by Topic*, AM. RED CROSS, <http://www.redcrossblood.org/donating-blood/eligibility-requirements/eligibility-criteria-topic#lifestyle> (last visited Sept. 17, 2015) (describing who is and is not eligible to donate blood).

8. See generally Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products, 80 Fed. Reg. 79913 (Dec. 23, 2015) available at <https://www.gpo.gov/fdsys/pkg/FR-2015-12-23/pdf/2015-32250.pdf>.

9. See generally *Obergefell v. Hodges*, 135 S.Ct. 2584 (2015).

10. See Christopher McAdam & Logan Parker, *An Antiquated Perspective: Lifetime Ban for MSM Blood Donations No Longer Global Norm*, 16 DEPAUL J. HEALTH CARE L. 21 (2014) (stating the AIDS crisis began in the 1980s).

11. See Shawn Carroll Casey, *Illicit Regulation: A Framework for Challenging the Procedural Validity of the “Gay Blood Ban”*, 66 FOOD & DRUG L. J. 551, 553 (2011) (stating the origin of AIDS was unknown and that its arrival created panic); see also Dwayne J. Bensing, Comment, *Science or Stigma: Potential Challenges to the FDA’s Ban on Gay Blood*, 14 U. PA. J. CONST. L. 485, 489 (2011) (stating that nothing was known about the disease so authorities lacked an appropriate response).

men, though within three years scientists learned the infections were not unique to that population or method—HIV could be sexually transmitted or blood-borne and affect anyone, regardless of sexual orientation.<sup>12</sup> In 1983, the Centers for Disease Control and Prevention (“CDC”) informed the public that certain groups were at a high risk of transmitting HIV, that no test was available to detect it, and *suggested* high-risk individuals refrain from donating blood, among other precautions.<sup>13</sup> “Sexually active homosexual or bisexual men with multiple partners” were among the groups labeled high-risk.<sup>14</sup> The FDA provided the first donation guidelines to blood banks as an additional measure to protect the blood supply from contamination.<sup>15</sup> The guidelines outlining high-risk groups and

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12. See Ryan H. Nelson, *An Indirect Challenge to the FDA’s “Gay Blood Ban”*, 23 TUL. J. L. & SEXUALITY 1, 2 (2011) (stating that AIDS was thought to affect gay men, predominately, if not exclusively); see McAdam & Parker, *supra* note 10, at 23 (stating it was later confirmed that AIDS “was both blood-borne and sexually transmitted”); see also Francine A. Hochburg, *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 (2002) (explaining that HIV is the acronym for human immunodeficiency virus and the end-stage disease is AIDS or acquired immune deficiency syndrome).

13. See CDC, *Current Trends Prevention of Acquired Immune Deficiency Syndrome (AIDS): Rep. of Inter-Agency Recommendations*, 32(8) Morbidity & Mortality Wkly Rep. 101, 101–03 (Mar. 4, 1983), available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/00001257.htm>; see Casey, *supra* note 11, at 555 (reiterating that the guideline was not mandatory); McAdam & Parker, *supra* note 10, at 25 (explaining that U.S. Public Health Service (“PHS”) “is housed under the Department of Health and Human Services (“HHS”)”); Casey, *supra* note 11, at 561 (explaining the “PHS includes the CDC, National Institutes for Health (NIH) and FDA”); Whitney Larkin, Comment, *Discriminatory Policy: Denying Gay Men the Opportunity to Donate Blood*, 11 HOUS. J. HEALTH L. & POL’Y 121, 132 (2011) (explaining the FDA has “regulatory jurisdiction over blood, bodily organs, tissue, and fluids”); Hochburg, *supra* note 12, at 243 n.64 (explaining 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 PHS agencies to implement its recommendations.”); McAdam & Parker, *supra* note 10 at 26 (explaining the Center for Biologics Evaluation and Research (“CBER”) is “[a] subdivision of the FDA, [...] and is] entrusted with drafting regulations to ensure the quality and safety of the nation’s blood supply. Together, the FDA and CBER are charged with licensing blood banks.”); Bensing, *supra* note 11, at 493–94 n.62 (explaining that Blood Products Advisory Committee (“BPAC”) is “a standing advisory committee to [...] [CBER], [...] 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.’... [and] advises 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].’”); Vianca Diaz, Comment, *A Time For Change: Why the MSM Lifetime Deferral Policy Should Be Amended*, 13 U. MD. L.J. RACE, RELIGION, GENDER, & CLASS 134, 139 (2013) (explaining the Advisory Committee on Blood and Tissue Safety and Availability (“ACBTSA”) “[h]as the authority [...] to advise, assist, consult with, and make policy recommendations to the Secretary and the Assistant Secretary for Health regarding . . . broad public health, ethical and legal issues related to transfusion and transplantation safety”).

14. CDC, *Current Trends Prevention of Acquired Immune Deficiency Syndrome (AIDS): Rep. of Inter-Agency Recommendations*, 32(8) Morbidity & Mortality Wkly Rep. 101, 101–03 (Mar. 4, 1983), available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/00001257.htm>.

15. See Casey, *supra* note 11, at 555 (stating that the FDA issued implementation guidelines); Mem. from John C. Petricciani, Nat’l Ctr. For Drugs & Biologics, FDA, to All Establishments Collecting Human

their relevant deferral periods have been amended several times.<sup>16</sup> From 1992 to 2015, the official policy provided for a permanent blood donation deferral for “men who have had sex with another man even one time since 1977.”<sup>17</sup>

Since the original guidelines were published, the medical community has gained a better understanding of HIV and AIDS.<sup>18</sup> First, it is common knowledge that neither are exclusive to the homosexual population or contracted only through intercourse.<sup>19</sup> Second, several tests are now available to determine if blood is infected with HIV.<sup>20</sup> Additionally, the FDA has enacted a multitude of requirements for blood bank licensing, including suitability of donor standards in 1984 and the requirement that all blood donations be tested for an extensive panel of blood-borne diseases in 1988.<sup>21</sup>

There has also been significant social progress, including both a diminishing stigma and movement toward legally recognizing a higher form of protection for members of the LGBTQ community.<sup>22</sup> For these reasons, advocates have repeatedly pressed for a revision to the lifetime ban imposed on

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Blood for Transfusion (Mar. 24, 1983) (on file with the author) (“advising all establishments collecting blood for transfusion to institute additional measures designed to decrease blood collection from individual donors and donor groups known to be at an increased risk for transmitting AIDS”).

16. See Michael Christian Belli, *The Constitutionality of the “Men Who Have Sex with Men” Blood Donor Exclusion Policy*, 4 J. L. SOC’Y 315, 339 (2003); *id.* at 339–42 (for a detailed explanation of revisions by year).

17. See generally Memorandum from Dir., 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), available at <http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/OtherRecommendationsforManufacturers/MemorandumtoBloodEstablishments/UCM062834.pdf>; see McAdam & Parker, *supra* note 10, at 27 (stating the MSM lifetime deferral policy became mandatory in 1992).

18. See *infra* Part III, C.

19. See McAdam & Parker, *supra* note 10, at 23 (stating it was later confirmed sexual orientation was not incident to the disease).

20. *Id.* at 29–30 (discussing the various tests that have been developed to detect AIDS).

21. John G. Culhane, *Bad Science, Worse Policy: The Exclusion of Gay Males from Donor Pools*, 24 ST. LOUIS U. PUB. L. REVIEW 129, 132–33 (2005) (explaining that “[b]lood and other bodily organs, tissue, and fluids come within the regulatory jurisdiction of the FDA. Because the FDA is charged with licensing blood banks, it is responsible for creating safeguards to minimize the risk that blood infected with infectious diseases, such as HIV, will find its way into a recipient body. To that end, the FDA has established a battery of requirements relating to the licensing of blood banks, the testing of blood prior to its release, and - with particular relevance here - the eligibility of donors.”); see McAdam & Parker, *supra* note 10, at 26 (stating “FDA requires blood donation centers to evaluate individuals prior to testing based on medical, social, and sexual history”); see generally 21 C.F.R. § 640.5 (1988) (“Testing the blood”); see generally 21 C.F.R. § 640.3 (1984) (“Suitability of donor”).

22. McAdam & Parker, *supra* note 10, at 51, 54–55 (attributing “time and activism” to the new perception of gay community then pointing to anti-discrimination laws, same sex marriage, and ethical considerations regarding treatment of MSM).

MSM, suggesting the deferral was unnecessary and discriminatory.<sup>23</sup> The policy discriminated against MSM because it did not align their deferral period with other high-risk groups or defer other groups who engage in risky behavior, perpetuating the false belief of a unique link between homosexual men and HIV.<sup>24</sup> Driven by fear, ignorance, and a lack of scientific knowledge, initial blood donation policy was unquestionably discriminatory, but as science and social understanding progressed it should have been revised.<sup>25</sup> Despite social and scientific advancements, the FDA has not amended the blood donation policy for MSM until now.<sup>26</sup>

In December 2014, the FDA announced it would recommend a change to the MSM lifetime deferral in favor of a one-year deferral, allowing men who have abstained from sex with another man for *one year* to donate blood.<sup>27</sup> The agency noted it considered the revision in light of scientific evidence supporting the safety of doing so but did not address the past or continued discriminatory impact.<sup>28</sup> In May 2015, it provided a draft of the guidelines for notice and comment and in December, handed down final guidance on the matter.<sup>29</sup>

At first blush, the revision appears to address what advocates have been calling for. Yet most consider the policy change an insufficient gesture that does

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23. See Nelson, *supra* note 12, at 2 (noting some advocates have called for a complete rescission of the ban and others seek a less harsh policy); see Diaz, *supra* note 12, at 140 (providing the blood banks position that the “current lifetime deferral for [MSM] is medically and scientifically unwarranted and should be modified.”); see Alissa Scheller & Anna Almendrala, *Why Even a 12-Month Ban on Blood Donations From Gay Men Makes No Sense*, HUFFPOST, (Dec. 23, 2014, 9:33 PM), [http://www.huffingtonpost.com/2014/12/23/gay-blood-ban-deferral\\_n\\_6374374.html](http://www.huffingtonpost.com/2014/12/23/gay-blood-ban-deferral_n_6374374.html) (quoting Dr. William Kobler, spokesman for the American Medical Association, “[t]he lifetime ban on blood donation for men who have sex with men is discriminatory and not based on sound science.”).

24. Diaz, *supra* note 12, at 135, 137 (explaining the unconstitutional and stigmatizing implications of the ban).

25. See McAdam & Parker, *supra* note 10, at 30–31 (explaining that “many countries recognize deferral policies were enacted during time of confusion, stigma, and limited science” and their bans have been reconsidered in light of scientific and social progress); *Id.* at 23 (stating many policies were guided by fear and ignorance).

26. See Belli, *supra* note 16 at 338.

27. Food & Drug Admin., FDA Comm’r Margaret A. Hamburg’s Statement on FDA’s Blood Donor Deferral Policy for Men Who Have Sex with Men (Dec. 23, 2014), *available at* <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm427843.htm>

28. *Id.*; see Dominic Holden, *FDA Recommends Relaxing Ban On Gay Men Donating Blood-With a Big Caveat*, BUZZFEED, (Dec. 23, 2014, 12:55 PM), <http://www.buzzfeed.com/dominicholden/fda-recommends-relaxing-ban-on-gay-men-donating-blood-with-a#.wk8pzp4gZ> (providing statements from several advocacy groups that call the revision just as discriminatory).

29. See *generally* Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products, 80 Fed. Reg. 27973 (proposed May 15, 2015), *available at* <http://www.gpo.gov/fdsys/pkg/FR-2015-05-15/pdf/2015-11690.pdf>; see *generally* Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products, 80 Fed. Reg. 79913 (Dec. 23, 2015) *available at* <https://www.gpo.gov/fdsys/pkg/FR-2015-12-23/pdf/2015-32250.pdf>.

not address the heart of the issue: the continued stigma and irrational discrimination against MSM. Facially, the revised ban allows more MSM to donate but in practice it continues to prevent most from doing so, based solely on sexual orientation.<sup>30</sup> From the first suggestions that HIV was uniquely or particularly related to male homosexuality, advocates have advanced public policy, scientific, administrative, and constitutional arguments against singling out the group and later against the lifetime deferral.<sup>31</sup> In light of the revised deferral, this Comment departs slightly from those paths and argues that the revision maintains the same discriminatory effect by going against notions of administrative constitutionalism, equal protection, and principles of bioethics. This Comment further argues that the revision does not effectively reflect scientific advancements, that science does not support singling out MSM as a category, and that the relevant science does not exist in a vacuum but must consider the social impact.

Part I describes the evolution of HIV/AIDS and the prohibition on MSM blood donation.<sup>32</sup> Part II describes previous attempts to revise the ban, the contours of the revision, and some defenses and reactions to the FDA's proposal and final guidance.<sup>33</sup> Part III argues that the FDA has an obligation to interpret its guidelines in tune with standard constitutional interpretations, that the direction of constitutional jurisprudence with respect to members of the LGBTQ community has been racing toward elevated scrutiny so the policy could soon face a potentially fatal constitutional challenge, and that despite scientific support for a one-year deferral over a lifetime ban, the use of MSM as a category is not supported by science.<sup>34</sup>

#### I. EVOLUTION OF BLOOD DONATION GUIDELINES IN THE CONTEXT OF HIV

The obscure infections later known as HIV were identified in 1980.<sup>35</sup> Between October 1980 and May 1981, five otherwise healthy, homosexual men in Los Angeles were treated for pneumocystis carinii pneumonia—a rare lung infection.<sup>36</sup> On June 5, 1981, the CDC described these cases in the *Morbidity*

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30. See Holden, *supra* note 28 (outlining some critics unfavorable response to the proposed revision); *id.* (quoting Gay Men's Health Crisis which explained the revision functioned as de facto lifetime ban).

31. *E.g.*, Diaz, *supra* note 12; *E.g.*, McAdam & Parker, *supra* note 10.

32. See *infra* Part I.

33. See *infra* Part II.

34. See *infra* Part III.

35. Matthew L. Morrison, Comment, *Bad Blood: An Examination of the Constitutional Deficiencies of the FDA's 'Gay Blood Ban'*, 99 MINN. L. REV. 2363, 2366 (2015).

36. McAdam & Parker, *supra* note 10, at 22; see Diaz, *supra* note 12, at 136 (explaining the men were from Los Angeles).

and *Mortality Weekly Report*, becoming the first record of the future epidemic.<sup>37</sup> The following month, the CDC reported that twenty-six homosexual men in California and New York developed Kaposi’s sarcoma (another rare infection).<sup>38</sup> Soon, doctors across the country began to disclose similar “opportunistic infections,” and reported 270 cases of these infections by the end of 1981.<sup>39</sup>

That same year, the CDC studied 116 homosexual men with similar infections and found most had multiple sexual partners.<sup>40</sup> This information, and the knowledge that only homosexual men had developed these infections, led to speculation that the infections were either caused by a sexually transmitted disease which caused a repeated infection and breakdown of the immune system or that they were an immune suppressant effect caused by overexposure to many different sources of sperm.<sup>41</sup> Some reasoned the disease must be linked to a homosexual lifestyle or sexual orientation.<sup>42</sup> The infections were referred to as the “gay plague, gay cancer, and gay-related immune disorder,” leading people to associate having HIV with being homosexual.<sup>43</sup>

Early the following year, an elderly hemophiliac patient contracted the same rare pneumonia, a condition his physician believed came from receiving contaminated clotting factor during a blood transfusion.<sup>44</sup> Up to that point, scientists only *suspected* the “opportunistic infections” could be spread through

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37. Diaz, *supra* note 12, at 136; *see also About the Morbidity & Mortality Wkly Rep. (MMWR) Series*, CDC.GOV, <http://www.cdc.gov/mmwr/about.html> (describing the *MMWR* series as “the agency’s primary vehicle for scientific publication of timely, reliable, authoritative, accurate, objective, and useful public health information and recommendations”).

38. McAdam & Parker, *supra* note 10, at 22 (citing CDC, *Kaposi’s Sarcoma and Pneumocystis Pneumonia Among Homosexual Men—New York City and California*, 30 *Morbidity & Mortality Wkly Rep.* 1 (July 3, 1981)).

39. Diaz, *supra* note 12, at 136; *see* Larkin, *supra* note 12, at 133 (defining opportunistic infections as “infections in people, caused by organisms that don’t usually cause disease in people with a healthy immune system.”); *see also* Belli, *supra* note 16, at 328–31 (discussing the pathology of HIV/AIDS in greater detail).

40. Larkin, *supra* note 12, at 133; *id.* at 134 (stating that each of the men in the study “had an average of 1,100 sexual encounters”).

41. *See* Belli, *supra* note 16, at 329 (stating homosexual men formed the initial population in which AIDS occurred); *see* Larkin, *supra* note 12, at 134 (describing speculation about what caused the infections).

42. McAdam & Parker, *supra* note 10, at 23.

43. *Id.*; *see* Diaz, *supra* note 12, at 137 (noting that because most cases of AIDS were homosexual men, a stigmatization was attached to that group).

44. *See* Adam R. Pulver, Comment, *Gay Blood Revisionism: A Critical Analysis of Advocacy and the “Gay Blood Ban”*, 17 L. & SEXUALITY 107, 110–11 (2008) (describing the circumstances of the hemophiliac patient); *id.* (“Factor VIII, a life-prolonging clotting factor derived from thousands of blood donors given to hemophiliacs.”); National Hemophilia Foundation, <https://www.hemophilia.org/Bleeding-Disorders/Types-of-Bleeding-Disorders/Other-Factor-Deficiencies/Factor-XIII> (last visited Nov. 28, 2015) (explaining that Factor VIII is a protein that can be added to blood in order to stabilize it).



blood.<sup>45</sup> Due to the patient's rapid death, doctors never confirmed the presence of HIV, but his was the first unofficial incident linked to a blood transfusion.<sup>46</sup> In July of 1982, the CDC identified three more people with hemophilia and the same signs of immune suppression and opportunistic infections.<sup>47</sup> The National Hemophilia Foundation publicly reassured hemophiliacs that the risk of contracting these infections via the blood supply was minimal but behind closed doors, the Foundation pressed the blood banks to stop accepting donations from homosexual men.<sup>48</sup> The blood banks opposed the exclusionary message and donation loss.<sup>49</sup> As the infections spread beyond the homosexual male community, the CDC hosted a meeting to evaluate ways to protect the blood supply.<sup>50</sup> Meeting attendees discussed providing donor deferral guidelines but the National Hemophilia Foundation, the gay community, and the FDA independently opposed this idea.<sup>51</sup> The meeting ended without resolution, in part because only the CDC believed a crisis was imminent.<sup>52</sup> In September, it

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45. See *id.* at 111 (explaining that the CDC feared AIDS could be transmitted via blood transfusion as well as through intercourse).

46. *Id.*

47. CDC, *Epidemiologic Notes and Reports Pneumocystis Carinii Pneumonia among Persons with Hemophilia A*, 31 Morbidity & Mortality Wkly Rep. 365 (July 16, 1982), available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/00001126.htm>; see generally CDC, *Epidemiologic Notes and Reports Update on Kaposi's Sarcoma and Opportunistic Infections in Previously Healthy Persons*, 31 Morbidity & Mortality Wkly Rep. 294 (June 11, 1982), available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/00001111.htm> (providing detailed statistics and characteristics about people infected between June 1, 1981 and May 28, 1982); see McAdam & Parker, *supra* note 10, at 23 (noting that people with these infections also included "intravenous-drug users, Haitians, hemophiliacs, and non-homosexual blood transfusion recipients").

48. Ronald Bayer, *Blood and AIDS in America Science, Politics, and the Making of an Iatrogenic Catastrophe*, in BLOOD FEUDS 20, 21 (Eric A. Feldman & Ronald Bayer eds., 1999) (explaining the position of the National Hemophilia Foundation); see Hochburg, *supra* note 12, at 244 (explaining that the National Hemophilia Foundation proposed forbidding homosexual men from donating blood).

49. See Bayer, *supra* note 48, at 23 (explaining the blood banks' position on excluding homosexual donors); see Hochburg, *supra* note 12, at 244 (explaining that the blood banks' stance on excluding homosexual donors).

50. See Bensing, *supra* note 11 at 489 (explaining that a response to the threat to the blood supply was necessary); Pulver, *supra* note 44, at 111 ("Meeting attendees included leaders from the National Institutes of Health, [FDA], the blood banking industry, hemophilic groups, and the National Gay Task Force").

51. See *id.* ("Hemophilic groups [...] were concerned about labeling hemophiliacs with the stigma of a 'gay disease,' and were also wary that panicked hemophiliacs might stop their Factor VIII treatment. The gay community [...] arguing that it was "too soon to push for guidelines", and that the civil rights of gays outweighed the inconclusive evidence about the risks of transmission. The FDA itself was also unpersuaded of any pressing emergency."); see Bayer, *supra* note 48, at 23 (explaining that the blood banks felt there was too much scientific uncertainty to support homosexual male donor exclusion).

52. See Pulver, *supra* note 43, at 112 (explaining there was a "wait and see attitude"); Cf. Bayer, *supra* note 48 at 24 (explaining that a decade later, Dr. James Curran, head of AIDS activities at the CDC, would reflect that the CDC was aware very early of a link between AIDS and the blood supply due to its experience with hepatitis and sexually transmitted diseases but because the CDC had no experience in with blood diseases, they were not taken seriously).

officially labeled the mystery infections “Acquired Immune Deficiency Syndrome” (“AIDS”).<sup>53</sup>

The end of the year brought two transmission cases confirming the link between AIDS and the blood supply, as well as the realization that AIDS had a “carrier state” in which people *appeared* healthy because the disease had not yet manifested itself.<sup>54</sup> This “latency period” meant there was no way to distinguish safe donors from asymptomatic carriers.<sup>55</sup> Further, no one could determine what *caused* AIDS so it was virtually impossible to create a test to detect it.<sup>56</sup>

A week before the next meeting, set for January 1983, the CDC’s director of AIDS activities “urged the gay community to seize the ‘political initiative with a call for voluntary withdrawal of all gay men from the donor pool . . . The thing, is people are dying. The medical problem is more important than the civil rights issue.’”<sup>57</sup> Around the same time, one plasma supplier announced its decision to prohibit homosexual men from donation.<sup>58</sup> At the meeting, the CDC presented evidence related to the risk of AIDS in the blood supply but attendees remained unconvinced, believing the data were minimal and inconclusive.<sup>59</sup> The CDC advanced two options: screen high-risk donors or adopt surrogate testing for another marker like hepatitis B, an infection with which approximately 80% of AIDS patients were affected.<sup>60</sup> The LGBTQ community protested questioning donors about sexual orientation and habits, stating it was “blood, not donors, that should be subject to scrutiny” and attempted to develop a method of self-exclusion.<sup>61</sup> The blood banking organizations continued to oppose excluding

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53. See Belli, *supra* note 16, at 328; CDC, *Current Trends Update on Acquired Immune Deficiency Syndrome (AIDS)—United States*, 31 Morbidity & Mortality Wkly Rep. 507 (Sept. 24, 1982), available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/00001163.htm> (“CDC defines a case of AIDS as a disease, at least moderately predictive of a defect in cell-mediated immunity, occurring in a person with no known cause for diminished resistance to that disease”).

54. Casey, *supra* note 11, at 553 (noting the first two confirmed transmission cases in December 1982); Pulver, *supra* note 44 at 110 (explaining that some individuals may not have symptoms because of the latency period between infection and detection while others do not have symptoms because they are not carriers but without a test, there was no way to distinguish between the two).

55. Casey, *supra* note 11, at 553 (explaining there was a period of time where the disease could go undetected); Pulver, *supra* note 44, at 110.

56. Casey, *supra* note 11, at 553 (explaining no one knew what caused AIDS).

57. See Bayer, *supra* note 48, at 23; Hochburg, *supra* note 12, at 244.

58. Bayer, *supra* note 48, at 23.

59. See *id.* (recalling the evidence presented by the CDC and the response of the blood banking community); See Pulver, *supra* note 44, at 112 (recalling the response of the blood banking community); Cf. Bayer, *supra* note 48, at 24 (“A decade later, Curran would note that the CDC’s failure at the meeting was rooted in its lack of credibility among blood bankers.”).

60. See *id.* (describing the potential ways to screen donors).

61. *Id.*; See *id.* at 24–5 (describing the efforts of the gay community).

homosexual males entirely but the National Hemophilia Foundation publically demanded it.<sup>62</sup>

By 1983, over 1,000 cases of AIDS were reported across the country.<sup>63</sup> Blood banks did not support the use of surrogate testing so it seemed the only viable course of action was to create an ad hoc screening policy.<sup>64</sup> In March, the CDC issued the first recommended guidelines for AIDS prevention through blood donation, which suggested people at an increased risk of carrying AIDS should not donate blood.<sup>65</sup> The guideline noted it was intended as an interim measure until accurate tests could be devised.<sup>66</sup> Three weeks later, the FDA released a memorandum to organizations responsible for collecting blood, outlining the persons with an increased risk for carrying AIDS, and encouraging blood banks to implement measures to reduce the chances of collecting infected blood.<sup>67</sup> Persons at an increased risk included: “persons with symptoms and signs suggestive of AIDS, sexually active homosexual or bisexual men with multiple partners, Haitian entrants to the United States, present or past abusers of intravenous drugs, and sexual partners of individuals at increased risk for AIDS.”<sup>68</sup>

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62. *Id.* at 24.

63. See McAdam & Parker, *supra* note 10, at 22.

64. See Bayer, *supra* note 48, at 27–29 (describing the controversy surrounding surrogate testing).

65. Casey, *supra* note 11, at 555; see generally CDC, *Current Trends Prevention of Acquired Immune Deficiency Syndrome (AIDS): Rep. of Inter-Agency Recommendations*, 32(8) Morbidity & Mortality Wkly Rep. 101-103 (Mar. 4, 1983), available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/00001257.htm> (“1. Sexual contact should be avoided with persons known or suspected to have AIDS. Members of high-risk groups should be aware that multiple sexual partners increase the probability of developing AIDS. 2. As a temporary measure, members of groups at increased risk for AIDS should refrain from donating plasma and/or blood. This recommendation includes all individuals belonging to such groups, *even though many individuals are at little risk of AIDS* [emphasis added]. Centers collecting plasma and/or blood should inform potential donors of this recommendation. 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* [emphasis added] to protect recipients of blood products and blood until specific laboratory tests are available. 3. Studies should be conducted to evaluate screening procedures for their effectiveness in identifying and excluding plasma and blood with a high probability of transmitting AIDS. These procedures should include specific laboratory tests as well as careful histories and physical examinations. 4. Physicians should adhere strictly to medical indications for transfusions, and autologous blood transfusions are encouraged. 5. Work should continue toward development of safer blood products for use by hemophilia patients. The National Hemophilia Foundation has made specific recommendations for management of patients with hemophilia”).

66. See generally CDC, *Current Trends Prevention of Acquired Immune Deficiency Syndrome (AIDS): Rep. of Inter-Agency Recommendations*, 32(8) Morbidity & Mortality Wkly Rep. 101–03 (Mar. 4, 1983), available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/00001257.htm>.

67. See McAdam & Parker, *supra* note 10, at 23 (stating the FDA established regulations); 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).

68. *Id.*

The FDA has revised portions of the original memorandum several times.<sup>69</sup> In 1984, the group “sexually active homosexual or bisexual men with multiple partners” became “males who have had sex with more than one male since 1979 and males whose partner has had sex with more than one male since 1979.”<sup>70</sup> In 1990, all high-risk deferral groups underwent similar changes, which prioritized risky behavior over status.<sup>71</sup> The 1992 memorandum re-labeled the relevant high-risk group “men who have had sex with another man since 1977” and moved sexual partners of those in all high-risk categories from lifetime deferral to a one-year deferral.<sup>72</sup> More importantly, the memorandum made clear that MSM *should not* donate blood, a change from earlier guidelines which functioned more like a suggestion.<sup>73</sup> This is the first time the guidelines were considered *mandatory*, confirming a lifetime deferral for MSM.<sup>74</sup>

In 1984 and 1988 respectively, the FDA codified the suitability standards for blood donors and the requirement that all blood be tested for infectious diseases.<sup>75</sup> The former are medical guidelines, intended to protect the health of the blood donor, but it is worth noting that this codified statute makes no reference to MSM or other high-risk persons, specifically.<sup>76</sup>

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69. Belli, *supra* note 16, at 339; *see id.* at 339–43 (for a detailed explanation of the revisions by year).

70. *Id.* at 339.

71. *See id.* at 340 (stating that “The 1990 memorandum emphasized risky behaviors over status under the theory that the former provide a more accurate basis for excluding those at high risk. The author of the memorandum observed, ‘the focus (of communications with potential donors) should be on behavior and not on stereotypes (e.g., many men who have had male-to-male sexual experiences do not identify themselves as ‘homosexual,’ ‘gay,’ or ‘bisexual’)).”

72. *See* McAdam & Parker, *supra* note 10, at 24; *see* Belli, *supra* note 16, at 341.

73. *See generally* Memorandum from Dir., 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), *available at* <http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/OtherRecommendationsforManufacturers/MemorandumtoBloodEstablishments/UCM062834.pdf>.

74. *See* Naomi G. Goldberg, M.P.P. & Gary J. Gates, Ph.D., *Effects of Lifting the Blood Donation Ban on Men Who Have Sex with Men*, 5 PITT. J. ENVTL. PUB. HEALTH L. 49, 51 (2011) (stating that men in the MSM category are given a lifetime deferral); *see* McAdam & Parker, *supra* note 10, at 27 (stating that guidelines are mandatory); *but see* Casey, *supra* note 11, at 552 (explaining the argument that because the FDA did not follow the proper procedure for enacting a binding regulation, this is technically only a guideline. However, under 21 C.F.R. § 640.2, the FDA is in charge of licensing blood centers and could revoke licenses of the establishments not in compliance with its directive, although that might be open to challenge. Therefore, this is treated as a mandatory regulation).

75. *See generally* 21 C.F.R. § 640.3 (1984); *see generally* 21 C.F.R. § 640.5 (1988).

76. *See* Belli, *supra* note 16, at 322 (explaining that 21 C.F.R. § 640.3 are “medical guidelines for selecting blood donors”); *see* Bensing, *supra* note 11, at 490 (stating the Code of Regulations does not specify MSM as high-risk); *see* Larkin, *supra* note 12, at 122–24 (describing the blood donation process as follows: Blood donors are educated on “risks of infectious diseases transmitted by donating blood.” Prospective donors must complete a health history form designed to identify possible exposure “to diseases that could taint the blood supply” or whether donating would risk their own health. If either risk is possible, the donor will be deferred. Then the donor is subjected to a mini physical. If they pass, they may donate.); *see id.* at 125 (describing people who may donate: healthy, aged 17, at least 110 pounds, do

Between 1983 and 1985, scientists identified three viruses as the probable cause of the infections; in 1986, the viruses were grouped and renamed “HIV.”<sup>77</sup> In 1985, the FDA approved the first HIV antibody blood test—an enzyme-linked immunosorbent assay (“ELISA”) test that could detect human antibodies produced in response to exposure to HIV.<sup>78</sup> Two years later, the FDA approved the “Western Blot” test to be used in conjunction with the ELISA test.<sup>79</sup> Although using the tests together produced almost 100% effective rate in the ability to detect HIV in blood, the combination did not overcome the latency problem.<sup>80</sup> In the early 2000s, scientists developed a “NAT” or nucleic acid test, which uses “primers that identify RNA or DNA in blood samples” and can detect an HIV infection in just under two weeks.<sup>81</sup>

## II. THE ROAD TO AMENDMENT: CONTOURS AND PERSPECTIVES OF CHANGE

### A. *Desperately Seeking Change*

The first major catalyst for a policy revision came in mid-2000, as the country faced a critical blood shortage.<sup>82</sup> An insufficient blood supply is as much a threat as a contaminated one.<sup>83</sup> Possibly in consideration of that fact, the Blood

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not fall into a deferral category.); *see id.* at 125–26 (noting that deferral categories speak to “(i) people who engage in high risk behavior; (ii) people who have been incarcerated; (iii) people with signs and symptoms of HIV; (iv) people who were born, lived in or visited Pattern II countries; and (v) rape victims” and that people in high-risk categories include: intravenous drug users, MSM, and prostitutes.); *see id.* at 126–7 (explaining the two deferral types, temporary and permanent, noting that permanent deferral is required when the donor “has an experience or condition that puts the recipient or donor at a health risk as a result of blood donation. The second category is defined by the donor’s behaviors that have put him or her at an increased risk for HIV or other serious diseases. And the last category is when a person has spent time in a particular geographic area that has a high incidence of HIV or other serious diseases.”); *see id.* at 127 (describing the relevant questions in the health history form as questions about “behavioral exclusions that would elevate a donor’s risk for HIV or other diseases transmitted through the blood stream. [Such as] whether a potential donor has ever had ‘sexual contact’ with a person with HIV, ever been paid for sex or had sex with someone who has paid for sex, or ever had a tattoo [and] behaviors and experiences that temporarily or permanently bar blood donation [including:] ‘From 1977 to present, have you [male donors] had sexual contact with another male, even once?’”).

77. *See* Belli, *supra* note 16, at 331–32 (describing that researchers identified which viruses were responsible for the epidemic and that they were grouped together and named HIV).

78. *Id.* at 333.

79. *Id.* at 335 (explaining the improvements the “Western Blot” test had over the “ELISA” test).

80. Diaz, *supra* note 12, at 145; *see* Casey, *supra* note 11, at 556 (explaining that although a test was developed to detect infected blood, the deferral categories were important because of the “latency period”).

81. *See* McAdam & Parker, *supra* note 10, at 29–30; *see* Morrison, *supra* note 35, at 2371.

82. Belli, *supra* note 16, at 317; *Id.* (explaining that to address the shortage, the Surgeon General created Advisory Committee on Blood and Tissues Safety and Availability to encourage blood donors to give regularly).

83. *See* Arthur Caplan, *Blood Stains-Why an Absurd Policy Banning Gay Men as Blood Donors Has Not Been Changed*, 10 AM. J. OF BIOETHICS 2 (2010).

Products Advisory Committee (“BPAC”) met to review the MSM deferral policy that fall.<sup>84</sup> At the meeting, the FDA asked BPAC whether scientific data supported a five-year deferral policy.<sup>85</sup> The two major blood banks took opposite stances on the suggestion; the American Red Cross (“ARC”) stated its opposition while the American Association of Blood Banks (“AABB”) offered its support, but BPAC voted against recommending an amendment.<sup>86</sup> Another six years passed before BPAC revisited the issue, holding a meeting in 2006 to collect the most current information regarding the safety of amending the policy.<sup>87</sup> At that meeting, ARC reversed its earlier position, calling the permanent ban “medically and scientifically unwarranted,” and at least one FDA official admitted the current risks were extremely low, but again, no amendment was made.<sup>88</sup>

In February 2010, the advocacy group Gay Men’s Health Crisis reignited the debate when it released a report condemning the lifetime deferral in light of scientific and societal progress.<sup>89</sup> The report stated the policy “reinforce[d] incorrect and outdated information about the spread of HIV that serve[d] to discriminate against and stigmatize gay and bisexual men” in light of detection rates in HIV testing and less restrictive referrals for other groups at an elevated risk.<sup>90</sup>

The following month, eighteen Senators, including then-Senator John Kerry, sent a letter to the Department of Health and Human Services (“HHS”)

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84. Pulver, *supra* note 44, at 118; *see* Belli, *supra* note 16, at 342–43 (explaining that two reasons BPAC met to consider changing the ban were the acceptance of the NAT test, and the FDA’s understanding “of blood-bank error rates, their types and frequencies”); *see generally* U.S. FOOD & DRUG ADMIN. BLOOD PRODS. ADVISORY COMM., TRANSCRIPT OF PROCEEDINGS: 67TH MEETING 201–02, (2000), available at <http://www.fda.gov/ohrms/dockets/ac/00/transcripts/3649t2.rtf>.

85. Belli, *supra* note 16, at 343.

86. *See* Pulver, *supra* note 44, at 118 (stating the American Association of Blood Banks supported the change and the American Red Cross opposed); *see also* Belli, *supra* note 16, at 343–348 (describing, at length, why the committee did not support the change to a 5-year deferral); *but see* Pulver, *supra* note 44, at 118 (noting that “[a]t the start of the meeting, the committee agreed that the permanent ban on gay men seemed discriminatory, lacked a firm foundation in science, and should be changed” and also that many groups supported a change in the policy).

87. *See* Goldberg, *supra* note 74, at 52.

88. *Id.*; *see id.* (providing that the AABB’s argument any deferral beyond a year was not necessary because that was the longest known latency period required to detect HIV and that one year would be consistent with other groups at a high-risk due to sexual exposure); *see id.* (recounting the statement of an FDA official who said that the “current risks are now so low that they cannot be measured directly and, hence, we rely on models to estimate the current residual risk, that is to say the risk after all the safeguards have been followed.”); *see* Bensing, *supra* note 11, at 494 (explaining that the committee voted against a change); *see generally* U.S. FOOD & DRUG ADMIN. BLOOD PRODS. ADVISORY COMM., TRANSCRIPT OF PROCEEDINGS: 87TH MEETING (2006), available at <http://www.fda.gov/ohrms/dockets/ac/06/transcripts/2006-4226t1.pdf>.

89. Diaz, *supra* note 12, at 138–39.

90. *See generally* Gay Men’s Health Crisis, *A Drive for Change: Reforming U.S. Blood Donation Policies* (Sean Cahill, Nathan Schaefer, & John A. Guidry eds., 2010).

demanding reconsideration of the MSM blood donor policy.<sup>91</sup> The FDA responded with a curt statement, declaring simply that the “ban was based on current science and data,” to which former Senator Kerry pushed back, pointing out the disparity between high-risk individuals such as prostitutes and sexual partners of those with HIV having a one-year deferral and homosexual activity burdened with a lifetime deferral, yet no policy at all for unprotected heterosexual intercourse.<sup>92</sup> Despite the FDA’s dismissive statement, support for a revision continued to pour in, so the Advisory Committee on Blood and Tissue Safety and Availability (“ACBTSA”) met again in June to reevaluate the ban’s social and scientific issues.<sup>93</sup> The day before the meeting, forty-three members of Congress showed their support for a revision with another letter to HHS, echoing ARC’s earlier sentiment in the lack of justification and scientific inexactitude in not deferring heterosexuals who engage in unprotected sex while permanently deferring “monogamous and married homosexual partners who practice safe sex”, and urged the agencies to forsake “blanket deferrals” in favor of screening for high-risk behavior.<sup>94</sup> The letter went so far as to state that, “keeping discriminatory policies on the books, and denying willing donors the opportunity to help others, put the integrity of the blood donation system at risk.”<sup>95</sup>

At the 2010 meeting, AABB, America’s Blood Centers, and ARC submitted a joint statement reaffirming their 2006 position that the MSM policy was “scientifically unwarranted,” stating it should be revised to parallel the policies for other groups with an increased risk of transmitting infections.<sup>96</sup> The

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91. Diaz, *supra* note 12, at 139; *see* Casey, *supra* note 11, at 552 (noting that Congress has pushed for change based on “sociological and scientific changes”); *see generally* Letter from Sen. John Kerry et al., U.S. Congress, to the Advisory Comm. on Blood Safety & Availability (Mar. 4, 2010), available at <http://hemophiliafed.org/uploads/2010/04/Senators-LETTER-TO-FDA-ON-MSM-2-3-4-2010-3.pdf>.

92. Diaz, *supra* note 12, at 139; *see generally* *Senators: Lift Ban on Gays Donating Blood*, CBSNEWS (Mar. 4, 2010, 3:32 PM), <http://www.cbsnews.com/news/senators-lift-ban-on-gays-donating-blood/> (providing portion of FDA response); *see generally* *Sen. John Kerry’s Open Letter to FDA Boss*, SAN DIEGO GAY & LESBIAN NEWS, (Mar. 10, 2010), <http://sdgln.com/health/2010/03/09/sen-john-kerry-s-open-letter-fda-boss#sthash.XF1Nx38y.dpbs> (Sen. Kerry responding to the FDA).

93. *See* Diaz, *supra* note 12, at 139–140 (stating who supported the meeting); *see generally* ADVISORY COMMITTEE ON BLOOD & TISSUE SAFETY, CAPTION NOTES (2010), available at [http://nih.granicus.com/TranscriptViewer.php?view\\_id=22&clip\\_id=45](http://nih.granicus.com/TranscriptViewer.php?view_id=22&clip_id=45).

94. Diaz, *supra* note 12, at 140; *see generally* Letter from Sen. John Kerry et al., U.S. Congress, to the Advisory Comm. on Blood Safety & Availability (Jun. 9, 2010), available at <http://farr.house.gov/index.php/press-releases-187/706-june-9-2010-lawmakers-call-for-fda-to-revise-blood-donation-policy>.

95. *See generally id.*

96. *See* Diaz, *supra* note 12, at 140 (providing the blood banks’ position that the MSM policy was “medically and scientifically unwarranted and should be modified and made comparable with criteria for other groups at increased risk for sexual transmission of transfusion-transmitted infections.”); *see generally* Am. Ass’n of Blood Banks, Am. Blood Ctrs. & Am. Red Cross, J. Statement Before the Advisory Comm. on Blood Safety & Availability: Donor Deferral for Men Who Have Had Sex with

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blood banks recommended a one-year deferral, but the committee once again voted to retain the lifetime ban.<sup>97</sup> Although it recognized the policy as “suboptimal” then, the committee declared there was not enough research to support the safety of changing the deferral to one year.<sup>98</sup> In 2012, HHS requested information to consider more suitable blood donation criteria for MSM.<sup>99</sup> Between 2012 and 2014, PHS received at least three more letters from Congress calling for a revision of the MSM ban.<sup>100</sup>

### B. After Three Decades, All We Have is a Shaky Start

In November 2014, ACBTSA met again to discuss a possible revision.<sup>101</sup> The meeting concluded with the recommendation of a one-year deferral on MSM blood donation and a joint statement from AABB and ARC endorsing it.<sup>102</sup> The

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Another Man (MSM) (June 15, 2010), available at <http://www.aabb.org/advocacy/statements/Pages/statement061510.aspx>.

97. See Diaz, *supra* note 12, at 140 (stating that the blood banks’ suggesting a one-year deferral); Bensing, *supra* note 11, at 487 (providing results of the vote).

98. See Goldberg, *supra* note 74, at 53 (quoting the Committee, “[w]hereas we believe that the current donor deferral policies are suboptimal in permitting some potentially high risk donations while preventing some potentially low risk donations, we find that currently available scientific data are inadequate to support change to a specific alternate policy”).

99. Diaz, *supra* note 12, at 143; see generally Request for Info (RFI) on Design of a Pilot Operational Study to Assess Alternative Blood Donor Deferral Criteria for Men Who Have Sex with Other Men (MSM), 77 Fed. Reg. 14801 (proposed Mar. 13, 2012), available at <http://www.gpo.gov/fdsys/pkg/FR-2012-03-13/html/2012-6091.htm>.

100. See McAdam & Parker, *supra* note 10, at 53 (quoting Sen. Kerry’s 2012 letter stating that the deferral should be guided by “the science of today and not the myths of twenty years ago.”); see generally Letter from Sen. John Kerry et al., U.S. Congress, to U.S. Dept. of Health & Human Svcs. (Jun. 8, 2012), available at <https://votesmart.org/public-statement/706449/letter-to-the-kathleen-sebelius-secretary-of-health-and-human-services#.VgLnGSBViko>; see generally Letter from Rep. Mike Quigley et al., U.S. Congress, to U.S. Dept. of Health & Human Svcs. (Aug. 1, 2013), available at <http://www.warren.senate.gov/files/documents/Bicameral%20MSM%20Blood%20Ban%202013.pdf>; see generally Letter from Sen. Elizabeth Warren et al., U.S. Congress, to U.S. Dept. of Health & Human Svcs. (Dec. 15, 2014), available at [http://www.warren.senate.gov/files/documents/2014-12-15\\_Letter\\_to\\_HHS.pdf](http://www.warren.senate.gov/files/documents/2014-12-15_Letter_to_HHS.pdf).

101. ADVISORY COMM. ON BLOOD & TISSUE SAFETY & AVAILABILITY (ACBTSA) U.S. DEPT. OF HEALTH & HUMAN SVCS., FORTY-FIFTH MEETING AGENDA (2014), available at <http://www.hhs.gov/ash/bloodsafety/advisorycommittee/acbtsa-2014-11-meeting-agenda.html>.

102. Letter from Jay E. Menitove, M.D. to Asst. Sec. for Health, U.S. Dept. of Health & Human Svcs. (Dec. 19, 2014), available at <http://www.hhs.gov/ash/bloodsafety/advisorycommittee/recommendations/nov2014-recommendations.pdf> (providing meeting recommendations from the Forty-Fifth Meeting of the ACBTSA, held Nov. 13-14, 2014); see generally Am. Ass’n of Blood Banks, Am. Blood Ctrs. & Am. Red Cross, J. Statement on ACBTSA Recommendation to Change MSM Deferral Policy (Nov. 2014), available at <http://www.aabb.org/advocacy/statements/Pages/statement141114.aspx>.



FDA looked to BPAC to provide scientific support for the change so BPAC held a meeting in early December to hear data on the matter.<sup>103</sup>

In a long-awaited move, the FDA released a statement on December 23, 2014 announcing it would recommend a revision to the MSM blood donor ban in the form of a one-year deferral, allowing men who have abstained from sex with another man in the past year to donate.<sup>104</sup> The press release noted that the FDA had a responsibility to regulate blood safety and that it had consulted with its related agencies to review the scientific data available in considering the propriety of amending the ban.<sup>105</sup> The FDA acknowledged the recommendation would align the MSM deferral period with other high-risk groups and that it was working to create a blood surveillance program that would “monitor the effect of a policy change and further help to ensure the continued safety of the blood supply.”<sup>106</sup>

Despite years of controversy over the lifetime ban, the proposal sparked instant criticism.<sup>107</sup> Some condemned the change as barely incremental, though others conceded most policies change *only* incrementally.<sup>108</sup> Senator Tammy Baldwin remarked the new policy was still unscientific and pressed for one “based on individual risk factors.”<sup>109</sup> Gay Men’s Health Crisis also called for a “risk-based . . . policy, regardless of sexual orientation or gender identity, and to stop perpetuating the stigma and discrimination.”<sup>110</sup> The group explained that “requiring celibacy for a year is a de facto lifetime ban,” which perpetuates the

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103. See BLOOD PRODUCTS ADVISORY COMM., MEETING MINUTES SUMMARY (Dec. 2, 2014), available at <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/BloodVaccinesandOtherBiologics/BloodProductsAdvisoryCommittee/ucm426205.htm> (stating BPAC was called on by the FDA to advise on the “value of HIV incidence measures in blood donors that may be suitable for inclusion in a planned general blood safety monitoring effort based upon laboratory markers detected at the time of blood donation”); see BPAC ADVISORY COMM., MEETING ANNOUNCEMENT (Nov. 14, 2014), available at <http://www.fda.gov/AdvisoryCommittees/ucm419754.htm> (stating in early December, BPAC would meet to “hear scientific data related to reconsideration of the current blood donor deferral policy” including presentations from ACBTSA’s November meeting”).

104. See generally Press Release, U.S. Food & Drug Admin., *supra* note 26.

105. *Id.*

106. *Id.*

107. See generally Holden, *supra* note 28; see Scheller & Almendrala, *supra* note 23 (stating “[Change] disappoint[ed] prominent gay rights groups and HIV/AIDS researchers, who called the yearlong waiting period medically unnecessary and unscientific”).

108. Sabrina Tavernise, *F.D.A. Easing Ban on Gays, to Let Some Give Blood*, NY TIMES (Dec. 23, 2014) (stating the change was barely incremental); but see *id.* (quoting Sean Cahill, Director of Health Policy Research at the Fenway Institute, who stated incremental is okay).

109. See Holden, *supra* note 28 (quoting Sen. Tammy Baldwin); see generally Press Release, Sen. Tammy Baldwin’s Statement Regarding FDA Announcement on Discriminatory Blood Donation Policy (Dec. 23, 2014), <http://www.baldwin.senate.gov/press-releases/ustatement-on-hhs-announcement-on-blood-donation-policy>.

110. Holden, *supra* note 28 (quoting Gay Men’s Health Crisis).

discrimination common to the AIDS epidemic because no such broad celibacy requirement is in place for heterosexuals.<sup>111</sup> The American Civil Liberties Union and the Human Rights Campaign made similar statements.<sup>112</sup> Lambda Legal agreed the revision should be backed by science and experience, rather than “fear, generalizations, and stereotypes,” and pointed out that available blood tests can identify “all known serious blood-borne pathogens” within less than two months of exposure so a longer deferral for anyone is unnecessary.<sup>113</sup> Another industry commentator described the “overly broad” nature of the revision which would burden an entire population with no accounting for monogamy, safe sex practices, or medication which almost eliminates the risk of infection.<sup>114</sup>

Almost exactly one year later, the FDA released its final guidance on the policy change.<sup>115</sup> The accompanying press release noted the FDA considered alternative options, including risk-based assessment which it declined based on lack of available scientific data, and pledged it would continue to explore other policies assuming they are in accordance with its “responsibility . . . to maintain a high level of blood product safety.”<sup>116</sup> The FDA website features a question and answer space for the new guideline and states that it considered public input before finalizing the guidance, but it seems not all voices were heard.<sup>117</sup> In the days that followed, advocates again expressed their frustration at the discrimination, stigmatization, and lack of scientific basis for a one-year MSM

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111. *See id.* (quoting Gay Men’s Health Crisis); *but see* Julie Zauzmer, *FDA to Propose Altering Ban on Gay and Bisexual Men Who Want to Donate Blood*, WASH. POST, Dec. 23, 2014, [https://www.washingtonpost.com/national/health-science/fda-to-propose-lifting-ban-on-gay-and-bisexual-men-who-want-to-donate-blood/2014/12/23/92af3734-8acd-11e4-9e8d-0c687bc18da4\\_story.html](https://www.washingtonpost.com/national/health-science/fda-to-propose-lifting-ban-on-gay-and-bisexual-men-who-want-to-donate-blood/2014/12/23/92af3734-8acd-11e4-9e8d-0c687bc18da4_story.html) (quoting Peter Marks, Deputy Dir. of the Ctr. for Biologics Evaluation & Research who said about half of the people excluded by the current MSM deferral could donate); *but see id.* (quoting Daniel Bruner, Dir. of Legal Services at Whitman-Walker Health, who also compared the proposed deferral to asking heterosexuals if they have had sex in the last year).

112. *See* Holden, *supra* note 28 (quoting Ian Thompson, a legislative representative at the American Civil Liberties Union who reiterated that this policy amounted to de facto discrimination and quoting David Stacy, Government Affairs Dir. at the Human Rights Campaign, who agreed the revision was stigmatizing and based on orientation).

113. *See* Holden, *supra* note 28 (quoting Scott Schottes at Lambda Legal).

114. *See* Zauzmer, *supra* note 111 (quoting Daniel Bruner, Dir. of Legal Services at Whitman-Walker Health).

115. *See generally* Press Release, U.S. Food & Drug Admin., FDA Updates Blood Donor Deferral Policy to Reflect the Most Current Scientific Evidence and Continue to Ensure the Safety of the U.S. Blood Supply (Dec. 21, 2015), *available at* <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm478031.htm>.

116. *See id.*

117. *See* FDA.GOV, <http://www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/QuestionsaboutBlood/ucm108186.htm> (last visited Jan. 29, 2016).

celibacy policy.<sup>118</sup> A recent poll indicated that only 6% of people support the new guideline.<sup>119</sup>

Notwithstanding the immense criticism, the FDA should be praised for finally addressing at least some problems with the original ban.<sup>120</sup> The revision brings the policy in line with deferrals for other high-risk populations, as well as some efforts of the international community.<sup>121</sup> The change also allows for a small increase in blood donation, thus reducing the national shortage by an estimated 2%.<sup>122</sup> Some commentators also suggest that the removal of the MSM lifetime ban on blood donation could prompt the FDA to consider changing the deferral periods for MSM organ and tissue donation, as well.<sup>123</sup>

### III. SO CLOSE AND YET SO FAR: ARGUMENTS AGAINST THE AMENDED POLICY

#### A. Administrative Avenues

From the administrative law perspective, challenges to the lifetime deferral on MSM blood donation included both procedural attacks on enactment and substantive attacks that it would be “arbitrary and capricious” under judicial review.<sup>124</sup> In light of the FDA’s final guidance, earlier procedural deficiencies are irrelevant. This section will briefly outline the possible outcome of a substantive challenge to the new policy, then argue that the FDA has an

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118. See Dominic Holden, *New FDA Policy Relaxes Ban On Gay Men Donating Blood*, BUZZFEED, (Dec. 21, 2015, 11:58 AM), <http://www.buzzfeed.com/dominicholden/new-fda-policy-relaxes-ban-on-gay-men-donating-blood#.xspVE9gOb> (quoting officials from the National Gay Blood Drive, Walter Whitman Health, and the Human Rights Campaign; presidential candidate Martin O’Malley; Rep. Jared Polis D-CO; and Sen. Tammy Baldwin); see Press Release, Sen. Elizabeth Warren, Warren Joins Quigley, Lee, and Baldwin in Responding to FDA Policy Change to Blood Donor Deferral Policy for MSM (Dec. 22, 2015), available at [http://www.warren.senate.gov/?p=press\\_release&id=1041](http://www.warren.senate.gov/?p=press_release&id=1041).

119. See Brian Ries, *FDA Eases Lifetime Ban on Blood Donations from Men Who Have Sex with Men*, MASHABLE, (Dec. 21, 2015), <http://mashable.com/2015/12/21/fda-gay-men-blood-donations/#GonrWO.dEGqw> (providing statistic of a poll conducted by YouGov).

120. See Holden, *supra* note 28 (quoting Sen. Baldwin who praised the revision as “needed progress”).

121. Press Release, U.S. Food & Drug Admin., FDA Comm’r Margaret A. Hamburg’s Statement on FDA’s Blood Donor Deferral Policy for Men Who Have Sex with Men (Dec. 23, 2014), available at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm427843.htm>; see McAdam & Parker, *supra* note 10, at 65 (stating that Australia and the United Kingdom both have one-year deferral policies for MSM).

122. See Tavernise, *supra* note 108 (noting that the revision could raise the blood supply by 2%).

123. Anna Almendrala, *Blood Donation Ban Is Only the First Barrier to Medical Equality For Gay Men*, HUFFPOST, (Dec. 24, 2014, 8:05 PM), [http://www.huffingtonpost.com/2014/12/24/gay-men-organ-donors\\_n\\_6378658.html](http://www.huffingtonpost.com/2014/12/24/gay-men-organ-donors_n_6378658.html).

124. Casey, *supra* note 11, at 562 (discussing procedural attacks); Bensing, *supra* note 11 at 502–07 (discussing substantive attacks).

obligation to interpret its guidelines in a way that addresses, if not alleviates, potential constitutional issues.<sup>125</sup>

### *I. Traditional Substantive Review*

Ordinarily, administrative procedure dictates that an agency is uniquely responsible for creating and giving meaning to its own guidelines and must adhere to the Administrative Procedure Act (“APA”) in doing so.<sup>126</sup> The APA allows judicial review of an agency action for “[a] person suffering legal wrong . . . , or adversely affected or aggrieved by agency action.”<sup>127</sup> Assuming *arguendo* that the FDA followed the proper procedure in enacting the guideline, an MSM prevented from donating blood could challenge it, if the guideline is entitled to judicial review.<sup>128</sup> After determining it is entitled to judicial review, a reviewing court would use one of three standards to determine whether the guideline is permissible: arbitrary and capricious, de novo, or substantial evidence.<sup>129</sup> The most appropriate standard would be arbitrary and capricious.<sup>130</sup> In utilizing this standard, the court would evaluate “whether the [action] was based on a consideration of the relevant factors and whether there has been a clear error of judgment.”<sup>131</sup> The court would also invalidate an action as arbitrary and

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125. See generally Gillian E. Metzger, *Ordinary Administrative Law as Constitutional Common Law*, 110 COLUM. L. REV. 479 (2010) (describing at length the link between administrative law and constitutional law, that a concept called the constitutional common law attaches to agency, and arguing its place in administrative law).

126. See McAdam & Parker, *supra* note 10, at 59 (stating that “[t]he APA governs the process by which federal agencies develop and issue regulations”); see also Bensing, *supra* note 11 at 502–503 (explaining a court must find the action is final before proceeding to judicial review, as well as procedure for establishing whether a guidance is a final action and possible challenges the FDA could face because it relies on information from an advisory committee).

127. Bensing, *supra* note 11, at 502 (quoting the Administrative Procedure Act, 5 U.S.C. § 702 (2006)).

128. *Id.* See *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 410 (1971) (stating that Administrative Procedure Act, 5 U.S.C. § 701 provides agency action may be judicially reviewed if there is no statutory prohibition and if it has not been committed to agency discretion by law, and that “committed to agency action” means “statutes are written so broadly that there is no law to apply”).

129. See Bensing, *supra* note 11, at 502 (describing the procedure of judicial review); See also *Citizens*, 401 U.S. at 413 (explaining that to find the standard of review, Administrative Procedure Act, 5 U.S.C. § 706 states that “agency action must be set aside if the action was ‘arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law’ or if the action failed to meet statutory, procedural, or constitutional requirements”); See Bensing, *supra* note 11, at 504 (explaining the scope of review with respect to formal and informal rulemaking).

130. *Citizens*, 401 U.S. at 414–15 (explaining the limited circumstances where the substantial evidence test or de novo review is appropriate); McAdam & Parker, *supra* note 10, at 59 (comparing the FDA guideline to the evaluation given to the action in *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402 (1971)).

131. See *Citizens*, 401 U.S. at 415 (“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”).

capricious if the agency put forth “insufficient reasons for treating similar situations differently.”<sup>132</sup> However, reviewing courts typically give significant deference to agencies and the FDA may get even greater deference because some agencies are considered experts in specialized issues.<sup>133</sup>

The FDA’s revised policy is arbitrary and capricious because it does not provide adequate reasons for treating similar situations differently and violates the public health principle to “treat like health risks alike.”<sup>134</sup> Under the original policy, all MSM, even those who practiced safe sex or were monogamous, were permanently deferred but their heterosexual partners were only deferred for one year and all other heterosexuals only deferred if they solicited sex for money.<sup>135</sup> This was criticized succinctly as “tolerating a wide range of risks associated with heterosexual sex while imposing a zero tolerance attitude toward MSM, regardless of the risk associated with individual behavior.”<sup>136</sup> The amendment only partially alleviates this problem. MSM who remain celibate for one year are now aligned with that of other high-risk groups, so the policy purports to treat at least some similar situations the same.<sup>137</sup> But the FDA ignores the similarity between “high-risk” heterosexual behaviors like general promiscuity, which are not even questioned, let alone addressed, and the perceived high-risk of sexually active MSM. These heterosexuals arguably present a higher risk than sexually active MSM because that group includes those who are not actually at high risk. The FDA rests its justification for the disparity on the statistic that MSM are more likely to have HIV but takes that statistic at face value and obscures the actual risk of MSM, an act that is not risky in and of itself, as compared to the actual risks of heterosexual sexual behavior. MSM are deferred for one year but heterosexuals are *only* deferred for one year *if* they have engaged in one specific risky sexual practice: prostitution. Leaving this group unaddressed allows the FDA to ignore the principle of treating like health risks alike.

A court may also consider an agency action irrational if the agency “entirely failed to consider an important aspect of the problem.”<sup>138</sup> The FDA entirely fails to consider *all* relevant factors and important aspects of the HIV problem. First, it does not account for the growing number of heterosexuals with HIV. Almost thirty years to the day after the CDC published the original guidelines outlining

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132. McAdam & Parker, *supra* note 10, at 61.

133. *Id.* at 660–661.

134. Belli, *supra* note 16, at 366.

135. Larkin, *supra* note 12, at 129 (explaining why MSM deferral is dissimilar to other deferrals); *see* Casey, *supra* note 11, at 556 (“The policy does not classify any heterosexual activity—including multiple, concurrent anonymous partners—as significantly high risk to warrant even temporary exclusion”).

136. Larkin, *supra* note 12, at 129.

137. *See* Press Release, U.S. Food & Drug Admin, *supra* note 115.

138. McAdam & Parker, *supra* note 10, at 61 (citing *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)).

homosexual and bisexual males as high-risk, it published another report stating that in 2009, 27% of HIV infections were attributed to heterosexual contact.<sup>139</sup> While MSM are statistically more likely to have HIV, the heterosexual population rate has been increasing steadily. If heterosexuals possess approximately one-third of the risk in transmitting HIV, why are they freely permitted to donate with little accountability for their sexual history? Additionally, the FDA ignores the fact that AIDS disproportionately burdens African Americans of any sexual orientation by 21%.<sup>140</sup> Second, the FDA fails to address data indicating that the chances of getting AIDS through blood transfusions are greater than through risky sex in the first place.<sup>141</sup> The CDC’s website clearly states that for every 10,000 people exposed to AIDS, 92.5% of the infections will have come from a blood transfusion but only 1.49% of infections will have come from anal sex and only 1.61% from all sex practices by persons of any orientation.<sup>142</sup> Despite *this* scientific data, the guideline singles out MSM-specific sexual practices but does not address any of these factors that are also relevant to protecting the blood supply.

Administrative challenges permit a court to evaluate a guideline on its merits without reaching the question of constitutionality, if it is able.<sup>143</sup> The court prefers to avoid constitutional challenges whenever possible. No version of the MSM guideline has been challenged in court on any grounds but some foreshadowing of a discriminatory challenge, although in the context of geographic and national origin as a basis for deferral, arose at the 1990 BPAC meeting.<sup>144</sup> One director at the Center for Biologics Evaluation and Research (“CBER”) stated that the “primary responsibility of the FDA is to assure the safety of the national blood supply. We are not a social service agency... [social injustice or discriminatory practice] issues lie outside the province of the FDA’s authority.”<sup>145</sup> The FDA is commanded to protect the blood supply, yet as an

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139. See CDC, *HIV Infection Among Heterosexuals at Increased Risk*, 62(10) Morbidity & Mortality Wkly Rep. 183, 183–88, Mar. 15, 2013, <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6210a2.htm>.

140. AIDS.GOV, <https://www.aids.gov/hiv-aids-basics/hiv-aids-101/statistics/> (last visited Sept. 26, 2015).

141. See Casey, *supra* note 11, at 553 (providing the statistical likelihood of contracting AIDS through blood transmission and intercourse).

142. CDC.GOV, <http://www.cdc.gov/hiv/policies/law/risk.html> (last visited Sept. 26, 2015).

143. See Bensing, *supra* note 11, at 502 (explaining that administrative law is another avenue for redress to an injury, in addition to constitutional law); see Metzger, *supra* note 125, at 489–90 (explaining that there are ways to avoid addressing some constitutional issues. For example, if court can do so because the APA already mandates a certain procedure or when “ordinary administrative law doctrines prohibit arbitrary agency decision-making has allowed the Court to avoid determining whether the Constitution requires agencies to issue certain standards”).

144. See Charlene Galarneau, *Blood Donation, Deferral, and Discrimination: FDA Donor Deferral Policy for Men Who Have Sex with Men*, AM. J. OF BIOETHICS, Feb. 2010, at 29, 36 (explaining a history of the deferral and resulting stigmatization of the Haitian risk group).

145. *Id.*

agency it is not exempt from considering its policies in light of potential constitutional questions, meaning the FDA should put forth guidelines that avoid judicial invalidation should the court be forced to consider the question of constitutionality.

## 2. *Canon of Constitutional Avoidance*

All branches of government are guided by the Constitution and, as part of the executive branch, agencies have a “legally enforceable duty to avoid” infringing it, in addition to their responsibilities under the APA.<sup>146</sup> There is a unique link between constitutional and administrative law because some administrative doctrines are created to meet constitutional requirements and “agencies are encouraged to take constitutional concerns seriously in their decision-making.”<sup>147</sup> This means administrative law runs parallel to the idea of “constitutional common law,” as coined by Henry Monaghan, which refers to “a substructure of substantive, procedural, and remedial rules drawing their inspiration and authority from, but not required by, various constitutional provisions [and] subject to amendment, modification, or even reversal by Congress.”<sup>148</sup> Constitutional common law finds an unacknowledged mooring in administrative law which has requirements under both the APA and the Constitution, although constitutional common law has been criticized as “judicial lawmaking” and the Supreme Court has downplayed the influence of the Constitution on judicial review.<sup>149</sup> However, the constitutional gloss over administrative agencies generally lends credence to the idea that the FDA has somewhat of an obligation, similar to the court’s use of the canon of constitutional avoidance, to avoid reaching constitutional lines when creating guidelines that may face judicial review.

In *F.C.C v. Fox Television Stations, Inc.*, the Supreme Court rejected the argument that “agency decisions implicating constitutional liberties trigger more stringent arbitrary and capricious review.”<sup>150</sup> Writing for the majority, Justice Scalia found “the canon of constitutional avoidance was an interpretive tool to be used only to construe ambiguous statutory language to avoid serious constitutional doubts.”<sup>151</sup> He noted that no precedent required the Court to apply the canon to limit the scope of authorized action and that the APA distinguishes

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146. Metzger, *supra* note 125, at 524.

147. *See id.* at 484 (describing the relationship between administrative and constitutional law).

148. *See id.* at 481 (explaining “constitutional common law” and pointing out the concept pervades administrative law).

149. *See id.* at 481, 483 (explaining criticisms of constitutional common law and the slight on the link between constitutional law and judicial review which was denounced in *F.C.C v. Fox Television Stations*, 556 U.S. 502 (2009)).

150. *Id.* at 484.

151. *F.C.C v. Fox Television Stations*, 556 U.S. 502, 516 (2009).

judicial review of arbitrary and capricious action from judicial review of action that is patently unlawful, which would include unconstitutional action.<sup>152</sup> He rejected the dissent’s idea of an agency requirement to “reconsider its policy in light of constitutional concerns” calling it “judicial arm-twisting.”<sup>153</sup>

Despite the holding in *Fox*, the suggestion of such a divide between constitutional and administrative law may not be entirely warranted.<sup>154</sup> The *Fox* Court attempted to separate the agency’s duty to avoid violating the Constitution, which is virtually undisputed, from the agency’s general obligation to consider constitutional gloss.<sup>155</sup> However, that separation is impossible as a practical matter because agencies already consider the constitutional gloss to avoid actual constitutional violations, especially where the Constitution is unclear.<sup>156</sup> *Fox* suggests constitutional law is precise, with a clear demarcation between what is and is not constitutional law yet administrative doctrines are actually grounded in both and sometimes agency action may fall somewhere on a continuum between needing judicial intervention and not being directly unconstitutional.<sup>157</sup> Much of constitutional law involves concepts that are imprecise, which affords agencies, including the FDA, wide latitude in determining whether its own policies comport with constitutional parameters.<sup>158</sup> The Court’s slight on the relationship may permit a feeling of nominal accountability for agencies with respect to their “constitutional judgments,” possibly allowing agencies to fly under the radar in enacting policies that are not directly unconstitutional but would benefit from being “constitutionally inspired.”<sup>159</sup> The real issue in *Fox* is whether courts should be able to use administrative law to *force* agencies to

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152. *Id.* See Metzger, *supra* note 125, at 484 (stating “the only context in which constitutionality bears upon judicial review of authorized agency action is when a court determines the agency action is unconstitutional”).

153. *Id.*

154. See *id.* (explaining that a strict separation between constitutional and administrative law is not correct).

155. See *id.* at 524 (explaining the *Fox* Court distinguished between duty to avoid violating the Constitution versus an obligation to “consider its norms and principles more generally”).

156. See *id.* (explaining that the Court tried to distinguish between a duty to avoid violating the Constitution versus consideration of the Constitution, generally).

157. See *id.* at 485, 516 (explaining that there is not always a clear line between what is governed by constitutional law and what is not but that administrative law is often rooted in both simultaneously which is what makes it constitutional common law and that because there is not clear divide, sometimes one given action both “implicate[s] constitutional values in a way that merits judicial response yet does not provide a sufficient basis for a court to hold the action unconstitutional or to preclude congressional revision of judicial determinations.”).

158. See Bensing, *supra* note 11, at 508 (noting that the imprecision of Constitutional law permits a wide range for agency interpretation).

159. See Metzger, *supra* note 125 at 486, 505 (explaining that because the court often ignores the link between the Constitution and administrative law, agencies are not always clear as to what is required and courts do not enforce the requirements).



“consider constitutional concerns” but it does not necessarily follow that judicial enforcement is required simply by suggesting agencies have an obligation to consider constitutional parameters in agency action.<sup>160</sup> The obligation is inferred from “government officials’ . . . independent duty to support” constitutional order.<sup>161</sup>

If the court is unwilling to force the issue of constitutional consideration, the opposite but possibly appropriate approach is the use of constitutional avoidance, which is widely embraced by the courts.<sup>162</sup> When the Supreme Court hears any controversy, it must adhere to the canon of constitutional avoidance, meaning it must find a way to resolve the legal question before it without deciding whether the question violates the Constitution, if possible.<sup>163</sup> In the administrative context, that means the Court will rely on the administrative parameters already in place in order to avoid reaching the constitutional question.<sup>164</sup> The FDA should take cue from the Court and construct its guidelines in a way that avoids the Court having to reach the constitutional question, should the guidelines face judicial review. Because the separation between administrative and constitutional law is not as wide as Justice Scalia suggested, “concern that a reviewing court may invoke the canon in lieu of [another test determining] deference may [incentivize] an agency to forgo broad assertions of authority or interpretations of ambiguous statutes” that would otherwise draw the agency toward the perpetually blurry lines that make up the parameters of the Constitution.<sup>165</sup> In doing this, the agency gives up some deference to make policy but also averts unfavorable judicial review that could undermine its decisions altogether.<sup>166</sup> The FDA should reevaluate its guideline so as not to implicate the Constitution because the current policy risks evaluation under

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160. *Id.* at 524.

161. *Id.* at 522.

162. *See id.* at 520 (explaining that constitutional avoidance is a “vibrant” part of the statutory interpretation approach).

163. *See Ashwander v. Tenn. Valley Auth.*, 297 U.S. 288, 347 (1936) (“The Court will not pass upon a constitutional question although properly presented by the record, if there is also present some other ground upon which the case may be disposed of. Thus, if a case can be decided on either of two grounds, one involving a constitutional question, the other a question of statutory construction or general law, the Court will decide only the latter”); *See also Metzger, supra* note 125, at 520–21 (explaining that court reliance on administrative laws rather than constitutional law is the equivalent of the canon of constitutional avoidance but also that “judicial development of ordinary administrative law doctrines to address constitutional concerns is more contentious” occasionally sanctioned and rarely overtly condemned however, as in *Fox*, the Court hesitates “to use ordinary administrative law as mechanism to encourage administrative constitutionalism.”).

164. Metzger, *supra* note 125, at 520.

165. *See id.* at 499 (suggesting that if an agency believes a reviewing court may use the canon of constitutional avoidance instead of *Chevron* deference, it may draft less ambiguous statutes or broad assertions).

166. *See id.* (stating the agency gives up power to protect itself from judicial scrutiny).

constitutional standards that it may not survive. If an MSM challenged the guideline, a court would necessarily have to attempt to decide the question before it without reaching the constitutional question but if it could not, it faces other problems explained below. Yet, even if a guideline might pass constitutional muster, agencies should not disregard issues that draw it near a constitutional question in the first place.<sup>167</sup>

However, actual constitutionality becomes less important if an agency can justify and explain its constitutional considerations in decision-making. “[C]areful explanation of how constitutional concerns were accommodated or why [they] are outweighed is all that an agency must supply. It then becomes the courts’ responsibility to determine whether the agency’s decision accords with constitutional requirements.”<sup>168</sup> In the context of the MSM guideline, the FDA might be required to explain the *science* they rely upon to justify the continued use of a policy that is so clearly discriminatory, which could pose problems explained below.

Even without a requirement that an agency consider constitutional concerns or an incentive to avoid judicial review lest the Court overturn the agency action, decision-making in enacting guidelines *should* be inspired by the reaches of the Constitution.<sup>169</sup> Congress gives agencies significant independent discretion in shaping national policy.<sup>170</sup> Sometimes “taking constitutional values into account may change shape of federal regulation and make it less effective in achieving congressional regulatory goals but Congress might well accept a trade-off of regulatory effectiveness for greater protection of constitutional values.”<sup>171</sup> Congress gave the FDA, as an agency of HHS, power to protect the health of the nation but Congress has also made clear it disfavors the FDA’s revised MSM blood ban. As shown by the statistics above, it is not even clear Congress has to trade effectiveness for a non-discriminatory policy. A blood deferral policy based on screening questions and risky behavior would satisfy both goals of policy effectiveness and constitutional avoidance.

But agencies should also *want* to embrace their influential role as leaders.<sup>172</sup> Agencies can exercise considerable influence in making policies that have

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167. *See id.* at 525 (noting that even if the agency may win on a direct constitutional challenge does not mean they should abandon all constitutional concerns).

168. *Id.* at 526.

169. *See id.* at 497 (arguing that should be guided by the Constitution’s principles).

170. *Id.* at 522.

171. *Id.* at 523.

172. *Id.* at 497 (noting also that “ the constitutional law-administrative law interplay is one curly dismissed in *Fox* and on other occasions, as well the Court displayed ambivalence about encouraging such administrative constitutionalism...[ but] link[sic] between [them] decision making surfaces with some regularity in judicial decisions and is often fostered by political branch enactments.”).

constitutional goals in mind.<sup>173</sup> Some agencies, including the Equal Employment Opportunity Commission and the Federal Communications Commission, have already used their positions to positively influence areas like pregnancy discrimination and non-discriminatory licensee requirements, respectively.<sup>174</sup> This suggests the FDA, as a recognized leader, owes the public something beyond its congressionally mandated task; a duty to aim higher than the minimum requirement. Rather than simply adjusting the ban based on “science,” the FDA should amend its guideline to affirmatively promote the values and address the concerns of recent jurisprudence on LGBTQ discrimination.

### *B. Constitutional Complications*

Commentators also argue the new deferral for MSM blood donations is as discriminatory as the original and may violate some guarantees protected by the Constitution. Both the Due Process Clause and the Equal Protection Clause of the Constitution are used to provide a framework to analyze possible discrimination, however the Due Process Clause is reserved for deprivations of a fundamental liberty or right and blood donation is unlikely to qualify as either.<sup>175</sup> Therefore, this comment proceeds via challenge to the Equal Protection Clause.

Although the ban unquestionably discriminated against homosexual men when it was enacted, and the new guideline likely does as well, traditional Equal Protection arguments have not gained traction because sexual orientation has never been considered a suspect or quasi-suspect class subject to elevated scrutiny against governmental discrimination. This section argues that the FDA’s revision amounts to both *de jure* and *de facto* discrimination and that, although it would be analyzed under (and may pass) rational basis scrutiny because sexual orientation is not a suspect class, given the Court’s recent decisions and the pro-LGBTQ direction of the other government branches, the Court is likely to make sexual orientation a suspect or quasi-suspect class soon, which would raise the scrutiny level of government action and require a complete overhaul of the FDA’s new guideline.

#### *1. De Jure and De Facto Discrimination*

The Equal Protection Clause requires all persons similarly situated be treated alike and the cases decided in accordance with it provide guideposts for

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173. *Id.* at 500.

174. *Id.* at 504.

175. See Morrison, *supra* note 35, at 2387 (stating that Due Process analysis requires infringement on a fundamental right).

analyzing differential treatment afforded to those persons.<sup>176</sup> Government actions fall into two classifications: facially discriminatory (de jure) or facially neutral with unequal application (de facto). If a government action is plainly discriminatory on its face, a plaintiff need not make any other showing before the action is evaluated. If a government action is facially neutral but a plaintiff claims a discriminatory impact, that plaintiff will also need to show discriminatory intent or purpose before evaluation.<sup>177</sup> To show discriminatory intent, the “challenged classification must single out a particular class for disadvantageous treatment and that such was motivated by discriminatory purpose.”<sup>178</sup> “Discriminatory purpose implies the decision maker selected or reaffirmed a course of action at least in part because of, not merely in spite of, its adverse effects upon an identifiable group.”<sup>179</sup> Proof is obtained from non-exclusive factors like whether history “reveals a series of official actions taken for invidious purposes,” substantive “departure from normal procedure,” or legislative and administrative history of discrimination.<sup>180</sup>

Both the original guideline and the revision to the MSM deferral result in de jure discrimination against MSM because the language of the guideline singles them out, although the FDA attempts to downplay the impact of the unambiguous language. The FDA website states the policy is not discriminatory because it 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 judgment* concerning the donor’s sexual orientation.”<sup>181</sup> Despite this self-serving statement, the FDA *does* make a judgment concerning sexual orientation, as illustrated by the 1992 memorandum and the BPAC meeting that preceded it. At the meeting, the agency discussed changing the deferral period for MSM and their female sexual partners.<sup>182</sup> Changing the deferral for female sexual partners but not MSM was justified as a “distinction between a person who themselves engaged in risky behavior versus persons who

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176. Belli, *supra* note 16, at 347 (citing Cleburne, Texas v. Cleburne Living Ctr., Inc., 473 U.S. 432, 439 (1985)) (“stating ‘The Equal Protection Clause [...] commands that no State shall ‘deny to any person within its jurisdiction the equal protection of the laws,’ which is essentially a direction that all persons similarly situated should be treated alike.”); Morrison, *supra* note 35, at 2389 (noting that the Equal Protection Clause reaches equity in differential treatment).

177. See Belli, *supra* note 16, at 348–49 (explaining what is required and what evidence will show its existence).

178. *Id.* at 348–49.

179. *Id.* at 349.

180. Village of Arlington Heights v. Metro. Housing Dev. Corp., 429 U.S. 252, 265–68 (1977).

181. FDA.GOV

<http://www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/QuestionsaboutBlood/ucm108186.htm> (emphasis added) (last visited Sept. 26, 2015).

182. See Galarneau, *supra* note 144, at 35 (stating that deferrals for both were considered at the 1992 BPAC meeting).

have been sexual partners of members of a high-risk group.”<sup>183</sup> When the committee also considered reducing the MSM deferral to one year, they were reminded of their earlier view that “persons who have ever had such high-risk behavior could potentially have it as a basis of a lifestyle choice.”<sup>184</sup> BPAC retained the MSM deferral in 1992 on the basis of judgment about MSM as a lifestyle choice. The revised guideline claims to be based entirely on scientific data, suggesting MSM is still viewed in the same light—that their lifestyle choice is risky—but despite this lifestyle choice, some blood donations are now acceptable because science can protect the blood supply enough to overcome them.

This discussion at the meeting alternatively reflects de facto discrimination. The impact of the ban is clear but its intent and purpose is demonstrated in noting that historically, the ban has been motivated by fear and discrimination.<sup>185</sup> With respect to de facto discrimination, proof in the form of a substantive departure may be relevant, “if the factors usually considered important by the decision-maker strongly favor a decision contrary to the one reached.”<sup>186</sup> As long as the MSM deferral has existed, the FDA has relied on the fact that the MSM group is statistically more likely to have HIV. Although it now claims science allows it to move the deferral from a lifetime to one year, that statistic while mostly irrelevant is still true. The blood tests the FDA relies upon have been in existence for years and can detect the presence of HIV in men who have had sex with men since last year or last month. Although the latency period plays a role in length of deferral, risky behavior should be deferred rather than people who identify with a certain sexual orientation. A factor that has continued to be important to the FDA is safety of the blood supply. It now finds it safe to allow a small portion of MSM to donate blood but entirely ignores the risk factor presented by a group that can already give it almost without restriction: heterosexuals.

## *2. The Scrutiny Level Should Be Elevated Beyond Rational Basis*

Equal Protection claims are reviewed under three standards of scrutiny: strict, intermediate, and rational basis.<sup>187</sup> Rational basis is the lowest form of review for an Equal Protection challenge.<sup>188</sup> Under rational basis review, “legislation is presumed to be valid and will be sustained if the classification

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183. *Id.*

184. *Id.*

185. *See id.* at 36 (describing the history of the blood deferral as against Haitians).

186. *Village of Arlington Heights*, 429 U.S. at 267–68.

187. *See McAdam & Parker, supra* note 10, at 56; *see id. at n.320* (explaining that strict scrutiny is the highest form of review and is reserved for suspect classifications like race, intermediate scrutiny is utilized to assess laws that implicate the quasi-suspect class gender, and all other legislation is reviewed under rational basis).

188. *See Diaz, supra* note 12, at 150 (stating that rational basis is the lowest standard of review).

drawn by the statute is rationally related to a legitimate government interest.”<sup>189</sup> Most government actions are presumed constitutional.<sup>190</sup> Sufficient scholarly work exists evaluating the original MSM deferral under rational basis review. The revision does not change that analysis; the same arguments made against the lifetime deferral apply with equal force to the one-year deferral minus those that spoke to the inequality of the timeframe. If the guideline is presented as a constitutional question, the Court may apply rational basis scrutiny because sexual orientation is not a class that automatically requires heightened scrutiny and the FDA relies on science to enact a guideline that relates to public health. Unless the Court found the scientific evidence the FDA relied on in perpetuating the ban was scientifically untenable, which it might for reasons discussed in Part III, C, the FDA could win. However, the Court is also poised to increase the scrutiny level for discrimination on the basis of sexual orientation as evidenced by the recent social and legal changes with respect to LGBTQ rights and a challenge to the FDA’s one-year ban would not survive elevated scrutiny.

*a. The Possibility of Heightened Scrutiny Due to Animus*

The next official step on the scrutiny ladder is intermediate but between that and rational basis lies an unofficial level sometimes labeled “rational basis with bite.”<sup>191</sup> Scrutiny beyond rational basis but not quite reaching the intermediate level has been found where the Court established “animus.”<sup>192</sup> An exact definition of animus has never been clearly delineated by the Court but it has been described as a “bare congressional desire to harm a politically unpopular group” or demonstrated by “fear, stereotype, bias, or a simple desire to exclude.”<sup>193</sup> Laws that reflect the latter grouping qualitatively “express, create, and enforce distinctions between social groups, tending to create a caste society” and both describe what the Equal Protection Clause is purported to protect

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189. Belli, *supra* note 16, at 347 (citing *City of Cleburne, TX v. Cleburne Living Ctr., Inc.*, 473 U.S. 432, 440 (1985)).

190. See Susannah W. Pollvogt, *Windsor, Animus, and the Future of Marriage Equality*, 113 COL L. REV. SIDEBAR 204, 207 (2013) (stating that rational basis is extremely deferential to government action and presumes constitutionality).

191. See McAdam & Parker, *supra* note 10, at 56 (explaining levels of scrutiny); see generally *Cleburne Living Ctr., Inc.*, 473 U.S. 432 (which explains that in order for a class to become one afforded more searching review than rational basis, it must show a constitutional interest at stake, the group must have immutable characteristics, and the group must be a discrete and insular minority, and it must lack political power); see Pollvogt, *supra* note 190, at 208 (explaining that rational basis with bite is a deviation from rational basis).

192. *Id.* at 206–08 (explaining the traditional two-tiered framework of Equal Protection Clause analysis and the instances where the Court has deviated and applied a standard between rational basis and strict scrutiny known as “rational basis with bite”).

193. *Id.* at 208–09.

against.<sup>194</sup> Evidence of animus may be direct or inferred which also reflects the distinction between de facto and de jure discrimination discussed above.<sup>195</sup>

*Lawrence v. Texas* extended the idea first considered in *Romer v. Evans*, that homosexuals should be given greater protection under the Equal Protection Clause and that a heightened scrutiny level might be more appropriate.<sup>196</sup> The *Lawrence* holding rested on the Due Process Clause but Justice O'Connor's concurrence implicated the Equal Protection Clause and purported to deviate from rational basis to protect persons affected by a law that reached and burdened sexual orientation but did not make it an official class due heightened protection.<sup>197</sup> More recently, in *U.S. v. Windsor*, Justice Kennedy spoke of animus and disparate treatment in the context of same-sex marriage, referring to variations of the word "dignity" eleven times in driving home the point that all persons seeking to get married should be viewed as equal under the law.<sup>198</sup> He spoke of the dignity of same-sex couples, their families, and their marriages and scolded Congress for interfering with it, noting that discrimination was not just the effect of the statute but its very essence as demonstrated by House reports defending "traditional heterosexual marriage."<sup>199</sup> He also noted that "[t]he avowed purpose and practical effect of the law here in question was to impose a disadvantage, a separate status, and so a stigma . . . [was] made lawful."<sup>200</sup>

It is possible that if the FDA guideline were brought before the Court on the discrimination question, it could be evaluated under the same "rational basis with bite" standard. The MSM one-year deferral burdens homosexual men as a class because it treats their behavior as different from other risky sexual practices. It's difficult to find "bare congressional desire to harm a politically unpopular group" because it does not come from Congress although it may

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194. *Id.* at 209.

195. *See id.* (explaining that the Court may look to direct evidence or infer animus from the structure of the law or lack of legitimate interest).

196. Morrison, *supra* note 35, at 2389 (noting that starting with *Romer v. Evans*, 517 U.S. 620 (1996), homosexuals were considered a class and in *Lawrence v. Texas*, 539 U.S. 558 (2003), they were given marginally heightened protection).

197. *See* Pollvogt, *supra* note 190, at 208 (explaining that in her concurring opinion in *Lawrence*, Justice O'Connor alluded to such an idea); *see Lawrence*, 539 U.S. at 580, 582 ("We have consistently held, however, that some objectives, such as 'a bare . . . desire to harm a politically unpopular group,' are not legitimate state interests. . . . "When a law exhibits such a desire to harm a politically unpopular group, we have applied a more searching form of rational basis review to strike down such laws under the Equal Protection Clause." Then stating that the question is whether moral disapproval can be a legitimate state interest then stating that such grounds were insufficient under rational basis review).

198. *United States v. Windsor*, 133 S. Ct. 2675, 2689, 2692–94, 2696 (2013).

199. *See id.* at 2693 (stating that the history of enactment and the text of DOMA demonstrate interference with dignity).

200. *Id.* at 2691.

amount to that level of legislation as an administrative guideline.<sup>201</sup> The one-year deferral does amount to animus because it is partially driven by fear, stereotype, and bias.<sup>202</sup> Although *Windsor* did not raise the scrutiny level afforded to sexual orientation either, this most recent departure from rational basis review to provide protection for homosexuals without committing to a higher level of scrutiny bolsters the foundation upon which the Court may build a shelter around sexual orientation. The judicial concept of animus toward LGBTQ rights discussed in a multitude of cases suggests the direction of jurisprudence makes it suitable for LGBTQ to become a protected class in the near future.

*b. The Possibility of Heightened Scrutiny Due to Changing Legal Climate*

In the past five years, our country has seen monumental steps toward LGBTQ rights in the abandonment of major federal policies that differentiated groups based on sexual orientation. In 2010, President Obama signed legislation to repeal “Don’t Ask, Don’t Tell,” the code that prohibited openly LGBTQ people from serving in the military.<sup>203</sup> The military is certainly not a “social service agency” and yet issues of discrimination did not “lie outside of its province.”<sup>204</sup> The very first objective of the law is to “determine any impacts to military readiness,” suggesting the primary goal in seeking to change its discriminatory policy is to evaluate any potential consequence to national security.<sup>205</sup> The FDA’s primary objective in considering a change to its policy was also to maintain safety, but rather than removing its discriminatory characteristics, the FDA promoted safety by only allowing a small number of additional donations from those on the outermost fringes of “risky behavior,” but continues to categorizes people based on their private sexual choices. In a formal statement addressing the repeal, the President stated he was proud to sign the legislation because it “bring[s] us closer to the principles of equality and fairness that define us as Americans.”<sup>206</sup> This example of the executive branch changing

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201. See Bensing, *supra* note 11, at 503 (explaining that an administrative guideline, while not generally considering binding or having the force and effect of law, can be construed as such if its “impact ‘is sufficiently direct and immediate and has a direct effect on . . . day-to-day business’”).

202. Pulver, *supra* note 44, at 108; see Galarneau, *supra* note 144, at 29 (stating the MSM isn’t discriminatory due to blatant homophobia but partially driven by “stereotypes about sex, gender, and sexual behaviors”).

203. McAdam & Parker, *supra* note 10, at 55; Don’t Ask, Don’t Tell Repeal Act of 2010, Pub. L. No. 111–321, 124 Stat. 3516.

204. See *infra* part III, section A, subsection 1, n. 139.

205. See *infra* part III, section A, subsection 1, n. 139.

206. Press Release, Office of the Press Secretary, Statement by the President on the Repeal of Don’t Ask, Don’t Tell (Sept. 20, 2011), available at <https://www.whitehouse.gov/the-press-office/2011/09/20/statement-president-repeal-dont-ask-dont-tell>.



discriminatory laws regarding LGBTQ rights should signal the FDA, also a part of the executive branch, to reconsider its policy language to reflect the same principles. Further, both the legislative and executive branches often compel “statutory and regulatory restrictions on administrative decision-making” that demonstrate their intention that agencies consider constitutional implications, further suggesting that the FDA be guided by the leader of its own branch of government as well as by the legislative branch.<sup>207</sup>

Three years later, *U.S. v. Windsor* struck down a provision of the Defense of Marriage Act (“DOMA”) as unconstitutional because its definition of marriage served to undercut the dignity afforded to people in same-sex marriages and violated their liberty interest under the Due Process Clause.<sup>208</sup> Then on June 26, 2015, the Supreme Court held that all same-sex couples have a constitutional right to marriage in *Obergefell v. Hodges*.<sup>209</sup> This opinion, also written by Justice Kennedy, focused on the institution of marriage and its meaning to *anyone* who seeks to enter into it.<sup>210</sup> The holding is grounded in the Due Process Clause but Justice Kennedy cited earlier cases as evidence that due process and equal protection are often two sides of the same coin, stating that “rights implicit in liberty and rights secured by equal protection may rest on different precepts and are not always co-extensive, yet each may be instructive as to the meaning and reach of the other.”<sup>211</sup> The opinion outlined how marriage has evolved, an evolution that has “strengthened, not weakened, the institution,” then analogized that evolution to treatment of the LGBTQ community, from the initial condemnation to the eventual public acceptance.<sup>212</sup> Implicit in the language is a principle reminiscent of a different opinion Justice Kennedy took part in, *Planned Parenthood of Pennsylvania v. Casey*. In considering the clear impropriety of earlier cases, *Casey* explained that in times of “national controversy,” “changed circumstances may impose new obligations.”<sup>213</sup> In both

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207. Metzger, *supra* note 125, at 502.

208. See generally *United States v. Windsor*, 133 S. Ct. 2675, 2693 (2013).

209. *Obergefell v. Hodges*, 135 S.Ct. 2584 (2015).

210. *Id.*

211. *Id.* at 2603.

212. *Id.* at 2596.

213. See *Planned Parenthood of S.E. PA v. Casey*, 505 U.S. 833, 861 (1992) (describing abortion as national controversy); see *id.* at 864 (explaining that when situations change, the court must reevaluate prior questions that have been decided); see *id.* at 863 (stating “[W]hile we think *Plessy* was wrong the day it was decided, we must also recognize that the *Plessy* Court’s explanation for its decision was so clearly at odds with the facts apparent to the Court in 1954 that the decision to reexamine *Plessy* was on this ground alone not only justified but required. *West Coast Hotel* and *Brown* each rested on facts, or an understanding of facts, changed from those which furnished the claimed justifications for the earlier constitutional resolutions. Each case was comprehensible as the Court’s response to facts that the country could understand, or had come to understand already, but which the Court of an earlier day, as its own declarations disclosed, had not been able to perceive.”).

*Casey* and *Obergefell*, Justice Kennedy reminded the Court that a change in understanding social issues may enable it to reconsider its harmful and stigmatizing precedent. The message also serves to “characterize animus as something akin to unconscious bias as opposed to malicious intent” in that bias is often perpetuated by history rather than by something darker.<sup>214</sup> In considering those judicial remarks, the FDA should take a hard look at the shadowy history of the MSM deferral and reconsider whether keeping a categorical ban on MSM behavior is the best way to preserve the safety of the blood supply or if there is an obligation to overhaul an entire deferral system that was predicated on discrimination.

The combined impact of the statements on LGBTQ rights from the judicial branch, including the criticism of the legislative branch in *Windsor*, the President repealing “Don’t Ask, Don’t Tell,” and Congress’ continued support for a less discriminatory revision of the MSM blood donation deferral suggests the FDA *must* move toward a less discriminatory practice in order to conform with other areas of government. While the revision from a lifetime deferral to a one-year deferral hides behind science for support, it was discriminatory when it was enacted and it is equally discriminatory now. A meaningful revision to the policy must be grounded in safety but the FDA cannot ignore the inherent discrimination in light of the governmental direction with respect to LGBTQ rights, even if ameliorating social justice is “not in their province.”

Although the FDA’s revision to the MSM deferral policy does not yet violate the Constitution as it does not relate to a liberty interest or affect a protected class due heightened scrutiny, it is difficult to say the FDA can ignore the current social climate or the potential for sexual orientation to *become* a protected class in the near future. With changes to major laws affecting LGBTQ rights and the Supreme Court’s recent decisions on the issue, it is possible the Court will soon elevate the scrutiny afforded to sexual orientation and the laws that discriminate against LGBTQ to a level beyond rational basis and the FDA should be prepared.

### C. *Synthetic Science Solves the Wrong Problem*

Scientific advancements in determining what causes HIV, as well as improved blood testing, have done much to prevent the spread of the disease through blood transfusion, making a lifetime deferral on MSM donating blood

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214. Pollvogt, *supra* note 190, at 210–11 (“Justice Kennedy described the exclusion of same-sex couples from marriage as a mere artifact of a less enlightened time, which took on a more negative cast only in comparison to evolving notions of justice. In so doing, Justice Kennedy characterized animus as something akin to unconscious bias as opposed to malicious intent.”).

unnecessary.<sup>215</sup> The FDA acknowledged this when it announced that moving to a one-year deferral was scientifically supported.<sup>216</sup> Although science technically supports the fact that moving from lifetime deferral to one year is safe, science does not support a celibacy requirement exclusively for MSM. MSM *are* statistically more likely to have HIV but HIV is neither exclusive to nor caused by men having sex with other men. Therefore, the FDA should consider the scientific arbitrariness of the classification and the scope of the ban should be revised rather than the length.

When AIDS was first reported, it was thought to come from *being gay*.<sup>217</sup> Although that was disproved less than two years later, all versions of the guidelines have mentioned some variation of homosexual men as a high-risk category.<sup>218</sup> Risky behavior such as unprotected sex, multiple partners, and sharing needles leads to the spread of AIDS.<sup>219</sup> The act of men having sex with men is not inherently risky.<sup>220</sup> The new policy prevents sexually active homosexual men from donating blood based on their sexual orientation rather than their actual risk to the blood supply—that isn't science. The agency forges a scientifically flawed distinction between MSM and heterosexual donors by categorizing and deferring donation based on one group's risky behaviors but not the other group's arguably riskier behaviors.<sup>221</sup> The FDA recognized early on that “describing behavior is a better way to achieve public policy goals rather than using labels,” but never ameliorated the negative impact of its categorical distinctions.<sup>222</sup> The oldest guidelines specified homosexual men as a high-risk category and newer ones addressed risky behavior of men having sex with other men generally, but all variations only address risky behavior of homosexual men and no one else. Of course, protecting the blood supply from HIV is the biggest

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215. McAdam & Parker, *supra* note 10, at 29–30 (describing the evolution of blood tests from ELISA and Western Blot to the nucleic acid test (“NAT”).

216. See Holden, *supra* note 28 (quoting Peter Marks, Deputy Director of the FDA's Center for Biologics Evaluation & Research “We would not recommend such a policy change if we didn't think the safety of the blood supply would be maintained”).

217. See McAdam & Parker, *supra* note 10, at 23 (stating it was later confirmed that sexual orientation was not incident to the disease).

218. See *Id.* at 27 (outlining the language revisions by year).

219. *But see* Hochburg, *supra* note 12, at 238 (“Because of the risks associated with blood donors donating infected blood during the window period, thereby introducing HIV into the blood supply, “[e]xclusion of blood donors with an increased risk of HIV infection is considered an effective strategy to reduce the residual risk of HIV contamination [of the blood supply].”).

220. See Scheller & Almendrala, *supra* note 23 (quoting Dr. Wm. Kobler, spokesman for the Am. Med. Assn., “The lifetime ban on blood donation for men who have sex with men is discriminatory and not based on sound science”).

221. See McAdam & Parker, *supra* note 10, at 61 (noting that the distinction between heterosexual and MSM donors is untenable because AIDS comes from engaging in risky behaviors).

222. See Culhane, *supra* note 21, at 133–34 (noting the irony in the language change which did not alleviate the discrimination despite it moving toward risky behavior and away from broad categories).

priority, which makes it somewhat acceptable that the FDA maintained a strict donation policy on some variation of this category, at least for a while. Yet, even if one concedes that “men who have had sex with another man even one time since 1977,” or even since last year, may have a statistically higher prevalence of AIDS than any other group, it is merely correlation, not causation.<sup>223</sup>

The FDA stated it examined alternatives to the one-year deferral but the available scientific evidence best supported this option.<sup>224</sup> The policy chosen has a demonstrated success rate in other countries with epidemiology similar to ours and was “based both on how the disease circulates in this country and on how donors here are screened.”<sup>225</sup> Information for less than a twelve-month deferral was not available.<sup>226</sup> The FDA noted that HIV is too prevalent in this country to completely lift the ban and move to risk-based screening like some countries.<sup>227</sup> By the agency’s calculation, individualized screening would cause the risk of receiving infected blood to quadruple from its current likelihood of one in 1.5 million.<sup>228</sup>

But in response to one advocacy group who protested the December 2014 deferral announcement, the FDA is on record stating that self-assessment is unreliable, burdensome to donation centers, and offensive to donors.<sup>229</sup> Self-assessments are used to screen heterosexual donors so it does not make sense that they would be less reliable for MSM donors.<sup>230</sup> Considering the blood shortage, it is hardly likely blood donation centers would be *burdened* by potentially eligible donors that might increase their workload. The claim that self-assessment might be offensive arguably pales in comparison to the offense currently claimed by advocacy groups.

The FDA claims to rely on science, but despite extensive research, the FDA admitted it “suffered from serious scientific deficiencies” and separately justified

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223. See Morrison, *supra* note 35, at 2373 (stating that the gay community is still the leader in AIDS statistics).

224. See Press Release, U.S. Food & Drug Admin, *supra* note 115.

225. See Emma Margolin, *FDA Ends Lifetime Ban On Blood Donations From Gay, Bisexual Men*, MSNBC, (Dec. 21, 2015, 6:15 PM), <http://www.msnbc.com/msnbc/fda-ends-lifetime-ban-blood-donations-gay-bisexual-men> (noting that the time-based deferral has been proven effective); see Donald G. McNeil Jr., *F.D.A. Ends Ban, Allowing Some Blood Donations by Gay Men*, NY TIMES, (Dec. 21, 2015), <http://nyti.ms/1S5snZ8> (citing Dr. Peter Marks’, deputy director of the FDA’s Center for Biologics Evaluation and Research explanation for the policy decision).

226. See Press Release, U.S. Food & Drug Admin, *supra* note 115.

227. See Holden, *supra* note 118.

228. See McNeil, *supra* note 225.

229. See Ed Coffin, *The FDA Responds to Criticism of ‘Loosening’ Ban on Blood Donations From Gay and Bi Men*, HUFFPOST, (Dec. 31, 2014, 5:51 PM), [http://www.huffingtonpost.com/ed-coffin/the-fda-responds-to-criti\\_b\\_6401460.html](http://www.huffingtonpost.com/ed-coffin/the-fda-responds-to-criti_b_6401460.html).

230. See *id.*

retaining the lifetime MSM policy based on data gaps as recently as 2007.<sup>231</sup> While this is not to say the FDA is not relying on current scientific data in promulgating the one-year deferral, its past performance should hardly garner public support of its provided justifications. Further, its continued reliance on antiquated and illogical categorizations in the face of actual science and social progress sabotages their overall credibility.<sup>232</sup>

In considering the grand scheme of protecting the nation's blood supply, donor deferral is but one piece.<sup>233</sup> Blood testing itself is another large component. It should not be surprising that human error in handling the blood detracts from the overall safety of the supply.<sup>234</sup> That includes both at the donation level and use level. The related medical fields have utilized a concept called "purity in the bag," which allows for more donors and the possibility of an increased blood supply by focusing on testing blood after it has been received.<sup>235</sup> While it is not advantageous to let just anyone donate, the practice would still ensure the safety of the blood supply regardless of deferral reason.

Currently, blood testing is so accurate that the possibility of *anyone* getting AIDS from a blood transfusion is small.<sup>236</sup> Despite this, successful transmission of AIDS is actually more likely to occur through transfusion of infected blood than through intercourse with an infected person, so the chances of getting HIV from blood donated by MSM is actually infinitesimal.<sup>237</sup> Regardless of the donor, at least one test can reveal an HIV infection in less than two weeks and all tests can detect blood-borne pathogens "within 45 days of exposure."<sup>238</sup> The National Institutes of Health ("NIH") explained that positive HIV test results

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231. See Galarneau, *supra* note 144, at 32–33 (describing the lack of justifiable data and analysis used by the FDA).

232. See *id.*

233. See Galarneau, *supra* note 144, at 30 (describing the FDA's multi layer protection model).

234. See Jay P. Brooks, *Using Basic Ethical Principles to Evaluate Safety Efforts in Transfusion Medicine*, J. OF BLOOD TRANSFUSION, Nov. 2011, at 1, 4 (explaining that error rates in blood transfusion exist). See Belli, *supra* note 16, at 334–37 (explaining reasons for error rates).

235. See Brooks, *supra* note 234, at 1 (explaining the concept of "purity in the bag" as testing the blood once its been received).

236. Zauzmer, *supra* note 111 (quoting Peter Marks, deputy director of the FDA's Center for Biologics Evaluation and Research, "[t]he chance of finding an HIV-contaminated unit in the blood supply, is 1 in 1.5 million"); See Hochburg, *supra* note 12, at 235 ("Direct blood contact is one of the most efficient, yet most preventable, forms of HIV transmission. In fact, an internationally recognized AIDS researcher asserts "the most successful single achievement in the prevention of HIV infection has been the drastic reduction in transfusion-acquired infection resulting mainly from effective screening of donated blood").

237. See Casey, *supra* note 11, at 553 (providing the risk of getting AIDS via intercourse as compared to getting AIDS thru a blood transfusion).

238. McAdam & Parker, *supra* note 10, at 49 (describing the use of "NAT" testing). See Holden, *supra* note 28 (quoting Scott Schoettes, Lambda Legal senior attorney and director of the HIV Project that blood tests can detect AIDS in as little as 45 days).

may show up between six weeks and six months so the year long ban is aimed at peace of mind rather than a buffer zone for test results.<sup>239</sup> Yet, the FDA has stated, “compelling scientific evidence [i]s not available . . . to support a change to a deferral period less than one year while still ensuring the safety of the blood supply,” double the time-frame provided by the NIH.<sup>240</sup> But, the ACBTSA agreed the one-year deferral could “be looked at as a starting point” and CBER commented that the FDA would use the surveillance system to determine whether another revision could be considered.<sup>241</sup> There seems to be a general consensus that even the one-year deferral is a time period chosen out of an abundance of caution but the agency is still focusing on the wrong problem. The length of the ban is not what troubles advocates; it is the implications of stigma and a de facto ban for all men who continue to safely engage in the behavior the FDA is so adamant about singling out.

Another consideration for protecting the blood supply is that our country is experiencing a blood shortage of crisis proportions. “In September 2014 ABC News reported severe blood shortages in major cities including Los Angeles, St. Louis, Detroit, Philadelphia and Baltimore, with some hospitals reporting to being down to a single day’s supply.”<sup>242</sup> The FDA claims it has a responsibility to maintain blood product safety but cannot ignore the fact that entirely removing the MSM ban could save approximately 657,000 lives, annually.<sup>243</sup>

The FDA promised it would continue to assess the policy as science progressed.<sup>244</sup> If the one-year deferral is considered only a starting point, its trajectory should be to eliminate broad overgeneralizations and end with a guideline that focuses on meaningful questions about risky behavior, focused on individual evaluation with assessment for donor suitability. One example would be to ask all donors, regardless of sexual orientation, “[i]n the past [two months],

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239. See Zauzmer, *supra* note 111 (Anthony Fauci, director of the National Institutes of Health’s National Institute of Allergy and Infectious Diseases).

240. See Tavernise, *supra* note 108 (quoting Dr. Peter Marks, deputy director of the FDA’s Center for Biologics Evaluation and Research, “[a]t this time we simply do not have the evidence to suggest that we can go to a shorter period.”); see also generally Press Release, U.S. Food & Drug Admin, *supra* note 115 (providing support for the same statement made last year).

241. See Brady Dennis, *Government Could Ease 31-Year-Old Ban on Blood Donations from Gay Men*, WASH. POST, (Nov. 29, 2014), [https://www.washingtonpost.com/national/health-science/government-could-ease-31-year-old-ban-on-blood-donations-from-gay-men/2014/11/29/92ab8fae-7037-11e4-893f-86bd390a3340\\_story.html](https://www.washingtonpost.com/national/health-science/government-could-ease-31-year-old-ban-on-blood-donations-from-gay-men/2014/11/29/92ab8fae-7037-11e4-893f-86bd390a3340_story.html) (quoting Jay Menitove of ACBTSA); see Tavernise, *supra* note 108 (quoting Peter Marks of CBER).

242. Kelsey Louie & Sarah Kate Ellis, *For Gay and Bi Blood Donors, New Rules but Same Ban*, HUFFPOST, (Apr. 3, 2015, 8:07 PM), [http://www.huffingtonpost.com/kelsey-louie/for-gay-and-bi-blood-dono\\_b\\_7000510.html](http://www.huffingtonpost.com/kelsey-louie/for-gay-and-bi-blood-dono_b_7000510.html).

243. See Zack Ford, *How The FDA’s Revised Blood Ban Caters to Religious Anti-Gay Beliefs*, THINK PROGRESS, (May. 12, 2015, 4:46 PM), <http://thinkprogress.org/lgbt/2015/05/12/3657901/gay-blood-donation-celibacy/> (providing estimate).

244. See Press Release, U.S. Food & Drug Admin, *supra* note 115.

have you engaged in HIV risk behaviors — including condomless anal or vaginal sex, or shared drug-injecting paraphernalia — with an HIV-positive person or someone whose HIV status you did not know?”<sup>245</sup> This would provide an arguably more accurate safety net for all persons.<sup>246</sup> Advocates have called for this type of change as opposed to keeping a deferral based on “sexual orientation or gender identity” which perpetuates stigma and discrimination.

The safety of moving to a risk-based screening has been documented abroad. In 2001, Italy began using to an individualized, “risk-based questionnaire for donors, as opposed to a blanket deferral of MSM donors.”<sup>247</sup> They saw an increase in HIV-positive donations but found heterosexual donors caused that increase.<sup>248</sup> In November 2015, France also reported an upcoming change to their MSM policy: MSM who have been celibate for one year may donate and MSM who have been monogamous or celibate “could donate after four months.”<sup>249</sup> Moving to a risk-based assessment system here would also allow a significant increase in blood donations, would help to decrease the blood shortage, and would work to erase the continued belief that homosexual men are “contaminated.”

Some may consider the additional costs and risk of error in screening so many donors as an obstacle, but those issues would arise with any increase in blood donation, as demonstrated in Italy.<sup>250</sup> There is no way to combat an increased risk in error; any increase in donor pool logically increases the risk of error. If ending the blood shortage is a priority, the FDA must be prepared to screen more blood and expect more errors. However, with respect to the additional cost, the FDA is unable to “consider financial matters when making policy decisions.”<sup>251</sup>

Risk, as a concept has been evaluated extensively and experts agree it is a “social, moral, economic and political concept as much as a scientific one.”<sup>252</sup> As one representative from the NIH predicted ten years ago, the MSM policy isn’t just about science, it’s a social justice problem and a fairness problem.<sup>253</sup>

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245. Tim Murphy, *Why Banning Gay Men from Donating Blood Is Dumb and Wrong*, N.Y. MAG. (Dec. 2, 2014, 2:50 PM), <http://nymag.com/daily/intelligencer/2014/12/banning-gay-men-from-donating-blood-is-wrong.html>.

246. *Id.*

247. McAdam & Parker, *supra* note 10, at 51 (use of blanket deferral); see Scheller & Almendrala, *supra* note 23 (noting Italy made this change in 2001).

248. McAdam & Parker, *supra* note 10, at 51 (noting the success in Italy’s policy).

249. See Holden, *supra* note 118 (providing information on France’s policy due to take effect Spring 2016).

250. See *id.* (indicating Italy saw no change).

251. Larkin, *supra* note 12, at 132.

252. See Galarneau, *supra* note 144, at 34.

253. *Id.* at 35.

An assertion that the risk is acceptable and backed by science does not eliminate responsibility to justify it.<sup>254</sup>

*D. The Ban Goes Against Patient Autonomy and Social Justice*

Almost as long as the MSM deferral has been in place, the weight of scholarly authority has attacked it from administrative and constitutional law perspectives. This Comment also evaluates the deferral from the bioethical and public health ethics standpoint.<sup>255</sup>

The height of the civil rights movement brought recognition to ideas of dignity and equality, impacting philosophical study, which began to focus on practical ethics as opposed to abstract ideas about morality.<sup>256</sup> Philosophers started to consider pragmatic issues like “abortion and euthanasia, the ethics of war and of capital punishment, and the allocation of scarce medical resources.”<sup>257</sup> This was one piece of a larger puzzle that created bioethics as a discipline.<sup>258</sup> The law powerfully informs “ethical reflection on moral responsibilities” which explains why lawmakers, government administrators, and a variety of professional organizations often seek bioethicists for consultation.<sup>259</sup> Therefore, the principles of bioethics and the study of dignity and fairness are relevant to a discussion about the need for a safe blood supply and the use of a discriminatory policy to achieve it. It has been argued that BPAC, and likely the FDA, lacked “the social, ethical, political, and economic expertise necessary to understand the full ramifications of the decisions it was making.”<sup>260</sup> Although the statement refers to the very early deferral conversations, it is arguably still true.<sup>261</sup>

There are various ethical paradigms in which to consider the breadth of issues that arise when considering the influence of bioethics on the law but this Comment will evaluate the MSM deferral under the Four Principles Approach, which employs the following duties: respect for autonomy, nonmaleficence, beneficence, and justice.<sup>262</sup>

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254. *Id.*

255. See generally Morrison, *supra* note 35, at 2363 (2015).

256. See A COMPANION TO BIOETHICS 7 (Helga Kuhse & Peter Singer, eds., 2009) (tracing the history of Bioethics).

257. *Id.*

258. *Id.*

259. See Tom L. Beauchamp & James F. Childress, PRINCIPLES OF BIOMEDICAL ETHICS 40 (4th ed. 1994) (explaining that the law is “a significant source for ethical reflection on moral responsibilities.”); see A COMPANION TO BIOETHICS, *supra* note 238, at 7 (“government commissions, law reform bodies, and professional organizations”).

260. See Galarneau, *supra* note 144, at 31.

261. *Id.* (explaining that the critique is still relevant).

262. See Gwendolyn P. Quinn, et al., *Preserving the Right to Future Children: An Ethical Case Analysis*, 12AM. J. OF BIOETHICS 6, 40 (2012) (quoting Beauchamp & Childress); see also Janet L. Dolgin & Lois L. Shepard, BIOETHICS AND THE LAW 20 (Aspen Publishers, 2005).



1. *Respect for Autonomy: "Otherness"*

The first pillar of bioethics describes the idea of choice and one's ability to make certain choices for himself.<sup>263</sup> Setting aside the question of whether being homosexual is a choice or an innate and immutable characteristic, engaging in homosexual behavior is a choice. A blood donation deferral category that singles out men who choose to engage in homosexual behavior is one of many ways the government acts to question the legitimacy of same-sex relations and the choice to engage in them.<sup>264</sup> Judicial precedent disfavors that governmental propensity in the context of continued oppression of people who choose to engage in homosexual acts or marry someone of the same sex.<sup>265</sup> In *Obergefell*, Justice Kennedy noted that the liberty contemplated by the Due Process Clause "extend[s] to certain personal choices central to individual dignity and autonomy, including intimate choices that define personal identity and beliefs."<sup>266</sup> The very holding of *Obergefell* rests on notions of autonomy and the freedom to engage in certain acts that are considered a fundamental right.<sup>267</sup> To be sure, there is no fundamental right to donate blood but there *is* a right to have the government respect one's autonomy and at the very least, notions of administrative constitutionalism instruct agencies to consider issues like discrimination.<sup>268</sup> Continued use of this particular deferral language is another avenue for the government to attempt to control disfavored behavior.

Discouraging autonomy calls to mind the notion of "otherness" which occurs when those of "privilege and power" are called on to define discrimination to the exclusion of anyone else.<sup>269</sup> This creates an "us" versus "them" scenario which contributes to a backhanded loss of autonomy. No one wants to be excluded from the "in" crowd so to avoid the "otherness", people who otherwise would not be forced to hide their true identity.

A second consideration is that the blood donor questionnaire itself assumes a "gender binary" or "an understanding of gender that classifies all persons as male or female and ignores persons who identify otherwise."<sup>270</sup> Again, setting aside the question of whether that sense of self-identity is something that can be altered, not all people simply identify as male or female, which can be confusing in the blood donation context. This results in burdening people in a certain

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263. Quinn, *supra* note 262, at 39 (quoting Beauchamp & Childress).

264. See Murphy, *supra* note 245.

265. See generally *Obergefell v. Hodges*, 135 S.Ct. 2584 (2015); see generally *Romer v. Evans*, 517 U.S. 620 (1996).

266. *Obergefell v. Hodges*, 135 S.Ct. 2584 (2015).

267. See generally *id.*

268. Nancy Leong, *Making Rights*, 92 B.U.L. REV. 405, 415–16 (2012).

269. See Fisher & Schonfeld, *supra* note 6, at 41 (describing the concept of "otherness").

270. See Galarneau, *supra* note 144, at 34.

category with a sense of “otherness” due to choices they have made about their gender.<sup>271</sup> Further, without considering the actual number of homosexual males infected with HIV, the guideline burdens the entire group by grouping risky donors with safe ones. The new blood donation guideline perpetuates problems of gender binary, exclusion, and government challenge to homosexual practices and conflicts with the ideas of autonomy.

## 2. *Nonmaleficence: Moral Panic Techniques*

The second pillar of the bioethical framework is maleficence; the idea that it is unjust to harm or inflict suffering on others.<sup>272</sup> One problem with the continued use of homosexual male behavior as a deferral indicator is what it implies. In one example, it was noted that monogamous homosexual men are barred but promiscuous heterosexuals are not, which “support[s] a longtime, ugly belief that gay men are in some sense contaminated.”<sup>273</sup> Others assert that because homosexuality was historically classified as a mental disorder and people still find homosexuals to be ill-omened, the lifetime ban is a way to repress homosexuality using science to instill fear.<sup>274</sup>

The revision lifts the lifetime ban in favor of a one-year deferral but because it functions as a de facto lifetime ban, the effects are the same. Whether there is a way to quantitatively say that people believe homosexual men are contaminated or have a mental disorder, the FDA deferral acts to perpetuate that belief. The simple act of singling them out without more than an unjustified reliance on science perpetuates a “moral panic.” A moral panic is defined as “a method of placing a social issue in terms of an illness. A panic links one suspect thing with one definitely bad thing, which gives the message that the suspect thing must actually be bad.”<sup>275</sup> Here, the deferral works to keep HIV synonymous with homosexual males, perpetuating the fallacy that they are more closely related than is actually correct.<sup>276</sup>

A second justification on which the FDA may implicitly rely is the history of HIV impact on hemophiliacs.<sup>277</sup> Hemophiliacs receive regular blood transfusions and were deeply and tragically affected by the lack of early information about HIV.<sup>278</sup> Much of the blame fell on those who delayed ensuring

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271. Fisher & Schonfeld, *supra* note 6, at 41.

272. Quinn, *supra* note 262, at 40.

273. See Murphy, *supra* note 245, at 228.

274. See Klugman, *supra* note 4, at 46.

275. See *id.* at 47.

276. See *id.*

277. See Caplan, *supra* note 83, at 2 (stating “the history of people suffering hemophilia” and that it “shapes the ongoing exclusion of gay men.”).

278. *Id.*

it was kept out the blood supply upon which this population so heavily relies.<sup>279</sup> Due to criticism of the way the situation was handled, regulators act with extreme caution.<sup>280</sup> Some compare using, as a basis for the blood donor deferral, the catastrophic consequence that HIV had on the hemophiliac population to the way the Tuskegee Study and the Holocaust underlie the field of human experimentation, which could be overstating the impact for effect.<sup>281</sup> Yet, hemophiliac safety alone cannot be used to justify mistreatment of MSM.

### 3. *Beneficence: Ideas of Civil Duty*

The bioethical principle of beneficence articulates the idea of “promoting good.”<sup>282</sup> The revised FDA ban deprives an entire class of persons from engaging in what some consider a civic duty: the opportunity to engage in the altruistic act of donating blood to save a life. Some men find a way to “beat the system” and lie on the blood bank questionnaire, just to have the ability to help those in need.<sup>283</sup> Many homosexual men did just that after the World Trade Center attacks.<sup>284</sup> The FDA recognizes that people want to help yet they cling to the stated obligation that safety is paramount.<sup>285</sup> This is a “classic framing of ethical dilemmas in public health: a collective good . . . is posited as in conflict with the interests or rights of individuals.”<sup>286</sup> In this case “donor rights to give blood and recipient rights to receive safe blood” are set up as necessarily opposing views, preventing any solution for both goals to be achieved.<sup>287</sup> Rather than promote good, the deferral policy constrains it.

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279. *Id.* (stating “the blame for the deaths of so many who require blood products was placed on those who did not react quickly enough to insure that HIV infected donors were kept out of the ranks of donors”).

280. *Id.* (stating “the legacy of the devastation of the hemophiliac community in the U.S. and other nations played a huge role in making regulators very nervous about relaxing standards”).

281. *Id.*; see Culhane, *supra* note 21, at 29 n.5.

282. Quinn, *supra* note 262, at 40.

283. See Murphy, *supra* note 245.

284. See *id.*; see also Brady Dennis, *Government Could Ease 31-Year-Old Ban on Blood Donations From Gay Men*, WASH. POST, (Nov. 29, 2014), [https://www.washingtonpost.com/national/health-science/government-could-ease-31-year-old-ban-on-blood-donations-from-gay-men/2014/11/29/92ab8fae-7037-11e4-893f-86bd390a3340\\_story.html](https://www.washingtonpost.com/national/health-science/government-could-ease-31-year-old-ban-on-blood-donations-from-gay-men/2014/11/29/92ab8fae-7037-11e4-893f-86bd390a3340_story.html) (quoting Ryan James Yezak of the National Gay Blood Drive, “The evidence is there; they’re just being cautious about implementing it . . . [But] we will get to where we want to be. . . . People want to serve their country. They want to do this thing that other humans partake in. Not being able to do this is wrong.” and Glenn Cohen, “The moral compass has shifted,” “We got rid of ‘Don’t Ask, Don’t Tell.’ You can shed your own blood for the country [if you’re gay]. But you can’t donate your blood to your fellow man? A lot of people take that as a second-class citizenship status.”).

285. See Galarneau, *supra* note 144, at 31 (quoting, “while appreciative. . .”).

286. See *id.*

287. See *id.*

#### 4. *Justice-Language*

The last pillar of bioethics focuses on fairness.<sup>288</sup> Discrimination, or the unfair treatment of a group, is the ultimate injustice.<sup>289</sup> “Social justice requires not the melting away of differences but promoting respect for group differences without oppression.”<sup>290</sup> Through the power of language, the deferral revision reinforces injustice in two ways. Much like the use of moral panic techniques, subtle use of language reinforces stigmatization.<sup>291</sup>

First, blood donation centers “have developed a metaphor that giving blood makes one morally virtuous.”<sup>292</sup> The implied alternative is that people who do not may be “morally suspect” or defective in some way, whether physically or in a social sense of not valuing life enough to donate blood to support it.<sup>293</sup> Although the blood donation industry fought to change the policy, they are constrained by the FDA through licensing and can only accept donations within FDA parameters.

Second, the FDA’s change in terminology through the years reflects at least a slight move away from sexual orientation and toward risky behavior.<sup>294</sup> Despite this, their continued singling out approved donors based on sexual orientation rather than actual risk perpetuates the stigma that advocates have been trying to overcome since the ban was enacted. Removing the lifetime deferral to include at least some MSM donors subtly reflects its acknowledgement of original overinclusiveness but it does not go far enough.

#### CONCLUSION

Although the move from a lifetime deferral to a one-year ban is a step in the right direction, it still acts as a de facto lifetime ban on most men in the MSM category. The new policy will allow more homosexual men to donate, increasing the blood supply, but this amendment to the deferral category continues to hold the MSM population under unnecessary scrutiny in light of scientific, legal, and social advancements. The FDA engages in a mindset that if a MSM continues to engage in risky behavior, he should be deferred. While the new policy brings MSM in line with other groups designated high-risk, the whole deferral system

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288. Quinn, *supra* note 262, at 40.

289. See Galarneau, *supra* note 144, at 32 (describing discrimination as injustice).

290. See *id.* at 37.

291. See Klugman, *supra* note 4, at 47 (“Whether its purposeful or just part of systemic subconscious, words have an effect on people’s perceptions and opinions.”).

292. See *id.*

293. See *id.* at 46.

294. See Goldberg, *supra* note 74, at 50 (explaining that until 1986, “categorizations focused on sexual orientation” and were changed to emphasize behavior); see Galarneau, *supra* note 144, at 30 (explaining the FDA recognized “HIV risk had a greater association with sexual behavior than with sexual identity.”).

should be dismantled in favor of actual risk-based screening rather than resting on statistical likelihood of risk, especially because the categories used to identify those at high-risk are both overinclusive (including men who are monogamous) and underinclusive (excluding heterosexuals who engage in risky behavior). The only fair and viable solution is to move away from categorical screening and toward risk-based screening.