

# **Good Public Health Policy, Better Public Health Law: Blood Donation, Individual Risk Assessments, & Lifting the Deferral for Men Who Have Sex With Men**

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## **ABSTRACT**

United States public health law balances safeguarding public health and respecting individual liberties, and the balance must always be evaluated. Food and Drug Administration (FDA), having only recently reduced its lifetime deferral for men who have sex with men (MSM) to a 12-month deferral, called for public comment on changing its guidelines once more to consider screening for individual behaviors instead of subpopulation or group identity. The transition from a purely discriminatory and unscientific public health measure to a non-discriminatory and evidence-based public health measure is and should be supported. Pre-screening donors for their individual behaviors and post-donation serological testing presents a more accurate means of ensuring blood security while providing opportunity to increase the blood supply.

Generalized deferrals may have been justified at time when human immunodeficiency virus (HIV) and similar viruses were difficult to definitively detect, treat, or prevent from spreading. That time has passed, and under public health law today a generalized MSM deferral is not necessary, proportional, or reasonable to protect the U.S. blood supply while avoiding harm to MSM. FDA should adopt individual risk assessment (IRA) as a sound blood security measure that would restore human dignity to MSM.

## **I. INTRODUCTION**

The massacre in an Orlando nightclub on June 12, 2016 exposed the gay community to vulnerability just as they may have started to feel less marginalized in the United States.<sup>1</sup> The anger and sadness that followed the tragedy felt by those within and without the lesbian, gay, bisexual and transgender (LGBT) community

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<sup>1</sup>Sheryl Gay Stolberg, *Orlando Attack Roils Gay Community, Painfully Accustomed to Violence*, N.Y. TIMES (June 12, 2016), <http://www.nytimes.com/2016/06/13/us/orlando-attack-roils-gay-community.html> [https://nyti.ms/2lntbktf].

sparked many questions about national safety and security yet yielded very few answers.<sup>2</sup>

In the carnage's aftermath, individuals across the United States felt the altruistic pull to go to their nearest blood donation center and provide a much-needed resource for those in need.<sup>3</sup> How ironic it was that while the camaraderie non-gay America felt for those men and women slain on June 12 empowered them to give of their hearts (and by their hearts), those gay Americans who may have felt a deeper bond to the victims could not express their support in the same way.<sup>4</sup>

Since the 1980s, MSM have been prohibited from donating blood.<sup>5</sup> Though not necessarily a precise term, "MSM" in this paper is used inclusively for men who identify as gay or bisexual, as well as men who identify as heterosexual or otherwise have or had sex with another man.<sup>6</sup> FDA treats this group as a single population (ignoring the nuances in doing so) and recommends a 12-month deferral for any man who had sex with another man within a year of their attempt to donate blood.<sup>7</sup> While a 12-month ban is an improvement over a lifetime prohibition, FDA still reinforces a discriminatory standard against all MSM, regardless of actual behaviors, and effectively creates a ban on most gay and bisexual men and other MSM from donating blood.<sup>8</sup> MSM who do not engage in risky behaviors are still deemed of equal threat for HIV as those MSM who do by virtue of their sexual partners alone.

Following the Orlando shooting and the revitalized scrutiny placed on both the 12-month deferral and, in the words of several U.S. Senators, "de facto lifetime ban" for active MSM, FDA is once again considering a change to the blood donation rules.<sup>9</sup>

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<sup>2</sup>Ariel Zambelich & Alyson Hurt, *3 Hours in Orlando: Piecing Together an Attack and Its Aftermath*, NAT'L PUB. RADIO (June 26, 2016), <http://www.npr.org/2016/06/16/482322488/orlando-shooting-what-happened-update> [<https://perma.cc/5XKS-ZSPJ>].

<sup>3</sup>Rick Neale, *Brevard Blood Skyrocket After Orlando Massacre*, FLA. TODAY (June 29, 2016), <http://www.floridatoday.com/story/news/2016/06/29/brevard-blood-donations-skyrocket-after-orlando-massacre/86480596/> [<https://perma.cc/5XKS-ZSPJ>].

<sup>4</sup>Gillian Mohny, *Call For Blood Donors After Orlando Massacre Excludes Many Gay, Bisexual Men*, ABC NEWS (June 12, 2016), <http://abcnews.go.com/Health/call-blood-donors-orlando-massacre-excludes-gay-bisexual/story?id=39796751> [<https://perma.cc/A2WA-8RJH>].

<sup>5</sup>Jessica Firger, *Will the FDA's Policy on Blood Donation From Gay Men Change After Orlando Massacre?*, NEWSWEEK (June 14, 2016), <http://www.newsweek.com/orlando-massacre-fda-blood-donation-ban-gay-men-470226> [<https://perma.cc/G27A-4ZXA>].

<sup>6</sup>Compare Rebecca Young & Ilan Meyer, *The Trouble With "MSM" and "WSW": Erasure of the Sexual-Minority Person in Public Health Discourse*, 95 AM. J. PUB. HEALTH 1114 (2005) (discussing the risk of under-inclusiveness with MSM and WSW labeling) with Shivananda Khan & Omar Khan, *The Trouble with MSM*, 96 AM. J. PUB. HEALTH 765, 766 (2006) (responding to Young & Meyer and advocating for the appropriate use of MSM, recognizing the "need [for] a shared vocabulary that is both specific to the needs of those with whom we work and accessible to the health and advocacy professionals.").

<sup>7</sup>Press Release, FDA, *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), <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm478031.htm>.

<sup>8</sup>Ben Spielberg, *The FDA's Unscientific and Anti-Gay Blood Donation Policy*, HUFFINGTON POST BLOG (June 17, 2016), [http://www.huffingtonpost.com/ben-spielberg/the-fdas-unscientific-and\\_b\\_10494620.html](http://www.huffingtonpost.com/ben-spielberg/the-fdas-unscientific-and_b_10494620.html) [<https://perma.cc/5WW5-ZHT4>].

<sup>9</sup>Alexandra Sifferlin, *The Ban on Gay Men Donating Blood Might Be Going Away*, TIME (July 26, 2016), <http://time.com/4424328/fda-gay-blood-donation-ban-update> [<https://perma.cc/TE5Y-6C3P>]. FDA has not attributed its proposed policy change to the Orlando massacre, however twenty-four U.S. Senators sent a letter to FDA on June 20, 2016 in response to the Orlando shooting and subsequent national

Shortly after the massacre, FDA requested public comments on changing the system from one that functionally bans most, if not all, MSM to one that gauges the feasibility of, *inter alia*, individual risk assessments for each potential donor.<sup>10</sup> Such a change would amount to a significant win for human dignity based in part on adherence to an ideal that every American be seen equally by society and that, insofar as blood donation goes, behavior-specific prohibitions could make for a safer system than group membership.<sup>11</sup>

Calls for just such a move go back long before Orlando and from a range of voices.<sup>12</sup> Major medical associations and organizations echoed these voices.<sup>13</sup> From the opposing side came similarly impassioned arguments for retaining a ban for fear of contaminating the blood supply with harmful pathogens, chiefly HIV.<sup>14</sup> In the 1980s, FDA weighed the valid concerns of both sides and, in the context of both the HIV crisis and inadequate means to mitigate HIV's risk, concluded that deferral was the best option available to keep the blood supply safe.<sup>15</sup>

Since then, however, knowledge about HIV has expanded, as have the means both to test for and prevent it.<sup>16</sup> In light of improved and proximate technological means to both prevent and screen for harmful contaminants the fear underscoring deferral is less founded than when the ban was introduced.<sup>17</sup> The public health justification for FDA's current policy on MSM donation is no longer necessary or appropriate.<sup>18</sup>

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attention paid to the 12-month blood deferral. The Senators stated that FDA should “move to a donor deferral policy based on individual risk factors” and that while the 12-month deferral was a “first-step” it nevertheless “perpetuate[s] inaccurate stereotypes” for MSM and “remains a de facto lifetime ban for many healthy gay and bisexual men.” See Letter from U.S. Senator Tammy Baldwin et. al, to Hon. Robert Califf, Commissioner, FDA (June 20, 2016), <https://www.baldwin.senate.gov/imo/media/doc/6.20.16%20Letter%20to%20FDA%20on%20MSM%20Blood%20Ban.pdf> [<https://perma.cc/7BDF-Q98N>].

<sup>10</sup>Blood Donor Deferral Policy for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products, 81 Fed. Reg. 49,673, 49,673–74 (July 28, 2016).

<sup>11</sup>Emily Greenhouse, *Breaking the Gay Blood Ban*, NEW YORKER (July 13, 2013), <http://www.newyorker.com/news/news-desk/breaking-the-gay-blood-ban> [<https://perma.cc/EW4S-BKCJ>].

<sup>12</sup>See, e.g., Charlene Galarneau, *Blood Donation, Deferral, and Discrimination: FDA Donor Deferral Policy for Men Who Have Sex With Men*, 10 AM. J. BIOETHICS 29 (2010).

<sup>13</sup>*Id.* at 31–32.

<sup>14</sup>See, e.g., William Leiss et. al, *Men Having Sex With Men Donor Deferral Risk Assessment: An Analysis Using Risk Management Principles*, 22 TRANSFUSION MED. R. 35 (2008). Various hemophilic associations, understandably, have weighed in on blood donor deferrals and largely oppose any changes that might increase the overall risk to the blood recipient. For these organizations, public health does not include considerations of social policy, fairness and equality. See World Fed'n Hemophilia, WFH Statement on MSM and Blood Donation (Mar. 13, 2015), <http://www.wfh.org/en/our-work/treatment-safety/wfh-statement-on-msm-and-blood-donation> [<https://perma.cc/VUZ7-YAG8>].

<sup>15</sup>Leiss, *supra* note 14, at 35.

<sup>16</sup>See generally C. Beyrer & S.D. Baral, *MSM, HIV and the Law: The Case for Gay, Bisexual and Other Men Who Have Sex With Men (MSM)*, Working Paper for the Third Meeting of the Technical Advisory Group of the Global Commission on HIV and the Law (2011); see also Culhane, *infra* note 18, at 130 (“While these exclusions stem primarily from fear of HIV infection, they are not justified by it.”); cf. *Jew Ho v. Williamson*, 103 F. 10 (C.C.N.D. Cal. 1900) (holding unlawful the discriminatory application of a public health intervention—quarantine against plague—against specifically San Francisco's Chinese residents absent evidence that plague was uniquely manifest among those residents alone or within their neighborhood alone).

<sup>17</sup>Maggie Koerth-Baker, *To Keep the Blood Supply Safe, Screening Blood is More Important than Banning Donors*, FIVETHIRTYEIGHT (June 16, 2016), <http://fivethirtyeight.com/features/to-keep-the->

FDA should adopt an individual risk assessment (IRA) model that utilizes both best practices for reducing risk while enabling low-risk individuals—whomever their sex partners—to donate blood.<sup>19</sup> IRA models assess individuals for their specific behaviors, such as drug use or transactional sex, and can permanently defer those persons who have a higher-risk profile while more reasonably deferring moderate risk persons and accepting those would-be donors who do pose low or no risk.<sup>20</sup> IRA enables more precise data capture than the current policy, which would provide better risk-management for the blood-recipient population; at the same time, by deferring individuals for specific behaviors instead of generalized traits FDA would increase the potential donor pool for blood and so address another public health need: adequate blood supplies.<sup>21</sup> Given that the major blood banks as well as hospitals and clinics profess to a near-chronic need for more blood both between and during emergencies and, according to the American Red Cross, only 10 percent of eligible Americans donate blood annually, increasing the eligible donor population and the actual donor population would be a net public health good.<sup>22</sup>

This paper addresses FDA's current policy and proposed recommendation on blood donation from a public health legal and policy perspective, and demonstrates that adopting an IRA model would appropriately ensure the safety of the national blood supply as well as the dignity of MSM individuals. The paper is organized into six sections, including this introduction. Section II discusses the background to FDA's recommendations beginning with the HIV crisis in the 1980s. Section III addresses the current deferral policy and the lack of evidence supporting it, the breadth of technological advancement and scientific understanding around HIV rendering a 12-month deferral obsolete, and the injury to human dignity the deferral imposes in part by being overly inclusive for MSM and under-inclusive non-MSM. Section IV looks at alternatives to the 12-month deferral beginning with IRA. Section V engages with selections from the public comments to FDA in response to the proposed recommendation and analyzes the substance of those submissions. Section VI concludes this analysis by recommending FDA develop and adopt IRA.

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blood-supply-safe-screening-blood-is-more-important-than-banning-donors [https://perma.cc/F4LF-3VM8].

<sup>18</sup>*Id.*; see also John Culhane, *Bad Science, Worse Policy: The Exclusion of Gay Males from Donor Pools*, 24 ST. LOUIS U. PUB. L. R. 129, 131–38 (2005).

<sup>19</sup>Barbara Suligoi et. al, *Changing Blood Donor Screening Criteria From Permanent Deferral for Men Who Have Sex With Men to Individual Sexual Risk Assessment: No Evidence of a Significant Impact on the Human Immunodeficiency Virus Epidemic in Italy*, 11 BLOOD TRANSFUSION 441 (2013).

<sup>20</sup>*Id.* Suligoi notes that the Italian pre-donation questionnaires did not discount deferral periods for using condoms, though condom usage may be a behavior that could reduce HIV risk prevalence while non-usage may increase risk.

<sup>21</sup>See *id.* at 446; see also Press Release, Am. Red Cross, *Significant Shortages Impact U.S. Blood Supply* (July 11, 2016), <http://www.redcross.org/news/article/Blood-Shortage-Donations-Matter-to-Patients-in-Need> [https://perma.cc/T6TP-FLBY].

<sup>22</sup>See Am. Red Cross, *Blood Facts and Statistics*, <http://www.redcrossblood.org/learn-about-blood/blood-facts-and-statistics#blood-supply> [https://perma.cc/ARM5-YACY] (last visited Aug. 19, 2017).

## II. BACKGROUND ON MSM DEFERRAL

FDA's mandate to keep the blood supply safe necessitates balancing individual rights and public health.<sup>23</sup> FDA indirectly regulates the blood donation system by establishing the normative recommendations to industry, and though they are not legally obligated to follow these recommendations blood banks and hospitals do so.<sup>24</sup> Blood banks, which are licensed through states, could certainly ignore FDA recommendations, but doing so might entail certain risks. Furthermore, FDA requires blood banks to register under federal law and may make inspections assessing compliance with recommendations. Thus, the industry simply disregarding FDA guidance is unlikely.<sup>25</sup>

A group deferral may have been both rational and lawful when there were less capable means of determining individual risk and screening blood for HIV.<sup>26</sup> The initial lifetime deferral could be justified when imposed in the 1980s and 1990s when placed in a context of a timeframe when individual behaviors could not be weeded out easily, technology was inadequate for both diagnosis and treatment for HIV, and the science around HIV was nascent at best.<sup>27</sup> The best science, evidence, and technology of that time could not keep the blood supply safe from HIV while permitting people from certain HIV-prevalent subgroups to donate.

Maintaining a functional ban today—when the science, evidence, and technology of this time have advanced—impugns the human dignity of the MSM community as well as the ethics of public health.<sup>28</sup> Technology alone has significantly improved with modern serological testing and HIV prophylaxis treatments making HIV much

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<sup>23</sup>21 C.F.R. § 10.115 (2017).

<sup>24</sup>Technically non-binding recommendations may not be law on paper yet regarded as law in practice. See *LGBTQ Donors*, AM. RED CROSS, <http://www.redcrossblood.org/donating-blood/lgbtq-donors> [https://perma.cc/92EF-HS3U] (last visited June 17, 2016) (“The FDA revised guidance states, ‘Defer for 12 months from the most recent sexual contact, a man who has had sex with another man during the past 12 months.’ All U.S. blood collection organizations *must follow this federal requirement.*”) (emphasis added).

FDA's long-standing recommendations against MSM blood donations has resulted in total or near-total compliance even among state and local public health authorities. See Mary Bassett, New York City Dep't Health & Mental Hygiene, PUBLIC COMMENT TO FDA RE: DOCKET NO. FDA-2016-N-1502 (Nov. 23, 2016) (using language that conveys FDA policy is considered on par with statutory or other legal instruments).

<sup>25</sup>42 U.S.C. § 262 (2012); 21 C.F.R. § 607.7 (2017). States likewise tend to defer to FDA policies and recommendations as quasi-legal norm-setters. California's legislature had bills before both houses that called upon the President of the United States and Secretary of Health and Human Services and FDA to change their positions, indicating that at least the largest state in the nation does not see itself as able to alter the national norm on blood donations. See, e.g., S.J. Res. 26 (Cal. 2016); Assemb. J. Res. 50 (Cal. 2014).

<sup>26</sup>See generally Francine A. Hochberg, *HIV/AIDS and Blood Donation Policies: A Comparative Study of Public Health Policies and Individual Rights Norms*, 12 DUKE J. COMP. & INT'L L. 231, 232–33 (2002). Hochberg concludes that where a public health measure is “effective” it may be necessary and acceptable. The risk for HIV infection is so great, and the harm HIV poses to the system no less so, that the infringement on MSM is justified. *Id.* at 249–50.

<sup>27</sup>*Id.* at 249–50.

<sup>28</sup>See, e.g., Michael Christian Belli, *The Constitutionality of the “Men Who Have Sex with Men” Blood Donor Exclusion Policy*, 4 J. L. SOC'Y 315, 363–75 (2003); see also Culhane, *supra* note 18, at 147–48; Galarneau, *supra* note 12, at 31–34.

less a threat to the blood supply regardless of a donor's background.<sup>29</sup> FDA should always ground its policies and recommendations in the best science and evidence available and, when either of those changes and especially when both do, should reassess its positions in the interests of fairness, inclusivity, and more-effective public health interventions.<sup>30</sup>

### A. A Public Health Legal Framework

Decided over a hundred years ago, the landmark case *Jacobson v. Massachusetts* resonates strongly today among both proponents and critics of state police powers in public health.<sup>31</sup> *Jacobson* framed American public health law, and police powers executed in the name of public health, as a careful balancing act that permitted public health interventions under condition that a “deliberative governmental process” existed to ensure that such interventions were limited.<sup>32</sup> The issue in *Jacobson* related to mandatory vaccination requirements against smallpox and whether Massachusetts had the authority to compel residents to be vaccinated under penalty for non-compliance (\$5 in 1905).<sup>33</sup> Jacobson protested, citing his freedom from bodily harm and claiming that the state was invading his personal liberty in violation of the 14th Amendment, but the U.S. Supreme Court found the state justified in its measures.<sup>34</sup> The health of the people is supreme; however, the people are no less empowered in their civil liberties and infringements thereon must pass constitutional tests.<sup>35</sup> In the case of *Jacobson* Massachusetts did pass just such tests, particularly as the State was fining or imprisoning and not forcibly vaccinating non-compliant individuals.<sup>36</sup>

*Jacobson* outlines four constraints that remain the corners of the framing today: public health interventions must be (1) necessary to address the harm, (2) reasonable and effective in their approach to addressing the harm, (3) proportional in relation to the harm, and (4) avoid causing further injury or harm to those affected by the intervention.<sup>37</sup> Public health law, public health policy, and even non-binding recommendations to public health industry are squared by the balancing of these constraints.

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<sup>29</sup>Belli, *supra* note 28, at 338–39; *see also* I. Glen Cohen et al., *Reconsideration of the Lifetime Ban on Blood Donation by Men Who Have Sex With Men*, 312 J. AM. MED. ASS'N 337, 338 (2014).

<sup>30</sup>Cohen, *supra* note 29, at 338.

<sup>31</sup>*See, e.g.*, Lawrence Gostin, *Jacobson v. Massachusetts at 100 Years: Police Power and Civil Liberties in Tension*, 95 AM. J. PUB. HEALTH 576, 577–81 (2005); *see also* *Jacobson v. Massachusetts*, 197 U.S. 11 (1905).

<sup>32</sup>Gostin, *supra* note 31, at 579.

<sup>33</sup>*Jacobson*, 197 U.S. at 12–13.

<sup>34</sup>*Id.* at 14.

<sup>35</sup>*Id.* at 25.

<sup>36</sup>*Id.* at 39.

<sup>37</sup>*Id.* at 26–27. Gostin revisits *Jacobson* in other writings and extracts a fifth constraint: fairness. The *Jacobson* court did not posit a standard of fairness because the statute in question was equally applied to everyone in Massachusetts. Nevertheless, fairness may have been in the background as a value guiding the court's thinking; at the very least, fairness was a criterion that other courts looked for in evaluating public health measures. *See* LAWRENCE GOSTIN, PUBLIC HEALTH LAW: POWER, DUTY, RESTRAINT 124–27 (3rd ed. 2016); *see also infra* note 38 and accompanying text.

As important as *Jacobson* in framing public health law is the slightly older and no-less-informative case of *Jew Ho v. Williamson*, which girds public health law as a matter of fairness.<sup>38</sup> The discriminatory quarantine against Chinese residents in San Francisco to curtail a risk of bubonic plague resembles the deferral against MSM.<sup>39</sup> Both involved isolation of groups considered at-risk for a particularly dangerous pathogen that was not exclusive to the group affected, and both can be framed from a standpoint of *salus populi suprema lex esto* (“the health of the people is supreme law”). However, where the measure in *Jew Ho* was struck down for health authorities acting with “an evil eye and an unequal hand,” the MSM deferral remained for thirty years before receiving a cosmetic alteration in spite of accumulated scientific evidence and technological progress.<sup>40</sup> The public health measure has a legitimate goal, but an illegitimate means of attaining that goal.<sup>41</sup>

### *B. Understanding the Lifetime Deferral*

FDA is responsible for safeguarding the national blood supply, thereby shouldering the burden of minimizing HIV’s threat.<sup>42</sup> FDA did not have effective serological tests available at the onset of the HIV crisis to screen donated blood or much knowledge around HIV’s epidemiology or virology.<sup>43</sup> Knowing only that HIV was highly prevalent in MSM and needing to protect the blood supply (and blood recipients) from threats, FDA recommended deferral for males with a sexual history that included sex with other men, an intervention that in its context was proportional to the grave threat HIV posed.<sup>44</sup> The collateral damage this caused to the gay community in the form of stigmatization and further marginalization was the unavoidable harm that came as a result of minimizing the risk of infection from donated blood.<sup>45</sup> The response was, at that time, justified to ensure public health safety against HIV contamination and, given the prevailing scientific ignorance about HIV, both reasonable and proportional to that threat.<sup>46</sup>

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<sup>38</sup>*Jew Ho v. Williamson*, 103 F. 10, 26–27 (C.C.N.D. Cal. 1900). *Jew Ho* forms one of the bases for modern American quarantine law and the limits applied therein. Quarantine is much like a blood donation deferral in that a deferral is, functionally, quarantining the blood of those deferred. Core to the *Jew Ho* decision was whether the public health measure was fair which the court unequivocally found it was not; fairness, as discussed *supra* note 37, frames public health legal determinations and unfair public health measures are vulnerable to legal illegitimacy.

<sup>39</sup>*See id.* at 26–27.

<sup>40</sup>*See id.* at 23–24; *see also* Gostin, *supra* note 31, at 579. Hochberg, *supra* note 26, misapplies *Jacobson* in part by ignoring the limits on public health interventions imposed by *Jew Ho*. To this day, courts uphold public health quarantines only when they are reasonable and proportional to those posing the risk and those at risk, with temporal constraints factoring into reasonableness and proportionality. *See Hickox v. Christie*, 205 F. Supp. 3d 579, 592–593 (D.N.J. 2016).

<sup>41</sup>*See, e.g.*, Belli, *supra* note 28, at 375.

<sup>42</sup>42 U.S.C. § 262 (2012); 21 C.F.R. § 610.40 (2017); *see also* Culhane, *supra* note 18, at 132–33.

<sup>43</sup>Belli, *supra* note 28, at 332–38.

<sup>44</sup>Belli, *supra* note 28, at 338; Galarneau, *supra* note 12, at 30.

<sup>45</sup>*See, e.g.*, Culhane, *supra* note 18, at 131–32 (“It may be difficult to recall the fear and panic that HIV infection created in the early 1980s. In that crucible, ill-informed public health policies were inevitable . . . Because the AIDS crisis was seen, with justification, as disproportionately affecting the gay male community, the FDA sought to permanently exclude all sexually active gay men from the blood donor pool.”).

<sup>46</sup>Gostin, *supra* note 31, at 579–80; *see also* Hochberg, *supra* note 26, and accompanying text.

Public health law has long favored interventions for the greater good even at the cost of individual rights, though this cost is not always borne equitably or fairly.<sup>47</sup> If it was reasonable to require smallpox vaccinations in the early 1900s in order to strengthen population resistance to a smallpox outbreak, it would also be reasonable to exclude a categorically risky group for HIV and persons with acquired immunodeficiency syndrome (AIDS) from donating blood and putting blood-recipients in jeopardy.<sup>48</sup> Individual rights and liberties are not absolute and burdens places on people or communities may even be justified, but so too the police powers exercisable by the government are limited, and where burdens are disproportionately placed those measures must be and remain both lawful and justified.<sup>49</sup> There are doubtless many preventive measures an epidemiologist could suggest that do not pass legal muster, and whatever their merits these measures would not be permissible.<sup>50</sup> Public health legal analysis is a process more than a platform that demands vigilant evaluation and reevaluation of any policy or practice that imposes a burden on anyone or any community.

### C. *The Interim Measure That Was Not*

The first serological tests became available in 1985, but FDA did not consider them reliable enough to alter the deferral policy.<sup>51</sup> Subsequent improvements in serological testing likewise did not yield significant changes to the deferral policy, at least as it pertained to MSM.<sup>52</sup> Only when the more advanced nucleic acid amplification test (NAT) became available in 1999 did FDA substantively reconsider the MSM lifetime deferral. However, FDA, by way of the Blood Product Advisory Committee (BPAC), rejected any change to the policy in its 2000 meeting based on the premise that it was still too risky to allow even a five-year deferral.<sup>53</sup> Why this

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<sup>47</sup>See Cohen, *supra* note 29, at 337; Galarneau, *supra* note 12, at 35–36 (discussing the inequitably tolerated risk-prevalence for HIV among certain non-MSM populations while deferring all MSM).

<sup>48</sup>Gostin, *supra* note 31, at 579–80; Hochberg, *supra* note 26. See also CDC FACT SHEET, Ctrs. for Disease Control and Prevention, HIV Among Gay and Bisexual Men (Feb. 2017), <https://www.cdc.gov/nchhstp/newsroom/docs/factsheets/cdc-msm-508.pdf> [hereinafter CDC Fact Sheets] [[http://perma.cc.W54G-WZPX](http://perma.cc/W54G-WZPX)]. Of the total gay and bisexual male population living in the United States, about 14 percent are living with HIV.

<sup>49</sup>See *Jew Ho v. Williamson*, 103 F. 10, 24 (C.C.N.D. Cal. 1900) (discussing how a community quarantine was not justifiable even where public health authorities might lawfully implement community quarantine); Gostin, *supra* note 31, at 579–80. Hochberg undermines her argument in saying “A public health policy . . . may appear to be overbroad in a legal analysis, while epidemiologists view it as a reasonable preventive measure.” Hochberg, *supra* note 26, at 241. Epidemiologists are neither inherently policy-makers nor legal experts and may determine that a measure is reasonable from their perspective, but nevertheless that measure must be *legally permissible* to be upheld under U.S. law.

<sup>50</sup>See Gostin, *supra* note 31, at 579–80.

<sup>51</sup>Belli, *supra* note 28, at 333–36. The enzyme-linked immunosorbent assay or ELISA test, approved in 1985, was valuable but produced a relatively high false-positive rate for HIV and was seen as “dangerously inadequate” for detecting low-risk individuals. *Id.* When paired with the later-developed Western blot test however the blood screening measure was considered 100 percent effective, but remained limited in its ability to detect low antibody levels. *Id.* This meant that during the latency period between HIV onset and a detectable viral load the ELISA-Western blot test was less effective. *Id.*

<sup>52</sup>*Id.* at 335–38, 341–45.

<sup>53</sup>*Id.* at 336–37. NAT is able to detect HIV genetic components prior to antibody generation, which drastically shortens the time window between exposure and measurement to between two and three weeks. *Id.* Even conservative estimates presented to the BPAC committee in 2000 suggested that 60 days would be sufficient. See FOOD & DRUG ADMIN., BLOOD PRODUCTS ADVISORY COMM.: DEFERRAL, OF BLOOD



was the case, or by what measure risk should be determined, was not made clear in the meeting transcript, though multiple BPAC members voiced their reasons for voting the way they did.<sup>54</sup> NAT allows for HIV diagnoses in as soon as one week, though the range can be as long as four weeks, and is highly effective.<sup>55</sup> In addition, current-generation antibody tests are able to detect HIV's presence between two and six weeks from onset, significantly shorter than FDA's past and present policy would imply as necessary.<sup>56</sup>

Nevertheless, the rationale FDA relied upon in maintaining a deferral in 2000 echoed the sentiments of its 1983 position: that the risk was still too great that infected blood "might sneak through" as a result of the increased quantity of suppliers presumably resulting from a change in the ban.<sup>57</sup> Or, as multiple committee members stated, the costs of implementing the sort of screening that objectively would make the blood supply safer were too high relative to the costs of a ban.<sup>58</sup> Or, because MSM was a choice much like drug use and prostitution, individuals who choose those behaviors and lifestyles forfeit their blood donation prospects.<sup>59</sup> Indeed, in the words of one committee member, quoting supportively a commenter, "I would recommend that the committee continue current deferral policies even in the face of possible cries of discrimination."<sup>60</sup> This position makes for bad policy, as FDA's mandate to protect the blood supply requires it to exclude any potential donor, MSM and non-MSM, who presents a risk for HIV, and given the testing window now

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OR PLASMA DONORS, OF MALES WHO HAVE HAD SEX WITH MALES, 67th Meeting, at 176–78 (Sept. 14, 2000), <https://www.fda.gov/ohrms/dockets/ac/00/transcripts/3649t1b.pdf> [<https://perma.cc/LW3E-MCWS>] (noting as well that the then-risk for HIV entering the blood system was 1 in 750000 and was likely an overestimate); *see also* Galarnau, *supra* note 12, at 30 (discussing the 2000 Blood Policy Advisory Committee meeting wherein a seven-six vote against changing the lifetime deferral for MSM was made); FOOD & DRUG ADMIN., BLOOD PRODUCTS ADVISORY COMM.: DEFERRAL, OF BLOOD OR PLASMA DONORS, OF MALES WHO HAVE HAD SEX WITH MALES, 67th Meeting, at 311–12, <https://www.fda.gov/ohrms/dockets/ac/00/transcripts/3649t1d.pdf> [<https://perma.cc/QHE4-8XG4>].

<sup>54</sup>FOOD & DRUG ADMIN., BLOOD PRODUCTS ADVISORY COMM.: DEFERRAL, OF BLOOD OR PLASMA DONORS, OF MALES WHO HAVE HAD SEX WITH MALES, 67th Meeting, at 312–14 (Sept. 14, 2000), <https://www.fda.gov/ohrms/dockets/ac/00/transcripts/3649t1d.pdf> [<https://perma.cc/QHE4-8XG4>].

<sup>55</sup>Ctrs. for Disease Control and Prevention, CDC: Testing, <http://www.cdc.gov/actagainstaids/campaigns/doingit/gettested> (last visited Nov. 30, 2016) [<https://perma.cc/SQ8N-TBWB>].

<sup>56</sup>*Id.*

<sup>57</sup>Belli, *supra* note 28, at 343.

<sup>58</sup>FOOD & DRUG ADMIN., BLOOD PRODUCTS ADVISORY COMM.: DEFERRAL, OF BLOOD OR PLASMA DONORS, OF MALES WHO HAVE HAD SEX WITH MALES, 67th Meeting, at 292 (Sept. 14 2000), <https://www.fda.gov/ohrms/dockets/ac/00/transcripts/3649t1c.pdf> [<https://perma.cc/HF57-FX8B>]. There is no specific mandate on FDA to consider costs in ensuring blood supply safety at the expense of scientific evidence undermining a policy's justification, and while cost is an important factor for industry FDA is held to different standards when executing its obligations. A law or principle rooted in justice being too expensive to adhere to is unlikely an adequate defense if failing to meet those obligations.

<sup>59</sup>FOOD & DRUG ADMIN., *supra* note 54, at 300 (mentioning also costs for a more inclusive system as justification against changing the policy: "Continuing to defer MSM donors permanently enhances the safety of the blood supply much more cost effectively than NAT"). Cost effectiveness certainly does contribute to analysis of a measure under the public health legal framework, however it is far from dispositive: a measure being cost effective does not make it necessary, reasonable, or fair.

<sup>60</sup>*Id.*

available the risk pool is narrowed essentially to only those who may have acquired the virus shortly before donation.<sup>61</sup>

For retaining the lifetime ban by a one-vote margin, FDA found itself subject to scathing criticism from civil society, academia, and former proponents of the deferral.<sup>62</sup> Even FDA's own Office of Biologics, the office that first suggested the deferral, had attached guiding language to the 1983 memorandum that led to the ban: such a measure was "interim" and to be in effect "until the AIDS problem is resolved or definitive tests become available."<sup>63</sup> This threshold is referred to sometimes by the acronym ALARA or "as low as reasonably achievable" and, in this context, means when definitive HIV tests are available to reasonably achieve the lowest risk possible.<sup>64</sup>

While initial serological tests were dismissed as falling short of "definitive" in part due to a long latency period, the NAT was a significant improvement that brought the risk of donation with a false-negative HIV test slipping into the blood supply down to an almost negligible level.<sup>65</sup> Moreover, the inconsistency in the application of FDA's rationale to other groups engaged in risky behaviors brought to light a subversive and unjustifiably discriminatory underpinning to the deferral.<sup>66</sup> FDA should base its decisions in science and evidence when FDA stated in response to data presented in 2000 that the numbers to calculate a change in risk were "iffy."<sup>67</sup> Still, the decision to maintain the deferral would not be changed for fifteen years even though the ALARA threshold was met, ostensibly because it was cheaper and easier to maintain a needlessly discriminatory ban than it was to utilize then-current evidence.<sup>68</sup>

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<sup>61</sup>Chana A. Sacks et. al, *Rethinking the Ban – The U.S. Blood Supply and Men Who Have Sex With Men*, NEW ENG. J. MED. 174, 176 (2016).

<sup>62</sup>Culhane, *supra* note 18, at 135–36.

<sup>63</sup>LAUREN B. LEVETON ET AL., HIV AND THE BLOOD SUPPLY: AN ANALYSIS OF CRISIS DECISIONMAKING 290–91 (1995) (Memorandum from Dr. John Preicciani, Dir., Office of Biologics, FDA, to All Establishments Collecting Human Blood For Transfusion on Mar. 24, 1983), <https://www.nap.edu/read/4989/chapter/15#291> [<https://perma.cc/UX7E-X2QM>]; *see also* Galarneau, *supra* note 12, at 30.

<sup>64</sup>Leiss, *supra* note 14, at 35.

<sup>65</sup>Belli, *supra* note 28, at 335–36. Earlier tests—ELISA and the Western blot test—were considered 100 percent effective but the latency period created a risk for false negatives that FDA could not tolerate. The Antigen Assay Kit was approved in 1996 that reduced up to 25 percent of the potential cases where HIV-infected blood entered the system. The NAT test became available in 1999 and offers the greatest potential to detect HIV in a significantly shorter time frame than earlier tests. *Id.* at 335–37.

<sup>66</sup>*Id.* at 366; *see also* Galarneau, *supra* note 12, at 36–37; Culhane, *supra* note 18, at 135–36.

<sup>67</sup>Galarneau, *supra* note 12, at 32 (quoting statements from the 2000 BPAC meeting where FDA officials said "[w]e don't have any better estimates [to calculate the actual change in risk where MSM are permitted to donate blood]," stating further that "[t]hese are very 'iffy' [sic] numbers . . ."). FDA would later in 2007 condemn itself for suffering from "serious scientific deficiencies" regarding the deferral. *Id.*; *see also* Blood Products Advisory Committee, 2000, Transcript 206 (Sept. 14, 2000), <https://www.fda.gov/ohrms/dockets/ac/00/transcripts/3649t1c.pdf> [<https://perma.cc/2E8F-BG7M>].

<sup>68</sup>Galarneau, *supra* note 12, at 32–33 ("BPAC focused its attention on scientific data related to a possible future policy, not on its ethical or economic implications, nor on scientific data justifying the current policy.").

#### *D. HIV is Not Limited to MSM*

HIV spreads most potently through blood and bodily fluids, underscoring the draconian measures FDA took to safeguard the blood supply during the early years of the HIV epidemic and defer multiple groups from donating blood, most notably MSM.<sup>69</sup> In the 1980s these steps were understandable, even among the gay community bearing the brunt of both the AIDS crisis as well as the false stereotype of being the principal HIV vectors.<sup>70</sup> Since the 1980s however, and with the progress made in serological testing for HIV and other infectious pathogens, FDA regularly evaluated and revised its deferral list except with regards to MSM.<sup>71</sup>

There are approximately 4.5 million MSM in the United States, among whom roughly 14 percent have HIV using current estimates.<sup>72</sup> To be sure, the HIV-positive MSM community is a sizeable population warranting a proper public health response, yet deferring the other 86 percent of the MSM community is not necessary to achieve safety for the blood supply today while accepting a lower, but non-zero, risk for other groups. The female partner of a man who has or had sex with another man is not immune to HIV or inherently has any reduced risk to exposure, but the female partner is unlikely to be deferred based solely on her sex partner.<sup>73</sup> Among female subpopulations, HIV prevalence is highest among black women and most new HIV diagnoses among women are in the black community, though FDA recommends no generalized prohibition on this group.<sup>74</sup> A heterosexual man may have a high-risk profile through certain behaviors that do not get captured, such as one-time unprotected sex with an unknown female in the past 12 months, but so long as he did not also have sex with a man he may donate blood.<sup>75</sup> Geographic origin bans, originally imposed on Haitians and other persons from places with high HIV

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<sup>69</sup>See Hochberg, *supra* note 26, at 238 (“Because of the risks associated with blood donors donating infected blood during the window period . . . [e]xclusion [sic] of blood donors with an increased risk of HIV infection is considered an effective strategy to reduce the residual risk of HIV contamination . . .”).

<sup>70</sup>Belli, *supra* note 28, at 365 (“When the original MSM Policy was implemented, the [MSM] Community agreed to it because there was little known about HIV, it was ravaging the Community and the FDA promulgated the Policy as an interim measure that would be modified as scientific understanding of HIV developed and testing methods became available.”).

<sup>71</sup>*Id.* While policies towards heterosexual groups have been modified, the policies towards MSM were left unchanged without explanation as to how or why technological and scientific advancements did not extend to their blood as it did for other groups’ blood.

<sup>72</sup>Jeremy A Grey et. al, *Estimating the Population Sizes of Men Who Have Sex with Men in US States and Counties Using Data from the American Community Survey*, 2 JMIR PUB. HEALTH SURVEILLANCE (2016), at 3; CDC FACT SHEET, *supra* note 48.

<sup>73</sup>Grey et. al, *id.*

<sup>74</sup>See CTS. FOR DISEASE CONTROL & PREVENTION, CDC FACT SHEET, *Today’s HIV/AIDS Epidemic* (Aug. 2016), <https://www.cdc.gov/nchstp/newsroom/docs/factsheets/todaysepidemic-508.pdf> [<https://perma.cc/P3E5-FVGU>] [hereinafter CDC FACT SHEET II] (noting that black women bear the highest burden for HIV incidence among women, even while overall HIV incidence among women is declining). The same reasoning that supports an MSM deferral should support a deferral for black women unless proponents to a deferral concede to a threshold prevalence for acceptable risk, at which point the discussion is no longer based on science alone.

<sup>75</sup>*Id.* See also Emily Greenhouse, *Breaking the Gay Blood Ban*, NEW YORKER (July 13, 2013), <http://www.newyorker.com/news/news-desk/breaking-the-gay-blood-ban> (“What sense is there in allowing a heterosexual man who’s had sex with a prostitute and a woman with H.I.V. to give—just as long as he hasn’t done any of that within the past year—while excluding a gay man in a committed relationship of fifty years?”).

prevalence, were implemented, removed, modified, reintroduced, and removed again since 1983 despite being based on the same reasoning behind an MSM deferral.<sup>76</sup> FDA policy changed despite no clear demonstration that those groups were any less likely or able to harbor HIV than any other group or that HIV was different in one population over another.<sup>77</sup> While FDA may not, today, have *Jew Ho's* “evil eye” as applied towards the MSM community, such a policy belies “an unequal hand” much alike a quarantine against Chinese persons.<sup>78</sup> Painting with a “broader brush” the entire MSM community as a unique HIV threat places too onerous a burden on this one group that is further demonstrably unscientific.<sup>79</sup>

Framing the question then as FDA has is convenient and laced with subtle prejudice but is no more or less scientifically valid than alternative framings and risk assessments.<sup>80</sup> IRA, by assessing individuals, could cut across groups and capture the individual behaviors that give rise to HIV risk prevalence and enable more refined and effective public health measures.<sup>81</sup> Such an approach is more tailored to the risk HIV poses and achieves FDA's goals better than a group deferral while concurrently avoiding harm to specific groups and impairing dignity.

### *E. Summary*

The deferral policy “tolerates a wide range of risks” commonplace among segments of the heterosexual community while imposing “zero tolerance” towards all MSM regardless of their individual behaviors.<sup>82</sup> FDA had long described itself as merely following the science, but scientific and evidentiary grounding was giving

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<sup>76</sup>Belli, *supra* note 28, at 339–42; *see also* CDC FACT SHEET II, *supra* note 74. HIV prevalence is highest in the American South, and particularly in the cities of New Orleans, Baton Rouge, Jackson, Miami, and Orlando. Given this fact, FDA could devise a policy deferring donors from these cities—MSM and non-MSM—for substantively the same reason as deferring MSM generally. The residents of these cities are, by virtue of where they live and no other consideration as to their behaviors, at higher risk for HIV acquisition. If such a policy clearly violates legal and ethical tenets for one group then it does so for all groups.

<sup>77</sup>Belli, *supra* note 28, at 367–69; *see also* Culhane, *supra* note 18, at 135–36.

<sup>78</sup>Gostin, *supra* note 31, at 579; *Jew Ho v. Williamson*, 103 F. 10 (C.C.N.D. Cal. 1900).

<sup>79</sup>Galarnau, *supra* note 12, at 35–37; *see also* Blood Products Advisory Committee, 2000, Transcript 310 (Sept. 14, 2000), <https://www.fda.gov/ohrms/dockets/ac/00/transcripts/3649t1d.pdf> [<https://perma.cc/UA64-TN74>] (quoting one of the committee members: “[I]f we really want to get subsets, we could really get a clear subset. Young males who have sex with a male who is black who has had an STD . . . [B]ut I think you have to paint with a broader brush than that, unfortunately, because, while that might grab the majority, there is still a large number outside that who you might not pick up.”). BPAC made clear in its 7-6 vote against changing the MSM deferral in 2000 that it prioritized unscientific values and over-inclusiveness, and did so explicitly.

<sup>80</sup>Galarnau, *supra* note 12, at 35–37.

<sup>81</sup>Suligoi, *supra* note 19, at 441.

<sup>82</sup>*Id.*; *see also* Blood Products Advisory Committee, *supra* note 67, at 252 (Dr. Smith, on behalf of Human Rights Campaign, Lambda Legal Defense Education Fund, and the Gay and Lesbian Medical Association). In response, Dr. Epstein for FDA replied that “We simply think it is two different issues. If we can make progress with respect to MSM risk, we will. And if we can make progress with respect to non-MSM risk, we will.” Dr. Epstein explained further that comparable risks and comparable behaviors are not connotative; a high-risk profile for a promiscuous heterosexual man may be differently factored than that for a promiscuous MSM, given HIV prevalence. This is certainly true, however as it stood then and stands to this day FDA does not do much by way of tracking—and deferring—a promiscuous heterosexual man from donating blood yet bars any and all MSM regardless of their risk profile. The risk may not be comparable to behavior but that is scant justification for a blind policy.

away as early as 1992.<sup>83</sup> FDA used the high-risk association between HIV and some MSM to exclude all MSM while loosening restrictions on other groups regardless of their risk association.<sup>84</sup> Considering the limits public health law imposes, such a discriminatory and arbitrary action should not have been sustained for as long as it was.<sup>85</sup> If the concern is really about keeping HIV out of the blood supply, then any risk above 0 percent should be regarded and addressed in uniform manner. When the means to address and remedy that risk, regardless of its proportion exist, and they do, then there is no scientific justification to say that the HIV risk prevalence for MSM warrants a separate public health measure.<sup>86</sup>

### III. FDA'S 12-MONTH DEFERRAL FOR MSM

In 2015, FDA partially yielded to its critics and adopted the current 12-month deferral for MSM.<sup>87</sup> The American Association of Blood Banks (AABB), America's Blood Centers, and even the American Red Cross—the industry leaders, who had earlier supported the zero tolerance approach—welcomed the change.<sup>88</sup> Perhaps most importantly from a public health point of view, the 12-month deferral brought the MSM community in line with most other deferral categories.<sup>89</sup> This was a “victory” for some groups entrenched in the fight for LGBT civil rights and equal protections.<sup>90</sup>

#### A. 12-Month Deferral Remains a Lifetime Deferral for Most MSM

Despite this change, a 12-month deferral for active MSM who present low or no risk for HIV contaminated blood donation remain deferred whatever their actual

<sup>83</sup>Galarneau, *supra* note 12, at 35–36 (“[The] characterization of sexual contact between males as ‘potentially . . . a basis of a lifestyle choice,’ and thus grounds for donor deferral, contradicts the FDA’s insistence that its deferral policy ‘is not based on any judgment concerning the donor’s sexual orientation.’”).

<sup>84</sup>*Id.* at 36.

<sup>85</sup>See Gostin, *supra* note 31, at 579–80; see also Blood Products Advisory Committee, *supra* note 79, at 309 (wherein one of the committee members commented that changing the deferral policy from a lifetime ban to a 5-year ban would de-penalize those males who had only “a single incidence” or “left behind” a lifestyle, suggesting that MSM is not a trait so much as it is a choice).

<sup>86</sup>Galarneau, *supra* note 12, at 35–36.

<sup>87</sup>See Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products; Guidance for Industry, 80 Fed. Reg. 79,913, 79,914 (Dec. 23, 2015); see also R.T. Winston Berkman & Li Zhou, *Ban the Ban: A Scientific and Cultural Analysis of the FDA’s Ban on Blood Donations from Men Who Have Sex with Men*, 1 COLUM. MED. R. 2, 4–5 (2015).

<sup>88</sup>See Press Release, Am. Red Cross, *Red Cross, AABB and America’s Blood Center’s Respond to the U.S. Food and Drug Administration’s (FDA) Recommendation to Change Blood Donation Deferral Criteria for Men Who Have Sex with Other Men (MSM)* (Dec. 23, 2014), <http://www.redcross.org/news/press-release/Red-Cross-responds-to-the-US-Food-and-Drug-Administrations-FDA-recommendation-to-change-blood-donation-deferral-criteria-for-men-who-have-had-sex-with-other-men-MSM> [<https://perma.cc/TY48-65CY>]; Berkman & Zhou, *supra* note 87, at 4–5; Culhane, *supra* note 18, at 135.

<sup>89</sup>See Eleftherios C. Vamvakas, *Scientific Background on the Risk Engendered by Reducing the Lifetime Blood Donation Deferral Period for Men Who Have Sex with Men*, 23 TRANSFUSION MED. R. 85, 100 (2009); Berkman & Zhou, *supra* note 87, at 4–5.

<sup>90</sup>Berkman & Zhou, *supra* note 87, at 5.

behaviors, and risk profiles, may be.<sup>91</sup> The current deferral policy operates from a premise that being MSM is itself an unhealthy behavior, like using intravenous drugs or sex work, and so warrants higher scrutiny absent good cause.<sup>92</sup> A sexually active heterosexual man or woman can donate blood with relative ease, but a man who has sex with another man, even if condoms are always used and neither are HIV positive, is regarded as having at least as much risk as someone treated for sexually transmitted infections.<sup>93</sup> Even with an effective donor-culture of self-selection, wherein individuals who suspect they may be higher risk or even have an infection including HIV consciously opt not to donate, FDA promotes a ban that is out of sync with both the science and social trend.<sup>94</sup> Moreover, FDA supports a ban despite the evidence they themselves conceded to: that a high HIV rate amongst the general MSM population does not translate to a high HIV rate amongst MSM blood donors or that the rate amongst MSM blood donors is too high to be effectively screened for.<sup>95</sup>

Twelve-month deferral is not inherently any safer than an alternative IRA from the perspective of securing the blood supply.<sup>96</sup> As mentioned earlier, with modern NAT and other improved serological tests, the window for undetectable HIV in the blood is significantly shorter than a 12-month deferral impliedly necessitates.<sup>97</sup> Studies on blood supply impacts have yet to demonstrate that lifting a ban would result in an uncontrolled or disproportionate increase in HIV-infected blood entering the blood supply, suggesting that those predictions were overly pessimistic.<sup>98</sup> This observation begs the question: at what point is it enough to say that what really matters is not who is having sex with whom, but rather the level of risk incurred by the individual?<sup>99</sup> Even a 12-month deferral, while certainly permitting some, or

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<sup>91</sup>*Id.* Recalling the estimated population for MSM in the United States this means up to 3.8 million Americans. Even if only a fraction of that population is likely to donate blood the deferral would not apply to them but for their sexual partners, not their individual risk.

<sup>92</sup>Galarneau, *supra* note 12, at 29, 34 (“The distance from ‘different’ to ‘dangerous’ is short . . . . The stigmatization associated with the stereotype that all MSM have lifelong and high HIV risk is rarely acknowledged as being personally or socially burdensome.”).

<sup>93</sup>*See, e.g.,* Culhane, *supra* note 18, at 135–36 (“A highly sexually active female, for example, would present a greater risk to the blood supply than a gay man who might be in a monogamous relationship . . . .”).

<sup>94</sup>Berkman & Zhou, *supra* note 87, at 5 (paraphrasing FDA’s own conclusion in the 2015 guidance document that male donors who identify as MSM have a *much* lower prevalence for HIV infection than the general MSM population: 0.25 percent for those who donate versus the approximate 11–12 percent HIV prevalence for the whole population); *see also* Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products; Guidance for Industry, 80 Fed. Reg. 79,913, 79,914 (Dec. 23, 2015).

<sup>95</sup>Berkman & Zhou, *supra* note 87, at 5.

<sup>96</sup>*See* M. Germain & G. Delage, *Models Used to Predict the Impact of Having Less Stringent Deferral Policies for Men Who Have Sex with Men: Can We Validate These Predictions?*, 10 INT’L SOC’Y BLOOD TRANSFUSION 263, 266–67 (2015) (concluding that current evidence does not validate deferrals, particularly 12-month or longer deferrals). *See generally* Vamvakas, *supra* note 89, at 92–93, 98–100.

<sup>97</sup>Belli, *supra* note 28, at 337.

<sup>98</sup>Germain & Delage, *supra* note 96, at 264–66.

<sup>99</sup>*See generally* Emmy De Buck et al., *Is Having Sex with Other Men a Risk Factor for Transfusion-Transmissible Infections in Male Blood Donors in Western Countries? A Systematic Review*, 10 PLOS ONE 13 (2015); *see also* Galarneau, *supra* note 12, at 34–35.

former, MSM to donate, would needlessly exclude significant portions of the active MSM, gay, and bisexual community solely on the grounds of their group identity.<sup>100</sup>

A change from lifetime deferrals to 12-month deferrals is only commendable if the discrimination against gay and bisexual men, or other MSM who engage in sex more than once a year, is ignored.<sup>101</sup> A 12-month deferral is in place for other groups considered risky, albeit for their actual behaviors versus any common trait, but no policy should be pursued *ad infinitum* that tramples the dignity of a distinct population through gross presumptions.<sup>102</sup> Further, where a policy is not just discriminatory on its face but is discriminatory in its application, the justification for a policy must be carefully scrutinized.<sup>103</sup>

Times have changed much since 1983, particularly in regards to normalizing MSM persons and their relationships.<sup>104</sup> Within recent years opinions have shifted significantly away from lifetime deferrals and even 12-month deferrals amongst both MSM and non-MSM.<sup>105</sup> Donors favor universal application and vetting when confronted with the disparate application of deferrals that are aimed at the same concern.<sup>106</sup>

In addition, the breadth of technology available to push risk downward is expanding. Pre-exposure prophylaxis (PrEP) shows great promise in reducing the risk for HIV acquisition by at least as much as 92 percent and could be distributed both to persons at risk for HIV and those who will receive blood transfusions.<sup>107</sup> Similarly, in November 2016, the National Institutes of Health (NIH) identified an antibody, N6, which in testing eliminated 98 percent of the virus in 16 of 20 strains, and may lead to superior treatment or PrEP options.<sup>108</sup> The risk profile for MSM is on the cusp of dramatic transformation, and it is possible that perspectives on risk, including self-perceptions, will change. Maintaining a deferral that is already based

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<sup>100</sup>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, 58–59 (2014); Mathew Morrison, *Bad Blood: An Examination of the Constitutional Deficiencies of the FDA's "Gay Blood Ban,"* 99 MINN. L. REV. 2363, 2391–93 (2015).

<sup>101</sup>Berkman & Zhou, *supra* note 87, at 2–5; Galarneau, *supra* note 12, at 32–36.

<sup>102</sup>Gostin, *supra* note 31, at 579–80; Beyrer, *supra* note 16.

<sup>103</sup>Beyrer, *supra* note 16.

<sup>104</sup>Emily Greenhouse, *Breaking the Gay Blood Ban*, NEW YORKER (July 13, 2013), <http://www.newyorker.com/news/news-desk/breaking-the-gay-blood-ban> [<https://perma.cc/7ZWD-YS6R>].

<sup>105</sup>Shana Hughes et al., *Saving Lives, Maintaining Safety, and Science-Based Policy: Qualitative Interview Findings from the Blood Donation Rules Opinion Study (Blood DROPS)*, 55 TRANSFUSION 2835, 2838–39 (2015).

<sup>106</sup>*Id.* at 2340.

<sup>107</sup>*Pre-Exposure Prophylaxis (PrEP)*, CENTERS FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/hiv/risk/prep> (last visited Nov. 29, 2016) [<https://perma.cc/5N4Z-PSWM>]. Blood recipients receiving an HIV suppressant might be a useful defense measure regardless of from whom any blood is received. *See Id.*

<sup>108</sup>*NIH Scientists Identify Potent Antibody that Neutralizes Nearly All HIV Strains*, NATIONAL INSTITUTE OF ALLERGY & INFECTIOUS DISEASES, <https://www.niaid.nih.gov/news-events/nih-scientists-identify-potent-antibody-neutralizes-nearly-all-hiv-strains> (last visited Nov. 29, 2016) [<https://perma.cc/T5BR-PGRH>].

on weak evidence and on outdated risk profiling is poor policy that is likely to be only further undermined.<sup>109</sup>

### *B. Lack of Evidence Supporting a 12-month Deferral*

One of the primary arguments against moving to the 12-month deferral, and the same argument against moving to IRA, stems from risk-prediction.<sup>110</sup> In many countries, MSM are at the greatest risk of HIV.<sup>111</sup> Allowing donors from this group arguably shifts some risk burden to those who received donated blood.<sup>112</sup> As a result of loosening MSM restrictions one could reasonably anticipate an increase in HIV-infected donors or blood being identified in pre- or post-donation, respectively, due to, *inter alia*, the absolute increase in blood donors.<sup>113</sup> As such, proponents of MSM deferral argue that this risk shifting is avoidable and so unethical to pursue, since the blood donor recipient should not be subjected to any greater risk for HIV than necessary.<sup>114</sup>

What remains to be seen, however, is the evidence of actual or disproportionate risk transfer, without which the argument against MSM blood donations is weak.<sup>115</sup> As studies show, the current blood supply system already tolerates certain risks that might exceed those posed by MSM blood donations, risks that proponents of MSM deferral should not discount when reconciling MSM blood donations.<sup>116</sup> Various studies conducted in Australia modeled what that increase might look like, following Australia's transition from a lifetime ban to a 12-month deferral, with estimates ranging from an additional three to almost two hundred HIV-positive cases.<sup>117</sup> Yet actual outcomes undermined those predictions: prior to Australia's transition there were approximately three cases a year, and afterwards there remained approximately three cases a year even while the donor pool increased.<sup>118</sup> A recent

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<sup>109</sup>See, e.g., Hughes, *supra* note 105, at 2837–39. Analyzing noncompliance with deferrals is beyond the scope of this paper but is well researched. See, e.g., *Id.* at 2837. Noncompliance with the deferral (while a small percentage) exists in part due to proactive individual testing and informed perceptions on one's risk. See *Id.*

<sup>110</sup>See Leiss, *supra* note 14, at 50–54.

<sup>111</sup>See Beyrer, *supra* note 16.

<sup>112</sup>Leiss, *supra* note 14, at 39, 48–49 (“The hypothetical benefit to homosexual men above may also be called a reduced risk of stigma, and when formulated in this way, one can see that changing the MSM donor rule to achieve this purpose would be, in effect, a covert risk transfer, that is, a transfer of risk from male homosexuals to recipients of blood.”).

<sup>113</sup>See Germain & Delage, *supra* note 96. Whether or not this increase in HIV-positive blood slipped past post-donation serological testing is another question, though proponents tend to think in terms of “worst case scenarios.” See, e.g., Yang, *infra* note 133. Given the effectiveness of modern serological testing, development of PReP and future treatments, and the narrow window in which potential donors actually pose a threat such worst-case scenarios appear to be based on inapplicable parameters. See generally Sacks, *supra* note 61.

<sup>114</sup>See Leiss, *supra* note 14; see also *supra* text accompanying note 112.

<sup>115</sup>See Germain & Delage, *supra* note 96. The legitimate concerns of proponents for a 12-month deferral are not shown to be only achieved with a 12-month deferral.

<sup>116</sup>See Vamvakas, *supra* note 89; Hughes, *supra* note 105.

<sup>117</sup>See Germain & Delage, *supra* note 96, at 265–66; see also De Buck, *supra* note 99.

<sup>118</sup>Germain & Delage, *supra* note 96, at 266. Why the predictive studies were so significantly off, with the lowest predicting a 100 percent increase that did not materialize, is uncertain. Germain & Delage hypothesize that the parameters used in each prediction model differed substantially. *Id.* at 266–67. It is possible that the predicted rates would be met later, but this is an unsupported claim. *Id.* at 267.



review of studies comparing model predictions for HIV-positive donations versus actual HIV-positive donations in the United Kingdom and Canada—which, like Australia, also switched to a temporary deferral period for MSM—found that the baseline rate for HIV contamination did not change in the two years following the revised policy.<sup>119</sup>

How these models failed to live up to their predictions when paired with empirical data is potentially an open question.<sup>120</sup> What does matter from a policy perspective is that the science does not support deferrals based solely on group HIV prevalence, leastways a 12-month deferral for all MSM.<sup>121</sup> Absent hard data, support for deferrals of any length falls to regulators' judgments regarding (1) the precautionary principle and (2) cost-benefits of a group deferral versus IRA.<sup>122</sup>

### 1. *The Precautionary Principle: Absolutes, Proportionality, and Acceptable Risk*

The precautionary principle, as manifested in blood safety, suggests to regulators that any change to the blood system that may increase risk should be resisted or at least heavily vetted.<sup>123</sup> In acting as risk managers, FDA should not unjustly or unfairly shift risk from one group to another under this principle.<sup>124</sup>

For the principle to be applied effectively it must apply comprehensively to the HIV risk resulting from behaviors, not selectively to one population over others.<sup>125</sup> Doing otherwise creates two problems: a discriminatory and over-inclusive ban for one group, and an under-inclusive false presumption of security for others.<sup>126</sup> Since

<sup>119</sup>Marc Germain, *The Risk of Allowing Blood Donation from Men Having Sex With Men After a Temporary Deferral: Predictions Versus Reality*, 56 TRANSFUSION 1603, 1605–06 (2016).

<sup>120</sup>*Id.* at 1607.

<sup>121</sup>See, e.g., Galarneau, *supra* note 12, at 32–37; see also *supra* text accompanying note 109.

<sup>122</sup>See De Buck, *supra* note 99, at 13. See generally Kumanan Wilson, *Framework for Applying the Precautionary Principle to Transfusion Safety*, 25 TRANSFUSION MED. R. 177 (2011). But see Marc Germain et. al, *The Precautionary Principle in Blood Safety: Not Quite the Same as Aiming for Zero Risk*, 26 TRANSFUSION MED. R. 181 (2012).

<sup>123</sup>Compare Wilson, *id.*, with Germain, *id.*

<sup>124</sup>Galarneau, *supra* note 12, at 33 (quoting the Blood Product Advisory Committee, 2000. Transcript 306 (Sept. 14, 2000), <https://www.fda.gov/ohrms/dockets/ac/00/transcripts/3649t1d.pdf>: “[T]he lifetime exclusion] is non-specific. It is overinclusive. But it works. It works because it captures the high-risk subset.”). However, the FDA’s reasoning leads to an irony where the safest measure would be to ban blood from *all* high risk groups, or worse a paradox: ban nearly all blood donations, since the least-risky measure available to the FDA is to preclude donations from anyone who might be at risk for HIV, which since HIV can infect almost everyone means the vast majority of people irrespective of their individual risk. See Dwayne Bensing, *Science or Stigma: Potential Challenges to the FDA’s Ban on Gay Blood*, 15 U. PA. J. CONST. L. 485, 501 (2011) (“While the MSM ban serves as a broad exclusion with the purpose of protecting the blood supply, it does so by being both over-inclusive in excluding healthy gay donors, and under-inclusive in admitting risky non-gay donors.”).

<sup>125</sup>Bensing, *id.* Unless FDA can base a claim to say that being MSM, all else held equal, is an HIV risk, treating MSM as if their mere existence is an HIV risk is unjust and any such policy unjustifiable. *Id.* See also Vamvakas, *supra* note 89, at 87–88, 99 (noting, *inter alia*, the tolerated and seemingly under-recognized risk in the current system).

<sup>126</sup>See Belli, *supra* note 28, at 364–65 (“To exclude gay men from the pool of eligible blood donors is not only discriminatory, but also creates a false sense of security amongst heterosexuals.”); Bensing, *supra* note 124, at 501 (“While the MSM ban serves as a broad exclusion with the purpose of protecting the blood supply, it does so by being both over-inclusive in excluding healthy gay donors, and under-inclusive in admitting risky non-gay donors.”).

the system already tolerates a certain level of risk for HIV infection from non-MSM sources, the question becomes whether the increased risk for HIV infection resulting from more donors who pass IRA is acceptable and proportional to the utility of blood received.<sup>127</sup> Absolute risk-free blood donation requires unrealized technology or restrictions on who can donate blood beyond what exists today, but there is already a trade-off made between the benefits of a robust blood supply and HIV risk.<sup>128</sup> Presently, the MSM policy is not a scientifically accurate trade-off, and it dismisses the benefits of greater blood supplies and the safeguards against blood-borne pathogens already in place in favor of unsubstantiated risk projections.<sup>129</sup>

## 2. *Blood and Irony: Cost-Benefits for MSM Blood Donations*

Should FDA adopt a more inclusive blood donation policy using IRA more pints of blood would be added to the blood supply to help address the perpetual shortage for blood.<sup>130</sup> This paper does not argue that an increase in blood donations will not have some increase in risk for HIV in absolute terms.<sup>131</sup> But, FDA concluded in 2006 that the current risk of HIV-infected blood slipping into the system was one in two million, a number so low that it could not be measured directly, and which implicitly includes noncompliant MSM donors as well as non-MSM donors who might otherwise pose a deferrable risk.<sup>132</sup> Risk calculations are thereby made using “worst case” scenarios in part because that is potentially the only way to meaningfully measure risk in the face of self-selection, IRA, and improved serological testing.<sup>133</sup> Where there is analysis of the actual risk MSM blood donations pose to the blood supply the data is weak to justify a group deferral, recalling as well that IRA does not mean no deferral, but rather individualized deferral.<sup>134</sup>

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<sup>127</sup>Galarneau, *supra* note 12, at 34.

<sup>128</sup>*Id.*; see also Bensing, *supra* note 124, at 501.

<sup>129</sup>Galarneau, *supra* note 12, at 34–37.

<sup>130</sup>See Berkman & Zhou, *supra* note 87, at 3–6 (suggesting between 130,150 and 219,200 more pints of blood); McAdam & Parker, *supra* note 100, at 62–64 (estimating about 219,000 additional pints of blood may be available from lifting the MSM deferral). Since the individual risk assessment would apply to all donors as well these figures are possibly a low estimate of the amount of blood potentially available for donation. One projection however is that the blood supply could increase by about 2 percent over current levels (with the 12-month deferral in effect). Ayako Miyashita & Gary J. Gates, *Effects of Lifting Blood Donation Bans on Men Who Have Sex With Men*, Williams Inst. (2014), <http://williamsinstitute.law.ucla.edu/wp-content/uploads/Blood-Ban-update-Jan-2015.pdf> [<https://perma.cc/6CXJ-TL5Z>].

<sup>131</sup>See, e.g., Suligoj, *supra* note 19, at 443–44. Blood supply increased in Italy following the switch to IRA, as did the number of HIV-infected blood caught in screening; however, the increase was proportional and statistically insignificant. See *id.*

<sup>132</sup>Jay Epstein, BPAC, FDA, *FDA Workshop on Behavior-Based Donor Deferrals in the NAT Era* (2006), quoted in Naomi Goldberg & Gary Gates, *Lifting the Blood Donation Ban on Men Who Have Sex With Men*, 5 PITT. J. ENVTL. PUB. HEALTH L. 49, 52 (2011). An FDA official, Dr. Jay Epstein, stated in 2006, “[O]ur current risks [for HIV contamination in the blood supply] are now so low that they cannot be measured directly . . . .”

<sup>133</sup>See H. Yang et al., *Modeling Complete Removal of Risk Assessment Questions in the USA Predicts the Risk of HIV Exposure in Blood Recipients Would Increase Despite the Use of Nucleic Acid Testing*, 110 VOX SANGUINIS 324, 327 (2016) (using “worst case” scenarios to model HIV risk to the blood supply).

<sup>134</sup>See De Buck, *supra* note 99; Suligoj, *supra* note 19.

No evidence has arisen indicating a genetic or serological distinction derived from a donor's sexual partners. Similarly, there is no known evidence indicating that current technology would be less effective at screening blood donated from an MSM individual than blood donated from a non-MSM donor.<sup>135</sup> For FDA to then adhere to its principles while retaining a 12-month deferral on all MSM, it must show that the available means to safeguard the blood supply for non-deferred populations are ineffective for any MSM donations.<sup>136</sup>

#### IV. IRA AND ITS ALTERNATIVES

Making IRA work in the United States would unquestionably require significant resources and study. FDA began this process with the proposed change to the recommendation and sought the input of the public, industry, and other experts.<sup>137</sup> Going forward, FDA could take the lessons learned in other places, like Italy, and glean from them what might work in the U.S. while also organically exploring means to implement an IRA procedure in FDA asked commenters to the public notice six questions, most of which were ignored by most commenters (as discussed in Section V).<sup>138</sup> Those questions, summarized here, asked (1) how to effectively identify at-risk individuals pre-donation, (2) which specific questions might capture at-risk individuals, (3) how questions on the questionnaire or in an interview can be effective yet understandable, acceptable, and culturally appropriate, (4) when a deferral of any length might be appropriate, (5) what procedural changes may be

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<sup>135</sup>See Ginsberg et al., *Should Men Who Have Sex With Men Be Allowed To Donate Blood in Israel?*, 5 ISR. J. HEALTH POL'Y RES. 60 (2016). Ginsberg projects that a no-deferral option for Israeli MSM would result in an increase in HIV-contaminated blood entering the system in exchange for a small increase in new donors. *Id.* This sort of reasoning is specious insofar as it excludes any options shorter than a 12-month deferral and, even in the worst-case scenario, provides no indication why or how public health measures could not effectively prevent contaminated blood from being detected. *See id.* Ginsberg also combines other groups into his analysis—intravenous drug users and immigrants from countries with high HIV prevalence—which renders the analysis imprecise. *Id.* Nevertheless, Ginsberg succinctly summarizes the counter-arguments to MSM blood donation well and, notably, without any scientific evidence to support a 12-month deferral as necessary, reasonable, proportional, least-harm-causing, or fair as opposed to a 3-month deferral or IRA-based deferral. *See id.*

<sup>136</sup>*Id.* at 5. Ginsberg provides six arguments against lifting deferral entirely on MSM and other groups: (a) the increased blood donations would be “negligible”, (b) a surge system for emergency blood donation already exists, (c) blood recipients have a right to a safe and adequate blood supply and any HIV transmission would be disastrous from the recipient's perspective, (d) risk-shifting is unethical if solely to address discontent, (e) members of the non-risk groups “will feel good” altruistically about having a safe blood supply, and (f) relaxing constraints “totally” on MSM and other groups will increase HIV-positive cases, so society would benefit more from reducing HIV-positive donations than “increasing the numbers of HIV-positive MSM who may give blood.” Ginsberg's points reflect non-scientific values and poor evidence sources to sustain them as public health policy, particularly as the goal for IRA is not to increase the number of HIV-positive donors but rather the number of “discontent” HIV-negative donors. Ginsberg's arguments would be stronger if he had data indicating that NAT or similar measures would be overwhelmed by the “negligible” increase in blood donors and rendered ineffectual, or if the presumption that all MSM donors would be HIV-positive were borne out in any research or studies.

<sup>137</sup>Blood Donor Deferral Policy for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products, 81 Fed. Reg. 49,673, 49,673–74 (July 28, 2016).

<sup>138</sup>*Id.*

necessary at blood collection establishments, and (6) how to best design a potential study to evaluate IRA and alternatives to the current deferral.<sup>139</sup>

Following FDA's line of inquiry, implementing IRA or any alternative to the 12-month deferral would require developing a better questionnaire and interview process for potential donors at the very least.<sup>140</sup> Similarly, blood banks and hospitals could augment screening techniques to determine donor risk profiles such as improved training for health care workers when interviewing donors pre- and/or post-donation.<sup>141</sup>

### A. IRA as the Alternative: Italy's Example

A growing number of countries have adopted an IRA model in soliciting blood donations, and data generated from studying these models is useful in analyzing and supporting FDA's proposed policy change.<sup>142</sup> Perhaps the best example for FDA to consider is Italy, which switched to IRA in 2001 and has longitudinal studies on the impact of the switch on the Italian blood supply.<sup>143</sup> Additionally, FDA may consider other nations for comparative review of IRA implementation and efficacy, like Mexico that adopted IRA in 2012.<sup>144</sup> Case studies of these policies would inform FDA on modeling IRA and lend support for such a shift to behavior-based deferral (using appropriate mechanisms and language for the American context).<sup>145</sup>

Italy moved to IRA in 2001 and is one of the best examples to study because of the length of time since the country adopted the blood donation policy.<sup>146</sup> HIV incidence peaked in Italy in 1987 and has stabilized around six cases per one

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<sup>139</sup>*Id.* at 7. Though beyond the scope of a public health legal analysis to answer in depth, these questions appear to frame well what FDA needs to know in order to design a future pilot for IRA study. The first three questions pertain solely to the questionnaire process while second three questions are broader. *Id.*

<sup>140</sup>Italy modified its donor questionnaires several times (in 1991, 2001, and 2005) to be more accurate and provide more meaningful information about the donor. See D.M. 15 gennaio 1991, in G.U. Serie Generale Jan. 24, 1991, n. 20; D.M. 26 gennaio 2001, in G.U. Serie Generale Apr. 3, 2001, n. 78; D.M. 3 marzo 2005, in G.U. Serie Generale Apr. 13, 2005, n. 85. The latter changes were made as IRA was taking hold in Italy with the purpose of making IRA effective in the Italian context. See *id.* See generally Suligoi, *supra* note 19 (referencing in English these reforms to Italy's questionnaires).

<sup>141</sup>See Suligoi, *supra* note 19, at 441, 446–47 (noting that doctors are held accountable under law for the interviewing and blood donation process); see also NORMA Oficial Mexicana NOM-252-SSA1-2012 Diario Oficial de la Federación [DOF] 25-12-2012 (Mex.) (stating that physicians are accountable in the blood donation process for ensuring that risky donors are appropriately deferred and further that blood received is adequately screened).

<sup>142</sup>See Suligoi, *supra* note 19, at 442; Dominique Mosbergen, *Argentina Lifts Ban on Gay Men Donating Blood*, HUFFINGTON POST (Sept. 21, 2015), [http://www.huffingtonpost.com/entry/argentina-gay-blood-ban\\_us\\_55ff91d9e4b00310edf79884](http://www.huffingtonpost.com/entry/argentina-gay-blood-ban_us_55ff91d9e4b00310edf79884) [https://perma.cc/7Q2C-YSJE].

<sup>143</sup>See Suligoi, *supra* note 19, at 442.

<sup>144</sup>NORMA Oficial Mexicana NOM-252-SSA1-2012 (Dec. 25, 2012), Para la disposición de sangre humana y sus componentes con fines terapéuticos [The Use of Blood and Blood Components for Therapeutic Purposes], Diario Oficial de la Federación [DOF] 25-12-2012 (Mex.), <http://www.dof.gob.mx/normasOficiales/4917/salud3a/salud3a.html> [https://perma.cc/22QB-KGQC].

<sup>145</sup>Mindy Goldman et al., *Donor Understanding and Attitudes About Current and Potential Deferral Criteria for High-Risk Sexual Behavior*, 51 TRANSFUSION 1829, 1832 (2011), <http://onlinelibrary.wiley.com/doi/10.1111/j.1537-2995.2011.03078.x/abstract> (showing strong support for expanded MSM blood donations).

<sup>146</sup>Melissa Kong, *United States' Blood Donor Policy on Gay Men: Adopting an Italian Individual Risk Assessment Policy*, 23 ANNALS HEALTH L. ADVANCE DIRECTIVE 101, 103, 106–08 (2014).

hundred thousand persons annually since 1998.<sup>147</sup> Like MSM in the United States, Italian MSM were deferred for life beginning as early as 1991.<sup>148</sup> In 2001, the Italian Ministry of Health switched to IRA and has adhered to this policy since then.<sup>149</sup> Health behaviors were assessed, with those behaviors deemed “at risk” or “high risk” deferred temporally or permanently, and applied to all persons.<sup>150</sup>

IRA in Italy begins with a self-completed questionnaire and subsequent interview with a physician appropriately trained in blood donation assessment.<sup>151</sup> Risky behaviors warranting a four-month deferral include having sex with a new partner whose sexual behavior or history is unknown to the potential donor (e.g. casual sex) and having had sex with a person who was or is HIV positive (or similarly positive for a blood-borne pathogen, such as hepatitis B or C).<sup>152</sup> High-risk behaviors warranting permanent deferral include: repeated sexual contact with a partner (or persons) whose sexual behaviors or history is unknown, sex with a sex worker, use of injected drugs, or repeated sex with a person infected with syphilis or HIV or a similar blood-borne pathogen.<sup>153</sup> The physician interviewing the potential donor is responsible for determining the risk level.<sup>154</sup> In addition, Italy employed NAT as well as screening assays such as Western Blot since 2001, with NAT becoming mandatory in 2008.<sup>155</sup>

Comparing the data from the time before IRA and after, two key statistics emerge: (1) HIV incidence had increased and prevalence decreased but neither change was statistically significant or clearly identifiable as resulting from MSM donations alone, and (2) over twice as many Italians were donating blood in 2010 than in 1999, with two male donors for every female donor.<sup>156</sup> HIV incidence was increasing in a majority of Western European countries during the study period, in between both MSM and heterosexual populations, rendering causality in Italy’s case difficult to ascertain.<sup>157</sup> Moreover, new cases for HIV in Italy were higher among heterosexuals

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<sup>147</sup>Suligoi, *supra* note 19, at 441.

<sup>148</sup>*Id.* at 442–443.

<sup>149</sup>*Id.*

<sup>150</sup>*Id.*

<sup>151</sup>*Id.*

<sup>152</sup>*Id.*

<sup>153</sup>*Id.*

<sup>154</sup>*Id.* Physicians are legally liable for their determination under Italian law, placing onus on them to accurately assess donors and prevent tainted blood from entering the supply. *Id.* at 446–47. FDA need not switch to IRA without similarly suggesting blood donation practices switch to procedures that generally strengthen blood supply security including health worker training and accountability mechanisms. *Id.* at 446.

<sup>155</sup>*Id.* at 443. The Western Blot test is a used to confirm HIV status by detecting anti-HIV antibodies in a blood samples using proteins indicative of HIV infection, to which any antibodies would detectably react if present in the sample.

<sup>156</sup>*Id.* at 444. In post-donation interviews, where some donors admitted to risks or reassessed risks previously reported, both MSM and heterosexual donors were substantially as likely to have directly or indirectly misrepresented their individual risk. This result suggests that the risk of misrepresentation in IRA, or any blood donation model, is at least similar between MSM and non-MSM populations and undermines a policy excluding one but ignoring the other when both present the same behavior.

<sup>157</sup>*Id.* at 445; *see also* A. Pharris et al., *Trends in HIV Surveillance Data in the EU/EEA, 2005 to 2014: New HIV Diagnoses Still Increases in Men Who Have Sex With Men*, 20 EUROSURVEILLANCE 3 (2015), <http://www.eurosurveillance.org/images/dynamic/EE/V20N47/art21313.pdf>. Immigrants

than for MSM in 2010, and higher incidence and prevalence among male donors versus female donors—regardless of sex partners—comports to data on HIV prevalence and incidence in the general population.<sup>158</sup> Since IRA was implemented, risk for HIV-infected donations increased proportionally for both MSM as well as heterosexual donors relative to the increase in blood donated.<sup>159</sup>

The Italian results underscore the merits of IRA as a mechanism which, when put in place, is no less safe procedurally than a blanket deferral and instead provides the blood system with more useable blood.<sup>160</sup> Certain constraints bear consideration, such as donor awareness of HIV risk factors and, perhaps significantly, the conditions under which donation occur.<sup>161</sup>

### B. Alternatives to IRA and the Existing Deferral Policy

FDA's proposed policy change specifically inquires about IRA, but there are other alternatives to the "existing timed-based deferrals."<sup>162</sup> Several alternatives are briefly evaluated below for achieving the greatest public health benefit with the most efficient mechanisms to ensure safety.<sup>163</sup> A pilot study in a specific location such as New York City might help FDA test, assess, and revise its recommendations before fully switching to a better policy supported through both public health legal analysis as well as scientific principles.<sup>164</sup> However, the following are options that FDA could consider that are not IRA in function or form.

#### 1. Less-Than-12-month Deferrals

As discussed earlier, serological tests exist which reduce the time frame for HIV testing as well as the risk of false negative results.<sup>165</sup> NAT in particular reduced the risk of HIV transmission through blood transfusion to one in two million donations

significantly drive HIV increase in MSM and heterosexual persons in Europe, though not exclusively so. As with the CDC however there is inadequate data regarding which behaviors are giving rise to the risk or driving the HIV increases.

<sup>158</sup>Suligoi, *supra* note 19, at 445; *see also* Kong, *supra* note 147, at 107 (noting the WHO in 2011 determined that 55.4 percent of new HIV infections in Italy were resulting from heterosexual activity and 38.1 percent from MSM activity).

<sup>159</sup>Suligoi, *supra* note 19, at 445. Suligoi identifies repeat donors—versus MSM or another categorization—as presenting a greater risk for HIV-infected blood tainting the blood supply and suggests these donors receive more scrutiny in the pre-donation interview.

<sup>160</sup>*Id.* at 446. Suligoi notes that the last recorded case at the time of publication for transfusion-transmitted HIV in Italy was in 2005, indicating that the five years following were marked with increasing blood donations from MSM and non-MSM populations but with no HIV transmission.

<sup>161</sup>*Id.* Italy places a trained physician in charge of interviewing donors pre- and post-donation, in an environment that "guarantees privacy and confidentiality." These practices may not exist in all blood donation environments in the United States, but are neither impossible nor imprudent to emulate when doing so may avoid harm otherwise caused by discriminatorily banning MSM. *See generally* Gostin, *supra* note 31, at 579.

<sup>162</sup>Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products; Guidance for Industry, 80 Fed. Reg. 79,913, 79,914 (Dec. 23, 2015).

<sup>163</sup>*Id.*

<sup>164</sup>*See* Blood Banks Letter, *infra* note 192, at 3–4 (suggesting a cautious but careful study that could be used to pilot the effectiveness of new questionnaires and donation procedures).

<sup>165</sup>Belli, *supra* note 28, at 335–37; Bensing, *supra* note 124, at 492–94.

and can detect HIV in the blood within nine to eleven days.<sup>166</sup> FDA could consider a time-based deferral for MSM that is far less than 12 months and allow at least some active MSM to donate blood, presuming they abstain from sexual activity with men for the determined length of time. For instance, Japan reconsidered its blood donation policy towards MSM donors in 2008 in light of NAT and implemented a six-month deferral.<sup>167</sup> Australia's Red Cross similarly advocated for a six-month deferral in place of the current 12 months Australia's regulators require.<sup>168</sup> FDA could consider a shorter deferral for MSM as well, but any time-based deferral should be based on the evidence around HIV transmission and detection, so as to avoid needless harm to low- and no-risk potential donors and beneficiaries of blood donations.<sup>169</sup>

## 2. No Deferrals; Rely Solely on Self-Selection and Blood Testing

FDA could consider abandoning deferrals altogether and rely on self-selection by potential donors and blood testing to screen out infected donations. In principle, effective pre-donation screening and post-donation screening could be sufficiently preventative.<sup>170</sup> However, such an approach may be needlessly cavalier when deferrals for risky behaviors are constructed reasonably while avoiding harm that is otherwise inflicted by a generalized ban.<sup>171</sup>

Though “worst case scenarios” fuel speculation and stoke fears, they may also serve as useful (albeit not exclusive) reference points when constructing policy.<sup>172</sup> One study estimated that poorly conceived pre-donation procedures to screen donations and sole reliance on blood testing could increase the risk of tainted blood entering the blood supply by as much as fourfold over present tolerances.<sup>173</sup> Multiple safeguards may provide both more opportunities to prevent infected blood from entering the system and greater peace of mind to recipients of donated blood.<sup>174</sup>

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<sup>166</sup>Bensing, *supra* note 124, at 493.

<sup>167</sup>McAdam & Parker, *supra* note 100, at 45, 50; *see also* JPN RED CROSS SOC'Y, [http://www.jrc.or.jp/donation/about/refrain/detail\\_04/](http://www.jrc.or.jp/donation/about/refrain/detail_04/).

<sup>168</sup>*No Change in Sexual Activity Based Deferrals Says Regulator*, AUSTL. RED CROSS (Jan. 1, 2014), <http://www.donateblood.com.au/media/news/no-change-sexual-activity-based-deferrals-says-regulator>; *see also* Germain, *supra* note 122, at 1604.

<sup>169</sup>*See, e.g.*, Hughes, *supra* note 105, at 2837 (wherein an interviewee responded to a question regarding Canada's MSM deferral being shortened from five years: “My partner and I have discussed getting married . . . because I'm probably going to continue to have sex with my partner, basically, that five-year ban would become a life sentence.”).

<sup>170</sup>Hochberg, *supra* note 26, at 262, 272–73, 278; *see also* Hughes, *supra* note 105, 2839–40.

<sup>171</sup>Gostin, *supra* note 31, at 579.

<sup>172</sup>*See, e.g.*, Ginsberg, *supra* note 135 (discussed in detail *supra*, notes 135–36).

<sup>173</sup>Yang, *supra* note 133, at 324, 327. The study suggests that the risk could be compensated for by very high self-selection in the face of a failed IRA; however, the study authors recognize their model presumes a failed IRA and does not account for effectively designed procedures; *see also* Maggie Koerth-Baker, *To Keep the Blood Supply Safe, Screening Blood is More Important than Banning Donors*, FIVETHIRTYEIGHT (June 16, 2016), <http://fivethirtyeight.com/features/to-keep-the-blood-supply-safe-screening-blood-is-more-important-than-banning-donors>.

<sup>174</sup>Galarneau, *supra* note 12, at 30 (“The FDA strategy for blood safety consists of ‘five overlapping layers of safeguards’: donor screening and deferral, a registry of deferred donors, blood testing, blood ‘quarantine’ . . . and oversight of the blood manufacturing process.”).

### 3. Permitting Non-Blood Donations by MSM and Phasing-In Blood Donations

FDA also could consider partially lifting the deferral on MSM and allowing them to donate blood plasma or blood platelets. This approach as was permitted in France as part of a strategy to bring MSM deferrals in line with deferrals applied to heterosexual blood donors.<sup>175</sup> MSM can donate blood plasma if they had not had more than one sex partner in the previous four months, and eventually the policy could extend to blood as well.<sup>176</sup> A graduated process may serve as a compromise between the current 12-month deferral and IRA; however, such a compromise would be borne of political and social considerations and not the evidence for IRA's efficacy.<sup>177</sup>

An extension to the French model, though one not seen in literature, is to pilot IRA in selected areas while retaining or shortening the MSM deferral elsewhere. FDA could then generate its own empirical studies that are similar to the study in Italy and under constraints and parameters reflecting at least one portion of the United States' demography.<sup>178</sup> Should those pilot studies reveal the merits of IRA locally, FDA may feel more confident to fully recommend IRA nationwide.<sup>179</sup>

## V. COMMENTS AND COMMENTARY TO FDA

A summary of public comments was reported at FDA's annual Blood Advisory Committee meeting on April 4–5, 2017.<sup>180</sup> The notice received 670 comments, with a clear majority of commenters disapproving of a transition away from the current policy.<sup>181</sup> However, as FDA noted, more than half of the comments made for keeping the deferral or, indeed, returning to indefinite deferral were likely from a single write-in campaign that did not address the specific questions or concerns FDA's proposal indicated.<sup>182</sup> At the same time, one of the comments in favor of changing the deferral policy included a petition with over 300 signatures, which if those signatures were instead provided as comments would balance out the aforementioned write-in campaign totals.<sup>183</sup> Without reference to any particular commenter as well,

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<sup>175</sup>Aurelien Breeden, *France to Lift Ban on Gay Men Donating Blood*, N.Y. TIMES (Nov. 4, 2015), [http://www.nytimes.com/2015/11/05/world/europe/france-gay-blood-donation.html?\\_r=0](http://www.nytimes.com/2015/11/05/world/europe/france-gay-blood-donation.html?_r=0).

<sup>176</sup>*Id.*

<sup>177</sup>See generally Suligoi, *supra* note 19; Galarneau, *supra* note 12, at 32–37.

<sup>178</sup>Suligoi, *supra* note 19, at 447.

<sup>179</sup>However, FDA need not recreate data that already exists and could solicit studies from those countries that have adopted IRA, such as Italy, Mexico, Spain, and others, for analysis and guidance in effectively implementing IRA in the United States as well.

<sup>180</sup>Summary of Responses to FDA Docket Opened July 26, 2016: Blood Donor Deferral Policy for Reducing the Risk of HIV Transmission by Blood and Blood Products (Apr. 4, 2017), <https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/BloodVaccinesandOtherBiologics/BloodProductsAdvisoryCommittee/UCM554820.pdf> [hereinafter Summary of Responses].

<sup>181</sup>*Id.* at 14. The comments themselves remain available in their entirety: <https://www.regulations.gov/docketBrowser?rpp=50&so=DESC&sb=postedDate&po=0&dct=PS&D=FDA-2016-N-1502>.

<sup>182</sup>*Id.*

<sup>183</sup>*Id.*



many of the comments against changing the deferral stem from perspectives that largely hold homosexuality itself as morally abhorrent; few if any of the comments provided any more than conclusory claims that MSM blood donation would lead to HIV transmission to blood recipients.<sup>184</sup> This is to say that those comments opposed to changing the policy on non-homophobic grounds relied on specious reasoning: HIV is high among gay men relative to non-gay men, HIV is in blood, and therefore gay men, and MSM generally, should not donate blood.<sup>185</sup> Even though there is some validity to concerns raised by some members of the public regarding HIV prevalence among MSM, FDA policy should be guided by sound science and strive to maximize equitable treatment and general applicability across population groups.

FDA's proposal called for public responses to a series of questions, of which a scant minority of respondents provided.<sup>186</sup> FDA noted that many responses called for an improved donor questionnaire, which based on the experiences reflected in other countries is likely a point of consensus across all views regarding blood donation.<sup>187</sup> Several respondents suggested stratified grades for risk based on answers to detailed questions asked of all potential donors, which is likely also an uncontroversial position and indeed one that is strongly endorsed this analysis as conducive for ensuring the public health.<sup>188</sup> On the question regarding deferral duration, respondents who supported deferral for high-risk members concluded that one to three months would be more appropriate given the advancements in NAT testing and the significantly shortened window wherein a positive case may not be identified.<sup>189</sup> Commenters encouraged private question/interview environments, electronic questionnaires, improved staff training, and a valid "I don't know" option so as to avoid guessing, and the risk of false information coloring a donor's answers.<sup>190</sup>

### A. Blood Banks

AABB, America's Blood Centers, and the American Red Cross issued a joint comment to FDA's proposal and concluded that, as the 12-month deferral went into effect in 2015, FDA should first assess the impact of the current policy before modifying it further.<sup>191</sup> While recognizing that stigmatization of the MSM community is occurring, although suggesting that the stigma is "perceived" and not experienced, and that it is important to maintain both a "safe [*sic*] and adequate" blood supply, the blood banks take a cautionary position against diving into a policy

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<sup>184</sup>All publicly available comments are listed here: <https://www.regulations.gov/docket/Browser?rpp=50&so=DESC&sb=postedDate&po=0&dc=PS&D=FDA-2016-N-1502>.

<sup>185</sup>*See generally id.* Contrary to certain assertions and inferences from commenters, HIV is not exclusive to blood of the MSM community.

<sup>186</sup>*See* Summary of Responses, *supra* note 181, at 15. Five percent of the total responses actually answered the questions FDA asked input on, possibly reflecting the emotional and knee-jerk reaction many people have to the issue of MSM blood donation but whether these same individuals have a solid grasp of all the science, evidence, pros and cons is not well reflected.

<sup>187</sup>*Id.* at 16.

<sup>188</sup>*Id.* at 19.

<sup>189</sup>*Id.* at 21.

<sup>190</sup>*Id.* at 22.

<sup>191</sup>AABB, Am. Blood Ctrs., & Am. Red Cross, Public Comment to FDA RE: Docket No. FDA-2016-N-1502 (Nov. 23, 2016), <https://www.regulations.gov/document?D=FDA-2016-N-1502-0131> [hereinafter Blood Banks Letter].

change in advance of further data on both the current deferral and how IRA might impact inventory and operations for blood centers.<sup>192</sup> The blood banks then provide a list of important questions that FDA should consider in evaluating the current 12-month deferral and for a future policy shift to IRA, such as whether infection marker rates have significantly increased in donors accepted under the current deferral policy.<sup>193</sup>

The blood banks however do not provide any evidence or support for their skepticism into the effectiveness of modern technology or the science around HIV. Instead, the comment echoes a precautionary sentiment that essentially reiterates the refrain often heard in this discussion without regard for actual science or technological accomplishment (which emerged in response to these same claims when they were made decades earlier), the current risk the system tolerates (or is ignorant of), and essentially without regard for unjustified discrimination that results from the current deferral.<sup>194</sup> This is somewhat ironic given that in 2006 the blood banks issued a statement to BPAC noting that duplicate NAT testing and other methods were in use nationwide, can detect HIV within 10 to 21 days, and “beyond this window period, there is no valid scientific reason to differentiate between individuals infected a few months or many years previously.”<sup>195</sup>

The blood banks—not strictly opposed to IRA but clearly cautious of any change that might incur costs to them—join the call for improving questionnaires and possibly the blood donation process to better capture data that might inform a policy change to IRA.<sup>196</sup> The blood banks helpfully provide suggestions for stages in developing the necessary data beginning with soliciting participation from the MSM community in developing appropriate questions.<sup>197</sup> The blood banks also suggest conducting a study or pilot for both any new questionnaires as well as other procedures in place of a systemic transition and utilizing available screening and data capture systems to enable critical analysis.<sup>198</sup>

### B. Public Health Agencies

Public health agencies, based in states and cities, work directly with the parties affected by the deferral as well as the beneficiaries of blood donations. New York City has more self-identified gay residents than any other city in the United States.<sup>199</sup> New York City bore witness to the HIV/AIDS epidemic at its worst in the 1980s and

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<sup>192</sup>*Id.*

<sup>193</sup>*Id.* Of course FDA, and the blood banks, could look to the data generated in countries that switched from a lifetime deferral to a 12-month deferral before the United States did and find that there was no significant (or even noticeable) change in risk. *See* Germain, *supra* note 119.

<sup>194</sup>*See* Bensing, *supra* note 124, at 501.

<sup>195</sup>America’s Blood Centers, Statement to BPAC RE: MSM Deferral (Mar. 9, 2006), [http://www.americasblood.org/media/27919/stmnt\\_060309\\_deferrals-msm.pdf](http://www.americasblood.org/media/27919/stmnt_060309_deferrals-msm.pdf) [<http://perma.cc/XFP9-2EB8>]. The blood banks supported a move to 12-month deferral, though by their own words there is no scientific justification for 12-months in particular.

<sup>196</sup>Blood Banks Letter, *supra* note 192.

<sup>197</sup>*Id.*

<sup>198</sup>*Id.*

<sup>199</sup>David Leonhardt, *New York Still Has More Gay Residents Than Anywhere Else in U.S.*, N.Y. TIMES (Mar. 23, 2015), [https://www.nytimes.com/2015/03/24/upshot/new-york-still-has-more-gay-residents-than-anywhere-else-in-us.html?mcubz=0&\\_r=0](https://www.nytimes.com/2015/03/24/upshot/new-york-still-has-more-gay-residents-than-anywhere-else-in-us.html?mcubz=0&_r=0). [<http://perma.cc/8Z7S-4RQF>].

continues to bear a great burden providing health and other services to people living with HIV.<sup>200</sup> The New York City Department of Health and Mental Hygiene carries a unique perspective shaped by its history and ongoing leadership role in the domestic HIV response.<sup>201</sup> The Department considers the 12-month deferral unjustified by the evidence and uninformed as to the particular behaviors conducive to or inhibiting HIV transmission.<sup>202</sup>

The Department characterizes the 12-month deferral as “unnecessarily” stigmatizing to gay and bisexual men and suggests that all sex between men is high-risk apropos nothing.<sup>203</sup> The Department suggests FDA adopt a policy that includes behavioral risk screens, rapid testing for potential donors with high-risk profiles, and continued use of FDA’s recommended NAT testing for donated blood.<sup>204</sup> This approach would rely on “evidence-based assessments” of each individual donor and permit greater data capture for those who are unknowingly HIV positive or at risk for HIV, particularly within the non-MSM community.<sup>205</sup> The Department makes its reasons clear and they go beyond equity for the MSM community: by identifying individuals regardless of sexual orientation who may be at risk for HIV, individual assessments can help connect at-risk or HIV positive persons to care and may not otherwise have access to or know they need.<sup>206</sup> As a matter of public health then—for the benefit of MSM and non-MSM—the Department comes out strongly in favor a policy transition to IRA.<sup>207</sup>

In addition to New York City’s Department of Health and Mental Hygiene, both the National Association of City and County Health Officials (NACCHO), whose membership includes public health officials across the United States, submitted comments in favor of a transition away from a 12-month deferral for MSM broadly and lifetime ban functionally for gay or active MSM donors.<sup>208</sup> Similarly, the National Alliance of State and Territorial AIDS Directors (NASTAD), which represents the senior HIV public health officials in each U.S. state and territory,

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<sup>200</sup>*AIDS in New York: A Biography*, N.Y. MAG. (June 5, 2006), <http://nymag.com/news/features/17158>. [<http://perma.cc/23N7-5KW4>].

<sup>201</sup>N.Y. City Dep’t Health & Mental Hygiene, Public Comment to FDA RE: Docket No. FDA-2016-N-1502 (Nov. 23, 2016), <https://www.regulations.gov/document?D=FDA-2016-N-1502-0351>. [<http://perma.cc/R7SX-X5YR>].

<sup>202</sup>*Id.*

<sup>203</sup>*Id.*

<sup>204</sup>*Id.*

<sup>205</sup>*Id.* at 2. The Department cites to a CDC report estimating that 1 in 8 persons in the United States living with HIV does so unknowingly, and that half of all persons who are at risk for HIV are heterosexually active. While MSM are not strictly homosexual or heterosexual as a group, the Department’s point is that restricting MSM alone from donating blood is an unsound policy given that non-MSM are also potential carriers. In the CDC report as well, MSM are significantly more likely to utilize pre-exposure prophylaxis than heterosexual individuals (~24.7 percent vs. ~0.4 percent). See Dawn Smith et al., *Vital Signs: Estimated Percentages and Numbers of Adults with Indications for Pre-exposure Prophylaxis to Prevent HIV Acquisition – United States*, 64 MORBIDITY & MORTALITY WKLY. 1291, 1291–92 (2015).

<sup>206</sup>*Id.*

<sup>207</sup>*Id.*

<sup>208</sup>See Nat’l Assoc. City & County Health Officials, Public Comment to FDA RE: Docket No. FDA 2016-N-1502 (Nov. 25, 2016), [http://www.naccho.org/uploads/downloadable-resources/NACCHO-Comment-Letter-FDA-Blood-Donor-Deferral-Policy\\_v2\\_clean.pdf](http://www.naccho.org/uploads/downloadable-resources/NACCHO-Comment-Letter-FDA-Blood-Donor-Deferral-Policy_v2_clean.pdf). [<http://perma.cc/3YDE-FU9R>].

stated that the current 12-month deferral does not reflect known evidence and science around HIV transmission or actual risk to the blood supply.<sup>209</sup> The 12-month ban in their view ignores technological improvements such as NAT and fails to consider or adopt best practices in screening (e.g. the questionnaires).<sup>210</sup> Particularly, NASTAD claims that NAT “renders the lifetime and yearlong ban . . . scientifically obsolete and unnecessary.”<sup>211</sup>

### C. Professional Associations

The American Medical Association (AMA), HIV Medicine Association (HIVMA), and American Plasma Users Coalition (APLUS) submitted comments to FDA in reflection of the interests of their constituencies. Associations like these can provide perspective and expertise on particular matters in health and medicine and carry significant weight in both establishing and reinforcing norms and standards across their professions and the industry at large.

The AMA, the largest organization representing physicians in the United States, states its position very clear from the outset of its letter to FDA: “Ensuring the safety of the nation’s blood supply and the welfare of patients who receive blood products is of the utmost importance. Advances in HIV screening technology, however, allow for a re-evaluation of current policy. The AMA . . . supports research into [IRA] criteria for blood donation.”<sup>212</sup> The AMA is critical of the current deferral as being unscientific in its ignoring HIV’s epidemiology and violating the ethical principle of formal equality, choosing instead to reiterate the fears and prejudices of the 1980s and 1990s.<sup>213</sup> AMA significantly discusses NAT testing and the comparative shortness of the window for HIV testing relative to windows for other STIs like hepatitis C.<sup>214</sup> AMA further points to the AABB’s own mandatory NAT screening for all blood donations, which AABB did not reference in its own cautionary joint letter to FDA.<sup>215</sup> Finally, in reference to some of the reasons FDA stated in not adopting IRA earlier, the AMA proposes that assessment and testing could benefit individuals at risk for HIV regardless of sexual orientation or sexual partners.<sup>216</sup>

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<sup>209</sup>See Nat’l All. State & Territorial AIDS Directors, Public Comment to FDA RE: Docket No. FDA 2016-N-1502 (Nov. 14, 2016), <https://www.regulations.gov/document?D=FDA-2016-N-1502-0117> [<http://perma.cc/B7BS-XXDF>].

<sup>210</sup>*Id.* One other comment letter came from a manufacturer of a pathogen-reduction system for platelets and plasma, stating that should their system be implemented universally IRA could be implemented and an MSM donation deferral for these products lifted immediately with minimal risk to recipients. The commenter suggests first studying the impact of both MSM donations for blood and blood products in contexts where their system is in use. See Cerus Corp., Public Comment to FDA RE: Docket No. FDA 2016-N-1502 (Nov. 14, 2016), <https://www.regulations.gov/document?D=FDA-2016-N-1502-0229>. [<http://perma.cc/6J4S-6AT5>].

<sup>211</sup>*Id.*

<sup>212</sup>Am. M. Assoc., Public Comment to FDA RE: Docket No. FDA 2016-N-1502 (Nov. 22, 2016), <https://www.regulations.gov/document?D=FDA-2016-N-1502-0125>. [<http://perma.cc/ZH9G-M92U>].

<sup>213</sup>*Id.*

<sup>214</sup>*Id.*

<sup>215</sup>*Id.*; see also Blood Banks Letter, *supra* note 192, which does not reference technological advancements like NAT or how such advancements are measurably inadequate to safeguard the blood supply.

<sup>216</sup>Am M. Assoc. *supra* note 213. The AMA mentioned three FDA justifications for not recommending IRA in 2015: (1) a logistical challenge in ensuring blood banks had trained medical

HIVMA, which represents HIV-specialty providers, focuses almost entirely on improving the questionnaires in its comment to FDA, and particularly emphasizes the need for advances in blood testing technology to be reflected in any FDA recommendations or policy.<sup>217</sup> Without criticizing the current policy outright, HIVMA encourages FDA to “give greater consideration to the pathogen detection sensitivity windows” in any new recommendations and to approve additional methodologies for pathogen testing and inactivation.<sup>218</sup> Questionnaires from countries using IRA—specifically Italy—should also be reviewed when FDA updates its questionnaire recommendations and education materials.<sup>219</sup>

APLUS represents a unique but critical constituency: the recipients of plasma-protein therapies. Approximately 125,000 Americans are dependent on such therapies.<sup>220</sup> APLUS does not support a policy transition away from a 12-month deferral for MSM, at least not before the effects of the current 12-month deferral can be evaluated, though when this should be is not discussed.<sup>221</sup> APLUS is dismissive of questionnaires, testing, and most technological advancements that transpired since the 1980s, stating simply “we believe donor screening, donor deferral, and donor testing measures alone are inadequate” and “current testing and donor questionnaires are not enough to guarantee safety.”<sup>222</sup> APLUS, like many other commenters, voiced concern over the adequacy of the current questionnaires and called for their improvement while at the same time expressing apprehension over whether improvement can be achieved. This stance suggests, that while their worries have not borne out, more research is needed into seeing how to effectively design a questionnaire before considering changes in the deferral policy.<sup>223</sup> Most tellingly,

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professionals, (2) epidemiological evidence that MSM were not as monogamous or practicing safe sex as they claim, and (3) HIV prevalence is higher among non-monogamous MSM than in non-monogamous non-MSM. How these conclusions were reached and whether they are justifications or mere excuses is not under review here, however it is troubling that FDA would prefer a knowingly less-safe system for blood donations because a safer system might be more costly and that the risk of non-monogamous MSM for contracting HIV being greater than that of non-MSM was reason enough to exclude MSM while permitting non-MSM to donate regardless of their monogamy or sexual practices. *See* FOOD & DRUG ADMIN., Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products: Guidance for Industry (2015), <https://www.fda.gov/downloads/biologicsbloodvaccines/guidancecomplianceregulatoryinformation/guidances/blood/ucm446580.pdf> [<http://perma.cc/H4XD-BPLS>].

<sup>217</sup>HIV M. Assoc., Public Comment to FDA RE: Docket No. FDA 2016-N-1502 (Nov. 21, 2016), <https://www.regulations.gov/document?D=FDA-2016-N-1502-0120> [<http://perma.cc/BDR2-P8CF>].

<sup>218</sup>*Id.*

<sup>219</sup>*Id.*

<sup>220</sup>Am. Plasma Users Coalition, Public Comment to FDA RE: Docket No. FDA 2016-N-1502 (Nov. 25, 2016), <https://www.regulations.gov/document?D=FDA-2016-N-1502-0141> [<http://perma.cc/6KEN-G6KK>].

<sup>221</sup>*Id.*

<sup>222</sup>*Id.* APLUS provides no justification or evidence for these conclusions in their letter. However, they reference the precautionary principle as essential in designing any policy that might impose uncertainty or risk but when “new science, epidemiology, or technologies are available, a review of the precautionary measures is appropriate.” Even though all three of these components have become available APLUS seems reluctant to discuss how advances in science and technology are inadequate or review the deferral any further than the transition from a lifetime ban to a functional lifetime ban.

<sup>223</sup>*Id.*

APLUS “support[s] research focused on high-risk behaviors of all donors” and states that IRA is a “desirable goal” that “could establish a pathway for controlled entry of high-risk donors.”<sup>224</sup>

#### *D. Conclusion on Comments and Commentary*

Ultimately, FDA must make a value determination: do they value inclusion, and so are willing to commit the time and resources in exploring how to include the MSM community while preserving safety in the blood supply? Or, do they value nominal precaution and so are willing to continue an deferral policy for all MSM while permitting most non-MSM to donate blood regardless of their individual behaviors and risk profiles?<sup>225</sup> FDA concluded its general summary of the comments in the BPAC meeting with the statement of principles that will guide FDA’s analytical and decision-making process: that “[it] will be based on gathering the necessary scientific evidence regarding policy change while ensuring the continued safety of the blood supply” and that FDA “will work to maximize transparency” in its process.<sup>226</sup> FDA owes a duty to the public—including the MSM community—to be fair and just in its recommendations and base those policies on the best available evidence as well as the core principles that underscore public health law and policy.

### **VI. CONCLUSION: IN FAVOR OF IRA**

FDA has been among those entities depriving MSM individuals based on unsupported justifications of public health.<sup>227</sup> Public health can be better supported—and both a safe and adequate blood supply better ensured—through adopting more tailored measures than a general MSM deferral.

FDA’s current recommendation, imposing a 12-month deferral for MSM, is needlessly over-inclusive and dangerously under-inclusive.<sup>228</sup> Firstly, under a *Jacobson* lens it is unnecessary to bar a large group of individuals for behaviors they themselves may not engage in.<sup>229</sup> It is, secondly, unreasonable to defer for 12-months these individuals when both the science and technology suggest that a deferral need not extend so long.<sup>230</sup> Thirdly, singling-out one group for prevalent behaviors while ignoring the risk posed by others for the same behaviors is unjustifiably disproportional as the risk is not tied to HIV prevalence in a community but rather

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<sup>224</sup>*Id.*

<sup>225</sup>Compare Leiss, *supra* note 14, at 35, with Galarneau, *supra* note 12, at 30. FDA has claimed that the deferral policy would be temporary until technology made testing definitive and the risk for HIV transmission as low as reasonably achievable. Given where testing is today FDA would need to define in clear terms what the threshold is for “as low as reasonably achieve able” if it decides to pursue a strict precautionary principle and under principles of equity and justness apply that standard to all blood donors. Whether this would reduce the pool of candidates or not is uncertain, though it would certainly require deferral for some non-MSM individuals who currently are permitted to donate blood.

<sup>226</sup>See Summary of Responses, *supra* note 181, at 34.

<sup>227</sup>See, e.g., Galarneau, *supra* note 12, at 29.

<sup>228</sup>See *supra* notes 124, 126.

<sup>229</sup>See Gostin, *supra* note 31, at 579.

<sup>230</sup>*Id.* Lesser horrors have been realized when brute effectiveness for an action is valued over (or in disregard to) its justness or reasonableness. Whatever prevalence for plague there was in San Francisco’s Chinatown may have been effectively contained by the quarantine, but *Jew Ho* asks for more and so more must be provided.

HIV prevalence in the blood supply itself.<sup>231</sup> Fourth, the harm caused by the generalized deferral is avoidable today and previous justifications for that harm do not carry forward.<sup>232</sup> Fifth, and finally, a deferral for 86 percent of the MSM community owing to the HIV status of the remaining 14 percent is prima facie unfair, and holding the whole MSM community responsible for risky behaviors that they do not all practice while turning a blind eye to those same behaviors as present in non-deferred communities is simply unjust.<sup>233</sup> Under this public health legal framework, FDA's current recommendation on blood deferral is neither lawful nor good.

Public health law is about balance, and for too long an unequal hand tilted the scales. Blood donation policy should be based on ensuring a safe and adequate blood supply. With new approaches and improved technology, FDA can and should recommend a policy that is maximally inclusive while retaining appropriate cognizance of the risk any contaminated blood poses. IRA could allow blood banks and hospitals to defer those individuals with behaviors or profiles that constitute unsafe risk to the blood supply and, having identified a potential person in need of counseling and care, refer them to essential services, while permitting people presenting low- or no-risk to donate. FDA ought to comply with its own stated principles and the expectations placed upon it by over a century of public health law and lift the unequal hand placed too long atop the MSM community.

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<sup>231</sup>*Id.*

<sup>232</sup>*Id.*

<sup>233</sup>*Id.*