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Target Article

Blood Donation, Deferral, and Discrimination: FDA Donor Deferral Policy for Men Who Have Sex With Men

Charlene Galarnau, Wellesley College

U.S. Food and Drug Administration (FDA) policy prohibits blood donation from men who have had sex with men (MSM) even one time since 1977. Growing moral criticism claims that this policy is discriminatory, a claim rejected by the FDA. An overview of U.S. blood donation, recent donor deferral policy, and the conventional ethical debate introduce the need for a different approach to analyzing discrimination claims. I draw on an institutional understanding of injustice to discern and describe five features of the MSM policy and its FDA context that contribute to its discriminatory effect. I note significant similarities in the 1980s policy of deferring Haitians, suggesting an historical pattern of discrimination in FDA deferral policy. Finally, I point to changes needed to move toward a nondiscriminatory deferral policy.

Keywords: blood donors, discrimination, ethics, FDA, sexual partners, social justice

It may be that our lack of interest in the ethics of health policy has given us the health-care system we deserve. (Churchill 2002, 63)

“From 1977 to the present, have you had sexual contact with another male, even once?” This question is asked of all males who volunteer to donate blood in the United States. A positive response earns the potential donor a “lifetime deferral,” a polite way of saying that he is forever prohibited from donating blood. The Food and Drug Administration (FDA) defends its deferral policy, while a wide public, including blood centers, medical professionals, academics, and elected public officials, criticizes the policy as discriminatory and calls for its review and revision.

Given the precious nature of blood, our biological necessity for it, and the many social and cultural associations we attach to it: life and death, purity and contamination, inalienable personhood and social cooperation, it is little surprise that blood donation and deferral policies elicit strong debate about justice, exclusion, safety, risks and community—especially so in an HIV (human immunodeficiency virus) context. Commonly understood as an example of individual altruism, blood donation is also a powerful expression of social solidarity, and unjustified exclusion from it can be a form of discrimination leading to social marginalization and stigmatization.

I begin with brief overviews of blood donation in the United States, donor deferral policy since 1983, and the conventional ethical debate. The heart of this article is my argument that the FDA’s deferral policy regarding men who

have sex with men (MSM) is discriminatory, not due to blatant homophobia, but due to (at least) five more subtle features of the policy and its institutional context that combine to create a discriminatory effect: assumed data justification, an ethically challenged regulatory process, stereotypes about sex, gender, and the sexual behaviors of both men and women, a tacit notion of acceptable risk in the blood supply, and a double standard in risk tolerance. A look back at the FDA’s deferral of Haitians in the 1980s reveals a similar pattern of discrimination, and a look forward suggests pragmatic strategies toward ending this MSM policy discrimination.

BLOOD DONATION, DEFERRAL POLICY, AND THE ETHICAL DEBATE

U.S. Blood Donation and Regulation

In 2006, 9.5 million blood donors gave more than more than 16 million units of blood. According to the 2007 National Blood Collection and Utilization Survey (NBCUS), most of this blood (14.55 million units) was “allogeneic,” meaning donated for transfusion into an unknown person, in contrast to donations “directed” to a known recipient or to “autologous” donations given for self-transfusion (DHHS 2008). Ninety-five percent of this allogeneic blood was collected by national and community blood centers, including the American Red Cross (ARC) and America’s Blood Centers (ABC), at local sites such as workplaces, schools, and community centers. The remaining 5% was collected directly by local hospitals (DHHS 2008).

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Although this most recent survey found the blood supply adequate for transfusion demand in 2006, NBCUS findings 2 years prior found that 16.0% of hospitals could not meet their nonsurgical blood needs on at least one day and 8.4% of hospitals experienced blood shortages that resulted in postponed elective surgery on one or more days (DHHS 2006, 31–32). Similarly a General Accounting Office report found that 18% of hospitals reported blood shortages in the course of a year and that shortages are predictable during summers and end of year holidays (GAO 2002). Likewise, blood centers regularly solicit donors with warnings of critically low blood supplies.

Various federal agencies contribute to blood safety, and here I focus on the FDA, specifically its Center for Biologics Evaluation and Research (CBER), due to its regulatory authority and responsibility for the safety of the U.S. blood supply. FDA regulations including donor deferral policies are developed with consultation from the Blood Products Advisory Committee (BPAC), a group of scientific experts that

reviews and evaluates available data concerning the safety, effectiveness, and appropriate use of blood, products derived from blood and serum or biotechnology which are intended for use in the diagnosis, prevention, or treatment of human diseases. (BPAC 2008a)

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” (holding blood until it shows acceptable test results), and oversight of blood manufacturing processes (FDA 2006, 11). Potential blood donors complete a donor history questionnaire, and those persons identified as “at increased risk” for transfusion-transmitted infections are deferred from giving blood. Donor eligibility standards are routinely modified as deemed important for blood safety and availability.

Deferrals are commonly distinguished as *clinical*, due to a medical condition such as heart disease or malaria; *geographic*, based on birth or residence in or travel to certain countries; or *behavioral*, related to sexual activity or intravenous (IV) drug use. Deferrals vary widely in duration: Persons are deferred for 2 weeks after certain immunizations, and for 4 weeks or longer after some others; for 1 year after receiving a tattoo or being treated for syphilis or gonorrhea; and permanently after traveling in specific areas, using IV drugs, or being a male who has had sexual contact with another male even once since 1977.

Donated whole blood is tested for an array of transfusion-transmitted infections including syphilis, HIV-1, HIV-2, HTLV (human T-lymphotropic virus)-I and HTLV-II, the viruses for hepatitis B and C, and West Nile virus. Nucleic acid amplification testing (NAT) for HIV-I and hepatitis C virus detects the genetic material of these viruses rather than the antibodies to them, thereby significantly reducing the window period of viral undetectability. With NAT, the window period for HIV is now 12 days (FDA 2002).

FDA Donor Deferral Policy and HIV

In March 1983 the U.S. Public Health Service including the FDA, Center for Disease Control (CDC), and the National Institutes of Health (NIH) warned that the then-mysterious disease we now know as HIV infection was likely transmitted by a blood-borne pathogen (CDC 1983). That same month, the FDA Office of Biologics (later renamed CBER) issued a landmark memorandum that identified certain individuals and groups as “at increased risk of AIDS” and effectively deferred them “until the AIDS problem is resolved or definitive tests become available” (IOM 1995, 290). Among persons labeled as at increased risk were “sexually active homosexual or bisexual men with multiple partners” and “sexual partners of individuals at increased risk of AIDS” (IOM 1995, 290). Prior to this exclusion, MSM had been relatively frequent blood donors motivated by a desire “to help develop a hepatitis B vaccine and to gain a social acceptance” (IOM 1995, 104).

In 1992 the FDA issued “Revised Recommendations” that changed both the criteria for donor exclusion and the deferral periods established in 1983. Recognizing that HIV risk had a greater association with sexual behavior than with sexual identity, the FDA revised the risk group from “sexually active homosexual or bisexual men with multiple partners” to “men who have had sex with another man even one time since 1977” (FDA 1992). These Revised Recommendations also stratified deferral periods such that MSM received a lifetime deferral while the deferral for female sexual partners of MSM was reduced to 12 months.

In 1997 BPAC voted 12-1 to reconsider the MSM policy. Several BPAC members expressed concern that the policy was discriminatory and a majority desired to revisit the policy in the near future with more scientific data in hand (BPAC 1997). The 1998 FDA Blood Donor Suitability Workshop (FDA 1988) reviewed the relevant scientific literature in light of a possible policy “relaxation” but it would be two more years before BPAC reconsidered the policy.

In 2000 BPAC discussed and voted on the question, “Do the available scientific data support the concept that men who have sex with other men, MSM, can be deferred from donating blood for a period of five years following MSM activity rather than being deferred for any MSM behavior since 1977?” In the closest possible vote, 7–6, the Committee rejected that “the available scientific data support the concept” of a 5-year deferral period. Each of BPAC’s two nonvoting members, a consumer representative and an industry representative, agreed with the minority vote. Notably, a straw poll taken earlier in the meeting had asked committee members whether “there should be a change in the question from having sex even once back through 1997 [sic 1977].” Eight of the 13 eligible voters responded “yes” (BPAC 2000, 286, 312). Echoing the 1997 BPAC meeting, Committee members in 2000 asked the FDA for more data in order to better assess a possible policy change (BPAC 2000, 287–313).

The 2006 “FDA Workshop on Behavior-Based Donor Deferrals in the NAT Era,” (FDA 2006), much like the 1998

Workshop, reviewed data related to the MSM deferral policy. It was in conjunction with this workshop that ARC ended its long standing support of the MSM policy and joined AABB and ABC in calling for a shorter MSM deferral period (Joint Statement 2006).

In 2010, the current MSM deferral policy remains the 1992 Revised Recommendations: lifetime deferral for MSM and a 12-month deferral for their female partners. No public FDA or BPAC reconsideration of this policy has taken place since the 2000 BPAC meeting, though the FDA has posted an online description and justification of the MSM policy (2007a).

The Ethical Debate

Public concern about government action related to blood safety arose early in the HIV epidemic. Activists from gay rights and AIDS organizations and from Haitian American and hemophiliac groups opposed, for different reasons, what they perceived as ethically problematic FDA actions (Bayer 1999; Kirp 1999; Resnick 1999). In 1995 an Institute of Medicine (IOM) investigation into federal decision making related to HIV in the blood supply in the mid-1980s released its report (IOM 1995). It found that the FDA “did not adequately use its regulatory authority” (7), that “a more systematic approach to blood safety regulation, one that is better suited to conditions of uncertainty, is needed” (14), and that the FDA lacked “independent information and an analytic capability of its own” (15). With specific regard to donor screening and deferral, the IOM declared that the FDA

failed to understand the extent to which nontechnical issues, that is, issues of how to compare risks (such as the risk of HIV transmission versus the risk of further stigmatizing homosexuals), were actually at stake. The BPAC did not have the social, ethical, political, and economic expertise necessary to understand the full ramifications of the decisions it was making. (126)

As I show later, this critical assessment of the FDA and BPAC remains relevant today.

Over the last decade, growing moral criticism has focused on the MSM deferral policy as discriminatory due to its unjustified lifetime deferral of MSM and its resultant stigmatization and social exclusion. Critics include elected officials at federal and county levels,¹ professional medical

associations,² university representatives,³ gay rights organizations (HRC 2009), legal scholars (Culhane 2005), and perhaps most influentially blood bankers, including ARC, AABB, and ABC (Joint Statement 2006).

The FDA response to these claims of discrimination is direct:

FDA’s deferral policy is based on the documented increased risk of certain transfusion transmissible infections, such as HIV, associated with male-to-male sex and is not based in any judgment concerning the donor’s sexual orientation. (FDA 2007a, 2)

Invoking its blood safety strategy of multiple overlapping safeguards, the FDA argues that HIV testing on donated blood is not 100% accurate and that human errors in the handling of blood units do occur. The agency recognizes that the MSM exclusion defers low-risk and no-risk donors:

While appreciative and supportive of the desire of potential blood donors to contribute to the health of others, FDA’s first obligation is to assure the safety of the blood supply and protect the health of blood recipients. (FDA 2007a, 2)

This FDA justification reflects a classic framing of ethical dilemmas in public health: A collective good—blood safety—is posited as in conflict with the interests or rights of individuals—MSM interests (Hochberg 2002).

In 2010 the FDA continues to frame blood safety and MSM interests as fundamentally opposed. A rights variant of this paradigm sets up a straw contest between donor rights to give blood and recipient rights to receive safe blood (Franklin 2007; Brooks 2004): “straw” because while the “right to donate” has been occasionally employed as an activist slogan, it is rarely functions as an argument by MSM policy critics. Here the interests of each “side” are too narrowly cast because each individual donor with individual interests is also a community member with community interests. Each “side” implicates the other: Blood safety requires a robust blood supply that necessarily relies on the commitment of individuals to blood donation, and all persons including MSM have an interest in blood safety since all persons are also potential blood recipients. While tensions between these individual and collective interests do

2. A representative of the Gay and Lesbian Medical Association testified at the 2000 BPAC meeting about the discriminatory nature of the policy (BPAC 2000, 251–255). The HIV Medicine Association has argued that given NAT testing, the MSM policy is “discriminatory and unnecessary” and “needlessly limit[s] and strain[s] the donor pool while promulgating the misconception that sexual orientation itself is a primary risk factor for the transmission of a deadly infectious disease” (Volberding 2004).

3. In January 2008, the President of San Jose State University suspended campus blood drives after determining that this FDA policy violates the University’s nondiscrimination policy (Kassing 2008). Many college student groups have opposed the FDA policy for the same reason. My involvement with this issue was sparked by student claims of discrimination at Tufts University in 2004 (Pesavento and Schmidt 2005).

1. In an April 2008 Congressional hearing, Representative Sam Farr (D-CA) requested that the 2009 Agriculture Appropriations bill that funds the FDA contain a requirement that the FDA reconsider its “discriminatory” MSM policy (Kaiser 2008b). This request was denied. In February 2008, the Board of Supervisors of Santa Clara County, California, voted to oppose the MSM policy and to encourage its lobbyists to work to end it (Kaiser 2008a).

exist, they are hardly as polarized as typically portrayed. A different analytical framework is needed to identify the discriminatory dimensions of this policy.

INSTITUTIONAL DISCRIMINATION: AN ETHICAL ANALYSIS

As commonly understood, discrimination entails the disadvantaged differential treatment of persons or groups by individuals, institutions, and/or social structures. Young explains that such injustice is

a consequence of often unconscious assumptions and reactions of well-meaning people in ordinary interactions, media and cultural stereotypes, and structural features of bureaucratic hierarchies and market mechanisms—in short, the normal processes of everyday life. (Young 1990, 41)

In other words, the root causes of injustice are often systemic and found in “everyday practices of a well-intentioned liberal society” and “in unquestioned norms, habits, and symbols, in the assumptions underlying institutional rules and the collective consequences of following those rules” (Young 1990, 41).

As such, this systemic and institutional sense of injustice is particularly well suited for identifying discrimination in public policy and related institutions. Here I analyze the MSM policy for assumptions, stereotypes, and practices characteristic of discrimination by examining FDA and related documents of the last two decades, including some print materials obtained by filing Freedom of Information requests. I discern five “everyday practices” that together create discrimination: (1) the assumption of data justification, (2) limits on ethics considerations in the FDA regulatory process, (3) stereotypes about gender, sex, and sexual behaviors, (4) the assumption of “acceptable” risk, and (5) an inequitable standard in risk tolerance.

The “Iffy” Science Behind the Policy: “Between a Bread Box and a Barn”

In November 2007 the FDA’s own Science and Technology Subcommittee concluded that

science at the FDA is in a precarious position: the Agency suffers from serious scientific deficiencies and is not positioned to meet current or emerging regulatory responsibilities. (FDA 1997b, 2)

This damning agency assessment is substantiated in part by CBER’s unconvincing data justification of the MSM deferral policy. At the 2000 BPAC meeting, an FDA official presented a mathematical model used to determine the change in risk to the blood supply if the current MSM lifetime deferral were shortened, and concluded:

So, let me summarize how the story looks for HIV. Again, with tremendous caveats because you understand that a lot of this data is based on one to four incidents of something being

measured. So it is hard to come up with good statistics on them (BPAC 2000, 214).

Pressed repeatedly by audience members to clarify key assumptions built into the model, he responded,

We don’t have any better estimates. I have tried to make that point very clear and I am glad you brought it up because I don’t think it was clear. These are very “iffy” numbers, and, unfortunately, it is all we have to go with. (BPAC 2000, 241)

At the meeting’s end, one BPAC member concluded that

although there was quantification of what could be quantified, the core assumptions were just that; assumptions. There was really no evidence.

So I was a little disturbed about being asked to choose between something that we could say with a fair bit of assurity was between the size of a bread box and a barn. (BPAC 2000, 291)

While some data uncertainty is inevitable, the FDA’s data report at this 2000 meeting, at the 2006 Workshop, and in the current MSM policy explanation hardly constitute a policy justification. Justification requires well-supported and convincing evidence of the need for this specific deferral policy—and such evidence has yet to be offered.⁴ In March 2008, the AABB’s FDA Liaison Committee, comprised of representatives from public agencies and private organizations from across the “blood community” requested that the FDA “revise public information materials on the MSM policy so that its scientific basis and rationale are clear and accessible to all” (AABB 2008, emphasis added).

Contributing to this data situation is the lack of data capacity within the FDA that leads to the Agency’s reliance on non-FDA researchers for policy-relevant data (BPAC 1990, 56; *Spartan Daily* 2008). In addition to constituting a “serious scientific deficiency,” this data context falls far short of 1995 IOM Report recommendations to the FDA (IOM 1995, 15):

The FDA should develop reliable sources of the information that it needs to make decisions about the blood supply. The FDA should have its own capacity to analyze this information and to predict the effects of regulatory decisions.

Also troubling is the FDA’s use of data gaps to justify MSM policy. For example, the FDA notes “the extreme paucity of data” on MSM subgroups (FDA 2006, 86), but

4. Moreover, the data presentation in the FDA’s current MSM policy explanation is plain sloppy (FDA 2007). None of the four references listed at the end of this document is cited in the document text. Furthermore, the references are of questionable value in justifying current U.S. policy: Two of the four references assess the risk effects of MSM policy change in other countries—Canada (Germain, Remis, and Delage 2003) and England (Soldan and Sinka 2003). A third reference compares HIV risk reduction in the United States given two types of NAT screening (Busch et al. 2005), and the fourth reference, “Presentation at FDA Blood Products Advisory Committee Meeting, September 2000,” includes no specific reference to author or page in this 315-page meeting transcript.

then uses this situation to justify permanently deferring all MSM saying, “no donor eligibility questions have been shown to reliably identify a subset of MSM” (FDA 2007a, 3).

Ultimately, though accurate and valid risk data are necessary, data alone is insufficient to justify donor deferral policies. Discrimination resides not in the risk itself but in the FDA response to the risk. The sheer presence of donor risk, even relatively high and well-documented risk, does not compel the FDA to invoke a lifetime donor deferral as a blood safety measure. Blood safety is, as the FDA asserts, the result of a mix of overlapping safeguards including blood testing, donor history questions, a range of deferral periods, and oversight of blood processing and record keeping. It is in this context of multiple safety options that the FDA has chosen to permanently defer MSM, and it is this policy choice that requires the FDA’s scientific and moral justification.

FDA Regulatory Context: Constraints on Ethics Considerations

A cursory review of the FDA’s blood regulatory process reveals two related structural obstacles to addressing the social and ethical dimensions of actual or proposed regulation: the FDA’s scientific focus combined with its unclear decision-making processes. CBER focuses on the scientific and technical aspects of biologics’ safety even though related regulations also have significant ethical, social, and economic consequences (FDA 2009). Jay Epstein, the FDA’s Director of the Office of Blood Research and Review and a long-time FDA spokesperson on MSM policy, describes this structural constraint:

We start with an FDA process, but we have an underlying problem of divided responsibilities. And the reason for that is that the lines have been drawn in a certain way over areas of responsibility. . . . The FDA is not supposed to look at cost. We’re supposed to look at . . . safety, effectiveness. We can go as far as to look at . . . public health, risk/benefit, but not the C word.

. . . That creates a problem in an era of limited resources and very difficult trade-offs. . . . But the process by which we decide which issues surface, how they surface, where they go, when the decision should be made, what is linked to what, that’s the part that is ill-defined.

. . . We recognize, for example, that the issue of safety advances and how to pay for them is linked to the reimbursement system. But, on the other hand, it’s been pointed out many times, and correctly, that that isn’t really FDA’s charge. But then whose charge is it, and what system do we have to ensure the integration? And I think that’s really where the challenges lie. I think we do have a pretty good idea what the particular concerns are, but we don’t have a system that decides which is the correct paradigm to address that issue. (ACBSA 2000, 88)

BPAC reflects this scientific directive, and carefully worded questions crafted by FDA staff define BPAC’s work. BPAC’s last significant discussion of the MSM policy in 2000 was framed by the FDA-posed question, “Do the available scientific data support the concept that men who have sex with

other men, MSM, can be deferred from donating blood for a period of five years following MSM activity rather than being deferred for any MSM behavior since 1977?” (BPAC 2000, 311). Not surprisingly, 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.

As CBER and BPAC largely ignore nonscientific issues, so too they ignore nonscientists. BPAC is comprised of 17 voting “scientific members” who are “technically qualified experts in their field” and “have experience interpreting complex data” (FDA n.d.). One expert member may also be “identified with consumer interest” and BPAC may include a nonvoting industry representative as its 18th member (BPAC 2008a).⁵ The FDA, not BPAC, is ultimately responsible for regulation, and even public BPAC meetings allow little time for public input, effectively excluding blood donors and recipients from significant participation.

Within this expert decision-making context, the data limits become even more problematic. As one BPAC presenter noted,

We have to work, just as we do with lots of blood-safety decisions, with the best data that we have and, if there are large errors, then we have to use common sense and we have to use the impressions of informed individuals. (BPAC 2000, 246)

As addressed in the next section, “common sense” and the “impressions of informed individuals” are model examples of the “unquestioned norms, habits, and symbols” at the heart of MSM policy discrimination.

Risk Grouping, Stereotypes, and Other Conceptual Confusions

The permanent deferral of all men who have had sexual contact with a man even once since 1977 aggregates individuals with widely disparate sexual experiences and behaviors, and assigns all of them an equivalent high-risk group status. This “conceptual round-up” is recognized and accepted by both the FDA and BPAC.⁶ Said one BPAC member (BPAC 2000, 295),

It is very crude to say it is the MSM population. We all know it is a subset of the MSM population as it is a subset of heterosexuals, et cetera. Unfortunately, the [donor] questionnaire that we have been using is just very crude at getting at that.

And FDA staff agreed: “It [the lifetime exclusion] is non-specific. It is overinclusive. But it works. It works because it captures the high-risk subset” (BPAC 2000, 306).

5. In late 2008, BPAC had 16 members, most of whom are clinical researchers with appointments at academic medical centers. Thirteen members held M.D. degrees, several held Ph.D. degrees or other graduate or professional degrees, and several held two or more graduate/professional degrees. The consumer representative held M.D. and Ph.D. degrees and an appointment at a major academic medical center (BPAC 2008b).

6. The term “conceptual round-up” is from Farmer (1992, 211).

Indeed, these “unfortunate” and “crude” tools of over-inclusivity and of homogenization of heterogeneous risk also “work” to stereotype, marginalize, and thus to produce personal and social harm (Kass 2001; Culhane 2005; BPAC 2000, 254). As Murray has observed (1991, 227), “The distance from ‘different’ to ‘dangerous’ is short.” Risk grouping is a powerful public health tool and as was noted in the early days of the HIV epidemic, “The political or social consequences of such grouping are rarely examined” (Oppenheimer 1988, 283). The stigmatization associated with the stereotype that all MSM have lifelong and high HIV risk is rarely acknowledged as being personally or socially burdensome (Malcolm et al. 1998; Maluwa et al. 2002).

Another consequence of stereotyping is that it “define[s] the questions raised and thus answered” (Oppenheimer 1988, 283). As the term “men who have sex with men” has become institutionalized in public health research and practice, Young and Meyer observe that “researchers ignore the important task of describing actual sexual behaviors, even though this information has greater relevance to public health” (2005, 1147). The assumption that all MSM are high risk has displaced the felt need to ask men about the nature or frequency of their male sexual contact, information needed to accurately identify risk within the MSM grouping.

Conceptual confusions and deeply entrenched norms about gender and sex abound in the blood policy realm, confusions and norms that marginalize gender and sexual minorities. The donor questionnaire, for example, assumes a gender binary, that is, an understanding of gender that classifies all persons as either male or female and ignores persons who identify otherwise. Both transgender persons who change their gender identity from male to female or vice versa and gender queer persons who reject this dualistic male or female identity option may have sexual contact unrecognized by this gender binary. A trans-woman who was born male bodied and now identifies as and “looks” female may not be asked “male” donor screening questions, including, “From 1977 to the present, have you had sexual contact with another male, even once?”⁷

Such limited language and omissions not only marginalize gender and sexual minorities but also fail to identify potential risk to the blood supply. Clear, accurate, and comprehensive concepts and categories are needed to inform effective and nondiscriminatory blood policy.

“Acceptable Risk”: What Is Safe?

“The blood supply is safer than ever” is a common FDA refrain, but what does this mean? According to the FDA (2006, 13),

our current risks are now so low that they cannot be measured directly and, hence, we rely on models to estimate current resid-

ual risk, that is to say the risk after all the safeguards have been followed.

These models show the residual risk of transmitting HIV and hepatitis C through a blood transfusion to be 1 in 2.1 million transfused units (FDA 2006, 14; Stramer 2007).

This current level of risk functions as “acceptable” to the FDA in two ways: first, in models the FDA relies on to estimate the change in risk if the current MSM policy were “relaxed.” This modeling uses the current 1 in 2.1 million risk as the baseline against which potential change is compared (FDA 2006, 59). In the second way, in relation to the MSM policy, the FDA states:

FDA would change this policy only if supported by scientific data showing that a change in policy would not present a *significant and preventable risk* to blood recipients. Scientific evidence has not yet been provided to FDA that shows that blood donated by MSM or a subgroup of these potential donors, is *as safe as blood from currently accepted donors*. (FDA 2007a, emphases added)

In both examples the current risk level is not justified with evidence but simply assumed to be acceptable. It is one thing to estimate the current risk of infectious disease in the blood supply, it is quite a different thing to determine what constitutes an “acceptable” risk. As Ronald Bayer has asserted (FDA 2006, 88), “The question of acceptable risk was, and has remained, essentially a moral question.” With a pointed ethical challenge to the FDA, Bayer continued (90):

How much risk is tolerable in blood donation? What price should one be willing to pay for achieving greater levels of security? Are there some risks that are so vanishingly remote, maybe detectable in models, that the imposition of costs in dollar terms or in terms of discrimination that they would require would be either an irrational expenditure or an unfair burden?

The FDA has not substantively and publicly addressed such normative questions about blood safety.

Reflecting its scientific focus, the FDA analyzes risk utilizing quantitative data and statistical modeling. In recent years this technical characterization of risk has prompted extensive review of the nature of risk, risk assessment, and risk communication in government regulatory processes (IOM 1996; Nelkin 1989; Stern and Fineberg 1996). These assessments generally agree that risk is a social, moral, economic, and political concept as well as a scientific one and that risk analysis should be, as Stern and Feinberg put it, an “analytic-deliberative process” in which scientific data are a necessary though not sufficient element (1996).

As an NIH representative at the 2006 Workshop concluded,

So, basically we are going to wind up at some point in the future where we are now, that this [MSM policy] is not a scientific issue very much. This is a social issue and a [donor] recruitment issue and a fairness issue. (FDA 2006, 391)

7. A recent blood journal article well illustrates this marginalization (Reik et al. 2006).

The FDA's assertion that the current risk in the blood supply is acceptable does not eliminate the Agency's responsibility to justify this position. Questions to be answered include: Why is this risk level acceptable? How did the FDA come to this conclusion? What social and scientific factors were accounted for? Who participated in determining it?

Inequitable Risk Tolerance: "Lifestyle Choice" Versus "Isolated Exposure"

In the MSM deferral policy, "iffy" scientific data, a technical regulatory process, gender and sex stereotypes, and assumptions regarding acceptable risk converge to create an inequitable standard of risk tolerance, cogently described at the 2000 BPAC meeting (BPAC 2000, 252–253):

The central flaw in the current donor deferral policy . . . [is that it] tolerates a wide range of risks associated with heterosexual sex while imposing a zero tolerance attitude towards MSMs regardless of the risk associated with individual behavior. For example, under the current policy, a man who engaged in one act of oral or anal sex with another man in 1978 and had been celibate ever since then would automatically be deferred while a woman who has had unprotected anal sex with multiple male partners over the past year with no knowledge of the personal histories remains in the donor pool. Similarly, a man who had oral sex with another man in 1979 would be excluded whereas a woman who had unprotected anal sex with the same man thirteen months ago would be allowed in the donor pool.

This raises a stark example of inequitable risk tolerance: MSM are deferred permanently while women who have sex with MSM are deferred for 12 months. How and why is this the case, especially given that the original 1983 FDA memo had called for the indefinite deferral of the female sexual partners of MSM?

Insight comes from the 1992 BPAC meeting where the Committee unanimously approved this 12-month deferral. Responding to complaints that the deferrals were "cumbersome," "hard to understand," and "simply inconsistent" and that they led to the unnecessary deferral of multiple-gallon donors (BPAC 1992, 316), Epstein offered this conceptual distinction:

In considering whether to modify the current lifetime deferrals, it may be useful to make a distinction between persons who themselves have engaged in high risk behavior versus persons who have been sexual partners of members of a high risk group. In the case of those who have had an *isolated or discreet sexual exposure* to an individual at increased AIDS risk, their issue is whether a negative antibody test [of the donated blood] after a definite period of time provides adequate assurance that HIV infection is not present. . . .

To what extent would the overall safety of the blood supply be affected by a change in donor deferral for HIV which permitted donation by *former members of high risk groups*? (BPAC 1992, 227–228, emphases added)

An AABB representative built on this risk distinction and proposed that the FDA

separate direct lifestyle choices associated with high risk of HIV exposure, such as IV drug use or homosexual or bisexual preference, from . . . a limited time period only of exposure or an innocent bystander type of exposure or accidental exposure. (BPAC 1992, 273–274)

A BPAC member confirmed, "They [the sexual partners] are not people that are engaging themselves in high risk behavior" (BPAC 1992, 331).

With little discussion, BPAC accepted this high-risk/low-risk dichotomy. Combined with recent data showing a shorter HIV window period (45 days), and with the meeting's momentum for abbreviated screening, consistent deferral, and reduced donor loss, this dichotomy solidified BPAC's unanimous approval of the statement, "Sexual partners of persons identified as having high risk behavior [MSM since 1977] should be excluded only if the sexual contact occurred in the last 12 months" (BPAC 1992, 332). Importantly, this decision rested on a largely implied agreement that the lifetime deferral of female partners of MSM was unnecessary, and that a 12-month deferral with the usual blood safety precautions adequately protected the blood supply.

This shortened deferral is ethically troubling in that its justification rests on the assumption that as a group these females have relatively low risk due to their infrequent sexual contact with MSM. Virtually no scientific evidence was presented at the 1992 BPAC meeting to support this behavioral assumption. Absent such evidence, this dichotomy reflects and reinforces common stereotypes: MSM as risky and potentially dangerous sexual beings while their female sexual partners are victims and "innocent bystanders."

One month after this decisive BPAC meeting, the FDA released its 1992 Revised Recommendations including the statement:

Based on updated scientific data which were presented at this [BPAC] meeting, modifications have been made to some of the deferral criteria . . . includ[ing] a 12 month instead of a lifetime deferral for sexual partners of persons with high risk behavior. (FDA 1992, 2)

Such representation of the scientific data presented hardly instills confidence in FDA policy justification.

At the 1992 BPAC meeting the Committee also defeated a proposal to reduce the deferral period for MSM. Epstein reminded the Committee that 4 years earlier it had considered and defeated this same proposal,

on the notion that persons who have ever had such high risk behavior could potentially have it as a *basis of a lifestyle choice* and might again engage in such behavior, and for whatever reason might deny it at the time of a subsequent collection. (BPAC 1992, 309, emphasis added)

This passage is remarkable in two ways: First, this 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" (FDA 2007a). A possible "lifestyle choice" is not a valid proxy for high-risk behavior. Second, it reveals that this high-risk/low-risk dichotomy—also influential in recent BPAC discussion (BPAC 2000, 302–306)—was used to justify MSM deferral policy as far back at the late 1980s.

A comparison of these two BPAC deferral discussions, one for the female partners of MSM and the other for MSM, is revealing. First, only MSM, not their female partners, were subject to the assumption that they might have made a lifestyle choice involving lifelong behavior. Female sexual contact with MSM was assumed to be discreet, isolated, and even accidental. Second, it was not suggested that female sexual partners of MSM might lie about their behavior as it was for MSM, again reflecting a stereotype about MSM as threats to the blood supply. Finally, several factors that were influential in the decision to shorten the deferral for female partners of MSM were simply not discussed in relation to the proposed MSM deferral. The desire for abridged screening and consistent deferral, the concern about donor loss, and the safety gained by the revised HIV window period were absent in the MSM discussion.

This inequitable tolerance of risk is potent evidence of the MSM deferral policy's discrimination. Here some of the "unquestioned norms, habits, and symbols, . . . the assumptions underlying institutional rules and the collective consequences of following those rules" surface most clearly (Young 1990, 41).

"The H in HIV Stands for Human, Not Haitian"

Though the FDA's indisputable discrimination against Haitians in its donor deferral policy from 1983 through 1990 does not constitute evidence of present discrimination against MSM, the many similarities between these two situations not only increase the plausibility of recent claims of discrimination but also suggest a historical pattern of institutionalized discrimination within FDA deferral policy.

In July 1982, the CDC reported 34 Haitians ill with unusual opportunistic infections much like those of a group of "homosexual" men (CDC 1982). In a 1983 memo, the FDA identified "Haitian entrants to the United States" as a risk group and indefinitely deferred them along with "sexually active homosexual or bisexual men with multiple partners" and others (FDA 1983). The following year this risk group was narrowed to Haitians entrants since 1977 (BPAC 1990, 24).

In 1985 the CDC declassified Haitians as a risk group due to the lack of epidemiological evidence that Haitian national origin was a risk factor for AIDS (CDC 1985). The New York City Health Commissioner had already taken Haitians off the City's list of AIDS risk groups, remarking, "There is no reason to continue to stigmatize Haitians at a time when they already face considerable job and housing discrimination" (D. J. Sencer, quoted in Sullivan, 1983). Notably, the FDA did not follow suit but rather continued to identify Haitians as a risk group and to indefinitely de-

fer them from blood donation. The last straw came in 1990 when the FDA expanded the risk group back to all Haitian immigrants (BPAC 1990, 25).

Haitians, Haitian Americans, and some blood centers strongly protested this (and the earlier) policy (Cineas 1983; Farmer 1992; Lambert 1990). Their resistance led to a special 1990 BPAC meeting called to hear testimony from concerned persons and to review the FDA's policy of deferring blood donors on the basis of geographic or national origin. Joel Solomon, then Director of CBER's Division of Blood and Blood Products, opened this special meeting notably dismissive of justice concerns:

I expect that some of today's speakers may concentrate on subjects that may be summed most properly under the heading of social injustice or discriminatory practices. However, it is most important that this audience and the Advisory Committee understand that the primary responsibility of the FDA is to assure the safety of the national blood supply. We are not a social service agency. We cannot correct all of the ills of society. I want to be quite clear in pointing out that we also have no desire to create any new ills for society. Our law requires us to assure that all drugs, including blood and blood products, are safe and effective. The purely societal issues are important, but except insofar as they may be affected by policies intended to protect blood safety, these issues lie outside the province of FDA's authority. (BPAC 1990, 9)

As more than two dozen mostly Haitian presenters addressed the Committee in Rockville, Maryland, that April day, more than 50,000 demonstrators marched in New York City to protest the policy (Lorch 1990). Two moments in the BPAC testimony were especially memorable (BPAC 1990): the assertion that "the H in HIV stands for human, not Haitian" (136), and Epstein's acknowledgment on behalf of the FDA that the recent policy change "was not subjected to close scientific scrutiny" and that given pressure to simplify donor exclusions, it was "an effort to make the exclusion consistent for the Africans and Haitians" (56–57). By the meeting's end, BPAC recommended that the FDA eliminate its donor deferrals based on geographic or national origin (186).⁸ Eight months later, the policy was rescinded effective January 1991 (Hilts 1990).

While differences exist between the experiences of Haitians and MSM in relation to HIV and FDA deferral policy, the similarities relevant to claims of discrimination are remarkable. Both Haitians and MSM were already stigmatized groups within U.S. society. Each group reported further stigmatization and social exclusion as a result of FDA deferral (BPAC 1990, 109, 116, 125; BPAC 2000, 254). Both Haitians and "homosexual and bisexual men" were initially identified as at increased risk on the basis of group identity—national origin and sexual identity/orientation, respectively—rather than on the basis of actual high-risk

8. BPAC also recommended that the FDA develop donor screening questions related to heterosexual HIV risk and consider the prescreening of first-time blood donors (BPAC 1990, 31).

behaviors. Despite the 1980s influence of gay rights groups (Bayer 1999), neither Haitians nor MSM were welcome participants in blood policy decision making. In each case, the FDA failed to provide clearly articulated scientific data and wider social justifications for its policies, and it relied heavily on unfounded assumptions and stereotypes in its decision making. Also in each case, prominent blood centers disagreed with FDA policy and recommended policy changes (BPAC 1990; FDA 2006, 74, 303ff.).

Together these similarities suggest a historical pattern of institutional discrimination in FDA donor deferral policy.

TOWARD A NONDISCRIMINATORY DEFERRAL POLICY

To Review five features of the MSM policy and its FDA context contribute to discrimination: the assumed data justification, the FDA's scientific orientation and weak regulatory process, sex and gender stereotyping, the assumption of acceptable risk, and finally inequitable risk tolerance. "Social justice," asserts Young, "requires not the melting away of differences, but institutions that promote reproduction of and respect for group differences without oppression" (1990, 47). What would it mean for the FDA to "promote reproduction of and respect for group differences without oppression" with regard to the MSM deferral policy? Given the multiple dimensions of the policy that contribute to its discrimination, multiple strategies for change are needed to move toward a nondiscriminatory policy. Research is needed on the actual risks of all potential donors, research that accounts for the full range of gender identities, sexual orientations, and sexual behaviors. A regulatory context is needed that requires serious deliberation of the ethical, social, political, and economic implications of proposed policies. This would necessitate a broadening of current FDA and BPAC decision makers to include potential blood donor and recipient representatives.

Risk grouping, the determination of acceptable risk, and effective blood safety strategies should be based on scientific research as well as on wider social and ethical considerations brought to bear by the already mentioned group of diverse decision makers. Conceptions of gender, sex, and sexual behavior operative in policy deliberations should be made explicit in an effort to reduce stereotyping and assumptions about "lifestyle choices."

The FDA should consider following the precedent it set in dealing with the discrimination claims regarding the 1980s Haitian deferral policy and call a special BPAC meeting to hear from concerned constituents and to reconsider the policy. While the 2006 FDA Workshop focused on this policy, it was not a decision-making venue and was dominated by invited presentations—largely by federal agency staff—with relatively little public participation and minimal open discussion. Such a meeting could consider policy alternatives raised but not seriously discussed at prior FDA meetings, for example, Busch's proposal for a pilot study involving a 1-year MSM deferral and the pretesting of first-time donors (FDA 2006, 369). Notably, BPAC recommended that the FDA consider pretesting first-time donors back in 1990 (BPAC 1990, 31).

The Secretary of the Department of Health and Human Services should revisit the 1995 IOM Report recommendations, including the IOM call for a Blood Safety Director "responsible for the federal government's efforts to maintain the safety of the nation's blood supply" (IOM 1995, 218). The IOM also proposed establishing a Blood Safety Council "with a significantly greater level of diversity, responsibility, and authority" than BPAC, comprised of "representatives from government agencies, academia, the blood bank community, industry, and the public," and "giv[ing] voice to the public's interest in having these institutions cooperate" (219). Given its recent wide-ranging discussions of the MSM deferral policy, the Secretary's Advisory Committee for Blood Safety and Availability (ACBSA) partially fulfills this role, and though it is nonregulatory, ACBSA should be centrally involved in any policy reconsideration (ACBSA 2000).

There are signs within the FDA that such changes would be welcome. In 2006, former Acting FDA Commissioner Andrew C. von Eschenbach declared,

Promoting nondiscrimination and equal access in all our programs and services is an integral part of leadership. It is also essential to accomplishing FDA's goals of promoting and protecting the health of all Americans. (2006)

FDA's Epstein has proposed a set of principles to guide blood safety decision making such as "the acceptance of risk is a political decision" and "decision making must be transparent if it is to obtain public endorsement," principles that, if enacted, would certainly help to reduce discrimination (ACBSA 2000, 68–69).

Finally, this analysis of systemic discrimination in national blood policy may serve as a model for a much-needed ethical analysis of the current blood shortage at the global level. Given the concentration of blood in wealthy Northern countries and the intensive resources used to reduce residual risk there, the history of blood importation and exportation across international boundaries, and the lack of a global blood infrastructure, this worldwide blood scarcity raises fundamentally questions that challenge national policies: about the nature of blood as a public good, the scope of the blood "community" and the meaning of solidarity within it, and national responsibilities in a global context.

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