

2005

Bad Science, Worse Policy: The Exclusion of Gay Males from Donor Pools

John G. Culhane

BAD SCIENCE, WORSE POLICY: THE EXCLUSION OF GAY MALES FROM DONOR POOLS

JOHN G. CULHANE*

I. INTRODUCTION

It is axiomatic that those responsible for public health policy often face difficult hurdles in gaining compliance with their initiatives.¹ Coercion is one tool for achieving such compliance, but is a last and limited resort.² For the most part, public health officials must rely on an artistic combination of education, intervention, and – critically – buy-in from the public they serve.³ To the extent that trust between public health and the population is compromised, so too is the ability of government to achieve favorable outcomes.⁴

Often the problem that public health encounters is not of its own making. Other governmental actors, as well as private forces, have too often behaved in ways that historically discriminate against subgroups of the population successfully consigned to the margins: people of color;⁵ prostitutes;⁶ women;⁷

* Professor of Law, Widener University School of Law; Lecturer, Yale University School of Public Health. I would like to extend more than the usual acknowledgment to my research assistants, Nancy Bourke and Kenny Levine. Both did an excellent job under intense time pressure, and this article could not have been completed in a timely way without them.

1. See Lawrence O. Gostin et al., *The Law and the Public's Health: A Study of Infectious Disease Law in the United States*, 99 COLUM. L. REV. 59, 94-95 (1999).

2. See *id.*

3. See *id.* at 120.

4. For a sharp summary of this point, see LAWRENCE O. GOSTIN, PUBLIC HEALTH LAW: DUTY, POWER, RESTRAINT 107-09 (2000).

5. The most infamous and most-often mentioned example of public health's own mistreatment of minority groups is the CDC-supported Tuskegee study of the course of syphilis infection in African-Americans who were neither told of the study nor offered antibiotics from the early 1930s until 1972. See *id.* at 124 (also citing other examples). See also Allan M. Brandt, *Racism and Research: The Case of the Tuskegee Syphilis Study*, 8 HASTINGS CENTER REP. 21, 21-29 (1978), reprinted in PUBLIC HEALTH LAW AND ETHICS: A READER 312-19 (Lawrence O. Gostin ed., 2002).

6. During the early part of the twentieth century, prostitutes and "those associated with them" were often regarded as vectors for the transmission of sexually transmissible diseases and subject to confinement. See, e.g., *Ex parte Company*, 139 N.E. 204, 204 (Ohio 1922).

and, with special relevance to this article, the gay/lesbian/bisexual/transgendered (“GLBT”) community.⁸ Thus, those responsible for public health face a wall of skepticism that they may not have been involved in creating. But some public health actors make a tough situation intractable by being part of the problem. As a first principle, public health must not act to fuel the fire of distrust, especially in minority communities, by acting in ways that can fairly be characterized as bigoted or illogical. This behavior erodes the fragile, and always contingent, trust that public health relies on to do its job. And there is no more important function of government than to safeguard the public’s health.

Governmental policy towards the GLBT community has often been inimical to the very goals it purports to serve. It has been unsupported by scientific research or basic logic, and is explainable only by unfounded assumptions about the citizens that government is supposed to serve.⁹ Public health officials have sometimes compounded the problem by standing on the wrong side of the issue, seemingly (or obviously) bowing to political pressure in enacting bad policy. This article explores two closely related, egregious instances of such wrong-headed policy-making: the exclusion of virtually all gay men from both the eligible pools of blood donors and anonymous sperm donors. While these exclusions stem primarily from the fear of HIV infection,¹⁰ they are not justified by it.

Both of these exclusionary policies sweep more broadly than justified by any reasonable reading of scientific literature. Any man who has had “sex” with any other man, even once, since 1977, is forever excluded from giving blood.¹¹ The blood policy, discussed more fully in Part II, contributes to the critical shortage of available blood for transfusion. Further, because the exclusion is not justified by consistently applied epidemiological principles, it feeds the notion that gay men are inherently dangerous carriers of disease.

Meanwhile, the men who had sex with them, and who often passed disease to their unsuspecting wives, went largely unpunished.

7. Pregnant women, in particular, have too often been seen as vessels rather than as persons with rights of their own. *See, e.g.*, N.Y. PUB. HEALTH § 2500(f) (2004) (1996 law mandating HIV testing of newborns; because of maternal antibodies in newborns, test actually tests mother without her consent); Brandt, *supra* note 5, at 319-20 (criticizing use of placebo drugs on pregnant women when efficacy of drug to prevent HIV transmission from mother to fetus had already been demonstrated).

8. *See infra* notes 112-118 and accompanying text.

9. As Professor Gostin has succinctly stated: “[S]creening is political – elected officials perceive some groups as blameworthy and some as innocent.” GOSTIN, *supra* note 4, at 201.

10. Obviously, HIV is not the only blood-borne pathogen that concerns policy makers. Hepatitis is also sexually transmissible, as are a host of other diseases. But most of the concern has focused on HIV, and a discussion of other sexually transmitted diseases is beyond the scope of this article.

11. *See infra* notes 30-32 and accompanying text.

This perception is detrimental to gay men in two related ways: First, it erodes self-esteem and contributes to a climate in which other kinds of discrimination are more easily justified. Second, the policy is so plainly absurd that it risks being ignored by gay men who *should* self-defer.¹²

Part III of this article describes and criticizes a more recent policy decision by public health officials that makes similar unsupported assumptions about gay men and their presumed status as HIV carriers. The Food and Drug Administration (“FDA”) has determined, after a protracted period of time, to consider and respond to comments that men who have had sex with men, even once during the past five years, are to be excluded from anonymous sperm donation.¹³ Given the shrinking window period during which the HIV virus might go undetected, and the need to test donated sperm both at the time of donation and six months later (after the sperm have been frozen),¹⁴ this policy is also bereft of justification. I argue that the FDA’s efforts to justify the exclusion are opaque and inconsistent with the treatment of other putative donors.

Part IV stands back a bit from these specific policies to place governmental action towards the GLBT community in a broader context. Focusing on two examples from rather different places on the political map, I argue that government policies too often contribute to a confusing and demonizing portrait of an entire community of people. I offer suggestions for a more sober approach to the issue of safety in the donor context, an approach that could safeguard the blood and sperm supply at a level deemed adequate in other contexts by recognizing true risks and responding only to those.

II. “PROTECTING” THE BLOOD SUPPLY THROUGH THE LIFETIME DEFERRAL OF MEN WHO HAVE SEX WITH MEN

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.¹⁵ Indeed, it was not even until 1985 that a reliable test for

12. In Part IV, I make some preliminary suggestions for a screening process that might do a better job of persuading at-risk donors to opt out.

13. See *infra* notes 54-56 and accompanying text.

14. See *infra* notes 58-62 and accompanying text.

15. For example, public health stumbled around in search of sound policy when faced with the difficult question of whether to close the gay bathhouses at the beginning of the HIV/AIDS epidemic. The problem is explored from a number of perspectives in *GAY BATHHOUSES AND PUBLIC HEALTH POLICY* (William J. Woods & Diane Binson eds., 2003), reviewed in John G. Culhane, *Sex, Fear, and Public Health Policy*, 4 YALE J. HEALTH POL’Y, L. & ETHICS (forthcoming 2004).

antibodies to the HIV virus was developed.¹⁶ 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.¹⁷

Incredibly, enormous advances in HIV testing, epidemiological and biological research into the transmission of the virus, and a safe blood supply have not caused this lifetime donor deferral policy to change.¹⁸ In this section, I discuss the source of authority and origin of the donor deferral policy, and examine a somewhat recent re-evaluation of the policy. In 2000, the FDA's Blood Products Advisory Committee recommended leaving the lifetime deferral in place.¹⁹ Its reasons for doing so cannot be justified.

Blood and other bodily organs, tissue, and fluids come within the regulatory jurisdiction of the FDA.²⁰ Because the FDA is charged with licensing blood banks,²¹ it is responsible for creating safeguards to minimize the risk that blood infected with infectious diseases, such as HIV, will find its

16. A layperson's account of the early history of HIV/AIDS, that mentions the development of the antibody test, can be found at AVERT.ORG, THE HISTORY OF AIDS: 1981-1986, at http://www.avert.org/his81_86.htm (last visited Nov. 17, 2004).

17. In 1983, the FDA recommended donor-screening procedures to exclude individuals at increased risk for transmitting HIV. The document that gave official imprimatur to the lifetime exclusion of MSM was issued in 1992. FOOD & DRUG ADMIN., DEP'T OF HEALTH & HUMAN SERVS., REVISED RECOMMENDATIONS FOR THE PREVENTION OF HUMAN IMMUNODEFICIENCY VIRUS (HIV) TRANSMISSION BY BLOOD AND BLOOD PRODUCTS 3 (1992), available at <http://www.fda.gov/cber/bldmem/hiv042392.pdf> (last visited Nov. 17, 2004) [hereinafter REVISED RECOMMENDATIONS]. Since then, the exclusion of potential donors based on sexual histories has been discussed often, and in-depth, by the FDA's Blood Products Advisory Committee ("BPAC"). This panel of non-FDA independent experts continues to recommend the permanent "deferral" (i.e., exclusion) of men who have sex with other men. According to the FDA, although a potential individual donor may practice safe sex, persons who have participated in high-risk behaviors are, as a group, still considered to be at increased risk of transmitting HIV. The BPAC met on Sept. 14-15, 2000 to revisit this issue. After much discussion, the BPAC recommended that men who had sex with other men since 1977 continue to be deferred from donating blood. See *infra* notes 47-53 and accompanying text for a critical discussion of this recommendation.

18. See Becky Orfinger, *FDA Committee Votes Against Relaxing Donor Ban* (2000), at <http://www.redcross.org/news/archives/2000/9-15-00b.html> (last viewed Nov. 17, 2004). See also FOOD & DRUG ADMIN., DEP'T OF HEALTH & HUMAN SERVS., BLOOD FREQUENTLY ASKED QUESTIONS (FAQS), at <http://www.fda.gov/cber/faq/bldfaq.htm> (last modified Mar. 15, 2004).

19. See *infra* notes 37-39 and accompanying text.

20. Authority vested in the Secretary of Health and Human Services under section 361 of the Public Health Service Act (42 U.S.C. § 264) includes the law enforcement functions of the FDA. These functions concern, among other subjects, blood and blood products, and have been re-delegated by the Secretary to the Commissioner of Food and Drugs. 21 C.F.R. § 5.10(a)(3) (2004).

21. See 42 U.S.C.A. § 262 (West 2004).

way into a recipient body.²² To that end, the FDA has established a battery of requirements relating to the licensing of blood banks,²³ the testing of blood prior to its release,²⁴ and – with particular relevance here – the eligibility of donors.²⁵

Some donor requirements are non-controversial, such as those relating to the frequency with which an individual may donate²⁶ and to general donor “good health.”²⁷ But the FDA has established a battery of additional exclusions. The *Guide to Inspections of Blood Banks of 1994*²⁸ adds to the list of conditions requiring donor deferral, and references another document, entitled *Revised Recommendations for the Prevention of HIV Transmission by Blood and Blood Products* (“Revised Recommendations”).²⁹ The Revised Recommendations, in turn, call for lifetime deferral of several large categories of donors, including “men who have had sex with another man even one time since 1977.”³⁰ In structuring the language of deferral in this way, the Revised Recommendations claim to be focusing on “behavior and not on stereotypes.”³¹ Thus, “many men who have had male-to-male sexual experiences do not identify themselves as ‘homosexual,’ ‘gay,’ or ‘bisexual,’ but would identify with the description ‘sex with another man.’”³²

The Revised Recommendations’ drafters were correct to note that describing behavior is a better means of achieving public policy goals than using labels, but the irony is that the FDA’s “men who have sex with men”

22. The FDA exercises this authority through the Center for Biologics Evaluation and Research (“CBER”), which has responsibility for regulating blood and blood products, as well as other biological products. CBER’s responsibilities in this regard derive from section 351 of the Public Health Service Act and from specific sections of the Food Drug and Cosmetic Act. CTR. FOR BIOLOGICS EVALUATION & RESEARCH, DEP’T OF HEALTH & HUMAN SERVS., ABOUT US, at <http://www.fda.gov/cber/about.htm> (last modified July 7, 2004).

23. See 21 C.F.R. § 606.100 (2004); 42 U.S.C.A. § 262 (West 2004).

24. See 21 C.F.R. § 610.40 (2004); *id.* § 640.5.

25. See *id.* § 1271.50.

26. *Id.* § 640.3(b).

27. *Id.*

28. OFFICE OF REGULATORY AFFAIRS & THE CTR. FOR BIOLOGICS EVALUATION & RESEARCH, DEP’T OF HEALTH & HUMAN SERVS., GUIDE TO INSPECTIONS OF BLOOD BANKS, at http://www.fda.gov/ora/inspect_ref/igs/blood.html (last visited Nov. 17, 2004).

29. REVISED RECOMMENDATIONS, *supra* note 17.

30. *Id.* at 3. The recommendations also exclude, among other categories of potential donors, “[p]ast or present intravenous drug users,” “[m]en and women who have engaged in sex for money or drugs since 1977,” “[p]ersons who have had sex with any person meeting the above descriptions during the preceding 12 months,” “[p]ersons who have had, or have been treated for, syphilis or gonorrhea during the preceding 12 months . . .,” and “[p]ersons born in or emigrating from countries where heterosexual activity is thought to play a major role in transmission of HIV-2 infection . . . and persons who have had sex with any [such emigrating] person.” *Id.* at 3-4.

31. *Id.* at 2.

32. *Id.*

category simply substitutes one harmful stereotype with another. By looking at sexual conduct as far back as 1977 – by this point, some *twenty-seven years* ago – the FDA is well outside of any consideration of etiologically relevant behavior and back into the very type-casting it purported to avoid. A closer look at the approved laboratory testing for HIV, coupled with the recent debate among members of the FDA’s Blood Products Advisory Committee (“Advisory Committee”) about whether to modify this absurdly overbroad exclusion, reveals the deficiency in the FDA’s approach to this issue.

Inasmuch as all donated blood is tested under strict, FDA-mandated conditions before being used,³³ there are only two plausible ways in which infected blood could find its way into a recipient. First, an infected unit of blood could be accidentally released.³⁴ Second, there is a short “window period” in which a person’s HIV infection is not detectable through approved testing methods.³⁵ Advances in testing have reduced this window period to under a month in most cases,³⁶ but the window remains open, if only a crack.

These two facts were central to the debate among Advisory Committee members during their meeting in late 2000 to consider whether the lifetime exclusion of “men who have sex with men” (“MSM”) was too broad.³⁷ On the table was a proposal to shorten the relevant behavioral period from pre-1977 to the past five years.³⁸ Thus, a prospective donor would only be excluded under the MSM category if he answered “yes” to the question: “Have you had sex with another man within the past five years?”

33. See *supra* note 24.

34. See, e.g., 42 U.S.C. § 1271.65(a) (West 2004) (delineating storage procedures for specimens from donors determined to be ineligible so as to prevent improper release).

35. According to the FDA, “Studies have shown that up to 2 months may elapse between the time of infection and the time the HIV antibody test is reactive.” FOOD & DRUG ADMIN., DEP’T OF HEALTH & HUMAN SERVS., BLOOD FREQUENTLY ASKED QUESTIONS (FAQS), at <http://www.fda.gov/cber/faq/bldfaq.htm> (last modified Mar. 15, 2004).

36. Since 2002, the routine use of nucleic acid testing (“NAT”) for the HIV virus itself (rather than its antibodies) has even further reduced the risk of transfusion transmission of HIV to about one unit per two million donations. *Id.* Nonetheless, “[w]hile HIV nucleic acid amplification assays are now extremely sensitive and can reliably detect HIV by days 9-11 of infection . . . , they are vulnerable to false-positive rates as high as 1%. Such tests remain relatively expensive and have not traditionally been used for routine clinical HIV screening.” Christopher D. Pilcher et al., *Acute HIV Revisited: New Opportunities for Treatment and Prevention*, 113 J. CLINICAL INVESTIGATION 937, 937 (2004) (footnote omitted), available at <http://www.jci.org/cgi/reprint/113/7/937.pdf>.

37. See CTR. FOR BIOLOGICS EVALUATION & RESEARCH, DEP’T OF HEALTH & HUMAN SERVS., BLOOD PRODUCTS ADVISORY COMM. 67TH MEETING 159 (Sept. 14, 2000), <http://www.fda.gov/ohrms/dockets/ac/00/transcripts/3649t1.rtf> [hereinafter ADVISORY COMMITTEE 67TH MEETING].

38. *Id.* at 158, 164, 201.

The Advisory Committee voted against the proposed change by the narrowest of margins (7-6).³⁹ The two primary blood banks stood on opposite sides of the debate; the American Association of Blood Banks (“AABB”) supported the relaxed requirement, while the American Red Cross (“Red Cross”) opposed it.⁴⁰ Dr. Dayton, who argued in support of the change, argued persuasively that the five-year deferral period would be so far outside the testing window that the proposed policy would introduce no new cases of infection.⁴¹

The sticking point was the possibility of erroneous introduction of an infected unit of blood into the supply.⁴² Dr. Dayton’s epidemiological analysis considered the prevalence of HIV infection in the MSM community and the number of additional donors who could be expected to enter the donation pool if the requirement were relaxed.⁴³ This number was then multiplied by the incidence of errors that might be expected, yielding a finding that changing the policy to a five-year deferral for MSM might result in a total of 1.7 infectious units per year entering the blood supply.⁴⁴

The Red Cross took a “zero tolerance” approach, and stated that it would not support any change in policy that would add any risk, however small, to the blood supply.⁴⁵ From its perspective, this orientation towards risk might seem logical – although even the Red Cross should consider the risk of blood shortages that might continue in the absence of this potential donor pool. Government officials, however, have a different responsibility: to treat like risks alike. As one participant at the Advisory Committee meeting stated: “[T]he current donor deferral policy tolerates a wide range of risks associated with heterosexual sex while imposing a zero tolerance attitude towards MSM regardless of the risk associated with individual behavior.”⁴⁶

This criticism is on the mark. 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, and whose understandable concern with his HIV status might have led him to be tested a number of times (with negative results). Further, the finding that relaxing the deferral requirement down to a still-too-long five years could increase the number of infected units by under two units per year,⁴⁷ even if true, arrives at that conclusion by asking the wrong question. Any change in the deferral policy that increases the

39. *Id.* at 311-12.

40. *Id.* at 250, 259, 284.

41. *Id.* at 214-15, 218.

42. See ADVISORY COMMITTEE 67TH MEETING, *supra* note 37, at 205, 215.

43. *Id.* at 204-05.

44. *Id.* at 210-11.

45. *Id.* at 256-58.

46. *Id.* at 252.

47. See ADVISORY COMMITTEE 67TH MEETING, *supra* note 37, at 211.

number of donors is, ipso facto, going to increase the number of infected units.⁴⁸ In a twist that is sadly familiar to members of the GLBT community, the continued exclusion is an artifact of a policy that was too exclusionary in the first place. Now that same policy is used to ground arguments against any change. The fact that other nations employ a similarly broad exclusion is no justification for the practice.⁴⁹

To understand the fallacy of such thinking, consider a different example. Imagine that HIV had first taken hold in the heterosexual population, and that an early policy had excluded anyone who had had certain kinds of sexual contact with a member of the opposite sex since 1977. Obviously, by bringing millions of people back into the donor pool, a change to such policy would result in some increase in the number of HIV-infected units. It is impossible, though, to imagine that this increased risk would be successfully used against changing the policy in such an obviously rational direction. On the other hand, intravenous drug users have been excluded from the start,⁵⁰ and it seems likely that a change of policy along the one narrowly rejected for MSM would also be rejected.

Of course, part of the reason for the difference is that the numbers of MSM and intravenous drug users are far smaller than the number of heterosexually active adults, so society can “afford” the continued exclusion in the former classes of cases. But no one who has observed government actions toward the gay community, or toward those with substance addiction problems, can honestly discount the effect of discrimination against these groups in the formulation of policy.

Finally, note that the exclusion does not define “sex.” This lack of specificity creates two related problems. First, the potential donor is left to define for himself what the term means. In the context in which the test is administered, at least some gay male donors could well assume that the question is concerned with only the riskiest behavior: unprotected (perhaps passive) anal intercourse.⁵¹ The inconsistency resulting from this “define it yourself” approach cannot be sound policy. Second, employing the amorphous

48. *Cf. id.* at 298-300 (commenting that relaxation of MSM donor deferral policy will create risk, albeit small).

49. See generally Francine A. Hochberg, Note, *HIV/AIDS and Blood Donation Policies: A Comparative Study of Public Health Policies and Individual Rights Norms*, 12 DUKE J. COMP. & INT'L L. 231 (2002) (listing exclusion policies of several other nations).

50. At least since 1992, “[p]ast or present intravenous drug users” have been excluded from the donor pool. REVISED RECOMMENDATIONS, *supra* note 17, at 3.

51. The CDC itself has stated that receptive anal intercourse presents about 100 times as great a risk of infection as insertive oral sex. CTRS. FOR DISEASE CONTROL & PREVENTION, *Interpreting HIV Prevention into the Medical Care of Persons Living with HIV*, 52 MORBIDITY & MORTALITY WEEKLY REP. (2003), available at <http://www.cdc.gov/mmwr/PDF/RR/RR5212.pdf>.

term “sex” as a disqualifier for all gay men compounds the problem addressed above. This ambiguity furthers the stereotypical image of gay men as dangerous just because of their “gayness,” as opposed to any specifically high-risk behavior. As is well-established, different sexual activities carry different risks.⁵² However, the FDA’s blunderbuss approach tramples all such distinctions, and, in the words of one astute commentator, “tends to screen donors on the basis of sexual orientation rather than on the basis of relative risk.”⁵³

III. REPEATING THE ERROR: THE ANONYMOUS SPERM DONATION RECOMMENDATIONS

On September 30, 1999, the FDA issued a proposed rule relating to donor suitability (later changed to “eligibility”) in the areas of human cells and tissues and their derivatives.⁵⁴ After a protracted comment period, the Final Rule was issued on May 25, 2004; it will go into effect one year from that date.⁵⁵ The subject of the present discussion is that portion of the rule relating to gay men who wish to become anonymous sperm donors. Under the FDA’s Draft Guidance Document, men who have had sex with men during the past five years should be excluded from the donor pool.⁵⁶ As will be demonstrated below, the FDA’s errors in this instance are different from those it has committed in the case of blood donations, but no less discriminatory and no more justified.

It is important to begin by describing the different procedures for the collection and use of blood on the one hand and sperm on the other. Blood from a donor is tested for HIV (and a host of other pathogens) and then, if unreactive, used for the benefit of one needing a transfusion.⁵⁷ Thus, only one sample of blood is tested from any prospective donor. Anonymous sperm donors, on the other hand, have their blood tested twice for HIV. It is tested once at the time of donation, and then six months later, after a mandatory

52. *See id.*

53. Letter from Jonathan Givner, Staff Attorney, Lambda Legal Defense and Education Fund, to Jill Warner, Regulatory Counsel to the Director, Center for Biologic Evaluation and Research 12 (Dec. 22, 2003) (on file with author).

54. Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products, 69 Fed. Reg. 29,786, 29,786, 29,787, 29,797 (May 25, 2004) (to be codified at 21 C.F.R. pts. 210, 211, 820, 1271).

55. *Id.* at 29,786.

56. CTR. FOR BIOLOGICS EVALUATION & RESEARCH, DEP’T OF HEALTH & HUMAN SERVS., GUIDANCE FOR INDUSTRY: ELIGIBILITY DETERMINATION FOR DONORS OF HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/PS) 16 (2004), <http://www.fda.gov/cber/gdlns/tissdonor.htm> (last visited Nov. 16, 2004) [hereinafter GUIDANCE FOR INDUSTRY].

57. *See* 21 C.F.R. §§ 610.40(a), 640.5(f) (2004).

quarantine period during which the sperm is frozen.⁵⁸ Thus, a donor who was newly infected with HIV at the time of initial donation might not test positive for the virus at the time of donation, but HIV (or antibodies to it) would appear when the donor's blood was retested at the end of the quarantine period.⁵⁹ In that case, the donor's sperm would obviously not be used.

This quarantine and re-testing, it must be emphasized, is a mandatory piece of the FDA's process for ensuring the safety of the donated product, and was established precisely to deal with the window period issue.⁶⁰ In 1999, the proposed regulations stated that the "retesting requirement is designed to address the 'window period' between the time of infection and the presence of detectable levels of antibodies to communicable diseases."⁶¹ The FDA's response to comments preceding the Final Rule reiterates this point.⁶² Given that the FDA's own policy deals with the window period, the blanket exclusion of even remotely sexually active gay men would seem to require another justification. Laboratory error is another source of concern, but the same double-testing requirement that addresses the window period also minimizes the possibility of lab error.⁶³

The FDA's response to these observations is a masterpiece of unpersuasive circumlocution, striking more for its omissions than for the positive comments it makes. The window period received a quick brush-off with the agency noting that even the best testing (for the virus itself) "may fail to detect early stage HIV" because of the low level of viremia.⁶⁴ As to laboratory error, the FDA simply ignored the obvious fact that double-testing would render such mistakes far less likely. Because of the imperfect nature of the tests themselves and the reporting of results, the agency concluded that screening for risk factors remained important.⁶⁵ It then noted that the rule *itself* does not

58. GUIDANCE FOR INDUSTRY, *supra* note 56, at 35.

59. *Id.*

60. Suitability Determination for Donors of Human Cellular and Tissue-Based Products, 64 Fed. Reg. 52,696, 52,706 (proposed Sept. 30, 1999) (to be codified at 21 C.F.R. pts. 210, 211, 820, 1271).

61. *Id.*

62. Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products, 69 Fed. Reg. 29,786, 29,800 (May 25, 2004) (to be codified at 21 C.F.R. pts. 210, 211, 820, 1271) ("The requirement to retest the donor . . . provide[s] an important added measure of protection by addressing the 'window period' between the time of infection and the presence of detectable levels of antigens and/or antibodies to communicable diseases and agents such as HIV.").

63. *Cf. supra* note 60 and accompanying text (mandatory process).

64. Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products, 69 Fed. Reg. 29,806.

65. *Id.*

exclude donors based on risk, and referred to the Guidance Document for details on such exclusions.⁶⁶

The Guidance Document itself, in a May 2004 draft,⁶⁷ sheds little light on the issue. Although the FDA is accurate in stating that the “guidance” does not rise to the level of a command, establishments in the cell and tissue donation business “must” ask questions about the donor’s “relevant social behavior, including risk factors for . . . communicable disease agents.”⁶⁸ The FDA then states its continuing “belief” that certain “conditions and behaviors” indicate higher risk.⁶⁹ Further, in the presence of one or more such factors, the FDA “recommend[s]” a determination of ineligibility.⁷⁰ Although recommendations are, by definition, not requirements, it seems highly unlikely that any establishment that wished to retain its license would ignore them.⁷¹

As previously noted, “men who have had sex with men in the preceding five years” are ineligible.⁷² Curiously, an exclusion relating to the MSM ban disqualifies “persons who have had sex in the preceding 12 months” with certain categories of other persons – including MSM.⁷³ The inconsistency of these two provisions should be apparent. If those who have had sexual relations with MSM are excluded for such a high-risk activity, why is this exclusion for one year only? The answer cannot be that one year is a sufficient amount of time for the window to close, because that same argument would suffice for MSM (especially given the extremely low probability of testing and reporting errors when a donor’s blood is drawn and tested at two times, six months apart).

One searches the Guidance Document and its supporting references in vain for further justification. The FDA mentions two sources for its continuing five-year exclusion of MSM. The first source is the ten-year-old Recommendation and Report issued by the Centers for Disease Control and Prevention (“CDC”) entitled *Guidelines for Preventing Transmission of Human Immunodeficiency Virus Through Transplantation of Human Tissues and Organs* (“Prevention Guidelines”).⁷⁴ The second source is a lengthy

66. *Id.*

67. GUIDANCE FOR INDUSTRY, *supra* note 56.

68. *Id.* at 1, 16.

69. *Id.* at 16.

70. *Id.*

71. *See infra* note 110 and accompanying text (statement of sperm bank director expressing fear that the FDA could shut down an establishment).

72. *See* GUIDANCE FOR INDUSTRY, *supra* note 56, at 16.

73. *See id.*

74. CTRS. FOR DISEASE CONTROL & PREVENTION, *Guidelines for Preventing Transmission of Human Immunodeficiency Virus Through Transplantation of Human Tissue and Organs*, 43 MORBIDITY & MORTALITY WEEKLY REP. (1994), available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/00031670.htm> (last visited Nov. 17, 2004) [hereinafter *Prevention Guidelines*].

transcript from a December 2001 meeting of the FDA's Blood Products Advisory Committee ("Advisory Committee").⁷⁵ As we shall see, neither document supports the FDA's continued five-year exclusion of MSM.

It is instructive to begin with the problems in organ donations to date that were identified in the Prevention Guidelines. Since the advent of HIV-antibody screening in 1985, the CDC has identified only four instances in which a donor whose HIV test was negative nonetheless transmitted HIV to a recipient.⁷⁶ None of these cases describes a situation presented in the frozen sperm donation context. In the first case, the required confirmatory test for HIV appears not to have been done.⁷⁷ In the second, eight months were permitted to lapse between the HIV test and the donation – a wide window indeed for HIV; the donor may not even have been exposed to the virus at the time of testing.⁷⁸ The third case involved an emergency condition in which there simply was not time to wait for the results of the test.⁷⁹ This situation could never arise in the context of sperm donation. The fourth case presented a true "window" problem. A negative antibody test at the time of donation likely meant seroconversion between testing and donation.⁸⁰ Again, the rules on frozen sperm eliminate this possibility because the donor must be tested at both the beginning and the end of the six-month period.⁸¹

Consider what these cases mean: To date, the possibility of HIV infection by an MSM who has been tested twice is purely theoretical. Although this fact does not mean that MSM do not pose a threat, it is useful to bear in mind that we are discussing a tiny, and so far, unrealized risk. The question thus remains why MSM are subject to such a lengthy exclusion. Alas, one reading these Prevention Guidelines in search of the justifications promised in the Draft Guidance Document is disappointed to find no such reasons. Instead, the Prevention Guidelines simply include MSM on the list of excluded donors,⁸² and refer the by-now industrious reader to even earlier CDC sources that supposedly establish the risk posed by MSM.⁸³ Three of these documents contain science that is almost (or, in one case, more than) twenty years old.⁸⁴

75. See generally FOOD & DRUG ADMIN., DEP'T OF HEALTH & HUMAN SERVS., BLOOD PRODUCTS ADVISORY COMMITTEE 70TH MEETING (Dec. 14, 2001), <http://www.fda.gov/ohrms/dockets/ac/01/transcripts/3817t2.doc> (last visited Nov. 16, 2004) [hereinafter ADVISORY COMMITTEE 70TH MEETING].

76. *Prevention Guidelines*, *supra* note 74, at 2, 5.

77. See *id.* at 2.

78. See *id.*

79. *Id.*

80. *Id.*

81. GUIDANCE FOR INDUSTRY, *supra* note 56, at 35.

82. *Prevention Guidelines*, *supra* note 74, at 12.

83. *Id.* at 15.

84. See CTRS. FOR DISEASE CONTROL & PREVENTION, *Current Trends Prevention of Acquired Immune Deficiency Syndrome (AIDS): Report of Inter-Agency Recommendations*, 32

The earliest reference is from 1983, and the other two are from 1985 – at or before the dawn of HIV-antibody testing.⁸⁵ An additional document refers to the risk of bone transplants.⁸⁶ The final document, from 1988, although more than fifteen years old itself, is at least on the right subject: It is the CDC's own release, entitled *Perspectives in Disease Prevention and Health Promotion, Semen Banking, Organ and Tissue Transplantation and HIV Antibody Testing*.⁸⁷ But this brief document does no more than restate the importance of freezing the sperm of anonymous donors so that it may be tested before and after the six-month quarantine period, and then refers back to one of the 1985 documents for a discussion of the risk issue.⁸⁸

In short, to seek the source of the Draft Guidance recommendations in the Prevention Guidelines is to embark on a spiraling journey back through time, with no independent justification for the continued ban from any source since 1985. At least the other cited support for the ban, the Advisory Committee transcript, is of more recent vintage. The Advisory Committee met in December 2001 to consider, among a group of questions, whether data were available to identify subgroups of MSM whose prevalence of HIV infection was closer to that of the general population.⁸⁹ With the question thus framed, the committee (doubtless influenced by a lengthy presentation by a CDC

MORBIDITY & MORTALITY WEEKLY REP. 101-3 (1983), available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/00001257.htm> (last visited Nov. 17, 2004) [hereinafter *Current Trends Prevention*]; CTRS. FOR DISEASE CONTROL & PREVENTION, *Provisional Public Health Service Inter-Agency Recommendations for Screening Donated Blood and Plasma for Antibody to the Virus Causing Acquired Immunodeficiency Syndrome*, 34 MORBIDITY & MORTALITY WEEKLY REP. 1-5 (1985), available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/00033029.htm> (last visited Nov. 17, 2004) [hereinafter *Provisional Public Health*]; CTRS. FOR DISEASE CONTROL & PREVENTION, *Epidemiologic Notes and Reports Testing Donors of Organs, Tissues, and Semen for Antibody to Human T-Lymphotropic Virus Type III/Lymphadenopathy-Associated Virus*, 34 MORBIDITY & MORTALITY WEEKLY REP. 294 (1985), available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/00000547.htm> (last visited Nov. 17, 2004) [hereinafter *Epidemiologic Notes*].

85. See *Current Trends Prevention*, *supra* note 84; *Provisional Public Health*, *supra* note 84; *Epidemiologic Notes*, *supra* note 84.

86. CTRS. FOR DISEASE CONTROL & PREVENTION, *Epidemiologic Notes and Reports Transmission of HIV Through Bone Transplantation: Case Report and Public Health Recommendations*, 37 MORBIDITY & MORTALITY WEEKLY REP. 597-99 (1988), available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/00001284.htm> (last visited Nov. 17, 2004).

87. CTRS. FOR DISEASE CONTROL & PREVENTION, *Perspectives in Disease Prevention and Health Promotion, Semen Banking, Organ and Tissue Transplantation, and HIV Antibody Testing*, 37 MORBIDITY & MORTALITY WEEKLY REP. 57-58, 63 (1988), available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/00001037.htm> (last visited Nov. 17, 2004).

88. *Id.*

89. ADVISORY COMMITTEE 70TH MEETING, *supra* note 75.

scientist who found high levels of HIV prevalence in young gay men) answered “no.”⁹⁰

In the waning minutes of a day-long session, however, several speakers expressed confusion and frustration over the way the question had been framed.⁹¹ Alternative questions were raised, but not voted on, in part because it was not always clear whether the speakers were discussing anonymous or directed sperm donations.⁹² One committee member, however, got closest to the proper question: “[Can] [e]xisting screening questions, laboratory tests and quarantine procedures . . . be used to identify a subset of men who have had sex with other men in which the prevalence rate of HIV . . . of the subjects is similar to that of the public?”⁹³

Note that the question weaves together all of the strands of the safety net rather than focusing on any one. This approach reflects common sense, inasmuch as donor questioning is the least reliable component of the screening process.⁹⁴ This point was as much as conceded by Dr. Linda Valleroy of the CDC at the meeting discussed in the text. In discussing a body of unpublished data, she noted that 883 out of four million first-time blood donors had tested positive for HIV, yielding a prevalence of .02%.⁹⁵ Of the 521 of the donors that the researchers were able to track down, some striking facts emerged. First, 34% of them had simply failed to report risks that, had they been disclosed, would have resulted in deferral.⁹⁶ This group would include but is not limited to MSM and shows that the screening allows people whom the CDC deems to be high risk to slip through, yet the rate of HIV infection through sperm donation is almost zero.⁹⁷ Another 22% of these 521 HIV-positive donors had risks that were non-deferrable, such as having had sex with an intravenous drug user, an MSM, or a commercial sex worker.⁹⁸ As previously noted, this begs the question of why such donors are not considered to pose unacceptably high risks, especially since MSM are.⁹⁹ Then followed the most astounding statement of all: “[A]nother 44[%] had no reportable risk, and this breaks down to that a certain percentage of them had had unprotected heterosexual sex which . . . is . . . just not considered a risk.”¹⁰⁰ This conclusion obviously relies on comparative prevalence to the exclusion of

90. *Id.*

91. *Id.*

92. *Id.*

93. *Id.* (comments of Dr. Stroncek).

94. *See* ADVISORY COMMITTEE 70TH MEETING, *supra* note 75.

95. *Id.*

96. *Id.*

97. *See supra* notes 76-81 and accompanying text.

98. ADVISORY COMMITTEE 70TH MEETING, *supra* note 75.

99. *See supra* notes 69-73.

100. ADVISORY COMMITTEE 70TH MEETING, *supra* note 75.

biological reality;¹⁰¹ unprotected heterosexual sex of course presents a risk of HIV transmission.¹⁰² And note that the absolute number of HIV-infected people slipping through the donor screening process substantially exceeds the number of MSM who donated.

As for the quarantining of sperm and the re-testing of donors, the statement of Dr. Charles Sims, the founder and co-director of a sperm bank organized almost thirty years ago,¹⁰³ was revealing. While the practices of blood-banking vary, those described by Dr. Sims offer strong comfort to those fearing window period or processing issues. Significantly, sperm donation bears little resemblance to blood donation, where the contact between the donor and the blood bank is fleeting; the donor gives blood and leaves, usually with no follow-up.¹⁰⁴ Sperm donors, on the other hand, are typically seen for donations several times per week, thereby establishing the predicate for an on-going relationship.¹⁰⁵ Moreover, Dr. Sims laid out a blood testing and sperm release schedule that goes well beyond what the FDA requires. First, the donors are tested and screened through a questionnaire at *three-month* intervals, not every six months.¹⁰⁶ After six months, the earliest specimen can be released (assuming three consecutive negative tests), but, in Dr. Sims's words, one specimen is "not enough inventory to release, so it's impractical."¹⁰⁷ Therefore, the *nine-month* screening and blood testing – by now the fourth such process, is the critical one. Once a donor tests negative at nine months, the "inventory" from the first three months can be released.¹⁰⁸

Dr. Sims also addressed the custodial issues that worry the FDA. It emerges from this presentation that the on-going contact, repeated testing, specimen storage and record-keeping make the sort of serious error that could

101. Indeed, the director of a sperm bank in California directly questioned the relevance of the prevalence data among sexually active young men to "men in their 30s and 40s who are in long-term mutually monogamous relationships. In fact, to take that number defies any sort of scientific mind-set or dignity." *Id.*

102. Indeed, on a world-wide basis the number of women who are carrying HIV has almost equaled the number of men; most of these women were infected through heterosexual sex. In July 2004, a consortium of international organizations, including the United Nations Programme on HIV/AIDS (UNAIDS), released a report which revealed that 48% of all HIV-infected persons worldwide are women. See UNAIDS, UNFPA & UNIFEM, WOMEN & HIV/AIDS: CONFRONTING THE CRISIS 1 (2004), available at http://www.unfpa.org/hiv/women/docs/women_aids.pdf (last visited Nov. 17, 2004).

103. Dr. Sims founded the California Cryobank in 1977. ADVISORY COMMITTEE 70TH MEETING, *supra* note 75.

104. *See id.*

105. *Id.*

106. *Id.*

107. *Id.*

108. ADVISORY COMMITTEE 70TH MEETING, *supra* note 75.

result in HIV infection extremely unlikely.¹⁰⁹ Further, Dr. Sims likely spoke for many licensees in expressing an additional incentive for careful compliance: “The fear, always, of course, is that we’re like a little insect in the forest and the FDA is the big elephant that comes on and steps on us without even seeing us.”¹¹⁰

In short, the FDA has failed to come to grips with the central and difficult issue of whether the exclusion of MSM from the sperm donor pool actually presents an unacceptable risk to recipients. Stating that the prevalence of HIV infection among gay men is higher than the prevalence among the general heterosexual population does not answer that question. If it did, we would be forced to ask what most people would rightly regard as unacceptable questions about, for example, the suitability of women of color as blood, organ or tissue donors, among whom the incidence of HIV infection in the United States is rising at the highest rate of all.¹¹¹

These comments are not made to suggest that potential donors should not be screened for behaviors that spike the risk of HIV and other serious infections to unacceptably high levels. But the blanket exclusion of all gay men (as a practical matter) from the sperm donation pool, regardless of specific behavior, sero-status, or other demographic indicators, is nothing more than discrimination in the guise of public health policy. In the final section of this Article, I tie this policy to other governmental actions and policies that devalue the GLBT community, and offer a few preliminary suggestions for a more nuanced kind of donor screening process.

IV. TOWARDS A SOUNDER PUBLIC HEALTH POLICY FOR MSM

It is difficult to determine the extent to which the continued exclusions of MSM from the blood and sperm donation pools are the results of deliberately discriminatory policy. Even if they are well-intentioned, however, their effect on the GLBT community is the same: to reduce confidence in public health. That effect is more likely because the exclusion is but one strand in a web of policy decisions – some clearly articulated, others less visible – that treat the community with scant respect. The remarks that follow describe two seemingly unrelated areas. Yet, it is precisely because the subjects are at such a distance from each other that the point about the suppression of the GLBT community resonates so powerfully.

Last year, a disturbing story came to light that shows the effect of political meddling on the mission of science. According to stories published on the

109. *See id.*

110. *Id.*

111. *Cf.* Jennifer Barrs, *Sexual Secrets, Risky Deceits*, TAMPA TRIB., June 24, 2004, Baylife, at 1 (summarizing CDC’s 2002 study that showed black women now account for 34% of AIDS cases).

same day in both *The New York Times* and the journal *Science*, officials at the National Institutes of Health (“NIH”) have been warning scientists seeking funding to avoid a list of words that might bring unwanted scrutiny from conservative members of Congress.¹¹² According to these NIH officials (who have been wise in providing this advice behind the scenes), the list of words and phrases is long and troubling: “gay”; “homosexual”; “transgender”; “men who have sex with men”; “needle exchange”; “condom effectiveness”; “commercial sex workers”; and, related only by political agenda, “abortion.”¹¹³ Thus, scientists have gotten creative in describing their research goals while avoiding these words. As one unnamed researcher at the University of California noted, though, when the proposal is for funding of a study of gay men and HIV testing, “[i]t’s hard not to mention [those words] in your abstract.”¹¹⁴ The NIH’s clandestine advice was apparently sound; just a few months after these stories ran, the NIH was asked by a congressional committee to “justify” its decisions (reached as the result of rigorous peer review) to fund some two hundred projects relating to sexuality, sexual orientation, or HIV prevention.¹¹⁵ One researcher named on fourteen of the “hit list” grants aptly termed the general feeling in the scientific community as “one of fear and intimidation.”¹¹⁶

Of course, it is fundamentally unfair to blame public health officials for this sorry state of affairs; the NIH, after all, was trying to assist the research community through these warnings. Yet these ameliorative actions are unlikely to dispel the sense of exclusion and demonization that the GLBT community (among others) experiences in such a climate – worse, public health officials will be seen as part of the problem. Seen in this light, the FDA’s continued exclusion of MSM from the blood and sperm donation pools is both a product of understandable fear of political reprisal and a sad contribution to the problem of mistrust.

Further, recent legal and political developments have provided further fuel for the GLBT community’s sense of outsider status. In particular, the political effort to ban same-sex marriage – through an amendment to the U.S. Constitution, no less – is dispiriting in the extreme. Countless thousands of gay, lesbian and transgendered families throughout the nation have seen, in stark ugliness, the extremism of politicians who tie the drive for legal

112. Erica Goode, *Certain Words Can Trip Up AIDS Grants, Scientists Say*, N.Y. TIMES, Apr. 18, 2003, at A10; Jocelyn Kaiser, *Studies of Gay Men, Prostitutes Come Under Scrutiny*, 300 SCIENCE 403, 403 (2003).

113. See Goode, *supra* note 112; Kaiser, *supra* note 112.

114. Goode, *supra* note 112.

115. See ASSOCIATION OF REPRODUCTIVE HEALTH PROFESSIONALS, “HIT LIST” TARGETS SCIENTISTS STUDYING HIV PREVENTION, SEXUALITY, at <http://www.arhp.org/corevalues/examples.cfm> (last updated Oct. 16, 2004).

116. *Id.*

recognition to the destruction of the institution of marriage. The recent hearings in the United States Senate on the Federal Marriage Amendment only underscored that this ugly movement rests solely on rhetoric and fear. Actual arguments in opposition have been limited to unsuccessful efforts to establish a correlation between same-sex marriage and the collapse of the overall institution of marriage.¹¹⁷ Worse, these opponents offer no alternative legal recourse to couples and families who are, in all material respects, leading lives parallel to those of legally married couples¹¹⁸ – but without any of the legal protections, and, significantly, without the approbation marriage confers.

Given this backdrop, it is even more imperative for the FDA to sweep away the absurdly overbroad MSM exclusions for those who wish to donate blood and sperm. Especially in the case of blood donation, denial of this opportunity insults and diminishes those gay men who wish to make this altruistic gesture. Donating blood is an intimate and, for some, a defining act of charity, kindness, and connection to those in need. It is therefore especially important for public health policy to exclude only those potential donors who pose a risk in excess of what is otherwise routinely acceptable. The brief remarks that follow sketch out a few baseline rules and assumptions that should guide policy revision.

As one speaker during the Advisory Committee meeting stated, the first step is to realize that screening provides false comfort.¹¹⁹ Dr. Valleroy's report cements the point; HIV-infected blood donors are slipping through the screen.¹²⁰ Thus, a re-imagining of the purpose and limits of screening is in order: Instead of excluding broad categories of people based on ancient and irrelevant conduct, the process should be seen as an opportunity for education and intervention. Potential donors should be asked about their health and their relevant risk behavior in a private and supportive setting. Those whose conduct indicates a high degree of risk within a *relevant* time period – men who have had unprotected anal sex with men; those who have injected drugs;

117. A debate that captures the opposing viewpoints can be found in the CNN program *Lou Dobbs Tonight* where Sens. Barbara Boxer and Sam Brownback faced off. *Lou Dobbs Tonight* (CNN television broadcast, July 14, 2004) (transcript available at <http://www.cnn.com/TRANSCRIPTS/040714/ldt.01.html>) (last visited Nov. 17, 2004).

118. A recent report by the Williams Project at UCLA School of Law revealed that same-sex couples in California had many of the same financial and economic issues as their opposite-sex counterparts, but obviously without the legal protection afforded by marriage. Moreover, some 70,000 children in the state were being raised by same-sex couples. These children were more likely to be under five, of color, adopted, and disabled than those being raised by opposite-sex couples. See R. BRADLEY SEARS & M.V. LEE BADGETT, WILLIAMS PROJECT, UCLA SCHOOL OF LAW, SAME-SEX COUPLES AND SAME-SEX COUPLES RAISING CHILDREN IN CALIFORNIA 2 (2004), available at <http://www1.law.ucla.edu/~williamsproj/publications/CA-SSCouples.pdf> (last visited Nov. 17, 2004).

119. ADVISORY COMMITTEE 70TH MEETING, *supra* note 75.

120. *Id.*

those engaging in heterosexual sex who have had multiple partners – should be urged to have their blood tested for HIV and other infectious, blood-borne diseases (particularly variants of hepatitis), assuming they are unaware of their status with regard to these pathogens. Blood and sperm donation centers could develop an important role in testing and counseling for HIV. Then, if a sufficiently specific risk exists, potential donors should be encouraged to return if and when the window of infection has closed.

In the case of blood donation, this temporary exclusion is necessary because of the continuing presence of the window period. Strictly speaking, deferral should not be needed in the case of sperm donation, but practicalities counsel a different result. Sperm recipients are not in the same life-or-death situation as blood recipients often are; an excess of caution, anchored in principles of consent,¹²¹ is probably the correct approach. Thus, a similar deferral period seems appropriate.

Forever deferring men who have had “sex” (undefined) since 1977 with men is pure discrimination. The five-year ban in the case of sperm donation is little better. With the presence of better testing and the concomitant shorter window period, one year would likely be safe. Two years would be fastidious, but arguably justified. Further, any period of exclusion that is decided upon must be applied with an even hand to those whose behavior – not their status – has placed them at risk. A more focused definition of “sex” could be part of the conversation that trained blood and sperm bank personnel conduct with potential donors. “Sex” that poses little or no risk should occasion no concern, and should not be the basis for any period of deferral.

V. CONCLUSION

The lifetime exclusion of men who have sex with men from donations of blood, tissue, and organs is an artifact of a policy that lacks current justification. While the focus of concern has often been on the rights of potential donors,¹²² this article has emphasized the public health costs of overbroad exclusion: no additional protection of the blood, tissue and organ supply on the one hand; mistrust of public health on the other. Such a lack of trust has effects far beyond the immediate problem of blood and sperm donations, as it compromises the ability of public health to gain support for sound initiatives. This point has been insufficiently appreciated. The FDA has

121. The consent here is a fiction, because the recipient may not be informed in detail about the screening and testing process and its reliability. The idea is that the recipient justifiably relies on the sperm or blood bank to safeguard the blood supply, so that any change in policy can only be supported if it would not compromise that safety in a way that a reasonable person would object to.

122. For an article that nicely summarizes and defends the constitutional arguments for blood donors’ rights, see Michael Christian Belli, *The Constitutionality of the “Men Who Have Sex With Men” Blood Donor Exclusion Policy*, 4 J.L. SOC’Y 315 (2003).

seen the exclusion as a win-win situation: increased safety at no cost. But this view overlooks the problem of unintended consequences. Ripples from this controversy extend far beyond the policies in place, entail too high a cost to the mission of public health, and offer little, if any, compensating benefit. The FDA must amend these exclusions immediately.