VIEWPOINT

Reconsideration of the Lifetime Ban on Blood Donation by Men Who Have Sex With Men

I. Glenn Cohen, JD
Harvard Law School, Cambridge, Massachusetts; and Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics, Cambridge, Massachusetts.

Jeremy Feigenbaum, JD
Harvard Law School, Cambridge, Massachusetts.

Eli Y. Adashi, MD, MS
Warren Alpert Medical School, Brown University, Providence, Rhode Island.

In 2013, the US Supreme Court took a historic step in *United States v Windsor* by striking down the Defense of Marriage Act on the grounds that it imposed a "disability on the class [of gay Americans] by refusing to acknowledge a status the State finds to be dignified and proper."[1] This milestone in gay rights stands in stark contrast to the ongoing lifetime ban imposed in 1983 on blood donation by men who have ever had sex with men (MSMs) even once.[2] As it stands, the US Food and Drug Administration (FDA) continues to uphold this 30-year-old policy, unaltered, on the grounds that MSMs remain at increased risk of contracting transfusion-transmissible pathogens such as human immunodeficiency virus (HIV).[2]

This indefinite and indiscriminate policy has hardly gone unchallenged. The American Red Cross, America's Blood Centers, and the American Association of Blood Banks have opposed the ban as "medically and scientifically unwarranted." More recently, the American Medical Association and the American Osteopathic Association called for the replacement of the current policy with "rational, scientifically based deferral periods that are fairly and consistently applied."[3,4] In addition, a bipartisan and bicameral contingent of members of Congress wrote former Department of Health and Human Services (DHHS) Secretary Kathleen Sebelius to "express concern with the progress of ... evaluations of the current blood donation criteria for men who have sex with men."[5] The above notwithstanding, the DHHS Advisory Committee on Blood Safety and Availability (ACBSA) reaffirmed the lifetime ban on blood donation by sexually active MSMs at its most recent meeting in December 2013.[6] A change in policy is presently contingent on the establishment of "an ongoing, integrated, coordinated, and nationally representative US transfusion transmissible infections monitoring system" and on the conclusion of several federally funded studies.[6] In this Viewpoint, we explore the shortcomings of the current policy of the FDA, examine its social, moral, and legal ramifications, and propose that an "assess and test" protocol, one focused on individual risk assessment, be instituted in its stead.

A Policy Out of Date and Place

Introduced in 1983 at the beginning of the AIDS epidemic, the lifetime exclusion of sexually active MSMs as prospective blood donors served a useful purpose at a point in time when the ascertainment of HIV status was not possible. However, much has changed over the last 3 decades. First, modern nucleic acid diagnostic technology has advanced to a point enabling ascertainment of HIV infection within weeks of the inciting exposure. Second, effectively designed screening tools focused on risk stratification and individualization are now practicable, thereby permitting the ascertainment of safe-sex practices, monogamy, or HIV status. Third, the current policy is increasingly incompatible with international norms. Indeed, several nations have recently limited their deferral periods for sexually active MSMs to 5 years (Canada), 1 year (United Kingdom), and 6 months (South Africa). Fourth, the current policy is both inconsistent and inequitable. While sexually active MSMs face a lifetime ban, men who have had sex with commercial sex workers or with HIV-positive women are deferred for no more than 12 months since that sexual encounter before regaining eligibility.[7] The same holds true for women who have had sex with HIV-positive men.[7]

> Viewed in the aggregate, the current FDA policy may be perpetuating outdated homophobic perceptions.

Viewed in the aggregate, the current FDA policy may be perpetuating outdated homophobic perceptions. Even though well intentioned and guided by a need to protect the integrity of the national blood supply, a policy that demands permanent deferrals for sexually active MSMs raises the specter of exclusion, stigmatization, and marginalization. Given the discerning capability of contemporary behavioral assessments and the ever-improving sensitivity of modern diagnostic technology, the disproportionate share of HIV cases among sexually active MSMs can no longer support the current restrictive policy of the FDA.

Legal Considerations

Legal scholars have advanced both constitutional and statutory challenges to the current lifetime deferral. Indeed, recent precedent suggests that the lifetime ban on blood donation by sexually active MSMs may be unconstitutional under the equal protection guarantee of the Fifth Amendment.[1,8] In the aftermath of *United States v Windsor*,[1] the US Court of Appeals for the Ninth Circuit reiterated the judiciary's commitment to eradicating discrimination against gay men and lesbians. Specifically, the Ninth Circuit concluded that "when state action discriminates on the basis of sexual orientation, we must examine its actual purposes and carefully consider the resulting inequality to ensure that our most fundamental institutions neither send nor reinforce messages of stigma or second-class status. In short, *Windsor*

Corresponding Author: Eli Y. Adashi, MD, MS, Warren Alpert Medical School, Brown University, 101 Dudley St, Providence, RI 02905 (eli_adashi@brown.edu).

Copyright 2014 American Medical Association. All rights reserved.

Downloaded From: http://jama.jamanetwork.com/ by a Landspitali University Hospital User on 08/01/2014

requires heightened scrutiny."[8] Thus, it is possible that the current FDA policy may not survive legal challenges. Indeed, the argument that the lifetime ban on blood donation by sexually active MSMs is unconstitutionally overinclusive or underinclusive finds support in the admission of ACBSA that its policy is "suboptimal in permitting some potentially high risk donations while preventing some potentially low risk donations."[9]

"Screen and Defer" vs "Assess and Test"

Policy makers could consider replacing the lifetime preclusion of sexually active MSMs from the blood donor pool with a temporary 12-month deferral period, meaning that MSMs would be precluded from donating blood for a 12-month period since their last sexual contact. As such, this modified "screen and defer" policy would introduce a measure of equity by harmonizing the diverse deferral periods presently in effect. Although symbolically appealing, this equally arbitrary deferral interval fails to address several of the deficiencies of the "screen and defer" paradigm. Indeed, it is the behavioral screen of prospective blood donors and not the length of the deferral period that is in need of reform. Moreover, donation of HIV-infected blood at any time during the first few weeks of an infection (ie, during the serologically undetectable "window period") could be readily detected by routine postdonation testing. Accordingly, the notion of a 12-month deferral interval offers little by way of further safety to the national blood supply (1-2 HIV-infected units transfused per 2 million transactions). Accordingly, policy makers should consider the abolition of the "screen and defer" practice and substitution with an "assess and test" approach. Specifically, a thoughtfully reformulated risk level–focused assessment of donor eligibility should be coupled with rigorous testing (and retesting) of identifiably high-risk groups who may present for donation.

"Assess and Test" in Action

Among nations striving to implement a rigorous, inclusive, and equitable approach to the donation of blood by MSMs, Italy has adopted several of the proposed features of the "assess and test" approach. In 2001, the Italian Ministry of Health replaced its systematic permanent deferral of MSM donors with an individual risk assessment approach.[10] As per the protocol establishing the individual risk assessment, prospective donors, MSM or otherwise, must complete an extensive questionnaire regarding their sexual history as well as undergo a face-to-face interview with a health care practitioner. Prospective donors deemed to represent low or no risk are ruled eligible to donate.[10] Prospective donors who have engaged in "risk" behaviors (eg, casual sex with an HIV-positive partner or with one of unknown status) face a temporary 4-month deferral followed by repeat assessment and testing and potential reinstitution of eligibility.[10] In contrast, prospective donors who have engaged in "high-risk" behaviors (eg, exchanging sex for money, injecting drugs, or having repeated sex with 1 or multiple HIV-positive partners) are permanently deferred.[10] Sexual orientation is not a disqualifier; instead, sexual orientation is one component of individualized risk assessment. Importantly, as recent data suggest, the Italian "assess and test" policy "has not led to a disproportionate increase of HIV-seropositive MSM" among prospective blood donors.[10]

Conclusions

The last several years have witnessed remarkable progress in lesbian, gay, bisexual, and transgender rights. In many states, MSMs now enjoy marriage equality.[1] Pursuant to the Don't Ask, Don't Tell Repeal Act of 2010, MSMs also now openly serve in the US armed forces. Finally, as one US court of appeals recently held, prospective jurors can no longer be excluded from jury service because of their sexual orientation. Despite these advances, sexually active MSMs are still deprived of the voluntary civic opportunity to partake in blood donation. Scientific advances in diagnostic technology and the experience of other nations establish that this status quo is no longer tenable, defensible, or necessary. Instead, every indication is that the lifetime ban on blood donation by sexually active MSMs, an exclusionary policy questioned on moral, scientific, and legal grounds, may be overdue for repeal and replacement with an inclusive and scientifically valid approach.

ARTICLE INFORMATION

Conflict of Interest Disclosures: The authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest and none were reported.

REFERENCES

1. *United States v Windsor*, 133 S Ct 2675. June 26, 2013. http://www.supremecourt.gov/opinions/12pdf/12-307_6j37.pdf. Accessed June 1, 2014.

2. US Food and Drug Administration. Blood donations from men who have sex with other men: questions and answers. August 19, 2013. http://www.fda.gov/biologicsbloodvaccines/bloodbloodproducts/questionsaboutblood/ucm108186.htm. Accessed June 1, 2014.

3. American Medical Association. AMA opposes lifetime ban on gay men donating blood. July 3, 2013. http://www.ama-assn.org/ams/pub/amawire/2013-july-03/2013-july-03-glbt.shtml. Accessed June 1, 2014.

4. American Osteopathic Association. American Osteopathic Association calls for removing FDA's blood donor ban. July 20, 2013. http://www.osteopathic.org/inside-aoa/news-and-publications/media-center/2013-news-releases/Pages/HOD-2013-increase-number-of-eligible-blood-donors.aspx. Accessed June 1, 2014.

5. Congress of the United States. Letter to Kathleen Sebelius, secretary, Department of Health and Human Services. August 1, 2013. http://www.warren.senate.gov/files/documents/Bicameral%20MSM%20Blood%20Ban%202013.pdf. Accessed June 1, 2014.

6. US Department of Health and Human Services. Forty-Fourth Meeting of the Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA). December 4-5, 2013. http://www.hhs.gov/ash/bloodsafety/advisorycommittee/recommendations/dec2013-recommendations.pdf. Accessed June 1, 2014.

7. US Department of Health and Human Services. Revised recommendations for the prevention of human immunodeficiency virus (HIV) transmission by blood and blood products. April 23, 1992. http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/OtherRecommendationsforManufacturers/MemorandumtoBloodEstablishments/UCM062834.pdf. Accessed June 1, 2014.

8. *SmithKline Beecham Corporation v Abbott Laboratories*, 740 F3d 471. January 21, 2014. http://www.gpo.gov/fdsys/pkg/USCOURTS-ca9-11-17357/pdf/USCOURTS-ca9-11-17357-0.pdf. Accessed June 1, 2014.

9. US Department of Health and Human Services. Advisory Committee on Blood and Tissue Safety and Availability recommendations. June 10-11, 2010. https://wayback.archive-it.org/3919/20140402193328/http:/www.hhs.gov/ash/bloodsafety/advisorycommittee/recommendations/06112010_recommendations.pdf. Accessed June 1, 2014.

10. Suligoi B, Pupella S, Regine V, Raimondo M, Velati C, Grazzini G. Changing blood donor screening criteria from permanent deferral for men who have sex with men to individual sexual risk assessment: no evidence of a significant impact on the human immunodeficiency virus epidemic in Italy. *Blood Transfus*. 2013;11(3):441-448.

Copyright 2014 American Medical Association. All rights reserved.

Downloaded From: http://jama.jamanetwork.com/ by a Landspitali University Hospital User on 08/01/2014