

Congress of the United States
Washington, DC 20510

June 9, 2010

Dr. Arthur W. Bracey
Chair
Advisory Committee on Blood Safety and Availability
Department of Health and Human Services
1101 Wootton Parkway, Suite 250
Rockville, Maryland 20852

Dear Dr. Bracey:

We are writing to express our support for your upcoming meeting of the Department of Health and Human Services (HHS) Advisory Committee on Blood Safety and Availability on June 10th and 11th to review the Federal policy that prohibits men who have had sex with other men (MSM) from ever donating blood. We join with medical experts at the American Red Cross, America's Blood Centers, AABB, and the American Medical Association, among others, in calling for a change in policy that better reflects the science of high risk behavior for HIV. The time has clearly come to review and modify this policy to strengthen the safety of the blood supply and remove any needless discriminatory rules from the process.

In the wake of the major blood donor organizations stating that the lifetime ban on MSM blood donors is "medically and scientifically unwarranted," we urge you to utilize the most up to date and comprehensive medical and scientific data regarding high risk behaviors in your considerations. In order to improve the integrity of the blood supply, we believe it is imperative that all high risk behaviors be appropriately targeted in the screening process and that similar deferral periods are established for similar risks.

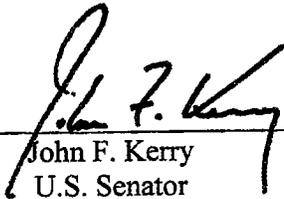
As the policy currently stands, a number of potential oversights and medically unjustifiable double standards seem apparent. For instance, there is no prescribed consideration of safer sex practices, individuals who routinely practice unsafe heterosexual sex face no deferral period at all while monogamous and married homosexual partners who practice safe sex are banned for life. In fact, a woman who has sexual relations with an HIV positive male is deferred for one year, while a man who has had sexual relations with another man, even a monogamous partner, is deferred for life. Even individuals who have paid prostitutes for heterosexual sex face a deferral period of one year while gay men face a lifetime ban. These do not strike us as scientifically sound conclusions.

The safety of our blood supply is of the utmost importance. With the advances in medicine over the course of the last three decades, we encourage you to look beyond blanket deferrals and consider screening based on real high risk behavior so we can update our blood donation policies from their early 1980's origins. By keeping discriminatory policies on the books, and denying willing donors the opportunity to help others we put the integrity of the blood donation system at risk.

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Thank you for your consideration of these concerns. We look forward to the Committee's recommendations for modifying this policy.

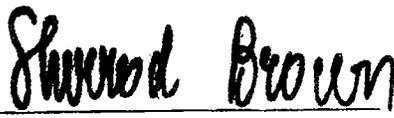
Sincerely,



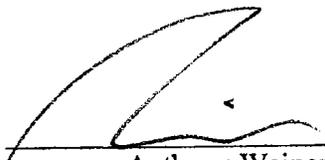
John F. Kerry
U.S. Senator



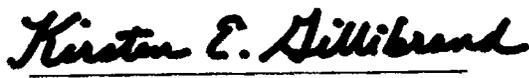
Mike Quigley
Member of Congress



Sherrod Brown
U.S. Senator



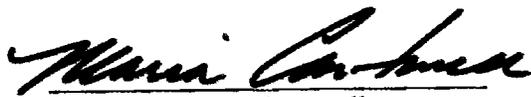
Anthony Weiner
Member of Congress



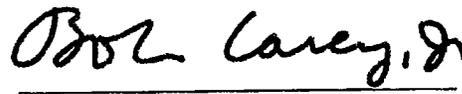
Kirsten Gillibrand
U.S. Senator



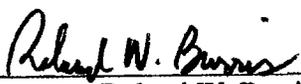
Sheldon Whitehouse
U.S. Senator



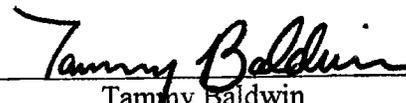
Maria Cantwell
U.S. Senator



Robert P. Casey
U.S. Senator



Roland W. Burris
U.S. Senator

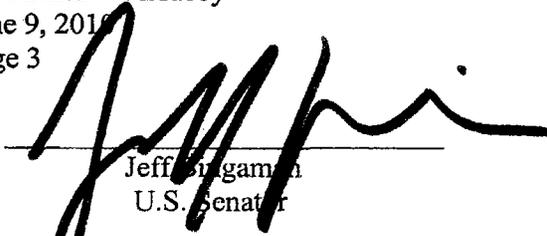


Tammy Baldwin
Member of Congress

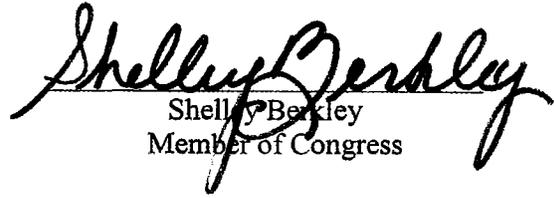
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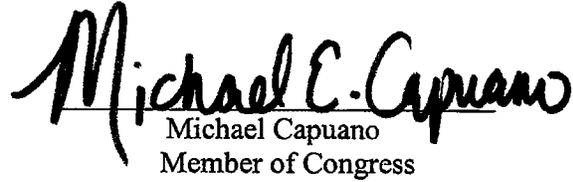
Jeff Bingaman
U.S. Senator



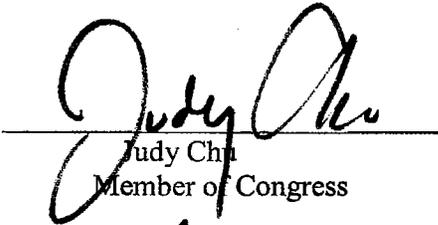
Shelley Berkley
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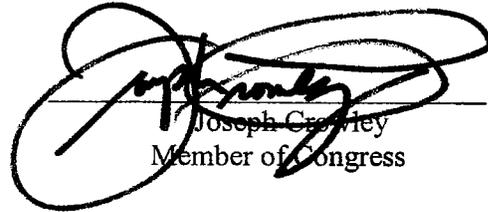
Lois Capos
Member of Congress



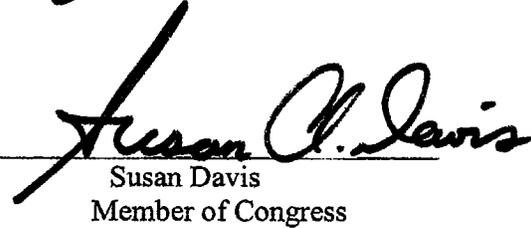
Michael Capuano
Member of Congress



Judy Chu
Member of Congress



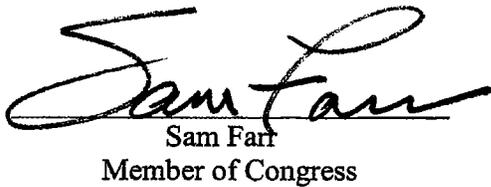
Joseph Crowley
Member of Congress



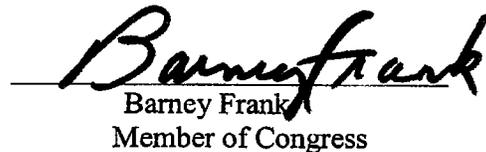
Susan Davis
Member of Congress



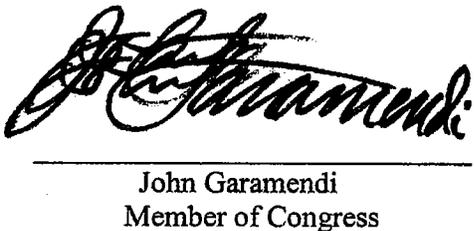
Diana DeGette
Member of Congress



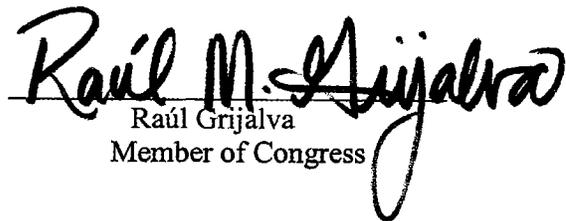
Sam Farr
Member of Congress



Barney Frank
Member of Congress



John Garamendi
Member of Congress

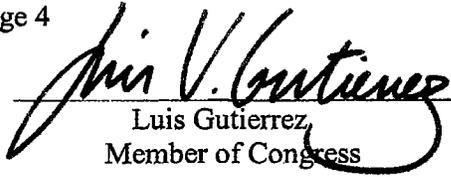


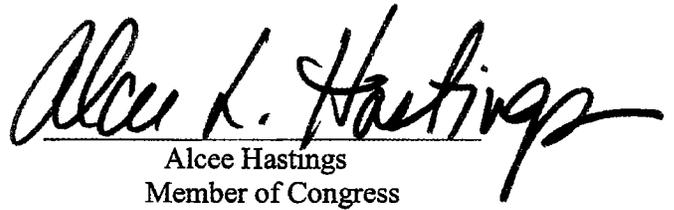
Raúl Grijalva
Member of Congress

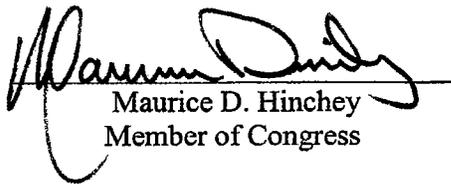
Dr. Arthur W. Bracey

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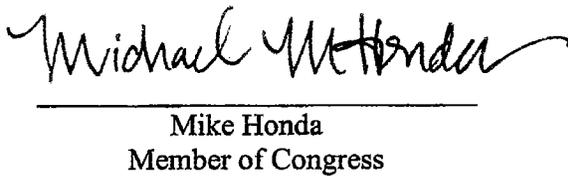
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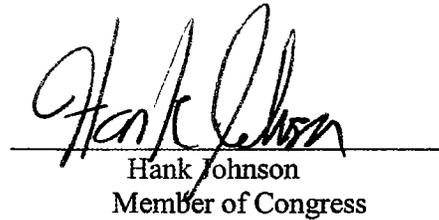

Luis Gutierrez
Member of Congress

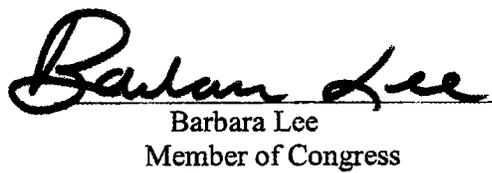

Alcee Hastings
Member of Congress

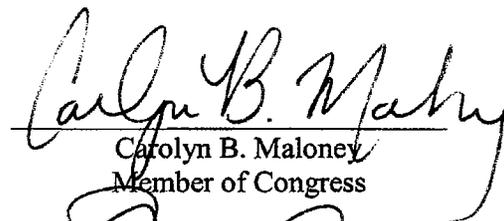

Maurice D. Hinchey
Member of Congress

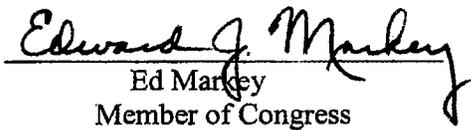

Rush Holt
Member of Congress

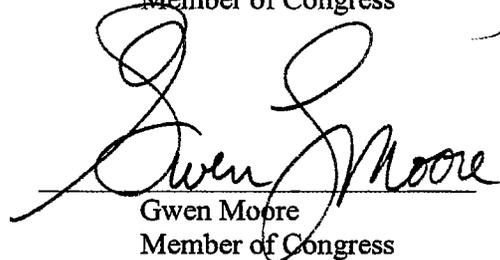

Mike Honda
Member of Congress

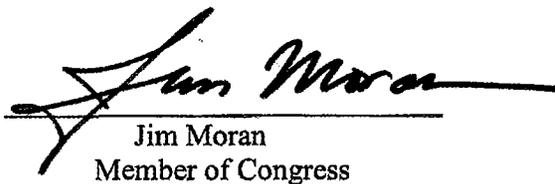

Hank Johnson
Member of Congress

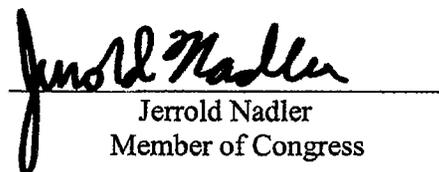

Barbara Lee
Member of Congress


Carolyn B. Maloney
Member of Congress


Ed Markey
Member of Congress


Gwen Moore
Member of Congress

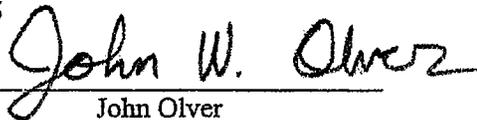

Jim Moran
Member of Congress


Jerrold Nadler
Member of Congress

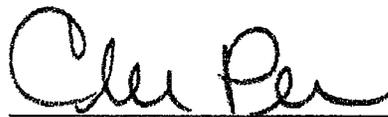
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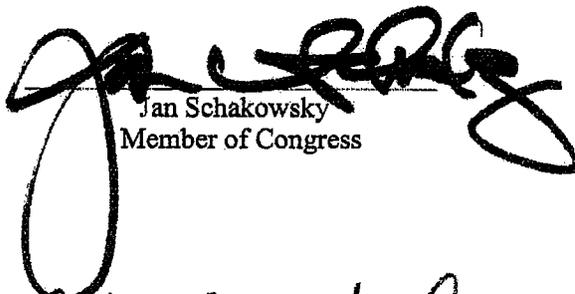
John Olver
Member of Congress



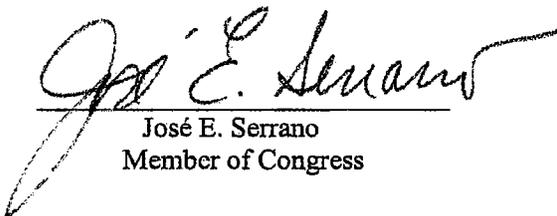
Chellie Pingree
Member of Congress



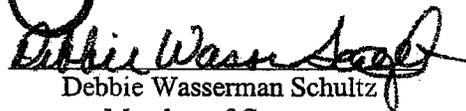
Steven Rothman
Member of Congress



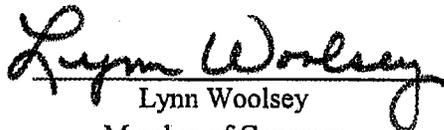
Jan Schakowsky
Member of Congress



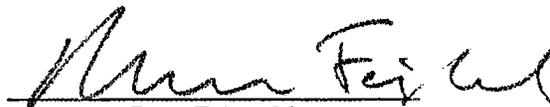
José E. Serrano
Member of Congress



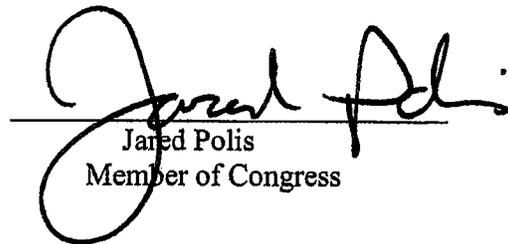
Debbie Wasserman Schultz
Member of Congress



Lynn Woolsey
Member of Congress



Russ Feingold
U.S. Senator



Jared Polis
Member of Congress

Blood, Organ, and Tissue Senior Executive Council Pre-decisional Briefing Document on Donor Deferral of Men who have had Sex with another Man (MSM)

Issues for BOTSEC Discussion

Current Food and Drug Administration (FDA) policy recommends that men who have had sex with another man (MSM) even one time since 1977 should be deferred indefinitely from donating blood. This policy is currently under review.

This pre-decisional briefing document summarizes significant issues to address in considering a policy change. It identifies a range of options, but does not recommend a specific policy option. It also asks the Blood, Organ, and Tissue Senior Executive Council (BOTSEC) to consider how Advisory Committee on Blood Safety and Availability (ACBSA) can help inform a policy decision on this issue.

Specifically the BOTSEC is asked to consider:

- Whether to revise current FDA blood donation policy on men who have had sex with another man (MSM) even one time since 1977.
- What questions the ACBSA should address to inform this policy decision.

Background

The MSM policy in its current form has been in place since September 1985, subsequent to the implementation of donor testing. This, and other related FDA policies are designed to address the major sources of risk to the blood supply such as the “window period” between infection and ability to detect infection with screening tests, the quarantine release error, and emerging infectious disease (EID) transmission. FDA has reviewed the policy periodically, most recently at a meeting of the FDA Blood Products Advisory Committee in 2000 and in a Public Workshop in 2006. After considering both reviews, FDA retained its policy.

More recently, members of Congress, advocacy groups, and others are pressing for a policy revision. This increased interest in a policy change is based on more sensitive blood screening tests which have reduced the “window period” to less than two weeks, and also the perception that deferral for MSM is more stringent than for other risk behaviors. Conversely, some patient advocacy groups, such as those representing the hemophilia community, are concerned with any change that is perceived as increasing the risk of transfusion-transmitted disease (TTD). The White House Office of the National AIDS Coordinator is also interested in this issue.

Data from the Centers for Disease Control and Prevention (CDC) indicate that HIV and other blood borne viruses are not randomly distributed in the population, but are concentrated within specific subgroups, including those whose sex partners have risk behavior(s) associated with higher prevalence of TTDs. Men who have had sex with other men have HIV prevalence that is much higher than the general population. CDC estimates that MSM account for 2% of the US population yet comprise 48% of the approximately one million people living with HIV.¹ Furthermore, MSM are the only risk group in the US for which the numbers of new HIV infections are estimated to be increasing.² The rate of HIV diagnoses in MSM is estimated to be more than 44 times that of other men and more than 40 times that of women.¹

Issues to Consider in Reviewing the MSM Deferral Policy

In addition to addressing the major sources of risk to the blood supply, based on scientific data, societal issues identified below will need to be considered in assessing a policy change. Moreover, if options are considered, each option will need to be assessed in relation to the feasibility of implementation (e.g., risk to the blood supply; cost to blood banks and potentially the government; development of measures/systems to assess the impact of a policy change; timeline for implementation; perceptions of discrimination, etc.).

- Congressional correspondence to HHS and FDA urging a policy change.
- A report by Gay Men's Health Crisis that calls for a policy change.³
- Perception that current policy is discriminatory toward MSM. For example, donors who engage in high risk heterosexual behavior are deferred for one year, whereas men who have had sex with men even once since 1977 are deferred permanently.
- Concerns raised as to whether the current blood donor questionnaire provides a "fair" assessment of high-risk behavior. The Human Rights Campaign (HRC) calls for a change to distinguish between high and low-risk behaviors. The HRC proposes that MSM at low-risk of acquiring HIV be permitted to donate following a twelve-month deferral from last sexual contact. The Gay Men's Health Crisis calls for eliminating any deferral for MSM at "low or no risk."
- Recommendations for change from the American Medical Association (AMA) and organizations engaged in blood collection and transfusion. The AMA supports a five-year deferral. The AABB, America's Blood Centers (ABC) and the American Red Cross (ARC) support a one-year deferral.
- Public perception that current policy limits the available blood supply by restricting eligible donors.
- Some colleges and universities have canceled blood drives due to student opposition to the lifetime deferral policy.
- Critical articles and an editorial regarding the MSM policy in *The American Journal of Bioethics*.⁴
- The MSM blood and human tissue donor policies are inconsistent (MSM deferral for blood is lifetime; deferral for human tissue is five years.)
- Other countries are re-evaluating deferrals. Though some restrictions have been eased, there are many variations in countries' policies and no consensus on one best approach. (See Appendix A.)

A Range of Options

Over the last several months, a PHS Workgroup discussed the above issues and identified possible options to the current policy. The attached matrix (Appendix B) presents the following "core options" for consideration: 1) Status quo (lifetime deferral), 2) 10-year deferral post MSM exposure, 3) 5-year deferral post MSM exposure, 4) 1-year deferral post MSM exposure, and 5) deferral based on risk exposures (i.e., deferral not based specifically on MSM behavior, but instead based on gender-neutral questions to assess high-risk sexual behaviors). Each of these "core options" should also be considered in relation to additional safety or monitoring enhancements that could/should be put in place to optimize policy implementation and effectiveness. (See further discussion of these enhancements below.)

None of the alternatives to current policy are estimated to increase the blood supply significantly (e.g., about 75,000 donors added if a one-year deferral; about 15,000 if a 5-year deferral). Of the alternative options considered, the PHS Workgroup considered the 10-year deferral least-preferable in that it would be a very modest change with limited impact and do little to reduce the perception of MSM discrimination. However, with a longer the deferral period (e.g., 10 years instead of one) the higher the likelihood of detecting other EIDs that might appear earlier or with higher frequency in men who have had sex with another man. Considering the limited impact of a 10-year deferral, if a policy revision were made, the PHS Workgroup's leading options to replace the indefinite deferral with a 5-year deferral, one-year deferral, or deferral based on revised questions about high-risk behavior. Per the attached matrix and discussion below, identifies benefits and limitations/risks to consider. (See Appendix B.)

Major Sources of Risk to the Blood Supply

Current Situation: Since 1985, the HIV risk from blood transfusions has been reduced from one per 2,500 donations in 1984 to an estimated risk of one per 1,467,000 donations.⁵ Policy options should be considered in the context of this current low risk to the blood supply.

- **Window period risk:** Though blood is screened using highly sensitive tests, a period of deferral is needed after high-risk exposure to prevent false negative tests. With current testing, the average “window period” for HIV transmission (the time interval between when an infected individual may transmit the disease and the time when screening tests become positive) is estimated to be 9.0 ± 0.6 days.⁶ A deferral period of one year is thought to be sufficient to address the risk of a false negative test in the “window period.”
- **Quarantine release errors:** Despite highly sensitive testing and current deferral policies, failures to identify infected donors in a timely manner and/or to prevent inadvertent release of unsuitable blood occur. Scientific models have shown that a change in the MSM deferral policy from an indefinite to a one- or 5-year deferral likely would result in a small but significant increase in risk of HIV transmission.⁷ This risk could be reduced if computerized inventory controls were in place throughout all blood establishments. This increased risk would be due primarily to erroneous release of infected units prior to their being discarded. An FDA sponsored risk analysis model estimated that the inadvertent release of one HIV infected unit could occur every 6 years with a one year MSM deferral and every 30 years with a 5 year MSM deferral. The same model indicated a 5% chance for the inadvertent release of one infected unit in any year (95% UCL).
- **Potential EID transmission:** MSM have an increased incidence and prevalence of several currently recognized transfusion-transmitted diseases (HBV, HIV, HCV, syphilis, CMV). Several of these – such as HIV – were identified in MSM before it was recognized that they could be transmitted by transfusion. This has led to concern that MSM might represent a harbinger of newly-identified transfusion transmissible EIDs. Although the association of EIDs with MSM behavior can not be quantified except through historical examples, a longer period of MSM deferral would present an enhanced opportunity to identify previously unrecognized EIDs in MSM and thus potentially prevent their transmission via blood or blood products.

Additional Safety Factors to Consider Putting in Place

Whether or not current policy is changed, the following safety enhancements would be important to consider. However, these activities may present implementation challenges and/or increases in cost:

- **Improve the donor history questionnaire vis-à-vis high risk behaviors:** The donor history questionnaire is a critical tool to elicit information on high risk behavior from potential donors. Improvements to the donor questionnaire should be considered in order to distinguish risk more reliably regardless of gender or gender sub-group. Revising and/or re-evaluating the questionnaire would be a significant undertaking. The Blood Donor History Screening Questionnaire was last revised in 2002 with attention to FDA regulations, questionnaire design, reactions from focus groups, and one-on-one cognitive interviews conducted by the National Center for Health Statistics. However, validation of donor history questions is an essential process to provide valid and reliable data and needs to be conducted periodically. A re-evaluation, including both qualitative and quantitative assessment, might lead to development or refinement of questions that assess risk more accurately than what is currently in place.

Currently-available scientific data appear, however, to be insufficient to identify questions that reliably identify risks among genders and sub-sets of behaviors. Other changes in questions asked of potential blood donors might allow for more precise identification of high-risk behavior. However, because of the higher HIV incidence in MSM, failure to detect high risk behavior in MSM by donor questioning (with resultant deferral) would represent a higher risk to the blood supply than a similar failure for women or heterosexual men. Regardless of any policy change, it would be advisable to put in place a plan to develop better questions designed to identify high-risk donors more accurately.

- **Implement MSM pre-screening:** Prescreening of MSM who would like to donate could identify individuals with positive viral markers for infection before donation. This would prevent infectious units from entering inventory and pre-screening information gathered would provide scientific and epidemiological data on HIV incidence and prevalence among MSM who want to donate blood. Some blood collection organizations along with gay and lesbian advocacy groups have stated their opposition to MSM pre-screening, viewing it as “replacing one discriminatory practice with another.” In addition, blood collection organizations are concerned that pre-screening would add cost and would disrupt standardized procedures in place at blood centers. Furthermore, prescreening, by definition, is incapable of reducing the threat from unknown EID.
- **Implement computerized inventory controls at blood banks:** Though not preventing collection of contaminated units, computerized inventory release controls would reduce operational errors of unsuitable blood release. This would provide benefit in the prevention of all currently recognized TTD, not just HIV. All major blood centers are computerized, but many smaller blood establishments (such as hospital-based collection centers) are not. Implementing computerized inventory release would be a potentially-significant financial and operational burden (at least initially) for these establishments. Federal funding could help reduce the financial burden.

Assessing Impact of a Policy Change

If any policy changes are adopted, it will be important to monitor the effects of the change. Ultimately, a national hemovigilance program of donor and recipient surveillance would serve an important role in monitoring the effects of the change. This should include tracking viral marker prevalence in MSM donors compared with other donors, determining the comparative incidence of new infections in these populations, and evaluating temporal trends in risk factors in donors who test HIV positive when attempting to donate. These activities also would help inform our understanding of potential emerging transfusion-transmitted diseases in the MSM or other populations. Adequate hemovigilance surveillance modules are under development but are not yet in place at this time.

Need for Additional Scientific Studies

Independent of any policy change, additional studies should be conducted to collect data on subsets of the MSM population who may not exhibit specific high risk behavior in relation to TTDs, evaluate the reliability of the current donor history questionnaire vis-à-vis MSM, and develop gender-neutral questions that are likely to elicit a reliable response to inquiries about high risk behavior.

Perspective Needed from the ACBSA

The issues and questions posed to the ACBSA and the Committee deliberations in June 2010 are critical as to how HHS will respond to requests to change the current policy on MSM blood donation. Therefore, careful consideration needs to be given to what commentary and/or recommendation HHS is seeking from this advisory group.

The PHS Workgroup recommends the ACBSA be asked to make a clear decision on whether current policy should be changed and, if so, what time period and safety enhancements should be put in place. It is proposed that the following set of questions be asked for discussion and decision. A vote is desired for Recommendation 1 and written recommendations for 1a, 1b, and 2.

For Discussion:

1. What are the most important factors (e.g. societal, scientific, and economic) to consider in making a policy change?

2. Is current available scientific information sufficient to support a policy change?
 - a. In particular, given the inherent limitations, are current US risk analyses sufficient to support a policy change?
3. What studies, if any, are needed before implementing a policy change?
4. What other studies, if any, should be initiated?
5. What monitoring tools or surveillance activities would need to be in place before implementing a policy change?
6. What additional safety measures, if any, are needed to assure blood safety under a revised deferral policy?

For Recommendation:

1. Should the current indefinite deferral for men who have had sex with another man even one time since 1977 be changed at the present time?
 - a. If yes, what alternative policy (e.g., improved donor history questionnaire, pre-screening, implementation of computerized inventory controls, etc.) does the Committee recommend?
 - b. If no, what studies are needed to establish a sound basis for a change in policy?
2. What further actions, if any, does the Committee recommend to monitor and improve blood safety?

Summary

Whether to retain or revise the current MSM deferral provision is an important and highly sensitive policy decision which requires thorough analysis and careful review. Focused commentary with useful suggestions for the Secretary from the ACBSA, followed by deliberations within HHS, is critical for this process to move forward.

References:

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4. The American Journal of Bioethics. 10 (2) 2010
5. <http://www3.interscience.wiley.com/cgi-in/fulltext/123320826/HTMLSTART>
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7. Anderson S, et al. Transfusion2009; 49:1102-1114

Appendix A: Overview of International Donor Deferral Policies for MSM

Appendix B: Pre-Decisional Deferral Option Matrix

Prepared by: PHS Working Group on MSM Blood Donor Deferral (H. Alter, B. Branson, RJ. Davey, A. Dayton, K Deasy, J. Epstein, S. Glynn , J. Holmberg, M. Kuehnert, , L. St. Martin, E. Ortiz-Rios, and A. Williams)