

March 25, 2010

The Honorable Carl Levin  
United States Senate  
Washington, DC 20510-6200

Dear Senator:

On behalf of people with bleeding disorders, the Hemophilia Federation of America (HFA) is writing to express our deep concern with a recent letter sent to the Food and Drug Administration (FDA) by seventeen United States Senators requesting 'a review of the lifetime deferral requirement for men who have sex with men wishing to donate blood...and to reexamine the deferral criteria for all blood donors to ensure all high-risk behaviors are appropriately addressed' through the current donor deferral policy.

The HFA is a national non-profit organization that assists and advocates for individuals with bleeding disorders. HFA strives to ensure availability of medically necessary treatment and access to the full range of clotting factor therapies. HFA seeks to address the evolving needs of the bleeding disorders community, and advocates for safe, affordable, and obtainable blood products and health coverage, as well as a better quality of life for all persons with bleeding disorders.

As the end users of blood and plasma products, this issue is one of safety, science and the need to adhere to the precautionary principle. Reducing the deferral period of donors involved in high risk activities adds to the potential for error by increasing the supply of tainted donations. An infected unit could be released during a window period or due to a quarantine release error. Even with the safeguard of serology testing, the window period and quarantine release errors can only be intercepted by deferrals. Unfortunately, the loss of healthy donor deferrals is a consequence of ensuring blood-borne infectious diseases such as HIV or hepatitis are not transmitted through a blood transfusion.

**HFA seeks to protect end users, recipients of blood and plasma components, through a comprehensive blood safety policy based on the precautionary principle.** High-risk activities or behaviors, must adequately consider specific threats involving window period risks, viral variance, chronic carriers missed by serologic tests (infectious non-seroconverters), and testing errors.

We support a review of the current policy but in the absence of scientific consensus that the action or change in policy is not harmful, the burden to prove an action or change in policy is *not* harmful is the responsibility of those who advocate taking the action or making the change. Should you need additional information or suggestions for patient centric data, please contact us directly or HFA's Public Policy Director, Kisa Carter at [k.carter@hemophiliafed.org](mailto:k.carter@hemophiliafed.org) or 202-675-6984.

Regards,



Chad Stevens  
Board President



Kimberly Haugstad  
Executive Director

cc: Jay S. Epstein, M.D., Director, Office of Blood Research and Review  
Center for Biologics Evaluation and Research, Food and Drug Administration

Attachments: Supporting examples and references

**Supporting Examples and References:**

The FDA current policy can be found at:

<http://www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/QuestionsaboutBlood/ucm108186.htm>

<http://www.fda.gov/downloads/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/Transcripts/Minut>

According to data presented at the 2010 Centers for Disease Control and Prevention (CDC) Conference on National STD Prevention, the rate of new HIV diagnoses among men who have sex with men (MSM) is more than 44 times that of other men and more than 40 times that of women. Furthermore, the rate of primary and secondary syphilis among MSM is more than 46 times that of other men and more than 71 times that of women. (CDC, 2010)

World Hemophilia Federation's position: <http://www.wfh.org/index.asp?lang=EN>

Committee of Ten Thousand (COTT) Press Release:

<http://hemophiliafed.org/wp-content/uploads/2010/03/COTT-Press-Release-on-MSM.doc>