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Issues - Blood Safety

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the Personal Responsibility and Work Opportunity Reconciliation Act of 1996. These programs include Emergency Assistance, Job Opportunities and Basic Skills Training, and three child care programs authorized under Title IV-A of the Social Security Act.

- **Malformed Frogs and Environmental Health:** On December 4-5, a workshop on Strategies for Assessing the Implications of Malformed Frogs for Environmental Health will be held at the Conference Center at the National Institute of Environmental Health Sciences in Research Triangle Park, NC.

- **FDA Advisory Panels:** On December 11, an FDA advisory panel will discuss and make recommendations on FDA's blood donor deferral policy which excludes men who have had sex with another man even once since 1977. On December 12, the panel will make recommendations on *in vitro* detection of HIV viral load and will hear a presentation on hepatitis C virus risk in sexual partners of HIV-positive individuals. On December 17, another panel will discuss public health issues of xenotransplantation or cross-species transplantation, including detection and identification of infectious retro viruses.

- **Medicare Compare:** HCFA's Medicare Compare, the Managed Care Plans Comparison Database, is now available on the Internet. HCFA, realizing the importance of providing comparison information to beneficiaries and those who counsel them in their decision making process, has worked hard to make Medicare Compare valuable and easy to use. Since this is HCFA's first version of the database, continuous improvements will be made to Medicare Compare throughout the quarterly updating process.

- **Medicare + Choice User Fees:** On December 2, HCFA published a regulation which notifies Medicare risk contracting plans that HCFA will collect $95 million in user fees in FY98. The $95 million fee will be collected by deducting .428 percent from each risk plan's total monthly Medicare payment starting in January 1998. Medicare + Choice plans will also be subject to these user fees once they begin to contract with the Medicare program after regulations are developed in June 1998. The fees will be used by HCFA to fund the Congressionally mandated Medicare + Choice information campaign for all Medicare beneficiaries.

- **Smoking Cessation:** On December 12, AHCPR, as a part of their collaboration with the Robert Wood Johnson Foundation (RWJ) to assist health care delivery systems in making tobacco cessation a priority, will provide copies of the Smoking Cessation Systems Guide to include in a mailing by RWJ to 31,000 managed care professionals. The mailing formally announces an undertaking over the next four years that will provide informational, educational, and technical assistance to managed care organizations implementing cessation programs, primarily based on the recommendations in the AHCPR-sponsored Smoking Cessation Guideline. Other partners in this effort are the American Association of Health Plans and the Centers for Disease Control and Prevention.

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FACSIMILE COVER SHEET

DATE: _____

TO: Todd Sammers

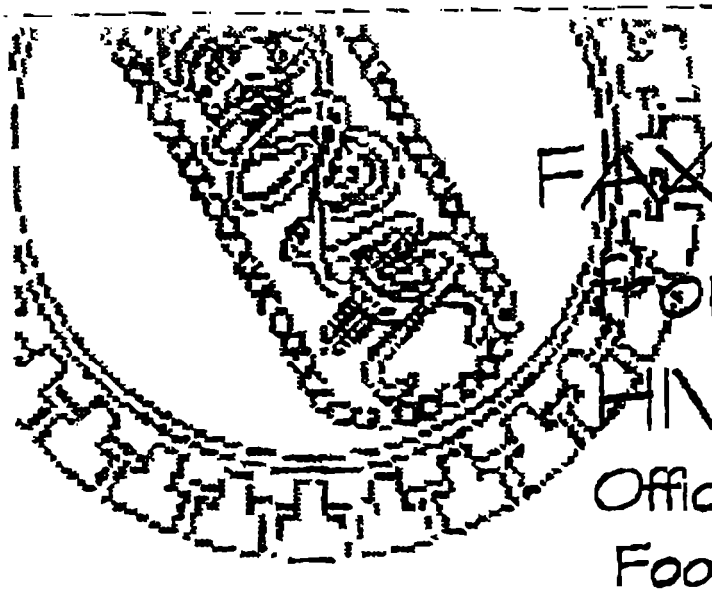
FROM:
___ Jane Silver
✓ Scott Sanders
___ Jim Oleson

TOTAL # OF PAGES: (INCLUDES COVER) 3

MESSAGE: Attached are the questions & the Committee votes on & their votes — Richard is around if you need details beyond what I know —

Have a good weekend!

S.



FAX Message
From Richard Klein
HIV/AIDS Program
Office of Special Health Issues
Food and Drug Administration

Date: 12/12/97
To: Scott Sanders. AmFAR
FAX No. 202 331 8606

Scott —

These are the Questions posed to the BPAC on MSM blood donors.

Richard

cover sheet plus 1 pages

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Blood Products Advisory Committee Meeting
December 11-12, 1997

Donor Deferral Policy Regarding Men Who Have Had Sex With Another Man, Even One Time, Since 1977

Questions:

1. Do the committee members agree that scientific data support the concept that history of male/male sex is a risk factor for transfusion-transmitted diseases? Unanimous Yes - 13 votes.

2. Do the committee members believe that FDA should ~~modify~~ reconsider its current recommendation that men who have had sex with men even one time since 1977 should not donate blood or blood components to be used for transfusion or further manufacturing? non-voting cons. rep = yes also. YES - 12 NO - 1 cons. rep - yes

3. If FDA's current recommendation should be modified, do the committee members agree with the following policy options? Tabled by vote of 8 yes 4 no 1 abst.

   a. Permanently defer men who have ever had sex with another man. cons. rep - yes

   b. Defer men who have had sex with another man in the last five years

   c. Defer men who have had sex with another man in the last two years.

   d. Defer men who have had sex with another man in the last 12 months

4. Are there other policy options that FDA should consider regarding male/male sex as a behavioral risk factor for donor deferral?

5. What additional studies are needed to clarify the underlying scientific issues?

Get more info on behavior.
" " " " analytical error.
Need studies of dif. Question formats - block risk factors - Computer questionaires

Retain policy but look for ways to modify - studies to clarify scientific issues around changing time limitations ⇒ Sero prevelance - Define what's in donor population. Study transmission issues ⇒ sex partners.

On behalf of the Gay and Lesbian Medical Association, I appreciate the opportunity to present our concerns about the FDA's blood donor deferral policy regarding men who have had sex with men since 1977. The Gay and Lesbian Medical Association is an organization of nearly 2,000 lesbian, gay, bisexual and transgendered physicians, medical students, and their supporters in all 50 states and 12 countries. Founded in 1981, GLMA works to promote quality health care for lesbian, gay, bisexual, and transgendered patients and to combat homophobia within the medical profession and in society at large.

As physicians, our members have a responsibility to their patients, to society, and to the public health. As an organization, GLMA has an additional responsibility to ensure that when health care policies are enacted they are based on sound scientific principles and evidence, and not on bias or prejudice against lesbian, gay, bisexual, or transgendered individuals.

Many of our member physicians provide physical and mental health services to a diverse population of lesbian, gay, bisexual, and transgendered patients. Additionally, a significant portion of our membership provides care to large numbers of HIV-infected

individuals. Our members' concerns regarding the deferral of men who have had sex with men is born out of this day-to-day experience of caring for a patient population that is frequently shunned, stigmatized, and often overtly discriminated against by society, health care institutions, and homophobic medical providers.

In 1983, AIDS was a new disease of unknown cause that was devastating the gay community—and that was presumed to be caused by a blood born pathogen transmissible by the exchange of semen and blood. Despite the lack of information available, GLMA was one of the first organizations to encourage gay and bisexual men who deemed themselves to be at risk or who had symptoms of AIDS to remove themselves from the blood donor pool. Simultaneously, as a means of helping to ensure an adequate blood supply, GLMA encouraged gay and bisexual men to find friends or family members who did not engage in behavior that put them at risk and who did not have symptoms of AIDS to donate blood.

GLMA's courageous stance early into the epidemic was possible because GLMA members were on the front-lines in addressing this new disease, and because GLMA members were some of the first physicians in the country to care for people who had AIDS. GLMA's

position was also consistent with the belief that all citizens of the U.S. have a civic responsibility to donate blood—a responsibility our country has historically encouraged.

When the FDA first developed blood donation guidelines in response to HIV/AIDS, little was known about the disease. Since that time, however, a number of new developments, most importantly the development of an HIV antibody test, have played a critical role in HIV/AIDS prevention, education, and treatment. Despite these developments, however, guidelines remain in place that continue to preclude certain people, such as gay men, from donating blood. These guidelines are commonly defended with the statement that "giving blood is a privilege, not a right"—a statement that flies in the face of the fact that giving blood has always been promoted as the responsibility of *all* citizens of the U.S. It is a statement that also ignores the scientific advancements that have allowed the FDA to develop a safe blood supply.

As you know, the current FDA recommendation states that any "male who has had sex with another male EVEN ONCE since 1977 . . . must not donate blood." Yet the advisory defers a woman who has had sex with that same man for only 12 months. Unless the FDA is willing to

recommend that screening of potential donors include asking what sex acts individuals are participating in, and then rank deferrals by the associated risk of oral, vaginal and anal sex, whether safer sex was used, and then factor in the number of sexual partners and concurrent drug use, such disparate deferral time periods between women and men and homosexual sex and heterosexual sex will continue to reflect bias and prejudice — and be discriminatory.

The deferral criteria was developed to protect the nation's blood supply and the workers who process blood donations. It was established during a time when anxiety about the nation's blood supply was high and scientific advancements in the detection of the HIV virus were slow in coming. In 1997, surely we do not intend to say that a man who had sex with another man in 1978 — 19 years ago — and has been celibate since cannot exercise his civic responsibility to give blood. Surely we do not intend to have a policy that does not permit a man who had oral sex with a man three years ago—and has tested negative for the HIV virus twice since then—to give blood yet welcomes a blood donation from a woman who anal sex with that same man 13 months ago. Surely we do not intend to have a policy that does not permit two men who have been in a

monogamous relationship throughout the AIDS epidemic from donating blood.

It is the responsibility of all people to assure an adequate and safe blood supply in the United States. Everyone must understand that they need to answer the screening questions honestly and self-defer if they may be at risk for being exposed to any disease that could be transferred through transfusion.

Any person having sex with multiple partners or unprotected sex with individuals whose serostatus or risk-factors are unknown, presents a possible risk to the blood supply — whether that person is male or female and whether their partners are of the same sex or the opposite sex. This activity should result in a finite deferral (as with gonorrhea and syphilis exposure). Similarly, an extended public health campaign should be undertaken to help the public understand who should give blood, who should self-defer from giving blood, and why. We need to remove the stigmatization from blood donor deferrals and emphasize that standards and protections apply to all people equally.

GLMA recommends that the FDA use the knowledge that has been gleaned from the ever-expanding field of AIDS research to create sound, logical and fair blood donation guidelines that today's significantly improved laboratory tests for HIV and a much better understanding of the "window" period of undetectable infections. If the FDA does not change its policy to better reflect the science of the epidemic it will confirm our worst fears—almost two full decades into this epidemic public health policy is politics as usual.

GLMA believes that it is *still* the responsibility of every individual to ensure that there is enough blood in our nation's blood supply and that it is *still* the duty of the federal government to ensure that *all* individuals in our society have an equal opportunity to meet that responsibility. To do less, when not scientifically or medically justified, is to make certain individuals in our society second class citizens.

The continued permanent deferral of HIV negative gay and bisexual men from donating blood is not scientifically justified, infringes on the rights of these individuals to meet their civic responsibilities, jeopardizes the availability of an adequate supply of blood products

throughout the nation, and is blatantly inconsistent with other deferrals.

GLMA believes that the Food and Drug Administration should immediately update the current donor deferral recommendations based on the best scientific information available in order to reflect equivalent standards of evaluating homosexual and heterosexual sex risks. This can be done to allow HIV negative persons with low risk behavior—regardless of sexual orientation—the opportunity to fully exercise the civic responsibility of donating blood. This change in policy would protect the nation's blood supply *and* uphold the basic tenet of citizenship—participation in society.

The Gay and Lesbian Medical Association is eager to work with you as you make your recommendations. Our members have a wealth of clinical and public health expertise that they would be happy to share with the FDA. Together we can ensure that appropriate standards that will protect the nation's blood supply are implemented. These standards should not be based on a donor's sexual orientation or the gender of their sexual partner.

Thank you for the opportunity to address you today. The nearly 2,000 members of GLMA are ready to provide any help you may need.

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TO: Todd Summers

FROM:
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TOTAL # OF PAGES: (INCLUDES COVER) 9

MESSAGE: Attached is the GLMA testimony from last week's FDA meeting.