Sunshine Meeting Notice

TIME AND DATE: 10:00 a.m., Wednesday, November 6, 1996.
STATUS: Closed.

MATTERS TO BE CONSIDERED:
1. Proposals relating to Federal Reserve System benefits.
2. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.
3. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION:
Mr. Joseph R. Coyne, Assistant to the Board; (202) 452-3204. You may call (202) 452-3207, beginning at approximately 5 p.m. two business days before this meeting, for a recorded announcement of bank and bank holding company applications scheduled for the meeting.

Dated: October 30, 1996.

Jennifer J. Johnson,
Deputy Secretary of the Board.

BILLING CODE 6210-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Clarification of Human Immunodeficiency Virus Screening Practices for Organ Donors

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In 1994, the Centers for Disease Control and Prevention (CDC) published revised guidelines for preventing transmission of human immunodeficiency virus through transplantation of human tissue and organs.1 The guidelines were developed to minimize the risk of HIV transmission to transplant recipients while maintaining the availability of suitable donor organs/tissues. In developing the document, CDC sought assistance from public and private health professionals, including expert consultants involved in organ/tissue transplantation, to ensure that the diverse circumstances surrounding transplants were considered. Reports from the organ procurement and transplantation community have indicated that, in attempts to ensure the highest level of safety, the guidelines have been interpreted in a way which has further compromised the already limited supply of human organs. The purpose of this notice is to clarify the recommendations concerning the use of organs from potential donors who test HIV-antibody negative but who have behavioral risk factors for HIV infection. The provisions in this notice apply only to screening of organ donors; they do not apply to screening of tissue, blood, or other donors.

FOR FURTHER INFORMATION CONTACT:
Martha F. Rogers, M.D., Division of HIV/AIDS Prevention, CDC, Mailstop E-45, 1600 Clifton Road, Atlanta, GA 30333, telephone 404-639-6130.

SUPPLEMENTARY INFORMATION: The prevention of HIV transmission from transplantation of human organs is based primarily on two considerations: (a) careful screening of potential donors for behaviors that place them at high risk of acquiring HIV infection; and (b) HIV-antibody testing of blood samples obtained from the potential donor. According to the 1994 guidelines, potential donors who test HIV-antibody negative but have one or more behavioral exclusionary criteria may be accepted as donors if

The risk to the recipient of not performing the transplant is deemed to be greater than the risk of HIV transmission and disease (e.g., emergent, life-threatening illness requiring transplantation when no other organs/tissues are available and no other lifesaving therapies exist). In such a case, informed consent regarding the possibility of HIV transmission should be obtained from the recipient.

CDC recognizes the life-extending and tissue-enhancing properties of organ transplantation. Therefore, when a potential organ donor tests HIV-antibody negative but has behavioral risk factors for HIV infection, the decision to accept an organ for transplantation should be made after consideration of the relevant risk factors for the individual recipient and with recognition of the very low incidence of HIV transmission in such situations. CDC recognizes the need for transplant centers, not organ procurement organizations, to deal with matters of patient consent in this setting.

In accepting an organ for transplantation, transplant teams should assess immediately the medical and

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1 CDC. Guidelines for preventing transmission of human immunodeficiency virus through transplantation of human tissue and organs. MMWR 1994;43(No. RR-8).
Food and Drug Administration

Notification of Plasma Product Withdrawals and Recalls; Notice of Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

SUMMARY: The Food and Drug Administration (FDA), the National Heart, Lung, and Blood Institute of the National Institutes of Health (NHLBI), and the Centers for Disease Control and Prevention (CDC) are sponsoring a meeting to discuss public notification of withdrawals and recalls of plasma-derived products. The goal of the meeting includes informing the public about available notification resources; describing the roles and responsibilities of public health service agencies, manufacturers, distributors, and private organizations in the notification process; stimulating discussion about improving the notification system; and soliciting public testimony regarding these issues.

DATES: The public meeting will be held on Tuesday, November 19, 1996, from 8 a.m. to 5 p.m. Registration for the public meeting is required by November 12, 1996. Written comments may be submitted at any time.

ADDRESSES: The public meeting will be held at the National Institutes of Health, Bldg. 10, Masur Auditorium, 9000 Rockville Pike, Bethesda, MD. Those persons interested in attending this meeting should fax their registration information, including name, title, firm name, address, telephone, and fax number, to the information contact person (below). Those persons interested in presenting information at the meeting should fax the above requested registration information and a copy or summary of their presentation to the information contact person (below). Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12240 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document.


SUPPLEMENTARY INFORMATION: Notifying users and recipients of plasma derivatives that are classified as recalled or market withdrawals in a timely and meaningful manner has emerged as an issue for FDA and the public health community. Recently, questions have been raised regarding how FDA and manufacturers reach these objectives, the role of other government agencies in the notification process, who should be notified, and the role of private organizations in disseminating information. Therefore, FDA, NHLBI, and CDC will hold a public meeting to allow interested persons to present their comments on these issues. Representatives from FDA’s Center for Biologics Evaluation and Research will chair the public meeting.

The main goal of this public meeting is to exchange information regarding the topics identified above. To achieve this goal, interested members of the public, including patient, industrial, medical, and regulatory communities are invited to attend the meeting. Public health service agencies will describe their roles and resources available for public notification of market withdrawals and recalls of plasma derived products. Manufacturers and distributors are requested to provide information regarding their procedures and roles regarding public notification. Private organizations, including volunteer groups and companies specializing in information dissemination, are requested to discuss their potential roles.

Persons interested in participating in the public meeting are requested to present their positions, rationales, and/or experiences regarding the following areas: (1) The nature and scope of notification regarding real or potential adverse experiences; (2) the timing of information dissemination regarding adverse experiences; (3) the best means of disseminating information; and (4) the means and level of notification that are needed, once a significant problem is identified. Information presented at this meeting will assist the sponsoring public health agencies in assessing the current mechanisms and efficiency of recipient notification, and will help to determine what future action may be appropriate.

Every effort will be made to accommodate each person who wants to present information at the public meeting. However, persons who want to ensure their participation at the meeting are encouraged, by the close of business on November 12, 1996, to fax to the contact person (address and fax number above) a written request for participation with the name, address, phone number, fax number, affiliation, topic of presentation, approximate amount of time requested for the presentation, and a copy or summary of their presentation. Public presentations will be limited to 5–10 minutes due to the time constraints of the meeting.

A schedule listing the persons making presentations and all presentation information submitted will be filed with the Dockets Management Branch (address above). The meeting schedule will be mailed or faxed to each presenter before the meeting. Interested persons attending the meeting who do not request an opportunity to make a presentation will be given an opportunity to make oral presentations at the conclusion of the meeting if time permits.

Transcripts of the public meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. The transcript of the public meeting and submitted comments will be available for public examination at the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.


William K. Hubbard,
Associate Commissioner for Policy Coordination.

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