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February 7, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville MD 20852

RE: Docket No. 99D-5347

"Precautionary Measures to Reduce the Possible Risk of Transmission of Zoonoses by Blood and Blood Products from Xenotransplantation Product Recipients and Their Close Contacts"

To Whom it May Concern:

The proposed guideline to "indefinitely defer" blood donations from xenotransplantation recipients, their close contacts and relevant hospital and laboratory personnel is inadequate and has no chance of protecting the U.S. blood supply as currently written. The mere fact that this blood guideline is being proposed demonstrates that xenotransplantation poses a threat to the public health and that previous draft guidelines from 1996--which also recommended blood bans from patients--are being ignored.

The FDA may be repeating mistakes it made while monitoring blood supplies during the AIDS crisis: by downplaying the risks of infection from pig viruses, suggesting weak blood donor screening strategies and by failing to offer a contingency plan in the event of a public health emergency.

The proposed guideline ignores the fact that, like "mad cow disease," symptoms of disease from a novel animal virus may not manifest themselves for decades after infection. At any given time, doctors and hospitals may determine that xenograft patients' close contacts are free of infection and able to give blood. But as with AIDS or "mad cow disease," these same individuals could develop a full-blown infection ten years down the road with devastating consequences for the blood supply. This guideline also ignores that, as with swine flu, some infections may be transmitted to casual contacts. Xenograft patients could transmit zoonotic diseases, not only to close contacts, but also to casual contacts who may unknowingly donate blood while infected with a zoonotic agent.

As happened during the AIDS crisis, and given some companies' failure to track patients treated with their xenotransplant products, it may be virtually impossible to locate all infected individuals or those who may have had contact with infected individuals. And it may be impossible to determine the original source of infection.

AIDS and the threat of "mad cow disease" have already reduced the number of blood donors in the U.S., Canada and abroad. FDA has acknowledged that if a xenotransplant-related virus entered the blood supply by mistake, the results would be disastrous." And yet it is unclear how the FDA plans to defer blood and plasma donations from xenograft patients and their contacts. Without clearly defined and standardized hospital procedures to prevent blood donations from these individuals, hospitals will be unable to safeguard the blood supply from zoonotic agents.

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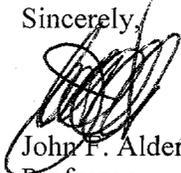
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Only a national, computerized, name-based registry listing the names and addresses of xenograft recipients and their contacts would allow the identification of these individuals, to prevent them from donating blood. Such a registry, however, is plagued by numerous legal problems, would be expensive to set up and manage, and will always be vulnerable to human error (such as if patients marry, change their names, relocate, or if hospital procedures are not carried out correctly.)

The Institute of Medicine and the General Accounting Office have already cited the FDA for its weak oversight of the nation's blood supply. The FDA has failed to provide appropriate oversight for human tissues infected with HIV and other viruses, for tracking and recall systems for defective medical devices, and medical implants. In 1996 the agency approved the use of a bioengineered plasma product that transmitted hepatitis A to hemophiliacs. We cannot afford any more public health disasters.

The FDA's current xenotransplant policy is based on containment rather than prevention of infectious diseases. If the FDA were truly interested in protecting the blood supply, it would ban xenotransplantation immediately.

Sincerely,



John F. Alderete, Ph.D.
Professor



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