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February 5, 2000

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852  
Via Fax: (301) 827-6870  
E-mail: fdadockets@oc.fda.gov

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"

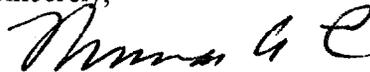
Dear FDA:

I wish to write in support of responsible scientific research and responsible use of the results of that research. I wish to support such research, not hinder it and think the serious work the FDA does to establish acceptable guidelines should be applauded.

I do not believe such rules should be made or promoted in Congress, nor by groups with unknown pedigree, such as the one from whom I received the enclosed email solicitation asking that I write in opposition to such research.

Thank you for the getting the best input on a challenging problem and opportunity and drawing sensible guidelines to promote responsible research and product development.

Sincerely,



Thomas A. Tisch

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99D-5347

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**THE FOLLOWING UNSOLICITED EMAIL SOLICITATION OF RESPONSE WAS RECEIVED FEB 5, 2000, AND IS ENCLOSED FOR REFERENCE ONLY. I DO NOT SUBSCRIBE TO THE CONTENTS OF THIS EMAIL:**

Date: Thu, 3 Feb 2000 18:53:27 -0500  
From: "alixfano" <alixfano@mindspring.com>  
Subject: "FrankenScience" ACTION ALERT - Sample E-Mail Included

PLEASE HELP PREVENT THE NEXT PLAGUE

XENOTRANSPLANTATION ACTION ALERT

Please Take a Moment to Send Off an E-Mail, Fax, or Letter to the FDA

DEADLINE: FEBRUARY 28, 2000

SAMPLE E-MAIL BELOW THIS MESSAGE

Dear Friends,

I am the Director of the Campaign for Responsible Transplantation (CRT) and I'm asking for your participation in this Action Alert. Founded in January 1998, CRT is an international coalition of physicians, scientists, and 80 public interest groups concerned about the misuse of genetic engineering technology. CRT was specifically launched to promote a ban on animal-to-human organ, cell and tissue transplantation (xenotransplantation), using parts from "humanized" pigs and nonhuman primates, because of the acknowledged risk of transferring potentially deadly animal viruses to humans. (see [www.crt-online.org](http://www.crt-online.org) to join us)

Multinational drug companies are investing millions of dollars to breed pigs with human genes, so their cells, tissues, and organs can be transplanted into humans.

The Food and Drug Administration, the World Health Organization and eminent scientists have acknowledged that xenotransplantation could transmit deadly animal viruses to patients and the general public. Baboon Cytomegalovirus was recently detected in stored blood from a recipient of a baboon liver who died in 1992. Pigs can carry bacterial, viral, fungal, protozoal and helminth pathogens, as well as prion proteins, implicated in "mad cow disease. Known pig viruses include the porcine endogenous retroviruses (PERVs) that have infected human cells. In 1998-99, the novel Malaysian "Nipah" virus jumped from pigs to humans, infected 269 people, killed over 100, left dozens brain-damaged, and led to the mass slaughter of one million pigs. The swine flu epidemic of 1918 killed 20-40 million people worldwide. We know relatively little about pig viruses, or animal viruses in general. There may be dozens waiting to be discovered.

The FDA, which is overseeing xenotransplantation, recently issued guidelines proposing that, xenotransplant patients, their "close contacts," and health care personnel, be barred from donating blood. CRT believes these guidelines are inadequate and short-sighted and will NOT protect the public health.

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CRT wants a xenotransplantation ban. CRT believes we should be preventing disease before it starts, to shrink the number of people on transplant waiting lists, investing in safer areas of research, such as cultivating human tissue for transplantation, and increasing human organ donation through legislation, as several European countries have done.

Please send your letters, faxes and e-mails to the FDA immediately. Be sure to include the Docket Number.

(Please Delete All References to This ACTION ALERT in Your Correspondence to FDA.)

Thank you!  
Alix Fano, MA  
Director  
Campaign for Responsible Transplantation  
<http://www.crt-online.org>

SAMPLE LETTER BELOW:

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Date, 2000

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Via Fax: (301) 827-6870  
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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.

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

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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 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.

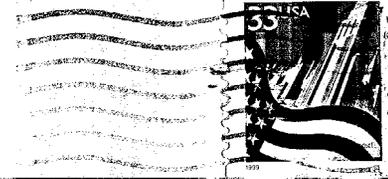
Only a national computerized name-based registry, listing the names and addresses of xenograft recipients and their contacts would allow the identification of these individuals, to prevent them from donating blood. Such a registry, however, is plagued by numerous legal problems; would be expensive to 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. 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.

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,  
Name  
Address  
City, State, Zip

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