

**ANIMAL
ALLIANCE
OF CANADA**

*Animal
Protection
through
Education &
Advocacy*

February 27, 2000

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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"

To whom it may concern :

On behalf of the Animal Alliance of Canada and our over 20,000 supporters across Canada, I would like to express our concerns about the proposed guideline for xenotransplantation recipients. Naturally, these concerns are based on the fact that the guideline will have implications not only on U.S. and Canadian citizens, but also on people around the world.

Animal Alliance of Canada is a national animal protection organization dedicated to long-term animal protection through education and legislative advocacy. We are deeply concerned with the concept of using animal cells, tissues and organs as a human replacement therapy. It is vital that the public be fully informed about the effects of this technology and, it is the role of health officials to ensure that this happens in an open and accessible manner.

We believe that the provision, as currently written, 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. or Canadian blood supply as currently. It is well-known that U.S. blood has been used in Canada. Hence a contamination of the U.S. blood supply will also mean one for Canada as well.

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Only a national computerized name-based registry with a direct link to an international registry, listing the names and addresses of patients and their close contacts would enable the appropriate authorities to prevent recipients from donating blood.

Unfortunately, such a registry, is plagued by problems: it is unduly invasive of privacy and restrictive of liberty; its procedures cannot be legally enforced; it 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.)

Moreover, the proposed guidelines ignore the fact that some viruses are latent. Xenotransplantation circumvents the species-barrier that exists to preserve the integrity of all species. It provides the mechanism from which viruses that have established a stable relationship with their host species are "suddenly" introduced into a new environment. The outcome and manifestation of this union, no researcher or scientist can predict. It is unclear whether agents, for example the pig virus that is responsible for "mad cow disease" and "Creutzfeld-Jakob Disease (CJD), lie dormant for decades after infection. Needless to say, their effects have devastating consequences for the blood supply. The guidelines also arbitrarily ignore the fact that some viruses may be transmitted like the common cold. Xenograft patients, therefore, could transmit zoonotic diseases, not only to close contacts, but to casual contacts who may unknowingly donate blood while infected with a new pig virus.

Because humans have been receiving cells, tissues and organs from animals for decades, all xenograft guidelines, including this one, are being proposed in hindsight. The absence of national and international name-based registries for xenograft patients and their contacts is astonishing, since these individuals may have already engaged in risky behaviours and/or donated blood. We would further contend that to date, the response of the FDA to xenotransplantation has been a result of industry demands, rather than public concerns.

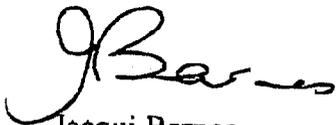
The threat of "mad cow disease" has already reduced the number of blood donors in the U.S., Canada and abroad. With the threat of known and unknown xenotransplant-related diseases, and the need to exclude xenograft patients and their "intimate" and "casual" contacts from donating blood, xenotransplantation will have the effect of shrinking the blood donor pool, and will thus exacerbate existing blood shortage problems.

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When dealing with infectious diseases, a public policy based on containment is unacceptable. If it truly wanted to protect the blood supply and the public health, the FDA must ban xenotransplantation (pre-clinical and clinical) research immediately.

Sincerely,



Jacqui Barnes
Director