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Via Fax: (301) 827-6870

January 12, 2000

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

Re: Docket No. 99D-5347

RE: 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 Sir or Madam::

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.

Only a national computerized name-based registry, listing the names and addresses of patients, their close contacts, and relevant health care personnel, would allow the identification of these people, to prevent them from donating blood.

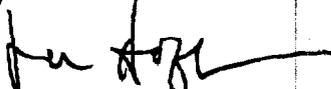
Such a registry, however, is plagued by problems: it is unduly invasive of privacy and restrictive of liberty; its procedures cannot be legally enforced; it would be expensive to set up and manage; and will always be vulnerable to human error (such as if a patient gets married, changes their name, relocates, or if database or hospital procedures are not explained or carried out correctly.)

Moreover, the proposed guidelines ignore the fact that some viruses are latent. Like mad cow disease; symptoms of disease from a pig virus, for example, may not manifest themselves for decades after infection, with 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 also 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 people may have already engaged in risky behaviors and/or donated blood.

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, their contacts, and health care personnel from donating blood, xenotransplantation will have the effect of shrinking the blood donor pool, and will thus exacerbate existing blood shortage problems.

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 would embrace prevention, and would ban xenotransplantation immediately.

99 D-5347 Sincerely,


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To the Honorable _____
Date: _____
U.S. House of Representatives
Washington, D.C. 20515

The Fiscal Year 2001 budget to be submitted by the Executive Branch of the government contains a provision whereby the Food and Drug Administration (FDA) is to be appropriated ten million dollars a year to police the Internet. I am vehemently opposed to my tax dollars being used to fund the FDA for this purpose. I believe that additional FDA power and funding would be used to deprive the American people of valuable health information and health products.

In the FY 2001 budget proposal, the FDA is asking Congress to pass new law that would give the agency repressive powers that would restrict the free flow of information on the Internet. I ask that you vote against any proposed law that gives the FDA more control over what I am allowed to read and put into my body. Some of the unconstitutional authority the FDA is seeking includes:

- Issuing subpoenas without a court order. Giving the FDA this new power is unconstitutional, and would will create a litigation monster whose annual appetite would rapidly exceed the ten million dollars a year the agency is seeking.
- Fining Internet pharmacies \$500,000.00 every time they sell a drug that does not meet the FDA's definition of a legal prescription. This type of excessive fine would enable the FDA to bankrupt any online pharmacy it decides to target in a capricious and arbitrary manner.
- Setting up "a rapid response team" to identify, investigate, and prosecute Web sites, i.e., the FDA is seeking to establish an army of storm-troopers to summarily shut down any web site it chooses.

Please do not be misled by the FDA's attempts to convince you that they are trying to protect the health of the American people by regulating the Internet. According to the April 15, 1998 issue of the Journal of the American Medical Association, adverse reactions to legally prescribed FDA-approved drugs are the fourth-to-sixth leading cause of death in the United States. Since this article was published almost two years ago, the FDA has done nothing to reduce the number of Americans dying from dangerous drugs, yet the FDA now seeks ten million tax dollars a year to attack health and pharmacy Web sites.

If the FDA convinces Congress to grant it more power and money to attack health web sites, American consumers will be denied access to innovative therapies and pay a lot more for their prescription drugs. I therefore ask that you write to me with your position on this issue so I will know how to cast my ballot this election.

Sincerely,

Name _____

Street _____

City _____ ST _____ Zip _____