

Re: Docket No. 99D-5347

Date, Feb. 11, 2000

Dockets Management Branch (HFA-305) 7Fp5d and Drug Administration FEB 14 08:42

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"Precautionary Measures are needed! Xenotransplantation could transmit deadly animal viruses to patients and the general public. Xenotransplantation ban.

Letter to FDA:

From: Lorraine Craig 25 1 st ave, verdun Qcm Montreal Canada h4g2v2

DEAR SIR OR MADAME:

Multinational drug companies (as you know) 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 scientists have acknowledged that xenotransplantation could transmit deadly animal viruses to patients and the general public. We know relatively little about pig viruses, or animal viruses in general. There may be dozens waiting to be discovered.

As the FDA, is overseeing xenotransplantation, recently issued guidelines proposing that, xenotransplant patients, their "close contacts," and health care personnel, be barred from donating blood.

Perhaps those guidelines are still inadequate and short-sighted

It will **NOT** protect the public health in the long run.

As a private citizen, I ask you to endorse a xenotransplantation ban. There are many other options available ie: Increasing human organ donation through legislation, as several European countries have done.

The proposed guideline ignores the fact that, like "mad cow disease," symptoms of disease from a novel animal virus may not show up for decades after infection. It seems this is not a wise choice. As with AIDS or "mad cow disease," individuals could develop a full-blown infection ten years down the road, with more hellish consequences for the blood supply. Like swine flu, some infections could be transmitted to casual contacts who could donate blood while infected.

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How will all those who are infected be traced?

The FDA has already admitted that if such a virus entered our blood supply by mistake, the results would be "disastrous". It is unclear how the FDA plans to screen blood donations from xenograft patients/ and thier contacts. Without clearly defined and standardized hospital procedures to prevent blood donations from these individuals, hospitals will be unable to safeguard the blood supply.

Perhaps a Clearing-House for screening would be a good idea even though it will never be a perfect solution.

In Canada we have had many problems with the **blood supply**. Many have **died**. **Precaution** should be the operative word. The Institute of Medicine and the General Accounting Office have already sited the FDA for poor oversight of the American blood supply. Remember HIV? And the approved use of a bioengineered plasma that transmitted hepatitis A to hemophiliacs. We cannot afford any more public health disasters.

When do we learn our lessons from the past?

Containment, is not prevention. If the FDA were truly interested in protecting the blood supply, it would ban xenotransplantation today!

Sincerely,

Romane Craig

Thank you!