

March 15, 2001

U. S. Food and Drug Administration
Dockets Management Branch
5630 Fishers Lane, Room 1061
Rockville, MD 20852

5321 '01 MAR 21 P1:24

Re: Docket number 00N-0989

Dear Sir or Madam:

I am writing regarding the proposed rule that would provide public access to most information on clinical trials involving gene therapy and xenotransplantation. I support this proposed rule strongly. The public ought to be aware of the latest work in both these potentially dangerous areas. Much of the information that would be disclosed about gene therapy under the proposed rule is already publicly discussed in open meetings of the Recombinant DNA Advisory Committee of the National Institutes of Health. Information about xenotransplantation trials will also be available publicly through the Secretary's Advisory Committee on Xenotransplantation.

The proposed rule will merely allow the public access to the same types of information available from other government agencies under the Freedom of Information Act. Because of serious risks to human health, all information should be made available except for patient identification. The FDA should be responsible for summarizing and distributing information submitted by the research sponsor, rather than leave it to the sponsor's discretion.

I am very opposed to xenografts and xenotransplants. The threats of inter-species viral transmission are too great. All inter-species grafts and transplants should be banned, including pigs as source animals. Pig viruses are just as dangerous as non-human primate viruses. Furthermore, there has never been a successful case of an animal organ being transplanted into a human being. Every single recipient has died after receiving an animal organ. Finally, the concept itself of sacrificing animals for use of their organs is wrong. It is presumptuous and arrogant to treat animals as if their sole reason for being is to satisfy our needs. Animals have intrinsic value and worth, apart from their relationship to the human race.

The United States should follow Europe's lead. In January 1999, the Council of Europe recommended a worldwide ban on xenotransplants. There are safer and more humane alternatives to xenotransplantation, such as aggressively promoting preventative medicine and increasing human organ donations. Please stop all xenotransplantation clinical trials.

Thank you very much for your consideration of this matter.

Yours truly,



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