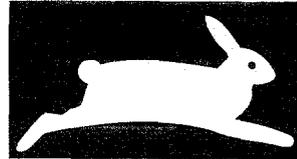


28th February 2001

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Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane
Room 10-61 HFA-305
Rockville, MD 20852

*Re: Docket No. 00N-0989
Public Comments*

On behalf of People for the Ethical Treatment of Animals (PETA) and our over 700,000 members, I submit the following public comments regarding a proposed rule by the Food and Drug Administration (FDA) to provide public access to study design and safety information for all new or ongoing trials involving gene therapy and xenotransplantation. PETA is opposed in principle to xenotransplantation, and has called on the U.S. government to immediately discontinue its funding of xenotransplantation research, and for the FDA to prohibit clinical trials in this area. That being said, we recognize the dangers inherent in these new technologies and the importance of extensive review and consideration of these issues by an informed public.

The proposed FDA rule will bring the agency's standards for public access to information regarding gene therapy and xenotransplantation in line with equivalent standards at other federal agencies. Moreover, the substantial public health risks posed by these new technologies merit the disclosure of such additional information as the names of physicians performing clinical trials, the names of participating medical centers where they are being carried out, and other related information. Exceptions should be limited to personal information regarding individual patients and the trade secrets of corporations.

The exclusive responsibility for summarizing and distributing information under the proposed rule should lie with the FDA; this important function must not be left to the discretion of the research sponsors.

On behalf of PETA and our 700,000 members, I thank the FDA for its consideration and hope the agency will act responsibly.

Yours truly,

Troy Seidle, B.Sc.

~ Research Associate ~

Research, Investigations & Rescue Department

00N-0989

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ORGANIZATION DEDICATED
TO PROTECTING
THE RIGHTS OF ALL ANIMALS

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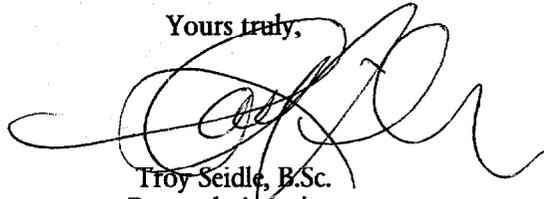
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