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March 17, 2001

Docket No. 00N-0989  
Dockets Management Branch  
Food and Drug Administration  
5630 Fishers Lane  
Room 10-61 HFA-305  
Rockville, MD 20852

Re: Docket No. 00N-0989

To whom it may concern,

I am writing in support of a proposed rule that would provide public access to study design and safety information on all new or ongoing clinical trials involving either gene therapy or xenotransplantation. Both are potentially dangerous areas that the public should know about. This proposed rule only brings gene therapy and xenotransplantation in compliance with the same types of information already released to the public by other government agencies.

Because of the grave public health risks, disclosure should include additional information such as names of physicians and participating medical centers. All information should be made public except trade secrets and patient identification. The FDA must assume the sole responsibility for summarizing and distributing information submitted by the research sponsors, rather than leave it to the sponsors' discretion.

I strongly believe that because of the public health risks, legal and ethical issues, enormous cost, serious animal welfare concerns, and the failure to adequately assess other alternatives, all xenotransplantation clinical trials should stop. Moreover, taxpayer moneys should not fund xenotransplantation research.

Sincerely,



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