

ROBERT L. TRIMBLE

9641 '01 MAR -5 A10:53

February 27, 2001

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

Re: Docket No. 00N-0989

Ladies and Gentlemen:

I support FDA's 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. Because of the grave public health risks, disclosure should also include additional information such as names of physicians conducting the trials and names of participating medical centers. All information should be made public except trade secrets and patient identification. In providing this information, 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.

Finally, 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, the U.S. government should stop funding xenotransplantation research.

Sincerely,



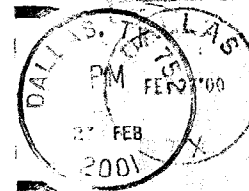
Robert L. Trimble

/lh

00N-0989

C6

Robert L. Trimble
100 Crescent Ct., #250
Dallas, TX 75201



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

20852+0001 