

March 15, 2001

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

To Whom It May Concern:

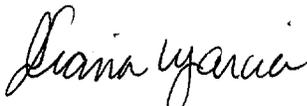
A proposed rule, docket number 00N-0989, from the FDA would provide public access to most of the study design and safety information on all new or ongoing clinical trials involving either gene therapy or xenotransplantation.

This proposal 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 grave public health risks, disclosure should include additional information such as physicians, medical centers, and so on – make public all information except trade secrets and patient identification.

The FDA must assume the sole responsibility for summarizing and distributing information submitted by the research sponsor, rather than leave it to the sponsor's discretion.

Because of the public health risks, ethical issues, cost uncertainty, and the inability to adequately assess other alternatives, all xenotransplantation clinical trials should stop.

Sincerely,



Diana Garcia

00N-0989

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