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March 6, 2001

U.S. Food and Drug Administration
Dockets Management Branch
5630 Fishers Lane, Room 1061
HFA-305
Rockville, Maryland 20853

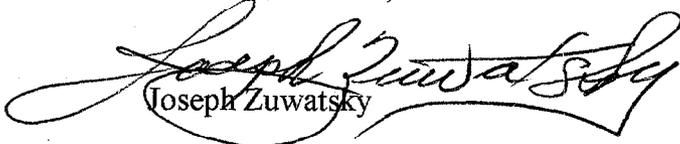
Re. Docket number 00N-0989

U.S. Food and Drug Administration, Dockets Management Branch:

Based on the following I believe it is in the public interest for the Food and Drug Administration (FDA) to 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 FDA proposal only brings gene therapy and xenotransplantation in compliance with the same types of information released to the public by other government agencies. Because of grave public health risks disclosure should include information on physicians, medical centers and so on. Make public all information except trade secrets and patent information.
- ◆ 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.

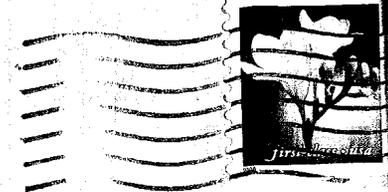
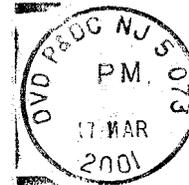
For all the animals,


Joseph Zuwatsky

00N-0989

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