

**Jane Hoffman
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March 7, 2001

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

2739 01 MAR 13 P1:33

Re: to Docket Number 00N-0989

Dear Sir or Madam:

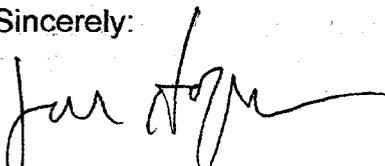
I understand a proposed rule from the Food and Drug Administration (FDA) would provide public access to study design and safety information on all new or ongoing clinical trials involving either gene therapy or xenotransplantation. I believe that both gene therapy and xenotransplantation are potentially dangerous areas affecting public health and that the public has a right to know about any such clinical trials.

Please keep in mind the following points:

- 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 conducting the trials and names of 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.
- 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 immediately.

Thank you for your attention;

Sincerely:


00N-0989

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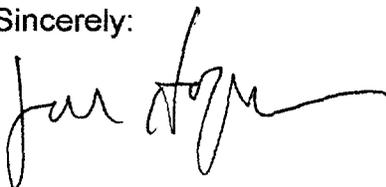
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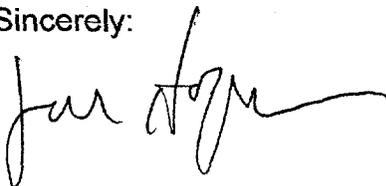
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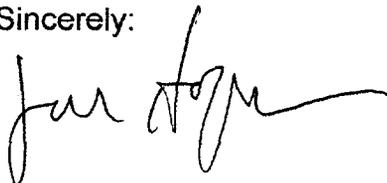
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