

Docket Number

00N-0989

A proposed rule from the Food and Drug Administration (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.

The FDA would not release confidential business information or personal information related to study participants.

In human gene therapy, the biological properties of living cells are altered for therapeutic use. Xenotransplantation is the transfer of organs from an animal to a human.

Much of the information that would be disclosed about gene therapy trials under this proposal is already publicly discussed in open meetings of the Recombinant DNA Advisory

Committee of the National Institutes of Health. Similarly, information about xenotransplantation trials

will also be publicly available through the 18-member Secretary's Advisory Committee on Xenotransplantation.

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March 20, 2001

I am writing to oppose xenotransplants. It is essential that the public know exactly what is going on in the fore front of medicine. Gene therapy and xenotransplants are potentially dangerous, that can threaten everyone.

I urge consideration of the following points:

- 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. C24

Thank you for your consideration,

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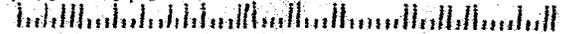
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