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US Food & Drug Administration
Dockets Management Branch
5630 Fishers Lane
Room 1061
HFA-305
Rockville, MD 20852

Docket No.: 00N-0989.

A proposed rule 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.

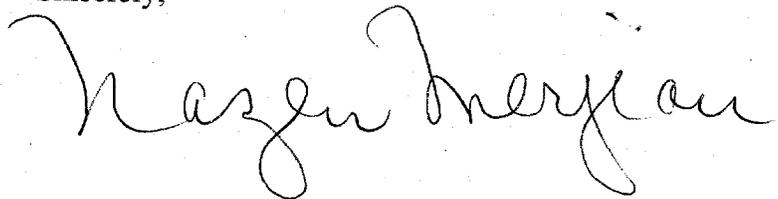
Much of what would be disclosed is already publically discussed in open meetings of the Recombinant DNA Advisory Committee of the NIH. Information about xenotransplantation trials will also be publically available through the Secretary's Advisory Committee on xenotransplantation.

Disclosure should include additional information such as physicians, medical centers, etc. and to make public all information 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,



Nazen Merjian
VFA

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