Docket number 00N-0989

3/9/01

Dear FDA,

218 '01 MAR 16 P3:34

Your proposal regarding gene therapy and xenotransplantation only lumps 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

he stopped.

Thank you,
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