

Know



nant 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, on which API Executive Director Alan Berger represents the animal advocacy movement.

"The public must know what's going on

in the forefront of medicine," said Alan. "Gene therapy and xenotransplants are potentially dangerous areas that can threaten us all."

You can help. There is a 90-day public comment period on the proposal.

In your comments, **due by April 18, 2001**, point out that:

- 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.

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 Recombi-

- 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.

You must refer to docket number 00N-0989 in your letter.

You must send your original letter and three copies to the FDA.

Contact:

U.S. Food and Drug Administration; Dockets Management Branch; 5630 Fishers Lane; Room 1061; HFA-305; Rockville, MD 20852; fax 301-827-6870; email "fdadockets@oc.fda.gov".

*This is very disturbing
Sincerely,
Mary Jo Furlano*



ANIMAL PROTECTION INSTITUTE

Mailing Address:
P.O. Box 22505
Sacramento, CA 95822

Street Address:
2831 Fruitridge Road
Sacramento, CA 95820

Ph. 916.731.5521
Fx. 916.731.4467
www.api4animals.org
info@api4animals.org



Recycled Paper/Soy Inks/Recyclable

00N-0989

C22



Ms. Marilyn L. Furlano
1111 Orange Ave.
Coronado, CA 92118



U.S. Food & Drug Administration
Dockets Management Branch
5630 Fisher's Lane Room 1061
HFA-305
Rockville, MD.

20237/0001

