U.S. House of Representatives
Committee on Commerce
Room 2125, Rayburn House Office Building
Washington, DC 20515–6115

April 3, 2000

The Honorable Jane Henney, M.D.
Commissioner
Food and Drug Administration
Room 14-71 (HF-1)
5600 Fishers Lane
Rockville, Maryland 20857

Dear Dr. Henney:

Pursuant to Rules X and XI of the U.S. House of Representatives, the Committee continues its examination of the adequacy of the FDA's oversight of gene transfer clinical trials. In particular, the Committee is concerned about how FDA handles adverse event information received from gene transfer clinical trials, with the NIH, clinical investigators, and sponsors. For example, the death of 18-year-old Jesse Gelsinger in the gene transfer clinical trial at the University of Pennsylvania has raised questions about the adequacy of FDA's oversight and the appropriateness of FDA's actions with regard to this matter.

To assist the Committee's inquiry, please provide the following material by April 13, 2000:

1. All records relating to all deaths possibly and/or probably associated with gene transfer clinical trials received by FDA since January 1, 1996.

2. All records relating to the experiment that resulted in the death of Jesse Gelsinger.

3. All records relating to communications between FDA and NIH concerning adverse drug events in gene transfer clinical trials, including the new interagency agreement on the sharing of confidential information.

4. A list and total number of gene transfer clinical trials and protocols for each category of vector (i.e., adenovirus, liposomes, naked DNA) used and the total number of gene transfer clinical trials and protocols. Please note currently open INDs, versus historic.

5. All records relating to all meetings, plans, and responses to appropriations measures to establish a database on gene transfer clinical trials, especially records relating to discussions with the NIH about collaborative database development.

6. All records relating to standard procedures and paperwork flow, for handling receipt of or processing of annual reports and adverse event reports.

7. All records relating to any FDA statements before government and/or scientific bodies concerning the risks and benefits of a particular gene transfer clinical trial, or gene transfer clinical trials, generally.

Please note that, for the purpose of responding to these requests, the terms "records" and "relating" should be interpreted in accordance with the attachment to this letter.

Furthermore, it may be necessary for Committee staff to interview FDA employees. Accordingly, we request that this letter serve as a general request that you make available to us FDA employees for interviews. No FDA personnel other than the interviewee will be permitted at the interview. The FDA employee has the option to appear alone, with private counsel, or with a counsel from the Department's Office of General Counsel who has no reporting relationship with the FDA or any individual at FDA. The purpose of these interviews would be to allow for more open and candid discussions between FDA personnel and Committee staff.

Thank you for your assistance. If you have any questions, please have your staff contact Alan Slobodin of the Majority Committee staff at (202) 225-2927 or John Ford of the Minority Committee staff at (202) 226-3400.

Sincerely,

Tom Bliley
Chairman

John D. Dingell
Ranking Member

Fred Upton
Chairman
Subcommittee on Oversight and Investigations

Ron Klink
Ranking Member
Subcommittee on Oversight and Investigations

Attachment

ATTACHMENT

1. The term "records" is to be construed in the broadest sense and shall mean any written or graphic material, however produced or reproduced, of any kind or description, consisting of the original and any non-identical copy (whether different from the original because of notes made on or attached to such copy or otherwise) and drafts and both sides thereof, whether printed or recorded electronically or magnetically or stored in any type of data bank, including, but not limited to, the following: correspondence, memoranda, records, summaries of personal conversations or interviews, minutes or records of meetings or conferences, opinions or reports of consultants, projections, statistical statements, drafts, contracts, agreements, purchase orders, invoices, confirmations, telegraphs, telexes, agendas, books, notes, pamphlets, periodicals, reports, studies, evaluations, opinions, logs, diaries, desk calendars, appointment books, tape recordings, video recordings, e-mails, voice mails, computer tapes, or other computer stored matter, magnetic tapes, microfilm, microfiche, punch cards, all other records kept by electronic, photographic, or mechanical means, charts, photographs, notebooks, drawings, plans, inter-office communications, intra-office and intra-departmental communications, transcripts, checks and canceled checks, bank statements, ledgers, books, records or statements of accounts, and papers and things similar to any of the foregoing, however denominated.

2. The terms "relating," "relate," or "regarding" as to any given subject means anything that constitutes, contains, embodies, identifies, deals with, or is in any manner whatsoever pertinent to that subject, including but not limited to records concerning the preparation of other records.