DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

FEB 0 9 2000

The Honorable Henry A. Waxman
U.S. House of Representatives
Washington, D.C. 20515

Dear Mr. Waxman:

I am writing in reply to your letter of January 31 to Dr. Ruth Kirschstein, Acting Director of the National Institutes of Health (NIH). You requested copies of the 652 serious adverse events cited in the December 21, 1999, letter from Dr. Varmus. We are pleased to respond to your request for additional information.

Copies of all of the serious adverse events that you requested are enclosed in notebooks marked 1 and 2. It is important to understand that these events were submitted to NIH in response to a special request to investigators issued October 1, 1999, for safety and toxicity data on human gene transfer studies using adenoviral vectors. These data represent serious adverse events in adenoviral vector studies over a six-year period starting in 1994 when the first adenovirus-based protocol began.

In your letter of January 10, you requested information about serious adverse events in gene transfer trials that employ other types of vectors. Therefore, we are also providing a compilation of all adverse event information for all human gene transfer trials that has been submitted to the NIH from 1989 through 1999. These are contained in notebooks marked 3, 4, and 5. The reports contained in these notebooks encompass all clinical trials using all viral-based vectors as well as non-viral delivery systems. Some of the adverse events were submitted by investigators when the event occurred. Other event reports were submitted in response to two requests for cumulative data made in April 1995 and July 1999. Please note that there will be some overlap between the information contained in notebooks marked 3, 4, and 5, and the adverse events in notebooks 1 and 2 that were reported in response to the October 1, 1999, request.

The adverse event data contained in the five notebooks are organized by the NIH/RAC protocol number. To facilitate your review, we have enclosed a list of the current gene transfer protocols registered with the NIH. The list includes the protocol number, title, and summary information (including the gene transfer system used in each experimental protocol).

The NIH appreciates your ongoing interest in our efforts to provide oversight of gene transfer clinical studies. If you need any additional information or have questions about the enclosed materials, please do not hesitate to let me know.

Sincerely,

Lana Skirboll

Lana Skirboll, Ph.D.
Director
Office of Science Policy

Enclosures: Protocol list and notebooks 1-5