DAN BIRTON, INDIANA CHAIRMAN

CHARRAN

BENJAMIN A. GLMAN, NEW YORK

J. DENNIS HASTERT, ILLINOIS

CONSTANCE A. MORELLA, MARYLAND

CHRISTOPHER SHAYS, CONNECTICUT

STEVEN SCHIFF, NEW MEXICO

CHRISTOPHER COX, CALIFORNIA

LEANA ROS-LEHTINEN, FLORIDA

JOHN M. MCHUGH, NEW YORK

STEPHEN HORN, CALIFORNIA

JOHN C. MICA, FLORIDA

THOMAS M. DAVIS III, VIRGINIA

DAVID M. MCHTOSH, RIDIANA

MARK E. SOUDER, INDIANA

JOE SCARBOROUGH, FLORIDA

JOHN SHADEGG, ARIZONA

STEVE C. LATOURETTE, OHIO

MARSHALL "MARK SANFORD, SOUTH CAROLINA

JONN E. SUNDURL NEW HAMPSHIRE

FETE SESSIONS, TEXAS

MIKE PAPPAS, NEW LERSEY

VIRCE SNOWBARGER, KANSAS

DOB BARR, SCORGIA

ROS POORTMAN, OHIO

ONE HUNDRED FIFTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON GOVERNMENT REFORM AND OVERSIGHT 2157 RAYBURN HOUSE OFFICE BUILDING WASHINGTON, DC 20515-6143

> MAJORITY (202) 226-5074 MHICRITY (202) 225-5051 TTY (202) 225-6852

February 2, 1998

HENRY A. WAXMAN, CALIFORNIA RANKING MINORITY MEMBER

TOM LANTOS, CALIFORNIA BOB WISE, WEST VINGINIA MAJOR R. OWENS, NEW YORK EDOLPHUS TOWNS, NEW YORK EDOLPHUS TOWNS, NEW YORK EDOLPHUS TOWNS, NEW YORK ALLE CALIFORNIA CARDAYN B. MALCHEK, NEW YORK THOMAS M. BARRETT, WISCONSIN ELEANOR HOLMES NORTON, DISTRICT OF CALUMAINE, MARYLANIA CHAKA FATTAH, PENNSYLVANIA CHAKA FATTAH, PENNSYLVANIA CHAKA FATTAH, PENNSYLVANIA CHIMES KUCINICH, CHICO SOON BOOK ALLINOIS DANNY K. DAYIS, ILLINOIS JOHN F. TIERNEY, MASSACHUSETTS JIM TURNER, TEXAS THOMAS H. ALLEN, MAINE

BERNARD SANDERS, VERMONT INDEPENDENT

Michael A. Friedman, Acting Commissioner U.S. Department of Health and Human Services Food and Drug Administration Parklawn Building - 5600 Fishers Lane Rockville, Maryland 20857

Dear Commissioner Friedman:

As you may know, the Committee on Government Reform and Oversight will hold hearings on the Food and Drug Administration in February. On February 4, the Committee is scheduled to receive testimony from several witnesses who have been patients in clinical drug trials or researchers in clinical drug trials. Because we would like to be adequately informed about the nature of their concerns, we are requesting that you provide a pre-hearing briefing concerning the clinical trials and individual case histories of the following people:

Mr. Berkeley Bedell

Mr. Jack Kunnari

Mr. Dustin Kunnari

Ms. Genevieve Sherman

Ms. Becky Nippert

Ms. Mary Jo Seigel

Ms. Ann Fonfa

Additionally, we are requesting a briefing concerning the clinical trials or other FDA regulated activities which the following researchers may have been involved:

Charles Simone, M.D. Arnold Eggers, M.D. Ralph Moss, Ph.D.

This request is being sent to you pursuant to 5 U.S.C. sec. 2954, which requires all Executive agencies "on request of ... any seven members" of the Government Reform and Oversight Committee to "submit any information requested of it relative to any matter within the jurisdiction of the committee."

Michael A. Friedman February 2, 1998 Page 2

Please contact Phil Barnett, Minority Chief Counsel by the end of today to arrange such a briefing. If you have any questions, Mr. Barnett can be reached at (202) 225-5051.

Sincerely,

Paul E. Kanjorski

Carolyn B. Maloney

Eleanor Holmes Norton

Tom Lantos

Edolphus Towns

Bernard Sanders

Elijah . Cummings