

HENRY A. WAXMAN, CALIFORNIA
EDWARD J. MARKEY, MASSACHUSETTS
RICK BOUCHER, VIRGINIA
EDOLPHUS TOWNS, NEW YORK
FRANK PALLONE, Jr., NEW JERSEY
BART GORDON, TENNESSEE
BOBBY L. RUSH, ILLINOIS
ANNA G. ESHOO, CALIFORNIA
BART STUPAK, MICHIGAN
ELIOT L. ENGEL, NEW YORK
ALBERT R. WYNN, MARYLAND
GENE GREEN, TEXAS
DIANA DeGETTE, COLORADO
VICE CHAIRMAN
LOIS CAPPS, CALIFORNIA
MIKE DOYLE, PENNSYLVANIA
JANE HARMAN, CALIFORNIA
TOM ALLEN, MAINE
JAN SCHAKOWSKY, ILLINOIS
HILDA L. SOLIS, CALIFORNIA
CHARLES A. GONZALEZ, TEXAS
JAY INSLEE, WASHINGTON
TAMMY BALDWIN, WISCONSIN
MIKE ROSS, ARKANSAS
DARLENE HOOLEY, OREGON
ANTHONY D. WEINER, NEW YORK
JIM MATHESON, UTAH
G.K. BUTTERFIELD, NORTH CAROLINA
CHARLIE MELANCON, LOUISIANA
JOHN BARROW, GEORGIA
BARON P. HILL, INDIANA

ONE HUNDRED TENTH CONGRESS

U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515-6115

JOHN D. DINGELL, MICHIGAN
CHAIRMAN

February 27, 2007

JOE BARTON, TEXAS
RANKING MEMBER
RALPH M. HALL, TEXAS
J. DENNIS HASTERT, ILLINOIS
FRED UPTON, MICHIGAN
CLIFF STEARNS, FLORIDA
NATHAN DEAL, GEORGIA
ED WHITFIELD, KENTUCKY
CHARLIE NORWOOD, GEORGIA
BARBARA CUBIN, WYOMING
JOHN SHIMKUS, ILLINOIS
HEATHER WILSON, NEW MEXICO
JOHN B. SHADEGG, ARIZONA
CHARLES W. "CHIP" PICKERING, MISSISSIPPI
VITO FOSSELLA, NEW YORK
STEVE BUYER, INDIANA
GEORGE RADANOVICH, CALIFORNIA
JOSEPH R. PITTS, PENNSYLVANIA
MARY BONO, CALIFORNIA
GREG WALDEN, OREGON
LEE TERRY, NEBRASKA
MIKE FERGUSON, NEW JERSEY
MIKE ROGERS, MICHIGAN
SUE MYRICK, NORTH CAROLINA
JOHN SULLIVAN, OKLAHOMA
TIM MURPHY, PENNSYLVANIA
MICHAEL C. BURGESS, TEXAS

DENNIS B. FITZGIBBONS, CHIEF OF STAFF
GREGG A. ROTHSCHILD, CHIEF COUNSEL

Ms. Sharon Price Hill
Chief Executive Officer and
Chairman of the Board
Copernicus Group IRB
118 MacKenan Drive, Suite 400
Cary, North Carolina 27511

Via FAX (919-465-4311)

Dear Ms. Hill:

Pursuant to Rules X and XI of the Rules of the U.S. House of Representatives, the Committee on Energy and Commerce and its Subcommittee on Oversight and Investigations are conducting an inquiry into the adequacy of the efforts of the U.S. Food and Drug Administration (FDA) to protect the American public from excessive risks from prescription drugs. As part of that investigation, we are examining the circumstances surrounding the Sanofi-Aventis antibiotic Ketek.

That drug was, in part, the subject of our hearing on February 13, 2007. During the course of that hearing certain questions arose regarding the proper protection of human subjects in a "usual care" clinical trial referred to as TREAT or study 3014. Your firm was identified as the for-profit Institutional Review Board (IRB) contracted by Aventis (now Sanofi-Aventis) to monitor the human subjects in the study.

In order to understand the conduct of that trial, we require certain information. We request that you provide us with all records relating to:

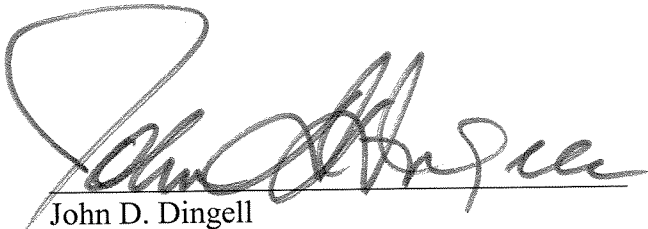
1. The contract between Copernicus and Aventis relating to study 3014.
2. The development of the protocol and the informed consent forms relating to study 3014.

Ms. Sharon Price Hill
Page 2

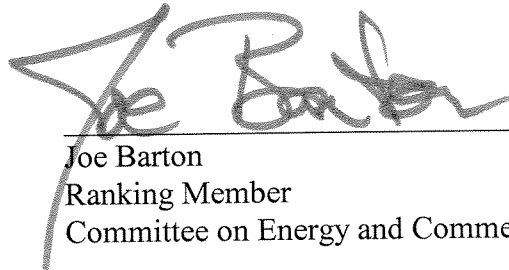
3. Adverse events reported to Copernicus relating to subjects in study 3014 regardless of the source of those reports.
4. Adverse events that Copernicus reported to the FDA relating to subjects in study 3014.
5. Financial arrangements between Copernicus and Aventis relating to study 3014.
6. The names and contact information for all Copernicus employees assigned to study 3014.

All the requested records should please be delivered to the Committee on Energy and Commerce offices at Room 316 Ford House Office Building by no later than the close of business on Friday, March 9, 2007. Please note that the words "records" and "relating to" should be interpreted as defined on the attachment to this letter. Should you have any questions regarding this request, please contact David Nelson of the Committee Majority staff at (202) 225-2927 or Alan Slobodin of the Committee Minority staff at (202) 225-3641.

Sincerely,



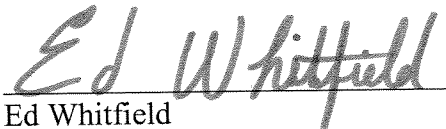
John D. Dingell
Chairman
Committee on Energy and Commerce



Joe Barton
Ranking Member
Committee on Energy and Commerce



Bart Stupak
Chairman
Subcommittee on Oversight
and Investigations



Ed Whitfield
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.