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

Mr. Fred Eshelman
Chief Executive Officer
PPD, Incorporated
3151 South 17th Street
Wilmington, North Carolina 28412

Via FAX (910-772-7056)

Dear Mr. Eshelman

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 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 monitoring of adverse events in a "usual care" clinical trial referred to as TREAT or study 3014. Your firm was identified as the Contract Research Organization (CRO) contracted by Aventis (now Sanofi-Aventis) to monitor 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 PPD, Inc (PPD) and Aventis relating to study 3014.
2. The development of the protocol, site selection and the informed consent forms relating to study 3014.
3. Adverse events reported by PPD to Copernicus (the private firm acting as the Institutional Review Board or IRB) relating to subjects in study 3014 regardless of the source of those reports.

4. Adverse events, protocol violations, or other data integrity questions that PPD reported to the FDA relating to subjects in study 3014;

5. Financial arrangements between PPD and Aventis relating to study 3014;

6. The names and contact information for all PPD employees assigned to study 3014;

7. Protocol violations or other study integrity issues that PPD reported to Aventis relating to study 3014;

8. Any and all due diligence performed by PPD on the study investigators or study sites that were used in study 3014 regardless of for whom such due diligence was performed;

9. All e-mails between or among PPD and Aventis, Copernicus, or FDA pertaining to study 3014 regardless of specific subject matter between December 1, 2001, and March 30, 2004.

Please provide all the requested records to the Committee offices at Room 316 Ford House Office Building, Washington, D.C., by no later than the close of business on Friday, March 9, 2007. Please interpret the words "records" and "relating to" in accordance with the attachment to this letter.

Should you have any questions regarding these requests, 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.