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ONE HUNDRED TENTH CONGRESS

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

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March 9, 2007

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Mr. Timothy Rothwell
Chairman
Group Pharmaceutical Activities
Sanofi-Aventis US
55 Corporate Drive
Bridgewater, NJ 08807

Via FAX: 202-942-5999 (Attn: Daniel Kracov, Arnold & Porter)

Dear Mr. Rothwell:

Pursuant to Rules X and XI of the Rules of the United States 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 FDA approval of 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 integrity of a "usual care" clinical trial referred to as TREAT or study 3014. In order to understand what information Sanofi-Aventis (formerly Aventis) possessed regarding protocol violations or data integrity questions that arose during the conduct of that trial, we require certain information. We request that you provide us with all records relating to:

1. The names and contact information for all Aventis employees, whether or not currently employed, assigned to study 3014, including the nature and dates of their responsibilities for this trial.
2. Protocol violations or other data/study integrity issues that Aventis became aware of and reported to the FDA prior to the submission of study 3014 to that Agency on July 24, 2002, and between July 24, 2002, and the Advisory Committee meeting on January 8, 2003.

3. Protocol violations or other data/study integrity issues that Aventis became aware of but failed to report to the FDA prior to the submission of study 3014 to that Agency on July 24, 2002, and between July 24, 2002, and the Advisory Committee meeting on January 8, 2003.
4. Any and all due diligence performed by Aventis or its agents of the study investigators or study sites that were used in study 3014.
5. All e-mails between or among Aventis and PPD, Copernicus, or the FDA pertaining to study 3014, regardless of specific subject matter, between December 1, 2001, and March 30, 2004.
6. All materials supplied by Aventis or its agents to PPD, Copernicus, or any other firm that Aventis employed to assist with study 3014 regarding reporting of protocol violations or other data/study integrity issues to the FDA. This includes but is not limited to “coaching” of study investigators or the employees of study investigators.
7. Meetings with officials of the Department of Health and Human Services (HHS), including the FDA. This includes, but is not limited to, Dr. Janet Woodcock, Dr. John Jenkins, Dr. Steve Galson, or individuals from the FDA Commissioner’s Office and the Office of General Counsel at HHS, including the Office of Chief Counsel at the FDA.
8. All trip reports of Nadine Grethe, Ranjan Khosia, anyone in your Quality Assurance Department, or by PPD monitors assigned to study 3014.
9. All TREAT team minutes and the TREAT team newsletters.

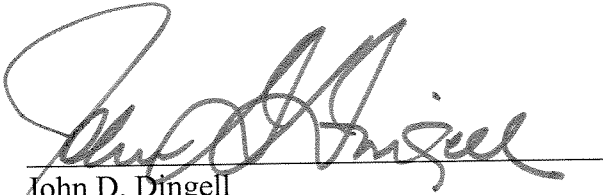
Please deliver all of the requested records to the office of the Committee on Energy and Commerce in room 316 Ford House Office Building, Washington, D.C. 20515, by no later than two weeks after the date of this letter. Please note that “Aventis” refers to Sanofi-Aventis and all its predecessor firms, as well as any individual employee or contractor of the firm, and that the words “records” and “relating to” should be interpreted as defined in the attachment to this letter.

Furthermore, unless you are notified to expand the production by the Committee staff, your responses to requests number 2, 3, and 4 may exclude records from sites that enrolled fewer than 15 patients. All personal identifiers of patients may be redacted provided that you supply codes or another mechanism to distinguish patients from one another.

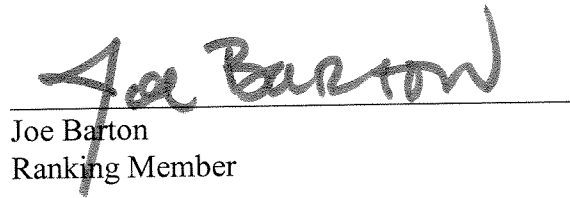
Mr. Timothy Rothwell
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If there are any questions regarding this request, please contact David Nelson of the Committee Majority staff at (202) 225-2927 or Alan Slobodin of the Committee Minority staff at (202) 225-3641.

Sincerely,



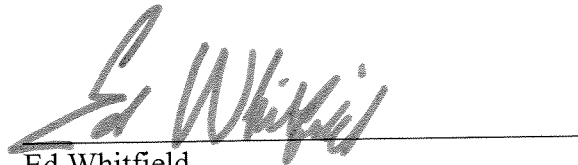
John D. Dingell
Chairman



Joe Barton
Ranking Member



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.