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

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October 14, 2008

The Honorable Andrew von Eschenbach, M.D.
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. von Eschenbach:

Under 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 investigating direct-to-consumer (DTC) advertising for pharmaceutical products.

The Food and Drug Administration's (FDA) has published a new Web site, "Be Smart About Prescription Drug Advertising – What You Should Know about Prescription Drug Advertisements". A news report from the Center for Science in the Public Interest indicates that FDA's Web site was developed by EthicAd, a non-profit organization funded by Shaw Science Partners, which is a public relations firm for the pharmaceutical industry. According to the Shaw Science Partners Web site, the company has worked on the launch of more than 30 drugs, including Procrit, whose DTC advertisements have been investigated by this Committee, and Rezulin, a drug that was removed from the market for safety problems.

FDA's Web site could be viewed as less of a guide to consumers and more of a guide to advertisers, with examples of proper and improper DTC ads. The Committee would like to know why FDA sought the assistance of a pharmaceutical public relations firm to help it advise consumers on how to interpret DTC advertisements.

Therefore, please provide to the Committee the following:

1. All records relating to the aforementioned DTC Web site;

2. All records of communications with EthicAd, or any of its agents, attorneys, or lobbyists;

3. All records of communications with Shaw Science Partners, or any of its agents, attorneys, or lobbyists;

4. All records relating to communications with the Pharmaceutical Research and Manufacturers of America, or any of its agents, attorneys, or lobbyists, relating to the aforementioned DTC Web site;

5. All records of payments made to EthicAd, or any of its agents, attorneys, or lobbyists;

6. All records of payments made to Shaw Science Partners, or any of its agents, attorneys, or lobbyists; and

7. All records of contracts or agreements among FDA and EthicAd or Shaw Science Partners.

Please deliver copies of the requested records to the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce, Room 316, Ford House Office Building, no later than two weeks from the date of this letter. Please note that for the purpose of responding to this request, the terms "record" and "relating" should be interpreted in accordance with the attachment to this letter. After review of the records, we may require additional records or staff interviews with agency officers or employees.

Thank you for your prompt attention to this matter. If you have any questions related to this request, please contact us or have your staff contact Paul Jung or David Nelson with the Committee staff at (202) 226-2424.

Sincerely,

John D. Dingell
Chairman

Bart Stupak
Chairman
Subcommittee on Oversight and Investigations

Attachment

cc: The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce

The Honorable John Shimkus, Ranking Member
Subcommittee on Oversight and Investigations

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," or "relate" 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.