ONE HUNDRED TENTH CONGRESS

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

JOHN D. DINGELL, MICHIGAN
CHAIRMAN

June 15, 2007

The Honorable Michael O. Leavitt
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Mr. Secretary:

Under 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 investigating the ability of the Food and Drug Administration (FDA) to protect the American public from excessive risks associated with prescription drugs. As part of that inquiry, the Committee has noted with increasing alarm reports that indicate that Erythropoiesis-Stimulating Agents (ESAs), commonly known as EPO products, when used at higher than recommended doses, appear to increase blood clots, stimulate tumor growth, and are associated with significantly higher mortality rates than placebos.

Appropriately, FDA convened an Oncology Drugs Advisory Committee (ODAC) meeting on May 10, 2007, to consider the overall safety of ESAs, including Procrit, Aranesp, and Epogen. During this meeting, ODAC members, as well as FDA officials, expressed skepticism about not only the safety claims of the sponsors, but also the "quality of life" claims contained in ESA labels. On March 9, 2007, FDA instituted an ESA class label change, which eliminated all references to improvements in quality of life from labels. The question remains, however, as to why these claims were allowed on ESA labels when the only approved indication for ESAs is to reduce the need for blood transfusions.

Moreover, the unapproved "quality of life" claims contained in the patient information section of the labels paved the way for misleading direct-to-consumer advertising, which led patients and doctors alike to the unsubstantiated belief that ESAs improve quality of life. Similar to many ODAC members, this Committee is interested in learning why FDA did not act sooner to both correct the labels and prevent the misleading advertising that was based upon the labeling.

Accordingly, we request that you produce the following documents relating the ESA "quality of life" claims:

1) Any and all records reflecting communication between Johnson & Johnson and FDA, FDA Office of Chief Counsel (OCC) or elsewhere within the Department of Health and Human Services (HHS) relating to advertising of Procrit between 1998 and 2005;

2) Any and all records reflecting communication between Amgen and FDA, OCC, or elsewhere within HHS relating to advertising of Aranesp, separately or bundled (for example with Neulasta or Neupogen);

3) Any and all records between Amgen and FDA, OCC, or elsewhere within HHS relating to "quality of life" claims including the claim that Aranesp may "relieve the symptoms of anemia" contained in the Aranesp package insert or label information; and

4) Any and all records between Johnson & Johnson and FDA, OCC, or elsewhere within HHS relating to "quality of life" claims contained in the Procrit label, including the claim that "symptoms [of weakness, dizziness, chest pain] may improve" with use of Procrit.

We appreciate your cooperation in this investigation. Please deliver copies of the requested records to the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce, Room 316 of the Ford House Office Building, by no later than 15 business days 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 and/or staff interviews with FDA personnel.

If you have any questions regarding these requests, please contact us or have your staff contact David Nelson or Joanne Royce with Committee staff at (202) 226-2424.

Sincerely,

John D. Dingell
Chairman

Bart Stupak
Chairman
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," 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.

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

The Honorable Ed Whitfield, Ranking Member
Subcommittee on Oversight and Investigations