ONE HUNDRED TENTH CONGRESS

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

JOHN D. DINGELL, MICHIGAN
CHAIRMAN

March 20, 2007

Mr. William C. Weldon
Chairman and CEO
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933

VIA FAX (202-589-1001)

Dear Mr. Weldon:

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 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 we note with increasing alarm reports indicating that Erythropoiesis-Stimulating Agents (ESAs), commonly known as EPO products, when used at higher than recommended doses, appear to cause increases in blood clots, seem to grow tumors and are associated with significantly higher mortality rates than placebo.

Johnson & Johnson (J&J) markets under the trade name Procrit these agents to treat chemotherapy-related anemia in cancer patients and anemia related to chronic renal failure. By some estimates, perhaps as much as $700 million in annual sales of Procrit and the Amgen EPO drugs Aransap and Epogen comes from uses that do not conform to the label. Appropriately, the FDA has announced that it will convene on May 10, 2007, an Oncology Drugs Advisory Committee (ODAC) to consider overall safety of these products.

Johnson & Johnson has agreed at the behest of the FDA to place black box warnings on the packaging indicating the severe consequences of off-label use. There have been, however, no indication that J&J will forego its direct to consumer advertising that drives off-label uses of prescription drugs. Nor has there been any public announcement of a cessation of financial incentives to physicians to increase the prescription of Procrit to their patients.

Accordingly, we request that you cease all direct to consumer advertising and physician incentives until the ODAC has met and FDA has had time to determine what, if any, additional measures need be taken to protect the public from unnecessary risks to human life from these products.

We further request that you preserve all records relating to the promotion of these products from October 1, 2006, forward. We also request that you preserve the records relating to all communications with the FDA since last September, including, but not limited to, any internal documents that discuss such communications or proposed communications. The words "records" and "relating to" are defined in the attachment to this letter.

Finally, we ask that you supply us with answers to these specific questions (and preserve all records relating to the answers):

1. When did J&J or any of its employees or consultants learn of the suspension of any EPO study (Phase II-IV) that was halted out of concern for the subjects in the study?

2. When did J&J notify the FDA of such suspensions and who in the Agency was notified?

3. Please describe all discussions J&J has had with the FDA or the Department of Health and Human Services (HHS) regarding direct to consumer advertising of Procrit since advising the Agency of any of the adverse events that are cautioned against in the black box warning announced last week.

4. Please describe all promotions that J&J undertakes that have the effect of relating the prescription of EPO products to the income of physicians or their practices.

Please provide your response by the close of business two weeks from the date of this letter. Should you have any questions regarding these requests, please contact David Nelson of the Committee Staff at (202) 225-2927.

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 Ed Whitfield, Ranking Member
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce

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.