ONE HUNDRED TENTH CONGRESS

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

JOHN D. DINGELL, MICHIGAN
CHAIRMAN

March 31, 2008

Mr. Kevin Sharer
Chairman, CEO, and President
Amgen Inc.
One Amgen Center Drive
Thousand Oaks, CA 91320-1799

VIA FAX (202-585-9729)

Dear Mr. Sharer:

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 the ability of the Food and Drug Administration (FDA) to protect the American public from excessive risks associated with prescription drugs.

Early last year, the Committee learned of disturbing safety issues in connection with a class of drugs known as Erythropoiesis-Stimulating Agents (ESAs), which are designed to prevent the need for blood transfusions in cancer and dialysis patients suffering from anemia. Since then, we have noted with increasing alarm clinical study reports that indicate ESAs, also known as EPO products, cause increased blood clots and mortality and may even enhance disease progression.

On March 13, 2008, FDA convened the third Oncologic Drugs Advisory Committee (ODAC) meeting held since the 1993 approval of Johnson & Johnson's PROCRIT for the treatment of chemotherapy-induced anemia. The first ODAC meeting was held in May 2004 to discuss adverse study findings of increased tumor growth and/or survival in patients with breast and head/neck cancer. The second ODAC meeting was convened in May 2007 when information from four more trials showed increased tumor promotion and decreased survival.

In light of additional adverse trial results, FDA convened the March 2008 ODAC meeting to reconsider the benefits and risks of ESAs when administered to patients with cancer.

Although ODAC did not vote to discontinue marketing for ESAs in the treatment of anemia due to concomitant cancer chemotherapy, the Advisory Committee did recommend substantial labeling changes.

We understand that Amgen has not engaged in direct-to-consumer (DTC) product advertising for either EPOGEN or Aranesp since their launch. We are aware, however, that Amgen markets Aranesp to physicians in conjunction with Neupogen and Neulasta and we are concerned that such "bundling" practices have helped fuel excessive and dangerous off-label use of Aranesp.

Accordingly, we request that you provide this Committee with the following records pertaining to Amgen's marketing strategies for Aranesp, Neupogen, and Neulasta:

1. Copies of your television and print advertisements pertaining to Neupogen and/or Neulasta, including copies of their run dates;

2. Copies of your contracts with oncologists pertaining to the practice of bundling or offering discounts on the purchase of Neupogen and/or Neulasta to physicians who sell certain amounts of Aranesp; and

3. All records relating to future plans for marketing Aranesp.

In addition, we ask that you provide answers to the following specific questions:

1. Since Aranesp was launched in 2001, how many physicians and/or oncology practices signed contracts pertaining to the practice of bundling or offering discounts on the purchase of Neupogen and/or Neulasta in return for sales/use of Aranesp?

2. Since Aranesp was launched in 2001, how much money has Amgen spent annually in connection with marketing the practice of bundling of sales of Neupogen and/or Neulasta and Aranesp, including costs of DTC advertising for Neupogen and/or Neulasta?

3. Since Aranesp was launched in 2001, how much money has Amgen made annually in connection with the bundling of its sales of Neupogen/Neulasta and Aranesp?

Please immediately provide copies of all Neupogen and/or Neulasta television advertisements to the Committee. Your responses to the remaining requests should be provided by the close of business two weeks from the date of this letter. The words "records" and "relating" are defined in the attachment to this letter. Should you have any questions regarding these requests, please contact Joanne Royce with the Committee staff at (202) 226-2424.

Sincerely,

John D. Dingell
Chairman

Bart Stupak
Chairman
Subcommittee on Oversight and Investigations

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.