United States Senate
COMMITTEE ON FINANCE
WASHINGTON, DC 20510–6200

August 17, 2007

Via Electronic Transmission

Mr. Kevin Sharer
Chief Executive Officer
Amgen Inc.
One Amgen Center Drive
Thousand Oaks, CA 91320-1799

Dear Mr. Sharer:

The United States Senate Committee on Finance (Committee) has jurisdiction over the Medicare and Medicaid programs and, accordingly, a responsibility to the more than 80 million Americans who receive health care coverage under those programs to oversee the proper administration of the programs, including the payment for prescription drugs regulated by the Food and Drug Administration (FDA).

Thank you for the briefing that Amgen Inc. (Amgen) provided my Committee staff on May 24, 2007, in response to my letter to you dated May 16, 2007. Additionally, thank you for your cooperation with the Committee's request for information related to erythropoiesis-stimulating agents (ESAs).

FDA Access to Study Data

In the May 16 letter, I expressed concerns regarding media reports that Amgen was providing FDA with limited access to study results and incomplete responses to the agency's requests for data. During the May 24 briefing, representatives from Amgen explained that the study data requested by the FDA did not belong to the company because the studies were conducted by third party researchers; therefore, Amgen did not have access to that data. Amgen representatives stated further that they made attempts to obtain the data and informed FDA that the company would not be able to meet the deadline for submission to the FDA for review prior to the Oncologic Drugs Advisory Committee (ODAC or Advisory Committee) meeting, which was held on May 10, 2007.

My Committee staff followed up with the FDA regarding this matter. While FDA officials did not dispute that Amgen informed them that the third party data would not be available in time for the ODAC meeting, they did voice concerns that Amgen did not take adequate steps to secure access to data from the completed trials in a timely fashion. According to the FDA, it is not uncommon for companies to make arrangements upfront with independent researchers to obtain access to primary data, i.e., the original data collected in the study, including data from individual patients, from studies involving their products. Documents provided by the FDA show that three years earlier, at a public meeting of the Advisory Committee on May 4, 2004, Amgen had cited 5 studies that

were being conducted to further investigate the risks of ESAs in cancer patients, including 4 independent, third party-sponsored clinical trials. However, FDA officials told my Committee staff that Amgen did not initiate discussions with the independent researchers to obtain access to the primary data until several months before the May 2007 ODAC meeting.

As I stated in my May 16 letter, it is essential that the FDA receive complete and accurate information in order for the agency to take appropriate and timely actions in response to emerging safety concerns. Although the primary data requested by the FDA were held by third party researchers, FDA officials said that Amgen had a "corporate responsibility" to make arrangements to secure access to that data at the time the company decided to use the third party studies as part of its assessment of ESA risks. In addition, FDA officials told my Committee staff that the agency needed the primary data in order to perform its own independent analysis of the results since the studies were being used by Amgen to address safety issues that were raised by the May 2004 ODAC. Accordingly, please provide detailed responses to the following requests:

(1) If in fact Amgen did not initiate discussions with the independent researchers for access to their data until several months before the second ODAC meeting, please explain why Amgen did not take earlier action.

(2) If Amgen did initiate discussions with the researchers prior to or soon after the first ODAC meeting in May 2004, please explain the more than 3-year delay in providing FDA access to the primary data. Also, specify when discussions with the researchers were initiated.

(3) What is the current status of Amgen's negotiations with the independent researchers to obtain access to their primary data?

Rebate Payments/Discounts to Physicians

In the May 16, 2007 letter, I cited a New York Times article, which reported that doctors may be profiting through rebates they receive from purchasing ESAs directly from Amgen and Johnson & Johnson and then collecting payments from Medicare and private insurers, which are often above the price they paid for the drugs. It is my understanding that the rebates are based on the amount of drugs purchased—the more a doctor buys, the higher the rebate. Overuse of ESAs is not only a financial concern to the Committee, but also a major patient safety concern given that recent clinical studies have identified increased risks of death, blood clots, strokes, heart attacks, and tumor growths when ESAs are given in higher than recommended doses.

As part of the Committee's ongoing inquiry into the potential impact of pricing practices on the utilization of ESAs, I request that Amgen provide the Committee with:

(1) the total and average amounts and range of rebate payments made to physicians, group practices, physician clinics, hospital outpatient departments, skilled nursing facilities, and home health agencies that purchased Aranesp and/or

Epogen from Amgen. Please provide the requested information for calendar years 2004, 2005, and 2006 by state.

(2) the number of physicians, group practices, physician clinics, hospital outpatient departments, skilled nursing facilities, and home health agencies in each state that received rebates from Amgen for Aranesp and Epogen in calendar years 2004, 2005, and 2006. As a preliminary response to this request, identify the five physicians, group practices, physician clinics, hospital outpatient departments, skilled nursing facilities, and home health agencies that received the highest rebate payments in each state in calendar years 2004, 2005, and 2006.

Thank you in advance for your prompt assistance.

Sincerely,

Charles E. Grassley
Ranking Member