Congress of the United States
House of Representatives
Washington, DC 20515

October 2, 2007

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

Dear Commissioner von Eschenbach:

The Committee on Ways and Means and the Committee on Oversight and Government Reform noted with great alarm the public health concerns raised in the FDA black box label that was issued last March which warned about the health risks of erythropoiesis-stimulating agents (ESAs), commonly known by their brand names of Epogen, Procrit, or Aranesp. While ESAs serve a valuable role in treating anemia for patients suffering from End Stage Renal Disease (ESRD) or cancer, we now know of clear health risks when ESAs are used to raise red blood cell levels too high.

According to the FDA label for Epogen and Procrit, ESAs increase the risk of death and cause tumor progression for certain cancer patients when administered to target a hemoglobin of greater than 12 grams per deciliter (g/dL). The label and accompanying FDA health advisory from March 2007 also warn about health risks for ESRD patients, cautioning that when used to target that same hemoglobin level, ESAs put patients suffering from chronic kidney failure at higher risk of death, blood clots, strokes, heart failure and heart attack.

The Committee on Ways and Means has jurisdiction over Medicare, and a responsibility to both the 43 million beneficiaries who receive health coverage from Medicare and to taxpayers. In 2005, Medicare spent over $17 billion providing care for the 320,000 Medicare beneficiaries on dialysis, of which nearly $2 billion was spent on ESAs. In addition, approximately 17 percent of Medicare beneficiaries suffer from cancers other than skin cancer, many of whom use ESAs to manage their anemia. Clearly, proper dosing of ESAs is critical to the care of Medicare beneficiaries. The Committee on Oversight and Government Reform joins in the request outlined in this letter, under their general oversight authority and pursuant to Rule X of the Rules of the United States House of Representatives.

Given concerns about the health risks of dosing ESAs in a way that raises hemoglobin levels too high, the Centers for Medicare and Medicaid Services (CMS) recently issued a

National Coverage Determination (NCD) on the use of ESAs in cancer and related neoplastic conditions. I am including for your review a copy of the CMS decision memo for ESA for non-renal disease indications.

As part of our ongoing work, we are writing to request your response to the following questions:

- What are the health risks associated with use of ESAs for cancer patients?
- What is FDA's assessment of the risks and benefits of ESA use for cancer patients? Are there benefits in terms of quality of life or better tumor outcomes associated with higher hemoglobin levels?
- Can you explain the FDA label's recommendation for ESA use for cancer patients?
- Does the CMS NCD conflict with the FDA label for dosing of ESAs in treating cancer patients? Is the NCD consistent with the scientific literature on this issue?

Please respond by October 12, 2007. I appreciate FDA's assistance in briefing Congressional staff on this issue, as I understand that Dr. John Jenkins has accepted our invitation to participate in a briefing on October 4th. If you have questions, please contact me or your staff may contact Jennifer Friedman at 202-225-3943.

Thank you for your assistance.

Sincerely,

Henry Waxman
Chairman
Committee on Oversight
and Government Reform

Pete Stark
Chairman
Subcommittee on Health
Committee on Ways and Means