

Dingell, Stupak Applaud FDA for ESA Label Change

Washington, DC - Reps. John D. Dingell (D-MI), Chairman of the Committee on Energy and Commerce, and Bart Stupak (D-MI), Chairman of the Oversight and Investigations Subcommittee, commented today on FDA's decision to make label changes to three Erythropoiesis-Stimulating Agents (ESAs) manufactured by Amgen.

For Immediate Release: August 5, 2008

Contact: Jodi Seth or Brin Frazier, 202-225-5735

Dingell, Stupak Applaud FDA for ESA Label Change

Washington, DC

- Reps. John D. Dingell (D-MI), Chairman of the Committee on Energy and Commerce, and Bart Stupak (D-MI), Chairman of the Oversight and Investigations Subcommittee, commented today on FDA's decision to make label changes to three Erythropoiesis-Stimulating Agents (ESAs) manufactured by Amgen.

Dingell approved the FDA's move stating, "Beginning last year, a steady stream of negative ESA study findings prodded FDA to take a series of remedial actions to protect the American people from these dangerous drugs. I applaud FDA's most recent action ordering Amgen to include additional safety related information to the drug label."

"Unfortunately, FDA allowed these unsafe drugs to be heavily marketed for five years," said Stupak. "I am happy that the FDA has further limited the use of these risky products."

Early last year, the lawmakers opened an investigation into the safety of ESAs after learning of alarming reports indicating that ESAs, when used at higher than recommended doses, appeared to increase blood clots, stimulate tumor growth, and produce significantly higher mortality rates than placebos.

Last

week, under new enforcement authority in the FDA Amendments Act of 2007, FDA ordered Amgen to make additional safety-related labeling changes for Aranesp, Epogen and Procrit -- three drugs approved to reduce the need for blood transfusions in cancer and dialysis patients suffering from anemia. Over Amgen's objection, the Agency ordered the company to change the Boxed Warnings and Indications and Usage sections of the label to reflect that ESAs should not be used in chemotherapy patients with curable cancer. FDA also ordered Amgen to include a warning that ESA therapy should not be initiated at hemoglobin levels greater than or equal to 10 g/dL.

Prepared by the Committee on Energy and Commerce

2125 Rayburn House Office Building, Washington, DC 20515