

Dingell, Stupak Call on Amgen, Johnson & Johnson to Suspend Direct-to-Consumer Marketing for Anemia Drugs

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NEWS RELEASE

Committee on Energy and Commerce

Rep. John D. Dingell, Chairman

For Immediate Release: March 21, 2007

Contact: Committee on Energy and Commerce Press Office / 202-225-5735

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Washington - Today, Reps. John D. Dingell (D-MI), Chairman of the House Committee on Energy and Commerce, and Bart Stupak (D-MI), Chairman of the Subcommittee on Oversight and Investigations, urged Amgen Inc. and Johnson & Johnson to suspend direct-to-consumer advertising and personal income incentives to prescribers of their anemia medications until the Food and Drug Administration has completed their safety review. The anemia medications include Erythropoiesis-Stimulating Agents (ESAs), commonly known as EPO products, Epoetin alfa (marketed as Procrit, Epogen), and Darbepoetin alfa (marketed as Aranesp).

The Committee on Energy and Commerce and its Oversight and Investigations Subcommittee are in the process of

conducting a broad investigation into FDA's ability to protect Americans from unsafe drugs and have been carefully tracking the alarming studies released recently.

"The FDA acted properly to demand a black label warning on these EPO products and to convene an Advisory Committee to determine the safety of these anemia drugs," said Dingell. "EPO products are being prescribed off-label with the result being increased deaths, tumor growth and blood clots and we are very concerned that direct-to-consumer advertising may be driving the improper use of these drugs."

"Hundreds of millions of dollars are spent by patients each year on off-label uses of EPO drugs that actually increase the risk of premature death," said Stupak. Noting that some doctors can greatly increase their incomes by prescribing this drug, he continued, "Patients are placed in danger when drug company advertising and incentives to physicians highlight the benefits but not the deadly risks associated with EPO drugs."

"Clearly off-label use of these dangerous drugs must be halted and that will not happen until the direct-to-consumer advertising is suspended and the financial incentives to physicians are curtailed," said Dingell.

The lawmakers also pointed out that until the Oncologic Drugs Advisory Committee has met on May 10, 2007, and the FDA has had the opportunity to weigh its recommendations, the full range of risks remains unknown.

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(See Letters to Amgen, Inc. and Johnson & Johnson)

Prepared by the Committee on Energy and Commerce

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