

Dingell, Stupak Consider Changing Law Over Heparin Failures

Reps. John D. Dingell (D-MI), Chairman of the Committee on Energy and Commerce, and Bart Stupak, Chairman of the Subcommittee on Oversight and Investigations, today called on the Health and Human Services (HHS) Secretary and Commissioner of the Food and Drug Administration (FDA) to account for the regulatory failure that resulted in four deaths and caused serious illness in more than 350 people who took the blood thinning drug Heparin.

NEWS RELEASE
Committee on Energy and Commerce

Rep. John D. Dingell, Chairman

For Immediate Release: February 21, 2008

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

Dingell, Stupak Consider Changing Law

Over Heparin Failures

Washington, DC — Reps. John D. Dingell (D-MI), Chairman of the Committee on Energy and Commerce, and Bart Stupak, Chairman of the Subcommittee on Oversight and Investigations, today called on the Health and Human Services (HHS) Secretary and Commissioner of the Food and Drug Administration (FDA) to account for the regulatory failure that resulted in four deaths and caused serious illness in more than 350 people who took the blood thinning drug Heparin.

In letters sent today to HHS Secretary Michael O. Leavitt and FDA Commissioner Andrew von Eschenbach, the congressmen requested documents relating to the FDA's foreign inspection program and the drug Heparin.

Noting that letters of request had been sent to both officials demanding interviews and documents on a tight deadline, Dingell said, "These Heparin tragedies are likely the result of FDA abandoning its preapproval inspection requirement, a critical policy was put in place two decades ago after a generic drug investigation by this Committee. This requirement was designed to protect consumers by ensuring that drug manufacturers operated appropriately and safely."

Since it appears that FDA feels free to ignore this long-standing policy, we are now considering whether such safeguard should be codified into law.”

“FDA has tried to pass this failure off as a clerical error by a reviewer unfamiliar with the names of Chinese companies,” said Stupak. “The fact that hundreds of Americans have been injured and four have been killed because the agency lacks an ability to catch such mistakes is serious enough. However, the further assertion by FDA that it is free to ignore its own preapproval policy raises concerns regarding the safety of the entire drug supply. Mr. Dingell and I will be looking at changes in law that will prohibit the marketing of any drug from a plant that has not been properly inspected.”

Read the Letters:

- Letter to FDA Commissioner von Eschenbach (pdf)
- Letter to HHS Secretary Leavitt (pdf)
- Letter to Mr. Robert Parkinson, Jr., Chairman of the Board and CEO of Baxter International Incorporated (pdf)

Prepared by the Committee on Energy and Commerce

2125 Rayburn House Office Building, Washington, DC 20515