

Dingell, Stupak Question Whether FDA Knowingly Allowed Potentially Unsafe & Ineffective Drugs into the U.S. Marketplace

Washington, D.C. – Democratic leaders of the U.S. House Committee on Energy and Commerce today questioned whether the Food and Drug Administration (FDA) knowingly allowed drugs suspected of being fraudulently approved and manufactured in gross violation of Good Manufacturing Practices (GMP) to continue being sold by Ranbaxy, Inc., in the United States.

For Immediate Release: July 17, 2008

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

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Reps.
John D. Dingell (D-MI), Chairman of the Committee, and Bart Stupak (D-MI), Chairman of its Subcommittee on Oversight and Investigations, responded to information contained in a Motion to Enforce Subpoenas and Points and Authorities filed on July 3, 2008, with the U.S. District Court for the District of Maryland.

The Motion, filed by the U.S. Department of Justice and U.S. Attorney's Office on behalf of FDA, states, "Allegations from reliable sources and supporting documents indicate a pattern of systematic fraudulent conduct, including submissions by Ranbaxy to the FDA that contain false and fabricated information about stability and bioequivalence, failure to timely report the distribution of drugs that were out of specification ("OSS"), and attempts to conceal violations of current Good Manufacturing Practices ("cGMPs") regulations from FDA. Specific allegations under investigation include fabricating bioequivalence and

stability data to support Abbreviated New Drug Applications (“ANDAs”) filed with FDA for generic drugs . . .”

“If these allegations are true, Ranbaxy has imperiled the safety of Americans in a manner similar to the generic drug scandal we uncovered twenty years ago,” said Dingell. “I would like to know whether FDA officials knew about these allegations and what, if any, action was taken.”

“One of the great reforms to come out of the generic drug scandals was the institution of pre-approval inspections,” said Stupak. “We learned from investigating contaminated heparin that such inspections were dispensed with in the case of the active pharmaceutical ingredient manufactured in China, which resulted in a public health disaster. Now it appears that such inspections in India – the second largest supplier of drugs to the United States – may be another example in which FDA found it inconvenient to assure the safety and effectiveness of drugs before approving them for marketing to American patients. If that is the case, then the American people should not have to wait until January for change and this Administration should clean house at the FDA now.”

Dingell and Stupak indicated that the Committee will soon commence a formal investigation into the Ranbaxy drug approvals and potential violations of GMP regulations.

Read the Motion

Prepared by the Committee on Energy and Commerce

2125 Rayburn House Office Building, Washington, DC 20515