

Dingell, Stupak Respond to FDA's Ranbaxy Announcement

Washington, D.C. - Democratic leaders of the House Committee on Energy and Commerce reacted to the Food and Drug Administration's (FDA) announcement today that it would partially restrict imports manufactured by Ranbaxy, Inc. at two of the company's plants in India.

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

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Washington, D.C. - Democratic leaders of the House Committee on Energy and Commerce reacted to the Food and Drug Administration's (FDA) announcement today that it would partially restrict imports manufactured by Ranbaxy, Inc. at two of the company's plants in India. In July, Reps. John D. Dingell (D-MI), Chairman of the Committee, and Bart Stupak (D-MI), Chairman of its Subcommittee on Oversight and Investigations, launched an investigation into whether the 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.

"The heparin fiasco made it clear that the FDA had compromised the policies that were put in place during the last generic drug scandal to protect the public from fraud," said Dingell. "This latest Ranbaxy announcement further confirms that those protective policies are in shambles. The FDA is not doing its best to protect the medicines that Americans depend on for their health."

"The Ranbaxy case is just more proof that the FDA and particularly its Center for Drug Evaluation and Research (CDER) have abandoned their mission," said Stupak. "I have instructed our investigators to follow all leads and run down all serious allegations in this case. Anyone who has information that may be useful to the investigation is urged to contact the Committee."

The FDA has refused to take meaningful regulatory action despite the fact that, for the past three years, it possessed credible information that Ranbaxy had engaged in a pattern of fraudulent behavior regarding its generic drug applications and records pertaining to good manufacturing practices. The FDA, for example, conducted preapproval inspections for only 17 percent of the Ranbaxy applications approved since January 2005. It also allowed Ranbaxy to perform the key bioequivalence studies for generic drug approvals in facilities owned by the firm and conducted by clinicians employed by the firm.

“Apparently this FDA places administrative convenience over its mission to protect the public health,” said Dingell. “We can no longer leave the methods of assuring drug safety up to discretion of this Agency.”

Stupak added, “Officials in the Center for Drugs and in the larger FDA are now on notice that we will accept no more excuses. The dedicated employees of the FDA and the American people deserve competent leadership in what should be the premier public safety Agency in the government and Chairman Dingell and I intend to see that they finally receive it.”

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Prepared by the Committee on Energy and Commerce

2125 Rayburn House Office Building, Washington, DC 20515