

## Dingell, Stupak Applaud FDA Steps on Food and Drug Safety, Pledge Continued Oversight

For Immediate Release:  
November 18, 2008  
Contact: Jodi Seth or Brin Frazier, 202-225-5735

### Dingell, Stupak Applaud FDA Steps on Food and Drug Safety, Pledge Continued Oversight

Washington,  
DC - In the past three weeks, the Food and Drug Administration (FDA) has taken actions, previously recommended by the Committee on Energy and Commerce, that are aimed at protecting Americans from tainted food, drugs and drug ingredients. Reps. John D. Dingell, the Chairman of the Committee on Energy and Commerce, and Bart Stupak, the Chairman of the Oversight and Investigations Subcommittee, today commented on the FDA's recent actions, saying that while these steps are needed, they are far from sufficient. The lawmakers pledged continued oversight and said that, in the next Congress, they will swiftly move legislation to implement badly-needed reforms at FDA.

"Over the course of our investigation, the Committee has found that FDA not only failed in its basic mission, but refused to admit its failures and take steps to protect Americans from unsafe food and drugs," Dingell said. "Now, the policy chieftains at FDA are scrambling to convince the new Administration that they are willing to do what they have failed to do for the past eight years. While this change of heart is welcome, I believe it is only because of the fine work of Chairman Stupak and the Oversight and Investigations Subcommittee. Regardless, in the 111th Congress, the Committee will swiftly move FDA reform legislation that is needed to ensure FDA does its job."

"The investigations that Chairman Dingell and I have led over the past two years found that the Bush Administration's political appointees and high-level FDA bureaucrats have lined their pockets with outrageous bonuses, while neglecting the agency's core mission of protecting Americans from contaminated food and unsafe drugs," said Stupak. "Now, in the Administration's final days, policymakers at FDA want to appear to be tough on industry. This latest posturing is no reason for FDA political appointees to retain their positions. I encourage the

incoming Obama Administration to clean house among FDA's political appointees and bring change to an agency that badly needs it."

Since

Democrats came into the majority in 2007, the Committee has held 16 days of hearings as part of the Committee's aggressive oversight aimed at prompting the FDA to protect Americans from unsafe food and drugs. The hearings and investigation exposed the inability and unwillingness of the FDA to protect Americans from contaminated food and drugs.

During

the past three weeks, FDA has taken enforcement actions that Dingell, Stupak, and other Members of the Committee on Energy and Commerce have urged over the last two years. Examples include:

On

October 28, FDA sent warning letters to Bayer regarding the marketing of aspirin combination products including Bayer Women's Low Dose Aspirin with calcium and Bayer Aspirin with Health Advantage (a dietary supplement with cholesterol lowering properties). This followed a Committee letter requesting an explanation for the lack of Agency action on the Bayer product that combined aspirin with the dietary supplement that allegedly lowers cholesterol. Subcommittee hearings revealed that the Agency had either not taken action or delayed action against a number of misleading direct-to-consumer ads, including a Johnson and Johnson ad that promoted off-label use of a drug that has been shown to shorten the lives of cancer patients when prescribed improperly.

On

November 6, Federal Marshals sent into Celsus Laboratories by FDA seizing eleven lots of contaminated heparin, the blood thinner whose active pharmaceutical ingredient (API) from China is responsible for a number of deaths here in the United States. At an April 29 hearing, FDA assured the Committee that the heparin contamination had been contained and that FDA had agreements from the US processors to test all lots. While the Agency refused to send out an import alert, the Agency maintained that all heparin API and raw heparin arriving at US ports was being tested. Apparently the FDA knew as early as April 8 that this processor was not taking the basic precautions to keep contaminated product out of the US drug supply.

On

November 10, FDA issued an import alert that required testing of all milk products and processed food containing milk solids from China for the presence of the chemical melamine that has killed 4 Chinese children and sickened over 50,000 others. Melamine contamination in foodstuffs from China has been the subject of Committee concern since

the imported wheat gluten processed into pet food killed thousands of household pets during 2007. As recently as October 2nd the Committee wrote FDA asking for a briefing on the steps that the Agency intended to take to protect Americans from the latest widespread contamination of food in China that could make its way into our food supply.

On November 14, FDA had the Department of Justice request an injunction against the production of generic drugs from the Little Falls, NJ plant of Actavis Totowa, a generic drug firm that had a history of unsafe manufacturing practices. The firm had recalled all its products from that plant and shut down as of August 1. On October 8, because of the similarity with the Ranbaxy situation, the Committee asked the FDA for information regarding its history of inspections of the plant prior to approving generic drug applications of the company.

In addition to prompting the FDA to take corrective actions, the Committee's investigation served as the basis for "the Food and Drug Administration Globalization Act," legislation aimed at implementing badly needed reforms at FDA and ensuring that the Agency has the resources necessary for it to fulfill its mission. Dingell has said that moving this legislation and addressing food and drug safety issues will be a key priority for the Committee in the 111th Congress. For information on the Food and Drug Administration Globalization Act, visit here :

For additional information on the Committee's investigation into drug safety, visit:  
<http://energycommerce.house.gov/Investigations/FDADrugSafety.shtml>

For information on the Committee's investigation into food safety, visit:  
<http://energycommerce.house.gov/Investigations/FDAFoodSafety.shtml>