Opening Statement of Chairman Bart Stupak
Oversight & Investigations Subcommittee
"The Adequacy of the FDA to Assure the Safety of the Drug Supply"
February 13, 2007

This is the first in a series of hearings this committee will be holding to evaluate the Food and Drug Administration's (FDA) ability to safely approve new drugs and provide post marketing surveillance of our Nation's drug supply.

This year, Congress must re-authorize the Prescription Drug User Fee Act (PDUFA) and the Pediatric Exclusivity law. PDUFA requires the FDA to quickly bring new drugs to the market. In its rush to approve new drugs, the FDA's ability to ensure a safe drug supply has been greatly compromised. Prior to PDUFA, seldom was the FDA forced to withdraw drugs from the market; within the first three years of PDUFA, seven drugs, resulting in more than a thousand deaths, had to be removed. Those seven deadly drugs rushed for approval under PDUFA were not needed to save lives.

In the 108th Congress, serious questions were raised about the antidepressants SSRI's use in adolescents. SSRI's have not been proven effective in treating adolescent depression. To the contrary their use may actually increase the suicide rate of its young patients. In response to these reports of increased suicide rates with SSRI use, FDA officials suppressed their own post marketing surveillance, prohibited FDA employees from discussing the report, and launched an investigation to find the person who leaked information to the press. Today, SSRI remain on the market without a clear medical benefit to the patient.

In the 108th and 109th Congress', the COX2 pain relievers, Vioxx and Bextra, were the subject hearings on the regulatory failure by the FDA. These pain relievers were supposed to be easier on the stomach and not cause ulcers for the chronic users. Post marketing surveillance revealed serious cardiac side effects. Instead of focusing on these serious side effects, the FDA became entwined in a 14 month battle on how the cardiovascular risks should be labeled. FDA officials sided with the drug manufacturer and down played the warnings and the serious side effects of Vioxx. As a result, the FDA may have allowed thousands of patients to die pre-maturely, because it failed to believe its own scientist and his post market surveillance findings.

Today, we will hear from a panel of whistleblowers who will describe how Ketek was approved by the FDA, even though the FDA knew the large safety study it required was fraught with data irregularities. Ketek is prescribed for non-life threatening illnesses

but the rush to approval has resulted in serious and deadly consequences. There have been approximately 10 deaths related to Ketek's use.

With each of these drugs, it appears that the FDA is not seriously questioning whether the "risks" out weighs the "benefits" of the new drug. One must ask, if the FDA is not protecting its client, the American people, whose interest is being protected?

The problems with the FDA's drug approval and post market surveillance cannot be totally blamed on PDUFA. While PDUFA may encourage a closer working relationship between regulators and drug companies, it is the FDA's leadership which has allowed the interaction to become incestuous. The FDA has blocked, misled, and ignored Congressional inquiries into its new drug and post marketing surveillance programs.

Our first witness, Sen., Charles Grassley, has been a champion in questioning, challenging and over seeing the FDA's drug approval and post marketing surveillance. As Chairman of the Senate Finance Committee, Senator Grassley has fought on behalf of the American people to ensure our Nation's drug supply is safe. Instead of working with Senator Grassley, the FDA has obstructed, resisted and denied his Congressional efforts to oversee and hold the FDA to its core mission of protecting Americans. The FDA has been so arrogant and embolden that it ignores the Senate Finance Committee's subpoenas. If the FDA willfully ignores a US Senate subpoena issued by the committee of jurisdiction, whose interest and mission is the FDA protecting?

Our second panel is made up of whistleblowers who will testify how their efforts to disclose serious medical risks with Ketek were ignored, covered up or dismissed by FDA officials. In order for these brave individuals to appear before this committee, each individual was subpoenaed.

Our final panel, Dr. Steven Nissen and Dr. David Graham- who was also subpoenaed - will state that FDA officials ignored well documented evidence, especially on Vioxx, and compromised patient safety in the new drug approval and post market surveillance programs.

The FDA has lost sight of it mission. When the US Congress or FDA scientists or experts in the medical field try to inject safety into the FDA drug approval process and post market surveillance, these individuals are ignored, ridiculed or silenced.

As I stated earlier, this is the first of several hearings this committee will be conducting on the FDA drug approval process. Congress must confront the FDA and return it to its core mission of protecting the American consumer, not the pharmaceutical industry.

Members of this committee should keep in mind these questions:

- Has the "culture" at the FDA lost sight of its core mission?

- Has PDUFA made the FDA more beholden to the pharmaceutical industry?

- Are the drug approval time limits found in PDUFA contributing to drugs being rushed to market without understanding the extent of the medical risks and benefits?

- Does the FDA adequately provide post market surveillance?

While Ketek and its FDA approval is the focus of this hearing, the American people and this Congress, must remain vigilant in shaping public policy and re-writing PDUFA to restore the FDA's core mission of ensuring America's drug supply is safe for all Americans.