Opening Statement
The Honorable Bart Stupak
Chairman
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
March 22, 2007

Good Morning. Today the Subcommittee continues its inquiry into the adequacy of the Food and Drug Administration's efforts to protect Americans from unsafe prescription drugs.

The FDA has a long history of not adequately protecting the American public from dangerous prescription drugs. The FDA has placed the approval and marketing of drugs above its public safety mission. The Government Accountability Office (GAO), the Institute of Medicine (IOM) and Members of FDA's own Drug Safety Advisory Committee have all released reports detailing the inadequacies of the FDA's drug approval process, post marketing surveillance, and inept leadership. Representatives from these organizations will present their testimony to us today. We welcome their analyses.

This Subcommittee has investigated three separate instances - the antidepressants (SSRI's), anti-inflammatory medications Vioxx & Bextra, and the antibiotic Ketek - where senior officials in FDA's Center for Drug Evaluation and Research (CDER) overruled competent, conscientious FDA medical officers' warnings that the drugs were not safe.

These senior FDA officials who overruled the FDA medical officers performed no independent analysis of the data , nor did they solicit the opinion of unbiased outside scientists. In fact, in the anti-depressant and Ketek cases, FDA officials took deliberate steps to withhold critical information from the Advisory Committees on the most important facts regarding the issues under consideration. In the Vioxx case, senior FDA officials refused to qallow and FDA official to share his critical study with the Advisory Committee.

FDA officials responsible for protecting Americans overruled their own scientists and chose instead to listen to the self-interested pleadings of the drug companies. In each case that this Committee examined - the increased suicide risk in adolescents from anti-depressant drugs, the unnecessary deaths from heart attack and stroke associated with Vioxx , and the liver deaths from the Ketek, - the FDA was ultimately forced to reverse its' prior decisions regarding the efficacy of the drugs..

Amazingly, these senior FDA officials are still in positions of authority at the FDA and their actions have forced many well-respected and conscientious professionals within FDA to leave their jobs. The American people cannot afford to continue to have senior FDA officials overruling sound scientific analysis in approving dangerous drugs

and forcing out professionals who expose the problems within the FDA approval and post marketing surveillance process.

On a positive note, our Congressional investigations have resulted in strengthened warnings and provided more information to protect consumers. With the SSRI's the FDA agreed to a black box warning and changed the labeling regarding efficacy in adolescents. With Bextra, the drug was pulled after our Committee staff began an investigation. With Ketek, just days before our hearing the FDA announced a new black box warning and limited Ketek's approved use.

Following inquiries by our committee, the Office of Oncology Drug Products advocated for a black box warning for the EPO drugs and convened an Advisory Committee to discuss the safety of EPO drugs. [Amgen, Johnson & Johnson, and Roche's world wide sales are about $10 billion for these EPO anemia-fighting drugs. But in recent months three "off-label" studies have been stopped because of serious adverse events such as blood clots, tumor growth and death.]

Another positive result of our bipartisan oversight and investigation work was that in November of 2004 the FDA requested the Institute of Medicine (IOM) to draft a detailed evaluation of the FDA's drug safety system. We will hear testimony today regarding the results of that IOM report and ways that the FDA can improve its drug safety.

Today, we will also have an opportunity to hear from Dr. Andrew von Eschenbach, the Commissioner of the Food and Drug Administration.

I look forward to the Commissioner's account of how his drug safety reforms will keep drugs like Ketek off the market. I also want to know what he will do to retain dedicated competent medical officers who are leaving the FDA. At our last FDE hearing, Doctors Ross and Powers were prime examples of scientists who became so disillusioned with the FDA's senior officials that they left the agency. Our country needs to keep doctors and scientists within the FDA, for their dedication is at the heart of drug safety.

As the full Committee moves forward with the re-authorization of the Prescription Drug User Fee Act (PDUFA) and reviews the Administration's draft, it is incumbent upon us to protect the American public and not the pharmaceutical companies' profits. Has this "partnership" between the FDA and the drug companies produced an agency which views its clients as the drug companies rather than the American public?

I'm curious to learn how Commissioner von Eschenbach's drug safety plan reverses the apparent partnership of automatic approval and encourages retaliation against those FDA employees who questions the agency.

I also want to hear that David Graham and other FDA employees will be listened to when they disagree with he efficacy and safety of drugs. I also hope to hear the Commissioner say that instead of discouraging dissent, he will encourage dissenting

views and that FDA Advisory Committees will hear from every FDA employee, expert and consumer who may have concerns about the safety of a drug.

I also hope to hear that both the pre-approval and post-marketing processes are going to become much, much more transparent so that the data can be evaluated inside and outside the FDA. I hope to hear a commitment that Advisory Committees will consist of members that are free of conflicts of interest. The most trusted medical journals have no trouble finding qualified peer reviewers who have no financial ties to the medical issues they are reviewing; I can't understand why the FDA can't field Advisory Committee experts who do not have an interest in the drug being reviewed.

I hope to see outside oversight on how FDA treats its whistleblowers. Specifically, I want to see the abolition of the Office of Internal Affairs and termination of the Memorandum of Understanding (MOU) that stripped the Inspector General of the responsibility for assuring the integrity of the FDA. This MOU is improper and has been systematically abused. FDA criminal investigators have been sent to harass and intimidate FDA scientists who have refused to compromise their scientific integrity. On the other hand, there have been no publicly disclosed investigations of the senior FDA officials that violate whistleblower rights.

I want to hear that FDA reviewers who uncover discrepancies, question data from drug companies, or scientific misconduct at clinical sites will not shunned. I hope that the Commissioner's statement s that he will not tolerate public dissent from within the Agency has not discouraged whistleblowers from coming forward.

I want to hear that FDA supervisors will not abuse their authority by ordering safety reviews to be changed, that advisory committees will not be misled, that drug companies will not decide the content and placement of safety information in labels, and that crucial safety data will not be ignored. I believe that FDA officials who abuse their authority by engaging in such activities endanger the public health and must be removed from their supervisory capacity.

I wish to hear that the safety of the American public is the paramount concern for the FDA when it comes to food, drugs and medical devices. More than just words, I wish to see examples that the Commissioner of the FDA can renew the DDA's mission to protect the American people and not the Pharmaceutical companies.
Without meaningful actions, how can Congress be expected to hand the FDA another 5 years of unquestionable carte blanche under PDUFA?