Statement of Henry A. Waxman
Committee on Energy and Commerce
Subcommittee on Oversight and Investigations Hearing on
"The Adequacy of FDA Efforts to Ensure a Safe Drug Supply"
March 22, 2007

Since its creation over a century ago, FDA has been a premier public health agency. Millions of Americans depend on it to protect us from unsafe foods, medicines, and medical devices. It is held up throughout the world as the gold standard. It is an agency that deserves our support in every way.

Recently there have been some very serious and concerning issues at FDA with respect to its regulation of drug safety. The series of post-market safety problems in the past few years—with drugs like Vioxx and Ketek—has demonstrated beyond a shadow of a doubt that FDA's drug safety oversight is in serious need of repair. These examples make it abundantly clear that drug safety is at least as important after approval as it is before.

The IOM has conducted a thorough examination of the current situation and concluded that our drug safety system is seriously dysfunctional. I'm glad that IOM could be here today to explain more about its findings.

The IOM report has made one thing quite clear: FDA cannot protect Americans from unsafe drugs unless Congress provides more resources and more legal authorities. Post-market drug safety oversight is currently grossly under-funded at FDA compared to the drug approval side. This is in spite of the fact that there is now an increased risk of approving unsafe drugs since PDUFA (the Prescription Drug User Fee Act) required that the timeline for drug approvals be accelerated.

In addition, the pharmaceutical industry has always fought giving FDA the modern enforcement powers it needs. For this reason, as the IOM report points out, FDA now lacks several critical authorities it needs to protect patients from unsafe drugs.

FDA lacks the authority to require post-market safety studies, even when they are necessary to determine a drug's risks.

FDA lacks the authority to impose necessary restrictions on the distribution of drugs shown to have risks.

FDA lacks the authority to place controls on the huge advertising campaigns at the launch of new drugs, which cause excessive use of drugs before their safety profile is clear.

And FDA lacks the authority to demand labeling changes after approval. FDA's authority under the current system is so weak, it guarantees that drug companies will be able to delay and water down needed warnings on drugs. The case of Vioxx is a tragic

illustration of this. FDA was forced to endure 14 months of haggling with the company before we finally saw a black box warning about the serious cardiac risks associated with the drug.

We simply have got to fix these problems.

We need strong leadership at the FDA to make the necessary changes. I am eager to hear from Dr. von Eschenbach today about the steps he intends to take to address the very serious concerns raised in the IOM report.

But clearly, Congress also has to do its part. I have my own ideas about some steps we can take—and I introduced a bill this week to address many of these areas.

We, here in Congress, owe it to the FDA to make certain that it has the basic tools and authorities it needs to fulfill its core mission—to protect the public health. We also must do what it takes to get FDA adequate funding to fulfill this mission. To do our job right, however, we need full and complete information from the FDA.

For the last century, FDA has protected the health of the American people. But it is now clear that a course correction is necessary to enable the agency to continue its historic mission.

I applaud Chairman Stupak for holding this hearing today and look forward to the witnesses' testimony.