Chairman Frank Pallone, Jr.
Subcommittee on Health
Hearing
"Assessing the Safety of Our Nation's Drug Supply"

Opening Statement

May 9, 2007

Good morning. Today the Subcommittee is holding a hearing to assess the safety of our nation's drug supply. Today's hearing is long overdue. For far too long this Subcommittee has been silent on the issue of drug safety in spite of growing concerns that the health and well being of millions of Americans may be at risk due to a broken and inadequate drug safety system.

In recent years there have been a number of revelations about drug safety that have shaken public confidence in the Food and Drug Administration's (FDA), ability to ensure that consumers have access to safe and effective medicines.

From Vioxx to Paxil, tens of thousands of patients have been placed in harms way due to the failings of our current drug safety system. As a result the American people have steadily begun to lose faith in the FDA. That must change. We must restore public confidence in FDA's ability to protect people from harmful products and safeguard the public health. But first the FDA must change.

There are a number of issues we must consider as we move forward. First and foremost, FDA is woefully under funded. This was highlighted repeatedly in the hearing we had a couple weeks ago on the reauthorization of the Prescription Drug User Fee Act (PDUFA). More money is necessary for FDA to carry out its responsibilities to protect consumers from harmful drugs.

Where that money will come from is of significant debate. There is growing concern regarding the increasing amount of user fees that FDA relies on to fund its budget. As I have said before, if given the option, I think everyone would agree that FDA should be funded more, if not entirely, by annual appropriations. But, realistically speaking, we are not in a place where we cannot rely upon user fees to help support the functions of the FDA. That is not to say that we should give the drug industry carte blanche on how these fees should be applied. FDA should have more flexibility about what functions these monies can be used for, such as post-market surveillance.

For far too many years, the focus of FDA has been to improve the amount of time it approves new drugs. This is, of course, a direct result of previous PDUFA agreements in which industry provides a new revenue stream to FDA and in exchange establishes benchmarks for a more timely drug approval process.

Unfortunately, however, this has caused an imbalance between the pre-approval process and the post-market monitoring of drugs. We must fix this imbalance and focus more of our attention on what happens with drugs once they reach the market place. Assessing the risk of a drug once it is on the market is just as important, if not more, than before it is approved.

How might we achieve a more robust post market drug safety system? Fortunately, we seem to already have many of the answers. First, we need to give FDA greater authority and flexibility to manage the risks associated with a new drug once it has been approved. Currently, FDA has little authority to control how a drug is marketed and how the risks and benefits are communicated to consumers. FDA should have more options to mitigate the risks consumers face from a particular drug other than pulling it off the market entirely. Let's give FDA the ability to require label changes should it deem them necessary. Similarly, FDA should have the authority to require as a condition of approval that manufactures follow through on their commitments to conduct and publish phase IV trials.

Even more important is ensuring that information about clinical trials, including their results, is made public. It makes no sense that we would allow such information to remain locked away at the discretion of the industry. If my Republicans friends are so keen on transparency in the health care market place, let's start with full transparency of clinical trials. Let the consumers and their doctors decide what they think is safe or not based on complete information. The results of these clinical trials contain valuable information for patients and their physicians, and we should demand that they be made available.

Finally, I want to voice my concern about Direct-To-Consumer (DTC) advertising. I realize that this is a very contentious issue and I appreciate the industry and FDA's willingness to work out a compromise, which was included in this year's PDUFA proposal. However, as I said a couple of weeks ago, I am not certain that the new program outlined in the PDUFA proposal will suffice. The fact that the program relies on voluntary participation from the industry strikes me as a program with no teeth. I am skeptical of these advertisements and the alleged value that they bring to consumers. We will have to look at this program further and ensure that consumers' best interests are being served well.

There are many other issues that need to be discussed as we talk about drug safety. That is why today's hearing is an important one, and like I said in the beginning of my statement, it is long overdue. I am looking forward to hearing from today's witnesses and I thank you for being here with us. I now recognize my good friend from Georgia, Mr. Deal, for five minutes for the purpose of making an opening statement.