Chairman Frank Pallone, Jr.
Subcommittee on Health
Hearing
Reauthorization of the Prescription Drug User Fee Act

April 17, 2007

Opening Statement

I would like to welcome everyone to today's hearing, which will be the first in a series of hearings over the next few weeks that will focus on issues involving the Food and Drug Administration (FDA), including the Medical Device User Fee and Modernization Act (MDUFMA) reauthorization; creating a pathway for FDA approval of follow-on biologics; as well as drug safety issues.

But today's hearing will focus on the "Reauthorization of the Prescription Drug User Fee Act", otherwise known as PDUFA. Originally authorized in 1992, PDUFA has provided FDA with the additional resources it needs to efficiently review an application for a new drug or biologic to enter the market.

Prior to the 1992 law, it would take FDA up to 29 months, sometimes longer, to approve a new drug application or biologic licensing agreement. This backlog was cause for concern for both patients and drug manufacturers.

Patients had to wait longer to receive new therapies for life threatening illnesses such as HIV/AIDS or cancer. Pharmaceutical companies were threatened by the loss of time they would have to recoup their investments on research and development.

In order to remedy these problems, Congress passed landmark legislation which established a user fee system in which drug manufacturers would provide a revenue source to the FDA to help expedite the review of new drug and biologic applications. Since its enactment the user fee program has been viewed largely as a success. It has allowed FDA to increase the size of its workforce in order to speed up review times. As a result, the median time between when a new drug application or biologic licensing agreement is submitted and FDA approval has decreased dramatically.

But shorter review times should not be the only measure of success for the program. As we set out to reauthorize this important program for a third time, we must examine a number of issues that remain unresolved.

For example, we must pay attention to the tradeoffs we make by expediting FDA's approval process. There are legitimate concerns, both in and outside of Congress, that in our rush to speed drugs to market, we could be overlooking critical safety issues and place patients at risk. We must strike the right balance between a timely pre-market review process and a robust post-marketing surveillance system to ensure patients have access to the safest and most effective medicines. Previous authorizations of PDUFA have focused more on the pre-market side of the process and I believe it is necessary for us to spend more time examining how we should strengthen our nation's post-market surveillance system this time around.

To that end, the agreement reached between the FDA and industry to increase the amount of user fees that can go towards post-marketing surveillance is a step in the right direction. But that is not to say that Congress should not take any steps further.

There are a number of proposals that would improve upon the FDA's ability to monitor a drug over the course of its life-cycle as the Institute of Medicine (IOM) suggested. We need to ensure that FDA has the resources and authority necessary to ensure the safety of a drug once it is already on the market. These are important issues that are quite literally life and death for millions of Americans. That is why the Subcommittee will examine drug safety in part today, but more thoroughly in a separate hearing as well.

Furthermore, while I am pleased to see that the FDA and the industry have reached an agreement on Direct-to-Consumer Advertising, I am not certain that what has been laid out will suffice. Under current law, FDA does not have prior-approval authority for prescription drug advertising. Rather, FDA relies on drug makers to voluntarily submit their ads for review. Nothing in the current proposal would change that. The program outlined in PDUFA IV still relies on the industry to voluntarily subject its ads to FDA review. This type of self-policing strikes me as something along the lines of the fox guarding the hen house. I realize there are constitutional concerns involved here, but this part of the proposal may need some work, particularly as it relates to the mass marketing of new drugs approved by the FDA.

In the end, I will say that many of us probably wish that there wasn't a need for the PDUFA program and that FDA could be funded entirely out of general revenues, but that possibility does not currently exist. In the absence of that, I think that the PDUFA program has worked well and there is strong support for its reauthorization. Now it is time for us to roll up our sleeves and get to work. I would like to thank our witnesses for being here today and I look forward to your testimony. I now recognize our Ranking Member, Mr. Deal, for five minutes for the purpose of delivering his opening statement.