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House of Representatives
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Opening Statement of Rep. Henry A. Waxman
Ranking Member, Committee on Energy and Commerce
Hearing on “Reauthorization of PDUFA: What It Means for
Jobs, Innovation, and Patients”
Subcommittee on Health
February 1, 2012

Today, we begin, once again, the process of reauthorizing the “UFAs” and our pediatric drug testing laws.

I have been a part of this process since the inception of each of these programs, starting first with the Prescription Drug User Fee Act in 1992. In every reauthorization, we have worked together on a bipartisan basis. That is how it should be given the role these laws play in helping FDA fulfill its vital public health mission – and that is how I hope it will be this year.

The drug and device user fee programs ensure that FDA gets critical dollars to allow the agency to complete its premarket review in a timely manner so that patients have access to therapies at the earliest possible time. The Best Pharmaceuticals for Children Act (BPCA) and the Pediatric Research Equity Act (PREA) give FDA the authority to obtain information about the use of drugs in children. And this year, for the first time, we will be establishing two new programs to help speed FDA’s review of low cost generics and biosimilars.

As we begin this process, these are the primary goals we need to keep in mind. We must reauthorize—and establish—these essential programs in a timely way so that FDA can do its job protecting the health and safety of American patients.

It would be irresponsible to allow this legislation to become a vehicle for the wish lists of members seeking to move their own controversial bills. We should continue the long tradition of “UFA” bipartisanship and work together to ensure this does not happen.

I am concerned, however, about some of the bills under consideration. Some of these bills would prevent FDA from insisting on adequate data from clinical trials and forcing it to approve drugs and devices on an incomplete record. These proposals could undermine the safety and efficacy of our drugs and devices. Another would enrich the pharmaceutical industry by gutting the time-tested system of incentives provided under Hatch-Waxman.

The cost of this windfall would be paid by American patients who would be forced to pay monopoly drug prices for 15 years.

Another controversial proposal the majority intends to consider would fundamentally reform FDA's mission by adding "economic growth, innovation, competitiveness, and job creation" to the agency's priorities.

I strongly support growth and job creation. But I hope we would all agree that FDA should not take jobs into consideration when it is reviewing the safety and effectiveness of a new medicine. We want FDA to ensure that our drugs and devices are safe and effective. Whether jobs will be created is simply not a part of that scientific public health equation.

It appears that many of these proposals are driven by rhetoric insisting that FDA has become too demanding of companies seeking to market their drugs and devices, which is allegedly driving innovation and jobs abroad. When we examine these claims, we must insist on data and on facts. Anecdotes from individual constituent companies do not qualify as fact.

I am aware of no reliable data showing that these claims are true. To the contrary, the studies show that FDA actually approves drugs faster than our counterparts in Europe. I am also aware of a study showing that FDA is quite flexible in its requirements in reviewing orphan drug applications. In fact, NORD is here today and will testify on this study.

We should all be united in the goal of ensuring that we have a strong, well-resourced FDA that is armed with a full complement of authorities to protect us from unsafe drugs and to assure that those drugs work. That is FDA's fundamental mission.

It is in no one's interest to have a weak FDA. American consumers depend on FDA to verify that the drugs and devices we take and use are truly safe and effective. If Americans lose confidence in the FDA, they will lose confidence in the pharmaceutical and medical device industries as well. That should be of utmost concern to us all.

Let me briefly make one final point. Mr. Pitts, I appreciate that you have agreed to make the increasing globalization of our drug supply a feature of our hearing. It is a critically important issue, given that more than 80% of active pharmaceutical ingredients are manufactured abroad.

FDA has indicated that it needs an updated set of tools to deal with this dramatically different marketplace and I look forward to hearing more on this issue from our witnesses today. Mr. Dingell, Mr. Pallone, Ms. DeGette, and I have proposed legislation—the Drug Safety Enhancement Act—that will go a long way toward providing FDA with these much-needed resources and authorities.

I look forward to hearing from our witnesses today and, I hope, to work with my colleagues on a bipartisan basis on these important matters.