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Opening Statement of Rep. Henry A. Waxman
Ranking Member, Committee on Energy and Commerce
“PDUFA V: Medical Innovation, Jobs, and Patients”
Subcommittee on Health
July 7, 2011

Thank you, Chairman Pitts, for holding this hearing today.

I think we can all agree it is critically important that there be vibrant and flourishing innovation in the pharmaceutical industry. The medicines this industry has brought us have saved countless lives and improved the quality of life for people the world over.

Unfortunately, by most accounts, we are in the midst of a dramatic slowdown in drug development in the United States.

The reasons for this slowdown are complex and multi-faceted. At a time when you would expect there to be a surge of innovation—for example, because there is an unprecedented number of drugs coming off patent—the opposite appears to be true. I hope our witnesses will help us understand what is causing this innovation deficit and what we can do to help our drug companies succeed.

A rising chorus of voices has begun to assert the view that it is the FDA that is responsible for this downward trend. These critics claim that FDA takes far longer to approve drugs than does its counterpart in Europe. Some claim it takes the U.S. twice as long as Europe; others claim it takes three times as long. These claims may sound convincing, but we have yet to see the data to support them.

I am aware of only one peer-reviewed study comparing drug approval times in the United States and Europe, and it found the exact opposite. This study, which examined the approval of 35 new cancer drugs, was conducted by one of our witnesses today, the Friends of Cancer Research. It found that the FDA is actually approving these life-saving therapies much faster than its European counterparts.

Some view every decision FDA makes through the prism of whether it is good for the pharmaceutical industry. But that’s not the right perspective. The question we should be asking is: what is the right decision for patients?

It is in no one's interest to have a weak FDA. American consumers depend on FDA to verify that the drugs we take are truly safe and effective. If Americans lose confidence in the FDA, they will lose confidence in the pharmaceutical industry as well.

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.

And that is why I will be strongly opposed to any legislative proposals that would prevent FDA from insisting on adequate data from clinical trials and force it to approve drugs on an incomplete record. These proposals would prove disastrous for the safety and efficacy of our drug supply.

The title of this hearing suggests that our colleagues across the aisle believe that FDA's mission should encompass job creation. Democrats have been leading the charge for legislation to promote jobs and we have been bitterly disappointed by the failure of the House to pass pro-jobs legislation.

But we should not be misled into believing that today's hearing is a genuine look at how to resolve our job shortage. 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 the drugs we take are safe and effective. Whether jobs will be created is simply not a part of that scientific public health equation.

I do believe there are areas in which the agency's regulation of drugs could improve. For example, improvements in FDA's scientific capacities will enable FDA to identify early endpoints that can predict whether a drug will be effective, which can result in better design of clinical trials and faster approval of new drugs.

Making these kinds of strides requires that we work from real data, not self-serving urban myths. It will also require a significant influx of resources. It is ironic that at the same time they are complaining that FDA should do a better job, the Republicans in the House have just passed an appropriations bill that would gut FDA funding by over \$500 million.

Let me turn briefly to another issue that will be explored today: the increasing globalization of our drug supply. The world has changed from the days of the original Food Drug and Cosmetic Act. Today, more than 80% of active pharmaceutical ingredients are manufactured abroad, with China and India comprising the largest sources. Just yesterday there was a report in *The Wall Street Journal* about the poor regulatory oversight of Chinese pharmaceutical manufacturers and the resulting compromised drug quality.

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.

Our staff has reached out to your staff, Chairman Pitts, and Chairman Upton's staff as well, requesting that we engage in a bipartisan process to look at this bill and work toward incorporating whatever we can ultimately agree upon into the PDUFA package next year. I hope, Mr. Chairman, that I can count on your commitment to work with us on this critically important legislation.

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.