

ONE HUNDRED TWELFTH CONGRESS  
**Congress of the United States**  
**House of Representatives**  
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**Opening Statement of Rep. Henry A. Waxman**  
**Ranking Member, Committee on Energy and Commerce**  
**Hearing on “FDA User Fees 2012: Hearing on Issues Related to Accelerated**  
**Approval, Medical Gas, Antibiotic Development**  
**and Downstream Pharmaceutical Supply Chain”**  
**Subcommittee on Health**  
**March 8, 2012**

Today’s hearing will examine some proposals designed to address an array of important public health issues. These proposals are not integral parts of the user fee agreements themselves, but would be added to the package of bills as they move.

Although we have not seen legislative text yet, the proposed list of user fee add-ons is long.

As each day passes, I am increasingly concerned about whether we will have time to get to bipartisan agreement on such an ambitious package of bills.

The policies we will be discussing today involve complex public health issues. For us to do a responsible job on these proposals, we need time and we need bipartisan agreement. We should not rush this work. We should prioritize getting it right—not just getting it done. If we are able to come to bipartisan agreement in the time available, it makes sense to move them along with the other bills. Otherwise, I hope we can all agree it will be better to wait so that we do not jeopardize the passage of the underlying user fee bills.

Let me turn to some of the specific proposals.

As we learned in the series of hearings this Subcommittee held in 2010, the problem of antibiotic resistance is a dire public health threat. And our arsenal of effective antibiotics is running dangerously low. So clearly we need to look at ways to incentivize the development of new antibiotics. The GAIN Act is a good first step at achieving this goal.

However, we should ensure that the bill is narrowly tailored to drugs that treat dangerous infections for which we don’t have adequate treatments. Otherwise, we risk worsening the problem of resistance. We also need to ensure that the bill mandates that FDA and other

agencies involved take steps to ensure that the efficacy of these newly developed antibiotics is preserved once they are on the market.

We will also hear today about FDA's Accelerated Approval system. We can all agree that we want the most effective, innovative medicines to be available at the earliest possible time.

So if there are improvements that could be made in the way FDA reviews these medicines, we should consider them. But I am concerned that some of these proposals are driven by unsubstantiated claims that FDA has become too demanding of drug companies, requiring too much data, and thereby allegedly keeping drugs from patients and driving innovation and jobs abroad.

As we have heard at previous hearings, there is apparently no reliable data to back these claims up. To the contrary, as the testimony of Friends of Cancer Research and FDA have shown, FDA actually approves novel drugs faster than its counterparts in Europe or anywhere else in the world. In the past, the National Organization for Rare Disorders has also testified about its study showing that FDA is quite flexible in its requirements for approving orphan drugs.

I am open to considering whether legislation can help FDA work with companies to get more breakthrough medicines to patients more quickly. However, we should ensure that any such adjustments do not alter FDA's approval standards.

Today's hearing will also examine efforts to improve the integrity of our drug supply chain. There is currently a regulatory void at the federal level because the U.S. does not currently have laws requiring the tracking and tracing of pharmaceuticals. Consequently some states have stepped in and enacted their own laws. As we will hear today, California currently has a law that would mandate one of the most robust pedigree systems in the country. Many have suggested that there is a need for a single federal system that would preempt these state laws. I believe having a system at the federal level could make sense if done correctly. But I would have grave concerns about preempting a strong state law, especially in California.