

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 “Review of the Proposed Generic Drug and Biosimilars, User Fees and**  
**Further Examination of Drug Shortages”**  
**Subcommittee on Health**  
**February 9, 2012**

Today, we begin the process of establishing two critically important programs at FDA that will help speed low-cost generic drugs and biosimilars to the market. Because these are new user fee programs that will now join the other long-existing programs, just yesterday, Representatives Murphy, Pallone, Pitts, and I introduced the Generic Drug and Biosimilars User Fee Act which will give FDA the authority and resources it needs to review generic drug and biosimilars applications in a timely and effective manner.

I am proud that we were able to work together in such a strong bipartisan fashion on this legislation. It reflects our shared commitment to ensuring that American patients have access to these life-saving medicines, early, and at a price they can afford. I also want to commend FDA and the biotech and generic drug industries for the hard work they put into negotiating these thoughtful and thorough proposals.

These programs are long-overdue. We have had a long history of success with the other user fee programs for brand-name drugs and medical devices.

In contrast, for some time now, FDA’s generic drug review program has been starved of resources, which resulted in a dramatic backlog of applications. That, of course, has meant fewer generic drugs on the market, and consequently higher medication prices for American patients. At long last, this legislation will help turn this untenable situation around.

Likewise, FDA will also now have the resources it needs to review applications for biosimilar drugs. By most accounts, biotech drugs are the most promising medicines on the horizon. This law will permit FDA to fully implement the newly established biosimilars pathway and, we will all begin to see its benefits soon.

On a different note, I am encouraged that the subcommittee is taking another look at the very dire situation surrounding drug shortages. This is the kind of issue that can and should be tackled on a bipartisan basis. It is a complex and multi-faceted problem, but I feel confident we will work together to find workable solutions.

Thank you for holding this hearing today, and I look forward to hearing from our witnesses.