

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
Markup of FDA User Fee Legislation
Subcommittee on Health
May 8, 2012

Thank you very much, Mr. Chairman. I want to start off by commending you for holding this markup and for leading our subcommittee to a bipartisan achievement. The consideration of this bill should be a model for legislative action.

This landmark legislation touches on some of the most essential areas at the FDA.

With this bill, we will reauthorize the drug and medical device user fee programs, which will ensure that FDA has the resources necessary to review applications and give patients access to therapies at the earliest possible time. We will also reauthorize the Best Pharmaceuticals for Children Act (BPCA) and the Pediatric Research Equity Act (PREA), which 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.

We will give FDA new tools to address the challenges posed by our increasingly globalized drug supply chain. We based these provisions on the Drug Safety Enhancement Act introduced by Mr. Dingell, Mr. Pallone, Ms. DeGette, and myself. We worked hard to come to bipartisan agreement in this area. When these provisions are enacted, Americans can take comfort in knowing that the drug supply will be safer as a result.

When we started this process, we had disagreements, but we resolved those disagreements.

We also have included some important provisions that will go a long way toward addressing the problems associated with drug shortages, which have unfortunately now become an all-too frequent occurrence.

Our bipartisan work has truly paid off.

While I support this bill, it is no secret that I continue to have strong concerns in the area of antibiotics.

As I have mentioned at previous hearings on this issue, I agree that we need to look at ways to incentivize the development of new antibiotics, given that our pipeline is running dangerously low. The GAIN Act is a good first step at achieving this goal. However, I regret that we failed to narrowly tailor the bill to target only drugs that treat dangerous infections for which we don't have adequate treatments. As the bill reads now, essentially any antibiotic can qualify for the incentives included in the bill. I hope we can continue to work on ways to address this issue.

I want to thank my colleagues on both sides of the aisle, and I particularly want us to pay recognition to the hard work that our staffs have done. On the Democratic side, I'd like to thank Rachel Sher, Eric Flamm, Arun Patel, and of course, Karen Nelson, Tiffany Guarascio, and Kim Trzeciak, on Rep. Dingell's staff. On the Republican side, I'd like to thank Ryan Long and Clay Alspach. Congratulations to all the staffs. They worked very, very hard and had to deal with a lot of complicated, difficult issues, but they accomplished what all of us wanted, which is a strong, bipartisan bill that we can move forward.