

ONE HUNDRED TWELFTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115

Majority (202) 225-2927
Minority (202) 225-3641

Opening Statement of Rep. Henry A. Waxman
Ranking Member, Committee on Energy and Commerce
Markup of H.R. 5651, the Food and Drug Administration Reform Act of 2012
Full Committee
May 9, 2012

This bill represents a significant bipartisan achievement. Its consideration is a model for legislative action.

When we began this process, there were wildly divergent views on the various issues contained in this bill. But we worked together and found ways to address those issues in a way that protects both innovation and patients.

As we all know, timely passage of this legislation is critical to the functioning of major parts of the FDA. Our reauthorization of FDA's drug and medical device user fee programs will provide resources to enable the efficient review of applications and give patients access to therapies at the earliest possible time. We are also reauthorizing two pediatric programs, the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act, which give FDA the authority to obtain information about the use of drugs in children.

This year we will be establishing two new programs to help speed FDA's review of low cost generics and biosimilars.

Generic drugs account for nearly 80% of all prescription drugs in the United States. They play a vital role in keeping our overall healthcare costs down. Unfortunately, in recent years, a lack of resources in FDA's generic drug review program has resulted in significant delays in the agency's review of generic applications. As a result, generic competition has suffered. The Generic Drug User Fee Act will provide a much-needed infusion of dollars that will enable the agency to finally reverse this trend. All of us will see the benefits when more low-cost generics are on the market.

The Biosimilars User Fee Act will similarly provide FDA with new dollars to review applications for biosimilars. More biosimilars on the market will not only lower prices, but will stimulate innovation.

The bill also includes provisions to modernize FDA's authorities with respect to the drug supply chain. FDA has been trying to keep pace with our increasingly globalized drug supply chain using an outdated statute. This legislation will give FDA critical new tools to police this dramatically different marketplace. We based these provisions on Mr. Dingell's, Mr. Pallone's, Ms. DeGette's, and my Drug Safety Enhancement Act. I am pleased that my colleagues on both sides of the aisle recognized the importance of this problem and worked on a bipartisan basis to address it.

When we started this process, I had a lot of concerns about many of the Republican proposals relating to medical devices. But we worked together to address those concerns and to assure that nothing in this bill will take us backwards in terms of patient safety.

We also have included some important provisions that will go a long way toward addressing 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. I agree that we need to look at ways to incentivize the development of new antibiotics. But I am disappointed that we did not adequately narrow the provisions of the GAIN Act to target only drugs that treat serious and life-threatening infections. As the bill reads now, essentially any antibiotic can qualify for the incentives included in the bill. That threatens to worsen the problem of antibiotic resistance.

I also think it is critical that when we get new antibiotics, we need to ensure that we take all necessary steps to prevent unnecessary use so that we preserve their effectiveness. I am happy the issue is being addressed in the report language that was added to the bill. But I hope we can continue to work to include a directive to HHS to institute programs that would preserve new antibiotics that are developed as a result of the GAIN Act.

Going forward, I hope we can continue to work on ways to address these issues.

I want to thank my colleagues on both sides of the aisle, and their staffs, for the hard work they have put into making this a strong, bipartisan bill. I particularly want to thank Mr. Pallone's and Mr. Dingell's staff members Tiffany Guarascio and Kim Trzeciak, as well as Mr. Upton's and Mr. Pitts' staff, Ryan Long and Clay Alspach. And, finally, my own staff: Karen Nelson, Rachel Sher, Eric Flamm, and Arun Patel.

I look forward to continuing to work together to move this important legislation through the floor and into law at the earliest possible moment.