

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
Hearing on “FDA User Fees 2012: How Innovation Helps Patients and Jobs”
Subcommittee on Health
April 18, 2012

Chairman Pitts, thank you for holding this hearing today.

Although we were not able to come to full agreement in time for the discussion draft released yesterday, I am very pleased with the progress that we have made on this user fee package thus far. And I am optimistic that we will get to full agreement soon.

We all know how important it is to reauthorize the underlying user fee programs in a timely way. No one is served by adding controversial proposals to the bill. That would only serve to slow the process.

So far, we have worked together to avoid weighing down this critical legislation with extraneous policies about which we cannot agree. This will ensure that we get the work on these critically important bills done in time.

I am particularly hopeful about the progress we have made in the area of drug safety as it relates to the increasingly globalized supply chain. Mr. Dingell has a strong bill that has served as a template in this area, and I appreciate all the work that Mr. Upton and Mr. Pitts have done to incorporate provisions modeled on that bill.

I want to note however that I continue to have strong concerns with respect to devices. We have all heard the increasing rhetoric that FDA is slowing innovation and forcing jobs abroad, but that does not justify the troubling provisions that could compromise patient safety that are under consideration. There are numerous examples of unsafe medical devices that have been permitted on the market and have caused incalculable suffering for victims. And that occurs under the current system with the powers FDA has today. Now is not the time to go backwards and take away important authorities from FDA that it needs to help ensure the safety and effectiveness of devices. I will continue to oppose the addition of any provisions that would prevent FDA from doing what it feels necessary to protect patients from unsafe and ineffective devices.

Let me turn now to the area of antibiotics. The discussion draft includes the GAIN Act, which is a good first step toward creating incentives for the development of new antibiotics, which we all agree we desperately need. I remain concerned that the bill does not narrowly target antibiotics that treat dangerous infections for which we don't have adequate treatments. The bill should also include provisions to ensure that the efficacy of these newly developed antibiotics is preserved once they are on the market. These are goals we should all share and I am optimistic that we will fix the bill to achieve them.

I also look forward to learning more today about a proposal put forward by the Infectious Disease Society of America, the Limited Population Antibacterial Drug or LPAD approval mechanism. This proposal would establish a more rapid regulatory pathway for new antibiotics targeted at the most serious infections.

The concept appears to have great promise at speeding important new antibiotics to the market, but I think we need to be assured that these drugs will not be inappropriately used. If we cannot get that assurance, we should all be concerned about moving forward with this kind of proposal.

Strengthening and improving FDA is in the interest of all Americans. I look forward to continuing to work with all of my colleagues on this Committee to reach bipartisan agreement on this critically important legislation.