

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 “Reauthorization of MDUFA: What It Means for**  
**Jobs, Innovation and Patients”**  
**Subcommittee on Health**  
**February 15, 2012**

Thank you, Chairman Pitts, for holding this important hearing.

Our goal today is to start the process of reauthorizing the Medical Device User Fee Act. I commend FDA and the industry for finally coming together to agree on a user fee proposal. It was a hard-fought compromise and I look forward to seeing the details.

But I’m pleased that there has been an agreement because I have very little faith in Congress to provide the appropriations for the FDA to do the job without a user fee. I’d prefer we do it that way, and those who don’t like the user fee will have to acknowledge that FDA will be short-funded and we won’t get these devices approved as quickly as possible.

The funds collected under this Act will provide FDA’s device program with critical dollars that enable the agency to fulfill its public health mission: to ensure that only safe and effective medical devices are marketed in the United States. That is our essential goal here. We should work together on a bipartisan basis to get it done.

The real compassion in this country is to make sure that we can get drugs and devices that work and that are safe to consumers, not just to get them out on the marketplace. It is to no one’s benefit to have drugs that are not safe or medical devices that are not safe or effective. The FDA, the device industry, and American patients are counting on us to do our job.

I am concerned, however, that some may try to hijack the reauthorization to advance proposals that would put the health of patients at risk.

Last year, Republican members of the Committee introduced a slate of ten bills that would make significant and harmful changes, in my view, in FDA’s device program. Unless we can reach consensus on these proposals, they should not be inserted into this must-pass reauthorization.

The newspapers are full of articles about the dangers of improperly designed medical devices. The prestigious Institute of Medicine concluded that our medical device laws need to be significantly strengthened. But many of these bills ignore the need for reforms that would protect patients. Instead, they read like a wish list assembled by lobbyists for the device industry.

The device industry claims that FDA regulation is killing jobs, stifling innovation, and depriving American patients of new medical devices. But there's no evidence to back these up except anecdotes. Anecdotes from individual companies are not enough.

And I think the industry knows that they need the FDA to do its job if they're going to have credibility in the marketplace.

I have been appalled by the quality of the so-called "studies" industry is using to advance these bills. Last July, I asked the editors of our nation's top medical journals to examine the methodology used in the leading industry papers asserting that FDA is too slow, burdensome, and unpredictable.

The editors said there were serious methodological flaws in both studies -- biased samples, small sample size, and botched statistical analysis, just to name a few -- rendering them essentially useless as part of any discussion of FDA's regulatory system. None of the editors felt that the methodology of these studies was worthy of publication in a peer-reviewed journal, yet they're put forward as a reason why we ought to change the law here in Congress.

Many in the device industry argue that Europe should be our model and they say new technologies are available years before they are on the market in the U.S.

But just yesterday, the New England Journal of Medicine published a study by Dr. Aaron Kesselheim finding numerous examples of high-risk devices that were first approved in the E.U. but either showed no benefit, or, worse, had substantial safety risks. I am glad Dr. Kesselheim is here today to testify about this study.

FDA's job is to protect the public health. Part of advancing public health is helping manufacturers win approval for innovative new devices. But FDA's core responsibility is ensuring that only safe and effective devices are permitted on the market.

When FDA falls short and allows dangerous devices like surgical mesh and metal-on-metal hip implants to be implanted in patients, the suffering of victims can be incalculable.

That is why I joined with Mr. Pallone, Mr. Dingell, and Ms. DeGette to request that the Committee hear from witnesses about the risks from dangerous devices. I want to thank Subcommittee Chairman Pitts and full Committee Chairman Upton for working with us to allow these witnesses to testify today on the second panel.

The reauthorization of MDUFA should be bipartisan, so I urge all members of the Committee to work together on this critically important program.