

ONE HUNDRED TWELFTH CONGRESS
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Opening Statement of Rep. Henry A. Waxman
Ranking Member, Committee on Energy and Commerce
“Impact of Medical Device Regulation on Jobs and Patients”
Subcommittee on Health
February 17, 2011

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

Let me start off with a couple of statements on which I think we can all agree: we all want to ensure that innovation in the medical device industry is vibrant and healthy, so that we have access to the best and newest technological advances. We also all want the medical devices we use to be as safe as possible and to have every confidence that they are effective. If there are factors that are preventing or inhibiting these things from occurring, we should all be united in doing whatever it takes to reverse those influences.

But we cannot have a conversation about innovation and speeding new devices to the market without talking about the importance of ensuring the safety and effectiveness of those devices.

So this hearing should be about how we can work together to meet these goals.

We will hear today from witnesses, invited by the Republicans, who will express their concerns that the FDA’s device regulatory system is inhibiting innovation, depriving patients of new and potentially life-saving devices, and costing Americans jobs. To focus on the other end of the equation, we have also invited two witnesses who will focus on FDA’s responsibility to ensure the safety and effectiveness of devices. We also are fortunate to have FDA itself here to respond to concerns on both issues.

We should carefully explore the concerns about the state of innovation in the device industry. It is important that we ask some hard questions about the facts and data underlying these assertions. Although Dr. Makower’s study, for instance, raises some important questions, it is also clear there are some significant limitations to what it tells us about what is actually going on. According to the study itself, it includes a very small portion of the device industry—only 204 out of some 16,000 companies registered with the FDA. It also includes a majority of

responses from companies that appear to have had very little previous experience with FDA's regulatory process.

The study asserts that it takes much longer for devices to reach the market as compared to the EU. Obviously, we would all be concerned if that was the case. But we need to make our judgments based on good data. I think there are some real questions about whether Dr. Makower's study demonstrates that these EU vs. US time differentials even exist, and whether Dr. Makower's study was comparing equivalent measures for times to market. I will look forward to hearing from our witnesses on these points.

I will also look forward to hearing from our witnesses about the need to assure that devices are safe and effective when they reach the market. There are countless, and often tragic, stories of patients injured, and even killed, by unsafe devices. The study that Dr. Nissen will describe today shows that many devices that were recalled for serious safety reasons were not reviewed by FDA under the more stringent premarket approval, or "PMA," process. That has got to be a concern. We need to ask why so many unsafe devices ultimately harm patients and explore what can be done to prevent injuries in the future.

In order to have a flourishing and innovative American device industry that puts safe and effective devices on the market, we need to have a strong and well-resourced FDA. That is in the best interest of American patients—but it is also in the interest of the device industry itself. If patients lose confidence in the FDA, they lose confidence in industry as well.

This is an issue that can and should be bipartisan. I look forward to hearing from our witnesses today and to working with my colleagues on this important matter.