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Opening Statement of Rep. Henry A. Waxman
Ranking Member, Committee on Energy and Commerce
"Regulatory Reform Series #5 - FDA Medical Device Regulation: Impact on American Patients, Innovation and Jobs"
Subcommittee on Oversight and Investigations
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Thank you, Chairman Stearns, for holding this important hearing today.

I think we can all agree it is critically important that innovation in the medical device industry is vibrant and healthy, and that patients have access to the best and newest technological advances. If FDA is unnecessarily impeding technological advances that improve the lives of patients, we should all be united in doing whatever it takes to remove these unnecessary regulatory barriers to public health

But we cannot have a conversation about the impact regulations and policies at FDA have on patient access and innovation without talking about the importance of ensuring the safety and effectiveness of medical devices. We should not forget that that is the fundamental mission of FDA.

Practically every month, there is a new report in the papers about horrific patient suffering from dangerous medical devices. Last year, *The New York Times* revealed that radiation machines have killed and disfigured patients. The Subcommittee on Health held a hearing on the issue and heard from a father whose son was killed by an overdose from radiation therapy. We learned this year that malfunctioning linear accelerators have left patients nearly comatose and unable to speak, eat, or walk.

Just last month, *The New York Times* reported on the suffering caused by faulty metal-on-metal hip implants. According to the *Times*, patients were promised these hips would last longer and enable more activity. About half a million patients got these devices. Now, they are being recalled due to high rates of failure and patients have suffered severe health effects and have been forced to undergo surgery to replace the defective devices.

And these are just the most recent examples. We've also heard about problems with implantable heart devices that shocked patients and led to at least 12 deaths. Implantable defibrillators made by another company were failing for years before the manufacturer told anyone.

Our focus in this Committee should be on how we can strengthen our device laws to protect patients from these grievous harms. Yet I fear that this is not the Committee's goal today. Instead of strengthening our device laws, Republican members have proposed radical changes to our device laws that could further imperil patients.

That is exactly the wrong direction for us to take.

We will hear testimony today that FDA is imposing new restrictions to innovation. Device industry advocates often refer to two industry-funded reports – one conducted by Dr. Josh Makower and one by the California Health Institute – that they say show that FDA is unduly slow, burdensome, and unpredictable.

Yet neither of these studies was published in a peer reviewed journal, and both of these studies were funded by and conducted for industry advocates. Because of the lack of independent validation for these reports, I asked my staff to request that the editors of our nation's top medical journals, one of whom is a witness today, examine the methodology of these two industry papers. All three editors we asked agreed to participate.

As our witness will describe today, there are 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.

We will also hear today from six witnesses who will express their concerns that the FDA's device regulatory system is depriving patients of new and potentially life-saving devices, inhibiting innovation, and costing Americans jobs.

FDA can and should do better in many of these cases. But we can't legislate by anecdote.

We need to ask why unsafe devices have gotten onto the market and harmed so many patients. Then we need to explore how we can strengthen the FDA review process to protect patients from these risks. The soon-to-be-released recommendations from the Institute of Medicine could provide a roadmap for how to improve FDA's regulatory oversight of medical devices.

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 the industries it regulates 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.