

COMMITTEE ON ENERGY AND COMMERCE
AND THE SUBCOMMITTEE ON HEALTH

CHAIRMAN FRANK PALLONE, JR.

HEALTH SUBCOMMITTEE HEARING

**“Medical Devices: Are Current Regulations
Doing Enough for Patients?”**

OPENING STATEMENT

June 18, 2009

Good morning. Today the Subcommittee is meeting to discuss the FDA’s regulation of and authorities over medical devices. The goal of today’s hearing is to determine if the current regulations are doing enough for patients while ensuring that these very important and sometimes life-saving devices are truly safe and effective. We are here to hear about where the current system works well and where shortfalls might be. There is evidence of an approval system is broken - that it's standards, its procedures and its rules don't meet modern needs of getting medical devices to those in need with confidence in they're safety.

We have made huge advances in medicine over the last few decades. Many illnesses that were once a death sentence are now preventable, curable or at least manageable through modern medical treatments. New and emerging technologies hold promises that our great grandparents could never have imagined and the medical device industry is one of the main drivers of this progress. From pacemakers to artificial hips to tongue depressors, we cannot enter the health care system without coming into contact with these devices.

We need an approval process that keeps pace with new technologies - a modern process consistent with progress in medicine.

We have to maintain the delicate balance between wanting to put these new technologies in the hands of patients who desperately need them and ensuring that the devices are actually safe for use in humans. It is a struggle that we in Congress are all too aware of. We have taken a similar approach with "preemption."

Last month, this Subcommittee held a hearing on the issue of preemption in the wake of the *Riegel vs. Medtronic* Supreme Court decision. The Supreme Court ruled that patients could not receive compensation for their injuries, medical expenses, and lost wages caused by defective premarket approval (PMA) devices or inadequate safety warnings. While state product liability provides incentives for companies to make safe products, it should not be the only tool we have to ensure that the medical devices that are on the market today are safe. We need to know that the approval process and the regulatory standards are strong and enforceable and that the agency is empowered with the ability to ensure the safety of these products.

It is for this reason that we are hear today at this hearing on the medical device approval process. I want a comprehensive overview of the major issues and potential problems that may arise in the regulation of medical devices. Of greatest importance to me, is to find out what the Food and Drug Administration needs to ensure that the medical devices on the market are safe and effective.

In the FDA Amendments Act of 2007, I requested a GAO study to look specifically at the 510(k) process and in particular focus on the pre-amendment devices that have never been through the FDA approval process. The GAO is here today and will talk about that report in more detail and I am interested to hear how the FDA is moving to review the high-risk, Class 3 devices that have yet to ever be approved formally as Congress instructed the FDA to do in the Safe Medical Device Act of 1990.

Why has it taken so long for FDA to act and what is the consequence of this inaction: are there devices being cleared onto the marketplace that shouldn't be?

But beyond this particular study, the GAO has written other reports on medical devices. These studies have highlighted some of the successes and possible failures in FDA's ability to properly assess the safety and effectiveness of devices as well as maintain sufficient post-market surveillance and controls to ensure the devices patients are using

continue to work the way they were supposed to. I am looking forward to hearing more about those findings as well.

I also look forward to our other witness testimony and hope that they give our committee members an in-depth look into how the process is working and where it may need to be fixed, either through legislation or through increased and enhanced oversight at the FDA. At the end of the day we are talking about real people here, patients who need to know that these devices will do what they say they will do and won't cause them avoidable harm.

I want to especially thank Marcia Crosse from the Government Accountability Office and her team's tireless efforts to ensure that we are responding to the needs of patients. I would like to now recognize the Ranking Member, Mr. Deal.