

TESTIMONY OF DR. ROBERT E. FISHELL

before the

**HOUSE ENERGY AND COMMERCE COMMITTEE
SUBCOMMITTEE ON OVERSIGHT AND
INVESTIGATIONS**

Regulatory Reform Series #5 - FDA Medical Device
Regulation: Impact on American Patients, Innovation and
Jobs

July 20, 2011

Chairman Stearns, Ranking Member DeGette, Members of the Subcommittee. My name is Robert Fischell and I am pleased to testify today about an issue of great importance to me, to patients, to physicians and the American public. For more than four decades I have dedicated my life to developing novel medical technologies, including an implantable insulin pump for diabetics, heart pacemakers, implantable defibrillators, and more than 10 million heart stents that have improved health and saved the lives of patients in the USA and throughout the world. I have personally been an inventor or co-inventor of more than ten medical devices including a new external device that is effective in eliminating the pain of migraine headaches. These technologies have also spurred tens of thousands of jobs in this country and have resulted in billions of dollars in US exports to other countries that value American medical devices.

Unfortunately, the environment that exists at FDA's Center for Devices and Radiological Health (CDRH) over the past few years is the worst I have experienced in my 42 year career innovating medical technologies. Given the success I have enjoyed over the years, some would ask why I am even bothering testifying today. It certainly is not in pursuit of money, I have enough to live very well. I am here today because of the millions of patients and physicians who are searching for therapies to improve the human condition. Unfortunately, it is not technology, science, ingenuity or the economy that is standing in the way of success in developing new medical technologies. It is the FDA. As a strong supporter of President Obama, this is not easy for me to say, but it is the truth.

Prior to 2008, CDRH division was demanding of safety and efficacy for the many new medical devices that I have invented. At that time they were reasonable in allowing clearance of devices that showed safety and efficacy. CDRH demonstrated the ability to properly weigh the benefits and risks of new medical devices as part of the premarket review process. CDRH leadership understood that medical devices may have some risks, but the corresponding benefits that patients realized with the therapy they provided were worth the risk associated with such devices.

Over the past few years I have personally been aware of many instances where product clearances were denied or significantly delayed by CDRH when the patient benefit clearly outweighed any potential risk to the patient. One example of this is a device that I invented that relieves the pain of migraine headache with no serious adverse effects. That device was not approved by CDRH even after the clinical trial proved safety and efficacy. Another example is an implantable heart defibrillator that included the ability to prevent death from a heart attack where CDRH stopped that company's ability to evaluate that urgently needed product even though the device would begin its study by merely recording data as to how heart attacks can be detected at the earliest possible moment. A somewhat trivial example is a small plastic valve that could open or close to allow liquid to flow that had its approval delayed by more than a year even after that valve was already approved by CDRH for other uses.

The failure of the current CDRH to efficiently and effectively review medical devices is a serious problem for the citizens of the USA. Many published reports suggest

that patients are being forced to travel outside the US for therapies that were developed in this country. Even worse, many patients do not have the resources to travel abroad and are forced to suffer, waiting desperately for FDA to clear or approve therapies that in some cases have been available years before they get approved in the US.

Beyond the adverse impact FDA is having on patient care, it is weakening the US leadership position in medical technology innovation and as a result, our economy. As someone who has enjoyed success in the medical device industry, I have been proactive in trying to assist the innovators, scientists and engineers of tomorrow. In addition to working on medical devices at the Johns Hopkins University, Applied Physics Laboratory for more than 20 years, I recently established the Fischell Department of Bioengineering and the Institute for Medical Devices at the University of Maryland. Today, I am truly concerned for the scientists, engineers and innovators about to embark on their careers. If I were to be starting out today, I would likely be unable to make the contribution to patient care I have made over the past 40+ years because I would be unable to raise the funding or endure the delays that exist with the current regulatory environment at FDA.

In dealing with the FDA today, the reviewers appear to be slowing down or totally denying clearances for valuable medical devices that would be of great benefit for patients in the US. By doing this they are proud of being really conservative. I am aware of examples where reviewers have changed the requirements for companies *during* the premarket review process with no credible evidence supporting the moving goal posts.

One such example has recently occurred with a device that I co-invented that improves the treatment for epilepsy using a tiny electrical stimulator implanted into the patient's cranial bone.

The inability for reviewers to be held accountable for their changing standards and increased risk-aversion is something Congress must address if we are to improve patient care, promote innovation and jumpstart our economy. While it may be difficult to legislate culture and restore the collaborative, reasonable and effective CDRH that existed a few years ago, I urge you to try. Patients, physicians, innovators and the American public are counting on you to step up and restore a reasonable and predictable CDRH that appropriately balances risks and benefits, works collaboratively with industry and understands that unnecessarily denying patients access to medical therapies means that FDA is failing in its primary mission which is to protect patients but also to allow clearance for devices to relieve the pain and suffering that many patient's would otherwise have to endure.

Thank you.