

**STATEMENT OF
WILLIAM H. MAISEL, MD, MPH
DIRECTOR, MEDICAL DEVICE SAFETY INSTITUTE
BETH ISRAEL DEACONESS MEDICAL CENTER
HARVARD MEDICAL SCHOOL**

**BEFORE THE
SENATE COMMITTEE ON HEALTH, EDUCATION, LABOR, & PENSIONS**

**PROTECTING PATIENTS FROM DEFECTIVE MEDICAL DEVICES
AUGUST 4, 2009**

INTRODUCTION

Thank you for the opportunity to speak today about the importance of the Medical Device Safety Act of 2009. My name is Dr. William Maisel. I am a practicing cardiologist at Beth Israel Deaconess Medical Center and Assistant Professor of Medicine at Harvard Medical School in Boston. I am also Founder and Director of the Medical Device Safety Institute (www.medicaldevicesafety.org), an industry-independent, non-profit organization dedicated to improving the safety of medical devices. I have served as a consultant to the FDA's Center for Devices and Radiological Health since 2003 and I have previously chaired the FDA's Post Market and Heart Device Advisory Panels.

I hope that by the conclusion of my brief remarks today you will appreciate that FDA marketing clearance or approval of a medical device does not guarantee its safety. In particular, manufacturers' responsibilities for product safety extend well beyond initial FDA approval. The U.S. Supreme Court ruled in their February 2008 decision, *Riegel v. Medtronic*, that manufacturers could not be sued under state law by patients harmed by product defects from FDA-approved medical devices¹. Because their lawsuits are "preempted", consumers are unable to seek compensation from manufacturers for their injuries, lost wages, or health expenses. Most importantly, the *Riegel* decision eliminates an important consumer safeguard - the threat of manufacturer liability – and will lead to less safe medical devices and an increased number of patient injuries. The Medical Device Safety Act of 2009 will restore the consumer safeguards that are necessary to ensure the safety of medical devices for the millions of patients who enjoy their benefits.

We are fortunate to have the preeminent medical regulatory system in the world. The U.S. Food and Drug Administration regulates more than 100,000 different medical devices manufactured by more than 15,000 companies². They receive several thousand new and supplemental device applications annually and they are mandated by Congress to complete their premarket evaluations in a timely fashion³. Thankfully, there are many superb FDA engineers, physicians, scientists, and public servants who work tirelessly to try to ensure that only safe and effective medical devices reach the American public.

FDA PRE-APPROVAL EVALUATION

To gain marketing approval from the FDA for a medical device, a manufacturer must demonstrate reasonable assurance of safety and effectiveness. During the pre-approval evaluation, several factors may limit the ability of the FDA to identify and predict which products will perform safely after approval. Product evaluation may include computer simulations, engineering analyses, non-clinical laboratory testing, animal testing, and

¹ *Riegel v. Medtronic*, 552 U.S. 2 (2008).

² Maisel WH. Medical device regulation: An Introduction for the practicing physician. *Ann Intern Med* 2004; 140: 296-302.

³ U.S. Department of Health and Human Services. Food and Drug Administration. Center for Devices and Radiological Health. Office of Device Evaluation: Annual Report – Fiscal Year 2006 and Fiscal Year 2007. Accessed July 28, 2009 at: <http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDRH/CDRHReports/ucm127516.pdf>

human clinical studies. Although some products undergo testing in humans before FDA approval, it is not a requirement.

The FDA annually receives hundreds of premarket approval (PMA) and PMA supplement applications. Although this represents only ~1% of all FDA-listed devices, PMA devices are implanted into tens of millions of patients and include the highest risk devices, such as coronary stents and implantable defibrillators⁴.

Unfortunately, it is not uncommon for unanswered questions regarding device safety and effectiveness to remain at the time of FDA approval. This creates the potential for a large number of patients to be rapidly exposed to a newly approved product in the absence of long-term follow-up data. For example, close to 268,000 patients had been implanted with the Medtronic Sprint Fidelis implantable defibrillator lead before it was recalled in October 2007 after it was determined that the wire was prone to fracture⁵. A fracture of the lead, which connects the implantable defibrillator to the heart, may result in serious health consequences, including painful electrical shocks or death. The Medtronic lead was approved on the basis of no human clinical data.

Mr. Sidney Engler, a patient of mine, unfortunately received this lead when he had an implantable defibrillator placed in February 2006. Mr. Engler is a decorated WWII veteran, having served in Europe from 1943 to 1945. On the night of August 14, 2008 while preparing to retire for the evening, the simple act of removing his shirt over his head caused his defective defibrillator lead to fracture. Mr. Engler suffered a cardiac arrest in front of his wife. He required CPR and received numerous unnecessary painful shocks from his defibrillator. Fortunately, due to the prompt response of his local EMTs, Sidney survived. Despite a prolonged hospital stay and months of rehabilitation, he has still not fully recovered.

Although Medtronic began receiving reports of lead fractures within months of initial U.S. market release, they did not recall the lead until more than 3 years later. An FDA inspection report, issued after the recall, cited Medtronic for “objectionable conditions” for failing to implement appropriate corrective and preventive action procedures related to the company’s investigation of the product anomaly⁶. In addition, when the FDA inspection team requested certain documents, FDA was told by Medtronic that “they were not able to...view them⁶.”

The delay in issuing a product recall, the FDA citation, and the failure to provide FDA with the requested documents did nothing to eliminate Medtronic’s protection under the

⁴ Government Accountability Office. Medical Devices: FDA Should Take Steps to Ensure That High-Risk Device Types Are Approved through the Most Stringent Premarket Review Process. January 2009. Accessed July 28, 2009 at: <http://www.gao.gov/new.items/d09190.pdf>

⁵ Maisel WH. Semper Fidelis – Consumer Protection for Patients with Implanted Medical Devices. N Engl J Med 2008; 358: 985-987.

⁶ U.S. Department of Health and Human Services. Food and Drug Administration Establishment Inspection Report FEI 2182208 Medtronic, Inc. Cardiac Rhythm Disease Management, 12/21/07. Accessed on July 28, 2009 at: <http://www.fda.gov/downloads/AboutFDA/CentersOffices/ORA/UCM133024.pdf>

preemption doctrine. Indeed, Medtronic claimed product liability immunity citing the U.S. Supreme Court's *Riegel* decision and the U.S. District Court agreed⁷.

FDA MANDATED POST-APPROVAL STUDIES

During premarket device evaluation, several factors may limit the ability of the FDA to identify and predict which products will perform safely after approval. There may be questions that cannot be answered in the premarket stage, or an issue may arise after the device is marketed. FDA may require manufacturers to perform post-approval studies as a "condition" of approval to provide on-going evaluation of the device's safety, effectiveness, and reliability after initial marketing approval. These post-approval studies are most often used to: 1) monitor device performance and safety during the transition from clinical trial to real-world use, 2) assess the long term safety, effectiveness, and reliability of the device, and 3) look for infrequent but important adverse events. These studies may also be initiated to evaluate an emerging public health concern in response to reported adverse events.

Despite the obvious importance of these studies in assessing device safety, the FDA and manufacturers have struggled to handle this responsibility. In 2005, the FDA reported that they "couldn't find" 22% of the required post-market medical device studies for the years 1998-2000 and acknowledged that some of the studies were never started⁸. And while efforts have been made to better track these required studies, a visit to the FDA's device post-approval study website demonstrates that more than one-third of manufacturers with on-going post-approval study responsibilities currently have an overdue report⁹. In 2005, Dr. Susan Gardner, Director of the FDA's Center for Devices and Radiological Health Office of Surveillance and Biometrics, spoke about the medical device post-approval studies observing that, "it looks like we have a fairly poor track record in getting these studies done"⁸.

ADVERSE EVENTS AND RECALLS

Despite their premarket medical device evaluation, the FDA annually receives reports of more than 200,000 device-related injuries and malfunctions, and more than 2000 device-related deaths¹⁰. It is challenging for the Agency to identify patterns of device malfunction among the deluge of adverse event reports. FDA initiatives to better integrate the premarket and postmarket workforces, to develop novel methods of surveillance, and to improve tracking of required manufacturer postmarket studies may help.

⁷ In re Medtronic, Inc. Sprint Fidelis Leads Product Liability Litigation, 592 F.Supp.2d 1147 (D. Minn., 2009).

⁸ U.S. Food and Drug Administration, Center for Devices and Radiological Health Medical Devices Advisory Committee Circulatory Systems Devices Panel. April 22, 2005. Accessed July 28, 2009 at: <http://www.fda.gov/ohrms/dockets/ac/05/transcripts/2005-4108t1.htm>

⁹ U.S. Food and Drug Administration. Post Approval Studies. Accessed July 28, 2009 at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma_pas.cfm

¹⁰ Center for Devices and Radiological Health. CDRH FY 2006 highlights. Accessed July 28, 2009 at: <http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDRH/CDRHReports/ucm129258.pdf>

Although manufacturers are required to report medical device-related adverse events and malfunctions that caused or could cause serious injury or death, not all manufacturers reliably report these events to the FDA. For example, EndoVascular Technologies, a subsidiary of Guidant Corporation, was charged with failing to report more than 2600 device malfunctions, 12 deaths, and numerous other complications related to use of its Ancure Endograft system for aortic aneurysms. The US Attorney noted that “Because of the company's conduct, thousands of patients underwent surgeries without knowing the risks they faced...”¹¹

Although the FDA can theoretically order a product recall in response to observed adverse events or device malfunctions, the vast majority of recalls are voluntarily initiated by the manufacturer. Because of the manufacturers’ inherent financial conflict of interest, the timing and extent of the product recalls are often controversial. In numerous cases, manufacturers have knowingly sold potentially defective devices without public disclosure^{5,12}. During fiscal year 2006, 651 recall actions were initiated involving 1,550 products – again reminding us that FDA product approval does not ensure device reliability and performance¹⁰.

PREEMPTION – LOSS OF AN IMPORTANT CONSUMER SAFEGUARD

It is clear that medical device manufacturers have responsibilities that extend far beyond FDA approval and that many companies have failed to meet their obligations. Yet, the U.S. Supreme Court ruled in their February 2008 decision, *Riegel v. Medtronic*, that manufacturers could not be sued under state law by patients harmed by product defects from FDA-approved medical devices¹. Because their lawsuits are “preempted”, consumers are unable to seek compensation from manufacturers for their injuries, lost wages, or health expenses. More importantly, however, the *Riegel* decision eliminates an important consumer safeguard - the threat of manufacturer liability – and will lead to less safe medical devices and an increased number of patient injuries. The idea that manufacturer liability for a medical device should end at FDA approval is a dangerous policy. Additional consumer protections, as offered by the Medical Device Safety Act of 2009, are essential.

CONCLUSIONS

Implanted medical devices have enriched and extended the lives of countless people, but device malfunctions and software glitches have become modern "diseases" that will continue to occur. Manufacturers have important responsibilities for product safety that extend well beyond FDA approval and we have witnessed the repeated failure of manufacturers to provide the public with timely, critical information about device performance, malfunctions, and "fixes" enabling potentially defective devices to reach unwary consumers. There are consumer protections for airline passengers, cable-

¹¹ Castellucci L. Guidant subsidiary pleads guilty, settles criminal charges related to aortic aneurysm device. Accessed July 28, 2009 at: <http://www.theheart.org/viewArticle.do?simpleName=347409>

¹² Maisel WH. Safety issues involving medical devices. Implications of recent implantable cardioverter-defibrillator malfunctions. JAMA 2005; 294: 955-958.

television customers, and cellular-telephone users, but surprisingly few for patients who receive life-sustaining medical devices. The Medical Device Safety Act of 2009 provides important and necessary safeguards for consumers that will minimize adverse health consequences and improve the safety of medical devices for the millions of patients who enjoy their benefits.