

**STATEMENT OF
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**BEFORE THE
HOUSE COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM**

**SHOULD FDA DRUG AND MEDICAL DEVICE REGULATION
BAR STATE LIABILITY CLAIMS?**

MAY 14, 2008

INTRODUCTION

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 Director of the Medical Device Safety Institute, an industry-independent organization dedicated to improving the safety of medical devices. I have served as a consultant to the FDA's Center for Devices and Radiologic Health since 2003 and have previously chaired the FDA's Post Market and Heart Device Advisory Panels.

I hope that by the conclusion of my brief comments today you will appreciate that FDA marketing clearance or approval of a medical product does not guarantee its safety. For this reason, it is critical that patients receive accurate, timely, easily understood information to assist them in making informed decisions. Manufacturers' responsibilities for product safety extend well beyond initial FDA approval and it is apparent that additional consumer safeguards are needed if we are to improve 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 companies¹. They receive several thousand new and supplemental device applications annually and they are mandated by Congress to complete their premarket evaluations in a timely fashion².

Mark Gleeson is a man whose very life depends on one of these implantable medical devices – in his case a pacemaker. Pacemakers are implanted to treat dangerous slow heart rhythms – and in Mr. Gleeson's case, every single beat of his heart comes from his device. The pacemaker itself consists of a battery and computer circuitry, sealed together in a metal housing. Pacemaker batteries typically last 5-10 years, so you can imagine how Mr. Gleeson must have felt when he required surgical replacement of his pacemaker after just 12 months due to a short circuit that caused the battery to wear out prematurely. Fortunately, Mr. Gleeson was able to safely have a new pacemaker fitted.

St. Jude Medical, the manufacturer of Mr. Gleeson's pacemaker, had become aware of the short circuit problem 2 years prior to Mark Gleeson's pacemaker failure because other faulty pacemakers had been returned to the manufacturer³. After studying the problem for over a year and validating a fix, St. Jude asked for and received FDA approval for a modified version of the device that corrected the problem⁴. This approval came several months prior to Mr. Gleeson's device failure although the reason for the

¹ Maisel WH. Medical device regulation: An Introduction for the practicing physician. *Ann Intern Med* 2004; 140: 296-302.

² Tillman D-B. Report from ODE. Accessed May 12, 2008 at:

<http://www.fda.gov/cdrh/present/advamed-052405-tillman-ode.ppt>

³ US Food and Drug Administration. *Consumer Complaint/Injury Report*. Rockville, Md; June 10, 2000. LOS-9364.

⁴ Fleckenstein JR. United States Food and Drug Administration: Los Angeles District. *Memorandum: F/U to Consumer Complaint*. Irvine, Calif; September 18, 2000. LOS-9364.

device modification and a patient warning were not publicly provided at that time. Furthermore, St. Jude Medical continued to distribute the already manufactured potentially faulty pacemakers⁵. Mark Gleeson was unlucky enough to receive one as his replacement device – even though corrected pacemakers had been built and were available. Eight months after receiving FDA approval for the corrected device and nearly 2.5 years after initially learning of the problem, St. Jude Medical issued a recall of 163,000 pacemakers, including Mark Gleeson’s new unit⁶.

Mr. Gleeson writes “...I have been on a journey through the Food and Drug Administration trying to determine why an incident dealing with a medical device was allowed to happen to me.” He adds, “Although my present pacemaker is working fine...every day I expect something to fail.”

I do not recount this story to suggest that St. Jude Medical broke any laws or failed to follow the FDA’s rules and regulations. Instead, the story highlights how patients may fail to receive critical information about their medical device’s performance and how they may be unnecessarily exposed to potentially faulty products despite the FDA’s approval process.

In 1998, the Advisory Commission on Consumer Protection and Quality in the Health Care Industry adopted a Patients' Bill of Rights whose primary tenet is that patients have "the right to receive accurate, easily understood information to assist them in making informed decisions.”⁷ Regrettably, patients like Mark Gleeson who are undergoing medical device implantation, often fail to receive critical information on device safety. The failure to publicly disclose adverse information about device safety subverts the process of informed consent and prevents patients from making educated treatment choices in consultation with their physician and family.

While Mark Gleeson’s case occurred several years ago, it is not an isolated event. Other manufacturers have knowingly sold potentially defective devices without public disclosure⁷. For example, Guidant Corporation identified and corrected a design flaw that could result in the short circuit of an implantable defibrillator, a device that treats both dangerous slow and dangerous fast heart rhythms. The company, however, continued to sell its inventory of potentially defective devices without public disclosure⁸. The FDA sometimes permits a potentially flawed product to be marketed unbeknownst to the consumer while the manufacturer submits a revised marketing application and awaits approval of the amended product design and manufacturing plan⁷.

⁵ Maisel WH. Malfunctions of implantable cardioverter defibrillators. *JAMA* 2005; 295: 161-2.

⁶ St. Jude Medical. Technical memo: Important advisory information: Premature battery depletion in the Trilogy family of pacemakers. July 9, 1999.

⁷ Maisel WH. Semper fidelis – Consumer protection for patients with implanted medical devices. *N Engl J Med* 2008; 358: 985-987.

⁸ Maisel WH. Safety issues involving medical devices. Implications of recent implantable cardioverter-defibrillator malfunctions. *JAMA* 2005; 294: 955-958.

FDA PRE-APPROVAL EVALUATION

To gain marketing clearance or 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 human clinical studies. Although many products undergo testing in humans before FDA approval, it is not a requirement.

Unanswered questions regarding device safety and effectiveness often 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 fracture⁸. A fracture of the lead, which connects the implantable defibrillator to the heart, may result in serious health consequences, including death. Human clinical testing had not been required during the Sprint Fidelis pre-approval process – and would have been unlikely to detect the subsequent abnormality.

FDA MANDATED POST-APPROVAL AND POST-CLEARANCE STUDIES

The 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 started⁹. And while efforts have been made to better track these required studies, a visit to the FDA’s device post-approval study website on May 6, 2008 demonstrated that 22% of manufacturers had submitted a report late and that nearly 1 in 20 manufacturers with on-going post-approval study responsibilities currently had an overdue report¹⁰. Lest you think that this problem applies only to medical devices, it was reported in April 2008 that 1,044, or 62 percent, of incomplete studies for conventional drugs and biotechnology medications had

⁹ U.S. Food and Drug Administration, Center for Devices and Radiologic Health Medical Devices Advisory Committee Circulatory Systems Devices Panel. April 22, 2005. Accessed May 12, 2008 at: <http://www.fda.gov/ohrms/dockets/ac/05/transcripts/2005-4108t1.htm>

¹⁰ U.S. Food and Drug Administration. Post approval studies. Accessed May 12, 2008 at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma_pas.cfm

yet to be started¹¹. In 2005, Dr. Susan Gardner, Director of the FDA's Center for Devices and Radiologic 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"⁹.

ADVERSE EVENTS AND RECALLS

The FDA annually receives reports of more than 200,000 device-related injuries and malfunctions, and more than 2000 device-related deaths¹². 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. In announcing the nearly \$100 million dollar settlement, the US Attorney noted that "Because of the company's conduct, thousands of patients underwent surgeries without knowing the risks they faced..."¹³.

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. 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 performance¹².

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. The failure of manufacturers and the FDA to provide the public with timely, critical information about device performance, malfunctions, and "fixes" enables potentially defective devices to reach unwary consumers. Patients like Mark Gleeson are sometimes forced to make life-changing decisions with insufficient and sometimes inaccurate information. We have consumer protections for airline passengers, cable-television customers, and cellular-telephone users, but few for patients who receive life-sustaining medical devices. Additional consumer safeguards are needed if we are to minimize adverse health consequences and improve the safety of medical devices for the millions of patients who enjoy their benefits.

¹¹ Blum J. Drugmakers didn't begin 1,044 promised U.S. studies. Accessed May 12, 2008 at: <http://www.bloomberg.com/apps/news?pid=20601124&sid=acu6znqklhBo&refer=home>

¹² Center for Devices and Radiologic Health. CDRH FY 2006 highlights. Accessed May 12, 2008 at: <http://www.fda.gov/cdrh/annual/fy2006/fy2006.pdf>

¹³ Castellucci L. Guidant subsidiary pleads guilty, settles criminal charges related to aortic aneurysm device. Accessed May 12, 2008 at: <http://www.theheart.org/viewArticle.do?simpleName=347409>