



Semper Fidelis — Consumer Protection for Patients with Implanted Medical Devices

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When the Food and Drug Administration (FDA) approved the Medtronic Sprint Fidelis implantable cardioverter–defibrillator (ICD) lead in 2004 on the basis of bench testing but no human

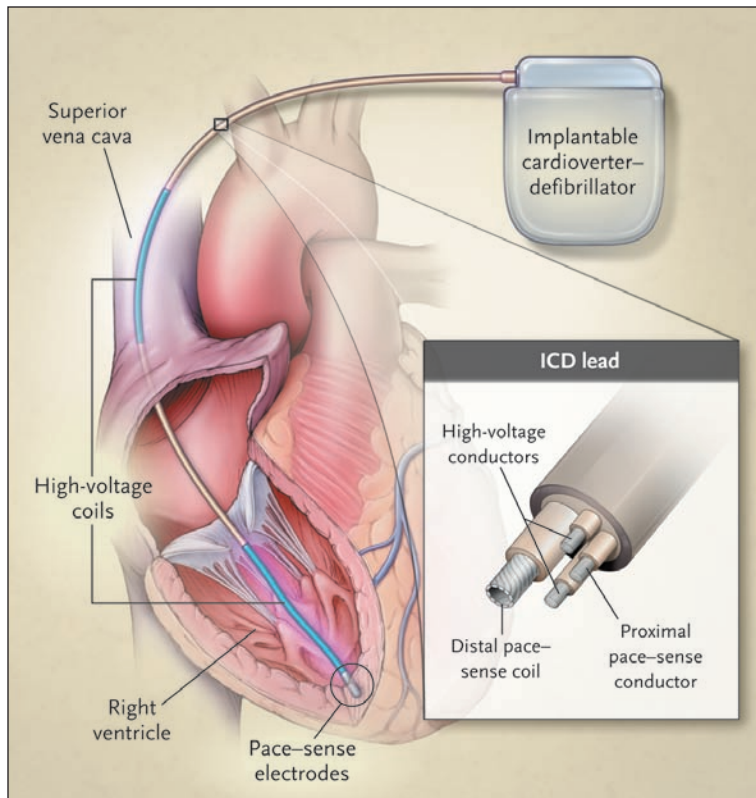
clinical data, there was no public outcry. Physicians rapidly incorporated the new electrode into their practice, welcoming its small diameter and ease of implantation. During the ensuing 3 years, 90% of Medtronic ICDs were implanted with this lead (see diagram). But in October 2007, after 38 months on the U.S. market and 268,000 implantations worldwide, the Fidelis was voluntarily recalled by Medtronic because of its propensity to fracture. The large number of affected patients, the billions of dollars at stake in the ICD market, and the controversy surrounding the timing of communication with physicians and patients about the lead's performance highlight the shortcomings of the reg-

ulatory system for medical devices and underscore the urgent need for legislation that will ensure adequate protection for the patients receiving them.

Obviously, no complex device can be 100% free of design, manufacturing, and performance flaws. Malfunctions inevitably occur, and manufacturers should be rewarded, not criticized, for identifying and correcting problems. The demands placed on ICD leads, in particular, are intense: they must withstand hundreds of millions of repetitive cardiac cycles, survive in the hostile environment of the human body, and allow delivery of high-voltage energy at a moment's notice. But ICD-lead fractures can result in clinically

significant adverse events, including a failure to pace, a failure to defibrillate, unnecessary shocks, and death.

After concerns arose about the performance of the Fidelis, Medtronic notified physicians by letter in March 2007 of “a limited number” of physicians who were seeing a higher-than-expected rate of lead fractures. Medtronic concluded that the lead's performance was “in line with other Medtronic leads” on the basis of two main factors: analysis of returned products (though such analysis is notoriously inaccurate because most malfunctioning leads are not removed from patients and returned to the manufacturer) and a small prospective postmarketing study that found a 1.1% rate of lead failure within 2 years of implantation. Medtronic failed to note that the study — which included fewer than 100 patients followed for 2 years — was grossly un-



ICD System Consisting of a Generator and a Lead.

Cardiac signals are conducted through pace-sense electrodes from the heart to the ICD generator. Low-voltage pacing therapy, when needed, is delivered through these electrodes to treat slow heart rhythms. The high-voltage shocks required for defibrillation are delivered through high-voltage conductors. Fracture of a pace-sense electrode may result in a failure to pace or in electrical “noise” that the ICD generator may misinterpret as a fast heart rhythm, which can result in an unnecessary shock. Fracture of a high-voltage conductor could result in a failure to defibrillate.

derpowered to detect even a moderate increase in fracture rate in the Fidelis as compared with its predecessors. In short, despite implantation of the device in hundreds of thousands of patients during several years on the market, the available postmarketing data were insufficient to provide a definitive conclusion about whether there was a performance problem. Medtronic therefore began collecting and analyzing data from more than 25,000 patients participating in its remote ICD-monitoring program.

Though publicly maintaining that the lead functioned within

acceptable parameters, Medtronic submitted an FDA application for design and manufacturing changes in May 2007 and, according to the FDA’s public premarket approval database, received approval 2 months later. Already-manufactured leads remained on hospital shelves and continued to be implanted. By October 2007, Medtronic had confirmed the occurrence of 665 fractures in returned leads, five patient deaths to which a Fidelis lead fracture may have contributed, and a 2.3% fracture rate within 30 months of implantation (according to an analysis of the remote-monitoring data).¹ Med-

tronic then voluntarily recalled the product and requested the return of unused leads.

Almost immediately, numerous lawsuits were filed against Medtronic alleging personal injury, negligence in manufacturing, and failure to warn patients about the possible defects in a timely manner. In reality, manufacturers have repeatedly and knowingly sold potentially defective devices without public disclosure. For example, after identifying and correcting a design flaw that could cause premature depletion of ICD batteries, Medtronic continued to sell its inventory of potentially defective ICDs without public disclosure.² Similarly, the two other major ICD manufacturers, Guidant (now part of Boston Scientific) and St. Jude Medical, have knowingly marketed potentially defective arrhythmia devices unbeknownst to the public.^{3,4} Often, a flawed product continues to be marketed while the manufacturer submits a revised marketing application to the FDA and awaits approval of the amended product design and manufacturing plan.

Nor is the failure to notify the public about important flaws unique to the arrhythmia-device industry. Last year, a U.S. House committee launched an investigation into whether the FDA took proper action after determining that Johnson & Johnson’s Cordis unit violated laws in manufacturing its drug-coated cardiac stent. The FDA did not issue a public warning letter until several months after inspections revealed manufacturing errors, and Cordis was permitted to continue marketing the device. The failure of manufacturers and the FDA to provide the public with timely, critical information about device perfor-

mance, malfunctions, and “fixes” enables potentially defective devices to reach unwary consumers.

Some argue that public disclosure of reliability information is overwhelming and anxiety-provoking for patients. A recent editorial in the *Wall Street Journal* opined that “the real danger to public health is the overreaction to medical risk,” noting that some patients refuse to have a device implanted because of concern about potential malfunctions.⁵ But isn’t that exactly the point — that when given information about reliability, some patients will choose not to have a device implanted? The solution is to educate patients, inform them about benefits and risks, and allow them to make their decision in consultation with their physician and family — a process called informed consent. The failure to publicly disclose adverse information about device safety subverts this process. Medtronic’s president and chief executive officer, Bill Hawkins, asserts that “society’s tolerance for any risks associated with medical technology is nearing zero.”²⁵ But society is not intolerant of all risk — just unnecessary, undisclosed, and preventable risk.

According to its mission statement, the FDA is “responsible for protecting the public health” and for “helping the public get the accurate, science-based information they need.” Unfortunately, the agency is failing to fulfill that mission. 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.” Regrettably, patients considering implantation of medical devices often fail to receive critical information on device safety.

The welfare of medical device recipients must become a higher priority for the FDA and manufacturers, and it is increasingly apparent that such a change will require Congressional action. Essential consumer protections are currently lacking. For example, patients with a recalled medical device are not even assured of a single visit with their health care provider at no cost to themselves (paid for by either insurance or the device manufacturer) to discuss the health implications of the recall. In addition, although FDA regulations protect human subjects participating in research studies, no such protections apply to the millions of patients who receive devices outside of clinical trials. Indeed, the vast majority of FDA approvals of medical devices occur without any representation of consumers’ interests, and decisions concerning postmarket safety rarely include input from patient-advocacy groups. Meanwhile, manufacturers have an inherent financial conflict of interest when addressing device-safety issues and have stronger legal obligations to their shareholders than to the patients who use their products. This imbalance must be corrected.

The Latin motto *semper fidelis* reminds us to remain faithful to certain core principles. To protect the well-being of the recipients of medical devices and to treat them ethically, we must ensure adherence to the principles of informed consent, patient autonomy, and public disclosure of important

safety information. 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. Remarkably, we have consumer protections for airline passengers, cable-television customers, and cellular-telephone users, but few for patients who receive life-sustaining medical devices. Only with well-defined, specific consumer protections for such patients can we hope to minimize adverse health consequences and avoid costly recalls of critical medical products.

Dr. Maisel is a consultant for the FDA and a member of the Medicare Coverage Advisory Committee. The opinions expressed in this article are those of the author and do not necessarily represent the opinions, practices, policies, or positions of the FDA or the Centers for Medicare and Medicaid Services. No other potential conflict of interest relevant to this article was reported.

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