Guidant Defibrillator Malfunction and the FDA

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The death in early 2005 of a 21-year-old man whose cardiac defibrillator short-circuited\(^1\) unleashed a series of events that culminated in a recall of thousands of defibrillators manufactured by Guidant Corp., the maker of the defibrillator implicated in Joshua Oukrop’s death, and that has raised significant questions about the federal government review process for medical devices. After Mr. Oukrop’s death, the New York Times submitted a Freedom of Information Act request for Guidant’s annual reports that had been submitted to the U.S. Food and Drug Administration (“FDA”).\(^2\) Initially the FDA denied access to the reports on the grounds that the reports contained trade secrets that must be deleted before public disclosure.\(^3\) The New York Times appealed the decision, and the FDA eventually relented and released the data.\(^4\)

Meanwhile, Guidant in May 2005 issued a safety advisory letter to physicians,\(^5\) informing the doctors that the company was aware of 25 other cases in which the same defibrillator device malfunctioned.\(^6\) In subsequent letters, Guidant did not recommend removal of the devices because of the risk that removal might do more harm than good. Guidant instead expressly left whether to remove the devices entirely to the discretion of individual physicians. In late May, a New York Times article revealed that Guidant had known of a history of flaws with certain of its implantable defibrillators, but had made no previous efforts to warn physicians.\(^7\) Later New York Times articles highlighted significant delays in the submission of information about the defibrillators to the FDA. For example, Guidant’s annual report covering the months from June 1, 2003 to May 31, 2004 – which included the information that the type of defibrillator involved in Mr. Oukrop’s death was short-circuiting at a rate of about once a month – was not submitted to the FDA until February 2005.\(^8\) In fact, the New York Times discovered that Guidant had developed a new model to correct the flaw in the devices as early as 2002, but had continued selling the older models without any warning for physicians.\(^9\) Because companies are not required to report all safety modifications immediately to the FDA, Guidant’s actions were not disclosed until the 2003 annual report, the one submitted in 2005.\(^10\) In the publicity firestorm that followed publication of the articles in the New York Times,

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3 Id.
4 Id.
5 Meier, supra note 1.
6 Id. See also Robert G. Hauser & Barry J. Maron, *Lessons From The Failure and Recall of an Implantable Cardioverter-Defibrillator*, 112 CIRCULATION 2040 (2005), available at http://circ.ahajournals.org/cgi/content/full/112/13/2040 (last visited May 6, 2006).
7 Meier, supra note 1.
8 Meier, supra note 2.
10 Meier, supra note 2.
Guidant in June 2005 announced the initiation of voluntary recall of several defibrillator models manufactured between 1997 and 2000.

The previous events have led people to question the FDA’s 90-day review policy for submitted reports. Some commentators believe the period of time is too long and is thus ineffective in informing the public of potentially hazardous devices.\(^{11}\) On the other hand, the annual reports submitted by medical device manufacturers contain very detailed information, and the director of the FDA has stated that he believes the release of such considerable amounts of data would not be an effective use of FDA resources.\(^ {12}\)

While the FDA’s position may be understandable, the life-sustaining role of many medical devices is precisely what makes timely disclosure such an important factor in preventing harm. For example, Mr. Oukrop died in March 2005. The FDA in February 2005 had received Guidant’s 2003 annual report with its revelation of the specific problem that caused Mr. Oukrop’s death. Had that annual report been received earlier or reviewed more quickly, the flaw might have been publicized in time to save Mr. Oukrop’s life.

Admittedly, mandating immediate review of such reports as Guidant’s 2003 annual report could have a significant economic impact on a federal agency that is not appropriately staffed to meet such obligations. This problem indicates a more fundamental issue. The burden of disclosure of medical device malfunctions has been placed significantly on the FDA, but why is a federal agency considered in a better position to disclose such problems than the companies that create the devices, are familiar with their performance, and hire suitable experts to evaluate the devices’ performance? The primary duty of timely public disclosure should fall on the manufacturer, which is usually the first to know of defects and their extent. Placing this burden almost exclusively on the FDA creates the delusion that, as long as a manufacturer complies with the agency’s reporting requirements, the manufacturer’s responsibility to the public has been fulfilled – a notion far from all principles of practical responsibility.

There have been ample discussions questioning the FDA’s contribution to the misfortunes resulting from the Guidant defibrillators, but there are reasons that the agency might have believed that the manufactured product did not pose immediate public risk. For example, the agency has regulations directed at potentially harmful malfunctions. The Safety Medical Devices Act of 1990 imposes reporting requirements on medical device manufacturers.\(^ {13}\) The Act identifies a series of reportable events that range from death, unreasonable risk of substantial harm, and serious harm. The Act also contains a provision stating that a report is required when a manufacturer becomes aware of a malfunction that is likely to cause or contribute to death if the malfunction occurs. In addition, the Act requires a manufacturer to submit reports within five business days once the manufacturer becomes aware of events that require remedial actions to prevent

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\(^{13}\) P.L. 101-629 (Nov. 28, 1990).
unreasonable risks that could lead to substantial harm.\textsuperscript{14} Medical device manufacturers also must submit an individual adverse event report to the FDA within 30 calendar days after becoming aware of a reportable death, serious injury, or malfunction.\textsuperscript{15}

In the case of the defibrillators, Guidant chose not to consider the defibrillator’s flaws as ones that could lead to catastrophic consequences even though a short circuit at a critical moment when the device’s life-sustaining function was needed could render the device useless. Viewed in light of applicable FDA regulations, there are serious doubts that Guidant’s actions were in accord with the federal rules. The FDA regulations consider it to be a reportable malfunction when a medical device fails to perform its essential functions of maintaining human life.\textsuperscript{16} The regulations state that a malfunction is not reportable if it is not likely to result in death, serious injury, or other significant adverse defects,\textsuperscript{17} but a short circuit in a life-sustaining device would seem to fall outside this exception and instead to qualify as a reportable event that deserved to be submitted to the FDA within five days of the company’s awareness. Certainly, such a flaw would seem too serious to wait for an annual report, especially an annual report submitted with great delay despite the significance of the device flaw and after years of awareness.

The general comments in this article should not be read to imply that every life-saving device must be completely flawless before public distribution. Certainly there will be times where significant medical need might justify public distribution of a less-than-perfect product. In such times, proper disclosures are necessary to allow physicians to take suitable precautions. Guidant, however, apparently supplied physicians with faulty life-sustaining devices without providing warning of a flaw in those devices even after the company apparently recognized that a flaw existed.\textsuperscript{18} Guidant also imposed on physicians the decision as to whether remedial action was necessary. These actions are far from just being irresponsible and unethical; they are highly disrespectful to the medical profession and to human life. Private companies should not be allowed to rely on the medical community or governmental agencies to cover for the company’s actions. Life is not a market subject to economic fluctuations; it is invaluable and irreplaceable.

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\textsuperscript{14} 21 C.F.R § 803.53 (2004).
\textsuperscript{15} Id. at § 803.50.
\textsuperscript{16} Id. at § 803.3(q).
\textsuperscript{17} Id.
\textsuperscript{18} Meier, supra note 9.