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Colloquy

To Recall or Not to Recall, That Is the Question: The Current Controversy over Medical Device Recalls

Ralph F. Hall*

*All things are difficult before they are easy.
- Thomas Fuller*

INTRODUCTION

At the age of seventeen, Joshua Oukrop learned that he suffered from a serious heart condition.¹ As a result of this condition, Mr. Oukrop received a Guidant Prizm 2[®] implantable cardioverter defibrillator (ICD).

The ICD treats a condition known as Sudden Cardiac Death (SCD). SCD is an electrical malfunction of the heart. Unless treated, SCD can cause death within seconds. With an ICD, the patient has an excellent chance of surviving an SCD episode. The ICD compresses the cardiac resuscitation equipment of an emergency room into a device the size of a deck of cards. To do so, the ICD must miniaturize the functionality of a desktop computer, operate for multiple years

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* Ralph F. Hall serves as a Visiting Associate Professor of Law at the University of Minnesota Law School, where, among other activities, he teaches a course in FDA law. Mr. Hall is also Counsel to the law firm of Baker & Daniels in Indianapolis, Indiana and Washington, D.C. Baker & Daniels represents a number of medical device companies, including Guidant Corporation. Mr. Hall is not involved in representing Guidant in any FDA matters. Mr. Hall was also employed by Guidant Corporation until 2003. He had no involvement in any of the Prizm 2 matters or related recalls. Mr. Hall wishes to thank Cory Olson and Robert Berlin for their assistance and insightful comments. The opinions expressed herein are those of the author only. This article does not assess or pass judgment on Guidant's actions. That is a task for different people at a different time and place.

1. Maura Lerner, *Hunting Down Dangers to the Heart*, STAR TRIB., July 24, 2005, at 1A.

on the power equivalent of several AA batteries, and deliver 750-volt shocks on seconds' notice all while performing in a hostile environment with reliability requirements that match or exceed those of NASA. It is no wonder that, along with Thomas Edison and Alexander Graham Bell, the inventors of the ICD have been inducted into the National Inventors Hall of Fame.²

In March 2005, Mr. Oukrop was cycling in Utah when he experienced an episode of SCD and required therapy from the ICD. Unbeknownst to him, his ICD suffered from an internal short circuit that prevented the device from delivering the lifesaving therapy when needed. Miles from any help, he passed away. His physicians have stated that had they known of the risk of this short circuit, they may well have replaced his device before this tragic event.³

It was subsequently disclosed that Guidant had received approximately twenty-five reports of similar malfunctions out of 24,000 Prizm 2 devices prior to the malfunction of Mr. Oukrop's ICD.⁴ Aware of only several reports at the time, Guidant changed its manufacturing processes in April 2002 to reduce the short circuit risk.⁵ It continued to sell ICDs manufactured using the older process while it phased in the newer version.

Until this information regarding prior device failures was about to become public in a New York Times article,⁶ Guidant had not notified physicians or patients of these failures or the manufacturing changes. Guidant justified its decision to continue selling these devices and not notify physicians on the grounds that the overall failure rate of the device, even including these events, is extremely low (and less than the company's internal notification trigger) and because the device

2. The National Inventors Hall of Fame recognized Michael Mirowski, Morton Mower, M. Stephen Heilman, and Alois Langer in 2002 for the invention of the ICD. For further information, see http://www.invent.org/hall_of_fame/1_1_search.asp (last visited Nov. 22, 2005).

3. Barry Meier, *Maker of Heart Device Kept Flaw from Doctors*, N.Y. Times, May 24, 2005.

4. Press Release, Guidant, Guidant Notifies Physicians Regarding VENTAK 1861 PRIZM 2 DR Implantable Defibrillator (May 25, 2005), www.guidant.com/news/500/web_release/nr_000546.shtml. This reflects an incidence rate of approximately 0.107%.

5. *Id.*

6. *Id.*

was performing better than its design specifications.⁷ In addition, Guidant concluded that the risk of explanting the device was greater than the risk of device malfunction. On May 23, 2005, the day before the New York Times article was to be published, Guidant commenced a physician notification of this potential malfunction.⁸ Over the next four months Guidant announced a series of additional physician notifications covering a significant number of similar products.⁹

A media frenzy erupted. Articles in the New York Times,¹⁰ Journal of the American Medical Association,¹¹ and the New England Journal of Medicine,¹² among others, debated these issues and criticized Guidant's decisions. Patient groups were highly critical.¹³ The debate focused on how manufacturers should handle low-frequency device malfunctions and when the public should be notified of possible device defects issues (in other words, what should "trigger" public notification of device

7. *Id.*

8. Press Release, Guidant, Guidant Notifies Physicians Regarding VENTAK 1861 PRIZM 2 DR Implantable Defibrillator (May 25, 2005), www.guidant.com/news/500/web_release/nr_000546.shtml.

9. Press Release, Guidant, Guidant Initiates Voluntary Physician Advisory on Certain Pacemakers (Sept. 22, 2005), http://www.guidant.com/news/500/web_release/nr_000576.shtml; Press Release, Guidant, Guidant Updates Corrective Actions Regarding Its VENTAK PRIZM AVT, VITALITY AVT, and CONTAK RENEWAL AVT Implantable Cardiac Defibrillators (July 22, 2005), http://www.guidant.com/news/500/web_release/nr_000561.shtml; Press Release, Guidant, Guidant Initiates Worldwide Physician Communications Regarding Important Safety Information and Corrective Action About Certain Pacemakers (July 18, 2005), http://www.guidant.com/news/500/web_release/nr_000558.shtml; Press Release, Guidant, Guidant Initiates Worldwide Physician Communications Regarding Important Safety Information and Corrective Action About Implantable Cardiac Defibrillators (June 24, 2005), http://www.guidant.com/news/500/web_release/nr_000554.shtml; Press Release, Guidant, Guidant Initiates Worldwide Physician Communications Regarding Important Safety Information and Corrective Action About Implantable Cardiac Defibrillators (June 17, 2005), http://www.guidant.com/news/500/web_release/nr_000548.shtml.

10. See Meier, *supra* note 3.

11. See, e.g., William H. Maisel, *Safety Issues Involving Medical Devices*, 294 J. AM. MED. ASS'N 955 (2005).

12. See, e.g., Robert Steinbrook, *The Controversy over Guidant's Implantable Defibrillators*, 353 NEW ENG. J. MED. 221 (2005).

13. See, e.g., Hypertrophic Cardiomyopathy Ass'n, Device Recalls and Alerts, www.4hcm.org/WCMS/index.php?id=46,149,0,0,1,0 (last visited November 21, 2005) ("In the case of the Guidant's Prizm 2 models there is no excuse to have withheld information of potential flaws in the device . . .").

issues). At what point should the manufacturer make a disclosure? To whom should the disclosure be made? How should the disclosure be published? What role should the physician play?

A sad but undeniable reality is that no matter how far we progress, all medical devices can fail or malfunction. So while devices such as the ICD have the power to save thousands, if not millions, of lives, a device failure can have tragic results for those whose lives depend upon it.

Events such as the death of Mr. Oukrop have focused intense attention on device malfunctions and the process of notifying the physician of these issues. In this ongoing debate, many stakeholders have been openly critical of how physicians, FDA, and, in particular, industry have handled decisions regarding recalls of products evidencing some risk of malfunction. Many assert that industry should be more open in disclosing even low-frequency or low-risk malfunction trends.

The debate revolves around one key policy question: What should happen when the manufacturer learns that a marketed implantable device is at risk of some, usually previously unknown, malfunction? Who gets told what, when, and by whom?

One cannot underscore the importance and complexity of this debate. In fact, these events led the Heart Rhythm Society (HRS) and FDA to come together to cosponsor a policy conference to address these issues. The conference, held on September 16, 2005, brought together physicians, industry, government, academics, and patients. A series of formal presentations, speaker panels, and open discussion sought to identify and frame the issues surrounding device malfunction notification.¹⁴ While the conference did not resolve the issues, it did create the groundwork for future discussions and led to the HRS's creation of a task force to address the problems. Other stakeholders, from patients to industry, are also contributing to this debate and the search for a solution.

14. The HRS is the medical society of electrophysiologists, cardiologists, and affiliated specialists who research and treat cardiac arrhythmias, often with devices such as ICDs and pacemakers. For information on the proceedings of this policy conference, see Heart Rhythm Society & FDA, Proceedings Document from the Policy Conference on Pacemaker and ICD Performance (Sept. 16, 2005) [hereinafter Proceedings], available at http://www.hrsonline.org/advocacyDocs/HRS-device_conference.pdf.

Guidant itself has created an independent task force to help answer these questions.

There is a consensus that the current system must change and improve. There is no agreement on what those changes should be. Exactly what these changes will be remains an open question—a question this colloquy seeks to help answer.

The articles that follow, many of which have their origin in the recent HRS policy conference, are intended to help identify the problems, and more importantly, the goals or objectives that any solutions to this difficult question must satisfy. In order to do so, several key stakeholders—FDA, physicians, and bioethicists—have provided their thoughts and recommendations on this issue. Patients¹⁵ and industry¹⁶ have also expressed their views. The commentary following these articles seeks to find the common ground, discuss the points of contention, and recommend a solution that satisfies the stakeholders' objectives.

FDA REGULATION OF MEDICAL DEVICES:

The FDA regulates all medical devices under a complex scheme of overlapping requirements.¹⁷ While it is impossible to address each of the multitude of requirements here, to understand the recall system and its issues, one must first understand three other key FDA regulatory processes: the approval process, device performance monitoring, and event reporting obligations.

THE APPROVAL PROCESS

The FDA approval process varies depending on the nature, and particularly the degree of risk, of the medical device.¹⁸ For example, ICDs are Class III medical devices, the classification reserved for the highest risk devices. As such, an ICD cannot be legally marketed in the United States unless FDA has approved a Premarket Approval application (PMA).¹⁹ The PMA application includes indications (or uses for the product),

15. Lisa Salberg, *Heart Rythm [sic] Society and the FDA Hold Policy Conference on Pacemaker and ICD Performance*, HEART LINK ONLINE, Oct. 7, 2005, www.enebuilder.net/hypertrophic/e_article000468321.cfm?x=b11,0,w.

16. See, e.g., Proceedings, *supra* note 14.

17. For the FDA's statutory authority to regulate medical devices, see Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301-397 (2000).

18. 21 U.S.C. § 360c.

19. 21 U.S.C. § 360e.

warnings and contraindications, product labeling, clinical trial results, and information on manufacturing processes.²⁰ The PMA process allows FDA to assess the risk and benefits of the device and to determine the appropriate uses for the device.²¹ The final approved product labeling²² discloses risks, warnings and contraindications associated with the device.²³ Products such as ICDs can only be prescribed by a physician.

A company must seek FDA approval before it can make a modification in a PMA device that affects the safety or efficacy of the device. To do so, the company must file a Supplemental Premarket Approval application (SPMA), setting forth the details and implications of the proposed change.²⁴ Not all changes require prior FDA approval, however. If a company changes a device in a way that *does not* affect the safety or efficacy of the device, the company may simply notify the FDA of the change after the fact through an “annual report.”²⁵ Generally, changes intended to improve yields or ease manufacturing are reported through this annual report process.

DEVICE PERFORMANCE MONITORING

Because of the critical nature of these medical devices, manufacturers must have substantial quality systems in place.²⁶ As part of the company’s quality system, the manufacturer must monitor the field performance of its

20. See 21 U.S.C. § 360e(c); 21 C.F.R. pt. 814 (2005) (providing overview of the PMA process).

21. 21 C.F.R. § 860.7 (2005).

22. “Labeling” is defined in 21 U.S.C. § 321(m) (2000). Labeling includes much more than simply the printing on the product box or container. For example, “labeling” includes physician manuals.

23. See 21 U.S.C. § 360e(c) (2000) (requiring application for premarket approval to include specimens of proposed labeling for the device); 21 C.F.R. § 814.82 (2005) (requiring “prominent display in the labeling of a device and in the advertising of any restricted device of warnings, hazards, or precautions important for the device’s safe and effective use”); 21 C.F.R. § 860.7 (2005).

24. 21 C.F.R. § 814.39 (2005).

25. *Id.*

26. See 21 U.S.C. § 360j (2000) (setting forth the statutory requirements for a medical device manufacturer’s quality system). The implementing quality system requirements in 21 C.F.R. pt. 820 include quality requirements for processes ranging from product design through manufacturing to distribution. The overarching management responsibilities for the effectiveness of the quality system are set forth in 21 C.F.R. § 820.20 (2005). The quality systems of most medical device manufacturers are also certified to the requirements in ISO 9001 or ISO 13485.

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devices, including any malfunctions (a process often referred to as “surveillance”). The manufacturer must investigate any report of a device malfunction, determine root cause of the problem, if possible, and take necessary corrective actions.²⁷ These surveillance and corrective actions also help the company. By determining the root cause of a malfunction, the company is able to learn from past events and improve the performance of future generations of products.

REPORTING

In addition to the duty to conduct product surveillance²⁸ and identify and correct problems, FDA requires manufacturers to report adverse events to FDA in the form of Medical Device Reports (MDRs).²⁹ MDRs detail any deaths, serious injuries, or malfunctions known or reported to the manufacturer that may be associated with a particular device.³⁰ Reports from physicians about patient events or from internally generated information and analysis can trigger MDRs. The reports must often be submitted before the completion of any factual or technical investigation. The public may access the reports through the Manufacturer and User Facility Device Experience (MAUDE) database.³¹

The manufacturer is not the only source of information to FDA. Device users such as hospitals, physicians, or other health care providers can also submit MDR reports directly to FDA.³² Medical literature also provides information about device performance.

Once it receives an MDR report, FDA enters it on the MAUDE database. This database is open to the public, enabling both the physician and patient to monitor their particular device’s performance. The MAUDE database is intended to facilitate physicians, researchers, or the public in

27. *See, e.g.*, 21 C.F.R. § 820.100 (2005).

28. *See* 21 U.S.C. § 360l (2000) (providing FDA’s authority for mandating post approval requirements including surveillance); 21 C.F.R. pt. 814 subpart E (2005) (same).

29. 21 U.S.C. § 360i (2000); 21 C.F.R. pt. 803 (2005).

30. 21 C.F.R. § 803.1.

31. To conduct a search of the MAUDE database, see <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.cfm> (last visited Nov. 22, 2005).

32. *See, e.g.*, 21 C.F.R. § 803.30 (describing MDR filing obligations of user facilities).

finding product malfunctions or adverse events, identifying trends, or otherwise advancing public health.

In addition to the MAUDE database, there are a number of public and private active surveillance systems. Rather than relying on the physician to voluntarily report field events as in a passive surveillance system such as the MDR process, an active surveillance system affirmatively collects data from a predetermined set of hospitals or physicians. Active surveillance systems such as MedSun³³ collect information both on actual malfunctions (the “numerator”) and on total device experience (the “denominator”) in order to ascertain overall device performance and the risk of malfunction.

FIELD ACTIONS OR RECALLS

The manufacturer also must notify physicians of certain types of product malfunctions or failures to meet product specifications. Currently, manufacturers may commence a product recall when the device fails to meet some material specification, is violative, or poses some unreasonable risk to public health.³⁴ The recall process uses information gathered through the various surveillance systems and quality system requirements discussed above. The notification process is comprised of three distinct tasks or systems:

1) the event reporting and analysis process, including the MDR reporting process described above, in which information about actual or potential malfunctions is collected and analyzed;

2) the process to decide whether to “trigger” a recall or product safety alert³⁵ and notify physicians about a specific issue; and

3) the process for implementing and communicating the recall information to physicians.

If the manufacturer concludes that some field action such as a recall (or a “correction” or “removal” action in FDA parlance), is needed, then the manufacturer must inform the FDA of the recall, the reasons for the recall, and the plan for

33. See MedSun, <https://www.medsun.net/about.html> (last visited Nov. 21, 2005).

34. 21 C.F.R. § 7.40 (2005).

35. For purposes of this discussion, the term “notification” or “safety alert” will generally be used to denote the process in which physicians are informed of device malfunction issues. Today, these actions are generally called “recalls.” As discussed later, this term is confusing and should be modified.

conducting the recall.³⁶ As part of this process, the manufacturer generally notifies the physicians treating affected patients about the device issue. In certain recalls, the company will also issue a press release both to better inform physicians and patients about the situation and to satisfy SEC requirements.

The FDA classifies the recall into one of three categories based on the level of risk to the public, with Class I recalls being those events which pose the greatest risk.³⁷ Due to the level of risk, the FDA generally issues its own press release for all Class I recalls. In addition, the FDA posts recall information on its website, no matter the class or risk posed. At the end of a field action, FDA often assesses the effectiveness of the recall.³⁸

In addition to recall notifications, ICD manufacturers provide device performance information to the user both in the physician's manual and in product performance reports that are generally prepared yearly and made public. These reports are not required and not all device manufacturers issue these voluntary product performance reports. While a number of factors are considered in deciding whether to issue a product performance report, these reports tend to be produced for more complex and lifesaving products.³⁹

Once a recall is triggered, the physician must work with the patient in determining the proper course of action. Historically, physicians have taken the relevant information and communicated with their patients, working together to make decisions that best address the needs of the individual patient.

36. 21 C.F.R. § 7.46 (2005); 21 C.F.R. pt. 806 (2005). FDA also has the authority to mandate a notification to health care providers regarding a device that "presents an unreasonable risk of substantial harm to the public health"; however, this authority is almost never used. See 21 U.S.C. § 360h(a) (2000).

37. 21 C.F.R. § 7.41 (2005).

38. 21 C.F.R. § 7.42 (2005).

39. For examples of ICD product performance reports, see Medtronic, Cardiac Rhythm Management, Product Performance Report 2005, www.medtronic.com/crm/performance/index.html; Guidant, Product Performance Report 2005, www.guidant.com/physician/product_performance_report.pdf; and St. Jude Medical, Product Performance Report 2005, www.sjm.com/documents/productperfreport.pdf.

SUMMARY

While the regulatory scheme governing medical devices is complex, the pertinent regulations relating to device approval, device monitoring, and product safety reporting are integral to the system for notifying physicians of device malfunctions. In each step, the manufacturer plays a pivotal role in providing the relevant information to both doctors and patients. Rather than monitoring the actual devices themselves, the FDA reviews the manufacturer's quality system and product malfunction data and reports and routinely inspects the manufacturers to ensure compliance with the various requirements.

THE ISSUES

With this background, one can understand the following articles and how the death of Mr. Oukrop raised a number of serious questions including:

- Are there adequate product performance surveillance systems?
- How should the system identify and respond to very low frequency events that could have very serious ramifications?
- What is the standard or "trigger" by which one decides whether to inform physicians of product performance issues?
- Is there a conflict of interest in having industry investigate product issues and (usually) making the decision as to whether to trigger a recall?
- What are the proper roles for FDA, industry and physicians?
- How should patients be informed of device issues and by whom?

This colloquy seeks to address these issues and offer some ideas for improvement.