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# F.D.A. Had Report of Short Circuit in Heart Devices

**By BARRY MEIER**

Months before the Food and Drug Administration issued a safety alert in June about problems with Guidant Corporation heart devices, the agency received a report from the company showing that some of those units were short-circuiting, agency records obtained by The New York Times show.

But the agency did not make that data public at the time because it treats the information it receives in such reports as confidential. While the agency has a policy of reviewing the reports within 90 days, it is unclear when regulators did so within that time frame or how they first interpreted the information.

As part of a lengthy annual report that Guidant submitted to the F.D.A. in February, the company disclosed data showing that one of its widely used defibrillators, the Ventak Prizm 2 DR, was short-circuiting at the rate of about one a month, a rate that some doctors say was troubling. A month later, a college student who had one of those units implanted in his chest died of sudden cardiac arrest.

In June, the F.D.A. issued an alert about the model, later updating it to say that the short circuits, while rare, posed a significant risk because they could render the device useless just when it was needed most. Defibrillators use jolts of electricity to stop erratic heart rhythms, which can be fatal.

Guidant, which knew about the model's flaw for three years but did not tell physicians about it until May, has recently found itself in the spotlight. But the disclosure that the F.D.A. also had data that might have alerted doctors is likely to increase scrutiny of the agency's policy of not releasing the information it requires heart device makers to submit, as well as how quickly it reviews such reports.

Dr. Daniel G. Schultz, the director of the F.D.A.'s Center for Devices and Radiological Health, said in an interview Friday that it would tie up too many resources to review hundreds of filings the F.D.A. receives each year and determine which data could be routinely released and what should be treated as confidential.

Makers of defibrillators and pacemakers, which regulate heart rhythms, must file annual reports with the F.D.A. that say how often, and why, their devices fail. The level of detail in these reports, which are submitted on paper, is far higher than is required for other

medical devices because of their life-sustaining roles. Those filings also include much more data than the summaries that companies give to doctors.

The issue of how much safety data is disclosed to doctors and patients is expected to be a major focus of a meeting on Friday of heart specialists in Washington that was called as a result of the Guidant controversy. That meeting may pit physicians who want more information about device failures against manufacturers, as well as other doctors, who say the current system is adequate to ensure patient safety.

Last year, both the F.D.A. and the drug industry came under fire for failing to release data about clinical drug trials like those involving the use of antidepressants in children. The Guidant controversy appears to be expanding that debate into the medical devices field.

Dr. Shultz said he did not believe that the effort of disclosing the massive amounts of data sent in by manufacturers would be an effective use of agency resources and time.

"It does not at first blush look like an efficient way of getting information to the public in a timely fashion," he said. He added that he hoped the meeting Friday would lead to improved communication between the agency, device makers and doctors about device-related problems.

The agency's inquiry into Guidant began after The Times reported in late May that the company had not told doctors about flaws in the Prizm 2 DR and kept selling older versions of the model after developing an improved one in 2002. Guidant has said it knows of 28 units that have short-circuited out of 26,000 made before the modification.

Dr. Schultz said he was not familiar with the February report from Guidant that broke out the short circuit figures. He said he did not have information about what percentage of reports were reviewed within 90 days.

Told of Dr. Schultz's comments about the agency's disclosure policies, Dr. Douglas P. Zipes, a professor at the Indiana University School of Medicine, said he took exception to them, saying he believed that the Guidant episode had highlighted gaps in how the F.D.A. oversaw the safety of heart devices. Dr. Zipes added that both the agency and manufacturers needed to provide doctors with more data about product failures.

"It would help us put into better perspective the quality of each manufacturer's devices," said Dr. Zipes, who is also a consultant to Medtronic, a major device manufacturer that also makes a defibrillator, and who will be participating in Friday's meeting.

Guidant has said it made all required disclosures to the F.D.A., including notifying the agency in its 2003 annual report about the manufacturing change to the Prizm 2 DR. The company also submitted several filings in recent years to a publicly available F.D.A. database about the failures of specific units, citing short circuits as the cause.

The F.D.A. does start investigations of product problems based on the reports in that database and in annual filings. But unless F.D.A. officials were closely monitoring the database, which receives tens of thousands of reports a year, the annual report in February may have been their first chance to gauge the Guidant problem's scope, because it was the first of the annual filings to say that a number of devices had failed because of electrical short circuits.

The problem came to light as a result of the death in March of Joshua Oukrop, a college student in Minnesota who received a flawed device. Since then, Guidant has issued recalls covering both that device and tens of thousands of other defibrillators and pacemakers.

The three largest makers of heart devices - Guidant, Medtronic and St. Jude Medical - regularly provide doctors with what are called product performance reports.

Medtronic's reports are the most detailed, breaking down the number of failures for a model into two broad categories: electrical failures and early battery depletion. Guidant and St. Jude provide only an estimated "survival" rate for each model over time, without giving the cause of failure. That rate indicates the risk that the device will have to be replaced because of a problem or because its batteries are depleted, which normally happens after five years.

In its 2004 product report, for example, Guidant reported that its Prizm DR 2 had an estimated survival rate of 98.14 percent after 3.5 years.

A Medtronic spokesman, Robert Clark, said the company believed that its annual reports gave doctors the information they needed in an easy-to-use format. Mr. Clark added that Medtronic did not believe that releasing the detailed F.D.A. reports would be helpful. But both Mr. Clark and a St. Jude spokeswoman, Charlotte Fransen, said their companies were interested in discussing such matters at Friday's meeting of heart specialists. A Guidant spokesman, Steven Tragash, did not respond to an e-mail inquiry about the issue.

Several doctors said that knowing specifically why devices are failing is important because some problems are more significant than others.

"Device failures that are abrupt and catastrophic are more critical than ones that happen slowly or don't interfere with life-saving functions," said Dr. Charles Swerdlow, a cardiologist in Los Angeles who is also a consultant to Medtronic.

The F.D.A. initially refused a Times request for several years of Guidant annual filings that was made under the Freedom of Information Act, contending that the filings contained trade secrets. The Times appealed that decision to the agency, and the F.D.A., without citing a specific reason, reversed its position and last week released much of the data.

Those filings show the wide gap between the data provided to the F.D.A. and that given to doctors. For each defibrillator model it sells, Guidant provides data that runs for three to four pages citing specific reasons for device failure, including memory problems and prematurely low batteries, and how many units failed for that reason.

In its 2004 filing, Guidant devoted a 96-page section to data on its defibrillator models. In a table on page 60 of that section, it reported that 10 Prizm 2 DR's had an "electrical short" between June 1, 2003, and May 31, 2004, the period covered by the filing. That is a failure rate of almost one device a month.

The filings may also raise new questions about Guidant's reporting of problems with the Prizm 2 DR. For instance, while Guidant has said that two of the units short-circuited in 2002, the 2004 report is the first annual filing to use the term "electrical short." The term "electrical overstress" was used in earlier filings, but it also appeared as a separate category from "electrical short" in the 2004 report. That report was submitted by Guidant this February, eight months after the period it covered. In the three prior years, Guidant took three months to file.

Mr. Tragash, the Guidant spokesman, did not respond to questions about specific reports but reiterated that the company had made all required disclosures.

In December, Guidant agreed to be acquired by Johnson & Johnson in a deal worth $25.4 billion. Johnson & Johnson has said it plans to proceed with the acquisition but is reviewing issues related to the device recalls.

The F.D.A. says its investigation of Guidant is continuing and it has not determined what action, if any, to take against the company.

In recent months, some of Guidant's most outspoken critics have been the doctors who treated Mr. Oukrop, the student who died. They say that if the company had made them aware of the problem, they would have quickly replaced Mr. Oukrop's defibrillator. On Friday, one of those physicians, Dr. Robert Hauser of Minneapolis, said he was irate to hear that the F.D.A. was given such data in February. Dr. Hauser said that if the agency had disclosed it, it might have saved Mr. Oukrop's life.

"They probably didn't even read the report," he said. "This is just scandalous."