The New York Times https://www.nytimes.com/2005/07/30/business/new-report-of-problems-at-guidant.html

New Report of Problems at Guidant

By Barry Meier

July 30, 2005

About two weeks before a college student with a flawed heart device died in March, another heart patient implanted with the same model that also failed almost died, according to a government filing by the device's maker, the Guidant Corporation.

The filing, which was first publicly disclosed earlier this month when the Food and Drug Administration posted it in a database, shows that a heart patient implanted with a specific type of Guidant unit "presented to a hospital" around the beginning of March after suffering cardiac arrest, an often fatal condition that the device known as a defibrillator is intended to prevent. (Doctors often use the term "presented" to describe a patient's condition upon arrival at an emergency room.)

It was determined by Guidant that the patient's device, known as a Ventak Prizm DR 2, had failed because it had short-circuited at some point, the filing shows, though it is not clear when Guidant made that determination. The patient was revived, possibly by the type of rescue defibrillator used by paramedics. Two weeks later, a 21-year-old college student, Joshua Oukrop, died of cardiac arrest. Guidant has previously said that his Prizm DR 2 had also short-circuited, though it said it was not known when it failed.

After Mr. Oukrop's death, it was disclosed by The New York Times in late May that Guidant officials had known for three years that the same model had repeatedly short-circuited but had decided not to alert doctors. Ever since, Guidant, which is based in Indianapolis, has found itself under intense scrutiny and has recalled tens of thousand of defibrillators and pacemakers, including some versions of the Prizm DR 2.

Yesterday, a spokesman for Guidant declined to respond to questions in an e-mail message seeking added information about the details of the incident.

Guidant, which is the country's second-biggest producer of heart devices, has said it was aware of three cases involving a Prizm DR 2 in which a patient had to be rescued using an external defibrillator and that such reports had been filed with the F.D.A., as was the case with this one. But earlier filings had suggested that such events took place inside hospitals or clinics -- during an implant procedure, for example -- where such failures pose less danger. Several doctors said the filing's language indicated that the cardiac arrest had occurred outside a hospital.

If so, the rescue of a patient who had cardiac arrest outside a hospital, coming so close in time to the death of Mr. Oukrop, may raise further questions about why Guidant executives decided not to issue a warning this spring about the Prizm DR 2. It may also increase scrutiny of the F.D.A.'s oversight of medical devices because, records show, the agency had received reports of both Mr. Oukrop's death and the near-death of the cardiac arrest patient on the same day, May 10.

The F.D.A. started looking into Guidant's handling of the Prizm DR 2 issue two weeks later, after The Times report about it. F.D.A. officials did not respond yesterday to questions about what, if anything, the agency did when the reports were received.

The agency later categorized the device's subsequent recall by Guidant as a Class I, the most serious recall classification and it is currently reviewing how Guidant assessed and responded to the device's hazards.

Shareholder-related lawsuits filed against Guidant have asserted that company executives did not disclose problems with the Prizm DR 2 and other devices earlier because they were concerned that doing so would have a negative effect on Johnson & Johnson's pending $25.4 billion plan to buy Guidant. Johnson & Johnson, which is based in New Brunswick, N.J., made the offer in December, in part to acquire Guidant's defibrillator unit.

Company officials have previously disputed that financial factors played any part in their decision, which was based on patient safety concerns. Because removing a device also poses risk.

The report filed by Guidant in May stated that the cardiac arrest patient "required intervention," a likely reference to the use of an emergency defibrillator. The nature of it is not stated and, because of patient confidentiality issues, both the identity of the patient and hospital are not listed on such F.D.A. device reports.

Dr. Eric N. Prystowsky of Indianapolis, who is an outside medical adviser to Guidant, said he did not recall if Guidant officials told him about the cardiac arrest incident. But both Dr. Prystowsky and other physicians said that any incident in which a defibrillator flaw

prevented it from providing life-saving therapy should be counted as a death in assessing that device's risks even if a patient survived the episode.

The exact date of the incident is also not clear. But Guidant's report about it to the F.D.A. states that the company was notified about the episode on March 4. It was 10 days later, on March 14, that Mr. Oukrop, the college student, died of cardiac arrest.

Two Minneapolis doctors who treated Mr. Oukrop, Dr. Robert G. Hauser and Dr. Barry Maron, said in separate interviews yesterday that they did not believe that Guidant officials told them about the cardiac arrest case during meetings in mid-May after their patient's death.

It was during that meeting, Dr. Hauser and Dr. Maron have said, that Guidant officials told them the company had fixed the electrical problem in April 2002 by changing how it made the Prizm DR 2.

Both Minneapolis doctors have said they were angered to learn about the problem after their patient's death because they would have quickly replaced the device had they known earlier. They said they urged Guidant officials to alert other doctors to the problem but that the company refused to do so.

The company did issue an alert in late May as The Times was preparing to publish an article about the device.