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Pacemakers by Guidant Have Flaw

By Barry Meier

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The Guidant Corporation, already embroiled in controversy over recalls of heart devices, alerted doctors yesterday that nine of its older pacemaker models were prone to failing. Some patients might need to have the units replaced, the company said.

The alert covers 28,000 pacemakers made from November 1997 to October 2000 and still implanted in patients. Guidant said that a component used to seal the pacemakers could degrade, allowing moisture to build up and causing the devices to fail. Such failure could cause "serious health complications" in some patients, the company said. The flaw may have contributed to one patient's death, though that is not clear.

The pacemaker alert follows Guidant's recalls in recent weeks of tens of thousands of implantable heart defibrillators. Guidant's long delays in notifying doctors about problems with some of those devices have thrown a spotlight on the issue of when and how device makers alert physicians and patients to product flaws. It has also raised questions about how the Food and Drug Administration discloses safety data it collects about medical devices.

Late yesterday, Senator Charles E. Grassley, Republican of Iowa and chairman of the Senate Finance Committee, signaled his interest in reviewing issues surrounding the recent Guidant recalls.

In a letter to the F.D.A. commissioner, Dr. Lester M. Crawford, Mr. Grassley requested that the agency provide him with five years of annual reports filed by Guidant for the defibrillators and pacemakers that were the subject of recent company alerts or recalls. The Senate Finance Committee has previously investigated the agency's handling of several drugs, including Vioxx.

In his letter, Senator Grassley also asked agency officials to explain why they did not routinely make public such reports, which are filed annually by heart device makers for each defibrillator and pacemaker they make. An article last month in The New York Times highlighted how those annual reports contain far more detailed product-safety and performance data about heart devices than companies routinely provide to doctors. However, the F.D.A. treats the reports as confidential.

In its alert yesterday, Guidant said that doctors should consider replacing the affected pacemakers in patients who depend on the device for survival or to prevent serious health consequences. That category roughly ranges from 20 percent to 40 percent of pacemaker patients, two doctors said.

Because of their age, most of the pacemakers at issue will need to be replaced soon anyway, since their batteries are nearly drained. The company said that it would pay for the replacements.

While both pacemakers and defibrillators are implanted under the skin, they serve different purposes. A pacemaker regulates a heart that is beating too fast or too slowly. A defibrillator emits an electrical shock intended to interrupt a chaotic and deadly type of heart rhythm.

Guidant's recent spate of recalls, including the one announced yesterday, is likely to play a role in discussions of second-quarter earnings results due this week from both Guidant and Johnson & Johnson, which agreed in December to buy Guidant for $25.4 billion.

Today, Wall Street analysts are expected to ask Johnson & Johnson executives, when they discuss the company's earnings, if Guidant's recent problems might affect the timing or price of Johnson & Johnson's planned acquisition.

Asked for comment yesterday, a spokesman for Johnson & Johnson, which is based in New Brunswick, N.J., referred to a statement made in mid-June in which the company said it would close the Guidant deal this quarter, though it added that it viewed Guidant's product problems as "serious matters."

The deal is valued at $76 a share to Guidant holders. But in recent weeks, the value of Guidant's stock has fluctuated sharply as investors have speculated on whether the deal's price will be revised. Yesterday, Guidant shares fell $2.10 to close at $67.31 a share, down 3 percent.

On Thursday, Guidant is set to announce second-quarter results. Those results will provide the first look at whether the company has suffered financial damage as a result of its recent recalls.

Analysts are split about how the steady beat of bad news from Guidant will affect its market share in the long term.

Guidant has been under scrutiny since late May when it was disclosed that the company failed to notify doctors for three years that an electrical defect in one defibrillator model could cause it to short-circuit when needed to save a patient's life. The company continued to sell units with the potential electrical flaw even after it began producing improved versions of the same model in which the problem had been fixed.

The F.D.A. is investigating how Guidant handled reviews of its products' dangers. Since late May, the company has issued alerts or recalled 11 models of defibrillators.

Yesterday, an F.D.A. spokeswoman said the agency was aware that Guidant had issued the pacemaker alert to doctors and that it was evaluating the matter. Guidant said it expected the F.D.A. to designate the alert as a recall, a formal classification that involves the type of physician notification that Guidant is already making.

A recall does not mean that a device should be removed. Instead, patients are typically advised to discuss with their doctors the risk posed by a device compared with the risk posed by the surgical procedure needed to replace it.

Several doctors said yesterday that they would probably recommend that pacemaker-dependent patients have the units replaced.

"To me, that is the conservative move," said Dr. Eric N. Prystowsky, a heart specialist in Indianapolis who is also a medical adviser to Guidant. Nine older pacemaker models are involved. They are the Pulsar Max, the Pulsar, the Discovery, the Meridian, the Pulsar Max II, the Discovery II, the Virtus Plus II, the Intellis II and the Contak TR. The company said that the units, which are of an earlier design, have not been implanted for the last four years.

Guidant said it had identified 69 devices that may have had the seal problem, out of some 78,000 devices in which that component was used. Currently, about 28,000 of those units are still implanted in patients, with 18,000 of them in the United States.

In 20 known cases, the problem caused pacemakers to fail, and in 5 such instances, patients blacked out, apparently because of inadequate blood flow. In two other instances, the flaw may have caused a pacemaker to keep pacing at a high rate.

In one such case, that flaw may have contributed to a patient's death. However, because the unit was not returned to Guidant for inspection, the company said it was not clear if the death was related to the device or to the patient's health problems.