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Inquiry Arranged by Guidant May Aid Lawsuits and Critics

By BARRY MEIER

The Guidant Corporation may have gotten more than it bargained for when it appointed a panel last year to look into its practices after it came under scrutiny for its failure to publicize flaws in its heart devices.

The 12-member panel not only urged the company to overhaul its disclosure process, but its full report, released yesterday, may provide plaintiffs' lawyers suing Guidant with a road map and may also help government agencies that are investigating the device maker.

Consider a memorandum written in January 2005 by a Guidant product review committee, which the outside panel cited in its report. At the time, Guidant executives were faced with the choice of recalling potentially defective heart defibrillators or allowing doctors to implant them. The flaw was so serious that months earlier the company had stopped producing the older models or even shipping them to hospitals.

"Even if implanting pre-fix devices turns out to pose a clinical risk," the Guidant memo said, "by the time statistical surety is reached most or all of the pre-fix devices will have been implanted making the issue of pre-implant recall moot."

It was not just Guidant's decision to continue the implants that the panel concluded was wrong. By quoting the memo, the panel appeared to reinforce its central finding that on patient safety issues, Guidant was a company driven by engineers, rather than doctors, and to underline the troubling consequences that can result.

The toughness of the report may reflect the person Guidant appointed to head the effort, Dr. Robert J. Myerburg, a professor of medicine at the University of Miami. In their 135-page report, Dr. Myerburg and the cardiologists and other experts on the panel were sharply critical of the company's decision to withhold device safety information from doctors, and they rebuffed its arguments for doing so.

"The public will never — and arguably should never — consider it 'good business' when information is withheld from patients and physicians," the panel said.

Dr. Myerburg, 69, has been involved in some of the landmark studies supporting the critical value of defibrillators, electrical devices that sense and interrupt potentially fatal heart rhythms. And over the years, he earned a reputation as a tough and fair-minded critic.

"He is absolutely a straight shooter," said Dr. Robert G. Hauser, one of two Minneapolis physicians who helped bring the problem with some Guidant defibrillators to light after one patient died when a unit short-circuited.

The death last March of that patient, a college student, set off a chain of events that would lead to the scrutiny of Guidant, the recalls of thousands of its devices, and some 145 lawsuits and investigations by the Food and Drug Administration and the Justice Department.

It also led to the move last summer by Guidant to appoint the outside panel to review its practices. Dr. Myerburg said he agreed to take the job after Guidant executives assured him of independence. He then recruited 11 experts, including cardiologists as well as authorities on medical ethics and regulatory affairs.

Dr. Myerburg said that he and other physicians on the panel had an immediate realization when they began work: for years, device makers had not provided them with detailed data on defibrillator failure, and they, as doctors, had been so taken with the life-saving technology that they had never asked for that data.

The result, Dr. Myerburg said, was that information about the potential of devices to fail, even in small numbers, had never been communicated to patients.

"The light went on," he said, "and one of the things that we realized is that industry had to be transparent with physicians about these devices so that physicians could be transparent with patients."

Over months, the Guidant panel interviewed company officials and requested and reviewed documents. In the process, Dr. Myerburg said he realized that engineers at Guidant were deciding medical issues without hearing from doctors.

More broadly, the panel found that the defibrillator industry, which has grown rapidly into a $10-billon-a-year business, had not updated its disclosure policies to keep pace with the growth, Dr. Myerburg said.

He said Guidant's board enthusiastically embraced his report when he presented it to them at a meeting on Monday. Guidant has said that it will adopt some of the measures proposed by the group, including appointing a company doctor charged with patient safety.

Dr. Myerburg said he also met on Sunday with top executives of Boston Scientific, who had flown out to Indianapolis to be briefed about his findings. Boston Scientific agreed in January to acquire Guidant for $27 billion.

In a statement issued yesterday, Boston Scientific said Dr. Myerburg's panel "has made a number of excellent recommendations, some of which should benefit both Guidant and Boston Scientific."

At the Sunday meeting, Dr. Myerburg said, Boston Scientific did not make commitments to adopt specific recommendations like the appointment of an outside medical panel to monitor device safety and advise Guidant about disclosures.

He said he understood that executives were reluctant to do so before the completion of the Guidant deal, which may occur later this month.

"Their main issue," he said, "was, Is the product fundamentally reliable, because the rest of the problems can be fixed."

But corporate executives are not the only ones carefully going through the panel's report. Its findings were also cited in a lawsuit filed yesterday against Guidant in a Minnesota state court on behalf of a heart patient who died in July. The suit contends that his death occurred because his defibrillator short-circuited and failed.

Tara D. Sutton, a plaintiffs' lawyer in Minneapolis, said yesterday that she thought that the panel's report would help establish punitive damages in the case because it provided further evidence that Guidant disregarded the safety and rights of patients.

A spokesman for Guidant, Steven Tragash, said yesterday that the company did not comment on litigation. Guidant has previously said that it did nothing wrong.