Device Maker's Quick Action on ICD Flaw Lauded

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Boston Scientific's rapid response to yet another potential safety issue with its pacemakers and implantable cardioverter defibrillators early this summer has brought praise from cardiologists who helped draft a proposal to guide responses to safety problems.

On June 23, Boston Scientific sent a letter to physicians informing them of a possibility of malfunction in a subset of two pacemaker models (Insignia and Nexus), as well as in the Contak Renewal TR and TR2 cardiac resynchronization pacemakers, and the Ventak Prizm 2, Vitality, and Vitality 2 ICDs. The company said that although the Food and Drug Administration might classify the action as a recall, it was initiating an "action to retrieve from hospital and sales force inventory all nonimplanted devices within this well-defined subset."

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Dr. Mark D. Carlson, chair of the Heart Rhythm Society Task Force on Device Performance Policies and Guidelines, lauded the company for not using the term "recall." That was one of the recommendations in the task force's April draft guidelines.

The word "has so many implications that don't necessarily apply to implantable devices," Dr. Carlson said in an interview. Recall "suggests that an action should be taken, and that places physicians in an awkward and sometimes clinically inappropriate situation," added Dr. Carlson, who is a professor of medicine and associate vice president for government relations at Case Western Reserve University in Cleveland.

In most cases, explanting a device is riskier than leaving it in, he said.

Boston Scientific said that 49,800 of the devices had been distributed, and that 27,200 had been implanted worldwide. Of those ICDs, there were five confirmed reports of malfunction associated with failure of a low-voltage capacitor from a single supplier.

Even though the company had not completed its root-cause analysis, it decided to notify physicians, patients, and the FDA of the potential problem. An analysis of the retrieved devices should be completed by the fall, according to the FDA.

The agency said in a statement that it backed Boston Scientific's plan to remove the devices from hospital inventories and to direct physicians to conduct follow-up exams with patients.

"While information about the problem with these devices is still very preliminary, FDA is committed to keeping the public informed," said Dr. Daniel Schultz, director of the agency's Center for Radiological Devices and Health.

Dr. Dwight Reynolds, president of the Heart Rhythm Society, agreed that the company's move was prudent and in line with the task force's recommendations. "I think the fact that they've announced fairly early in their evaluation process that this problem exists is a testament to their commitment to what everyone has espoused: that early disclosure of events is appropriate," Dr. Reynolds told INTERNAL MEDICINE NEWS.

The day after the society's draft was released, Boston Scientific, which had just completed its purchase of Guidant Corp., said that it would follow all of the recommendations.

Guidant's devices have been the subject of multiple safety notices and recalls since early 2005, including the one in June. The

Heart Attack Info For Older Adults

The National Institute on Aging has added information about heart attack to its SeniorHealth Web site, which provides health information for older Americans.

The fact sheet includes information about signs, causes, risk factors, diagnosis, and treatment of heart attack.

For more information, visit www.nihseniorhealth.gov. ■

company has been repeatedly criticized for a failure to notify physicians or patients on a timely basis.

The perception that the devices are unsafe has led to anxiety among patients, Dr. Reynolds said. Although the numbers of those who have sought explantation or refused implantation are hard to quantify, he said he has heard many anecdotal reports. A colleague told him last fall that two patients who were ICD candidates told the cardiologist they would not consider the implants "because they don't trust them." The fear seems to have dissipated recently, however, he said.

He added that physicians have been concerned about quality issues and have reflected that concern in less enthusiasm for implanting the Guidant devices. But, he said, it's not an attitude that is "either pervasive or likely to be sustained."

And both he and Dr. Carlson said that Boston Scientific is doing a good job of moving forward.

"I think they've now acknowledged that the patients' and physicians' right to know supersedes concerns about what their responses might be," Dr. Reynolds said.

Physicians have been concerned about the communications process in the last year, Dr. Carlson said. However, he added, "I'm hopeful and extremely optimistic that those problems are behind us."

Dr. Carlson has consulting or speaking relationships with Guidant, St. Jude Medical Inc., and Medtronic Inc. Dr. Reynolds is a consultant, and has received honoraria as a speaker, for Medtronic.

Boston Scientific also recently has hired someone to be a point person on product safety: William E. Young, who will have the title of vice president of quality assurance and reliability for the cardiac rhythm management group.

The Heart Rhythm Society's guidelines are expected to be published in October, most likely in the society's journal, Heart Rhythm, Dr. Carlson said. ■

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Dr. Steven Nissen, on concerns that commercial influences are undermining public confidence in the FDA, p. 60