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FDA Releases Results of Study on Defibrillator and Pacemaker Malfunctions Part of Agency Drive to Improve Device Safety Monitoring and Public Communications

In its ongoing commitment to improve the safety monitoring of implantable cardiac devices and provide earlier notice to doctors and patients of potential problems, the U.S. Food and Drug Administration (FDA) released its retrospective review of malfunctions of implantable cardioverter defibrillators (ICD) and pacemakers occurring from 1990-2002. The findings were presented today at the Heart Rhythm Society "Policy Conference on Pacemaker and ICD Performance," in Washington, DC.

The meeting is a gathering of clinicians, FDA medical and scientific staff, and other stakeholders, to discuss ways in which the agency can increase its collaborations with the clinical community to improve the quality of information that is made available to doctors and patients for making individual medical decisions about the safe and effective use of implantable defibrillators. This is part of a broader effort inside FDA to increase its collaboration with medical professional societies.

The study is part of the FDA device center's continuing efforts to improve the medical information it makes available from routine surveillance reports that the agency receives as part of its post market safety monitoring. Overall, the study found that the number of malfunctioning pacemakers removed and replaced in patients has decreased, while the numbers for ICDs have increased. The reasons for the increase in ICD malfunction rates have not been established, but potentially could relate to the increased complexity of these devices, manufacturing challenges posed by device complexity, or increased reporting by physicians.

The study also concluded that careful monitoring of device performance is needed, along with better ways for doctors to return explanted devices to companies for analysis and to report adverse events.

"The FDA is committed to continuing to improve the quality of information that patients and doctors have to make decisions about the safe and effective use of these critical, life-saving technologies," said Scott Gottlieb, MD, FDA Deputy Commissioner for Scientific and Medical Affairs. "Pacemakers and ICDs have saved many lives and the benefits of the devices clearly outweigh the risks. All sophisticated medical devices like these have certain risks. Our challenge remains to uncover these risks, measure them, and make information available to patients and doctors to help guide their personalized decisions about where the benefits of technologies like these outweigh known or potential risks from their use."

From 1990 to 2002, there were approximately 2.25 million pacemakers (PMs) and 416,000 ICDs implanted in the United States. During the same time period, 17,323 devices (8834 PMs and 8489 ICDs) were removed from patients due to confirmed device malfunction. The annual ICD malfunction replacement rate of 20.7 per 1,000 implants was significantly higher than the PM malfunction replacement rate of 4.6 replacements per 1000 implants. The PM malfunction replacement rate decreased significantly during the study. In contrast, the ICD malfunction replacement rate trended down during the first half of the 1990's but increased during the latter half of the study. In addition, more than 50% of the ICD malfunctions occurred during the last three years of the study. PM or ICD malfunctions were directly responsible for 61 confirmed deaths out of the nearly three million devices implanted during this time period. However, the vast majority of reported malfunctions did not lead to death or serious injury, and were detected in time to ensure that patients would continue to receive therapy when it was needed.

"It is important for patients to understand that there is no action that they need to take as a result of this report. It does alert FDA that there is a trend that needs to be addressed and points out the need for our agency to improve the way it regulates these products, and we are doing just that," said Daniel Schultz, MD, Director of FDA's Center for Devices and Radiological Health (CDRH). "We have already begun to better coordinate our pre and post-market regulation of these devices, to strengthen the link between how these products are approved and how they are monitored after clinical use. We are also considering whether we need additional data from manufacturers in their annual reports, and how we can communicate more effectively with physicians and patients when these devices malfunction."

As part of FDA's goal to improve device safety monitoring and issue earlier communications, the top priorities underway are:

- Increasing CDRH's ability to obtain critical information about medical device failures and to communicate this information clearly and rapidly to physicians and the public so they can use it to make sound,

informed medical decisions.

- Better coordination of company annual report information within CDRH to allow for an integrated approach, leading to more efficient and timely review.
- For ICDs in particular, formation of a working group tasked with improving communication within CDRH so information about problems with ICDs and pacemakers can be quickly reviewed and evaluated by staff, and shared more rapidly with the public.
- Operational changes made as the result of an ongoing internal review of CDRH's post-market program, which tracks the performance of medical devices once they reach the market and are in general use. The following changes are being considered:

    1. Design of an electronic system for adverse event reporting to make the information available to CDRH analysts more quickly.
    2. Targeting resources to inspections of firms that manufacture potentially higher risk devices.
    3. Developing guidance for companies that submit annual reports to make sure they provide information about failures and problems in a way that assures prompt, efficient review by FDA.
    4. Developing guidance that more clearly defines when changes to devices need prior review and approval by FDA before being implemented.

The study abstract and FDA's presentations from the Heart Rhythm Society meeting are available on FDA's web site at http://www.fda.gov/cdrh/ocd/icd/. The complete study will be submitted to a medical journal for publication.

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Speech by FDA Deputy Commissioner Scott Gottlieb, M.D., to the Heart Rhythm Society (Sept. 16, 2005)