Department of Justice

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MEDICAL DEVICE MANUFACTURER GUIDANT SENTENCED FOR FAILURE TO REPORT DEFIBRILLATOR SAFETY PROBLEMS TO FDA

Boston Scientific Subsidiary Sentenced to Pay Criminal Penalty of More Than $296 Million and Three Years Probation

WASHINGTON – Guidant LLC, a wholly-owned subsidiary of Boston Scientific Corporation, was formally convicted and sentenced today in St. Paul, Minn., before U.S. District Court Judge Donovan W. Frank for criminal violations relating to its interactions with the Food and Drug Administration (FDA). Judge Frank sentenced Guidant to pay more than $296 million in criminal fines and forfeiture and also to submit to the supervision of the U.S. Probation Office for three years. The Justice Department brought criminal charges against Guidant for its mishandling of short-circuiting failures of three models of its implantable cardioverter defibrillators: the Ventak Prizm 2 DR (Model 1861) and the Contak Renewal (Models H135 and H155). Guidant's Cardiac Rhythm Management division, which produced the defibrillators, is headquartered in Arden Hills, Minn. The company pleaded guilty to the charges last April.

Implantable cardioverter defibrillators are lifesaving devices used to detect and treat abnormal heart rhythms that can result in sudden cardiac death. The devices, once surgically implanted, continually monitor the electrical activity in a patient's heart for deadly arrhythmias and deliver an electrical shock to the heart in an effort to return the heartbeat to normal rhythm. If they fail to operate properly when needed, a person can die within minutes.

Judge Frank sentenced Guidant for withholding information from the FDA regarding catastrophic failures in some of its lifesaving devices. Guidant made decisions at various junctures to conceal information from the FDA and medical professionals regarding the device failures. In June 2005, the company finally went public about the problem with information it had known for 10 months, and then only after three deaths had occurred.

The Justice Department's sentencing memorandum filed with the court explains how Guidant decided to continue to implant hundreds of defective Renewal devices, even after the company had decided to stop shipping them from the factory due to the seriousness of the health risk they represented. Guidant developed a strategy to mitigate the health risk while not raising FDA concerns about the problem. This strategy included

the company advising its sales representatives to tell physicians that “nothing was broken” with the Renewal, and falsely telling the FDA that changes it proposed to the device in response to the electrical short-circuiting “were not being done to correct device flaws that threaten patient safety” but were rather “to improve process throughout.”

Under today’s sentence, Guidant is required to forfeit $42,079,675 to the United States and pay a criminal fine of $253,962,251. In addition, Guidant was sentenced to three years of probation. During that period, Guidant is required to make quarterly reports to the Probation Office and to submit to regular, unannounced inspections of its records by the Probation Office. The court also required Guidant to notify its employees and shareholders of its criminal conviction.

“The sentence the court imposed reflects the seriousness of Guidant’s conduct,” said Tony West, Assistant Attorney General for the Civil Division of the Department of Justice. “Patients are put at risk when health care companies fail to meet their responsibility to provide complete and accurate information to the FDA.”

Guidant was charged in federal district court on Feb. 25, 2010. Last April, Judge Frank rejected a proposed plea agreement between the government and Guidant.

“The safety and integrity of critical medical devices is assured only by close FDA oversight,” said First Assistant U.S. Attorney John Marti of the District of Minnesota. “This agency can only perform its mandated duty when medical device manufacturers provide the agency with timely and accurate information. When Guidant withheld important information, patient safety was jeopardized. The court’s sentence recognizes the harm of Guidant’s conduct.”

“FDA always works closely with companies to support compliance with standards that prevent serious safety problems from occurring. However, as today's sentence demonstrates, when companies fail to comply, we will use our enforcement tools to ensure the safety and efficacy of the medical products that Americans rely on every day,” said Margaret Hamburg, M.D., Commissioner of the FDA.

The case was investigated by the FDA’s Office of Criminal Investigations and is being prosecuted by Assistant U.S. Attorney Robert M. Lewis of the U.S. Attorney’s Office for the District of Minnesota, and Justice Department Trial Attorneys Ross S. Goldstein and Matthew S. Ebert of the Civil Division’s Office of Consumer Litigation. Additional assistance has been provided by Steven Tave of FDA’s Office of Chief Counsel.

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