ILLINOIS ATTORNEY GENERAL LISA MADIGAN

PRESS RELEASE

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MADIGAN JOINS SETTLEMENT TO ENSURE DEFIBRILLATOR MANUFACTURER RELEASES SAFETY DATA

Chicago - Attorney General Lisa Madigan today announced that Illinois and 35 other states have reached a settlement requiring that one of the world's largest manufacturers of implantable cardioverter defibrillators (ICDs) significantly change its conduct in evaluating and publicly disseminating safety information.

Physicians surgically implant ICDs into a patient's chest to monitor for abnormal heart rhythms. If the heart stops, the device delivers a small jolt of electricity to start the heart functioning again.

The settlement resolves a lawsuit against Guidant Corporation, an Indiana corporation and wholly-owned subsidiary of Boston Scientific. The suit alleged that Guidant continued to sell the unmodified Ventak Prizm ICD after the company had modified the device to correct a potentially life-threatening wiring problem that could cause the unit to short circuit. In 2005, Madigan and the other attorneys general began an investigation which resulted in the allegation that until 2005, Guidant had failed to inform doctors or the public that it had continued selling the unmodified ICD in 2002 and 2003.

“Guidant absolutely should have informed physicians and the public of updated safety information and of the fact that the company continued to sell the unmodified devices,” Madigan said. “As a result of this settlement, Guidant will now clearly disclose critical safety information.”

As part of the settlement, Guidant has agreed to implement important ICD safety programs and publicly report critical safety information about the potentially life-saving devices it manufactures.

Specifically, Guidant has agreed to undertake the following steps as part of the settlement:

- Establish a patient safety advisory board consisting of independent experts to evaluate data concerning ICD performance;

- Establish a patient safety officer position, staffed by a physician whose primary responsibility is to advance ICD patient safety;

- Clearly disclose and disseminate to the public specific information on a quarterly basis, including worldwide failure data, survival probability estimates and current information in the event of an FDA recall of any ICD;

• Post a notice on its website within 30 days of any modification to any of its ICDs to correct a failure pattern;

• Solicit the return of out-of-service ICDs; and

• Maintain a data system to track the serial numbers, implant and explant dates of all ICDs Guidant distributes in the U.S.

Guidant also is conducting a warranty program to provide consumers who wish to replace their Prizm ICD with a new device at no cost and to reimburse consumers up to $2,500 for out-of-pocket expenses incurred with the replacement. As a result of today's settlement, Guidant has agreed to extend this warranty program for an additional six months. Also as part of the settlement, Guidant will pay $16,750,000 to the states, up to $1 million of which will be used to reimburse warranty program participants for expenses they incurred beyond $2,500.

Illinois' $605,000 share of the multi-state settlement will be used to fund enforcement of the state's consumer protection laws.

Assistant Attorney General Cassandra Karimi handled the case for Madigan's Consumer Fraud Bureau.

-30-

Return to August 2007 Press Releases