DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS
Office of Consumer Protection

DCCA News Release

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HAWAI`I TO RECEIVE $390,000 FROM DEFIBRILLATOR MANUFACTURER

HONOLULU – The State Office of Consumer Protection (OCP) announced today that Hawai`i, along with 34 other states and the District of Columbia, has reached a settlement with Guidant Corporation, a wholly-owned subsidiary of Boston Scientific and one of the world's three largest manufacturers of Implantable Cardioverter Defibrillators (ICDs).

ICDs are medical devices that doctors surgically implant in a patient's chest to monitor for abnormal heart rhythms. If the heart stops, the ICD delivers a small jolt of electricity to start the heart functioning again. The settlement concerns the sale of one particular ICD, the Ventak Prizm 2 DR Model 1861 (Prizm).

The states began investigating Guidant when they learned that Guidant made changes in 2002 to correct a Prizm wiring problem that could cause the unit to short circuit. If the device short-circuited, it could fail to deliver a life-saving jump-start to a patient's heart. Guidant continued to sell unmodified Prizms even after making two separate changes to correct the wiring problem. Guidant did not inform physicians or the public until May 2005 that it had continued to sell unmodified Prizms in 2002 and 2003.

Pursuant to the settlement, Guidant has agreed to implement certain ICD safety programs, publicly report important safety information about the potentially life-saving heart devices it manufactures and pay a $16,500,000 penalty to the states. Hawai`i's share of the $16,750,000 is $390,000, which will be used to fund consumer education and enforcement of consumer protection laws in the state.

In addition, Guidant agreed to:

- 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 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
- Maintain a data system to track the serial numbers, implant dates and explant dates of all ICDs Guidant distributes in the United States

Currently, Guidant is conducting a warranty program to provide consumers who wish to replace their Prizms with a new device at no cost and to reimburse consumers up to $2,500 for out-of-pocket expenses they incur with this replacement. Guidant has also agreed to extend this warranty program for an additional six months. The states will use up to $1,000,000 of the $16,750,000 payment to reimburse warranty program participants for expenses they incurred beyond $2,500.

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