



Boston Scientific Heart Defibrillator Recall Under Investigation

Written On March 31, 2010 By Bob Kraft

The Department of Justice and the Securities and Exchange Commission are investigating medical device maker Boston Scientific Corp.'s recent recall of implantable heart defibrillators, according to an internal company memorandum reviewed by The Wall Street Journal.

Last year, Boston Scientific agreed to settle a Justice Department investigation into problems with Guidant Corp. defibrillators by paying \$296 million and pleaded guilty to two misdemeanor charges for failing to include information in reports to the FDA. Also last year, the company agreed to pay \$22 million to resolve allegations its Guidant unit paid kickbacks to doctors to get them to use pacemakers, ICDs and other products. Here are excerpts from the Wall Street Journal article:

Prosecutors have sent Boston Scientific a subpoena, and the Securities and Exchange Commission has begun an informal inquiry, said the memorandum, which General Counsel Timothy Pratt sent to certain employees Friday.

The two agencies "are requesting information in connection with the recent" recall, the memorandum said. "We are cooperating with these investigations."

The company declined to comment on the memo.

Boston Scientific halted sales and began retrieving all unsold defibrillators on March 15, after discovering it had not asked regulators to approve two manufacturing changes. The Natick, Mass., company described the situation as a documentation problem, saying no patients had been injured.

The company is now waiting for the Food and Drug Administration to clear the manufacturing changes. The FDA is also investigating the recall, as well as Boston Scientific's previous failures to follow reporting requirements.

According to the memorandum, SEC and Justice investigators are seeking company documents regarding the company's discovery that it hadn't gotten FDA approval, as well as communications with regulators, physicians and stock analysts about the withdrawal. Investigators are also seeking any reports of injuries, the memorandum said.

Implantable cardioverter defibrillators, or ICDs, are implanted in patients' chests to deliver electronic shocks to hearts that are beating abnormally so they return to a normal rhythm.