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In a landmark guilty plea, a major health care corporation pled guilty toda San Francisco federal court to 10 felonies and agreed to pay $92.4 million settle criminal and civil charges that it covered up thousands of incidents i which a medical device used to treat aneurysms in the aorta malfunctionec Among the thousands of incidents covered up by the company were 12 de and dozens of invasive surgeries.

The guilty plea represents the largest amount ever paid by a defendant for failing to report malfunctions of a medical device to the Food & Drug Administration ("FDA"), and one of the first times there have been felony convictions for such conduct. It is also the second largest criminal and civ settlement in the history of the Northern District of California. The guilty plea and civil settlement was announced today at a press conference by the U.S. Attorney's Office for the Northern District of California, the U.S. Department of Justice's Office of Consumer Litigation and Civil Fraud Section, the FDA and the Federal Bureau of Investigation.

The defendant, Endovascular Technologies, Inc. ("EVT"), is a wholly owr subsidiary of Guidant Corporation ("Guidant"). The subsidiary is based ir Menlo Park, California. According to Guidant's website (www.guidant.cc the Menlo Park facility where the Ancure device was manufactured is alsc listed as one of Guidant's operating facilities. Guidant is a Fortune 500 company based in Indianapolis, Indiana. The criminal charges relate to a medical device known as the Ancure Endograft System ("Ancure Device" The Ancure Device treats abdominal aortic aneurysms, a potentially life

threatening condition commonly associated with people with heart disease The Ancure Device is inserted into the patient's body during a surgical procedure.

Under federal law, a company is required to report to FDA any incident in which its medical device may have caused or contributed to a death or seri injury or the medical device experienced a malfunction that would be likel cause or contribute to a death or serious injury if the malfunction were to recur. The reports to FDA are called Medical Device Reports. In this cas the company was aware of every malfunction because, as a condition of F approval, it had a sales representative present in the operating room during each surgery and the reports of those failures were repeatedly tabulated an distributed to company officials. In failing to file thousands of Medical Device Reports, the defendant concealed the true extent of problems with Ancure Device from patients, doctors and the public.

According to a Criminal Information which charges EVT with 10 felonies Ancure Device was approved for commercial distribution in the United St in September 1999. It was withdrawn from the market on March 15, 2001 During that 19-month span, the company filed a total of 172 Medical Devi Reports with FDA concerning the Ancure Device. In pleading guilty, the defendant admitted that there were an additional 2,628 Medical Device Reports that it had failed to file–each representing an incident in which the Ancure Device malfunctioned or its use was associated with death or seric injury–out of a total of 7,632 medical devices that were sold. Among the unreported incidents were 12 deaths and 57 emergency procedures in whic physician converted the operation into a more invasive procedure. Such a conversion could occur when the delivery system of the Ancure Device became stuck or lodged in the patient's body and could not be removed without opening the patient's stomach during a surgery and slicing open th aorta to remove the broken device and fix the aneurysm.

Company sales representatives attempted to avoid surgical conversions–w were reportable to FDA–by instructing doctors in a technique to free the delivery system of the Ancure Device when it became stuck in a patient's body. The technique had been devised in part by a company sales representative. It involved breaking the handle of the device and removing the catheters housed within the delivery system of the Ancure Device individually from the patient's body. During the relevant time, the handle breaking technique had not been tested; doctors had not been trained on its use; sales representatives who described the technique to doctors during surgery had not been trained by the company on its use; the instructions accompanying the product did not explain the procedure, and the defendar failed to seek prior approval of FDA. After a patient died in a case in whi the handle breaking technique was used, a group of defendant's employees concluded that FDA had to be informed about its use. The company failed do so, even as its sales representatives continued to describe the handle breaking technique to doctors during surgeries.

Guidant Corporation's EVT division pled guilty to a Criminal Information charging it with nine counts of introducing a misbranded medical device i interstate commerce, in violation of 21 U.S.C. §§ 331(a) and 333(a)(2). T Criminal Information was filed under seal on June 9, 2003. It was unseale this morning. The corporation then pled guilty and was sentenced before District Judge Susan Illston in San Francisco federal court.

In addition to the nine misbranding counts, the company also pled guilty t one count of making false statements to the FDA, in violation of 18 U.S.C 1001. That charge stems from an inspection conducted by FDA of the company's Menlo Park headquarters in July 2000. During the inspection, FDA official asked specifically for all complaints the company had receiv about one type of malfunction. The company intentionally misled the inspector by giving him a list of 55 complaints when, in fact, the company knew that there had been hundreds of complaints about this particular malfunction.

As part of the plea agreement and a civil settlement agreement, Guidant's EVT subsidiary will pay $92.4 million. In dollar terms, this is the second largest global criminal and civil settlement in the history of the Northern District of California.

Under the civil settlement, EVT will pay $49 million to settle claims that t company's actions caused Medicare, Medicaid and the Veterans Affairs Program to pay millions of dollars for the adulterated and misbranded devices. Both EVT and Guidant have agreed to enter into a corporate integrity agreement with the Office of Inspector General for the Departme of Health and Human Services. Also, as part of the plea agreement, Guida as well as EVT, have agreed to cooperate in the United States' continuing investigation into criminal activities associated with the Ancure product.

According to the charges, the government first became aware of the allegations of fraud and cover up in October 2000 when a group of seven anonymous employees wrote a letter to FDA. Later, an investigation authorized by the defendant which concluded that some of the complaints the Anonymous Seven were accurate, and that the company was significar out of compliance with FDA regulations and its own internal policies.

On March 23, 2001, Guidant's EVT division informed FDA that it had fail to file 2,623 MDRs and that the company had inappropriately provided information to doctors about the handle breaking technique. The Ancure Device was suspended from sale at that time. Later, FDA permitted the Ancure Device to be sold with modifications in its warnings to customers the instructions provided to physicians. It is still on the market. The allegations in the Criminal Information and Plea Agreement concern the delivery system of the Ancure Device only, and not the functioning of the Device in those cases where it was successfully implanted without incider

Assistant Attorney General Robert McCallum said, "FDA requirements regarding medical devices are not mere technicalities, but can literally be a matter of life and death for patients receiving these devices. As today's gu plea and civil settlement demonstrate, the Department of Justice will vigorously prosecute those who seek to evade FDA's requirements, as wel those who seek to profit by claiming payment from federal healthcare programs for potentially unsafe medical devices."

In announcing the guilty pleas, U.S. Attorney Kevin V. Ryan, a member o President Bush's Corporate Fraud Task Force said, "Guidant's EVT divisic violated the fundamental trust that exists between the medical device indu doctors, patients, and the public at large. Because of the company's condu thousands of patients underwent surgeries without knowing the risks they faced, and their doctors–through no fault of their own–were unprepared to deal with those risks. These actions were criminal, and I am happy to say today, for the first time in more than three years, the public will be able to learn the truth."

FBI Special Agent in Charge Mark Mershon said, "Much of the success o this investigation is attributable to seven Endovascular Techologies employees who were courageous in reporting their first-hand accounts of witnessing deceptive conduct. Today's plea agreement helps enurse that patients who are facing significant medical challenges know tha the federa government is policing health care, including the medical device industry.

FDA Commissioner Dr. Mark McClellan said, ""Medical device and drug firms have a serious responsibility to report deaths and injuries associated with their products to the FDA. Guidant's failure to do so and, worse, its attempt to cover it up, not only violated the law, but put additional patient undergoing these procedures at risk. We will not tolerate such threats to th public health."

The FDA also made the following announcement to patients who had received the device: "No patient implanted with Ancure is affected by this action, as the malfunctions in this Plea Agreement relate only to the delive system for the Ancure Device. Patient monitoring and follow-up in accordance with the instructions for use continues to be important in assur sustained exclusion of the patient's aneurysm.

The prosecution of the criminal case is the result of three-year investigatio by special agents of the FDA, Office of Criminal Investigations, and the F DOJ Trial Attorney Douglas Stearn and Assistant U.S. Attorney Matthew Jacobs are prosecuting the criminal case with the assistance of Elaine McCoy. The civil case was being handled by Assistant U.S. Attorney Sar Winslow and DOJ Trial Attorney Lani Remick.

A copy of this press release may be found on the U.S. Attorney's Office's website at www.usdoj.gov/usao/can. Related court documents and

information may be found on the District Court website at www.cand.uscourts.gov or on http://pacer.cand.uscourts/gov.

All press inquiries to the U.S. Attorney's Office should be directed to Assistant U.S. Attorney Matthew J. Jacobs at (415) 436-7181.