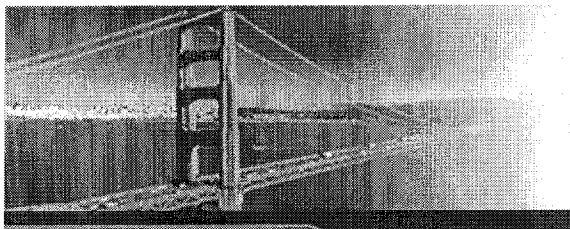

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In a landmark guilty plea, a major health care corporation pled guilty today in San Francisco federal court to 10 felonies and agreed to pay $92.4 million to settle criminal and civil charges that it covered up thousands of incidents in which a medical device used to treat aneurysms in the aorta malfunctioned. Among the thousands of incidents covered up by the company were 12 deaths 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 civil 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 owned subsidiary of Guidant Corporation ("Guidant"). The subsidiary is based in Menlo Park, California. According to Guidant's website (www.guidant.com), the Menlo Park facility where the Ancure device was manufactured is also 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 serious injury or the medical device experienced a malfunction that would be likely to 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 case, the company was aware of every malfunction because, as a condition of FDA approval, it had a sales representative present in the operating room during each surgery and the reports of those failures were repeatedly tabulated and distributed to company officials. In failing to file thousands of Medical Device Reports, the defendant concealed the true extent of problems with the Ancure Device from patients, doctors and the public.

According to a Criminal Information which charges EVT with 10 felonies, the Ancure Device was approved for commercial distribution in the United States 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 Device 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 serious 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 which a 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 the aorta to remove the broken device and fix the aneurysm.

Company sales representatives attempted to avoid surgical conversions-which 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 defendant failed to seek prior approval of FDA. After a patient died in a case in which 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 to 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 into interstate commerce, in violation of 21 U.S.C. §§ 331(a) and 333(a)(2). The Criminal Information was filed under seal on June 9, 2003. It was unsealed 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 to 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, the FDA official asked specifically for all complaints the company had received 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 the 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 Department of Health and Human Services. Also, as part of the plea agreement, Guidant, 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 by the Anonymous Seven were accurate, and that the company was significantly out of compliance with FDA regulations and its own internal policies.

On March 23, 2001, Guidant's EVT division informed FDA that it had failed 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 and 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 incident.

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 guilty plea and civil settlement demonstrate, the Department of Justice will vigorously prosecute those who seek to evade FDA's requirements, as well as 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 of President Bush's Corporate Fraud Task Force said, "Guidant's EVT division violated the fundamental trust that exists between the medical device industry, doctors, patients, and the public at large. Because of the company's conduct, 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 that 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 of 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 federal 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 patients undergoing these procedures at risk. We will not tolerate such threats to the 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 delivery system for the Ancure Device. Patient monitoring and follow-up in accordance with the instructions for use continues to be important in assuring sustained exclusion of the patient's aneurysm.

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