6/21/06

Pittsburgh VAMC
MCI#: 2006-01390-HI-0308
Alleged Implanted Defective Stent-Graft Devices

(b)(3):5 U.S.C. App 3 (IG Act),(b)(6)

Background: The complainant, [redacted] alleged that the facility has possibly received and might have been implanting defective aneurysm stents since September 1999. The maker of the stents, Guidant Corporation subsidiary Endovascular Technologies, admitted that the company failed to report as many as 2600 incidents of malfunctions of the device. According to the FDA, complications with the device led to internal bleeding, damaged arteries, and/or surgery to remove the device.

The complainant faxed a copy of a newspaper advertisement. The advertisement was placed by James Rolshouse & Associates, a personal injury law firm licensed in Minnesota and whose principle office is in Burnsville, Minnesota. The advertisement reads *"Aneurysm surgery at the University Drive VA Hospital Since September 1999?.....If you or a loved one suffered serious complications or died after aneurysm surgery, especially if you received a letter about the device from the VA administration or manufacturer you may be entitled to money damages....."*

Allegations: The complainant had sent a letter to the Director of the Pittsburgh VAMC. In his letter to the OIG he stated that he had not received a response from the medical center. He wrote "I feel that an official investigation should be done to make sure this does not happen again or in the future at any other VA hospital. It is also felt that an investigation should be done so that there is no chance of covering this up and keeping it within the VA hospital."

Findings: The Ancure Endograft System was approved by the FDA in September 1999. In March 2001, the company withdrew the device from the market. Guidant and Endovascular Technologies reintroduced the device in August 2001 with FDA-approved modifications in the device's warnings to customers and instructions to doctors. On June 16, 2003, Guidant announced that it would stop making the endograft system. According to the FDA *Consumer Magazine*, the problem was with the Ancure delivery system and not the implant itself. The FDA recommended that patients continue with routine monitoring and follow-up visits to a doctor.

Endovascular Technologies submitted 172 Medical Device Reports to the FDA from September 1999 to March 2001. The FDA first became aware of allegations of fraud and cover up in October 2000 after receiving an anonymous letter from seven employees. An investigation was conducted by the FDA's Office of Criminal Investigations and the FBI. In March 2001, the company admitted that it failed to submit 2628 additional Medical Device Reports out of a total of 7632 devices sold. Among the unreported incidents were 12 deaths and 57 emergency operations performed when the devices' delivery system became stuck in the patient's body. In June 2003, Endovascular Technologies pleaded guilty to nine counts of misbranding medical devices and one count of making false statements to the FDA. The company agreed to pay $92.4 million dollars to settle criminal and civil charges.

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Review of Capri does not indicate that the complainant has undergone surgery, primary or specialty care treatment, or lab work at the VAMC. The patient had 3 musculoskeletal system radiographic films done in 2001; otherwise no record of treatment at the VAMC appears in Capri.

The facility director was contacted and asked if any veterans at the Pittsburgh VAMC had received the Ancure device and if any complications had occurred. He forwarded a VHA issue brief dated November 4, 2005. The issue brief indicates that the device was utilized at the Pittsburgh VAMC from September 1999 until March 24, 2003, and was implanted in 31 patients. Prior to the manufacturer's decision in June 2003 to cease production of the device, surgeons at the VAMC electively began to use competitors' products for reasons unrelated to device performance.

On June 16, 2003, providers were notified in writing by Guidant that the corporation had decided to cease manufacturing the device beyond October 2003. The company cited fewer endoluminal repairs than projected, lower market share than expected, and problem's with the device's delivery system as reasons for product discontinuation. By June 2003, over 18,000 Ancure devices had been inserted worldwide. Reportedly the long term data related to the device has not been good and only the delivery system for initial insertion has been problematic.

The issue brief reports that no Pittsburgh VAMC patients had complications related to insertion of the Ancure Endograft System. It notes that no bleeding, arterial damoage or surgery to remove the device at the time of insertion occurred at the Pittsburgh VAMC. Of the 31 patients who received the implant, two subsequently developed endoleaks and required open operation, device removal and standard repair. Reportedly neither of these occurrences was related to the deployment mechanism and these patients have recovered from their surgeries without evidence of persisting sequellae. The issue brief indicates that endoleaks are a potential complication after all endovascular implantations or procedures. The medical center indicated that no complaints, patient incident reports, or tort claims have been identified.

At the time of Guidant's communication with providers in June 2003, a sample letter was provided by the company that could be used for patient education about the delivery system and the device. The medical center reported that after reviewing all of the cases at the Pittsburgh VAMC in which the device was implanted, it was determined that no deployment system failures had occurred and no patients were believed to have been impacted. Because none of the 31 veterans appeared to have been impacted and after discussion with VACO, the VAMC decided not to notify any of the patients.

Conclusion: The complainant did not receive an Ancure Endograft System at a VAMC. The complainant sent in an advertisement from the Pittsburgh Gazette by the legal firm of James Rolhouse and Associates. The The FBI and FDA investigated the manufacturer resulting in a guilty pleas and a settlement with the FDA. The FDA website indicates that it is not the devices that are defective but the delivery system that was used to implant the devices. The defect was reportedly related to complications associated with

the delivery system used in implanting the device. The VAMC reportedly implanted 31 of the stent-graft devices after they were approved by the FDA in September 1999 until March 2003. In June 2003, the manufacturer's parent company announced that it would stop making the device after October 2003. The VHA issues brief indicates that none of the 31 patients who received the Ancure Endograft System implant at the Pittsburgh VAMC experienced delivery system related complications at the time of deployment. Since the device is no longer available, the manufacturer has pled guilty in Federal Court, and patients who have the implant in place are reportedly not at risk. The hotline will be administratively closed.

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