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Lessons from Frankenstein: Don't Create a Whistleblower [Ober|Kaler]

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Given the publicity generated by large settlements paid to whistleblowers, many individuals are regularly on the prowl for a qui tam lawsuit that will yield a large bounty. These eager whistleblowers may be likely to pursue a qui tam suit under the False Claims Act (FCA) with little provocation. Other potential whistleblowers who are more hesitant to move forward with a qui tam suit may be encouraged to do so by health care providers who mishandle their concerns. Boston Scientific's recent $30 million settlement of a qui tam lawsuit illustrates for health care providers how the early mishandling of an internal investigation can mushroom into significant financial exposure under the FCA.

Boston Scientific's Guidant subsidiary manufactured an implantable cardioverter defibrillator (ICD), a class III medical device. In August 2002, a Guidant ICD was allegedly implanted in a patient in a Buffalo, New York hospital. Approximately three months after the ICD was implanted, it allegedly malfunctioned and the patient was hospitalized. A Guidant salesman visited the patient in the hospital to investigate the incident. Several months later the device allegedly malfunctioned again.

Those events led the patient to research the performance of ICDs manufactured by Guidant. The patient eventually concluded that his Guidant ICD was allegedly defective and scheduled surgery to have it removed and replaced with a different model. The night before the surgery, the surgeon cancelled the procedure, advising the patient it was not necessary and therefore would not be rescheduled. The Guidant salesman who had investigated the prior incident had allegedly intervened to convince the patient's surgeon and insurance company that the surgery was unnecessary because the patient's Guidant ICD was not defective. The patient ultimately found another surgeon to implant a replacement device. Thereafter, Guidant sent several letters to the patient that contained allegedly false statements regarding the Guidant ICD that had been implanted in the patient, design changes that were made to the ICD by Guidant, and FDA approval of such changes.

The patient contacted the FDA regarding his interactions with Guidant, and, ultimately, filed a qui tam lawsuit against Guidant and related entities, alleging that the Medicare program and the Veterans Administration had been overbilled for defective ICDs manufactured by Guidant. The lawsuit was reportedly settled for $30 million.

The Guidant case highlights several important lessons for health care providers:

- Everyone is a potential whistleblower who can file a qui tam lawsuit under the FCA, including current and former employees, customers, vendors, and competitors.
- Any whistleblower complaint, whether formal or informal, can eventually wind its way to the attention of the Justice Department and lead to a full-blown case under the FCA with extraordinary financial exposure for the provider.
- Mishandling a disgruntled person, including by retaliation, manipulation, deception, or concealment, may turn that person into a whistleblower.
- Once a whistleblower is created, a provider may easily lose control over the future course of events.
- Providers need systems in place that enable the early detection of issues that may impact the billing of federal and state health care programs.
- Providers need to investigate potential billing issues promptly, carefully and effectively to correct compliance concerns and avoid their recurrence.

- The effective handling of an internal investigation includes the appropriate management of potential whistleblowers.
- Mishandling an internal investigation may lead to whistleblower lawsuits and FCA liability.