Medical Devices Play a Large Role in Massachusetts Health Care Fraud Unit Cases: September 2008 – September 2009

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A retrospective review of the cases brought by the Massachusetts U.S. Attorney's Office Health Care Fraud Unit between September 2008 and September 2009 reveals a high number of cases involving medical devices as compared to drugs or other medical products. Medical devices include a wide range of products, such as implants, stents, heart pacemakers, fetal monitors, x-ray equipment, and thermometers. They are used in patients for the purposes of diagnosis, therapy or surgery. By definition, medical devices do not achieve their primary intended purposes through "chemical action" and are not "dependent upon being mobilized" to achieve their primary intended purposes. Medical devices often require approval by the Food & Drug Administration ("FDA") before they may be legally distributed and marketed.

The gamut of products that may be considered medical devices are reflected in the cases brought by the Health Care Fraud Unit over this past year.

Bioelectrical Impedance Analysis ("BIA") Software Cases

With the announcement of the sentencing of RJL Sciences, Inc. and its President, Rudolph J. Liedtke, on September 24, 2008, and the guilty plea and sentencing of Norma Muurahainen on October 30, 2008, the Health Care Fraud Unit in the District of Massachusetts appears to have concluded its prosecutions relating to the distribution of software used with Bioelectrical Impedance Analysis ("BIA") devices for the calculation of body cell mass and diagnosis of AIDS wasting. These cases stemmed from three types of computer software designed by RJL and Liedtke to convert the resistance and reactance measurements generated by a BIA device into estimates of body composition — specifically body cell mass — that could be used to verify whether an AIDS patient was "wasting" — a condition involving profound involuntary weight loss in AIDS patients. According to the government's charges, the three types of BIA software were "medical devices" covered by the Food, Drug & Cosmetic Act ("FDCA") and RJL and Liedtke failed to obtain the necessary FDA approvals before distributing the software. Furthermore, the government charged that the distribution of the devices increased the market for the drug Serostim, manufactured by the Serono Labs, Inc. and approved by the FDA to treat AIDS wasting.

In April 2005, RJL and Liedtke pled guilty to involvement in a federal conspiracy to introduce and deliver into commerce "adulterated medical devices," consisting of the three types of BIA computer software. Soon thereafter, in December 2005, Serono Labs pled guilty to involvement in the conspiracy and paid a total of $704 million to resolve criminal and civil charges against it.

Muurahainen was the medical director at Serono Labs from December 1997 to 2002. According to the government's charges, Muurahainen promoted the use of RJL's BIA devices and computer software to measure body cell mass for the purpose of diagnosing AIDS wasting and thereby encouraged physicians to write prescriptions for Serostim. On October 30, 2008, Muurahainen pled guilty to three misdemeanor counts of causing the introduction into interstate commerce of the "adulterated" RJL BIA computer software. She was sentenced to one year of probation and fined $150,000.

On September 24, 2008, RJL and Liedtke were sentenced. RJL was fined $5,000; Liedtke was sentenced to three years' probation and fined $10,000.

Cases Related to Stryker's Medical Devices Used in Healing Fractured or Broken Bones

Beginning in November 2008, the Health Care Fraud Unit initiated a series of cases related to three medical devices used in healing fractured or broken bones, all of which were manufactured and sold by Stryker, a Hopkinton corporation referred to as "XYZ Corp." in the government pleadings. The first device — an implant to promote growth in certain long bone non-unions — was approved by the FDA

pursuant to a Humanitarian Device Exemption ("HDE") for "use as an alternative to autograft in recalcitrant long bone nonunions where use of autograft is unfeasible and alternative treatments have failed." The second device — a putty to promote bone growth in certain spinal fusions — received a similar HDE approval by the FDA, for "use as an alternative to autograft in compromised patients requiring revision posterolateral (intertransverse) lumbar spinal fusion, for whom autologous bone and bone marrow harvest are not feasible or are not expected to promote fusion." The third device — "a bone void filler for surgically created osseous defects or osseous defects resulting from traumatic injury" — was approved for marketing by the FDA.

Pursuant to the HDE Exemption, Stryker could only ship the first two devices to a medical facility if the facility established a local institutional review board ("IRB") and the IRB approved the use of the device. According to the government's charges, Stryker gave its sales force the responsibility of obtaining IRB approvals and rewarded sales force employees with bonuses for obtaining a certain number of IRB approvals over a particular period of time.

On November 18, 2008, Darnell Martin, a former territory manager and regional manager of Stryker, pled guilty to one count of making a false statement and one count of misbranding a medical device as a result of sales practices relating to the three devices. The former count stemmed from Martin's alleged falsification of an IRB approval in order to falsely support the shipment of Stryker's first HDE device. The latter count stemmed from a scheme whereby Martin and others purportedly promoted the sales and use of the second and third devices together despite that this combined use was not approved by the FDA. According to the charges, Martin and others prepared "mixing instructions" setting forth how the two products should be combined. The government alleged that these documents constituted "labeling" of the two devices and that neither device was approved for combined use.

Thereafter, two other former territory managers, Justin Demming and Shane Doyle, pled guilty to misbranding a medical device as a result of the managers' involvement in the scheme to promote the sales and use of the latter two devices combined together. As with Martin, Demming and Doyle were purported to have prepared "mixing instructions" setting forth how the two products should be combined. Demming's guilty plea was on February 10, 2009 and Doyle's guilty plea was on April 14, 2009.

Each of the plea agreements provide for potential cooperation by Martin, Demming and Doyle. Accordingly, other cases may likely come relating to the three devices distributed by Stryker.

NeuroMetrix NC-stat System Case

On February 9, 2009, NeuroMetrix, Inc. announced that it had reached a resolution with the Health Care Fraud Unit and the Office of the Inspector General of the U.S. Department of Health and Human Services ("OIG") resulting from ongoing criminal and civil investigations into NeuroMetrix's sales and marketing practices with respect to a medical device known as the NC-stat System. The NC-stat System is a device that assists doctors in the diagnosis of neuropathies in peripheral nerves and the spine that may be associated with ailments such as carpal tunnel syndrome, leg pain and diabetes.

The criminal investigation stemmed from allegations that NeuroMetrix engaged in unlawful kickbacks through two referral programs. Under these programs, NeuroMetrix paid doctors in the form of free boxes of disposable biosensors to induce the doctors to recommend the NC-stat System to their colleagues for procedures that were reimbursed by Medicare. The government alleged that as a result of these payments, NeuroMetrix caused the submission of false and fraudulent claims to Medicare. NeuroMetrix resolved these allegations through a three-year Deferred Prosecution Agreement under which NeuroMetrix agreed to pay a criminal penalty of $1.2 million and abide by the terms of the agreement requiring, among other things, remedial measures and full cooperation for the term of the agreement.

The civil investigation stemmed from the kickback allegations, along with allegations that NeuroMetrix caused doctors to improperly bill studies conducted through the NC-stat System under a higher billing code than the billing code that actually reflected work performed by doctors using the System. Specifically, the government claimed that NeuroMetrix caused doctors to bill for nerve conduction studies as if an "F-wave" had been measured when no such measurement was actually obtained, causing the submission of inflated Medicare claims. NeuroMetrix resolved these allegations through a Settlement Agreement under which NeuroMetrix agreed to pay $2,498,337.

Finally, NeuroMetrix entered into a five year Corporate Integrity Agreement ("CIA") with the OIG under which it agreed to engage in specific training, increased compliance procedures and OIG monitoring of compliance with the CIA and enforcement of breaches with enumerated penalties.

We anticipate that the Health Care Fraud Unit will continue to bring increasing numbers of cases involving medical devices. This trend is reflective of the wide variety of medical devices in development that require FDA approval.

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