JUSTICE NEWS

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Minnesota-Based St. Jude Medical Pays U.S. $16 Million to Settle Claims that Company Paid Kickbacks to Physicians

WASHINGTON – St. Jude Medical Inc. of St. Paul, Minn., has agreed to pay the United States $16 million to resolve allegations that the company used post-market studies and a registry to pay kickbacks to induce physicians to implant the company's pacemakers and defibrillators, the Justice Department announced today.

Post-market studies are intended to assess the clinical performance of a medical device or drug after that device or drug has been approved by the Food and Drug Administration. Registries are collections of data maintained by a device manufacturer concerning its products that have been sold and implanted in patients.

The United States contends that St. Jude used three post-market studies and a device registry as vehicles to pay participating physicians kickbacks to induce them to implant St. Jude pacemakers and defibrillators. Although St. Jude collected data and information from participating physicians, it is alleged that the company knowingly and intentionally used the studies and registry as a means of increasing its device sales by paying certain physicians to select St. Jude pacemakers and I mplantable cardioverter defibrillator for their patients. In each case, St. Jude paid each participating physician a fee that ranged up to $2,000 per patient. The United States alleges that St. Jude solicited physicians for the studies in order to retain their business and/or convert their business from a competitor's product.

“When companies pay kickbacks to health care providers in order to pad their bottom line, it taints the information patients rely on to make informed choices about their health,” said Tony West, Assistant Attorney General for the Civil Division. “It is critical that physicians base their decisions on which medical device to implant on the best interest of the patient, not on whether a device manufacturer will pay an extra fee or honoraria for the implant.”

“Medical device and pharmaceutical companies can use post-market studies legitimately to obtain information about how their products work in the field, but they cannot use those studies, and the honoraria associated with them, to induce physicians to select their products. Cardiologists and electrophysiologists should make their decisions on which pacemaker or defibrillator to implant in a patient based on their independent medical judgment, not based on how much the manufacturer is paying them to implant the device,” said Carmen Ortiz, U.S. Attorney for the District of Massachusetts.

This action was initiated by the filing of a *qui tam* action under the False Claims Act (FCA) by a relator, Charles Donigian. The FCA permits a whistle blower to recover a share of the government recovery, and in this case Mr. Donigian will recover $2.64 million.

This resolution is part of the government's emphasis on combating health care fraud and another step for the Health Care Fraud Prevention and Enforcement Action Team initiative, which was announced by Attorney General Eric Holder and Kathleen Sebelius, Secretary of the Department of Health and Human Services in May 2009. The partnership between the two departments has focused efforts to reduce and prevent Medicare and Medicaid financial fraud through enhanced cooperation. One of the most powerful tools in that effort is the False Claims Act, which the Justice Department has used to recover more than $6.8 billion since January 2009 in cases involving fraud against federal health care programs.

The settlement was the result of an investigation by the Justice Department's Civil Division, the U.S. Attorney's Office for the District of Massachusetts, the Office of Inspector General at the U.S. Department of Health and Human Services and the FBI.

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