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JEFFREY NEWMAN LAW ANNOUNCES \$11.5 MILLION SETTLEMENT IN WHISTLEBLOWER FRAUD CASE AGAINST MEDICAL DEVICE DISTRIBUTOR ANGIODYNAMICS INC. FOR SELLING GELSPHERE DEVICE FOR UNAPPROVED CHEMOTHERAPY ELUTING PURPOSES

False Claims Lawsuit reveals sales of embolic device for uses other than those approved by the Food and Drug Administration.

BOSTON, MA. ***FOR IMMEDIATE RELEASE*** AngioDynamics, Inc., a medical device company based in Latham, New York, will pay \$11.5 Million to the Federal government and various states to settle a False Claims Act whistleblower lawsuit alleging that the company, the exclusive distributor for the medical device called Gelspheres, sold it as a drug eluting device when the FDA had cleared it only for embolization (blood blockage) of hypervascular tumors. The case stemmed from an action filed by Whistleblower Ryan Bliss pursuant to the provisions of The False Claims Act, on behalf of the federal and state governments. Mr. Bliss, of Massachusetts, was a Senior Product Manager responsible for marketing for BTG plc and its subsidiary Biocompatibles Inc., manufacturer of the Gelspheres. Mr. Bliss was represented by Jeffrey A. Newman Esq. of the Newman Law Offices of Boston and his able co-counsel Paul Lawrence of Virginia of the firm Waters & Kraus of Dallas, Texas. “Through the courage and persistence of Mr. Bliss, AngioDynamics and BTG’s marketing of the device involved 100% for use as a drug delivery device which was never approved by the FDA. AngioDynamics never shared with medical providers that the FDA had refused to approve LC Bead for drug delivery and distributed the device for that purpose anyway,” Mr. Newman said.

BTG and Biocompatibles, the bead makers, settled their portion of the case for \$36 million in November 2016. The allegations of the case included accusations that BTG’s subsidiary lied to the FDA and caused violations of the False Claims Act.

At the core of the medical device marketing fraud case is a product sold in the United States as LC Bead, which was cleared by the FDA for what is called “bland” embolization only, a use involving blocking the flow of blood to tumors. AngioDynamics pushed the LC Bead as a chemotherapy drug delivery device that physicians could use for treatment of patients with

various forms of cancer-a use the FDA never approved. AngioDynamics never shared with medical providers that the FDA had refused to approve LC Bead for drug delivery and distributed the device for that purpose anyway. Medicare and other federal health care programs do not cover devices for that purpose that are not approved or cleared by the FDA.

In the [settlement agreement](#), the government contends that AngioDynamics submitted or caused to be submitted claims for payment to the Medicare Program. Notwithstanding AngioDynamics' knowledge of the limited clearance indications for the LC Bead, AngioDynamics marketed and distributed LC Bead to be used as a drug delivery device in combination with chemotherapeutic agents, specifically in a medical procedure known as drug-eluting bead transarterial chemoembolization or "DEB-TACE." The settlement agreement also states that AngioDynamics was aware that many insurers declined to provide coverage for DEB-TACE due in part to the lack of FDA approval for LC Bead as a drug delivery combination product. Nonetheless, AngioDynamics used materials that instructed providers to submit claims for DEB-TACE procedures by using inaccurate billing codes intended for bland embolization procedures. For the United States, the case was overseen by Colin M. Huntley, Assistant Director of the Civil Division of the Department of Justice in Washington D.C..

Mr. Bliss was represented by Mr. Newman and Rea Kasemi of the Newman Law Offices.

About Mr. Newman

Jeffrey A. Newman Esq. and his firm represent whistleblowers throughout the United States from his primary office in Boston, Massachusetts. He handles a variety of different kinds of whistleblower actions including Medicare fraud cases, Customs fraud cases, Ambulance fraudulent billing cases, Tax evasion cases, and Financial fraud cases under the Securities and Exchange Commission whistleblower program. In 2016, he settled a case against RehabCare/Kindred in the amount of \$125 million for fraudulent billing by skilled nursing facilities and has since settled numerous cases including the BTG and AngioDynamics matters.

Contact Jeffrey Newman at 1-800-682-7157 to learn more about his whistleblower practice and the cases he handles. For more information, please also visit his website at www.jeffreynewmanlaw.com