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JEFFREY NEWMAN LAW ANNOUNCES WHISTLEBLOWER CASE AGAINST BRITISH MEDICAL DEVICE COMPANY BIOCOMPATIBLES AND BTG PLC IN $36 MILLION CIVIL & CRIMINAL SETTLEMENT WITH U.S. DEPARTMENT OF JUSTICE

False Claims Act lawsuit revealed BTG subsidiary Biocompatibles fraudulently marketed its LC Bead device for a use that had been denied approval by the FDA

BOSTON, MA – November 7, 2016

British medical device maker BTG PLC and its subsidiary, Biocompatibles, Inc., have agreed to pay $36 million to the U.S. Government to resolve federal and state False Claims Act allegations resulting from the off-label promotion of LC Bead, a medical device approved for use only for embolization of hypervascular tumors. $25 million of the settlement is to resolve the civil qui tam action, which alleged fraud, and $11 million of the settlement is a criminal fine against Biocompatibles.

The whistleblower, Ryan Bliss, is represented by Jeffrey A. Newman, Esq., of Jeffrey Newman Law, and co-counsel Paul Lawrence II of Waters & Kraus of Dallas. In the complaint, Mr. Bliss, who oversaw the marketing of Biocompatibles' medical products in North America, revealed detailed allegations that Biocompatibles lied to the Food and Drug Administration (FDA) about a drug delivery device called LC Bead and sold it for millions of dollars in the U.S. without clearance.

The suit alleged that Biocompatibles violated marketing regulations in its promotion activities to U.S. doctors by pushing 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 had never approved. LC Bead was only cleared by the FDA for so-called "bland" embolization of blood vessels (i.e. blocking of blood supply) for the treatment of hypervascular tumors. The unapproved use of LC Bead as a drug delivery device (wherein the beads are loaded with a chemotherapy drug) caused health care providers across the country to submit false claims for payment to Medicare, Medicaid and other federal health care programs, the government alleged.

In 2009, Biocompatibles, which has its headquarters in Britain, filed with the FDA for Premarket Approval (PMA) of LC Bead to deliver chemotherapy drugs in humans. The FDA denied approval, stating there was not enough evidence demonstrating sufficient survival benefit to patients. Despite this, the company continued to sell the

LC Bead in the United States for use as a drug delivery device and continues to do so. While Biocompatibles pleaded guilty to criminal charges that the company violated a law that prohibits the introduction of misbranded medical devices into interstate commerce, none of the management was prosecuted for any criminal wrongdoing.

“What’s remarkable about this case is that Biocompatibles had obtained clearance from the FDA for one use, when LC Bead was specifically designed and exclusively marketed to U.S. doctors for a completely different use that the FDA had refused to approve. The company went on to instruct providers to submit claims using the code established for approved procedures knowing that insurers would have denied coverage otherwise,” said attorney Newman.

LC Bead continues to be sold as drug eluting beads throughout the United States, and the same product is sold outside the United States but is marketed under the name DC Bead. The federal government and various states will receive a portion of the funds to settle allegations of fraudulent billing to state Medicaid programs.

Mr. Bliss was awarded a portion of the funds collected by the government in this case pursuant to the False Claims Act, which allows private citizens to file actions on behalf of the government revealing fraudulent billing to government agencies.

About Jeffrey Newman Law
Jeffrey Newman Law is a law firm dedicated to representing whistleblowers nationwide in False Claims Act (or “qui tam”) litigation involving fraud against the government. Founded by Jeffrey A. Newman, Esq, the firm has a consistent track record of winning landmark, multi-million dollar settlements in cases involving Medicare and Medicaid, as well as in SEC and IRS whistleblower actions. In 2016 alone, the firm settled three cases amounting to over $165 million. For more information, please visit www.jeffreynewmanlaw.com or contact Jeffrey Newman Law via phone at 1-800-682-7157.

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JEFFREY NEWMAN LAW ANNOUNCES $11.5 MILLION SETTLEMENT IN WHISTLEBLOWER FRAUD CASE AGAINST MEDICAL DEVICE DISTRIBUTOR ANGIODYNAMICS FOR SELLING GELSPHERE DEVICE FOR UNAPPROVED CHEMOTHERAPY-ELUTING PURPOSE

False Claims Act lawsuit revealed sales of embolic device for use other than that approved by the Food and Drug Administration

BOSTON, MA – July 18, 2018

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 United States distributor for the medical device called Gelspheres (or LC Bead), 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 qui tam 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 Gelspheres. Mr. Bliss was represented by Jeffrey A. Newman of Boston and his able co-counsel Paul Lawrence of the firm Waters & Kraus in Dallas, Texas.

“Through the courage and persistence of Mr. Bliss, his lawsuit revealed that AngioDynamics’ and BTG’s marketing of the device was 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, but 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 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 uses that are not approved or cleared by the FDA.

In the settlement agreement, the government contends that AngioDynamics submitted or caused to be submitted false claims for payment to the Medicare program. Notwithstanding AngioDynamics' knowledge of the limited clearance indication for 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 Jeffrey Newman Law. Mr. Newman and his firm represent whistleblowers throughout the United States from his primary office in Boston, Massachusetts. He handles a variety of types 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 causing 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.