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**JeffreyNewmanLaw 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 uses that had been denied approval by the FDA*

BOSTON, MA, - 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 (FCA) 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 marketing of Biocompatibles' medical products in North America, revealed detailed information alleging that Biocompatibles lied to the Federal 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, 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 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 of Government agencies.

#### **About Jeffrey Newman Law**

Jeffrey Newman Law is a law firm dedicated to representing whistleblowers nation wide 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, Medicaid, Pharmaceutical and healthcare fraud as well as other 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](http://www.jeffreynewmanlaw.com) or contact Jeffrey Newman Law via phone at 1-800-682-7157.