JUSTICE NEWS

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE Monday, November 7, 2016

Medical Device Maker Biocompatibles Pleads Guilty to Misbranding and Agrees to Pay $36 Million to Resolve Criminal Liability and False Claims Act Allegations

Pennsylvania-based medical device manufacturer Biocompatibles Inc., a subsidiary of BTG plc, pleaded guilty today to misbranding its embolic device LC Bead and will pay more than $36 million to resolve criminal and civil liability arising out of its illegal conduct, the Justice Department announced today. LC Bead is used to treat liver cancer, among other diseases.

Under the terms of the plea agreement before the U.S. District Court for the District of Columbia, Biocompatibles pleaded guilty to a misdemeanor charge in connection with the company's misbranding of LC Bead, in violation of the Food, Drug and Cosmetic Act. LC Bead was cleared by the U.S. Food and Drug Administration (FDA) as an embolization device that can be placed in blood vessels to block or reduce blood flow to certain types of tumors and arteriovenous malformations. LC Bead has never been cleared or approved by FDA as a drug-device combination product or for use as a drug-delivery device or "drug-eluting" bead.

As part of the criminal resolution, Biocompatibles will pay an $8.75 million criminal fine for the misbranding of LC Bead and a criminal forfeiture of $2.25 million. The FDA sought assurances in 2004 that Biocompatibles would not use FDA clearance for the device for embolization to market the device for drug delivery, according to a statement of offense to which the company agreed. Biocompatibles told the FDA that "under no circumstance" would the company use the embolization clearance to market the device for drug delivery. However, two years later, Biocompatibles began marketing LC Bead for drug delivery through the company it hired to carry out its sales and distribution in the United States. According to the statement of offense, the distribution company told its sales representatives that LC Bead was "[a] drug-delivery device" and trained its sales representatives to "aggressively penetrate the chemoembolization market." Sales representatives subsequently told health care providers that the device increased the level of chemotherapy delivered to a liver tumor and resulted in "better tumor response rates," despite the lack of FDA clearance or approval for that use and despite the absence at that time of statistically significant evidence to support such claims.

"The FDA approval process serves an important role in ensuring that federal health care participants receive devices that are safe, effective and medically appropriate," said Principal Deputy Assistant Attorney General Benjamin C. Mizer, head of the Justice Department's Civil Division. "We will not permit companies to circumvent that process and put profits over patient safety."

"This company is being held criminally and civilly responsible for misbranding a medical device and marketing it for the treatment of seriously ill cancer patients," said U.S. Attorney Channing D. Phillips for the

District of Columbia. “Working with the FDA and other law enforcement partners, we are committed to holding companies accountable for violating the integrity of the FDA approval process.”

In addition, Biocompatibles will pay $25 million to resolve civil allegations under the False Claims Act that the company caused false claims to be submitted to government healthcare programs for procedures in which LC Bead was loaded with chemotherapy drugs and used as a drug-delivery device. When LC Bead was combined with prescription drugs for use as a drug-eluting bead, it constituted a new combination drug-device product that was not approved or cleared by the FDA and not covered by Medicare and other federal health care programs. The federal share of the civil settlement is approximately $23.6 million, and the state Medicaid share of the civil settlement is approximately $1.4 million.

As part of the civil settlement, the government alleged that when LC Bead entered the U.S. market in 2005, Biocompatibles intended for LC Bead to be used as a drug-delivery device in combination with chemotherapy drugs, despite the lack of FDA approval as a drug-device combination product. In December 2009, Biocompatibles filed an application with FDA for approval of LC Bead as a drug-eluting bead combination product. However, FDA informed the company that it was not accepting the application because clinical studies did not provide adequate evidence of a therapeutic benefit. Nonetheless, Biocompatibles’ distributor routinely advised healthcare providers that LC Bead provided “better” or “superior” therapy for certain types of cancer when, in fact, there was insufficient clinical evidence to support these claims.

“The FDA plays a fundamental role in ensuring the safety and efficacy of medical devices and drugs in this country,” said U.S. Attorney Richard L. Durbin Jr. of the Western District of Texas. “The FDA approval process and clinical studies serve to ensure that patients receive devices that meet those standards. We will vigorously pursue those who ignore or seek to circumvent these important patient protections.”

“U.S. consumers rely on the FDA to ensure that there is a reasonable assurance of safety and effectiveness for the approved uses of medical devices,” said Director George M. Karavetsos of FDA Office of Criminal Investigations. “When manufacturers ignore FDA’s regulatory authority, they undermine these important assurances.”

The civil settlement with Biocompatibles resolves a lawsuit filed under the whistleblower provision of the False Claims Act, which permits private parties to file suit on behalf of the United States for false claims and share in a portion of the government’s recovery. The civil lawsuit was filed in the Western District of Texas and is captioned *United States ex rel. Ryan Bliss v. Biocompatibles, Inc., et al.* As part of today’s resolution, Bliss will receive approximately $5.1 million from the civil settlement.

This settlement illustrates the government’s emphasis on combating health care fraud and marks another achievement for the Health Care Fraud Prevention and Enforcement Action Team (HEAT) initiative, which was announced in May 2009 by the Attorney General and the Secretary of Health and Human Services. 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 this effort is the False Claims Act. Since January 2009, the Justice Department has recovered a total of more than $31.6 billion through False Claims Act cases, with more than $19.2 billion of that amount recovered in cases involving fraud against federal health care programs.

The settlement with Biocompatibles was the result of a coordinated effort among the U.S. Attorney’s Offices for the District of Columbia and the Western District of Texas, and the Civil Division’s Consumer Protection Branch and Commercial Litigation Branch, with assistance from the FDA’s Office of Chief Counsel, HHS’ Office of Counsel to the Inspector General and the Department of Defense’s Defense Criminal Investigative Service. The criminal investigation was conducted by the FDA’s Office of Criminal Investigations.

Except for the conduct admitted in connection with the criminal plea, the claims resolved by the civil settlement are allegations only, and there has been no determination of liability.

For more information about the Consumer Protection Branch and its enforcement efforts, visit its website at http://www.justice.gov/civil/consumer-protection-branch. For more information on the Commercial Litigation Branch's Fraud Section, visit https://www.justice.gov/civil/fraud-section.

16-1301

Civil Division

Topic:
Consumer Protection

Download Compliance Program and Certifications
Download Information
Download Plea Agreement
Download Statement of Offense

Updated November 7, 2016