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District of Maryland

FOR IMMEDIATE RELEASE

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**Allergan To Pay \$3.5 Million To Settle False Claims Act
Allegations Relating To LAP-BAND Bariatric Medical
Device**

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CONTACT ELIZABETH MORSE

www.justice.gov/usao/md

(410) 209-4885

Baltimore, Maryland – New Jersey-based Allergan Inc. has agreed to pay \$3.5 million to resolve allegations that Allergan caused health care providers to submit false claims to Medicare and other federal healthcare programs relating to the LAP-BAND Adjustable Gastric Banding System, a device approved by the U.S. Food and Drug Administration for weight reduction for adult patients with obesity who have failed more conservative weight-reduction alternatives.

The settlement agreement was announced today by United States Attorney for the District of Maryland Robert K. Hur; Maureen Dixon, Special Agent in Charge for the Office of Inspector General for the Department of Health and Human Services; and Robert E. Craig Jr., Special Agent in Charge for the Defense Criminal Investigative Service, Mid-Atlantic Field Office.

“Patients have every right to expect that medical devices used during surgery are free of defects. Patients also have the right to expect that procedures involving medical devices have been subject to the rigorous review and approval process of the Food and Drug Administration. When marketing and selling medical devices that may have defects or may be used in unapproved procedures, patients can be put at risk,” said Robert K. Hur, United States Attorney for the District of Maryland.

Allergan distributed, marketed, and sold the LAP-BAND, an inflatable silicone band that is placed around a patient's stomach during a surgical procedure. Adding or removing saline fluid through a subcutaneous access port adjusts the LAP-BAND, which in turn constricts or expands the size of the stomach pouch.

The United States alleged that between January 2008 and November 2010, Allergan knowingly sold LAP-BANDs with defective or flawed access ports. To conceal the defect or flaw and to induce health care professionals to continue using the LAP-BAND, Allergan misrepresented facts concerning the cause of access port leaks to the public, health care professionals, and the FDA; failed to collect or maintain required data and complaint files; and offered and provided remuneration to health care professionals who reported access port leaks. Additionally, the United States alleged that between 2008 and 2012, Allergan knowingly advertised, marketed, and distributed the LAP-BAND for use in two procedures that were not approved by the Food and Drug Administration. Some of these procedures were not reasonable and necessary for the diagnosis or treatment of an illness or injury. To market and to induce health care professionals to use the LAP-BAND for these uses, Allergan provided remuneration to health care professionals in connection with proctoring, workshops, advisory boards, and training events in which these two uses were discussed and/or demonstrated.

The civil settlement 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 obtain a portion of the government's recovery. The civil lawsuit was filed in the District of Maryland and is captioned United States ex rel. Schwartz and Tinsley v. Allergan, CCB-10-2796. As part of today's resolution, Dr. Schwartz and Mr. Tinsley will receive approximately \$594,064 from the settlement.

The Federal share of the civil settlement is \$3,300,360 and the state Medicaid share of the civil settlement is \$199,640. The claims resolved by this settlement are allegations only, and there has been no determination of liability.

U.S. Attorney Robert K. Hur commended the HHS Office of Inspector General, Office of Personnel Management OIG, and the Department of Defense's Criminal Investigative Services for their work in the investigation. Assistance also was provided by the National Association of Medicaid Fraud Control Units and offices of various state Attorneys General. The case was handled by Assistant United States Attorney Roann Nichols and Assistant Director Edward Crooke of the Department of Justice Civil Fraud Section.

Component(s):

USAO - Maryland

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