

JUSTICE NEWS

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE

Tuesday, March 1, 2016

Medical Equipment Company Will Pay \$646 Million for Making Illegal Payments to Doctors and Hospitals in United States and Latin America

Olympus Corp. of the Americas, Nation's Largest Distributor of Endoscopes, Also Agrees to Reforms and Subsidiary Admits to Foreign Bribery

The United States' largest distributor of endoscopes and related equipment will pay \$623.2 million to resolve criminal charges and civil claims relating to a scheme to pay kickbacks to doctors and hospitals, U.S. Attorney Paul J. Fishman of the District of New Jersey and Principal Deputy Assistant Attorney General Benjamin C. Mizer of the Justice Department's Civil Division announced today. U.S. Attorney Fishman and Principal Deputy Assistant Attorney General David Bitkower of the Justice Department's Criminal Division also announced that a subsidiary of the distributor will pay \$22.8 million to resolve criminal charges relating to the Foreign Corrupt Practices Act (FCPA) in Latin America.

Anti-Kickback Statute Violations

Olympus Corp. of the Americas (OCA) was charged in a criminal complaint filed today in Newark, New Jersey, federal court with conspiracy to violate the Anti-Kickback Statute (AKS), which prohibits payments to induce purchases paid for by federal health care programs. OCA has entered into a three-year deferred prosecution agreement (DPA) that will allow it to avoid conviction if it complies with the reform and compliance requirements outlined in the agreement.

"For years, Olympus Corporation of the Americas and Olympus Latin America dropped the compliance ball and failed to have in place policies and practices that would have prevented the substantial kickbacks and bribes they paid," said U.S. Attorney Fishman. "It is appropriate that they be punished for that. At the same time, the deferred prosecution agreement takes into account the companies' cooperation and commitment to fully functional corporate compliance."

As a result of the conduct outlined in the government's criminal complaint and DPA, OCA has agreed to pay a \$312.4 million criminal penalty and an additional \$310.8 million to settle civil claims under the federal and various state False Claims Acts, the largest total amount paid in U.S. history for violations involving the AKS by a medical device company.

"The Department of Justice has longstanding concerns about improper financial relationships between medical device manufacturers and the health care providers who prescribe or use their products," said Principal Deputy Assistant Attorney General Mizer. "Such relationships can improperly influence a provider's judgment about a patient's health care needs, result in the use of inferior or overpriced equipment, and drive up health care costs for everybody. In addition to yielding a substantial recovery for taxpayers, this settlement should send a clear message that we will not tolerate these types of abusive arrangements, and the pernicious effects they can have on our health care system."

In a separate DPA, Olympus Latin America Inc. (OLA), a subsidiary of OCA, will pay a \$22.8 million criminal penalty for violations of the FCPA.

The criminal complaint against OCA, which OCA agrees is true, charges that OCA won new business and rewarded sales by giving doctors and hospitals kickbacks, including consulting payments, foreign travel, lavish meals, millions of dollars in grants and free endoscopes. For example:

- OCA gave a hospital a \$5,000 grant to facilitate a \$750,000 sale;
- OCA held up a \$50,000 research grant until a second hospital signed a deal to purchase Olympus equipment;
- OCA paid for a trip for three doctors to travel to Japan in 2007 as a quid pro quo for their hospital's decision to switch from a competitor to Olympus; and
- a doctor with a major role in a New York medical center's buying decisions received free use of \$400,000 in equipment for his private practice.

These and other kickbacks helped OCA obtain more than \$600 million in sales and realize gross profits of more than \$230 million.

The criminal complaint alleges that the improper payments happened while Olympus lacked training and compliance programs. Unlike other medical and surgical products companies, Olympus did not create the position of compliance officer until 2009 and did not hire an experienced compliance professional until August 2010.

The DPA requires OCA to adopt several compliance measures to remedy its problems:

- OCA must enhance its compliance training and maintain an effective compliance program;
- OCA must maintain a confidential hotline and website for OCA employees and customers to report wrongdoing;
- OCA's chief executive officer and board of directors must certify annually that the program is effective; and
- OCA must adopt an executive financial recoupment program requiring executives who engage in misconduct or fail to promote compliance to forfeit up to three years of performance pay.

Larry Mackey, a former federal prosecutor best known for trying the Oklahoma City bombing cases, has been selected as an independent monitor to evaluate and oversee Olympus' compliance with the DPA. He was selected by U.S. Attorney Fishman under department guidelines and approved by the Deputy Attorney General. The DPA and monitor will remain in place for three years and can be extended for another two years if Olympus violates the DPA.

In the civil settlement, Olympus agrees to pay \$310.8 million to the federal government and the states to resolve claims that Olympus's payment of kickbacks caused false claims to be submitted to federal health care programs Medicare, Medicaid and TRICARE, and thus violated not only the AKS but also the federal and various state False Claims Acts. The federal share of the civil settlement is \$267,288,323, and Olympus will pay \$43,512,053 million to participating states that contributed to the falsely claimed Medicaid payments at issue.

The civil settlement resolves a lawsuit filed by John Slowik, the former chief compliance officer of OCA, in the District of New Jersey, under the federal and various state False Claims Acts. The acts permit whistleblowers to file suit for false claims against the government entities and to share in any recovery. Mr. Slowik will

receive \$44,102,573 million from the federal share and \$7 million from the state share of the civil settlement amount.

FCPA Violations

In a separate criminal complaint filed today in Newark federal court, OCA's Miami-based subsidiary OLA was charged with FCPA violations in connection with improper payments to health officials in Central and South America, and OLA entered into a separate three-year DPA. According to court documents, from 2006 until August 2011, OLA implemented a plan to increase medical equipment sales in Central and South America by providing payments to health care practitioners at government-owned health care facilities. These payments included cash, money transfers, personal grants, personal travel and free or heavily discounted equipment. The primary method to deliver these illicit benefits was through "training centers," nominally set up to educate and train doctors, but which OLA used to provide benefits to pre-selected practitioners. OLA and its conspirators paid nearly \$3 million to practitioners to induce the purchase of Olympus products and recognized more than \$7.5 million in profits as a result.

"Olympus Latin America admitted to bribing publicly employed health care providers and hospital officials across Central and South America so that it could illegally win business and sell its products," said Principal Deputy Assistant Attorney General Bitkower. "OLA's illegal tactics in Central and South America mirrored Olympus's conduct in the United States. The FCPA resolution announced today demonstrates the department's commitment to ensuring the integrity of the health-care equipment market, regardless whether the illegal bribes occur in the U.S. or abroad."

OLA entered into the DPA with the Criminal Division's Fraud Section and the U.S. Attorney's Office of the District of New Jersey. The agreement requires OLA to pay a criminal penalty of \$22.8 million, retain the same compliance monitor as for OLA (Mr. Mackey) for a period of three years and implement a number of compliance measures. The department reached this resolution based on a number of factors, including that OLA did not voluntarily disclose the misconduct in a timely manner, but OLA did receive credit of a 20 percent reduction on its penalty for its cooperation, including its extensive internal investigation, translation of numerous foreign language documents and collecting, analyzing and organizing voluminous evidence.

Corporate Integrity Agreement

In addition to the criminal and civil resolutions, Olympus executed a corporate integrity agreement (CIA) with the Department of Health and Human Services-Office of Inspector General (HHS-OIG). The CIA details the compliance program OCA must maintain, which must include:

- compliance responsibilities for OCA management and the board of directors;
- a health care compliance code of conduct that includes certain standards;
- training and education that includes specified standards;
- requirements for consulting arrangements, grants and charitable contributions, management of field assets and review of travel expenses;
- risk assessment and mitigation process; and
- review procedures for testing the compliance program.

"Olympus Corp. of the Americas' and its subsidiaries' greed-fueled kickback scheme threatened the impartiality of medical decision-making and the financial integrity of Medicare and Medicaid," said Special Agent in Charge Scott J. Lampert of the U.S. Department of Health and Human Services, Office of Inspector General (HHS-OIG). "Working with our law enforcement partners, we remain vigilant and committed to

protecting beneficiaries and taxpayers from those seeking to unlawfully enrich themselves.”

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The U.S. Attorney’s Office of the District of New Jersey prosecuted the criminal case under the AKS against Olympus and, with the Civil Division’s Commercial Litigation Branch, reached the civil settlement. The U.S. Attorney’s Office of the District of New Jersey and the Criminal Division’s Fraud Section prosecuted the criminal case under the FCPA against OLA. The HHS Office of Counsel to the Inspector General, the FBI, HHS-OIG Office of Criminal Investigations and the National Association of Medicaid Fraud Control Units provided assistance.

The FBI’s Newark Field Office, HHS-OIG and the FBI Allentown, Pennsylvania, Field Office investigated the case.

Assistant U.S. Attorneys R. David Walk Jr. and Deborah J. Gannett of the District of New Jersey’s Health Care and Government Fraud Unit in Newark represented the government in the AKS criminal prosecution. Assistant U.S. Attorney David E. Dauenheimer of the District of New Jersey and Senior Trial Counsel David T. Cohen of the Civil Division’s Commercial Litigation Branch represented the government in the prosecution of the civil case. Mary Riordan and Nicole Caucci of the HHS-OIG negotiated the CIA.

Fraud Section Trial Attorney James P. McDonald and Assistant U.S. Attorneys Walk and Gannett prosecuted the FCPA case. The Criminal Division’s Office of International Affairs provided significant assistance in this matter.

U.S. Attorney Fishman reorganized the health care fraud practice at the U.S. Attorney’s Office of the District of New Jersey, including creating a stand-alone Health Care and Government Fraud Unit, which handles both criminal and civil investigations and prosecutions of health care fraud offenses. Since 2010, the office has recovered more than \$1.29 billion in health care fraud and government fraud settlements, judgments, fines, restitution and forfeiture under the False Claims Act, the Food, Drug and Cosmetic Act and other statutes.

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 \$27.4 billion through False Claims Act cases, with more than \$17.4 billion of that amount recovered in cases involving fraud against federal health care programs.

16-234

Civil Division

Criminal Division

Topic:

Healthcare Fraud

Updated March 1, 2016