



## **Justice Department Announces Largest Settlement Ever For Violations Of The Anti-Kickback Statute By A Medical Device Company**

Sara M. Lord

On March 1, 2016, the United States Department of Justice (DOJ) announced that Olympus Corp. of the Americas (OCA), the nation's largest distributor of endoscopes and related equipment, had agreed to pay \$623.2 million to resolve criminal charges and civil claims relating to a scheme to pay kickbacks to doctors and hospitals. A subsidiary of the company, Olympus Latin America, Inc. (OLA), will pay another \$22.8 million to resolve criminal charges relating to the Foreign Corrupt Practices Act (FCPA) in Latin America. The settlement, which has been billed as the largest total amount paid in U.S. history for violations involving the AKS by a medical device company, includes several components.

A criminal complaint charging OCA with conspiracy to violate the Anti-Kickback Statute (AKS) was filed in New Jersey, with OCA entering into a three-year deferred prosecution agreement (DPA) under which the charge will be dismissed if it satisfies the requirements in the agreement.. The criminal complaint charges that OCA provided doctors and hospitals with such kickbacks as consulting payments, foreign travel, lavish meals, millions of dollars in grants and free endoscopes, which helped OCA obtain more than \$600 million in sales with gross profits of more than \$230 million. Based on this conduct alleged in the criminal complaint, OCA will pay \$312.4 million in criminal penalties.

Because, according to the criminal complaint, the illegal kickbacks were paid as OCA lacked training and compliance programs, the DPA also requires OCA to adopt several compliance measures, including enhancing its compliance training, maintaining a confidential hotline and website, requiring the CEO and Board of Directors to certify annually that the compliance program is effective, and adopting an executive financial recoupment program whereby executives who engaged in misconduct or failed to promote compliance must forfeit up to three years of performance pay.

Under the civil settlement, which resolves a whistleblower lawsuit filed by the former chief compliance officer, OCA agreed to pay \$310.8 million to the federal government and the states to resolve claims that the payment of kickbacks caused false claims to be submitted to Medicare, Medicaid and TRICARE, in violation of the federal and various state False Claims Acts. The qui tam relator will receive \$44,102,573 million from the federal share and \$7 million from the state share of the civil settlement amount.

In a separate criminal complaint that was also filed in New Jersey, OLA was charged with violating the FCPA in connection with improper payments to health officials in Central and South America, and also entered into a separate three-year DPA. According to court documents, from 2006 until August 2011, OLA increased its medical equipment sales in Central and South America by providing payments, including cash, money transfers, personal grants, personal travel and free or heavily discounted equipment, to health care practitioners at government-owned health care facilities. The DPA requires OLA to pay a criminal penalty of \$22.8 million, retain the same compliance monitor as for OLA, and implement a number of compliance measures.

In addition to these criminal and civil resolutions, OCA executed a corporate integrity agreement (CIA) with the Department of Health and Human Services-Office of Inspector General (HHS-OIG).

## Authors and Contributors

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**Sara M. Lord**

Partner, DC Office  
202.677.4054  
sara.lord@agg.com

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**Atlanta Office**

171 17th Street, NW  
Suite 2100  
Atlanta, GA 30363

**Washington, DC Office**

1775 Pennsylvania Avenue, NW  
Suite 1000  
Washington, DC 20006

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