

**Government of the District of Columbia
OFFICE OF THE INSPECTOR GENERAL**



Inspector General
July 16, 2014

**Astellas Pharma US Inc. Pays \$7.3 Million to Resolve False Claims Act Allegations
Relating to Marketing of Drug Mycamine**

Interim Inspector General Blanche L. Bruce announced today that the District of Columbia has joined the states and the federal government to settle allegations that Astellas Pharma US Inc. (Astellas) caused false claims to be submitted to federal and state health care programs in connection with its marketing and promotion of the drug Mycamine for pediatric use. Astellas Pharma US Inc., located in Northbrook, Ill., manufactures and sells pharmaceutical drugs, including Mycamine.

The settlement resolves allegations that, between 2005 and 2010, Astellas knowingly marketed and promoted the sale of Mycamine for pediatric use, which was not a medically accepted indication and, therefore, not covered by federal health care programs. Mycamine is a sterile, lyophilized antifungal agent. During this time period, the FDA approved Mycamine to treat adult patients suffering from serious and invasive infections caused by the fungus *Candida*, including infections in the esophagus, the blood, and the abdomen, and to prevent *Candida* infections in adults undergoing stem cell transplants. From 2005 through June 2013, however, Mycamine was not approved to treat pediatric patients for any use.

The allegations resolved by this settlement were originally raised in a lawsuit filed against Astellas in the United States District Court for the Eastern District of Pennsylvania under the *qui tam*, or whistleblower, provisions of the False Claims Act and analogous state false claims statutes, which allow private citizens with knowledge of false claims to bring civil actions on behalf of the government and to share in any recovery. As part of the settlement the District will receive more than \$124,000 in restitution and other recoveries.

A National Association of Medicaid Fraud Control Units (NAMFCU) Team participated in the investigation and conducted the settlement negotiations with Astellas on behalf of the states, and included representatives from the Offices of the Attorneys General for the states of California, New York, South Carolina, and Texas. Interim Inspector General Bruce commended Medicaid Fraud Control Unit attorney Marcus A. Weeks for his work on this matter.