

GOVERNMENT OF THE DISTRICT OF COLUMBIA
Office of the Inspector General



Inspector General
August 22, 2013

**WYETH PAYS \$491 MILLION TO RESOLVE ALLEGATIONS OF OFF-LABEL
MARKETING OF RAPAMUNE**

Inspector General Charles J. Willoughby announced today that the District of Columbia has joined with other states and the federal government in a \$491 million settlement to resolve civil and criminal allegations that Wyeth Pharmaceuticals, Inc. (Wyeth), a Delaware corporation headquartered in Collegeville, PA, promoted the sale and use of Rapamune for uses for which it had not been approved by the Food and Drug Administration (FDA). Rapamune is FDA approved for kidney transplant patients, prescribed to prevent the body from rejecting a donor organ that has been transplanted into the body.

The investigation resulted from *qui tam* actions filed in the United States District Courts for the Eastern District of Pennsylvania and the Western District of Oklahoma under the federal False Claims Act and various state false claims statutes. The complaints alleged that Wyeth knowingly promoted the sale and use of Rapamune in (a) connection with solid organ transplants in patients other than kidney transplant patients; and (b) treatment regimens with transplant patients who used another immunosuppressant drug before using Rapamune and who did not receive Rapamune at or around the time of a kidney transplant.

Wyeth has agreed to pay the states and the federal government \$257,400,000 in civil damages and penalties to resolve the civil allegations of off-label marketing of Rapamune. Over \$60 million of this amount will go to state Medicaid programs, which are funded jointly by state and the federal governments. The total portion of the settlement amount recovered by the District of Columbia is \$133,227. The remaining \$197,266,067 is designated for other federal healthcare programs affected by Wyeth's conduct. Additionally, Wyeth has pled guilty in federal court in Oklahoma to violations of the U.S. Food, Drug, and Cosmetic Act, and has agreed to pay \$233,600,000 in criminal fines and forfeitures.

In late 2009, Pfizer Inc., a Delaware corporation headquartered in New York City, acquired Wyeth. The off-label marketing, and the conduct to which Wyeth pled guilty, occurred prior to Pfizer's acquisition of Wyeth. Pfizer cooperated fully with the federal government and the states in the investigation.

A team from the National Association of Medicaid Fraud Control Units (NAMFCU) conducted the settlement negotiations with Wyeth & Pfizer on behalf of the states and included representatives from the Offices of the Attorneys General for the states of Massachusetts, Virginia, Florida, Michigan, and South Carolina. Inspector General Willoughby recognized Medicaid Fraud Control Unit attorney Elaine Block and auditor E-Rika Sellers for their work on this matter.