Government of the District of Columbia
OFFICE OF THE INSPECTOR GENERAL

Inspector General
October 1, 2014

SHIRE PHARMACEUTICALS PAYS $56.5 MILLION TO RESOLVE OFF-LABEL MARKETING ALLEGATIONS

Interim Inspector General Blanche L. Bruce announced today that the District of Columbia has joined with other states and the federal government to settle allegations that Shire Pharmaceuticals, LLC (Shire) engaged in off-label marketing campaigns that improperly promoted five of its drugs: Adderrall XR; Vyvanse; Daytrona; Lialda; and Pentasa. Shire, a Pennsylvania-based company, will pay the states and the federal government $56.5 million, of which, $48.1 million will go to the Medicaid programs to resolve civil allegations that the company unlawfully marketed these drugs and thereby caused false claims to be submitted to government health care programs.

Adderrall XR, Vyvanse, and Daytrona are approved by the United States Food and Drug Administration (FDA) for the treatment of Attention Deficit Hyperactivity Disorder (ADHD). Lialda and Pentasa are approved for the treatment of mild to moderately active ulcerative colitis. Specifically, it was alleged that Shire:

- promoted Adderall XR as clinically superior to other ADHD drugs, despite a lack of clinical data to support such claims, and for the treatment of Conduct Disorder, an indication not approved by the FDA;
- promoted Vyvanse as preventing certain negative consequences of ADHD and as less abuseble than Adderrall XR or other ADHD medications, despite a lack of clinical data to support such claims;
- promoted Daytrona as less abuseable than pill-based medications, despite a lack of clinical data to support such claims, and that Daytrona, a patch applied product, demonstrated difficulty in sticking to the patient's body, making it therapeutically less effective;
- promoted Lialda for the prevention of colorectal cancer, an indication not approved by the FDA, and marketed Lialda as having greater efficacy than other medications, despite a lack of clinical data sufficient to support such a claim; and
- promoted Pentasa for the treatment of indeterminate colitis and Crohn's Disease, indications for which it had not been FDA-approved.

As a condition for the settlement, Shire has entered into a Corporate Integrity Agreement (CIA) with the United States Department of Health and Human Services Office of the Inspector General, which will closely monitor the company's future marketing and sales practices.

This settlement is significant for D.C. because it is one of the first national settlements in which Medicaid managed care damages as well as fee-for-service damages have been calculated and included as part of the recovery in the settlement. D.C.'s Medicaid program has increasingly used a managed care model for the delivery of health care benefits to its recipients, resulting in a larger amount of its Medicaid budget being spent on managed care. Including managed care damages as well as traditional fee-for-service damages in the damage calculation ensures that the District's Medicaid program will be made whole for losses suffered as a result of Shire's alleged conduct.

The settlement resulted from two *qui tam* lawsuits originally filed by whistleblowers in the United States District Courts for the Eastern District of Pennsylvania and the Northern District of Illinois under the federal False Claims Act and various state false claims statutes.

A National Association of Medicaid Fraud Control Units (NAMFCU) Team, which included representatives from the Offices of the Attorneys General for the states of California, Indiana, Michigan, and New York, participated in the investigation and conducted the settlement negotiations with Shire on behalf of the states. Shire was fully cooperative throughout the investigation, and the NAMFCU Team recognizes the company's willingness to work with NAMFCU to resolve this matter. Ms. Bruce recognized the efforts of Medicaid Fraud Control Unit attorney Marcus A. Weeks and auditor Yolanda Mobuary for their work on this case.