

GOVERNMENT OF THE DISTRICT OF COLUMBIA
Office of the Inspector General

Inspector General
November 6, 2012



BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.
PAYS \$95 MILLION DOLLARS TO RESOLVE
OFF-LABEL MARKETING ALLEGATIONS

Inspector General Charles J. Willoughby announced today that the District of Columbia has joined with other states and the federal government to settle allegations that Boehringer Ingelheim Pharmaceuticals, Inc. (BIPI) paid kickbacks and engaged in off-label marketing campaigns that improperly promoted four drugs: Atrovent, Combivent, Micardis, and Aggrenox. BIPI, a Connecticut-based company, will pay the states and the federal government \$95 million, of which \$34,468,649.22 will go to Medicaid programs to resolve civil allegations that the company unlawfully marketed Aggrenox, Combivent, Atrovent, and Micardis, and thereby caused false claims to be submitted to government health care programs.

Specifically, this settlement resolves allegations that BIPI unlawfully marketed these drugs for a variety of uses not approved by the United States Food and Drug Administration (FDA), including Aggrenox for certain cardiovascular events such as myocardial infarction and peripheral vascular disease; Combivent for use prior to another bronchodilator in treating Chronic Obstructive Pulmonary Disease; and Micardis for treatment of early diabetic kidney disease. Additionally, the settlement resolves allegations that BIPI knowingly promoted the sale and use of Combivent and Atrovent at doses that exceeded those covered by federal health care programs and that BIPI knowingly made unsubstantiated claims about the efficacy of Aggrenox, including that it was superior to the drug Plavix. Finally, the agreement resolves allegations that the company paid kickbacks to health care professionals as inducement to prescribe BIPI drugs.

As a condition of the settlement, BIPI will enter 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.

The investigation resulted from a *qui tam* action originally filed in the United States District Court for the District of Maryland under the federal False Claims Act and

various state false claims statutes. As part of the settlement, the District of Columbia will receive \$101,393 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 BIPI on behalf of the states, and included representatives from the Offices of the Attorneys General for the states of Ohio, Florida, Virginia, South Carolina, and Oregon. Mr. Willoughby acknowledged the D.C. Department of Health Care Finance for providing the necessary data and Medicaid Fraud Control Unit attorneys Elaine Block and Dangkhua Nguyen and auditor LaShawn Brooks for analyzing the data and processing this matter for the District.