

GOVERNMENT OF THE DISTRICT OF COLUMBIA
Office of the Inspector General

Inspector General
September 2, 2010



**PHARMACEUTICAL COMPANY ALLERGAN TO PAY \$600 MILLION FOR
OFF-LABEL MARKETING OF BOTOX**

Inspector General Charles J. Willoughby announced on September 1, 2010, that the District of Columbia joined the federal government and states to reach an agreement in principle with pharmaceutical manufacturer, Allergan, Inc. to settle allegations of improper off-label marketing of the drug Botox. As a result, Allergan will pay the states and the federal government \$225 million dollars, of which \$33 million dollars is for Medicaid nationwide. Additionally, the Office of the United States Attorney for the Northern District of Georgia filed a one count information in the United States District Court alleging a misdemeanor violation of the Food, Drug and Cosmetic Act. In a plea agreement with the United States, Allergan has agreed to enter a guilty plea and pay an additional \$350 million dollars in criminal fines and \$25 million in forfeiture to resolve this Information.

The national federal and state settlement totaling \$600 million dollars resolves allegations that Allergan promoted the drug Botox for uses other than what the Food and Drug Administration approved. Botox was initially approved for strabismus (crossed eyes) and blepharospasm (uncontrollable eye blinking), cervical dystonia (abnormal head and neck posture with involuntary contractions) and underarm sweating.

The investigation revealed that Allergan engaged in a nation-wide off-label marketing campaign of Botox targeting patients suffering from headache, pain, overactive bladder and spasticity. The marketing plan included providing physicians “free” reimbursement services and support which included coaching physicians to use a muscle spasm code in order to obtain reimbursement for this off-label use. Allergan also funded continuing medical education programs, honoraria, and grants to health care professionals to promote off-label uses for Botox.

This settlement reimburses the federal government and participating states for excessive amounts paid by the Medicaid program as a result of Allergan’s improper off-label marketing campaign and other improper conduct. Additionally, Allergan entered into a Corporate Integrity Agreement (CIA) with the Department of Health and Human Services, Office of Inspector General, requiring strict scrutiny of its future marketing and practices.

A team from the National Association of Medicaid Fraud Control Units participated in the investigation and represented the interests of the states during negotiations with Allergan. Team members included representatives from Oregon, Georgia, and New York.

Mr. Willoughby acknowledged the D.C. Department of Health Care Finance for providing data to the Medicaid Fraud Control Unit to analyze and report to the team. In addition, he praised the work of attorney Dangkhwa Nguyen and auditor LaShawn Brooks for their work on the investigation of the matter and analysis of the D.C. utilization data.