

**GOVERNMENT OF THE DISTRICT OF COLUMBIA**  
**Office of the Inspector General**



Inspector General

June 2, 2009

**ELI LILLY TO PAY MORE THAN \$1.4 BILLION FOR OFF- LABEL  
DRUG MARKETING**

Inspector General Charles J. Willoughby announced today that the District of Columbia joined with the states and federal government and reached an agreement with Eli Lilly and Company, to settle allegations it engaged in an off-label marketing campaign that improperly promoted the anti-psychotic drug, Zyprexa. Eli Lilly will pay the states and the federal government a total of \$800 million in damages and penalties to compensate Medicaid and various federal healthcare programs for harm suffered as a result of this conduct. In addition, the United States Attorney for the Eastern District of Pennsylvania has filed a criminal Information in United States District Court charging Eli Lilly with a misdemeanor violation of the Food, Drug and Cosmetic Act. In a plea agreement filed with the Court, Eli Lilly has agreed to pay a \$615 million criminal fine to resolve the charge. The District of Columbia's share of the settlement is \$1,881,094.00.

Zyprexa is one of a newer generation of antipsychotic medications (called atypical antipsychotics) used to treat certain psychological disorders. Between September 1999 and December 31, 2005, Eli Lilly willfully promoted the sale and use of Zyprexa, primarily through a marketing campaign called "Viva Zyprexa," for certain uses which the Food and Drug Administration had not approved. The promotional activities undertaken by Eli Lilly in the "Viva Zyprexa" campaign promoted Zyprexa not only to psychiatrists, but also to primary care physicians, for such unapproved uses as the treatment of depression, anxiety, irritability, disrupted sleep, nausea and gambling addiction. In implementing the campaign, Eli Lilly also provided remuneration and other things of value to physicians and other health care professionals. As a result of these promotional activities, Eli Lilly caused physicians to prescribe Zyprexa for children and adolescents, dementia patients in long term care facilities, and in unapproved dosage amounts, all of which are uses that were not medically accepted indications for which state Medicaid programs would approve reimbursement.

As part of the settlement, Eli Lilly will enter a Corporate Integrity Agreement with the United States Department of Health and Human Services, the Office of the Inspector General, which will closely monitor the company's future marketing and sales practices.

This settlement is based on four *qui tam* cases that were filed or consolidated in the United States District Court for the Eastern District of Pennsylvania by various relators - private parties that filed actions under state and federal false claims statutes.

A National Association of Medicaid Fraud Control Units team participated in the investigation and conducted the settlement negotiations with Eli Lilly on behalf of the settling states. Team members included representatives from Massachusetts, New York, Ohio, Delaware, New Jersey, Texas and Illinois. Mr. Willoughby praised the excellent work of District of Columbia Medicaid Fraud Control Unit staff members who contributed to this settlement, Attorney Dangkhua Nguyen and Auditor Clark Geiger.