GOVERNMENT OF THE DISTRICT OF COLUMBIA
Office of the Inspector General

Inspector General
May 4, 2010

ASTRAZENECA TO PAY $520 MILLION TO SETTLE CLAIMS OF OFF-LABEL DRUG MARKETING

Inspector General Charles J. Willoughby announced today that the District of Columbia has joined with the states and federal government and reached an agreement in principle with AstraZeneca Pharmaceuticals LP, to settle allegations it engaged in an off-label marketing campaign that improperly promoted the antipsychotic drug, Seroquel. AstraZeneca will pay the states and the federal government a total of $520 million in damages and penalties to compensate Medicaid and various federal healthcare programs for harm suffered as a result of this conduct. The settlement will recover $1,257,018 for the D.C. Medicaid program.

Seroquel is one of a newer generation of antipsychotic medications (called atypical antipsychotics) used to treat certain psychological disorders. From January 1, 2001, through December 31, 2006, AstraZeneca promoted the sale and use of Seroquel for certain uses that the Food and Drug Administration had not approved. The settlement resolves a government investigation into promotional activities undertaken by AstraZeneca that were directed not only to psychiatrists but also to primary care physicians and other health care professionals for unapproved uses in the treatment of medical conditions such as aggression, Alzheimer's disorder, anger management, anxiety, attention deficit hyperactivity disorder, dementia, and sleeplessness.

In implementing its marketing campaign, AstraZeneca was also alleged to have made illegal payments to physicians, paying their travel expenses to resort locations to "advise" AstraZeneca about marketing messages for unapproved uses, to serve as authors of articles written by AstraZeneca and its agents, and to conduct studies for unapproved uses of Seroquel. The settlement resolves claims that, as a result of these promotional activities, AstraZeneca caused physicians to prescribe Seroquel for children, adolescents, and dementia patients in long term care facilities, which are uses that were not medically accepted indications for which state Medicaid programs would approve reimbursement.

As part of the settlement, AstraZeneca will enter into a Corporate Integrity Agreement 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 based on *qui tam* cases that were filed in the United States District Court for the Eastern District of Pennsylvania by relators – private parties who 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 AstraZeneca on behalf of the settling states. Team members included representatives from New York, Massachusetts, Illinois, Ohio, New Jersey, Texas, and California. Mr. Willoughby praised the efforts of D.C. Medicaid Fraud Control Unit Director Susan Bieber Kennedy and Auditor Clark Geiger for their work on this matter.