Government of the District of Columbia

OFFICE OF THE INSPECTOR GENERAL

Inspector General
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D.C. MEDICAID PROGRAM TO RECEIVE $3 MILLION FROM DRUG SETTLEMENT

WASHINGTON, D.C. – D.C. Inspector General Charles J. Willoughby and D.C. Attorney General Irvin B. Nathan announced today that the District of Columbia Medicaid program will receive more than $3 million from a settlement announced this week involving the District, the federal government and most state governments, New Jersey-based pharmaceutical manufacturer Johnson & Johnson, and its subsidiary Janssen Pharmaceuticals, Inc. (Janssen).

In the civil settlement, the companies will pay more than $1.2 billion to D.C., states, and the federal government to resolve allegations of unlawful marketing practices to promote the sales of their atypical antipsychotic drugs Risperdal and Invega. In addition, Janssen will plead guilty in federal court to a criminal misdemeanor charge of misbranding Risperdal in violation of the Food, Drug, and Cosmetic Act. As part of the criminal plea, Janssen has agreed to pay an additional $400 million in criminal fines and forfeitures. The settlement resolves four *qui tam*, or whistleblower, lawsuits filed in the United States District Court for the Eastern District of Pennsylvania, under the provisions of the D.C. False Claims Act, the federal False Claims Act, and similar state False Claims statutes.

Johnson & Johnson and Janssen allegedly promoted, marketed, and introduced Risperdal and Invega into interstate commerce for uses that were not approved by the Food and Drug Administration (FDA) and for uses that were not medically indicated. D.C. and the states contend that during the period January 1, 1999, through December 31, 2005, the companies: 1) promoted Risperdal for off-label uses; 2) made false and misleading statements about the safety and efficacy of Risperdal; and 3) paid illegal kickbacks to health care professionals and long-term care pharmacy providers to induce them to promote or prescribe Risperdal to children, adolescents, and the elderly when there was no FDA approval for Risperdal use in these patient populations. The states further contend that from January 1, 2007, through December 31, 2009, the companies promoted Invega for off-label uses and made false and misleading statements about the safety and efficacy of Invega. The manufacturers' alleged unlawful conduct caused false and/or fraudulent claims to be submitted to or caused purchases by government-funded health care programs, including the state Medicaid programs.

As part of the global resolution, the companies 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 practices.

A team from the National Association of Medicaid Fraud Control Units worked closely with the federal government on the investigation and conducted the settlement negotiations with the pharmaceutical manufacturers on behalf of the states.

Inspector General Willoughby commended former Medicaid Fraud Control Unit attorney Elaine Block and auditor LaShawn Brooks for their work on this matter.