GOVERNMENT OF THE DISTRICT OF COLUMBIA
Office of the Inspector General

Inspector General
October 6, 2010

NOVARTIS TO PAY $422.5 MILLION TO SETTLE CLAIMS OF OFF-LABEL DRUG MARKETING AND KICKBACKS

Inspector General Charles J. Willoughby announced today that the District of Columbia has joined with the states and the federal government to reach an agreement in principle with Novartis Pharmaceuticals Corporation (Novartis) to settle allegations it improperly promoted Trileptal and engaged in unlawful kickback schemes to induce physicians to prescribe Trileptal, Diovan, Zelnorm, Sandostatin, Exforge and Tekturna. As a result, Novartis will pay the states and the federal government $237.5 million in damages and penalties for losses to the Medicaid and other federal health care programs. Additionally, the Office of the United States Attorney for the Eastern District of Pennsylvania filed a one count Information against Novartis Pharmaceuticals Corporation 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, Novartis has agreed to plead guilty and pay $185 million to resolve the criminal case. Novartis is a pharmaceutical manufacturer incorporated in Delaware and headquartered in East Hanover, New Jersey.

Trileptal is an anti-epileptic drug approved by the Food and Drug Administration (FDA) for the treatment of partial seizures in patients who have epilepsy. The civil settlement resolves claims from January 1, 2001, through June 30, 2005, that Novartis promoted the sale and use of Trileptal for certain uses not approved by the FDA. The settlement resolves a government investigation into promotional activities by Novartis, which were directed at psychiatrists and other health care professionals, to induce physicians to prescribe Trileptal for unapproved uses such as the treatment of bipolar disorder and neuropathic pain. Novartis also offered and paid illegal remuneration to health care professionals to induce them to promote and prescribe Trileptal.

The settlement also resolves allegations that from January 1, 2002, to December 31, 2009, Novartis provided illegal remuneration, through mechanisms such as payments for speaker programs, advisory boards, and the giving of gifts, (including entertainment, travel, and meals), to health care professionals to induce them to promote and prescribe the drugs Diovan, Zelnorm, Sandostatin, Exforge, and Tekturna.

As one of the conditions of the settlement, Novartis will enter into a Corporate Integrity Agreement with the Office of the Inspector General of the United States Department of Health and Human Services, which will closely monitor Novartis' practices going forward.

These settlements are based on four separate *qui tam* lawsuits filed by private individuals; three of which were consolidated in the United States District Court for the Eastern District of Pennsylvania and one of which was filed in the Middle District of Florida under state and federal false claims statutes.

A team formed by the National Association of Medicaid Fraud Control Units participated in the investigation and represented the interests of the states during negotiations with Novartis. Team members included representatives from Ohio, Florida and New York. Mr. Willoughby acknowledged the D.C. Department of Health Care Finance for its assistance with providing data to the Medicaid Fraud Control Unit (MFCU), and thanked MFCU attorney Dangkhoa Nguyen and auditor LaShawn Brooks for their work on this matter.