

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

Inspector General  
January 6, 2009



DISTRICT PARTICIPATES IN SETTLEMENT WITH PHARMACEUTICAL  
COMPANY-  
CEPHALON TO PAY  
\$425 MILLION FOR OFF-LABEL DRUG MARKETING

District of Columbia Inspector General Charles J. Willoughby announced on January 7, 2009, that the District of Columbia, through that the National Association of Medicaid Fraud Control Units joined the federal government to reach an agreement with pharmaceutical manufacturer, Cephalon, Inc. to settle allegations of improper off-label marketing of three pharmaceutical drugs. As a result, Cephalon will pay the states and the federal government \$375 million in damages and penalties for 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 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, Cephalon has agreed to pay \$50 million to resolve this Information. The District of Columbia Medicaid settlement totals \$189,279.

The national federal and state settlement totaling \$425 million dollars resolves allegations that Cephalon promoted the drugs Provigil, Gabitril, and Actiq for uses other than what the Food and Drug Administration approved. Cephalon also funded continuing medical education programs, through millions of dollars in grants, to promote off-label uses for these drugs. Cephalon's conduct with respect to the drugs consisted of the following:

**Provigil:** Although FDA-approved to treat only narcolepsy and sleep disorders, Cephalon marketed Provigil as a non-stimulant drug to treat sleepiness, tiredness, decreased activity, lack of energy and fatigue.

**Gabitril:** Although FDA-approved as a partial treatment for seizures, Cephalon marketed Gabitril as a remedy for anxiety, insomnia, and pain. Following reports of seizures in patients taking Gabitril that did not have epilepsy, the FDA required Cephalon to send a warning to physicians advising them of the risks of seizures in connection with off-label Gabitril use.

**Actiq:** Although FDA-approved to treat opioid-tolerant cancer patients (or those patients for whom morphine-based painkillers are no longer effective), Cephalon marketed Actiq for conditions including migraines, sickle-cell pain crises, injuries, and in anticipation of changing wound dressing or radiation therapy.

This settlement reimburses the federal government and the participating states for excessive amounts paid by the Medicaid program as a result of Cephalon's improper off-label marketing campaign. Additionally, Cephalon entered into a Corporate Integrity Agreement (CIA) with the Department of Health and Human Services, Office of the Inspector General, requiring strict scrutiny of its future marketing and sales 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 Cephalon, Inc. Team members included representatives from South Carolina, New Jersey, Ohio, Oregon and Virginia. Inspector General Willoughby commended the efforts of Auditor Clark Geiger of the D.C. Medicaid Fraud Control Unit for his exemplary work with regard to the data analysis.