

# Breaking Legal NEWS

## Off-Label, Medicaid Fraud Whistleblower Settlement

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(See Editors' Note On Last Page)

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\$425 Million Cephalon Civil Settlement and Criminal Fine In America's Largest Biotechnology Medicaid Fraud Case; Philadelphia-Based Qui Tam Whistleblower Attorney Brian P. Kenney, Esq. Filed First Complaint With Client's Off-Label Marketing Allegations In 2003; Additional Complaints Were Filed; \$375 Million Civil Settlement, \$50 Million Corporate Criminal Fine Today

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PHILADELPHIA – Biotech drug manufacturer Cephalon, Inc. (“Cephalon”) flouted federal regulations on a grand scale for years by off-label marketing its first three prescription drugs far beyond the cancer pain, epilepsy and narcolepsy specialists for whose patients those drugs had been FDA-approved. Instead, Cephalon focused its national marketing muscle on unapproved uses, targeting medical specialists with bigger patient populations, according to a Complaint filed in 2003 by Philadelphia qui tam whistleblower attorney Brian P. Kenney, Esq. The complaint was unsealed today with Cephalon's \$375 million nationwide Medicaid fraud settlement and \$50 million corporate criminal plea.

Kenney, lead partner of Philadelphia-based, Kenney Egan, McCafferty & Young, P.C., represents whistleblowers across the U.S. His whistleblower client is a former medical sales representative, area trainer and institutional representative for the Frazer, Pennsylvania-based drug manufacturer. In 2003, on her behalf, Kenney brought qui tam whistleblower Medicaid fraud allegations against Cephalon to the government.

Kenney's filing, under seal as required by law, was the first complaint filed in the federal–state investigation that resulted in today's national settlement and corporate criminal plea. A total of four whistleblower Complaints were unsealed today by the U.S. Attorney's Office for the Eastern District of Pennsylvania, along with the filing of a new federal Complaint, settlement agreement, and corporate integrity agreement, which settle all four whistleblower cases, Kenney explained.

Additionally, Cephalon entered a corporate criminal plea and paid a \$50 million fine. The criminal case was based upon information provided by relators in the civil case, Kenney noted.

The first drugs on which Cephalon started its business are the three prescription medicines listed in Kenney's client's Complaint, the whistleblower attorney noted. Today, Cephalon's Web site presents nine medications, including those original three:

Actiq®, a fentanyl-based “medicated lozenge on a handle”<sup>1</sup>. The drug was FDA approved only for “breakthrough” pain in cancer patients with malignancy who are already on opiates for persistent pain. One January 2007 study by a Midwest pharmacy benefit manager estimated that 90 percent of Actiq's sales were off-label. A *Wall Street*

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<sup>1</sup> <http://www.cephalon.com/patients/our-products/>

*Journal* article in 2006 stated that just 1% of Actiq prescriptions written since January of that year were issued by oncologists. More than 100 deaths from the drug were reported by Cephalon, the 2006 article states.

Gabapentin®, approved for partial epileptic seizures in adults and children over 12 years of age. Because the patient base of epileptologists and neurologists was limited, Cephalon off-label promoted the drug to pain clinics as an alternative to benzodiazepine, the generic name for Valium® and Xanax®, and later to psychiatrists for depression, mood disorder and anxiety. In none of these specialty areas did Cephalon have approvals, scientific evidence or other bases for marketing the drug in this way, according to Kenney's Complaint; and

Provigil®, which Cephalon describes as, "Originally approved for the treatment of excessive daytime sleepiness associated with narcolepsy, today PROVIGIL is the only FDA-approved prescription medicine for treatment of excessive sleepiness associated with obstructive sleep apnea/hypopnea syndrome and shift work sleep disorder."<sup>1</sup>

Under FDA rules, prescription drug manufacturers and marketers may only promote their products for approved uses. Physicians are free to prescribe drugs for conditions beyond those for which approval has been received but marketing to induce off-label, unapproved use is not permitted.

Under Medicaid, the state-and-federally underwritten program for low-income and disabled Americans, reimbursement is allowed only for the FDA-approved use of a drug, not for off-label use, Kenney, a former federal prosecutor, explained.

Kenney's qui tam whistleblower client was one of Cephalon's original 27 sales hires in 1994. She brought her Cephalon allegations to Kenney after her concerns grew over Gabapentin's off-label marketing, "... to pediatric patients and to psychiatrists for mood disorder, anxiety or pain," according to Kenney's Complaint. Neither psychiatrists nor pain specialists had approved use for the drug, which impacted the central nervous system, the Complaint states.

"Neither medical science or Cephalon have a clue as to how Gabapentin works, let alone if it can be prescribed in psychiatry instead of Valium® or Xanax®," Kenney said. "My client, a marketing rep, was told by superiors to recommend dosage levels to psychiatrists, even for juveniles. Her concerns about Gabapentin marketing fell on deaf ears; she began to receive progressively worse performance evaluations and, in 2003, was terminated by Cephalon."

Among schemes to support off-label marketing alleged in the relators' and government Complaints are:

- Intensively marketing Actiq to physical medicine and rehabilitation, and pain management specialists;
- Encouraging sales reps to make false statements about the efficacy of Gabapentin, and providing dosing recommendations when none have been determined for depression;
- Leaving "huge doses of Gabapentin" with psychiatrists when no approved use or dosage existed for psychiatrists;
- Encouraging sales representatives to recruit psychiatrists by paying the physicians honoraria in return for recommending Gabapentin to other psychiatrists;

- Assisting physicians in securing Medicaid reimbursement for Actiq when off-label use was ineligible for Medicaid payment;
- Giving illegal kickbacks to physicians;
- Promoting Actiq for unapproved conditions including migraine and back pain, fibromyalgia, post-operative pain, and pain associated with certain neurologic disorders;
- Displaying or otherwise using unapproved collateral to market drugs during physician calls but specifically not leaving behind any of the unapproved material with physicians;
- Targeting physicians writing a large number of narcotic and controlled substance prescriptions regardless of specialty, even though Actiq was approved only for breakthrough cancer pain;
- Disguising payments to physicians as preceptorship or speaking fees; and
- Changing a Cephalon bonus incentive program to reward off-label marketing success.

Federal and state False Claims Acts allow private citizens with knowledge of fraud to help the government recover ill-gotten gains and additional civil penalties. These statutes allow the government to collect up to three times the amount defrauded, in addition to civil penalties of \$5,500 to \$11,000 per false claim. Kenney noted that whistleblowers, legally known as “qui tam relators,” can receive between 15 and 30 percent of the government’s recovery.

Today’s 50-state settlement was achieved through the efforts of the U.S. Attorney’s Office in the Eastern District of Pennsylvania, Laurie Magid, Acting U.S. Attorney. The federal Government is represented by Assistant U.S. Attorney Marilyn May, of the office’s Civil Division.

Several state prosecutors working with the National Association of Medicaid Fraud Control Units (“NAMFCU”), coordinated by South Carolina Assistant Deputy Attorney Charles W. Gambrell, Jr.; Special Agents of the FDA; and Special Agents of the Department of Health and Human Services Office of the Inspector General also assisted in the investigation and prosecution of the Cephalon case.

In executing the False Claims Act Settlement Agreement, Cephalon denied liability, wrongdoing or improper conduct.

UNITED STATES OF AMERICA *ex rel.* LUCIA PACCIONE. *States ex rel.* LUCIA PACCIONE, and LUCIA PACCIONE, individually v. CEPHALON, INC., Eastern District of Pennsylvania, , 036268.

Attn: Editors

Call Brian P. Kenney, Esq., at 610-940-9099 to arrange availability; for the complete news release; or other information about this case, including filed documents or other public material. You can also visit <http://www.PRforLAW.com> where the complete Kenney news release, along with filed public documents will be posted as they become available or call PRforLAW, LLC at 215-736-0198.

About Kenney, Egan, McCafferty & Young, P.C. (<http://www.kemy-law.com>)

A nationally known law firm, Kenney Egan McCafferty & Young, P.C. (“KEMY”) was founded by former veteran federal prosecutors now zealously advocating in the public interest for individuals, corporations, labor organizations, and employee benefit plan clients. As independent investigators and inspectors general KEMY attorneys are retained by business, government and NGO entities to conduct sensitive internal investigations. For plaintiff or defense, the suburban Philadelphia firm focuses its practice on False Claims Act matters, [Corporate Investigations, Wage & Hour/Overtime Litigation](#), [Health Care Fraud and Abuse](#), and [White-Collar Criminal Defense](#).

The Kenney, Egan, McCafferty & Young, P.C. Qui Tam False Claims Act Practice

The attorneys of Kenney Egan McCafferty & Young, P.C. ("KEMY") have extensive experience representing relators (whistleblowers) alleging fraud against the government under qui tam provisions of federal and state False Claims Acts. As a federal prosecutor, Brian J. Kenney, Esq. handled False Claims Act matters at the U.S. Department of Justice. Today, in KEMY's second decade of representing whistleblowers across the country, Kenney and other KEMY attorneys have helped state and federal governments recover more than \$500 million in False Claims Act cases.

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