From:	Lowney, Karen </O=CEPHALON/OU=US01 ADMINISTRATIVE GROUP/CN=RECIPIENTS /CN=KLOWNEY>
To:	Rausch, Christopher; Assis, Julie; Powell, Heather
Sent:	9/29/2008 3:38:10 PM
Subject:	FW: Press Release
Attachments:	Press Release.pdf

Attached is the DOJ press release. Please don't forward.

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From: Baldassano, Valli F.
Sent: Monday, September 29, 2008 11:29 AM
To: Lowney, Karen
Subject: FW: Press Release

Best regards,

Valli

Valli Baldassano

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PLAINTIFFS TRIAL EXHIBIT
P-19258_00001

U.S. Department of Justice

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Eastern District of Pennsylvania

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For Immediate Release

September 29, 2008

PHARMACEUTICAL COMPANY CEPHALON TO PAY $425 MILLION FOR OFF-LABEL DRUG MARKETING

PHILADELPHIA - United States Attorney General Michael B. Mukasey and Acting United States Attorney Laurie Magid today announced the filing of a criminal information[1] against, and a civil settlement with, the pharmaceutical company Cephalon, headquartered in West Chester, PA, for the off-label marketing of three of its drugs. Joining Magid in today's announcement were FDA Special Agent-in-Charge Kim Rice, Special Agent-in-Charge of the Office of Inspector General for the Department of Health and Human Services Philadelphia Patrick Doyle, Special Agent-in-Charge of United States Postal Service Office of Inspector General Elizabeth Farcht.

The information alleges that from approximately January 2001 through at least 2006, Cephalon promoted the drugs Actiq, Gabitril, and Provigil for uses other than what the federal Food and Drug Administration approved. The company is charged with one count of Distribution of Misbranded Drugs: Inadequate Directions for Use, a misdemeanor offense.

Under the provisions of the Food, Drug and Cosmetic Act, a company must specify the intended uses of a product in its new drug application to the FDA. Before approving a drug, the FDA must determine that the drug is safe and effective for the use proposed by the company. Once approved, the drug may not be marketed or promoted for so-called "off label" uses - meaning any use not specified in an application and approved by FDA.

The FDA approved Actiq, a fentanyl product manufactured as a lollipop, for use only in opioid-tolerant cancer patients (meaning those patients for whom morphine-based painkillers are no longer effective). The drug is a strong and highly addictive narcotic, with significant potential for abuse. From 2001 through at least 2006, Cephalon was allegedly promoting the drug for non-cancer patients to use for such maladies as migraines, sickle-cell pain crises, injuries, and in anticipation of changing wound dressings or radiation therapy. Cephalon also promoted Actiq for use in patients who were not yet opioid-tolerant, and for whom it could have life-threatening

[1]An Indictment or Information is an accusation. A defendant is presumed innocent unless and until proven guilty.

results.

The FDA approved Gabitril for use as an anti-epilepsy drug in the treatment of partial seizures. From 2001 to 2005, Cephalon allegedly promoted Gabitril as a remedy for anxiety, insomnia, and pain. In 2005, following reports of seizures in patients taking Gabitril who did not have epilepsy, the FDA required Cephalon to send a warning letter to doctors advising them of the connection between off-label Gabitril use and risk of seizures. The company then ceased promotion of the drug.

The FDA first approved Provigil to treat excessive daytime sleepiness associated with narcolepsy, then expanded the label to include treatment of excessive sleepiness associated with sleep apnea, and shift work sleep disorder. From 2001 through 2006, Cephalon allegedly promoted Provigil as a non-stimulant drug for the treatment of sleepiness, tiredness, decreased activity, lack of energy, and fatigue. In 2002, the FDA sent Cephalon a letter instructing the company not to continue to promote Provigil off-label. The company ignored the FDA's letter.

Defendant Cephalon undertook its off-label promotional practices using a variety of techniques. It trained its sales force to disregard the restrictions of the FDA-approved label, and to promote the drugs for off-label uses. For example, the Actiq label stated that the drug was for "opioid tolerant cancer patients with breakthrough cancer pain, to be prescribed by oncologist or pain specialists familiar with opioids." Using the mantra "pain is pain," Cephalon instructed the Actiq sales representatives to focus on physicians other than oncologists, including general practitioners, and to promote the drug for many uses other than breakthrough cancer pain. In the case of Gabitril, which had been approved for use for epilepsy, Cephalon told the sales force to visit not just neurologists, but also psychiatrists, and to promote the drug for anxiety and other psychiatric indications. Cephalon also structured its sales quota and bonuses in such a way that sales representatives could reach their sales goals only if they promoted and sold the drugs for off-label uses.

"These are potentially harmful drugs that were being peddled as if they were, in the case of Actiq, actual lollipops instead of a potent pain medication intended for a specific class of patients," said Magid. "This company subverted the very process put in place to protect the public from harm, and put patients' health at risk for nothing more than boosting its bottom line. People have an absolute right to their doctors' best medical judgement. They need to know the recommendations a doctor makes are not influenced by sales tactics designed to convince the doctor that the drug being prescribed is safe for uses beyond what the FDA has approved."

Defendant Cephalon employed sales representatives and retained medical professionals to speak to doctors about off-label uses of Actiq, Gabitril, and Provigil. The company funded continuing medical education programs, through millions of dollars in grants, to promote off-label uses of its drugs, in violation of the FDA's requirements.

In a plea agreement with the United States, Cephalon agrees to pay $50 million to resolve this information, of which $40 million will be applied to a criminal fine, and $10 million will be applied as substitute assets to satisfy the forfeiture obligation.

In a separate civil settlement among Cephalon, the United States and various states, executed contemporaneously with this guilty plea agreement, Cephalon will pay $375 million, plus interest, to resolve False Claims Act claims by the United States Medicaid and Medicare Trust Funds and other federal programs and agencies, including Tricare, the Federal Employees Health Benefit program, the Postal Worker's Compensation Program, the Federal Employees Compensation Act Program, the Energy Employees Occupational Illness Compensation Program, Department of Veterans Affairs, Defense Logistics Agency, Bureau of Prisons, and the Public Health Service Entities. The state Medicaid programs and the District of Columbia will share $116 million of the civil settlement.

"This settlement is further evidence of the Department's willingness to prosecute cases involving violations of the FDCA and to recover taxpayer dollars used to pay for drugs sold as a result of illegal marketing campaigns," said Assistant Attorney General Gregory Katsas.

"Today's settlement demonstrates the government's continued scrutiny of sales and marketing practices by pharmaceutical companies that put profits ahead of the public health," said Special Agent-in-Charge Kim Rice of FDA's Office of Criminal Investigations. "The FDA will continue to seek this kind of criminal resolution and stiff sanctions when pharmaceutical companies undermine the drug approval process by promoting drugs for uses for which they have not been proven to be safe and effective."

"This case should serve as still another warning to all those who break the law in order to improve their profits," said Patrick Doyle, head of the Philadelphia Regional Office of the Department of Health and Human Services Office of Inspector General (OIG). "OIG, working with our law enforcement partners, will pursue and bring to justice those who would steal from vulnerable beneficiaries and the taxpayers."

The civil settlement also resolves four qui tam ("whistle blower") actions filed in the Eastern District of Pennsylvania: United States of America ex rel. Lucia Paccione v. Cephalon, Inc., Civil Action No. 03-6268; United States of America and the States of California, Delaware, Florida, Hawaii, Illinois, Louisiana, Massachusetts, Nevada, New Hampshire, New Mexico, Texas, Tennessee and Virginia and the District of Columbia ex rel. Joseph Piacentile v. Cephalon, Inc., Civil Action No. 03-6277; United States of America; the States of California, Delaware, Florida, Hawaii, Illinois, Massachusetts, Nevada, New Mexico, Tennessee, Texas, Virginia, the District of Columbia, and New York; ex rel. Bruce Boise v. Cephalon, Inc., Civil Action No. 04-4401 and United States of America ex rel. Michael Makalusky v. Cephalon, Inc.,

Civil Action No. 05-1904. Three of those cases were filed by former Cephalon sales representatives who were disturbed by the company's off-label marketing practices. The relators will receive $46,469,978 from the federal share of the settlement amount.

United States Postal Service Office of Inspector General Special Agent- in-Charge Elizabeth A. Farcht stated, "These types of investigations are an important part of the Postal Service Office of Inspector General's mission to prevent and detect fraud, waste, and misconduct in the Postal Service, and to promote the integrity and efficiency of postal programs. This includes federal programs that the postal service participates in or contributes to such as the federal workers' compensation program, under which these drugs were paid for by the postal service. Drugs promoted off-label can lead to potential safety issues and unnecessary, inflated program costs for the Postal Service and others."

As part of the resolution of these allegations, the HHS Office of Inspector General and Cephalon have entered into a five-year Corporate Integrity Agreement. The Agreement requires that Cephalon send doctors a letter advising of this resolution, and give them a means to report questionable conduct of sales representatives; that it post payments to doctors on its web site; and that its Board and top management regularly certify that the company has an effective compliance program and is in compliance with all applicable requirements.

The case was investigated by the Food and Drug Administration's Office of Criminal Investigation, the Department of Health and Human Services' Office of the Inspector General, the Postal Service Office of the Inspector General, and the Office of Personnel Management Office of Inspector General. The case was prepared by Assistant United States Attorney Marilyn May and Assistant United States Attorney Cathy Votaw, together with Jeffrey Steger of the Department of Justice Office of Consumer Litigation.

Assistance was provided by Laura Pawlowski from the FDA Office of Chief Counsel, as well as representatives of the National Association of Medicaid Fraud Control Units, headed by Charles William Gambrell, Jr., Director South Carolina Medicaid Fraud Control Unit, and the Connecticut Attorney General's Office. The Corporate Integrity Agreement was negotiated by Mary Riordan and Maame Gyamfi in the Office of General Counsel, Office of Inspector General, Department of Health and Human Services. The Department of Justice acknowledges Cephalon's cooperation with the investigation and resolution of this case.

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