## Pharmaceutical Company Fined $425 Million; Learned ‘Painful’ Lesson

In September 2008, the U.S. Department of Justice filed an information against the Philadelphia-based pharmaceutical company Cephalon, sending a clear message that ‘pain is not created equally.’ The company – which had directed its sales force using the mantra ‘pain is pain’ in an effort to increase its bottom line – agreed to pay a $40-million fine and forfeit $10 million in assets to resolve the criminal information. The Postal Service will receive $4 million from the criminal fines, and the asset forfeiture amount to be paid to the Postal Service is pending. Cephalon also agreed to pay $375 million to resolve False Claims Act allegations filed by various federal programs and agencies. The Postal Service received approximately $767,000 for civil damages and investigative costs. In October 2008, the company pled guilty to distributing misbranded drugs.

The settlement stemmed from an investigation into four *qui tam* complaints. A *qui tam* is a provision under the False Claims Act. It allows a private person, “known as the “relator,” who has knowledge of fraud committed against the federal government to bring suit on the United States’ behalf when the private person has information that the named defendant has knowingly submitted or caused the submission of false or fraudulent claims to the United States. In this case, three of the actions were filed by former Cephalon employees. The Office of Inspector General (OIG) for the Postal Service joined the OIG of Health and Human Services, the Office of Personnel Management and the Food and Drug Administration (FDA) Office of Investigations in investigating the company in 2004, because the Postal Service was paying for these drugs for postal employees on workers’ compensation.

The information accused Cephalon of misrepresenting its drug that was federally approved as a pain-killer for cancer patients. Cephalon instructed its sales representatives to broaden their target audience to include general practitioners as well as oncologists. In the case of Cephalon’s FDA-approved epilepsy drug, it directed its sales force to visit not only neurologists, who were federally approved to prescribe the drug, but also to visit psychiatrists, to whom the sales force promoted the drug for anxiety and other psychiatric symptoms. Cephalon structured its sales quota and bonuses in such a way that sales representatives could reach sales goals *only* if they promoted and sold the drugs for non-FDA approved uses. Additionally, the Cephalon funded continuing medical education programs, through millions of dollars in grants, to promote off-label uses of its drugs, which violated the FDA-approved uses of the drugs.

Special Agent in Charge Elizabeth A. Farcht of the Inspector General's Eastern Area Field Office, 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."