

Eli Lilly Pays a Record \$1.4 Billion to Settle Federal and State Fraud Investigations into Illegal Zyprexa Off-Label Marketing Practices

PHILADELPHIA, Jan. 15 /PRNewswire/ -- Eli Lilly and Company announced today it has agreed to plead guilty to criminal conduct and to pay more than 1.4 billion in criminal and civil fines, penalties and damages arising from allegations made in multiple whistleblower lawsuits that the pharmaceutical giant defrauded Medicare, Medicaid and other government-funded health care programs in connection with its market practices for its blockbuster atypical antipsychotic, Zyprexa. The settlement is the largest *qui tam* settlement in U.S. history.

Lilly engaged in a nationwide campaign to market Zyprexa off-label for untested and unapproved uses and, as part of that campaign, Lilly minimized and misrepresented the dangers of Zyprexa, placing company profits above the public safety according to two *qui tam* Complaints filed by whistleblower attorneys Brian Kenney and Tavy Deming of Kenney, Egan, McCafferty & Young ("KEMY").

The *qui tam* Complaints were filed on behalf of Steven Woodward, a former Lilly Long Term Care ("LTC") Zyprexa sales representatives from Florida and Jaydeen Vicente a former Lilly LTC representative from California. The Complaints were the first *qui tam* claims to focus on off-label marketing in Lilly's Long Term Care Sales division.

The Complaints allege that Lilly established a LTC sales force created for a singular purpose - to promote Zyprexa exclusively off-label by extolling the drug's efficacy for a litany of non-indicated uses to control through sedation elderly nursing home residents exhibiting symptoms of agitation, anxiety, insomnia. Lilly staffed the LTC sales force with 180 "specialty" sales representatives, chosen for their special skill sets that translated into heightened aptitude for selling. Lilly's aggressive LTC sales approach succeeded. According to the Woodward and Vicente complaints, the off-label Zyprexa revenues generated per LTC sales representative far exceeded the revenues generated per representative in any other Zyprexa sales division.

According to Deming, Lilly had no legitimate purpose in creating a sales force to call upon nursing homes and other elder care facilities because Zyprexa is not approved for any use in that patient population in addition to the fact that the typical residents of these homes were not schizophrenic or bipolar. "Our clients questioned their superiors about the legality of Lilly's Zyprexa marketing practices," explained Deming, "but they were instructed that as long as they adhered to Lilly's LTC marketing message, the LTC marketing tactics were not illegal."

Because of the lack of any FDA-approved use in the LTC demographic, LTC sales representatives were instructed to focus on "behavior treatment," *i.e.*, Zyprexa's efficacy in treating disruptive and combative patients and patients exhibiting signs of anxiety, depression, and loss of concentration who were demanding of caregiver time and effort. Lilly's Zyprexa marketing arm, the Zyprexa Brand Team, created marketing tools tailored to the LTC symptom-based sales message, such as colorful visual detail aids that stressed Zyprexa's ability to "restore calm" in elderly patients.

Because one of Zyprexa's primary side effects is somnolence or drowsiness, Zyprexa was often used to sedate patients, a practice that was commonly referred to as "snowing." According to Kenney, "Lilly even devised a LTC sales slogan used nationwide - '5 at 5 pm,' which was shorthand for dosing elderly patients with 5 milligrams of Zyprexa at 5 pm to keep patients calm throughout the night." "It's particularly disturbing that such a potent drug, with so many serious adverse side effects, was so blatantly abused in a vulnerable patient population whose health is already at risk," stated Kenney. Kenney added that "at many nursing homes this potent antipsychotic was essentially used as a 'chemical restraint' for the elderly for whom Zyprexa had no other health benefit."

The Zyprexa's label currently bears a black box warning, the FDA's strongest warning, cautioning of the increased risk of death when Zyprexa is used to treat elderly patients with dementia. According to Deming, "prescribing atypical antipsychotics like Zyprexa off-label to treat behavioral disorders in elderly patients with dementia has been shown in clinical studies to be associated with nearly a two-fold increase in mortality, primarily due either to heart-related events, such as heart failure and sudden death, or to infections such as pneumonia."

The federal investigation into Lilly's Zyprexa marketing practices was conducted by the U.S. Attorney's Office for the Eastern District of Pennsylvania under the direction of acting U.S. Attorney Laurie Magid, Assistant U.S. Attorney Virginia Gibson, Chief of the Civil Division and Assistant U.S. Attorney Joe Trautwein.

Massachusetts Assistant Attorney General Bill Patten and Delaware Deputy Attorney General Dan Miller led the investigation on behalf of the states and the National Association of Medicaid Fraud Control Units ("NAMFCU").

UNITED STATES *ex rel.* STEVEN WOODWARD *et al.* v. ELI LILLY AND COMPANY, *et al.*, Eastern District of Pennsylvania, CA No. 06-5526.

UNITED STATES *ex rel.* JAYDEEN VICENTE *et al.* v. ELI LILLY AND COMPANY, Eastern District of Pennsylvania, CA No. 07-1791.

Attn: Editors

Call Tavy Deming or Brian P. Kenney at 610-940-0327 to arrange availability for the complete news release; or other public material related to the case.

About Kenney, Egan, McCafferty & Young, P.C. (<http://www.quitam-lawyer.com>) A nationally known law firm, Kenney, Egan, McCafferty & Young, P.C. ("KEMY") was founded by former veteran federal prosecutors who now zealously advocate in the public interest for individuals, corporations, labor organizations, and employee benefit plan clients. The firm specializes in qui tam and tax whistleblower litigation and has recovered more than \$2 billion for the government in False Claims Act and tax whistleblower cases.

Brian P. Kenney, Esq.

Tavy Deming, Esq.

Kenney, Egan, McCafferty & Young, P.C.

3031C Walton Road, Suite 202

Plymouth Meeting, PA 19462  
610-940-0327  
[www.quitam-lawyer.com](http://www.quitam-lawyer.com)

CONTACT: Brian P. Kenney, Esq., or Tavy Deming, Esq., both of Kenney, Egan,  
McCafferty & Young, P.C., +1-610-940-0327