

Pfizer Pays a Record Amount to Settle Federal and State Fraud Investigations Into Illegal Off-Label Marketing Practices

Kenney, Egan McCafferty & Young Represent Geodon and Zyvox Whistleblowers

PHILADELPHIA, Sept. 2 /PRNewswire/ -- Pfizer, Inc. announced today it has agreed to plead guilty to criminal conduct and to pay more than \$2 billion in criminal and civil fines, penalties and damages to settle 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 four of its drugs. The settlement is the largest qui tam settlement in U.S. history.

Brian Kenney and Tavy Deming of Kenney Egan McCafferty & Young represented the Geodon whistleblowers and served as co-counsel to the Zyvox whistleblower.

As part of the record settlement, Pfizer agreed to pay \$300 million to resolve allegations that it engaged in off-label marketing of its blockbuster atypical antipsychotic Geodon, which generated over \$1 billion dollars in sales in 2008. The allegations were first made in a qui tam lawsuit filed by Kenney and Deming on behalf of Harrisburg psychiatrist, Dr. Stefan Kruszewski. Pfizer also agreed to pay \$100 million to resolve allegations that it improperly marketed its antibiotic Zyvox. That case was filed by Ronald Rainero, a former Pfizer sales manager from New Jersey.

Geodon is FDA-approved only to treat patients ages 18-65 diagnosed with schizophrenia or acute manic or mixed episodes associated with bipolar disorder. However, according to the whistleblower suit unsealed today, Pfizer illegally promoted the sale and use of Geodon for a variety of off-label conditions, including depression, bipolar maintenance, mood disorder, anxiety, aggression, dementia, attention deficit hyperactivity disorder, obsessive compulsive disorder, autism, posttraumatic stress disorder, and for pediatric, adolescent and geriatric patients.

According to Kenney, "Pfizer targeted pediatrics and adolescents to expand off-label use and maintained on its payroll an army of more than 250 child psychiatrists nationwide." Kenney stated that, "Pfizer regularly paid generous speaking fees to these child psychiatrists to give what were basically promotional lectures about the benefits of Geodon to their peers, who were naturally also child psychiatrists, despite the fact the drug is not FDA-approved or medically indicated to treat children at all." According to Kenney, "the purpose and intent of paying so many child psychiatrists is clear -- to gain a foothold within the fastest growing market for antipsychotics -- children. The practice of expansive off-label use is dangerous, particularly in children because the drug has not been evaluated for its safety for the unique physiological make up of children."

According to Deming, even though it is illegal for drug makers to engage in off-label promotion, they find ways to do so because there is so much money to be made from the practice. Deming stated that "less than 5% of the United States population is diagnosed with schizophrenia or bipolar disorder, yet in 2008 Geodon surpassed the blockbuster benchmark of \$1 billion in sales." Deming explained that "after drug makers obtain initial FDA approval for a specific use, they often don't bother with expensive testing that would allow them to request a label extension for other uses. They just market the drug off-label." According to Deming, "if Pfizer had limited its Geodon marketing to on-label uses, as required by law, Pfizer would never have achieved anywhere near the more than \$1 billion in Geodon sales that occurred in 2008."

Pfizer's marketing campaign also emphasized what Pfizer alleged was Geodon's comparatively safe metabolic profile, urging doctors to switch patients on other allegedly more dangerous atypical antipsychotics, such as Zyprexa, Seroquel and Risperdal, to Geodon. According to Kenney, Pfizer's switching campaign "endangered patients by ignoring or materially understating Geodon's serious, and even life threatening, side effects."

According to Kenney, "among Geodon's most dangerous side effects is its potential to affect the heart's rhythm, a condition known as QT prolongation. If the QT interval is increased excessively, conditions are created whereby

unstable heart rhythms can intercede and disrupt the normal, regular rhythm essential for heart function." According to Kenney, "such ventricular rhythm disturbances greatly increase the risk of sudden cardiac death."

Kenney and Deming also served as co-counsel to whistleblower Ronald Rainero, a former Pfizer sales manager who brought a qui tam lawsuit against Pfizer for unlawful marketing practices relating to the antibiotic Zyvox.

As part of the overall settlement, Pfizer agreed to pay \$100 million to resolve allegations that it engaged in the marketing of Zyvox for a variety of off-label conditions beyond the methicillin-resistant *Staphylococcus aureus* ("MRSA") infections for which Zyvox was FDA-approved.

Rainero's complaint alleges that Pfizer made and/or disseminated unsubstantiated and/or false representations or statements about the safety and efficacy of Zyvox in order to further the off label campaigns.

The federal investigation into Pfizer's Geodon marketing practices was conducted by the U.S. Attorney's Office for the Eastern District of Pennsylvania under the direction of U.S. Attorney Michael Levy, Assistant U.S. Attorney Marilyn May and Assistant U.S. Attorney Charlene Keller Fullmer. The federal investigation into Pfizer's Zyvox marketing practices was conducted by the U.S. Attorney's Office for the District of Massachusetts under the direction of Acting U.S. Attorney Michael K. Loucks and Assistant U.S. Attorney Sara Bloom.

Massachusetts Assistant Attorney General Bob Patten led the Geodon and Zyvox investigation on behalf of the states and the National Association of Medicaid Fraud Control Units ("NAMFCU").

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