

## **AstraZeneca Pays \$520 Million to Settle Seroquel Whistleblower Claims**

Kenney & McCafferty Represent Whistleblower Dr. Stefan Kruszewski

PHILADELPHIA, PA April 28, 2010 - AstraZeneca has agreed to pay \$520 million in civil fines, penalties and damages to settle allegations that the company defrauded Medicare, Medicaid and other government-funded health care programs in connection with its marketing and promotional practices for the blockbuster atypical antipsychotic Seroquel. This is the largest settlement of off-label marketing claims brought under the False Claims Act to date that involved civil-only fines. The \$520 million settlement resolves a *qui tam* lawsuit filed by whistleblower Dr. Stefan Kruszewski, one of two relators to file a case. Dr. Kruszewski was represented by Brian Kenney and Tavy Deming of the Kenney & McCafferty law firm, along with William Leonard of Obermayer, Rebmann, Maxwell & Hippel.

Seroquel, a potent atypical antipsychotic, was FDA-approved only for two narrow uses in adults, schizophrenia and manic episodes associated with bipolar I disorder, at the time that Dr. Kruszewski filed his complaint. Harvard-trained psychiatrist Dr. Kruszewski alleged, however, that AstraZeneca engaged in an egregious, long term off-label marketing scheme by specifically targeting children and the elderly when those uses were never properly tested or approved by the FDA and that AstraZeneca marketed the drug for a litany of off-label uses, including depression, anxiety, ADHD and insomnia.

Dr. Kruszewski's complaint further alleged that AstraZeneca arranged for clinical trials that embellished efficacy data and also downplayed the drug's serious side effects. Dr. Kruszewski alleged that AstraZeneca used these studies to stifle physician concerns about the drug's serious treatment-emergent side effects, including type II diabetes, hyperglycemia, cardiovascular complications, heart attacks, stroke, and, in some cases, an increase in the risk of mortality.

"The manipulation and misuse of Seroquel scientific data to support AstraZeneca's off-label marketing campaign was the most disturbing aspect of the case to me," Dr. Kruszewski said. "There were strong indications from AstraZeneca's earliest clinical trials that Seroquel increased the risk of diabetes and induced profound sedation out of proportion to its weak antipsychotic effects."

Kruszewski added that "rather than properly warning doctors and the public, AstraZeneca intentionally covered up the evidence on diabetes and other serious side effects and used the sedative property of Seroquel as a selling point." "In the elderly population, they basically marketed Seroquel as an expensive sleeping pill and put hundreds of thousands of patients at risk for serious medical complications, premature cardiovascular disease, pneumonias, and premature death."

"This was a well thought out marketing campaign that operated on many levels," stated Brian Kenney. "AstraZeneca orchestrated scientific studies, ghost written articles, and the payment of large fees to academic psychiatrists to act as 'thought leaders' to promote the

drug off label. The success can be seen in the huge numbers the campaign generated with 4.9 billion in sales in 2009.” “It’s particularly disconcerting that AstraZeneca successfully co-opted large portions of psychiatric academic community,” added Mr. Kenney.

“From the outset of this case, Dr. Kruszewski was passionate about bringing to light AstraZeneca’s concealment of unfavorable Seroquel studies as well as the company’s improper use of what he deemed to be flawed scientific studies to promote the drug off label,” said Tavy Deming.

The U.S. Attorney's Office for the Eastern District of Pennsylvania conducted the federal investigation into AstraZeneca's Seroquel marketing practices under the direction of U.S. Attorney Michael Levy, Assistant U.S. Attorneys Virginia Gibson and Colin Cherico.

U.S. ex rel. STEFAN KRUSZEWSKI, MD v. ASTRAZENECA PHARMACEUTICALS, LP., Eastern District of Pennsylvania, C.A. No. 06-4004.

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 & McCafferty, P.C. (<http://www.quitam-lawyer.com>)

Kenney & McCafferty ("K&M") specializes in qui tam and tax whistleblower litigation. K&M represents whistleblowers nationwide and has recovered more than \$4 billion for the government in False Claims Act and tax whistleblower cases. Recent K&M pharmaceutical False Claims Act settlements include Pfizer, Inc./Geodon; Eli Lilly/Zyprexa; and Cephalon, Inc./Actiq, Provigil and Gabitril..

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