

Kickbacks to Doctors and Illegal Off label Promotion Found,

Novartis Agrees To \$422.5 Million Settlement With Federal Prosecutors

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Novartis Pharmaceuticals Corp. and federal prosecutors reached a global resolution of criminal allegations regarding the alleged off-label promotion of the Novartis drug Trileptal, approved by the FDA for the treatment of epilepsy, as well as civil allegations relating to Trileptal and five other Novartis drugs. The civil claims concerned the alleged off-label promotion of Trileptal and the payment of kickbacks to health care providers to induce them to prescribe the six drugs, according to Department of Justice officials.

Under the agreement, reached with the U.S. Attorney's Office for the Eastern District of Pennsylvania, Novartis will plead guilty to a misdemeanor misbranding violation of the Federal Food, Drug and Cosmetic Act and pay a fine and forfeiture totaling \$185 million with respect to Trileptal. In addition, the settlement resolves civil allegations brought under the False Claims Act related to the six products. Novartis agreed to pay \$237.5 million as part of the civil settlement, which resolves four qui tam actions brought in federal courts in Florida and Pennsylvania by former Novartis employees. The qui tam relators will share more than \$25.6 million of the federal recovery.

The company also will enter into a five-year corporate integrity agreement (CIA) with the Department of Health and Human Services Office of Inspector General. Novartis said that the terms of the CIA — which include monitoring, auditing, training, education, reporting and disclosure obligations — “will expand upon the company's already strong commitment to sustainable performance built on a solid foundation of ethical values at all levels of business.”

A criminal information filed Sept. 30 charged Novartis with introducing misbranded drugs into interstate commerce between July 2000 and December 2001, alleging that the company promoted Trileptal for off-label uses including the treatment of neuropathic pain and bipolar disease. Novartis said it received a subpoena from federal prosecutors in Philadelphia in 2005 regarding promotional practices related to Trileptal. The company noted that before then it had “already taken steps to correct the challenged practices and comply with new government guidance.” Novartis also said that it had cooperated fully with the government throughout the course of the investigations regarding the six products.

As a mental health reporter for the Boston Globe, Alison Bass knows the side effects of the potent drugs used to treat emotional and mental illness. But as she recounts in her new book, *Side Effects: A Bestselling Drug on Trial*, these effects are not always caused simply by patients' taking medications that are not shown to be safe for them. In all too many cases, they are the consequence of a drug manufacturer's putting profits before the well-being of its customers.

This is a compelling story worthy of a Michael Moore docudrama. It relates how pharmacological research has mis-evolved in the face of unconscionable greed. The cast of characters includes bad guys, devoted do-gooders ridiculed and fired from their jobs, honest researchers thwarted from doing true investigative analysis, and young victims in no position to protect and defend themselves. Its plot is full of intrigue and money placed in questionable places.