



U.S. Department of Justice

United States Attorney

Eastern District of Pennsylvania

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## **NOVARTIS PHARMACEUTICALS CORPORATION SENTENCED FOR OFF-LABEL DRUG MARKETING**

PHILADELPHIA – Novartis Pharmaceuticals Corporation (“NPC”) was formally sentenced today for the off-label marketing of the anti-epileptic drug Trileptal, announced United States Attorney Zane David Memeger. The company pleaded guilty November 2, 2010 to a criminal information before U.S. District Court Judge Joel H. Slomsky. Consistent with the terms of the plea agreement, NPC was ordered to pay a criminal fine and forfeiture of \$185M for illegally marketing and promoting Trileptal for uses not approved by the Food and Drug Administration (“FDA”).

The information filed by the government charged NPC with introducing misbranded drugs into interstate commerce between July 2000 and December 2001. The FDA had approved Trileptal (chemical name “oxcarbazepine”) for the treatment of epilepsy patients but NPC’s management created marketing materials promoting Trileptal for off-label uses, including neuropathic pain and bipolar disease. The information charged that NPC decided to market and promote Trileptal as a treatment for both of these indications and directed its sales force to visit doctors who would not normally prescribe Trileptal due to the nature of their practice. The company also allegedly funded continuing medical education programs, using other medical professionals to promote off-label uses of Trileptal. According to the information, NPC profited by hundreds of millions of dollars from this misbranding and off-label promotion of Trileptal.

In a separate civil settlement agreement, announced in September, NPC agreed to pay the United States and participating states \$237.5 million, plus interest, to settle federal False Claims Act allegations that it caused invalid claims for payment for Trileptal, Diovan, Tekturna, Exforge, Sandostatin and Zelnorm to be submitted to government programs such as Medicare, Medicaid, TRICARE, and the Federal Employees Health Benefits Program and caused purchases of those drugs by the Department of Veterans Affairs, Department of Defense, Defense Logistics Agency, and the Department of Labor. The state Medicaid programs and the District of Columbia will share \$88,258,694 of the settlement.

“Part of the mission of this office is to ensure that individuals and companies comply with the law, that government programs financed with American tax dollars are not exploited, and that the public is protected from unsafe practices,” said Memeger.

“The sentence levied today demonstrates the government's continued commitment to hold pharmaceutical companies accountable for illegal promotional activity that put their profits ahead of the public health,” said Acting Special Agent in Charge Kathleen Martin-Weis. “The FDA will continue to pursue criminal resolutions when pharmaceutical companies undermine the drug approval process by promoting drugs for uses not approved by the FDA as safe and effective.”

This resolution is part of the Eastern District of Pennsylvania’s Special Focus team Health Care Fraud initiative.

This case was investigated by the Food and Drug Administration’s Office of Criminal Investigations, the Department of Health and Human Services Office of the Inspector General, and the United States Postal Service Office of Inspector General. Assistance was provided by representatives of the FDA’s Office of Chief Counsel and the National Association of Medicaid Fraud Control Units. The Corporate Integrity Agreement was negotiated by Department of Health and Human Services’ Office of the Inspector General.

The criminal case was prosecuted by Assistant United States Attorneys Karen Marston, Frank Costello, Special Assistant United States Attorney Catherine Votaw, and Department of Justice Office of Consumer Litigation Trial Attorney Patrick Jasperse. The civil case was prosecuted by Assistant United States Attorneys Marilyn May, Jacqueline Romero, and Paul Kaufman and by United States Department of Justice Civil Frauds Division Trial Attorney Jessica Champa.

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