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NOVARTIS PHARMACEUTICALS CORPORATION TO PAY
\$422.5 MILLION FOR OFF-LABEL DRUG MARKETING
Company reaches plea and civil settlement agreements

PHILADELPHIA – A criminal information¹ was filed today against Novartis Pharmaceuticals Corporation (“NPC”) for the off-label marketing of the anti-epileptic drug Trileptal, announced Assistant Attorney General for the Justice Department’s Civil Division Tony West and United States Attorney Zane David Memeger. NPC has agreed to plead guilty and pay a criminal fine and forfeiture of \$185 million. NPC will also pay \$237.5 million to resolve civil liabilities for its off-label marketing of Trileptal and payment of kickbacks to health care providers to induce them to prescribe Trileptal, as well as Diovan, Exforge, Tekturna, Zelnorm, and Sandostatin.

Joining in today’s announcement were Special Agent-in-Charge Thomas P. Doyle of the Food and Drug Administration’s Office of Criminal Investigation, Special Agent-in-Charge Nicholas DiGiulio of the Department of Health and Human Services’ Office of Inspector General, and Special Agent-in-Charge Elizabeth Farcht of the United States Postal Service’s Office of Inspector General.

The information charges NPC with introducing misbranded drugs into interstate commerce between July 2000 and December 2001. The Food and Drug Administration (“FDA”) had approved Trileptal (chemical name “oxcarbazepine”) for the treatment of epilepsy patients. According to the information, NPC’s management created marketing materials promoting Trileptal for off-label uses, including neuropathic pain and bipolar disease, which were not FDA-approved uses. NPC allegedly targeted psychiatrists and pain specialists, who were known to use anti-epileptic drugs like Trileptal off-label. The information charges 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.

¹An information is an accusation. A defendant is presumed innocent unless and until proven guilty.

“This resolution demonstrates the Department of Justice’s ongoing dedication to taking action against pharmaceutical fraud in all its forms,” said Tony West, Assistant Attorney General for the Civil Division of the Department of Justice. “Unlawful off-label promotion and providing illegal inducements to health care professionals undermine the integrity of our health care system and we will continue to pursue these types of violations.”

“Off-label marketing can undermine the doctor-patient relationship and adversely influence the clear judgment that a doctor’s patients have come to rely on and trust,” said Memeger. “Pharmaceutical companies have a legal obligation to promote the drugs they manufacture only for uses that the Food and Drug Administration has deemed are safe and effective. That legal obligation takes priority over a company’s bottom line. This prosecution demonstrates our continuing commitment to ensure that pharmaceutical companies comply with the law.”

In a separate civil settlement agreement, NPC agreed to pay the United States and participating states \$237.5 million, plus interest, to settle 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.

The civil settlement resolves claims that NPC knowingly promoted the sale of Trileptal for off-label uses including bipolar disorder and neuropathic pain, and paid illegal kickbacks to health care professionals through mechanisms such as speaker programs, advisory boards, entertainment, travel and meals to induce them to prescribe Trileptal, as well as Diovan, Zelnorm, Sandostatin, Exforge and Tekturna.

“Today's settlement demonstrates the government's continued scrutiny of the sales and marketing practices of pharmaceutical companies that put profits ahead of the public health,” said Special Agent-in-Charge Thomas Doyle, FDA’s Office of Criminal Investigations. “We will continue to seek this kind of criminal resolution and stiff sanctions when pharmaceutical companies undermine the drug approval process by promoting drugs for uses not approved by the FDA as safe and effective.”

“OIG will carefully monitor the Corporate Integrity Agreement to ensure that Novartis is more transparent in its business transactions, that its Board of Directors is held more accountable, and that the names of physicians receiving payments are publicly disclosed,” said Department of Health and Human Services Inspector General Daniel R. Levinson. “The result will be stronger protections for patients and the nation's taxpayers.”

“This settlement is a significant victory in the on-going effort against fraudulent workers’ compensation claims,” said Special Agent-in-Charge Elizabeth Farcht, of the United States

Postal Service Office of Inspector General’s Eastern Area Field Office. “The workers’ compensation program benefits thousands of postal employees and the Postal Service pays millions of dollars for these benefits. When our employees are treated with drugs promoted for use in an off-label manner, this has the potential for causing patient harm and leads to inflated program costs for the Postal Service. This is why it is important that we participate in these joint investigations,”

This settlement also resolves four qui tam (“whistle blower”) actions: *United States ex rel. Jim Austin v. Novartis Pharmaceuticals Corporation*, Civil Action No. 03-1551 (United States District Court for the Middle District of Florida); *United States ex rel. Daryl Copeland v. Novartis Pharmaceuticals Corp.*, Civil Action No. 06-1630 (United States District Court for the Eastern District of Pennsylvania); *United States ex rel. Steve McKee v. Novartis Pharmaceuticals Corporation*, Civil Action No. 04-1664 (United States District Court for the Eastern District of Pennsylvania); *United States ex rel. Jeremy Garrity v. Novartis Pharmaceuticals Corporation*, Civil Action No. 08-2588 (United States District Court for the Eastern District of Pennsylvania). These cases were filed by former NPC employees who identified the company’s illegal marketing practices. To encourage individuals to come forward and identify companies that defraud the government, federal law permits whistle blowers to share in the recovery for such fraud. In this case, the whistle blowers will share in \$25,675,035 of the federal recovery.

NPC also signed a Corporate Integrity Agreement (CIA) with the Department of Health and Human Services, Office of Inspector General (HHS-OIG). The company is subject to exclusion from Federal health care programs, including Medicare and Medicaid, for a material breach of this CIA and subject to monetary penalties for less significant breaches. Among other things, the CIA requires the Board of Directors (or a committee of the Board) to annually review the company's compliance program with the help of an outside expert and certify its effectiveness; that certain senior executives annually certify that their departments or functional areas are compliant; that NPC send doctors a letter notifying them about the settlement; and that the company posts on its website information about payments to doctors, such as honoraria, travel or lodging. The five-year agreement further requires the implementation of a compliance program addressing promotional activities.

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.

NPC's guilty plea and sentence are not final until accepted by the United States District Court. The U.S. Attorney's Office acknowledges NPC's cooperation with the investigation and resolution of this case.

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