Novartis fined $422.5M in marketing, kickback case

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U.S. Attorney Zane David Memeger, from left, speaks as Nicholas DiGiulio from the Department of Health and Human Services and Thomas Doyle from the Food and Drug Administration look on during a news conference about Novartis Pharmaceuticals Corp., Thursday, Sept. 30, 2010, in Philadelphia. The U.S. Justice Department says the pharmaceutical maker has agreed to pay $422.5 million stemming from illegal marketing of the anti-epileptic drug Trileptal and five other drugs. (AP Photo/Matt Slocum)

(AP) -- Novartis Pharmaceuticals Corp. will pay $422.5 million in penalties for marketing an epilepsy medicine for unapproved uses and for paying kickbacks to doctors to prescribe it and five other drugs, federal officials announced Thursday.

The company agreed to plead guilty to distribution of a misbranded drug, a misdemeanor, and pay a criminal fine and forfeiture totaling

$185 million in the case involving Trileptal, U.S. Attorney Zane Memeger said at news conference in Philadelphia.

"Every day in this country, patients rely on sound advice from their doctors," Memeger said. "Off-label marketing ... can undermine the doctor-patient relationship."

Novartis will also pay $237.5 million to resolve civil liabilities over the kickbacks and the off-label marketing of Trileptal, an anti-epileptic medicine, according to a settlement agreement.

The drug maker illegally marketed Trileptal as a treatment for bipolar disorder and nerve pain, sending its sales force to the offices of neurologists, psychiatrists and pain specialists, Memeger said.

While doctors are permitted to prescribe medications for off-label uses based on their medical experience, pharmaceutical companies are not allowed to market or promote drugs for uses not approved by the Food and Drug Administration, Memeger said.

"That legal obligation takes priority over generating profits," he said.

Federal prosecutors do not allege any patients were harmed by the off-label marketing.

"NPC is pleased to have this matter behind us, and will continue to work with the government and other organizations to improve health care for all Americans," the company said in a statement. "We are committed to high standards of ethical business conduct and regulatory compliance in the sale and marketing of our products."

The criminal information filed Thursday in Philadelphia alleges that Novartis sought FDA approval in 1995 to sell Trileptal as a treatment for

mania - a component of bipolar disorder - but that it was not effective in clinical trials.

After beginning sales of Trileptal as an anti-epileptic drug in January 2000, the company was disappointed by poor sales and sought new ways to promote it. Novartis trained and rewarded sales reps for off-label marketing, the information said.

Prosecutors allege Novartis marketed the drug off-label from July 2000 through at least June 2004.

Recent sales figures for Trileptal are not reported because it is no longer a top 20 product, Novartis spokeswoman Julie Masow said.

The government also alleges Novartis paid kickbacks to induce doctors to prescribe Trileptal as well as Diovan, Exforge, Tekturna, Zelnorm and Sandostatin.

The announcement Thursday resolves four whistle-blower lawsuits filed by former Novartis employees who reported the off-label marketing. They will share $25.6 million of the penalty money.

Novartis became aware of the government's investigation five years ago and had set aside $397 million by the end of 2009 in anticipation of a resolution, according to a quarterly financial report the company filed Jan. 26.

The drug maker, which cooperated with the probe, has entered into a corporate integrity agreement with the government that will subject the company to strict monitoring.

Novartis Pharmaceuticals, based in East Hanover, N.J., is a subsidiary of Swiss company Novartis AG, the world's third-biggest drug maker by

revenue.