

# Drug maker Novartis pays \$390 million to settle kickback claims

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Last month Swiss drug maker Novartis agreed to pay \$390 million to settle a federal case charging that the company allegedly gave kickbacks to specialty pharmacies in order to boost sales of its products. The US Justice Department was preparing to seek \$3.35 billion in damages if the case went to trial. As part of the settlement, the company admits to no wrongdoing and, in fact, continues to employ the same tactic.

According to a June court filing by the Justice Department, Novartis allegedly orchestrated kickback schemes to promote its iron chelation drug Exjade and its immunosuppressant drug Myfortic.

Novartis gave rebates to the specialty pharmacy companies Accredo, BioScrip and US Bioservices in exchange for recommending that patients get refills of Exjade; likewise, the company gave “performance rebates” to five other specialty pharmacies (Kilgore’s, Bryant’s, Baylor, Twenty Ten, and Transcript) to induce the pharmacies to recommend Myfortic over the competitor drug CellCept and generic versions of CellCept.

The court filing stemmed from a 2011 whistleblower lawsuit brought by a former Novartis sales manager who claims the company paid doctors for travel and speaker dinners in exchange for prescribing the company’s drugs. The filing states that as a result of the kickback scheme, the specialty pharmacies received \$492.9 million in reimbursement from Medicaid and Medicare for Exjade and \$14.6 million in reimbursement for Myfortic.

The company says that the rebates are used to ensure patient compliance. Chief executive Joe Jimenez says that Novartis continues to employ this “quite common” practice. “We continue to maintain that specialty pharmacies must continue to play a role in ensuring patient adherence,” he said in a statement announcing

the settlement. “How that is going to play out as to whether we change our behavior or not remains to be seen.”

Valeant Pharmaceuticals, which is notorious for purchasing drugs from other companies and then dramatically hiking their prices, is facing similar questions from the Justice Department over its relationship to the mail-order specialty pharmacy Philidor Rx Services LLC.

Pharmaceutical companies often use specialty pharmacies to distribute and administer their products because it is a way of ensuring that their high-priced drugs get sold, instead of less-expensive generic alternatives. Specialty pharmacies were initially established to assist patients with complex drugs that required complicated administration for diseases like cancer or rare genetic disorders, but are now used for more common ailments.

“What was started as administering complex, costly drugs has been co-opted as a sales/marketing tool to drive the growth of minor differentiation standard retail drugs,” says Ronny Gal, a pharmaceutical analyst at Sanford Bernstein, a global asset management firm, as quoted in the *New York Times*.

Novartis was formed in 1996 through the merger of Ciba-Geigy and Sandoz. It is now the largest pharmaceutical company in the world, with global sales of \$47.1 billion in 2014.

The company has gained notoriety over the pricing of its cancer drug Gleevec, which has more than tripled in price since it was first approved in 2001. (See: “Doctors protest high prices of cancer drugs in US”). In the late 1990s and early 2000s, the company unsuccessfully sought patent protection for Gleevec in India in an effort to sell the drug for \$2,666 per month, instead of the \$177-266 per month priced by generic

competitors.

In 2010, the company's US subsidiary, Novartis Pharmaceuticals Corporation, paid \$180 million to resolve allegations it was selling its seizure drug Trileptal for off-label uses, pleading guilty to misdemeanor misbranding of the drug. It also paid \$237.5 million to resolve civil allegations of off-label marketing of five other products: Diovan, Exforge, Sandostatin, Tekturna and Zelnorm. In addition to illegally marketing the products for unapproved uses, the company is alleged to have offered doctor's financial inducements to prescribe the drugs, including entertainment, travel, and payments for speaker programs.

As a result of the 2010 settlement, Novartis signed a "Corporate Integrity Agreement" requiring the company to establish an internal compliance program for the next five years. Since the most recent violations took place within this five-year period, Novartis could have potentially been excluded from lucrative contracts with federal health care plans, but the Justice Department chose not to pursue this in its filing.

The Novartis settlement is but another example of the rampant criminality and parasitism found throughout the pharmaceutical industry. Indeed, these companies see cash settlements for criminal behavior as merely the cost of doing business, even as the Justice Department has ramped up the size of the penalties.

Recent major settlements include the \$950 million paid by Merck in 2011 for downplaying the cardiovascular safety risks of its pain drug Vioxx; the \$1.6 billion paid by Abbott Laboratories in 2012 for the off-label promotion of its seizure drug Depakote; and the \$3 billion paid by GlaxoSmithKline in 2012 for the off-label marketing of its anti-depressant drugs Paxil and Welbutrin, various kickback schemes, and withholding safety data from the FDA to downplay the health risks associated with its diabetes drug Avandias. According to *FiercePharma*, the pharmaceutical industry was fined \$14 billion for such practices between 2002 and 2012.

While the actions of these drug companies have placed millions of lives at risk, the civil and criminal penalties are paltry in comparison to the industry's profits. Between 2003 and 2012, for example, the 11 largest drug makers made \$711.4 billion in profits, according to an analysis of corporate filings by the

lobbying group Health Care for America Now (HCAN). Novartis alone pulled in \$83.1 billion during this period.



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