

## Merck to Pay \$950 Million in Vioxx Settlement

The Wall Street Journal November 23, 2011

[Merck](#) & Co. agreed to pay \$950 million and plead guilty to a criminal misdemeanor charge to resolve government allegations that the company illegally promoted its former painkiller Vioxx and deceived the government about the drug's safety.

The settlement of a seven-year U.S. government investigation brings Merck closer to resolving the mountain of litigation that followed the company's 2004 withdrawal of the big-selling drug from the market after a study showed it increased the risk for heart attacks and strokes.

It marks the latest big payout by a drug company to settle health-care fraud allegations, underscoring heightened government scrutiny of the way drug makers do business. [GlaxoSmithKline](#) PLC recently reached an agreement in principle to pay \$3 billion to settle U.S. allegations of improper drug marketing. [Pfizer](#) Inc., [Eli Lilly](#) & Co. and [AstraZeneca](#) PLC also have reached costly settlements in recent years.

The DOJ said Merck illegally promoted Vioxx for rheumatoid arthritis before the FDA approved that use.

The Merck settlement also boosts the company's Vioxx-related legal costs. The company previously agreed to pay \$4.85 billion to settle thousands of product-liability lawsuits alleging Vioxx caused injuries and deaths.

Merck recorded more than \$11 billion in Vioxx sales during the drug's years on the market from mid-1999 to September 2004. The company has paid nearly \$6 billion in litigation settlements so far, not including legal-defense costs and possible payments from pending litigation.

Merck, of Whitehouse Station, N.J., had reserved the \$950 million settlement amount in 2010, but the final agreement—with more details about the allegations—was announced Tuesday by the U.S. Department of Justice.

The Justice Department said Merck illegally promoted Vioxx for rheumatoid arthritis before that use was approved by the Food and Drug Administration in 2002. The drug was initially approved in 1999 to treat certain types of pain. Drug companies are barred from promoting drugs for unauthorized, or "off label," uses, though doctors may prescribe off-label uses.

Merck agreed to plead guilty to introducing a "misbranded" Vioxx into interstate commerce, which is a misdemeanor violation of the Food, Drug and Cosmetic Act, and to pay a \$321.6 million criminal fine. The company agreed to pay \$628.4 million to settle civil allegations.

Merck spokesman Ronald Rogers said some sales representatives promoted Vioxx to treat rheumatoid arthritis before FDA approval, and said Merck's planned guilty plea to a violation of the Food, Drug and Cosmetic Act would be the first such plea in the company's history.

The government also made allegations against Merck in parallel civil litigation related to Vioxx in addition to the criminal charges.

According to the government, Merck representatives made inaccurate, unsupported or misleading statements about Vioxx's cardiovascular safety, in order to increase sales of the drug. The government also said Merck made false statements to state Medicaid agencies about the drug's safety.

Merck isn't admitting liability or wrongdoing in the civil aspect of the settlement. Mr. Rogers said Merck expressly denies the civil allegations.

"We believe that Merck acted responsibly and in good faith in connection with the conduct at issue in these civil settlement agreements, including activities concerning the safety profile of Vioxx," said Merck General Counsel Bruce Kuhlik in a statement.

That position is consistent with Merck's position throughout the product-liability litigation: The company never admitted liability in lawsuits alleging Vioxx caused heart attacks and strokes, and that Merck failed to properly warn of these risks. Merck's 2007 settlement of the product-liability cases included no admission of wrongdoing.

Some juries concluded otherwise, awarding multimillion-dollar payments to former Vioxx users or their families in trials, while Merck won other product-liability trials.

A majority of the money from Tuesday's settlement will go to the federal government, with the rest shared among 43 states and the District of Columbia. Several states didn't participate in the settlement, and litigation remains outstanding.

Merck shares fell 33 cents, or 1%, to \$33.81 in 4 p.m. New York Stock Exchange trading Tuesday.