

Justice Department says Shire will pay \$56.5M fine

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The U.S. Department of Justice said Wednesday that Irish drugmaker Shire will pay \$56.5 million to settle allegations it broke the law in promoting five different drugs, including its attention deficit disorder drugs Adderall XR and Vyvanse.

According to a whistleblower lawsuit, Shire said ADHD patients who took Adderall XR would be "indistinguishable" from people who don't have the condition. It also suggested that the drug would prevent patients from getting bad grades, losing their jobs, engaging in criminal behavior, getting into traffic accidents, and acquiring sexually transmitted diseases. Shire is also alleged to have marketed Adderall XR as a treatment for conduct disorder even though it did not have approval to do so.

Shire is alleged to have said Vyvanse would also help prevent car accidents, divorce, arrests, and unemployment. It also allegedly said Vyvanse and its Daytrana patch were less likely to be abused than other medications. The government said Shire marketed Lialda, a treatment for ulcerative colitis, for the prevention of colorectal cancer.

The Justice Department said the claims made by Shire representatives are not backed by evidence from clinical trials. The allegations cover activities stretching from January 2004 to September 2010.

Shire confirmed it had agreed to settle the investigation, and also said it will make an additional payment of \$2.9 million to the state of Louisiana to resolve allegations it violated state law. The company did not

acknowledge any wrongdoing. Shire PLC will pay \$35.7 million to the federal government and \$20.8 million to state Medicaid programs.

The company reported \$359.5 million in revenue from Vyvance during second quarter. That was almost 25 percent of its total revenue.

In July, Dublin-based Shire agreed to combine with U.S. drugmaker AbbVie in a deal valued at about \$55 billion. The new company will be controlled by AbbVie's shareholders, but it will be based overseas, allowing it to benefit from lower corporate tax rates.

U. S.-traded shares of Shire rose \$5.35, or 2.1 percent, to \$256.09 on Wednesday and lost 35 cents to \$255.74 in aftermarket trading.

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