

Merck will pay \$950M to settle Vioxx investigation

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(AP) -- The Department of Justice said Tuesday that drugmaker Merck will pay \$950 million to resolve investigations into its marketing of the painkiller Vioxx.

The agency said Merck will pay \$321.6 million in criminal fines and \$628.4 million as a civil settlement agreement. It will also plead guilty to a misdemeanor charge that it marketed Vioxx as a treatment for rheumatoid arthritis before getting Food and Drug Administration approval.

The government will get \$426.4 million from the settlement, and \$202 million will be distributed to state Medicaid programs for 43 states and the District of Columbia.

Merck stopped selling Vioxx in September 2004 after evidence showed the drug doubled the risk of heart attack and stroke. In 2007 the company paid \$4.85 billion to settle around 50,000 Vioxx-related lawsuits. The Justice Department said the settlement resolves allegations that Merck made false, unproven, or misleading statements about Vioxx's safety to increase sales and made false statements to Medicaid agencies about its safety.

Merck said the settlement does not constitute an admission of any liability or wrongdoing, and it said the government acknowledged that there was no basis to conclude that Merck's upper-level management was involved in the violations.

Merck also entered into an agreement about its sales, marketing, publication, and government pricing activities. The Justice Department said that agreement strengthens oversight of the company. It will require top officials to complete annual compliance certifications, and the company will post information about physician payments on its website.

The Whitehouse Station, N.J., company took a charge of \$950 million in the third quarter of 2010

to cover the anticipated settlement payments.

Vioxx was approved by the FDA in May 1999, but the government did not initially approve the drug for use in rheumatoid arthritis. That meant doctors could write prescriptions for Vioxx for rheumatoid arthritis patients, but Merck could not promote the drug for that use. The Justice Department said Merck promoted Vioxx for rheumatoid arthritis for three years and continued to do so after getting an FDA warning letter in September 2001. The drug was approved as a treatment for rheumatoid arthritis in April 2002.

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