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U.S. Pharmaceutical Company Merck Sharp & Dohme to Pay Nearly One Billion Dollars Over Promotion of Vioxx®

Merck to Pay $950 Million for Illegal Marketing

WASHINGTON – American pharmaceutical company Merck, Sharp & Dohme has agreed to pay $950 million to resolve criminal charges and civil claims related to its promotion and marketing of the painkiller Vioxx® (rofecoxib), the Justice Department announced today. Under the terms of the resolution, Merck will plead guilty to a one-count information charging a single violation of the Food Drug and Cosmetic Act (FDCA) for introducing a misbranded drug, Vioxx®, into interstate commerce. Under the terms of its plea agreement with the United States, Merck will plead guilty to a misdemeanor for its illegal promotional activity and will pay a $321,636,000 criminal fine.

Merck is also entering into a civil settlement agreement under which it will pay $628,364,000 to resolve additional allegations regarding off-label marketing of Vioxx® and false statements about the drug's cardiovascular safety. Of the total civil settlement, $426,389,000 will be recovered by the United States, and the remaining share of $201,975,000 will be distributed to the participating Medicaid states. The settlement and plea conclude a long-running investigation of Merck's promotion of Vioxx®, which was withdrawn from the marketplace in September 2004.

Merck's criminal plea relates to misbranding of Vioxx® by promoting the drug for treating rheumatoid arthritis, before that use was approved by the Food and Drug Administration (FDA). Under the provisions of the FDCA, a company is required to specify the intended uses of a product in its new drug application to FDA. Once approved, the drug may not be marketed or promoted for so-called "off-label" uses – any use not specified in an application and approved by FDA – unless the company applies to the FDA for approval of the additional use. The FDA approved Vioxx® for three indications in May 1999, but did not approve its use against rheumatoid arthritis until April 2002. In the interim, for nearly three years, Merck promoted Vioxx® for rheumatoid arthritis, conduct for which it was admonished in an FDA warning letter issued in September 2001.

The parallel civil settlement covers a broader range of allegedly illegal conduct by Merck. The settlement resolves allegations that Merck representatives made inaccurate, unsupported, or misleading statements about Vioxx's cardiovascular safety in order to increase sales of the drug, resulting in payments by the federal government. It also resolves allegations that Merck made false statements to state Medicaid agencies about the cardiovascular safety of Vioxx, and that those agencies relied on Merck's false claims in making payment decisions about the drug. Finally, like the criminal plea, the civil settlement also recovers damages for allegedly false claims caused by Merck's unlawful promotion of Vioxx for rheumatoid arthritis.

"When a pharmaceutical company ignores FDA rules aimed at keeping our medicines safe and effective, that company undermines the ability of health care providers to make the best medical

decisions on behalf of their patients," said Tony West, Assistant Attorney General for the Civil Division of the Department of Justice. "As this plea agreement and civil settlement make clear, we will not hesitate to pursue those who skirt the proper drug approval process and make misleading statements about the safety and efficacy of their products."

"Today's resolution appropriately reflects the severity of Merck's conduct; it is yet another reminder that the United States will not tolerate misconduct by drug companies that bends the rules and puts patient safety at risk," announced Carmen M. Ortiz, U.S. Attorney for the District of Massachusetts. "Any marketing activity that ignores the importance of FDA approval, or that makes unsupported safety claims about a drug is unacceptable, and will be pursued vigorously in both the criminal and civil arena."

As part of the settlement, Merck has also agreed to enter into an expansive corporate integrity agreement with the Office of Inspector General of the Department of Health and Human Services (HHS-OIG), which will strengthen the system of reviews and oversight procedures imposed on the company. Although Vioxx is no longer on the market, this ongoing monitoring of Merck's conduct is aimed to deter and detect similar conduct in the future.

"We will continue to work with our law enforcement partners to aggressively investigate and prosecute pharmaceutical companies – no matter how large – when they improperly market their products," said Daniel R. Levinson, Inspector General of the United States Department of Health and Human Services. "Merck's comprehensive corporate integrity agreement requires top company officials to complete annual compliance certifications, and obligates Merck to post information about physician payments on its website."

This case was handled by the Justice Department's Civil Division and the U.S. Attorney's Office for the District of Massachusetts. The investigation was conducted by HHS-OIG, the FBI, the Office of Criminal Investigations for the FDA, the Veterans Administration's Office of Criminal Investigations, the Office of the Inspector General for the Office of Personnel Management, the National Association of Medicaid Fraud Control Units, and the offices of various state attorneys general.