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Merck to Plead Guilty, Pay $950M in U.S. Vioxx Probe

By Jef Feeley and David Voreacos - Nov 23, 2011

Merck & Co. (MRK), the second-largest U.S. drugmaker, will pay $950 million and a unit of the company will plead guilty to a criminal misdemeanor charge to resolve a U.S. probe of its illegal marketing of the painkiller Vioxx.

Merck Sharp & Dohme will plead guilty to one count of misbranding Vioxx, the company and U.S. prosecutors said yesterday. The company will pay a $321.6 million criminal fine and $628.3 million to resolve civil claims that it sold Vioxx for unapproved uses and made false statements about its cardiovascular safety.

The "resolution appropriately reflects the severity of Merck's conduct and is yet another reminder that the government will not tolerate misconduct by drug companies that bend the rules and put patient safety at risk," Carmen Ortiz, the U.S. attorney in Boston, said yesterday in a statement. Prosecutors in her office led the seven-year investigation into the company's Vioxx marketing tactics.

Approved by the Food and Drug Administration in 1999, Vioxx became Merck's third largest-selling drug by 2003, generating $2.5 billion in annual sales. The company pulled Vioxx off the market in 2004 after a study found it posed an increased risk of heart attacks and strokes.

Patient Lawsuits

The company, based in Whitehouse Station, New Jersey, already paid $4.85 billion to settle thousands of patient lawsuits claiming injuries, and another $1.9 billion for legal costs. It set aside $950 million in October 2010 for the criminal settlement announced yesterday.

"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," Bruce N. Kuhlik, the company's general counsel, said in a statement.

The shares fell 38 cents, or 1.1 percent, to $33.43 at 9:41 a.m. in New York Stock Exchange composite trading.

Merck Sharp & Dohme will plead guilty to violating the Food, Drug and Cosmetic Act by distributing a misbranded drug, the Justice Department said. The company will admit that between May 1999 and April 2002, it sold Vioxx for rheumatoid arthritis when it was not approved by the FDA for that use. Merck got such an approval in April 2002.

Warning Letter

Before that approval, the company touted Vioxx to physicians for rheumatoid arthritis, prompting the FDA to send a warning letter on Sept. 17, 2001. The letter said Merck made a misleading claim suggesting that "Vioxx is effective for the treatment of rheumatoid arthritis when this has not been demonstrated," according to the criminal charge that Merck Sharp & Dohme will admit in federal court in Boston.

The charge also cites eight instances of sales representatives recording in their notes of calls to physicians how they promoted Vioxx for rheumatoid arthritis.

As part of the plea agreement, prosecutors acknowledged that "there was no basis for a finding of high-level management participation in the violation," Merck said in a statement.

Merck previously disclosed that federal prosecutors in Boston had identified the company in March 2009 as a target of a grand jury investigation. Prosecutors began examining the company's handling of internal research into Vioxx's heart- attack and stroke risks and the company's marketing tactics in selling the drug starting in 2004, the company said yesterday.

The company won 11 of 16 Vioxx lawsuits at trial before agreeing in 2007 to create the $4.85 billion settlement fund. The accord called for the company to pay about $4 billion to resolve heart-attack claims and about $850 million to settle stroke suits, according to court filings.

Potential Harm

Former Vioxx users who sued in state and federal courts claimed Merck didn't adequately disclose safety data to the FDA, failed to properly warn doctors and patients of the drug's risks, and misrepresented the potential harm in marketing materials.

They accused Merck officials of withholding data in 2000 about a clinical trial that found Vioxx caused five times more heart attacks than another painkiller and publishing misleading and inaccurate information about the drug's health risks.

The civil claims, which were brought by both state and federal governments, focused on the sale of Vioxx for unapproved uses and misleading statements Merck officials allegedly made about the painkiller's safety, according to court filings outlining the settlement.

Sales Practices

Regulators said Merck employees made “false representations concerning the safety of Vioxx to state Medicaid agencies” on which state officials relied in deciding to cover Vioxx prescriptions, according to the court filings. Medicaid is the state-federal health-care funding program.

The settlement also resolves claims brought by 43 state attorneys general over the company’s marketing and sales practices in connection with Vioxx, Merck officials said in their statement. The states will share about $202 million. The federal government will get $426.4 million.

Litigation over reimbursement for state Medicaid programs continues with seven states, the company said.

In the only case over the Medicaid claims to go to trial, a federal judge in New Orleans concluded last year Merck didn’t have to pay $20 million in damages over claims it misled state officials about Vioxx. Merck won judgments in three states, according to spokesman Ronald Rogers.

Dropped Appeal

Louisiana’s lawyers decided to drop their appeal of that ruling and the state will receive more than $9.7 million as its share of settlement of Medicaid claims over Merck’s Vioxx marketing, officials said in a statement yesterday.

The company agreed in 2008 to pay $58 million to settle claims by 29 states that the company’s TV ads for Vioxx were deceptive and hid the drug’s health risks. Under that accord, Merck officials have to submit all future TV ads to the FDA for review.

As part of the settlement announced yesterday, Merck also agreed to set up a monitoring program to insure compliance with federal laws and regulations in connection with the marketing of its drugs, the company said.

The Louisiana case is State of Louisiana v. Merck Sharp & Dohme Corp., 05-3700, U.S. District Court, Eastern District of Louisiana (New Orleans).

To contact the reporters on this story: Jef Feeley in Wilmington, Delaware, at jfeeley@bloomberg.net; David Voreacos in Newark, New Jersey, at dvoreacos@bloomberg.net.

To contact the editor responsible for this story: Michael Hytha at mhytha@bloomberg.net.