

## Pfizer to pay \$2.3 billion, agrees to criminal plea

By Ransdell Pierson, Jeremy Pelofsky

NEW YORK/WASHINGTON (Reuters) - Pfizer Inc agreed on Wednesday to plead guilty to a U.S. criminal charge relating to promotion of its now-withdrawn Bextra pain medicine and will pay a record \$2.3 billion to settle allegations it improperly marketed 13 medicines.

The world's biggest drugmaker was slapped with the huge fines by the U.S. government after being deemed a repeat offender in pitching drugs to patients and doctors for unapproved uses.

Pfizer pleaded guilty in 2004 to an earlier criminal charge of improper sales tactics and its practices have been under U.S. supervision since then.

"If another one of these charges crops up, it would raise questions whether Jeff Kindler is keeping everyone at Pfizer on a tight enough leash," said Miller Tabak analyst Les Funtleyder, referring to Pfizer's chief executive office

Kindler had been Pfizer's general counsel from 2002 until taking the helm in 2006. Pfizer declined to comment when asked if he had negotiated the 2004 settlement, and whether he had recommended any safeguards at the time to prevent the kind of recurrent improprieties described on Wednesday.

The company in January said it took a \$2.3 billion charge late last year to resolve allegations involving Bextra and other drugs, but did not provide details at the time

"The size and seriousness of this resolution, including the huge criminal fine of \$1.3 billion, reflect the seriousness and scope of Pfizer's crimes," said Mike Loucks, acting U.S. attorney for the District of Massachusetts.

The settlement includes a \$1.3 billion criminal fine related to methods of selling Bextra, which was withdrawn from the market in 2005 on safety concerns. Pfizer acquired Bextra in its 2003 purchase of Pharmacia Corp.

Pfizer's marketing team promoted Bextra for acute pain, surgical pain and other unapproved uses, while its salesforce promoted the drug directly to doctors for those unapproved uses and dosages, according to the U.S. Department of Justice.

The company and Pharmacia also used advisory boards, consultant meetings and provided travel to lavish resorts to improperly promote Bextra to doctors and made misleading claims about the drug's safety and efficacy, the government said.

The settlement also includes \$1 billion in civil payments related to so-called "off-label" sales of drugs -- meaning for uses not authorized by the U.S. Food and Drug Administration -- and payments to healthcare professionals. Pfizer denied all of the civil allegations, except for acknowledging improper promotions of the antibiotic Zyvox.

"We regret certain actions taken in the past, but are proud of the action we've taken to strengthen our internal controls," said Amy Schulman, Pfizer's general counsel.

Justice Department officials said cracking down on fraud in the healthcare industry was a key priority and comes as President Barack Obama is trying to push through reforms of the \$2.5 trillion healthcare system to clip soaring costs.

The settlement and guilty plea are not expected to significantly hurt Pfizer's ability to sell drugs, Morningstar analyst Damien Conover said. "However, it could send the wrong message at a time when you're making some pretty critical negotiations with the U.S. government on healthcare reform."

Sandra Jordan, a former federal prosecutor and professor at the Charlotte School of Law in North Carolina, said: "Pfizer can survive this and pay the money. If it had fought the government at trial and lost, and a judge imposed a criminal sentence, that could have resulted in a corporate death penalty. That would have put Pfizer out of business."

The settlement is the largest to date for improper marketing of prescription drugs, topping the \$1.42 billion Eli Lilly and Co agreed to pay earlier this year for off-label sales of its Zyprexa schizophrenia drug.

Pfizer said it will pay \$503 million to resolve practices involving Bextra, \$301 million related to its schizophrenia drug Geodon, \$98 million for Zyvox and about \$50 million for its blockbuster Lyrica used to treat nerve pain and seizures.

On top of the \$2.3 billion fine, Pfizer said it would take new charges of up to \$33 million to resolve state civil consumer fraud allegations related to promotions of Geodon.

"Pfizer ripped off taxpayers across the country to pad its bottom line," New York Attorney General Andrew Cuomo said.

The company said most alleged improprieties took place during or before 2005. But some were as recent as 2007, while Pfizer was essentially still on probation for improper Neurontin promotions.

Pfizer did not specify whether it had disciplined any executives in connection with the latest infractions.

Six whistleblowers, including John Kopchinski, a former sales representative who exposed Pfizer's Bextra marketing tactics, sparking the government probes, will be rewarded with more than \$102 million under the False Claims Act. Kopchinski's share was expected to be more than \$51.5 million.

In the 2004 case, Pfizer agreed to pay \$430 million to federal and state governments and pleaded guilty to criminal charges of illegally marketing epilepsy drug Neurontin for migraine headaches, pain and bipolar disorder. Pfizer obtained Neurontin in its 2000 acquisition of Warner Lambert Corp.

Due to the earlier settlement, Pfizer's marketing practices have been under federal supervision for the past five years.

Under the new settlement, Pfizer must adhere to a specified compliance program for five more years. The pact will require it to post on its website information about payments to doctors such as travel, and set up a system for doctors to report questionable conduct by Pfizer's representatives.

Pfizer shares fell 10 cents, or 0.6 percent, to close at \$16.28 on the New York Stock Exchange.

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