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Janssen Pleads Guilty to Selling Risperdal Off-Label

Sophia Pearson
November 07, 2013 4:47 PM

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Nov 07 2013 17:47:18

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(Updates with ElderCare sales force in 17th paragraph.)

By Sophia Pearson

Nov. 7 (Bloomberg) -- **Johnson & Johnson's** Janssen unit pleaded guilty to misbranding its anti-psychotic medication Risperdal as part of a \$2.2 billion settlement with U.S. prosecutors, the largest for a single drug.

The company, based in Titusville, New Jersey, entered the guilty plea today to one misdemeanor at a hearing before U.S. District Judge **Timothy Savage** in Philadelphia.

"Did Janssen do what the government said it did?" Savage asked a lawyer for Johnson & Johnson during the hourlong hearing.

"Yes your honor," Joseph Braunreuther, J&J's deputy general counsel, replied before entering the plea on Janssen's behalf.

The \$2.2 billion settlement, the government's third-largest with a pharmaceutical company and the result of whistle-blower suits, includes \$1.6 billion in civil payments to the U.S. and 45 states for Risperdal and two other drugs. Under Janssen's plea agreement announced Nov. 4, the unit will pay a \$334 million fine and forfeit \$66 million.

Janssen pleaded guilty to marketing the drug to elderly patients with dementia for uses not approved by the U.S. **Food and Drug Administration**. The company settled civil claims that it marketed Risperdal without approval for the elderly, children and the mentally disabled, and that it paid kickbacks to physicians and **Omnicare Inc.**, the largest pharmacy for nursing homes. Janssen has denied the civil allegations.

'Calculated Manner'

Janssen allegedly sought to sell Risperdal, which was approved by the FDA in 1993 for the management of psychotic disorders, for a wide range of off-label treatments including bipolar disorder, dementia and mood and anxiety disorders, according to a criminal information filed Nov. 4.

The company acted in a "calculated manner" with intent to "maximize profits with no regard to risk," Savage said before approving the terms of the plea agreement.

Janssen pleaded guilty to conduct from March 2002 to December 2003, although the scope of the off-label marketing is broader than that timeframe, prosecutors said today. Negotiations over the criminal plea took more than a year, **Richard Scheff**, an attorney for Janssen, told Savage today.

The settlement is the largest in U.S. history involving a single drug, U.S. Attorney **Zane Memeger** in Philadelphia said today after the hearing. It's the result of four lawsuits filed in federal court in Philadelphia by whistle-blowers under the False Claims Act, which allow private citizens to sue on behalf of the government and share in the recoveries. The Justice Department joined those cases.

'Accepts Accountability'

J&J, the world's largest seller of health-care products, said on Nov. 4 that the settlement brings closure to a complex legal case spanning almost a decade.

While Janssen "accepts accountability" for the actions described in the guilty plea, the company denies liability or wrongdoing in the civil settlement, J&J said.

As part of the settlement, New Brunswick, New Jersey-based J&J signed a five-year corporate integrity agreement with the inspector general of the Department of Health and Human Services. It lets J&J recoup bonuses and other long-term incentives for those engaged in "significant misconduct."

"This company is going to be under a magnifying glass for a period of time," Savage said.

Biggest Seller

Risperdal was once J&J's biggest seller, generating worldwide sales of \$24.2 billion from 2003 to 2010. Sales peaked at \$4.5 billion in 2007 before declining when J&J lost patent protection on the drug. The medication has been linked to excessive weight gain and diabetes.

The U.S. government has been probing Risperdal sales practices since 2004, including allegations the company marketed the drug for unapproved uses.

The company targeted elderly patients beginning in 1998 when it started an ElderCare sales force that promoted the medication to nursing homes, according to plea documents filed in the case. By 1999, a marketing campaign titled "Hostile Outside, Fragile Inside," triggered criticism from the FDA as "misleading" for using material that implied Risperdal was found to be safe and effective for the elderly when in fact the elderly hadn't been specifically studied in clinical trials, according to prosecutors.

The drug was later approved for other uses, including for children in 2006.

J&J fell 35 cents to \$92.6 at 4:15 p.m. in New York.

The criminal case is U.S. v. Janssen Pharmaceuticals, 13- cr-00605, U.S. District Court, Eastern District of Pennsylvania (Philadelphia).

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