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J&J Improperly Marketed Drug, South Carolina Says (Update1)

By Margaret Cronin Fisk

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May 24 (Bloomberg) -- Johnson & Johnson, the world's largest maker of health care products, was sued by the state of South Carolina over claims the company's Janssen LP unit fraudulently marketed the antipsychotic drug Risperdal.

The companies promoted the drug for unapproved uses, contrary to U.S. Food and Drug Administration regulations, and concealed the risk of diabetes and other side effects, the state said in its complaint.

Janssen and New Brunswick, New Jersey-based Johnson & Johnson "have engaged in a protracted and willful course of corporate misconduct and misrepresentation," the state said in its complaint. "As a direct result of defendants' marketing efforts, the state has paid millions of dollars for non-medically accepted indications of Risperdal," the state said.

The suit is one of at least 12 state claims against marketers of so-called atypical antipsychotics, a class of drugs that includes Eli Lilly & Co.'s Zyprexa, AstraZeneca Plc's Seroquel and Risperdal. Lilly was sued by at least eight states. Johnson & Johnson has been sued by Pennsylvania and Louisiana. Alaska's suit against Lilly over Zyprexa is set for trial in March 2008.

Janssen will "vigorously defend" itself against the lawsuit, said company spokesman Michael Heinley. "Janssen has always been committed to the highest ethical standards and responsible behavior," Heinley said in an e-mailed statement today.

Janssen's Disclosures

"Janssen routinely informs and fully discloses all appropriate information about Risperdal to the medical community, government agencies and other payers, and this includes FDA-approved information about the product's

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efficacy and safety profile," Heinley wrote.

The suit was filed in state court last month and transferred to federal court May 22. South Carolina says in the suit that the company owes the state for the cost of prescriptions and harm to patients.

Risperdal, Zyprexa and Seroquel have been linked to excessive weight gain and increased risk of diabetes. In September 2003, the FDA required the three companies to place warnings on the drugs' labels.

The three drugs, approved for schizophrenia and bipolar disorder, are among the top-selling medications in the world. Lilly's global sales of Zyprexa were \$4.36 billion in 2006, Risperdal sales were \$4.18 billion and Seroquel's worldwide sales in 2006 were \$3.4 billion.

South Carolina's attorney general sued Johnson & Johnson on behalf of its Medicaid program, the state Department of Mental Health and the South Carolina State Employees Health Plan, seeking reimbursement for money paid for prescriptions for non-approved uses and for "Risperdal-related illnesses," the state said in its complaint.

'No Valid Scientific Evidence'

Johnson & Johnson's Janssen unit, based in Titusville, New Jersey, improperly promoted the drug for use by children and for treatment of dementia in the elderly, South Carolina said in the complaint. "There is no valid scientific evidence to support defendants' contention that Risperdal is safe and effective for treatment of any non-medically accepted indication, including any use in children," according to the suit.

The state also seeks punitive damages and money for individual claims submitted to the South Carolina Medicaid program. "All prescriptions for Risperdal submitted to the state's Medicaid program constitute false claims under the Medicaid Fraud Act," the state said in its complaint.

Triple Reimbursement

This law allows South Carolina to be reimbursed for three times the cost of the drugs plus \$2,000 per false claim, the state said.

"Since it was first approved in 1993, Risperdal has helped millions of patients around the world who suffer from the debilitating effects of bipolar mania and schizophrenia," Heinley said. "Recently, it became the first FDA-approved medication to treat the irritability associated with autistic disorder in children and adolescents ages 5 to 16 years," he said.

Johnson & Johnson shares fell 33 cents to \$63.48 in New York Stock Exchange composite trading.

The lawsuit is South Carolina v. Janssen Pharmaceutica Inc., No. 7:07-cv-01452, U.S. District Court, District of South Carolina (Spartanburg).

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