

Johnson & Johnson ("J&J") has purportedly reached a settlement with the Justice Department which will have the healthcare giant paying \$2.2 billion to resolve unlawful marketing claims. The settlement would include a criminal fine of approximately \$400 million for the unlawful promotion of the antipsychotic drug Risperdal. The final total of the proposed settlement will depend on which states that have sued J&J sign on to the agreement. Details of the settlement will likely be announced within the next few weeks.

Under federal law, drug companies may only market prescription drugs for uses approved by the Food & Drug Administration ("FDA"). Physicians are permitted to prescribe drugs for unapproved (off-label) uses, but drug companies are prohibited from marketing drugs for those off-label uses. Pending cases by the federal government and various states accuse J&J of violating the law through improper marketing tactics.

Risperdal had been J&J's top-selling drug with \$2.2 billion in sales in 2007 alone, the year before the drug lost its patent protection in the U.S. The drug was approved for treatment of mental illnesses such as schizophrenia, bipolar mania, and irritability in autistic patients. The unlawful marketing allegations against J&J accused the company of promoting Risperdal as a treatment for anxiety among patients with dementia and Alzheimer's, both unapproved uses. In addition to resolving claims of improper marketing of Risperdal, the proposed settlement would also resolve investigations into the promotion of Invega, another schizophrenia drug, and the heart-failure drug Natrecor, as well as an investigation of whether J&J improperly paid kickbacks to nursing home pharmacy operator Omnicare to boost sales of certain J&J medications to nursing home patients.

The proposed settlement involving J&J would follow a number of recent settlements of qui tam ("whistleblower") lawsuits against drug companies. In early July, GlaxoSmithKline agreed to pay \$3 billion to resolve illegal drug marketing claims involving the antidepressant drugs Paxil and Wellbutrin and the diabetes drug Avandia. In 2009, Pfizer agreed to pay \$2.3 billion to resolve unlawful promotion claims regarding the now-withdrawn painkiller Bextra and other drugs. Also in 2009, Eli Lilly agreed to pay \$1.4 billion to settle unlawful marketing drugs involving its antipsychotic medication Zyprexa.