



Johnson & Johnson in Healthcare Fraud Settlement



U.S. Attorney General Eric Holder announced yesterday that Johnson & Johnson is to pay \$2.2 billion in a bid to end civil and criminal investigations into bribes made to pharmacists and the marketing of pharmaceuticals for unapproved uses.

Marking one of the largest health care fraud settlements in US history, this case has been ongoing for years and covers the marketing of the anti-psychotic drugs Risperdal and Invega, as well as the heart medication Natrecor.

According to the complaint, these were promoted for off-label uses by J&J and its subsidiary Janssen Pharmaceuticals Inc between 1999 and 2005, with US government insurance programs incurring costs of hundreds of millions of dollars in uncovered claims.

As part of the settlement, Janssen will plead guilty to a single misdemeanor violation for its promotion of Risperdal, which was falsely marketed for the use of controlling aggression and anxiety in elderly dementia patients, and treating behavioral disturbances in children and in individuals with disabilities.

Furthermore, Omnicare Inc, the largest pharmacy specializing in dispensing drugs to nursing home patients in the US, received millions of dollars in kickbacks from the company for a variety of alleged reasons such as "educational funding."

In his statement Attorney General Holder described Johnson & Johnson's conduct as "recklessly putting at risk" the health of children, dementia patients and others to whom the drug was prescribed at a time when it was only FDA approved to treat schizophrenia.

To further push sales, Janssen used an aggressive promotion policy, including paying their sales representatives incentives and bonuses for off-label marketing and on total sales.

Though doctors are entitled to prescribe drugs for unapproved off-label use under FDA regulations, the pharmaceutical companies are only allowed to promote their drugs for FDA-approved uses.

When repeated warnings to Janssen were ignored the FDA said it went on to initiate a criminal complaint. John Roth, director of the FDA's Office of Criminal Investigations, confirmed that his team of investigators dedicated a substantial amount of time and resources to this case and as part of the settlement, Justice Department lawyers filed a civil complaint against Johnson & Johnson.

In their statement, Johnson & Johnson said that the settlement of "the civil allegations is not an admission of any liability or wrongdoing, and the company expressly denies the government's civil allegations."

Yesterday's settlement also resolved allegations that J&J and a subsidiary, Scios Inc., had promoted the drug Natrecor for off-label, unapproved use, whereas a securities filing in 2011 disclosed by J&J showed an agreement to resolve criminal penalties related to the promotion of Risperdal had been reached, but that certain issues remained on what was one of the company's biggest sellers.

Following Monday's announcement J&J shares were down almost 1% on the New York Stock Exchange.

The company follows in the footsteps of most large drugmakers who, over the past decade, have had to pay substantial fines to the US government and various states for alleged improper marketing of their medicines. These include Pfizer Inc and Britain's GlaxoSmithKline Plc.

Source: [Reuters](#)

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