

# J&J To Pay \$2.2B To Settle Marketing Allegations

Matthew Perrone, The Associated Press



WASHINGTON (AP) — Johnson & Johnson and its subsidiaries have agreed to pay over \$2.2 billion to resolve criminal and civil allegations that the company promoted powerful psychiatric drugs for unapproved uses in children, seniors and disabled patients, the Department of Justice announced on Monday.

The allegations include paying kickbacks to physicians and pharmacies to recommend and prescribe Risperdal and Invega, both antipsychotic drugs, and Natrecor, which is used to treat heart failure.

The figure includes \$1.72 billion in civil settlements with federal and state governments as well as \$485 million in criminal fines and forfeited profits.

The agreement is the third-largest U.S. settlement involving a drugmaker, and the latest in a string of legal actions against drug companies that allegedly put profits ahead of patients. In recent years, the government has cracked down on the pharmaceutical industry's aggressive marketing tactics, which include pushing medicines for unapproved, or off-label, uses. While doctors are allowed to prescribe medicines for any use, drugmakers cannot promote them in any way that is not approved by FDA.

"Every time pharmaceutical companies engage in this type of conduct, they corrupt medical decisions by health care providers, jeopardize the public health, and take money out of taxpayers' pockets," said Attorney General Eric Holder, in prepared remarks at a news conference.

J&J said in a statement, "This resolution allows us to move forward and continue to focus on delivering innovative solutions that improve and enhance the health and well-being of patients."

In its plea agreement, J&J subsidiary Janssen Pharmaceuticals admitted that it promoted Risperdal to nursing home doctors and nurses to control erratic behavior

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in seniors with dementia between 2002 and 2003. Today that use is explicitly barred in the drug's warning label because it can increase the risk of stroke and death in elderly patients. Antipsychotic drugs are known for their sedative effects and are occasionally used to treat post-traumatic stress and sleep disorders, though those uses have never been approved by the FDA.

Janssen agreed to plead guilty to violating FDA drug marketing laws and will pay \$400 million in fines and forfeited sales. The plea is subject to acceptance in U.S. District Court.

In a separate civil complaint, the government alleged that J&J and Janssen also promoted Risperdal and a similar drug Invega, to control numerous behavior problems in seniors, children and the mentally disabled between 1999 and 2005.

Documents filed in the case include numerous objections the government sent to the company or its subsidiaries dating back over a decade. In a 1999 letter, the FDA wrote to J&J's Janssen subsidiary, saying that "disseminating materials that state or imply that Risperdal has been determined to be safe and effective for the elderly population ... are misleading."

Despite such warnings, the company's marketing material targeted nursing homes and doctors who treated the elderly, even appointing a special "ElderCare sales force." Marketing materials distributed by these sales representatives emphasized Risperdal as a treatment for seniors suffering from anxiety, agitation, depression and hostility, but did not mention that the drug was only FDA-approved for schizophrenia.

At the same time the drugmaker was allegedly paying kickbacks to the nation's largest long-term care pharmacy to recommend the drug to prescribers. J&J paid millions in supposed grants and education funds to Omnicare in an effort to induce the company and its hundreds of consultant pharmacists to recommend Risperdal and other J&J drugs. The government said the payments amounted to kickbacks that J&J used to extend its sales operation.

Similarly, the company set business goals of increasing sales for children and adolescents, even though Risperdal was not approved for any use in these patients until late 2006.

Janssen instructed its sales representatives to call on child psychiatrists and to market Risperdal as a treatment for common childhood disorders, such as attention deficit hyperactivity disorder and autism.

The off-label prescribing of Risperdal contributed to millions of dollars in federal and state spending by health programs like Medicare, Medicaid and the Department of Veterans' Affairs.

"Through these alleged actions, these companies lined their pockets at the expense of American taxpayers, patients and the private insurance industry," Holder said, adding that the company's alleged conduct "put at risk the health of some of the

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most vulnerable members of our society — including young children, the elderly and the disabled."

J&J and Janssen agreed to pay \$1.27 billion to resolve civil allegations that its marketing led to false payments submitted to government health programs. The company paid another \$149 million to settle allegations over its kickbacks to Omnicare.

In a separate civil complaint, the government alleged that J&J and its subsidiary Scios, promoted its heart failure drug Natreacor as a regular treatment for patients — though there was allegedly no scientific evidence to support this approach. The company's marketing resulted in patients undergoing expensive drug infusions up to twice a week for several weeks or months.

J&J and Scios agreed to pay \$184 million to settle civil allegations that the company's promotion led to false payments for government health plans.

Both state and federal governments are spending more than ever on prescription drugs, as Medicare and Medicaid swell with aging baby boomers. That increased spending has attracted scrutiny from prosecutors looking to recover taxpayer dollars.

Last year British drugmaker GlaxoSmithKline paid a record \$3 billion in fines to settle criminal and civil violations involving 10 of its drugs. In 2009, Eli Lilly & Co paid \$1.42 billion to settle similar allegations that the company promoted its antipsychotics Zyprexa for seniors with dementia.

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