

Feds, J&J Agree to \$2.2 Billion Settlement in Risperdal Suit

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It is the biggest settlement yet for a single drug, said Zane Memeger, U.S. attorney for the Eastern District of Pennsylvania, where the case was handled.

Janssen Pharmaceuticals is scheduled to plead guilty Thursday to a charge related to its marketing of Risperdal, which had been approved by the US. Food and Drug Administration for treatment of schizophrenia, but was marketed for elderly patients with dementia and mentally-ill children.

"The Department of Justice takes the FDA procedure seriously," Memeger said following a formal announcement of the deal in Washington, D.C., on Monday. "Companies that decide to put profit over patients will be prosecuted."

Janssen will pay \$334 million as a criminal fine. \$66 million as a substitute for forfeiture of the drugs, and it has agreed to a separate civil settlement with the federal government and several states for about \$1.3 billion, according to the plea and sentencing agreement.

Johnson & Johnson will also pay \$149 million to settle claims related to kickbacks it allegedly paid to a long-term care pharmacy, according to Attorney General Eric Holder Jr., who gave a prepared statement at a press conference Monday morning.

"In addition to these claims, we allege that Johnson & Johnson and its subsidiary, Scios incorporated, promoted the heart failure drug Natrecor for off-label uses that caused patients to submit to costly infusions of the drug—without credible scientific evidence that it would have any health benefit for those patients," Holder said in the statement. "In a separate matter that was resolved in 2009, Scios pleaded guilty to misbranding Natrecor and paid a criminal fine of \$85 million. To resolve current allegations

associated with the settlement we announce today. The companies have agreed to pay an additional \$184 million."

In March 2012, Johnson & Johnson had paid \$118 million to resolve similar claims about Risperdal in Texas—that amount is included in the \$2.2 billion total.

Starting in 2004, relators began filing qui tam actions over the marketing of Risperdal. Four cases were consolidated in the U.S. District Court for the Eastern District of Pennsylvania—Janssen is a Pennsylvania corporation headquartered in New Jersey.

Whistleblowers from the Eastern District of Pennsylvania will be awarded \$112 million—Victoria Starr, the first to file, will be getting \$110 million from the federal government's share of the Risperdal settlement, and Kurtis Barry will be getting \$2 million from the federal government's share of the Invega settlement, according to the U.S. Attorney's Office in Philadelphia.

The assistant U.S. attorneys who worked on the case in the Eastern District of Pennsylvania were Charlene Fullmer, Mary Catherine Frye, Albert Glenn and Scott Cullen.

Regarding the conduct of the drug companies, Stephen Sheller of Sheller P.C. said, "They targeted children and the elderly."

Sheller represents Starr and has separate cases related to Risperdal's effects on children, allegedly causing boys to develop breasts, currently pending. One of those children was giving a deposition in his office when the Risperdal settlement was announced Monday.

Thomas Sheridan of Sheridan & Murray, who represented Barry, said that the size of the settlement was possible larger because of the volume of sales for Risperdal, which, he said, was at one point the leading antipsychotic drug on the market.

Sales for the drug approached \$2 billion in one year, he said, explaining that companies typically get limited approval for their drugs—like the FDA's approval for Risperdal in the relatively small schizophrenia market—so they try to capture pieces of other drug markets through promotion of off-label uses.

Barry had contributed evidence that the sales goals set by the company for the drugs went beyond what would be possible from the schizophrenia market share, according to Sheridan. What was striking about this case, Sheridan said, was that the pharmaceutical company marketed the off-label uses for its drug to the "most vulnerable members of society."

Johnson & Johnson has also agreed to go into a corporate integrity agreement, or CIA, with the U.S. Department of Health and Human Services.

"Among other things, the CIA requires to change its executive compensation program to permit the company to recoup annual bonuses and other long-term incentives from covered executives if they, or their subordinates, engage in significant misconduct," according to a release from the Department of Justice.

"The CIA also requires pharmaceutical businesses to implement and maintain transparency regarding their research practices, publication policies and payments to physicians. On an annual basis, management employees, including senior executives and certain members of J&J's independent board of directors, must certify compliance with provisions of the CIA. J&J must submit detailed annual reports to HHS-OIG about its compliance program and its business operations," it says.

Janssen is expected to plead guilty to one count of introducing misbranded Risperdal into interstate commerce in front of U.S. District Judge Timothy J. Savage on Thursday morning.