J&J Pays $2.2B Over Charges Of Improper Risperdal Marketing

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risperdal.jpg

After two years of negotiations, Johnson & Johnson and its subsidiaries have agreed to pay more than $2.2 billion to resolve criminal and civil lawsuits that alleged the healthcare giant illegally marketed its Risperal antipsychotic and two other medicines, and also paid kickbacks to physicians and Omnicare, the largest nursing home pharmacy to boost prescriptions.

In announcing the deal, which resulted from multiple investigations into J&J business practices over the past decade, the US Department of Justice called the agreement one of the "largest healthcare fraud settlements in US history." The criminal fines and forfeiture total $485 million, while the civil settlement with the federal and state governments amounts to $1.72 billion (here is the criminal information, the plea agreement, one civil settlement and another civil settlement, and a link to all of the exhibits).

"The conduct at issue in this case jeopardized the health and safety of patients and damaged the public trust," US Attorney General Eric Holder says in a statement, whose office relied, in part, on various lawsuits filed by whistleblowers, some of whom were J&J employees. They will collect, in total, nearly $168 million.

"…Through these alleged actions, these companies lined their pockets at the expense of American taxpayers, patients, and the private insurance industry. They drove up costs for everyone in the health care system and negatively impacted the long-term solvency of essential health care programs like Medicare," Holder continues. "...These are not victimless crimes."

In the agreement, the Janssen unit that markets Risperdal pleaded guilty to misbranding by promoting the drug to treat psychotic symptoms and associated behaviors that were displayed by elderly patients. While these patients suffered from dementia, they were not schizophrenic, even though the drug was approved by the FDA only to treat schizophrenia.

The agreement, however, does not include lawsuits brought by three states where J&J (JNJ) has appealed judgments over Risperdal marketing. For instance, J&J was ordered by a South Carolina judge to pay $327 million for deceptive marketing, which he called detestable (look here). And in Louisiana, a jury ordered J&J to pay $257.7 million in damages for making misleading safety claims, and $73 million in legal fees were later added. In Arkansas, J&J is waiting a date to argue before the state Supreme Court.

The settlement is only the latest instance in which a large drugmaker has paid sizeable penalties for bad behavior. Over the past decade, a string of such deals has been reached with US authorities. Last year, GlaxoSmithKline paid $3 billion in connection with off-label promotion of several drugs, failing to report safety data and reporting false prices (more here). Others that paid big fines included Pfizer and Eli Lilly.

The pharmaceutical industry asserts that such practices occurred in the past, but industry critics maintain infractions will continue until US authorities move to exclude key executives from participating in federal healthcare programs, a step that is rarely taken (see this). "The settlement would be better news for everyone - stockholders, patients, payers - if one could believe that the company has changed its ways and there won't be another settlement of something else a few years from now," says Erik Gordon, a professor at the Ross School of Business at the University of Michigan and a professor at the University of Michigan Law School.

The settlement may mark a turning point for J&J, which has suffered years of damaging publicity over numerous probes and lawsuits concerning Risperdal marketing. Specifically, the health care giant has faced repeated allegations that its Janssen unit downplayed or hid the risks of diabetes and weight gain associated with the drug from physicians and patients.

The charges, in fact, eventually encompassed J&J ceo Alex Gorsky, who the feds tried to depose during their investigation. From October 1998 to October 2001, Gorsky was Janssen's vp of marketing, and from October 2001 to early 2003, he was the Janssen president. During that time, he was responsible for selling Risperdal, and Omnicare was the biggest Risperdal customer.

Although investors have long since discounted the effects of a costly settlement, the settlement may represent an opportunity for J&J to restore its reputation, which has also been sullied by protracted litigation over the safety of widely used hip implants as well as manufacturing problems that caused countless product recalls and resulted in an ongoing consent decree with the FDA.

"Today, we reached closure on complex legal matters spanning almost a decade. 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 around the world," says Michael Ullmann, J&J general counsel, in a statement. Although in a note to employees today, he also writes that J&J does "not agree with all of the government's allegations and strongly believe some of them are not supported by the facts."

In any event, some observers were critical of the settlement. "The lesson that pharmaceutical companies can take away from J&J's $2.2 billion settlement with the DOJ is that the deceptive practice of off-label marketing of drugs is economically advantageous," says Bonnie Patten, executive director of Truth In Advertising, a non profit organization. She notes that Risperdal sales between 1999 and 2005 totaled some $9 billion. "The real winner today is Johnson & Johnson."

As part of the settlement, J&J entered into a five-year corporate integrity agreement, which requires the company to develop compliance procedures in order to avoid a repeat of the bad behavior (here is the CIA and appendices). The agreement supercedes an earlier CIA signed three years ago as part of an $81 million settlement to resolve criminal and civil lawsuits filed over off-label marketing of the Topamax epilepsy drug (see this).

What sort of bad behavior? In court documents, the government charged that Janssen created written sales aids for use by its ElderCare sales reps that emphasized symptoms but minimized any mention of the approved use. The healthcare giant also provided incentives for off-label promotion by basing rep bonuses on total Risperdal sales in their territories, not just for uses approved by the FDA.

The feds noted the "FDA repeatedly advised Janssen that marketing Risperdal as safe and effective for the elderly would be 'misleading,' and cautioned that behavioral disturbances in elderly dementia patients were not necessarily manifestations of psychotic disorders and might even be 'appropriate responses to the deplorable conditions under which some demented patients are housed, thus raising an ethical question regarding the use of an antipsychotic medication for inappropriate behavioral control.' " J&J was similarly charged with inappropriate marketing of the Invega antipsychotic.

More from the feds: J&J was aware Risperdal posed serious health risks for the elderly, including an increased risk of strokes, but downplayed the risk. For instance, when a J&J study of Risperdal showed a significant risk of strokes and other adverse events in elderly dementia patients, the feds allege that Janssen combined the study data with other studies to make it appear there was a lower overall risk.

And a year after J&J received results of a second study confirming the increased risk for elderly patients taking Risperdal, but had not published the data, one physician who worked on the study cautioned Janssen that "(a)t this point, so long after (the study) has been completed… we must be concerned that this gives the strong appearance that Janssen is purposely withholding the findings."

"I think what got to (the whistleblower) was what the company was doing to the elderly, how they were promoting this drug to that niche market of people that couldn't do anything in response, who really didn't have anyone looking out for them. I think that was the final straw" Brian McCormick, an attorney at the Sheller law firm that represented one of the whistleblowers, told the American Law Journal television program earlier this year.

The feds also allege that J&J received results of studies indicating that Risperdal posed the same diabetes risk as other antipsychotics, the healthcare giant retained outside consultants to re-analyze the results and later published articles asserting that Risperdal was actually associated with a lower risk of developing diabetes.

What else? The feds charge that J&J promoted Risperdal as safe for children, despite such risks as gynecomastica, which is the abnormal development of large mammary glands in males, but the product labeling lacked sufficient warnings. The initial Risperdal labeling allegedly downplayed the risk of increased prolactin levels and failed to suggest that a test should be used (back story).

"This is a company that's not taking resonsiblity for their misconduct," says Steve Sheller, who represented one of the whistleblowers. "I know what evidence was produced because I was lead counsel in one of the cases, and I know how they negotiated to get out of the deal so they could get it settled… It's a disgrace."

Then there were charges involving Omnicare. A whistleblower lawsuit filed in 2010 alleged that J&J paid millions of dollars in kickbacks to Omnicare as part of so-called market share rebate payments, data-purchase agreements, 'grants' and 'educational funding.' The payments were intended to induce Omnicare and its hundreds of consultant pharmacists to engage in 'active intervention programs' to promote Risperdal and other J&J drugs in nursing homes, according to the feds.

As part of the deal, J&J agreed to pay $149 million to resolve charges the kickbacks caused Omnicare (OCR) to submit false claims to federal health care programs. The federal share of this settlement is $132 million, and the five participating states will receive $17 million. In 2009, by the way, Omnicare paid $98 million to resolve civil charges of accepting kickbacks (see this).

The deal also resolves a civil lawsuit that alleges JNJ and its Scios subsidiary caused false and fraudulent claims to be submitted to federal health care programs for the Natrecor heart failure drug. Shortly after the med was approved, Scios began marketing Natrecor for scheduled, serial outpatient infusions for patients with less severe heart failure, which was not approved by the FDA. The feds charged Scios lacked scientific evidence to promote this use and paid doctors to talk it up at meetings (here is the criminal information, the plea agreement and the civil settlement).

The sales tactics that were identified in a whistleblower lawsuit by Joe Strom, a former Scios area manager, included organizing third-party continuing medical education programs that were actually controlled, promoted and designed by Scios, and distributing third-party articles to physicians and touting the off-label benefits of Natrecor, while not disclosing that the article was funded in part or in full by Defendants; and educating physicians on Medicare reimbursement codes for off-label uses (back story and his lawsuit).

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