

Big Pharma Exposed ,Ä Again

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How would you feel if you learned your elderly mother or your child was being treated with a drug never intended to be used as medication for their illness? Or that they had been prescribed a drug intended to quell psychotic symptoms, even though they weren't experiencing any such symptoms?

This apparently happened to millions who were improperly given Risperdal, a Johnson & Johnson-produced drug designed to treat schizophrenia, according to a recent [press release](#) from the U.S. Department of Justice. According to the Justice Dept., the drug was promoted as a medication for the treatment of anxiety, agitation, depression, hostility, confusion and other symptoms, even though it was never approved for those uses. The press release details why "global health care giant" Johnson & Johnson agreed to a \$2.2 billion settlement for criminal and civil violations principally related to Risperdal.

What makes this situation all the more deplorable is that the Food and Drug Administration (FDA) was aware of much of this activity and "repeatedly advised," "cautioned," sent "warnings" and even "repeatedly warned" Johnson & Johnson (and its subsidiaries) about the fraudulent activity, but it took almost a decade before J & J agreed to the settlement.

While the settlement is one of the largest in U.S. history, the most alarming part of the Dept. of Justice press release details what Johnson & Johnson was allegedly caught doing – and to whom. The release references a related civil complaint, filed Nov. 4, 2013, that alleges J & J and its subsidiaries:

- "caused false claims to be submitted to federal health care programs by promoting Risperdal for off-label uses that federal health care programs did not cover, making false and misleading statements about the safety and efficacy of Risperdal and paying kickbacks to physicians to prescribe Risperdal"
- "marketed Risperdal to control the behaviors and conduct of the nation's most vulnerable patients: elderly nursing home residents, children and individuals with mental disabilities"
- "[made] false and misleading statements about the safety and efficacy of Risperdal and [paid] kickbacks to physicians to prescribe Risperdal"
- "were aware that Risperdal posed serious health risks for the elderly, including an increased risk of strokes, but that the companies downplayed these risks"
- "combined the study data with other studies to make it appear that there was a lower overall risk of adverse events"
- "knew that patients taking Risperdal had an increased risk of developing diabetes, but nonetheless promoted Risperdal as 'uncompromised by safety concerns (does not cause diabetes)'"
- "retained outside consultants to re-analyze the study results and ultimately published articles stating that Risperdal was actually associated with a *lower* risk of developing diabetes" [emphasis added]
- "touted Risperdal as having 'proven efficacy' and 'an excellent safety and tolerability profile' in geriatric patients"
- "promoted the antipsychotic drug for use in children and individuals with mental disabilities. The complaint alleges that J & J and Janssen (their subsidiary) knew that Risperdal posed

certain health risks to children, including the risk of elevated levels of prolactin, a hormone that can stimulate breast development and milk production"

- "instructed its sales representatives to call on child psychiatrists, as well as mental health facilities that primarily treated children, and to market Risperdal as safe and effective for symptoms of various childhood disorders, such as attention deficit hyperactivity disorder, oppositional defiant disorder, obsessive-compulsive disorder and autism"
- "paid speaker fees to doctors to influence them to write prescriptions for Risperdal. Sales representatives allegedly told these doctors that if they wanted to receive payments for speaking, they needed to increase their Risperdal prescriptions"
- "paid millions of dollars in kickbacks to Omnicare under the guise of market share rebate payments, data-purchase agreements, 'grants' and 'educational funding.' These kickbacks were intended to induce Omnicare and its hundreds of consultant pharmacists to engage in "active intervention programs" to promote the use of Risperdal and other J & J drugs in nursing homes. Omnicare's consultant pharmacists regularly reviewed nursing home patients' medical charts and made recommendations to physicians on what drugs should be prescribed for those patients."
- "caused false and fraudulent claims to be submitted to federal health care programs for the heart failure drug Natrecor (another drug)"
- "misleadingly used a small pilot study to encourage the serial outpatient use of the drug (Natrecor)"
- "sponsored an extensive speaker program through which doctors were paid to tout the purported benefits of serial outpatient use of Natrecor"
- "urged doctors and hospitals to set up outpatient clinics specifically to administer the serial outpatient infusions (of Natrecor), in some cases providing funds to defray the costs of setting up the clinics, and supplied providers with extensive resources and support for billing Medicare for the outpatient infusions"

While you probably assumed or at least suspected much of what you just read, the Justice Department release lays it out in black and white. Taken together, these "allegations" give us an insight into the current drug cartel practices in the United States and likely most of the world.

Many consumers saw a short article about the settlement online or in their local paper and likely noted the sizable \$2.2 billion fine. The fine is substantial, but as [one news source](#) revealed,

"Risperdal brought in \$3.1 billion in sales"² in 2004 alone, which is more than enough to cover the fines almost 10 years later, with money left over.

The same news source noted that "Johnson & Johnson was not the only company marketing drugs to older dementia patients and the long-term care facilities where they were treated. Within the past five years, federal officials have reached similar agreements regarding Zyprexa, made by Eli Lilly; Seroquel, made by AstraZeneca; and Depakote, by Abbott, which is now AbbVie."² (It appears that trying to find a drug company guilty of fraud is like trying to find a motorist exceeding the speed limit on a Los Angeles freeway.)

The take-home message here is one of graphic greed. First, everyone is considered a target for drug companies wishing to expand their bottom line: children, elderly, the mentally ill – everyone, but especially those who don't make their own health care decisions.

Second, everyone should be considered complicit in the drug companies' sales schemes, (until proven otherwise): educational speakers, medical doctors, pharmacists, mental health professionals – anyone who can write a prescription and get a kickback.

Third, all reports, research papers, journal articles, conferences papers, and any information

sheets produced by those who have a vested interest in the sale of any drug should be considered suspect and potentially fraudulent.

There is no way to know how many millions of elderly, children and others were victims of the unbridled greed displayed by Johnson & Johnson. What is perhaps more important is informing your patients so they can protect themselves and their families from continuing to be victims of this type of activity.

If the drug companies are willing to take advantage of children and the elderly, there is nothing to suggest it isn't happening, to some degree, to everyone.

References

1. "Johnson & Johnson to Pay More Than \$2.2 Billion to Resolve Criminal and Civil Investigations." Department of Justice, Office of Public Affairs. Nov. 4, 2013.
 2. "J.&J. to Pay \$2.2 Billion in Risperdal Settlement." *The New York Times*. Nov. 4, 2013.
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