

Johnson & Johnson's \$2.2 Billion Settlement

Johnson & Johnson has worked hard to gain the reputation of being one of the most ethical companies in the world, yet it recently agreed to pay approximately \$2.2 billion to resolve criminal and civil claims of unethical and illegal behavior.

The website of the international healthcare company Johnson & Johnson (J&J) proudly proclaims the values in its Credo, or code of conduct, as “to put the needs and well-being of the people we serve first.” It then lists the company’s responsibilities: first to product users—doctors, nurses, and patients—and then to its vendors and distributors to make a fair profit. The next area of responsibility is to its employees, with a proviso that management actions must be just and ethical. Its third responsibility isn’t only to the communities where the firm operates but also to the world at large. Its final responsibility is to its stockholders.

Over the years, J&J has put its Credo into practice in many ways. In early October 1982, several bottles of Tylenol sold in the Chicago area were tampered with and laced with poison, which caused several deaths. Within days, the company decided on a nationwide recall of 31 million bottles of the product,

estimated to cost \$100 million. New tamper-resistant packaging was quickly rolled out to beat the expected competition, and J&J decided to absorb the increased packaging cost.

J&J’s 2012 Citizenship & Sustainability Report describes more recent ethics-related accolades—the company received 20 different recognitions for various aspects of its business operations, including being named the 18th most reputable company in the United States and 12th most admired company overall. J&J was also placed on lists of best places for working mothers, diversity, green practices, Latinas, LGBT equality, corporate citizenship, and sustainability, among others.

Despite all these indications of a strong ethical culture within the company, a number of civil and criminal actions have been lodged against J&J. The most recent is a massive \$2.2 billion settlement made in early November 2013 that resolves criminal and civil investigations into promotion of unapproved, or off-label, uses for three drugs and alleged kickbacks to physicians and a nursing home pharmacy distributor. In a November 4, 2013, press release published by the Department of Jus-

tice (DOJ), U.S. Attorney General Eric Holder said, “The conduct at issue in this case jeopardized the health and safety of patients and damaged the public trust.” (See www.justice.gov/opa/pr/2013/November/13-ag-1170.html for more details.)

The Criminal Case

In the criminal complaint, the DOJ charged that J&J’s subsidiary Janssen Pharmaceuticals marketed the atypical antipsychotic drug Risperdal to the elderly and children for off-label treatment that the U.S. Food and Drug Administration (FDA) hadn’t approved as safe and effective. The FDA only approved Risperdal for treatment of schizophrenia, not behaviors exhibited by nonpsychotic elderly and other patients with dementia.

Clinical trials of Risperdal had shown the drug increased the risk of strokes in the elderly and diabetes in all patients. Despite these findings, Janssen established a specialized ElderCare sales force to promote Risperdal use by these patients. The clinical trials also had insufficient representation of the elderly. Janssen also promoted Risperdal for use in treating attention deficit disorder (ADD) in children, for which apparently no



evidence of safety and effectiveness from clinical trials was presented.

The penalty for this criminal case was a guilty plea to a misdemeanor that Janssen had mislabeled the product. (It makes me wonder what circumstances would lead to a felony conviction.) Further, even after making label changes required by the FDA, the complaint states that Janssen directed its sales force “not to change its symptom-based message for the promotion of Risperdal and... [to continue] promoting Risperdal to treat symptoms and behavioral disturbances of dementia which were not within Risperdal’s indication.” Criminal fines and forfeiture of profits totaled \$485 million, including a fine of \$85 million relating to a similar case involving the congestive heart failure drug Natrecor.

The settlement also includes an extensive five-year corporate integrity agreement between J&J and various federal healthcare agencies. The agreement “includes provisions requiring J&J to implement major changes to the way its pharmaceutical affiliates do business.” In addition to submitting detailed annual reports about its compliance program and its business operations, J&J must:

- ◆ “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.”
- ◆ “Implement and maintain transparency regarding their research practices, publication policies, and payments to

physicians.”

- ◆ Obtain certifications of compliance with provisions of the corporate integrity agreement from senior executives and certain board members.

The detailed 69-page agreement requires specific corporate integrity obligations, some of which had already been put into place. The obligations include appointment of a senior-level compliance officer and dedicated board of directors subcommittee; written standards in the form of specific policies and procedures; training and education regarding the corporate integrity agreement and general compliance; risk assessment and mitigation planning program; independent review and oversight; a disclosure program, including a toll-free compliance telephone line; and reporting of physician payments.

Daniel R. Levinson, inspector general of the U.S. Department of Health and Human Services, said his office “will work aggressively with our law enforcement partners to hold companies accountable for marketing and promotion that violate laws intended to protect the public.”

Civil Suits

The state of Pennsylvania filed a civil complaint against Janssen in November 2013 that alleges Janssen “aggressively marketed Risperdal as having an ‘unparalleled safety profile’ and being effective in controlling behavioral disturbances in the elderly,” yet it failed to immediately publish the results of clinical trials performed in 2003 that showed adverse re-

sults in using Risperdal to treat the elderly—they were eventually published in March 2006. Janssen also allegedly paid millions of dollars in kickbacks to physicians in the form of “speaker’s fees” at continuing medical education programs designed to motivate the prescribing of Risperdal, even for unapproved uses.

The complaint also asserts that although Risperdal wasn’t approved for use by children for any purpose until late 2006, Janssen promoted its use from at least 1999 through 2005 “to treat children for a variety of unapproved uses.”

And according to a civil complaint filed in January 2010 in Massachusetts, Janssen made payments to Omnicare, Inc. (OCR), the nation’s largest distributor of pharmacy dispensing products and services to nursing homes and other long-term care facilities. At the time, it was one of Janssen’s largest customers. The payments involved “tens of millions of dollars in kickbacks to induce Omnicare to purchase and to recommend Risperdal and other J&J drugs... These kickbacks took various forms, including market share rebate payments conditioned on Omnicare engaging in ‘active intervention programs’ (AIP) for J&J drugs.” An AIP was later defined in the complaint as a formal signed initiative “which is designed to appropriately shift market share to [J&J]’s Product.” Annual sales of J&J products to OCR climbed from \$100 million to \$280 million, with Risperdal alone representing \$100 million. For a substantial portion of these purchases, OCR submitted claims for reimbursement

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to the federal Medicaid program.

Payments under all the civil settlements with various states and the federal government total \$1.72 billion. Under the provisions of the False Claims Act, whistleblowers will receive approximately \$268 million from the federal government's share of this amount.

Lesson Learned?

Despite agreeing to make these huge payments, J&J's response was a common legalistic boilerplate:

"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." J&J also publicly minimized the significance of the integrity agreement, stating it "is largely consistent with existing compliance programs, and reflects [J&J's] commitment to ensuring integrity in the delivery of essential medicines to patients." I wonder whether there will be any deterrent effect on future behavior by J&J subsidiaries and others in the pharmaceutical industry—some of whom have also paid sizeable amounts. Perhaps felony convictions of executives and even larger financial penalties are necessary to avoid the apparent attitude that such payments are "just another cost of doing business."

The major lesson all companies should learn is that it's critical to have a functioning and effective program in place to assure proper oversight and effective monitoring of full compliance with the ethical framework that has been established, and the tone at the top

must permeate operations throughout the organization. **SF**

Curtis C. Verschoor, CMA, CPA, is the Emeritus Ledger & Quill Research Professor, School of Accountancy and MIS, and an honorary Senior Wicklander Research Fellow in the Institute for Business and Professional Ethics, both at DePaul University, Chicago. He is also a Research Scholar in the Center for Business Ethics at Bentley University, Waltham, Mass. He was selected by Trust Across America as one of North America's Top Thought Leaders in Trustworthy Business Behavior—2014. John Wiley & Sons has published his latest book, Audit Committee Essentials. You can reach him at curtisverschoor@sbcglobal.net.