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In Focus

It's time for J&J to challenge the Credo...again

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It has been 18 months since Alex Gorsky replaced Bill Weldon as chief executive officer of Johnson & Johnson. The reputation of the company Gorsky inherited from his predecessor Bill Weldon is a far cry from what Weldon inherited in 2002 from his immediate predecessor Ralph Larsen and the legendary James Burke, who preceded Larsen.

The questions and challenges facing Gorsky and J&J are daunting: Will J&J ever regain its once stellar reputation for ethics and social responsibility? Does J&J's famous Credo, emblazoned on an imposing stone structure at the entrance to its corporate headquarters, possess any remaining relevance or should Gorsky take a sledgehammer to the Credo and rebuild a meaningful and vigorous value system for the company from scratch?

A decade ago the idea of jettisoning its beloved Credo would have been heresy at J&J. But today it is an option the company needs to seriously consider, just as it did almost 40 years ago (more about that later). Former Chairman Robert Wood Johnson, a member of the company's founding family, composed the Credo in 1943 just before the company went public. Four decades later, the Credo helped steer J&J through its greatest challenge: a series of deadly tampering incidents involving Tylenol capsules. (To this day it remains a mystery who did it.)

Weldon's tenure at J&J included ethical and quality lapses in all three of its major divisions—Pharmaceutical, Medical Devices and Diagnostics, and Consumer. Its Janssen Pharmaceuticals division is facing potentially over $2 billion in fines and civil liabilities stemming from the improper marketing of Risperdal to children, infants, and the elderly. On August 23, 2010, J&J recalled 100,000 boxes of its 1-Day Acuvue TruEye contact lenses after customers in Japan complained of stinging or pain. A short time later, DuPuy Orthopedics recalled two products used in hip replacement surgeries after the FDA reported nearly 400 complaints. However, it is the company's McNeil Consumer Healthcare division that has became the face of the company's quality and ethical problems. In less than a year between September 2009 and July 2010, McNeil conducted seven recalls of over 136 million bottles of medicine. The recalls included many of J&J's most well known brands—Tylenol, Children and Infant's Tylenol, Tylenol Arthritis Pain Caplets, Benadryl, Children's and Infant's Benadryl, Motrin, Rolaids, Simply Sleep, St. Joseph's Aspirin, and Zyrtec.

In press reports, J&J has stoutly maintained that the defective products seriously injured no one, a fact supported thus far

by the FDA. Weldon himself insists that the various ethical and quality lapses occurring during his tenure were unrelated to each other. What united them, however, was that J&J's vaunted Credo was missing in action in all of them.

Some of the recalls were due to a chemical odor in packaging. Others were due to Current Good Manufacturing Practice violations uncovered by FDA inspections. After noting that J&J had failed to adequately follow up on hundreds of complaints from consumers, in February 2010 the FDA met with company official to express concern over J&J's "pattern of non-compliance" and to discuss, in the words of deputy commissioner Joshua Sharfstein, whether McNeil's "corporate culture supported a robust quality system to ensure the purity, potency, and safety of its product." In March 2011, three J&J plants were placed under FDA supervision pursuant to a consent decree.

J&J's quality problems began soon after it degraded its institutional compliance capabilities. With the assistance of McKinsey & Co., in 2007 J&J reduced quality & control staff at the corporate level by 35%. According to a 2010 *Fortune* magazine article, between 2005 and 2009 the number of employees at its problematic Fort Washington, PA, plant was cut by almost a third, including, former employees reported, the entire corporate compliance group that oversaw the quality control operations. The result, according to a court affidavit submitted by former SEC Commissioner Harvey Pitt, was that "the same staff responsible for establishing sector business strategy and goals were also responsible for managing quality compliance and risk." One former quality control employee said that the team testing the production line was referred to as the "EZ Pass System."

The pressure to do more with less can be traced back to J&J's $16.6-billion acquisition of Pfizer's consumer healthcare division in 2006. The company (no doubt egged on by consultants and investment bankers) estimated the merger would create cost savings of $500 to $600 million. At the same time, Pfizer moved McNeil from the pharmaceutical group, where quality, safety, and regulatory compliance were second nature, to the consumer group where dramatic cost cutting was undertaken to justify the price tag of the merger. Others cite the pressures on Weldon and J&J emanating from the increasingly challenging pharmaceutical industry environment with important patents (such as epileptic seizure drug Topomax) expiring and new discoveries becoming more elusive just as pricing pressure was increasing.

In 2012, J&J's board of directors entered into a settlement agreement to a shareholder derivative lawsuit whereby, among other things, the Board agreed to provide greater oversight of the chief compliance and quality officers. Perhaps the most telling fact about the settlement was that the Credo was not mentioned once in a document ("Governance Reforms") submitted by the company to describe the elaborate steps it would take to improve quality and safety. The legal hardware changes mandated by the settlement will not, however, solve the company's ethical drift software problems. The solution to those problems inevitably leads back to the Credo.

Today J&J executives pay reflexive and unquestioning homage to the Credo. However, the nexus between the firm's prosperity and its fidelity to patients and the medical community was never obvious or easy. In 1975, a year before he was scheduled to take over as CEO, then President James Burke initiated a "challenge" to the Credo. At the time the Credo was 30 years old and Burke wondered whether it was still relevant. Burke, according to a Harvard Business School case study, thought it was better to "tear it off the walls" than to have the Credo stand for nothing. In a remarkable series of meetings captured on film, senior executives openly challenged the Credo and questioned whether they could run a profitable business while adhering to it. It was a healthy and cathartic process. What emerged was a stronger and deeper commitment to a slightly reworded Credo. Less than a decade later, this vigorous challenge to the Credo proved critical during the Tylenol crisis.

It was the Credo—which proclaims that "our first responsibility is to doctors, nurses and patients, mothers and fathers"—that guided Burke and his crisis management team throughout the crisis. It was the Credo that led J&J to institute a broad national recall of Tylenol when the directors of both the FDA and the FBI advocated less drastic actions. It was the Credo that turned the Tylenol crisis into J&J's finest hour and cemented its reputation as the gold standard in corporate ethics. Patients knew that when push came to shove J&J would choose to do the right thing. Thanks to Burke's challenge the Credo was not just a slogan on the wall.

Is the Credo today a living, breathing set of values and beliefs that inspire and guide the actions of J&J employees or is it

a set of fine sounding platitudes carved into stone that are no longer relevant to the way J&J manages and makes decisions? Are consent decrees and settlement agreements more important than the Credo at today's J&J? If so, then maybe Alex Gorsky should take a sledgehammer to the Credo in the J&J lobby just as Burke was willing to tear it down from the walls. A serious challenge to the J&J Credo is long overdue because the company needs a vigorous and vital Credo--not a stone monument and not a series of legal settlements--to regain its once sterling reputation for ethical behavior and social responsibility.

Asked to comment on the need for a vigorous challenge to the continued relevance and appropriateness of the Credo, Ernie Knewitz, VP, media relations, responded by email that: “The principles of Our Credo are embedded in our company. They direct and guide our actions in addressing customer and patient needs, how we treat our employees, even in down business cycles, and how we interact and support our communities and provide fair returns for our stockholders.”

Knewitz wrote “management teams across Johnson & Johnson regularly challenge the way in which we lead our businesses and how we are meeting the principles of Our Credo.” He also noted that “Mr. Gorsky, as well as other leaders deeper in the organization, have held sessions similar to” the one conducted by James Burke in 1975. “From the outcome of those sessions,” Knewitz added, “it is clear that Our Credo is a living document that serves as the foundation of our business and that it is more relevant today than ever.”

Meanwhile J&J's quality control problems continue. In October it recalled 200,000 bottles of Motrin Infant's Drops when plastic particles were found in samples. A week later, it recalled a lot of injectable Risperdal Consta after a detecting a mold bacterium that could cause low risk infections at the injection point. Both products were manufactured by outside sub-contractors. Also last month, it was reported that J.P. Morgan Chase, plagued by its own ethical and compliance troubles, appointed Bill Weldon—already a director of the parent company board—chairman of its main banking subsidiary.

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