

Johnson & Johnson: An ethical analysis of broken trust

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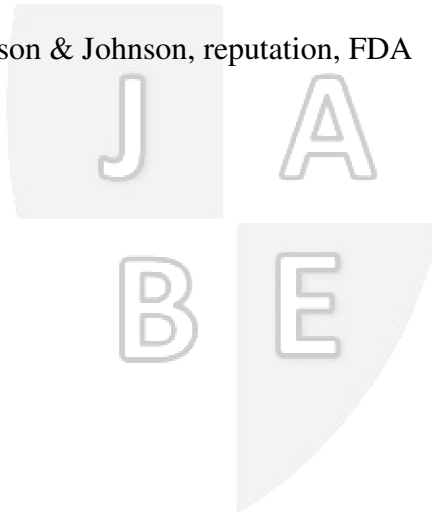
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ABSTRACT

For several decades, Johnson & Johnson has been the exemplar of superb ethical behavior in light of the prompt actions it undertook during the 1982 Tylenol cyanide poisoning incident. Now several decades later, J&J's Consumer Product Division has put the company and its reputation in jeopardy by its slow and ineffective response to a series of ongoing problems. This article provides an ethical analysis of those events and addresses the negative impact on Johnson and Johnson's once sterling reputation.

Business, ethics, recalls, Johnson & Johnson, reputation, FDA



INTRODUCTION:

For several decades, Johnson & Johnson has been the exemplar of superb ethical behavior in light of the prompt actions it undertook during the 1982 Tylenol cyanide poisoning incident that left seven dead in the Chicago area. After the 1982 incident, Tylenol quickly returned to category dominance. A few years later when yet another cyanide-laced Tylenol capsule resulted in the death of a New York woman, Johnson & Johnson and its McNeil subsidiary once again took quick action by only making a compressed and easier-to-detect-tampering version of a Tylenol pill available in the marketplace. The 1986 incident had little impact on sales or J&J's corporate reputation (Davidson & Samghabadi, 1986). Consumer safety and trust were of paramount importance to J&J. The firm validated the utility of their Our Credo philosophy in managerial decision-making during these crisis situations. For several decades thereafter, Johnson & Johnson has consistently and publicly expressed their continuing commitment to this credo.

Now several decades later, J&J's Consumer Product Division has put the company and its reputation in jeopardy by its slow and ineffective response to a series of ongoing problems that center on inadequate quality control inside some of the manufacturing plants and slow, reluctant, and ineffective corrective action in response to consumer complaints and growing FDA concerns. The end result is broken trust with consumers and growing damage to J&J's once pristine reputation.

The issues arising from recent multiple J&J recalls of Tylenol and other McNeil consumer products are fairly clear (Kimes, 2010, September 6 & 7; Singer & Abelson, 2011, January 15). Here the famous Our Credo oriented corporate culture significantly failed to protect consumers and other stakeholders from both defective products and questionable marketing. Moreover, the more recent problems with Tylenol have raised the broader issue of whether the McNeil problems are, as J&J maintains, unique to that division or are symptomatic of a broader breakdown in J&J's ethical culture. This article will examine what occurred in terms of modern ethical business theory using a framework outlined by Trevino and Nelson (2011) in the 5th edition of *Managing Business Ethics (Straight Talk About How to do it Right)*. Their work is a major resource for organizational analysis of ethical and unethical corporate behavior.

STEP ONE: GATHER THE FACTS

On December 17, 2010 a Verified Amended Shareholder Derivative Complaint against nominal defendant Johnson and Johnson was filed at the United States District Court of New Jersey (Civil Action No. 10-2033). This complaint was filed on behalf of individuals, relief associations and pension fund common stock shareholders who originate from several U.S. states and believe that the corporation and its culture had been harmed by mismanagement at J&J's consumer division, and in particular, by operations affiliated with J&J's subsidiary, McNeil Laboratories' Consumer Healthcare unit. Legal issues, per se, will not be addressed since the case is still pending. It is useful to note that this type of suit, unlike most shareholder actions, is not for recovery of lost income but rather an attempt to force the Board of Directors to change the course of the Corporation in order to protect future income. Instead the focus herein will be on the series of events that led to the filing of this case and a corresponding ethical analysis. However, this case raises the very basic question of whether the Our Credo based corporate culture of J&J has changed throughout the corporation or only at the McNeil subsidiary.

A New York Times article (Singer & Abelson, 2011) reported that in 2010 the McNeil Consumer Healthcare unit of J&J recalled about 288 million items including adult and children's pill medications and around 136 million bottles of liquid Tylenol, Motrin, Zyrtec and Benadryl for infants and children. The FDA stated that some of the products included in the recalls may contain a higher concentration of active ingredients, others may contain inactive ingredients that may not meet internal testing requirements, and others may be contaminated with bacteria or contain tiny particles of wood, glass, or metal. (Civil Action No. 10-2033). As recently as mid-February 2011 J&J recalled 70,000 syringes preloaded with its injectable anti-psychotic drug, Invega, due to cracked syringes and possible infection risk (Loftus, 2011). It also recalled its Securestrap Hernia product due to non-sterile packaging, and 395 injection pens in the U.S. and Germany which were pre-loaded with the rheumatoid arthritis drug, Simponi, due to possible dosage problems.

Specific recalls during 2010 alone as delineated in the shareholders case (Civil Action No. 10-2033) are as follows:

- Tylenol 8 Hour Caplet (50 count); about 128,000 bottles; October 18, 2010; due to musty or moldy smell emanating from the pills
- Benadryl Fastmelt tablets; 4,000,000 packages; Motrin caplets (800,000 packages); Extra Strength Roloids and Mylanta products (71,000 caplets); November 15, 2010; due to manufacturing insufficiencies (outside of specifications)
- Tylenol Cold Multi-Symptom liquid medication (9,000,000 bottles); November 24, 2010; due to the presence of alcohol from flavoring agents noted as an inactive ingredient on the package but not on the front panel
- Mylanta (12,000,000 bottles) and AlternaGel liquid antacid (about 85,000 bottles; November 29, 2010 in order to update the labeling to note the presence of small amounts of alcohol (less than 1%))
- Acuvue TruEye contact lenses (about 492,000 boxes); December 1, 2010; due to irritation and pain among users as a result of higher-than-expected levels of a type of acid used in the manufacturing process and not fully removed in the rinsing process
- Roloids (over 13,000,000 packages); December 9, 2010; due to metal and wood particles in the products

An online search will reveal that there were earlier recalls including one in April 2007 when bacteriological contamination led to a recall of all previously produced lots of the newly released children's Listerine Cool Blue mouthwash. The bacteria involved were highly antibiotic resistant and potentially deadly to children with impaired immune systems. In November 2008 there was a recall of Infants' Mylicon Gas Relief Dye Free Drops (a Merck/J&J joint venture at their Lancaster, PA plant) due to possible contamination by metal fragments (2008, Reuters, November 10). The various recalls cited above are described to illustrate that there have been ongoing problems connected to the production of J&J's consumer products. Those problems potentially impact on the potency, purity, consistency and safety of a wide variety of over-the-counter drugs for adults and children. What makes these recalls particularly puzzling is the effort J&J has made to position itself as the leading supplier of medications to infants and children. Marketing ethicists have noted that companies have particular responsibilities in protecting such vulnerable segments in the marketplace (Brenkert, 2008; Murphy, Lacznik & Klein, 2005).

It seems that J&J has had ongoing manufacturing and related quality control problems at most of its McNeil manufacturing plants, including the Fort Washington, Pennsylvania facility

and the Las Piedras, Puerto Rico facilities in particular (Sharfstein, 2010). Moreover, it appears that J&J was not in compliance with current Good Manufacturing Practices (cGMP). As alleged in the legal case that was filed in New Jersey, "...the J&J board of directors (the "Board") was warned, specifically and repeatedly over a number of years, that J&J's drug and medical device manufacturing and marketing practices represented systemic and widespread violations of the law." (Civil Action No. 10-2033, p.2) The legal case further states there were, "six FDA warning letters and additional violation notices specifically identifying unlawful marketing practices or public health and safety violations and demanding that J&J cease the identified practices and all similar misconduct." (Civil Action No. 10-2033, p. 2) J&J closed the Fort Washington plant in April 2010 for a \$100 million overhaul (Singer & Abelson, 2011). These types of breaches are not trivial because they violate the core of the voluntary FDA surveillance system which is intended to protect public health and well-being.

Another concern relates to an earlier problem—the so-called "phantom" recall of Motrin from retail stores that occurred around June 2008. J&J's McNeil subsidiary hired a contractor to remove approximately 88,104 packages of that medication from stores due to a concern with how the pills dissolved (U.S. Food & Drug Administration, 2010). Members at a Congressional hearing were informed the subcontractor had been instructed by J&J to tell employees that there was to be no mention of a recall. Instead the subcontractors' employees were to "simply act" like regular customers and buy the medication (CSCS, 2010). Needless to say, concerns have been raised about the surreptitious nature of this approach to a medication concern. The FDA did contact McNeil and asked it to remove the remaining product from store shelves. The firm did so in July 2009, eight months after learning of the problem with Motrin (Hensley, 2010). The basic problem here is that the FDA has no statutory authority to force recalls and relies on companies like J&J voluntarily informing the agency of such actions. That system cannot operate effectively to protect public health if companies conduct "phantom" recalls.

Defects and recalls is one of 16 possible crisis management categories and accounted for 6% of news reports in 2010 (Institute for Crisis Management, 2011). In that report they also conclude that, since 2001, the majority of crises were caused by managers. Moreover, the ICM reported that pharmaceuticals were the most crisis prone industry in 2004 (Institute for Crisis Management, 2005). A review of their annual reports since that time finds that industry continues to be listed in the top ten in subsequent years. In the 2011 report, pharmaceuticals were number six on the list and, across all industries J&J was listed as drawing the most headlines for defects and recalls.

As previously noted, the FDA essentially operates a cooperative system since they lack the statutory authority to demand recalls or removals from the marketplace. This voluntary system depends on companies discharging their ethical obligation to protect public health. J&J's problems, particularly their "phantom" recall, have led to proposed legislation, and a recent survey from within the industry found that 86% of the respondents indicated that the FDA should have the power to force drug recalls just as it does for defective food products (Pellek, 2011). Although this legislation is undesirable to companies given the cost involved with recalls and their loss of control over the process, the vote may reflect a perception within the industry that highly publicized recalls potentially damage the reputation of the industry as a whole.

Other problems in various divisions of J&J have also surfaced in recent years. On August 24, 2010 the FDA ordered J&J to stop sales of an orthopedic device (Corail Hip System) because the firm was marketing it for an unapproved use (Civil Action No. 10-2033). A much larger problem here is the recall of over 90,000 possibly defective hip replacements which

represents a potential liability to J&J of over \$1 billion (Litigation and Settlement News, 2011, February 3). Also, Risperdal, approved by the FDA for treating psychotic disorders in adults, was being illegally marketed and promoted for off-label uses. It is also alleged that Topamax, an anti-epileptic drug, which showed evidence of serious side effects in clinical trials was being marketed for a host of ailments and diseases for which FDA approval had not been granted (Civil Action No. 10-2033). While off label use of pharmaceuticals is a fairly common practice in the “art of medicine,” drug manufacturers are not permitted to directly promote to physicians off-label uses (Johns Hopkins, 2011 June).

Furthermore, Natrecor, which was approved by the FDA to treat patients with congestive heart failure and related breathing problems was being infused into patients in outpatient settings and J&J allegedly encouraged the growth of these types of facilities for administering the infusions despite risks to patients and a lack of scientific evidence that regularly scheduled infusions was safe or effective (Civil Action No. 10-2033). A New York Times article (2005, August 9), indicated that J&J was asked to begin warning doctors against the drug’s use in outpatients, a treatment that was not approved by the FDA; however, that use was known to be a big money maker for the firm. Another concern revolved around the sale and marketing of biliary stents. Biliary stents were designed for cancer patients. The purpose of the stent is to aid drainage in the bile duct. J&J has been accused of funding studies for off-label use (e.g., peripheral vascular disease) and providing unsolicited marketing and promotional literature to doctors for unapproved use of those stents. It is further alleged that sales representatives were given mandatory quotas and bonuses for selling certain numbers of stents for off-label use and that sales representatives provided physicians with manuals that showed them how to falsely file for reimbursement for off-label use of the device (Civil Action No. 10-2033).

What can be gleaned from these facts is that J&J’s actions (or lack thereof) have directly resulted in a series of problems that have negatively impacted the reputation of the firm. Unlike the Tylenol situation in 1982, these issues were internal and caused by management lapses at J&J. Moreover, it appears that J&J has been slow to respond to a myriad of problems: that their responses have been largely guided by considerations of legal vulnerability, and that these developments may represent a major change from what consumers have come to know and expect from a company that has been held in high regard by the buying public for decades. Those expectations reflect over 30 years of successful public relations structured around J&J’s continuing commitment to their famous Our Credo. On their Web site they clearly state, “The values that guide our decision making are spelled out in Our Credo. Put simply, Our Credo challenges us to put the needs and well-being of the people we serve first.”

(<http://www.jnj.com/connect/about-jnj/jnj-credo/?flash=true>, paragraph 1).

STEP TWO: IDENTIFY THE PERTINENT ETHICAL ISSUES/POINTS OF ETHICAL CONFLICT

The primary ethical problem that surfaces is that J&J faces major challenges within all three of its business groups (pharmaceuticals, medical devices and consumer products). Many of these problems represent significant potential or actual harm to consumers. In particular the firm has been accused of not addressing the quality control concerns in a timely fashion, and of inadequate responsiveness to consumer and patient complaints arising from product problems. Also, it has been alleged that the firm has continued to engage in aggressive (and at times, illegal) marketing efforts to sell those medications and devices in order to keep their sales and

profits high with little regard for the well-being of consumers and patients. A recent analysis found over 60 ethical issues raised by recent J&J actions (2011, Paine).

STEP THREE: IDENTIFY THE RELEVANT AFFECTED PARTIES

One relevant element relates to stakeholder theory. Stakeholders are individuals and entities that have a vested interest in the firm. It is important to identify who will be harmed by actions undertaken by the firm and to what extent. In this case, key stakeholders would include consumers, the medical community, the FDA, shareholders, J&J employees, and J&J management and its Board of Directors. The situation at J&J is relatively unique since in 1982 they were lauded for appropriately representing the interest of all relevant stakeholders and in 2010 were excoriated for the opposite. Customers, medical personnel, J&J employees and executives, regulators and legislators all have expressed a deep disappointment at recent company actions. Even business professors and ethicists no longer have J&J as an immediate answer to the question, "Can you name one ethical company?" The only happy group of stakeholders appears to be the lawyers.

More specifically J&J has long had a credo in place that identifies and prioritizes their primary stakeholders. In part it states the following key principles:

We believe our first responsibility is to the doctors, nurses, and patients, to mothers and all others who use our products and services. In meeting their needs, everything must be of high quality... We are responsible to our employees, the men and women who work with us throughout the world... We are responsible to the communities in which we live and work... Our final responsibility is to our stockholders. Businesses must make a sound profit. We must experiment with new ideas. Research must be carried on, innovative programs developed and mistakes paid for. New equipment must be purchased, new facilities provided, and new products launched. Reserves must be created to provide for adverse times. When we operate according to these principles, the stockholders should realize a fair return." (as cited in Hartley, 2005, p. 311)

In a New York Times article Meier (2010, December 17, p. B1) quoted Dr. Stephen Graves, the Director of Australia's orthopedic database as stating, "When it is clear to the orthopedic community that a company has not been honest, that is a problem. I think J&J has a major issue." The company initially exacerbated this concern by claiming that the problem was not with the product, but rather with how it was inserted by surgeons. A confidential witness in the New Jersey shareholders case (Civil Action No. 10-2033) indicated that there was a clear direction to sell Risperdal (approved by the FDA to treat psychotic disorders in adults) to elderly patients for treatment of dementia and Alzheimer's disease, both unapproved uses of the drug. Another complaint in that legal document is that Topamax (an anti-epileptic drug) was being aggressively marketed as a potential treatment for a number of conditions for which there was not any valid scientific evidence supporting its safe use. It is further alleged that J&J trained its sales force to mislead physicians into believing that such evidence existed (Civil Action No. 10-2033). Another concern revolved around J&J supposedly encouraging the establishment of infusion clinics that would provide outpatient infusions of Natrecor. According to an article published in The New York Times (2005, August 9) this drug was not approved by the FDA to be used in outpatient settings and should have been strictly limited to the treatment of acutely ill patients in hospitals. However, use of this drug in outpatient facilities had turned into a big money maker for J&J. Another money-related issue concerns the equipment that was being used

at the Fort Washington plant. A confidential witness stated that he had learned that certain equipment needed to be replaced but upper management refused to do so due to cost-saving measures (Civil Action No. 10-2033). It should also be noted that the “ORA FOAI Electronic Reading Room> McNeil Healthcare” section of the FDA website documents multiple cGMP violations at the main McNeil production facilities dating back over ten years.

Although there have been no reported deaths from the various OTC situations cited above, J&J has engaged in activities that represent a serious breach of trust with its stakeholders. It appears that J&J was attempting to put its stockholders first by engaging in activities that were designed to fatten the bottom line but in an ironic twist, it is stockholders who are becoming vocal about short-sighted practices and the apparent lack of appropriate action that have seriously damaged the company name and reputation. Also, it appears that J&J, particularly at its McNeil subsidiary and probably at Dupuy and several other operating units as well, may have lost sight of long-held and cherished corporate values.

Key stakeholders were clearly let down by J&J. Physicians and others in the medical community were misled by some of the information that was provided and/or told to them. Parents, who are responsible for making decisions in the best interests of their children, found themselves administering medication to them that did not comport with current Good Manufacturing Practices. Pharmacists and other suppliers lacked desired products as did brand loyalists. Adults (particularly the elderly), suffering from various maladies, must rely on the wisdom and guidance of members of the medical community and companies like J&J. Shareholders, in turn, suffered from short-sighted decisions made by managers and the Board of Directors. Employees’ livelihoods were put at risk by the temporary closing of the Fort Washington plant and subsequent remuneration restrictions throughout J&J because of the reduced sales of the consumer operating units. Plus, the overall profitability and reputation of a once stellar company was damaged. In 2010 alone consumer product sales were \$1.2 billion under the 2009 sales figure. That represents an abrupt reversal of the past pattern of increases as documented in multiple J&J annual reports. It is said that companies are able to build up trust accounts (Trevino & Nelson, 2011). Much like a bank account where deposits can be made and withdrawn, J&J made a substantial deposit to its trust account through the proper handling of the 1982 Tylenol poisoning incident. However, recent actions (or lack thereof), have contributed to withdrawals from J&J’s trust account. As Trevino and Nelson (2011) note, trust has both economic and moral value.

STEP FOUR: IDENTIFY THE POSSIBLE CONSEQUENCES OF ALTERNATIVE COURSES OF ACTION

Traditional utilitarian theory suggests that decision-making ought to be conducted in such a way that total benefits exceed total costs by the maximum amount possible (e.g., the greatest good for the greatest number of stakeholders). This approach to decision-making is often used in situations involving eminent domain (e.g., the “cost” of displacing homeowners as compared to the “benefit” to society of highway construction proceeding in a given area). However, as noted by Trevino and Nelson (2011, p. 41), “...it is often difficult to obtain the information required to evaluate all of the consequences for all stakeholders who may be directly or indirectly affected by an action or decision.” Moreover, it can be difficult to quantify the extent of the “benefits” and “costs.” Pharmaceutical recalls can have multiple causes (Priporas & Vangelinos, 2008) and much of the relevant information is proprietary and unavailable. What is clear is that both the immediate and the longer term costs to almost all stakeholders of recent J&J actions far outweigh

the relatively limited cost benefits gained by not taking needed corrective action in a timely and effective manner. For example, the complete renovation of the Fort Washington production facility will cost over \$100 million. The 2011 J&J Annual Report (released in 2011) indicated that J&J consumer sales dropped over \$1 billion from 2009-2010. Major additional costs were incurred in the various recalls. A real issue here is whether or not J&J's reservoir of goodwill will be drained to the point where there are continuing profit reductions associated with further reduced sales. There will be a variety of outlays associated with plant renovations, use of outside consultants mandated by the FDA under the Consent Decree, marketing expenditures as brands return to crowded shelves, and a growing number of legal proceedings.

The foregoing information clearly indicates that a host of individuals were affected by inaction and slowness to respond by company officials. Vulnerable groups such as children, senior citizens, and others experiencing health problems were put at risk. Fortunately, however, there were no deaths clearly linked to cGMP violations but that is not true for pharmaceuticals and medical appliances. Consequently, J&J had an ethical responsibility to respond more quickly with respect to ensuring its facilities were adhering to accepted quality control standards, equipment should have been replaced and/or monitored more regularly, and recalls should have been implemented much sooner than they were. Moreover, problems with over-the-counter medications would not have occurred had the firm worked more closely with the FDA to resolve the issues documented during recent site visits.

STEP FIVE: IDENTIFY RELEVANT OBLIGATIONS

Relevant obligations center on duties. The question becomes one of asking to what extent the firm had a duty to investigate and correct problems (1) that were occurring inside its plants and (2) with the marketing efforts of the operating units of a highly decentralized corporation. Did J&J have an obligation to inform doctors, nurses, and others in the medical community sooner than they did and more fully? To what extent did the firm have an obligation to notify the media and consuming public about the problems? Did J&J have a moral as well as a legal duty to respond appropriately to FDA warning letters and to voluntarily recall affected products or remove them entirely from the market? Did J&J have a responsibility to train its salespeople to adhere to ethical marketing practices? Did J&J have an obligation to ensure that its marketing materials did not mislead? An analysis of Johnson and Johnson's own public statements and documents used to train and direct personnel indicates that they were committed to discharge all of these duties in an exemplary fashion. However, they apparently did not do so in accordance with their stated values.

STEP SIX: IDENTIFY YOUR RELEVANT COMMUNITY STANDARDS THAT SHOULD GUIDE YOU AS A PERSON OF INTEGRITY

The relevant community includes the various stakeholders mentioned in J&J's credo plus the pharmaceutical industry in general and the FDA in particular. It should be noted that while other pharmaceutical firms have faced similar problems in the same timeframe, the situation at McNeil and Johnson & Johnson stands out in terms of the number and variety of problems. Big Pharma in general would likely not be pleased with additional scrutiny (and possibly more government regulation) of its operations as a result of J&J's missteps. Patients and the medical community at large would expect a firm such as J&J, that has made its name and reputation on caring for the vulnerable (babies and children in particular), to consistently and reliably produce

high quality products and remove defective products rapidly from the marketplace. They would also expect a quick and thorough investigation when problems arose and fast and effective corrective action. They would expect the firm to engage in whatever activities need to be undertaken, despite attendant costs, to ensure that their well being is being protected. Trust was earned and enhanced during the 1980s when J&J and its McNeil subsidiary were so quick to recall Tylenol due to cyanide poisoning incidents that resulted in multiple deaths. In the aftermath of those events, J&J was instrumental in developing tamper-resistant packaging that is now the industry standard. One has to wonder what has changed inside some operating units and possibly throughout this company since those days. A major limitation here is that Johnson & Johnson has imposed very strict limitations on the amount of information available from within the firm during recent years. This makes any analysis of the company situation preliminary until more information from various lawsuits and company documents pertinent to discovery become available.

STEP 7: CHECK YOUR GUT

A “gut” decision should have been an easy call. When OTC products have a moldy smell, when wood, metal, and other particles are turning up in medications that are designed to be ingested, when individuals have to undergo a repeat of surgical procedures to replace defective medical devices, there is no need for second guessing whether something needs to be done to address those situations. At the very least, inspections and corrective action needed to be carried out in the problem facilities. Products, particularly surgical devices should not be released into the market based on faulty or inadequate scientific testing. Under circumstances when medical devices are released in good faith but problems arise, at the very least, the medical community ought to be informed so they and their patients can make appropriate decisions. When the FDA issues warning letters, appropriate responses are expected. Most employees want to feel good about themselves and the firms they work for. Good, responsible ethical training should be provided and employees should be rewarded (or punished) based on adherence to (or disregard of) the code of conduct that is in place. The Our Credo and J&J’s own policies and procedures and training activities all could be rapidly mobilized to support the above mentioned actions.

STEP 8: WHAT WILL YOU DECIDE?

It is clear that J&J has made withdrawals from its “trust” bank in recent years. The decision should have been made to take corrective action much sooner than what occurred. However, the series of problems that have plagued J&J in recent years do not rise to the level of concern that was raised during the Tylenol poisonings so full-blown media attention by top officials at J&J, and the media, was not warranted or expected. However, it is difficult to understand why this once stellar firm allowed so many problems to continue and for so long. It is also unclear why J&J was so unresponsive to warning letters issued by the FDA. Most marketing professionals know that it can take decades to establish a name and reputation of trust but only one or a few brief lapses to destroy a company image. There already are some preliminary indications from different surveys that have been undertaken that indicate J&J’s good corporate reputation is beginning to wane. For example, J&J ranked #4 in the *Fortune Magazine’s* 2009 list of the World’s Most Admired Companies (<http://money.cnn.com/magazines/fortune/mostadmired/2010/>). However, in the 2010 ratings

J&J had dropped to #17

(<http://money.cnn.com/magazines/fortune/mostadmired/2011/index.html>). The continuing negative publicity associated with the events described herein is likely to have a cumulative negative impact on Johnson and Johnson's once sterling reputation. In turn there are likely to be negative impacts on sales and profitability.

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