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A Matter of Trust: Johnson & Johnson Product Recalls

*This case was written by **Anand,** IBS Hyderabad. It was compiled from published sources, and is intended to be used as a basis for class discussion rather than to illustrate either effective or ineffective handling of a management situation.*

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A Matter of Trust: Johnson & Johnson Product Recalls

"I know that we let the public down. We did not maintain our high quality standards. Children do not have access to our important medicines. I accept full accountability for the problems and I will take full accountability for fixing them."

– William Weldon, CEO, Johnson & Johnson, in 2010.[1]

"This is not the first time a multinational corporation appears to have under reacted to a limited product problem that turned into a big public relations headache. Coca-Cola was slow to respond to reports in 1999 that several hundred people in Western Europe had become sick after drinking Coke."

– Stephen A. Greyser, Professor Emeritus of Marketing, Harvard Business School, in 2010.[2]

"Looking for Tylenol pain relief products?" asked some signs at a CVS[3] drugstores located in suburban Boston at the beginning of 2011. Trying to help customers who might be searching unsuccessfully for Tylenol, the signs suggested, "Try CVS/pharmacy brand" and little red flags peeping out of shelves guided people toward the alternatives available. While the signs remained silent about Tylenol, this hint ended most customers' search for Tylenol and served as a subtle confirmation of its absence from the store.[4] Some customers who probed further soon realized that it was not just Tylenol but an entire range of drugs from the much trusted brand Johnson and Johnson (J&J) that were not to be found in any store they visited. These drugs included Motrin, Rolaids, Mylanta, Pepcid AC, some Neutrogena skin care products, and children's Tylenol liquid and adult Tylenol.

Regular customers had no clue why the drugs were missing nor had they any reason to suspect that there was anything wrong with the medicines offered by a reputed brand that had a history of more than a century making itself synonymous with quality and buyer's trust. It was surprising to some of those who were not following J&J closely for unaware of quality related issues in some of its products which had started to surface since 2008. But some quick enquiries at drug stores and a little research about the non-availability of these drugs brought to light one of the most unnerving revelations. The mentioned drugs were in short supply because McNeil Consumer Healthcare (MNCH)[5], which was a part of J&J, had recalled about 288 million products in the last one year (2010) due to alleged defects in the products. These included 136 million bottles of liquid Tylenol, Motrin, Zyrtec, and Benadryl for infants and children.

1 Parija Kavilanz, "Johnson & Johnson CEO: 'We Made a Mistake'," *CNN Money*, http://money.cnn.com, September 30, 2010.

2 Natasha Singer, "In Recall, a Role Model Stumbles," *The New York Times*, January 17, 2010.

3 CVS is a drugstore retail chain in the US.

4 Natasha Singer and Reed Abelson, "Can Johnson & Johnson Get Its Act Together?" *The New York Times*, January15, 2011.

5 Founded in 1879 by Robert McNeil as a retail pharmacy, it was converted into a direct drug and pharmaceuticals marketing company by his son Robert Lincoln McNeil in 1933 with the new name McNeil Laboratories.

In 1959, J&J acquired McNeil Laboratories which was renamed as McNeil Consumer Healthcare (MNCH) after some intermediary corporate restructurings and name changes. The company was involved in manufacturing and marketing of over-the-counter as well as prescription drugs.

Those who cared to look into the entire series of events soon realized that the Food and Drug Administrator (FDA)[6] of the US had alleged serious quality lapses at the MNCH facility and criticized it for failing to adhere to the "best manufacturing practices," which were mandatory for the pharmaceutical industry. The FDA had also accused the company of resorting to a soft market withdrawal of the products by hiring contractors to buy the entire available lot from the shelves of retail locations and stated that it might consider initiating criminal proceedings against J&J for its lapses and wrongful product recall which had undermined public health.

JOHNSON & JOHNSON

Robert Wood Johnson (Robert), an American entrepreneur, was born on February 20, 1845[7], in Carbondale, Pennsylvania. In 1864[8], he moved to New York City to work at Roushton & Aspinwall where he came into contact with George J Seaburgy (George),[9] who was later to become Robert's partner in their company Seabury and Johnson. Both Robert and George were inspired by Joseph Lister's[10] inventions and ventured to make medical instruments and products that would be useful in the surgery room. Their firm specialized in manufacturing medical instruments and surgical tools. With Robert's entrepreneurial abilities and George's expertise in the medical instruments area, Seabury & Johnson achieved phenomenal success. However, some disputes arose between them later and, in 1880, Robert sold his shares to George and agreed not to go into the medical business for ten years in exchange for a monthly compensation.

Robert found that two other members in his family were interested in starting a medical products business — Edward Mead Johnson (Mead) and James Wood Johnson (James). As Robert was not allowed to re-enter the medical products business under the terms of his agreement with George, James and Mead started a family business called Johnson and Johnson (J&J). However, since the new firm did not have the capital to run a start-up company, it struggled to stay afloat. On the other side, George was unable to pay Robert the monthly payments that had been agreed upon when he left the partnership. So by mid-summer of 1886[11], Robert was able to re-enter the medical products business with the lapsing of the agreed monthly payment from George. He then joined his family firm J&J as its president, bringing with him his business talent and providing the capital for a fresh start.

J&J began the production of dressings in 1886 at a factory located in New Jersey. It employed 14 people and had its headquarters in New York. From this modest start, the company grew quickly and in about two years, it was earning a net profit of $25,000.

The company began to grow even more rapidly when it came under the chairmanship of James after Robert died in 1910. Its first foreign subsidiary was established in Canada in 1919. Expansions overseas began with the establishment of a J&J subsidiary in Great Britain in 1924 (Exhibit I: Important events in the history of J&J). At the age of 25, Robert's son, Robert Wood Johnson Junior (Robert Jr.), who had joined the company as a mill hand, become the vice president. He was elected as president in 1932. In 1943, Robert Jr. gave a corporate credo for J&J, prioritizing the company's social responsibilities toward customers, employees, the community and the environment, and to stockholders.

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6 FDA was an agency under the aegis of Department of Health and Human Services in the US which was responsible for protecting public health and safety.

7 John Louie Ramos, "Biography: Robert W. Johnson," *Helium*, www.helium.com, June 20, 2010.

8 Wikipedia contributors, "Robert Wood Johnson I", *Wikipedia, The Free Encyclopedia*, http://en.wikipedia.org/wiki/Robert_Wood_Johnson_I, December 2, 2010, (Retrieved on May 16, 2011).

9 George J Seaburgy was a renowned chemist and pharmacist. He was a member of the American Pharmaceutical Association and was even elected President of the New York State Pharmaceutical Association in 1895.

10 Joseph Lister was a British surgeon and a pioneer of antiseptic surgery, who promoted the idea of sterile surgery. He introduced Carbonic Acid to sterilize surgical instruments and to clean wounds, which led to reducing post-operative infections and made surgery safer for patients.

11 Margaret, "The Anniversary of Our First Building!," *Kilmer House*, www.kilmerhouse.com, January 8, 2009.

The very next year, in 1944, J&J was listed on the New York Stock Exchange and it changed from being a family-owned company to a public company. In 1959, J&J acquired McNeil Laboratories, Inc., which at that time used to make a non aspirin-based pain reliever named Tylenol (a prescription drug then). By 1960, Tylenol, under the J&J umbrella, had been brought into the Over-the-Counter (OTC) medication categoryJ&J. Tylenol, was positioned as a premium priced medicine after J&J acquired MNCH in 1959. But by 1975, due to increasing competition from Datril, Bristol-Myers Company's notably lower priceddrug, J&J was forced to reduce Tylenol prices to make it a relatively competitively priced product with a mass market focus. This strategy resulted in making Tylenol the market leader, beating not only Datril but other competing products also.

Toward the end of the first decade of the 2000s, J&J was seen as one of the most trusted and reputed brands in the US. It fared very well on the US Reputation Quotient conducted by Harris Interactive[12] which annually ranked the 60 most visible companies in the US. In the 2010 version of the survey, J&J was ranked second, missing first position by a very thin margin. Moreover, a public opinion poll conducted by the Center for Corporate Citizenship[13] at Boston College in collaboration with the Reputation Institute[14] ranked J&J alongside Walt Disney (NYSE: DIS) and Kraft Foods (NYSE: KFT) in a list of companies which the general masses perceived as being the most "socially responsible."[15] (Exhibit II: Leading Rewards and Recognition).

J&J had been following a very aggressive program of acquisitions, which made it one of the most diversified (Exhibit III: Principal Competitors, Subsidiaries and Operating Groups of J&J) companies at the end of first decade of the 2000s. It operated under three business segments: pharmaceutical, professional, and consumer (Table 1: Share of three business segments where J&J operated). The diversification process over the years also resulted in a broad-based product range across business segments (Exhibit VI: Major Consumer Brands under J&J group), which included common household medicine names like Motrin and Tylenol. On an aggregate basis, J&J generated revenue through its 190 operating subsidiary companies spread over 51 countries which used their marketing organization that sold different J&J products in more than 175 countries. By 2010, about fifty percent of its revenue was being generated outside the United States.

Table 1

Share of Three Business Segments where J&J Operated

Segment	Percent of Revenue	Percent of Operating Income
Pharmaceutical Segment	39	61
Professional Segment	36	27
Consumer Segment	25	12

Source: compiled from various sources.

[12] Harris interactive is a marketing research and consultancy company based in New York (USA).

[13] Established in 1985, the Center for Corporate Citizenship is a membership-based research organization under the aegis of the Carroll School of Management at Boston Collage.

[14] Established in 1997, Reputation Institute is a private research and advisory firm which also identifies best practices from around the world in order to advise and help businesses in corporate reputation measurement and management.

[15] Andreas von der Heydt, "2010 Harris Reputation Quotient Summary Report," *Consumer Goods Club*, April 6, 2010.

THE CRISIS

Based on the FDA's reports alleging lapses and misconduct at J&J, the matter was taken up by the House Committee on Oversight and Government Reform (HCOGR)[16] of the US Congress. FDA testified that MNCH had quality problems with one of its products which J&J had discovered in 2008 itself. It further stated that the company had reported the problem to FDA only after a significant delay in 2009. When the issue was reported, FDA had asked MNCH to carry out a product recall. But instead of a full and public recall of the product, the J&J unit had carried out a secret recall in which it did not inform the public about the product deficiencies. Instead, it had hired contractors to buy the entire available lot of the drug from the shelves of retail locations across the region. FDA claimed that it was not aware of the secret nature of the recall until mid-2009 after which it advised MNCH to carry out a full product recall in July 2009. The FDA said that based on further investigations into the "patterns of violations in manufacturing and quality control practices that had led to a number of recent recalls,"[17] (which later continued till the first quarter of 2011; Exhibit V: List significant of developments at J&J since phantom product recall)[18] it was considering further action against the J&J unit which might include criminal proceedings and penalties.[19]

Later, based on its criminal investigations and findings, the FDA reported in early 2011 that the company "has failed to correct certain quality control and procedural problems documented in prior inspections and cited in a January 2010 warning letter to the company."[20] Based on these reported failures in coming up to the prescribed quality standards under a "Consent Decree" in March 2011, the FDA took control of J&J's three Tylenol manufacturing facilities.[21]

This was a big blow to the the company which had enjoyed an enviable reputation in the eyes of its consumers with a corporate credo that said, "We believe our first responsibility is to the doctors, nurses and patients, to mothers and fathers and all others who use our products and services. In meeting their needs everything we do must be of high quality."[22] As industry experts discussed the long-term impact of these recalls and quality issues on the J&J brand and the possibility of its erstwhile loyal customers permanently switching to other available competing brands, the press carried reactions of consumers like Thien-Kim Lam, a mother of two who used to buy some of the J&J products in question, including Tylenol, for herself and her family. She was quoted as saying that she would not "even consider buying them any more."[23]

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16 The Committee on Oversight and Government Reform (HCOGR) is an apex monitoring and oversight body of the Legislative House (Congress) of US which has legislative jurisdiction to investigate and bring to justice virtually everything government does with a purpose to expose waste and fraud. It works through different subcommittees, each of which is focused on specific areas of government activities. Each subcommittee is headed by a chairman and members who are members of the legislative house.

17 Manmeet Kaur, "FDA Looking Into J&J's Recall of Children's Medicines," *The Money Times*, June 12, 2010.

18 David Voreacos, Alex Nussbaum and Greg Farrell, "Johnson & Johnson's Quality Catastrophe," *Business Week*, March 31, 2011.

19 Natasha Singer, "F.D.A. Weighs More Penalties In Drug Recall By J.&J. Unit," *New York Times*, May 28, 2010.

20 Ashley Perrone, "Johnson & Johnson's Tylenol Factory Fails FDA Inspection," *The Stillman Exchange*, December 7, 2010.

21 Ransdell Pierson, "FDA to Oversee J&J Plants After flood of Recalls," *Reuters*, March 11, 2011.

22 Robert Wood Johnson, "Our Credo," *Johnson & Johnson*, www.jjdevcorp.com, (Retrieved on May 16, 2011).

23 Natasha Singer and Reed Abelson, "Can Johnson & Johnson Get Its Act Together?" *The New York Times*, January15, 2011.

THE "PHANTOM RECALL"

Product recalls were not a new phenomenon either in the pharmaceutical industry or in J&J. In fact, J&J had an exemplary track record in managing such crises in the past which had built consumer confidence in the company, making it an enviable brand. But this time around, it was the nature of the initial recalls, the delay in the formal recalls, the prolonged series of recalls, and the FDA finding multiple lapses in the manufacturing and quality control processes which brought to the issue a significantly high level of attention from society, the regulator, as the well as the governing and supervisory bodies.

As more and more recalls were ordered and new information on the alleged lapses at J&J came to light, the matter was taken up for investigation by the HCOGR in May 2010. The enquiry and hearings which followed revealed that the J&J unit (MNCH) had known of problems with the Motrin formulation in 2008[24] but rather than issuing a regular product recall, had gone in for hiring contractors to secretly buy the entire lot of the product available with the retailers. The act attracted widespread criticism and was later termed by the HCOGR[25] as the "phantom recall." Investigations also brought to light another attempt by MNCH to carry out one more "soft market withdrawal" by secretly buying these products in the form of more than 88000 Motrin tablets in June 2009.[26] In mid September 2010, the chairman of HCOGR, Edolphus "Ed" Towns (Edolphus)[27], released a new series of emails from one of the contractors who allegedly was hired to "secretly buy the troubled products". These emails dated toward the end of June 2009 suggested that "the company planned to extend the phantom recall to other defective products" as well.[28]

More disturbingly, the HCOGR reports also pointed toward the FDA's alleged misrepresentation of facts about the secret recall. In the second hearing of the committee toward the end of September 2010, FDA deputy commissioner, Joshua Sharfstein (Joshua), testified that in April 2009, J&J had informed the FDA of its plans to repurchase the Motrin pills which did not dissolve correctly. More importantly, the FDA maintained at the hearing that the "regulators were not aware of the deceptive nature of the recall" carried out during the second half of 2008 and the early part of 2009.[29] Later, the FDA spokeswoman Elaine Bobo (Elaine) said that when the FDA learned about MNCH's secret purchasing of Motrin pills off the shelves involving contracted agencies, it had advised the J&J consumer unit "to do a full recall, which the company agreed to initiate in July 2009."[30] Contradicting the FDA's stand that it had been unaware of the matter and much to the concern of consumers and the legislative committee, the HCOGR revealed in its release that it had conclusive evidence to suggest that FDA officials were told by J&J about the hiring of contractors to buy back the defective products from stores and retail locations before the activity was undertaken. The committee release further brought to light the fact that the FDA was informed by

[24] Dawn Fallik, "State Sues Johnson & Johnson Over 'Phantom' Motrin Recall," *Walletpop*, www.walletpop.com , January 12, 2011.

[25] Matthew Perrone, "FDA Docs: J&J Knew of Problems with Motrin in 2008," *Business Week*, May 27, 2010.

[26] Parija Kavilanz, "Johnson & Johnson May Have Planned Phantom Tylenol Recall," *CNN Money*, http://money.cnn.com, September 16, 2010.

[27] Edolphus "Ed" Towns (Edolphus) was the US representative who also served as the chairman of HCOGR from January 2009 to January 2011.

[28] Mike Lillis, "House to Examine Johnson & Johnson 'Phantom Recall'," *The Hill*, September 16, 2010.

[29] Matthew Perrone, "J&J, FDA Leaders Take Heat for 'Phantom' Recall," *Physorg*, www.physorg.com, September 30, 2010.

[30] Ransdell Pierson, "UPDATE 2-Panel Asks if FDA Knew About Secret J&J Recall," *Reuters*, September 21, 2010.

the J&J unit about its soft market withdrawal intentions before April 2009 and that MNCH had also communicated to the FDA about its aim to complete Motrin's phantom recall by July 15, 2009.[31]

In May 2010, based on its investigations into the allegations of secret recall and manufacturing lapses by MNCH, the HCOGR called upon J&J CEO William Weldon (William) to testify before the committee. William did not turn up for this first hearing as he was reportedly recovering from a back injury. Instead, he was represented by Colleen Goggins (Colleen) who was the worldwide chairman of J&J's consumer healthcare group. On September16, 2010, the legislative committee sent a second notice to William and also asked Colleen to testify in the case. Interestingly, immediately after this second notice, J&J announced that Colleen, who until then had been widely considered as William's successor for the post of CEO at J&J, would retire by March 1, 2011.[32] At the second hearing which was held toward the end of September 2010, William and Colleen appeared before the committee. When the lawmakers charged the company with manufacturing lapses and wrongful phantom recalls and accused J&J of placing profits before consumer health and welfare, the CEO admitted that J&J had made a mistake in conducting the phantom recall which had misled the US.[33]

Not much after the CEO's admission — around the middle of January 2011 — the state of Oregon sued J&J for the phantom recall, alleging that the company had put fears of negative publicity ahead of consumer interests. Highlighting the reasons behind the legal action by the state, John Kroger (John), the State of Oregon Attorney General said, "Part of our goal here is not just to hold Johnson & Johnson accountable, but to send a very strong message that if you have a defective health product, you cannot do a phantom recall…. The thing that's scary is that, if a company does a successful phantom recall, no one knows about it."[34]

J&J CRISIS (1982): THE GOLD STANDARD IN BRAND CRISIS MANAGEMENT

This was not the first time that J&J had faced a major product quality related crisis. A major Tylenol tragedy had occurred in 1982 as well. In September 1982[35], seven people died in the Chicago area after reportedly ingesting Tylenol pain relief capsules. Investigations found that the medicine had been laced with potassium cynide. In an immediate response, J&JJ&J recalled all of the estimated 31 million bottles of Tylenol products that were in circulation, on October 5, 1982.[36] The subsequent investigation by the FDA found out that the tampering had been done not at the manufacturing level but at the retail level. But by then, the damage had been done. Within one week of the incident, J&J's stocks dropped by 18%. Also, the market share of Tylenol dropped from 35% to 8%.

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[31] "New Documents Prove FDA Knew and Misled Congress," *Committee on Oversight and Government Reform*, http://oversight.house.gov, (Retrieved on May 16, 2011).

[32] Jonathan D. Rockoff and Peter Loftus, "J&J Consumer Chief to Retire," *The Wall Street Journal*, September 17, 2010.

[33] Susan Heavey, "UPDATE 3-J&J Admits Misleading U.S. Motrin Recall," *Reuters*, September 30, 2010.

[34] Tracy Staton, "Oregon Sues J&J Over 'Phantom' Motrin Recall," *Fiercepharma*, www.fiercepharma.com, January 13, 2011.

[35] Sworsky Mary, Dougal April and Salamie David, "Johnson & Johnson," *International Directory of Company Histories*, www.encyclopedia.com, (Retrieved on May 16, 2011).

[36] Wikipedia contributors, "Chicago Tylenol murders," *Wikipedia, The Free Encyclopedia*, http://en.wikipedia.org/w/index.php?title=Chicago_Tylenol_murders&oldid=425861985, April 25, 2011, (Retrieved on May 16, 2011).

The tragedy led to a transformation in the packaging of OTC products along with a revision in the US anti-tampering laws which made them more stringent. Guidelines were issued for tamper-resistant packaging while within a year the FDA introduced a new set of strict regulations to deal with any attempt to tamper with any such product in future. To bring Tylenol back in the stores, J&J used a triple-layered protected packaging with the purpose of gaining back public confidence in the product. J&J further employed several marketing and price promotion techniques to recoup its losses. In one such move, the company offered to replace all the Tylenol capsules which had been bought by retail consumers with solid tablets in a free exchange offer since the investigation reports revealed that the tampering had been done only with the Tylenol capsules. In an exemplary display of commitment toward adhering to quality standards and ensuring public health and safety, not only did J&J halt Tylenol production and advertisement but also circulated warnings to the distributors and hospitals about the exact nature of the crisis and related precautions. The company's honest efforts in handling the tampering incident showed the way in which crisis management had to be done and resulted in J&J regaining 90% of its earlier customers within months of the incident. Later in 1991, almost a decade after the crisis was reported, the legal battle in this regard was resolved wherein claims of survivors of the incident were settled for about $35 million by the company.

Back then, the company had appeared honest, proactive, and responsive and its exemplary handling of the crisis earned it widespread appreciation from the media and society at large. Observes noted that J&J had followed the classic path in brand crisis management and that Harvard Business School had later adapted it into a case study to teach its future executives about the classic approach to Brand Crisis Management. Accepted as the Gold Standard in Brand Crisis Management, this approach prescribed that every executive of the company should "communicate clearly with the public about a crisis, cooperate with government officials, swiftly begin its own investigation of a problem, and, if necessary, quickly institute a product recall."[37]

J&J CRISIS (2010): CRISIS IN BRAND CRISIS MANAGEMENT

The troubled waters at J&J had started to become evident much in 2008 when J&Jthe company found that some batches of its painkiller Motrin were not dissolving in water as they were supposed to. The company halted distribution of Motrin and told the FDA that it would conduct random checks of retailers' shelves to confirm if the problem required a product recall. But later, the FDA alleged that rather than just checking randomly for the stated purpose, a contractor working for J&J went on to buy all the defective medicines under orders from J&J which, without mentioning the word "recall", directed it to buy all the available lots of Motrin from the retailers.

Though a product recall was not something new to J&J, the way it handled the matter this time was different. The company reportedly removed the Motrin painkiller quietly from the market, buying back the stock through contractors posing as customers and thereby misled consumers and the U.S. regulators.

After the contentious phantom recall which allegedly continued till the first half of 2009, the event was followed by a series of publicly announced product recalls which continued in the first quarter of 2011 (Exhibit V: List significant of developments at J&J since phantom product recall). This included a major product recall on April 30, 2010.[38] On that occasion, J&J voluntarily recalled 43 of its drugs including OTC drugs and children's medicines, including its major brands and household names like Tylenol, Motrin, Zyrtec, and Benadryl. The recall was on account of some manufacturing defects in products manufactured at its Pennsylvania production facilities which

[37] Bob Ferrari, "Johnson and Johnson's Product Recall — Untimely Reaction to Supply Risk?" *Supply Chain Matters*, www.theferrarigroup.com/supply-chain-matters/2010/01/18/johnson-and-johnsons-product-recall-untimely-reaction-to-supply-risk/, January 18, 2010, (Retrieved on May 16, 2011).

[38] Wikipedia contributors, "2010 Johnson & Johnson Children's Product Recall," *Wikipedia, The Free Encyclopedia*, http://en.wikipedia.org/wiki/2010_Johnson_%26_Johnson_children%27s_product_recall, September 30, 2010, (Retrieved on May 16, 2011).

were shut down after this recall. In another setback, there were also reports of moldy smells emanating from OTC medicines made at a plant in Puerto Rico. At that time, most of the OTC drugs sold by MNCH in the US market were produced only by this Puerto Rico plant. Investigation by the FDA into the plant's adherence to manufacturing and quality control standards revealed that the plant had some unresolved quality control issues. The plant, the FDA said, had thick dust, grime, and contaminated ingredients.[39]

When questions on quality control involving multiple production facilities and a range of products started coming up in August 2010, the J&J CEO said the MNCH problems were not a J&J-wide phenomenon. Emphasizing the initiatives taken by J&J to deal with the quality control problems, William added that the company was creating a new position in quality control. Ajit Shetty (Ajit) was being appointed the quality control czar across J&J units, and he would report directly to William.[40] The appointment was preceded by the submission of a Comprehensive Action Plan (CAP) by J&J in July 2010 to the industry regulator on revamping and improving upon the quality standards of its manufacturing facilities. Later when he appeared and testified before the HCOGR, William underlined J&J's commitment to getting back to the quality standards expected of it while also mentioning the company's plan to spend $100 million to upgrade and rebuild its equipment, systems, and facilities to state-of-the-art standards across MNCH[41]. Experts, who studied the J&J crisis, found this a logical move and some of them dubbed the poor quality control as essentially a fall-out of an inefficient organizational and reporting structure.

Some press investigation reports focused on another aspect of this development. They quoted a J&J staffer as saying that William was now "resurrecting a concept that was dismantled under his watch." Referring to four former staff members of J&J, the report further mentioned that J&J had a corporate compliance group headed by a corporate compliance officer that oversaw all the different companies in the group, monitoring their adherence to quality standards. This group conducted a biannual audit of the group's operating companies and helped in setting up management action plans to improve quality control. In 2007, a year before the product control and quality control issues started to emerge, there was a drastic reduction effected in this group and its operating mechanism. "The whole idea was creating a Hawthorne effect: If people know they're being watched, they'll do better," said a former J&J executive, adding that after cutting down of the group, some unit divisions had started deviating from their focus on quality. [42]

But the series of recalls continued even after the initiatives taken by William in July 2010. In December 2010, the problem worsened as the company recalled about 12 million bottles of OTC Mylantha, almost 85,000 bottles of its AlternaGel liquid antacid, and around 13 million packages of Rolaids softchews. The recall of the first two of these three products was made on account of the presence of small amounts of alcohol in the flavoring agents which were not noted on the product packaging. [43] The Rolaids softchews were recalled "after consumers reported finding metal and wood particles" in the product.[44]

These recalls continued in the early months of 2011 as well. Acting under the CAP submitted to the FDA in July 2009, the company tried without much success to come up to the quality standards mandated by the FDA. Successive failures in satisfying FDA investigators on quality resulted in

[39] Pierson Ransdell, "J&J Heartburn Worsens with Mylanta Recall," *MSNBC*, December 2, 2010.

[40] Lianne Dane, "Johnson & Johnson Announces Manufacturing Reorganisation, New Quality Control Position," *First World*, www.firstwordplus.com, August 18, 2010.

[41] David Voreacos, Alex Nussbaum and Greg Farrell, "Johnson & Johnson's Quality Catastrophe," *Business Week*, March 31, 2011.

[42] Mina Kimes, "Johnson & Johnson CEO Bill Weldon's Painful Year," *Fortune*, www.cnnmoney.com, September 7, 2010.

[43] Ransdell Pierson, "J&J Heartburn Worsens as Mylanta Joins Recall List," *International Business Times*, www.ibtimes.com, December 2, 2010.

[44] Molly Peterson and David Olmos, "Johnson & Johnson Recalls Rolaids after Complaints," *Bloomberg*, www.bloomberg.com, December 10, 2010.

the next major blow being delivered to the reputation of J&J in early March 2011. MNCH had to reach a consent decree with the FDA for three of its plants — two in Pennsylvania and the other in Puerto Rico.[45] The decree mandated that the plants would remain under enhanced oversight for the next five years. It was to include a formal appointment of an independent expert who would oversee upgrades in plants under surveillance to cure for the violations of FDA quality standards. A plant under consent decree could resume production only after its quality upgrades had been certified as meeting FDA standards. Though there was no upfront penalty levied, any further violation of consent decree terms would attract a penalty of $10 million per year for MNCH. "This is a strong, but necessary, step to ensure that the products manufactured by this company meet federal standards for quality, safety and purity," said Deborah Autor (Deborah), FDA's drug division's head of compliance. [46]

During the second week of May 2011, yet another recall, this time of J&J's HIV/AIDS drug Prezista dented customer confidence even further, leaving many wondering whether this would be the final recall in the series.[47]

"This is an instance where behavior is more important than communications; communications and good public relations can be very helpful, but it can't overcome bad behavior." said Stephen A. Greyser (Stephen), Professor Emeritus of Marketing at Harvard Business School, who wrote the case study on J&J's Gold Standard Brand Crisis Management efforts of 1982.[48]

A MATTER OF TRUST

Pharmaceutical companies' superior quality which brings the life critical customer confidence to products has been their major success factor. It was on this major count that J&J was alleged to have failed. For the many customers who had been paying premium prices for J&J products throughout their lives and had depended on this long trusted brand to deliver health products and medicines they could use with complete confidence, it meant a loss of confidence in the company. Advertisements such as those at the CVS stores were reportedly successful in persuading a large number of these disappointed customers to try cheaper alternatives. This reportedly caused a permanent shift of J&J's loyal customers. Most of them reportedly questioned the justification for paying a higher price for J&J products without having confidence in the quality as they had earlier had.[49]

The crisis harmed J&J's once-pristine image and had begun to take a significant toll on its financial results. The latest financials provided a glimpse into the financial impact of the crisis. Revenues for the fourth quarter of 2010 fell short of forecasts due to the reported decline in sales resulting from a fall in consumer confidence on the heels of a series of product recalls in the US markets. The company had a net income of 70 cents per share in the last quarter of 2010 compared to 79 cents per share a year earlier over the same period (Exhibit VI: Abstracts from J&J's Quarterly Financial Reports).[50]

Over the course of 2010, recalls adversely affected the sales of the J&J consumer healthcare segment. In 2010 third quarter consumer segment sales declined 10.6% to $3.6 billion, with OTC pharmaceutical and nutritional sales declining by 19.4%. The product recall and suspension of

[45] Reed Abelson, "Johnson & Johnson Unit Signs Consent Decree with F.D.A," *New York Times*, March 10, 2011.

[46] Ransdell Pierson, "UPDATE 4-FDA to Oversee J&J Plants after Flood of Recalls," *Reuters*, March 10, 2011.

[47] High Wycombe, "Janssen Identifies Trace Amounts of TBA in 5 Batches of PREZISTA® (darunavir) in the EU and Canada," *Johnson & Johnson*, May 11, 2011.

[48] Natasha Singer, "In Recall, a Role Model Stumbles," *The New York Times*, January 17, 2010.

[49] Natasha Singer and Reed Abelson, "Can Johnson & Johnson Get Its Act Together?" *The New York Times*, January15, 2011.

[50] Reuters, "J&J Sales Disappoint, Recalls Hit Consumer Brands," *CNBC*, January 25, 2011.

manufacturing at the Fort Washington, Pennsylvania, plant resulted in a $240 million negative impact on revenues."[51] The overall U.S. sales of J&J's consumer products plunged 25 percent[52] in the third quarter as scores of formulations became unavailable and customers opted for generic store brands instead.

Expectedly, it was a boon for the alternatives available for children's liquid medicines with cheaper brands like Perrigo Co. trying to fill the gap. Analysts said that J&J had to work hard to convince buyers to come back once production resumed. "In a climate in which Americans have come to expect perfection in consumer goods, companies are better off overreacting than underreacting when product problems arise." said Michael Braun, an assistant professor of marketing at the M.I.T. Sloan School of Management.

Some critics said that some of the blame lay with the FDA, which could have acted sooner. They added that even if the FDA had been technically aware of the Mortrin recall, it did not excuse what J&J had done. The "Motrin incident highlights the agency's reliance on voluntary company actions and the need for greater agency power to demand recalls." said Joshua Sharfstein, FDA Deputy Commissioner.

J&J, reeling under the blows dealt to it by dented consumer confidence, criminal investigation by the FDA, the consent decree, and a reported loss of market share, had just one piece of good news — J&Jthe huge diversified healthcare company was, by and large, able to keep investors' confidence intact. The share prices of J&J largely followed the broader market despite the multiple setbacks it had had in the recent past.

Toward the end of April 2011, William said, that, "he hoped the many product recalls are behind J&J, but can't make any promises."[53] As the company started its fight back to restore trust in the brand, industry experts commented that the biggest challenge before J&J was to win back the loyal consumers of the products in question, many of whom had reportedly switched to other brands.

[51] Zacks Investment Research, "Product Recalls Continue at J&J," *Daily Markets*, www.dailymarkets.com, January 17, 2011.

[52] Natasha Singer, "In Recall, a Role Model Stumbles," *The New York Times*, January 17, 2010.

[53] Linda A. Johnson, "CEO: J&J learned lessons, improved after recalls," *Business Week*, April 28, 2011.

Exhibit I

Important Events in the History of J&J

Year	Events
1886	Johnson brothers begin producing dressings in New Brunswick, New Jersey.
1887	Company is incorporated as Johnson & Johnson.
1893	Johnson's Baby Powder is introduced.
1921	Band-Aid brand adhesive bandages make their debut.
1924	Overseas expansion begins with the establishment of subsidiary Johnson & Johnson Limited in the United Kingdom.
1932	Robert Johnson, known as 'the General,' takes over as president.
1943	Johnson writes the company credo.
1944	Company goes public on the New York Stock Exchange.
1959	McNeil Laboratories, Inc. (McNeil Labs) is acquired.
1960	McNeil Labs introduces Tylenol as an OTC pain reliever
1961	Janssen Pharmaceutica is acquired.
1975	Through a significant price decrease, Tylenol is transformed into a mass-marketed product.
1982	Tylenol tampering tragedy occurs.
1988	Acuvue disposable contact lenses are introduced.
1989	J&J and Merck form joint venture to develop OTC versions of Merck's prescription medications.
1994	Neutrogena Corporation is acquired.
1995	Merck and J&J launch Pepcid AC; company acquires the clinical diagnostics unit of Eastman Kodak Company.
1996	J&J acquires Cordis Corporation.
1998	DePuy, Inc. is acquired, and a companywide restructuring is launched.
1999	Centocor, Inc. merges with J&J.

Source:www.fundinguniverse.com/company-histories/Johnson-amp;-Johnson-Company-History.html (Retrieved on May 16, 2011).

Exhibit II

Leading Rewards and Recognition

J&J continues to be a member company of the FTSE4Good Index, the responsible investment index calculated by global index provider the FTSE Group.
J&J is ranked #2 by *Diversity Inc* magazine on its "2010 *DiversityInc* Top 50 Companies for Diversity®" list.
Working Mother magazine has named J&J one of the "Top 100 Companies for Working Mothers" every year since the list was initiated 25 years ago.
Barron's magazine, in 2010, ranked J&J #2 in the World's Most Respected Companies list, a survey of top investors to rank the world's largest companies on strength of management, business strategy, ethical business practices, competitive edge, shareholder orientation, and consistent revenue/profit growth.
J&J is named as "One of the Best Places to Work" in the 2010 survey by Human Rights Campaign, the largest Civil Rights organization in the USA.
US Reputation Quotient published by Harris Interactive, which annually ranks the 60 most visible companies in the US, ranks J&J as the second most visible company in the US for the year 2010.
A public opinion poll conducted by the Center for Corporate Citizenship at Boston College in collaboration with the Reputation Institute ranks J&J as the most "socially responsible company for the year 2010.

Source: Compiled using various sources.

Exhibit III

Principal Competitors, Subsidiaries and Operating Groups of J&J

Principal Competitors	Principal Subsidiaries	Principal Operating Group
Abbott Laboratories	Advanced Sterilization Products	Consumer and Personal Care Group
Affymetrix, Inc.	Centocor	Medical Devices and Diagnostics Group
Alberto-Culver Company	Cordis Corporation	Pharmaceuticals Group.
American Home Products Corporation	DePuy	
Amgen Inc.	Ethicon, Inc.	
Aventis	Ethicon Endo-Surgery, Inc.	
Bausch & Lomb Incorporated	Independence Technology	
Baxter International Inc.	Indigo Medical, Inc.	
Bayer AG	Janssen Pharmaceutica Inc.	
Beckman Coulter, Inc.	Johnson & Johnson Consumer Products, Inc.	
Becton, Dickinson & Company	Johnson & Johnson Development Corporation	

Principal Competitors	Principal Subsidiaries	Principal Operating Group
Bristol-Myers Squibb Company	Johnson & Johnson Health Care Systems Inc.	
Carter-Wallace, Inc.	Johnson & Johnson Medical	
Colgate-Palmolive Company	Johnson & Johnson-Merck Consumer Pharmaceuticals Co. (50%)	
Dade Behring Inc.	Johnson & Johnson Sales and Logistics Company	
The Dial Corporation	Johnson & Johnson Vision Care, Inc.	
Eli Lilly and Company	LifeScan, Inc.	
Genentech, Inc.	McNeil Consumer Healthcare	
The Gillette Company	McNeil Specialty Products Company	
Glaxo Wellcome plc	Neutrogena Corporation	
Kimberly-Clark Corporation	Noramco, Inc.	
L'Oréal USA, Inc.	Ortho Biotech Inc.	
Medtronic, Inc.	Ortho-Clinical Diagnostics, Inc.	
Merck & Co., Inc.	Ortho Dermatological	
Minnesota Mining and Manufacturing Company	Ortho-McNeil Pharmaceutical, Inc.	
Nestlé S.A.	Personal Products Company	
Novartis AG	R.W. Johnson Pharmaceutical Research Institute	
Perrigo Company	Therakos, Inc.	
Pfizer Inc.	The company has additional subsidiaries in Canada, Argentina, Brazil, Chile, Colombia, Mexico, Panama, Peru, Uruguay, Venezuela, Austria, Belgium, the Czech Republic, France, Germany, Greece, Hungary, Ireland, Italy, the Netherlands, Poland, Portugal, Russia, Scotland, Slovenia, Spain, Sweden, Switzerland, Turkey, the United Kingdom, Australia, China, Egypt, Hong Kong, India, Indonesia, Israel, Japan, Korea, Malaysia, Morocco, Pakistan, the Philippines, Singapore, South Africa, Taiwan, Thailand, the United Arab Emirates, and Zimbabwe.	
Pharmacia Corporation		
The Procter & Gamble Company		
Roche Holding Ltd.		
SmithKline Beecham plc		
St. Jude Medical, Inc.		
Unilever		
United States Surgical Corporation.		

Source: Adapted using data from www.fundinguniverse.com/company-histories/Johnson-amp;-Johnson-Company-History.html (Retrieved on May 16, 2011).

Exhibit IV

Major Consumer Brands under J&J Group

Acuvue	Delfen	Mylanta	Rembrandt
Actifed	Desitin	Nasalcrom	Remicade
Ambi	Dolormin	Neko	RoC
Aveeno	E.P.T.	Neosporin	Rogaine
Bactidol	Efferdent	Neutrogena	Rolaids
Band-Aid	First-Aid	Nicoderm	Shower to Shower
Benadryl	Gynol	Nicorette	Simply Sleep
Benecol	Healthy Woman	Nizoral	Sinutab
Bengay	Imodium	Nu-Gauze	Splenda
Benylin	Johnson's Baby	O.B.	St. Joseph
Bonamine	Johnson & Johnson Red Cross	OneTouch	Stayfree
Caladryl	Jontex	Pediacare	Steri-Pad
Carefree	K-Y	Penaten	Stim-u-dent
Clean & Clear	Lactaid	Pepcid	Sudacare
Coach	Listerine	Pepcid AC	Sudafed
Coach Professional	Listermint	Polysporin	Tucks Pads
Coach Sport	Lubriderm	Ponstan	Tylenol
Codral	Luden's	Priligy	Tylenol Baby
Combantrin	Micatin	Purell	Tylenol Children
Compeed	Monistat	Quantrel	Unicap
Conceptrol	Motrin	REACH	Vania
Cortaid	Motrin Children	Reactine	Visine
Cortef	Myadec	Regaine	Zyrtec

Source: Wikipedia contributors, "Johnson & Johnson," Wikipedia, The Free Encyclopedia, http://en.wikipedia.org/wiki/Johnson_%26_Johnson, May 16, 2011, (Retrieved on May 16, 2011).

Exhibit V

List of Significant Developments at J&J Since Phantom Product Recall

August 2008	Contractors buy defective Motrin from retail locations. The FDA claims later that it was not informed about the "phantom recall" by J&J.
November 2009	MNCH pulls out around 6.3 million Tylenol Arthritis Pain caplets bottles manufactured in Puerto Rico.
January 2010	MNCH pullout expands to Benadryl Allergy, Tylenol, Children's Tylenol Meltaway, and Rolaids.
April 2010	J&J recalls 136 million bottles of medicines manufactured in Fort Washington, Pennsylvania, and shuts production facility.
May 2010	The FDA says that it might pursue criminal charges against J&J.
June 2010	MNCH recalls five more lots of Benadryl and Tylenol products manufactured at its Puerto Rico manufacturing facility.
July 2010	J&J submits revamp and remedy plan for troubled MNCH plants to the FDA.
August 2010	J&J creates a new quality control position and appoints Ajit as quality-control czar, responsible for group-wide supervision of adherence to standards.
August 2010	J&J calls back 100,000 boxes of 1-Day Acuvue TruEye contact lenses.
August 2010	J&J unit DePuy recalls ASR hips.
December 2010	J&J recalls 13 million packages of Rolaids softchews. Buyers complain of finding wood and metal particles in them.
December 2010	Company withdraws 13 million packages of Rolaids soft chews. Complaints from consumers report finding metal and wood particles in the product.
January 2011	J&J recalls 43 million bottles of Rolaids, Tylenol, Benadryl, and Sinutab.
January 2011	2010 earnings announcement: lost sales from recalls and plant slowdowns are estimated at $900 million.
February 2011	The company recalls 70,000 syringes preloaded with the antipsychotic Invega.
March 2011	J&J recalls 585,000 surgical sutures. Sterile packaging concerns caused the pull out.
March 2011	Animas unit pulls out 384,000 insulin-pump cartridges which were feared to have leakages.
March 2011	FDA announces the consent decree that gives the regulator expanded oversight of MNCH's three plants.
March 2011	MNCH recalls around 34,000 bottles of Tylenol 8-Hour Extended Release caplets after a musty odor was reported to be emanating from them.
March 2011	MNCH expanded a wholesale-level recall of Tylenol, Benadryl and Sudafed products.
April 2011	Around 57,000 bottles of Topamax are pulled back. Recall is done on account of a reported foul odor.
May 2011	About 2,000 bottles of HIV/AIDS drug Prezista are recalled from four European countries. Some complaints of musty or moldy odors are reported.

Source: David Voreacos, Alex Nussbaum and Greg Farrell, "Johnson & Johnson's quality catastrophe," MSN Money, http://money.msn.com, April 1, 2011, (Adapted and updated).

Exhibit VI

Abstracts from J&J's Quarterly Financial Reports

In Millions of USD (except for per share items)	3 Months Ending 2011-04-03	3 Months Ending 2011-01-02	3 Months Ending 2010-10-03	3 Months Ending 2010-07-04	3 Months Ending 2010-04-04
Total Revenue	16,173.00	15,644.00	14,982.00	15,330.00	15,631.00
Cost of Revenue, Total	4,778.00	5,040.00	4,594.00	4,630.00	4,528.00
Gross Profit	11,395.00	10,604.00	10,388.00	10,700.00	11,103.00
Selling/General/Admin. Expenses, Total	5,056.00	5,180.00	4,709.00	4,756.00	4,779.00
Research & Development	1,738.00	1,982.00	1,657.00	1,648.00	1,557.00
Other Operating Expenses, Total	-13	1,100.00	-292	18	-1,594.00
Total Operating Expense	11,663.00	13,416.00	10,763.00	11,110.00	9,351.00
Operating Income	4,510.00	2,228.00	4,219.00	4,220.00	6,280.00
Income Before Tax	4,510.00	2,228.00	4,219.00	4,220.00	6,280.00
Income After Tax	3,476.00	1,942.00	3,417.00	3,449.00	4,526.00
Diluted Weighted Average Shares	2,772.70	2,781.60	2,786.40	2,796.00	2,797.30
Diluted EPS Excluding Extraordinary Items	1.25	0.7	1.23	1.23	1.62

Source: Adapted using data from www.google.com/finance?q=jnj *(Retrieved on May 16, 2011).*

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