salmonella was found in the product; Samuel Lightsey, a plant operator at the company; and the company's former quality-assurance manager, Mary Wilkerson. The indictment alleges that the four engaged in a conspiracy to hide the fact that tests showed the presence of salmonella in the peanut meal, or peanut base, the company's product. The indictment makes the stunning allegation that the group worked together to fabricate test results to show salmonella-free product when salmonella was present.

Experts note that criminal charges in food-poisoning cases are rare because the proof of intent, or *mens rea*, is difficult or impossible to demonstrate when there is a one-time problem. However, as the indictment notes, Mr. Parnell was being notified by customers that his company's product was testing positive, and yet he still continued production without cleaning up the plant. The indictment also alleges that the four who are charged misled FDA inspectors in January 2009, conduct that added obstruction of justice to the charges in the indictment.

Mr. Parnell's lawyer vows to fight the charges and to demonstrate that Mr. Parnell and the others never intentionally shipped tainted product.[49] However, one portion of the indictment includes an e-mail from an employee that the peanut meal containers at the plant (in 2007) were covered with dust and rat feces. Mr. Parnell responded to the employee, "Clean 'em all up and ship them."[50]

Discussion Questions

1. Discuss the theories for imposing liability on Peanut Corp.
2. Are the e-mails admissible as evidence?
3. Mr. Parnell's father, Hugh Parnell Sr. said, "He's being railroaded. Why would anybody send something out that would ruin his own company? It's like an auto dealer sending a car out with no brakes."[51] What defense is he raising for his son?

Sources

Schmidt, Julie, "Peanut President Refuses to Testify," *USA Today*, February 12, 2009, p. 2B.
Zhang, Jane, "Peanut Corp. for Bankruptcy," *Wall Street Journal*, February 14–15, 2009, p. A3.

Case 7.7

Tylenol: The Swing in Product Safety

The Chicago Capsule Poisonings

In 1982, 23-year-old Diane Elsroth died after taking a Tylenol capsule laced with cyanide. Within five days of her death, seven more people died from taking tainted Tylenol purchased from stores in the Chicago area.

At that time, Tylenol generated $525 million per year for McNeil Consumer Products, Inc., a subsidiary of Johnson & Johnson. The capsule form of the pain reliever represented 30 percent of Tylenol sales. McNeil's marketing studies indicated that consumers found the capsules easy to swallow and believed, without substantiation, that Tylenol in capsule form worked faster than Tylenol tablets.

The capsule's design, however, meant they could be taken apart, tainted, and then restored to the packaging without evidence of tampering. After the Chicago poisonings, which were never solved, McNeil and Johnson & Johnson executives were told at a

[49]Sabrina Tavernise, "Charges Filed in Peanut Salmonella Case," *New York Times*, February 22, 2013, p. B6.

[50]From the indictment, http://www.justice.gov/opa/pr/2013/February/13-civ-220.html.

[51]Ilan Bray and Julie Jargon, "Career in Peanuts Began as a Detour From Oceanography," *Wall Street Journal*, Feb. 19, 2009, p. A6.

meeting that processes for sealing the capsules had been greatly improved, but no one could give the assurance that they were tamperproof.

The executives realized that abandoning the capsule would give their competitors, Bristol-Myers (Excedrin) and American Home Products (Anacin), a market advantage, plus the cost would be $150 million just for 1982. Jim Burke, then-CEO of Johnson & Johnson, told the others that without a tamperproof package for the capsules, they would risk the survival of not only Tylenol but also Johnson & Johnson. The executives decided to abandon the capsule.

Frank Young, a Food and Drug Administration (FDA) commissioner, stated at the time, "This is a matter of Johnson & Johnson's own business judgment, and represents a responsible action under tough circumstances."[52]

Johnson & Johnson quickly developed "caplets"—tablets in the shape of a capsule—and then offered consumers a coupon for a bottle of the new caplets if they turned in their capsules. Within five days of the announcement of the capsule recall and caplets offer, 200,000 consumers had responded. Johnson & Johnson had eliminated a key product in its line—one that customers clearly preferred—in the interest of safety. Otto Lerbinger of Boston University's College of Communication cited Johnson & Johnson as a "model of corporate social responsibility for its actions."[53]

President Ronald Reagan, addressing a group of business executives, said, "Jim Burke, of Johnson & Johnson, you have our deepest admiration. In recent days you have lived up to the very highest ideals of corporate responsibility and grace under pressure."[54]

Within one year of the Tylenol poisonings, Johnson & Johnson regained its 40 percent market share for Tylenol. Although many attribute the regain of market share to tamperproof packaging, the other companies had moved to that form as well. However, it is interesting to note that McNeil was able to have its new product and packaging on the shelves within weeks of the fatal incidents. There had been some preparation for the change prior to the fatalities, but the tragedy was the motivation for the change to safer packaging and product forms.

McNeil has continued to enjoy the goodwill from its rapid response to the poisonings as well as its willingness to take the financial hit for what experts believed was a very small risk that more cyanide-laced Tylenol was out on the shelves. In fact, the recall was so indelibly etched in the public's mind and in the minds of those in the field of business ethics that McNeil, Johnson & Johnson, and Tylenol itself were often given free passes on conduct that did pose safety risks to customers. As new issues with Tylenol have developed, McNeil seems to be given the benefit of the doubt because of the goodwill and reputational capital it purchased with the capsule recalls.[55]

Tylenol and Liver Damage

On December 21, 1994, the *Journal of the American Medical Association* (*JAMA*) published the results of a five-and-a-half-year study showing that moderate overdoses of acetaminophen (known most widely by the brand name Tylenol) led to liver damage in 10 patients.[56] The damage occurred even in patients who did not drink and was most pronounced in those who did drink or had not been eating. Further, the study by

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[52]"Drug Firm Pulls All Its Capsules off the Market." *(Phoenix) Arizona Republic*, February 18, 1986, p. A2.

[53]Pat Guy and Clifford Glickman. "J & J Uses Candor in Crisis," *USA Today*, February 12, 1986, p. 2B.

[54]"The Tylenol Rescue." *Newsweek*. March 3. 1986. p. 52.

[55]"Legacy of Tampering," *Arizona Republic*. September 29, 1992, p. A1.

[56]"Acetaminophen Overdoses Linked to Liver Damage," *Mesa (Arizona) Tribune*, December 21, 1994, p. A12; and Doug Levy, "Acetaminophen Overuse Can Lead to Liver Damage," *USA Today*, December 22, 1994, p. 1D.

Dr. David Whitcomb at the University of Pittsburgh Medical School found that taking one pill of acetaminophen per day for a year may double the risk of kidney failure.[57] By 2001, 450 deaths resulted from liver failure due to Tylenol overdoses.

At that time, the American Association of Poison Control Centers called acetaminophen poisonings the most common of all reported poisonings.[58] The number of pediatric poisonings from overdoses of acetaminophen has more than tripled since 1996. As a result, the FDA adjusted the adult and pediatric doses that were acceptable in 2009. However, adult deaths from overexposure are more likely to be the result of suicidal ingestion.

Tylenol is a stunning source of revenue for McNeil and Johnson & Johnson, with revenue totals growing at double-digit rates as Tylenol expands market presence into 5,000 convenience stores with new and smaller packaging of its product and its new formulas, such as Tylenol PM.[59]

Tylenol users who claimed they were victims of overdose and liver damage and the lack of effective warnings have not been successful against Johnson & Johnson.[60] McNeil has modified the recommended dosages, the ad claims, and language on its labels. The product labels before current modification read, "Gentle on an infant's stomach," and Tylenol's ad slogan was "Nothing's safer." That language has been removed, and McNeil added to its infant Tylenol label: "Taking more than the recommended dose ... could cause serious health risks" because of liver damage in children.[61]

McNeil also responded to data that showed patients who combine Tylenol with alcohol have produced 200 cases of liver damage in the past twenty years, with fatality in 20 percent of those cases. The level of alcohol use by patients among these cases was multiple drinks every day. McNeil modified its labels to include bold warnings about alcohol use and the dangers of combining Tylenol with any drinking.

Despite the extensive coverage of the issues surrounding Infant Tylenol, Tylenol overdoses, and issues with liver damage from combining alcohol and Tylenol, the company did not experience any loss of market share or even extensive negative media coverage. The goodwill from Tylenol's earlier recall appeared to see it through these crises. However, others issues were emerging.

The Tylenol Quality Control Program

In May 2010, the FDA was considering bringing criminal charges against McNeil for a pattern of violations in its quality control in the production of children's Tylenol. The charges would spring from the April 30, 2010, recall by McNeil of 136 million bottles of liquid pediatric Tylenol, Motrin, Benadryl, and Zyrtec because the medicines contained too much metal debris or too much of the necessary active ingredient in these over-the-counter drugs. Because of the presence of metal debris, the medicine batches failed FDA testing. However, prior to the FDA testing and the recall, there was evidence that McNeil was aware of the developing problem but took no public action. A purchase order that the company turned over to congressional investigators indicated that McNeil had hired a contractor in 2009 to visit 5,000 stores and buy Motrin from the shelves. The contractor's PowerPoint materials instructed employees to act like any other customer

[57] "Second Tylenol Study Links Heavy Use to Kidney Risk," *(Phoenix) Arizona Republic*. December 22, 1994, p. A6.

[58] www.aapcc.com. Accessed June 10, 2010.

[59] Thomas Easton and Stephan Herrera, "J&J's Dirty Little Secret," *Forbes*, January 12, 1998, 42–44.

[60] Deborah Sharp, "Alcohol-Tylenol Death Goes to Trial in Florida," *USA Today*, March 24, 1997, p. 3A.

[61] Richard Cole, "Tylenol Agrees to Warning on Labels of Risk to Children," *Arizona Republic*, October 19, 1997, p. A5.

and make "no mention of this being a recall when making a purchase."[62] McNeil indicated to congressional investigators that "The Motrin Purchase Project" was created by a McNeil subcontractor without its knowledge and approval. McNeil said it notified the FDA about two Motrin lots that did not dissolve properly and that it was removing the Motrin from the shelves.

The evidence submitted for the hearings showed that McNeil had received forty-six complaints from consumers about black particles in Tylenol and other McNeil products. However, McNeil did not notify the FDA, nor did it recall the medicines. The inaction in the face of customer harm represented the straw that broke the FDA's back of tolerance, because the company, at that point, was finishing two years of an ongoing tussle with regulators over quality control. At one plant that manufactured Children's Tylenol, seven batches of product were released after testing revealed problems in three batches. The agency's frustration in dealing with the plants and managers for inaction and ongoing violations led to the review of the company for possible criminal charges.

The surreptitious removal of Motrin from retail stores because McNeil had discovered quality-control problems with that product was referred to by the FDA as, in effect, an unannounced, or "phantom," recall.[63] Also in 2008, McNeil failed to notify the FDA that it had received complaints from customers about a moldy smell in some of the products made in its Puerto Rican production facilities and, at the same time, failed to disclose complaints from customers about stomach problems experienced after they had used the "moldy" products. McNeil tested the products and found no problems, but the complaints continued through 2009. Further testing showed that the medicine had been contaminated by a chemical used in the plant for the treatment of wooden shipping pallets. One member of Congress noted that the recall on the "smell" issue took one year and that it should have taken three days. At another plant, the FDA found that the company "knowingly" used an ingredient that was tainted with *Burkholderia cepacia*, a bacteria that most healthy people can handle, but that can cause serious infections in those with chronic illnesses such as cystic fibrosis.[64] Another member of Congress said of the congressional inquiry, "We are not getting the kind of information and cooperation from Johnson that I would like."[65]

As consumers purchased generic brands to substitute for the recalled Tylenol products, McNeil's sales of Tylenol dropped 55 percent, a loss of $1.4 billion in sales. Its market share dropped to number eight after being at number two, behind only Advil prior to the public disclosure of the issues and the lack of a recall.[66] The FDA and Johnson & Johnson entered into a consent decree that required McNeil to correct the problems that had been discovered in several of the company's plants, including revamping the production and testing requirements that would require independent verification. McNeil terminated several executives, including its vice president for OTC drugs, and restructured the management team as well as the supervisory teams at many of its production facilities.

As a result of the Tylenol issues, the FDA began inspections of other OTC manufacturers that resulted in forty-three letters being sent to OTC drug factories for their failure to correct "shoddy manufacturing practices that may have exposed patients to health

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[62]Natasha Singer, "Johnson & Johnson Seen as Uncooperative on Recall Inquiry," *New York Times*, June 11, 20[illegible] pp. B1, B4.

[63]Natasha Singer, "F.D.A. Weighs More Penalties In Drug Recall," *New York Times*, May 28, 2010, p. A1.

[64]Alison Young, "Plant in Recall Had Other Violations," *USA Today*, May 27, 2010, p. 3A.

[65]Natasha Singer, "Johnson & Johnson Seen as Uncooperative on Recall Inquiry," *New York Times*, June 11, 20[illegible] p. B1.

[66]Jonathan D. Rockoff, "J & J Recalls Infants' Tylenol," *Wall Street Journal*, February 18–19, 2012, p. B1.

risks."[67] The letters indicated that FDA inspectors had found insects in equipment and ingredients, improper testing, failure to conduct required tests, and disregard for customer complaints. More than half of the plants inspected had violations, even if those violations did not rise to the level of receiving the agency's letter warning.

In congressional hearings on the issues discovered at McNeil, the House Committee on Oversight and Government Reform chastised McNeil executives: "The information I've seen during the course of our investigation raises questions about the integrity of the company. It paints a picture of a company that is deceptive, dishonest, and has risked the health of many of our children."[68]

In 2012, McNeil suffered another setback when it had to issue a recall for 574,000 bottles of Infant Tylenol due to design defects in the bottles. The recall came shortly after the company had met standards and returned the infant Tylenol to the market. One expert on pharmaceutical marketing noted that restoring consumer confidence is difficult and, "Now, they have another uphill battle."[69]

Discussion Questions

1. Were the shareholders' interests ignored in the decision to take a $150 million write-off and a possible loss of $525 million in annual sales by abandoning the capsules?
2. Suppose that you were a Tylenol competitor. Would you have continued selling your capsules?
3. Was Mr. Burke's action a long-term decision? Did it take into account the interests of all stakeholders? How did Mr. Burke's action help the company with the liver-damage issues? Mr. Burke, who served as Johnson & Johnson's CEO from 1970–1989, died on October 1, 2012. A full-page ad in the *Wall Street Journal* on October 2, 2012, read, "What you taught us will live on. In fond memory of James E. Burke."[70] Have Burke's teachings survived?
4. What can you conclude from the quick development and appearance of the new product line?
5. Following the 2010 misstep, Tylenol's competitors sent out free samples and coupons to Tylenol customers who participated in the Tylenol recall as a way of getting them to try their products. Why would such a campaign at this time result in more sales of their products? What is different about this issue versus the cyanide poisonings? Make a list of the distinctions between the two series of events, including descriptions of company and customer responses.
6. General Robert Wood Johnson, the CEO of Johnson & Johnson from 1932 to 1963, wrote a credo for his company that states the company's first responsibility is to the people who use its products and services; the second responsibility is to its employees; the third, to the community and its environment; and the fourth, to the stockholders.[71] ollow its credo?
7. Why did the company drag its heels on the later recalls? What was the purpose of the phantom contractor and the resulting unannounced recall?
8. Did the company ride the coattails of its recall recognition from the 1987 poisonings for too long? Was hubris involved?
9. A lawyer who represents clients suing McNeil offered the following observations: "It [McNeil] markets itself as a company that takes children's safety very seriously and that's why they can charge a premium price for the Tylenol. People are willing to pay a premium price because of a reputation for safety. Now they're being deceived."[72] Another lawyer who represents companies before the FDA added, "The value of the brand is such that that's got to be the first thought."[73] What thoughts are the lawyers offering on cost analysis in ethical issues through their experiences and observations?

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[67]Alison Young, "FDA Warns 43 Drug Manufacturers," *USA Today*, May 27, 2010, p. 3A.

[68]Mina Kimes, "Why J & J's Headache Won't Go Away," *Fortune*, September 6, 2010, p. 100.

[69]*Id.*

[70]*Wall Street Journal*, October 2, 2012, p. A7.

[71]"Brief History of Johnson & Johnson," company pamphlet, 1992.

[72]Carrie Levine, "Tylenol's Growing Headache," *National Law Journal*, June 7, 2010, p.A1.

[73]*Id.*