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## CASES FOR DISCUSSION

### *Dow Corning*

In the winter of 1992 John Swanson, head of Dow Corning's highly respected ethics program, was called to a meeting with Keith R. McKennon, the recently appointed CEO of Dow Corning to discuss a lawsuit Swanson's wife, Colleen, had filed against the company three months earlier. The suit alleged that the company had hidden the risks of using its silicon gel implants which doctors had implanted in her breasts in 1974 and that had subsequently ruptured, allowing the silicon to harden and migrate into her body where it caused intense burning pain, rashes, debilitating weight loss, chronic fatigue, and numerous other ailments. An angry McKennon demanded: "Look, what does Colleen want out of this? Does she want a zillion dollars? This could be messy. Can't we just talk this out and see if we can get it resolved?" The two men were unable to reach a resolution about the pending lawsuit, one of many thousands that would eventually force the company into bankruptcy.<sup>1</sup>

Founded in 1943 as a joint venture between Corning Glass Works and Dow Chemical Company, Dow Corning was wholly owned by its founding parents who set up the company to develop, manufacture, and sell silicone-based polymer products. With 1990 net income of \$171 million on sales of \$1.7 billion and 8000 employees, the company, which was based in Midland, Michigan, was considered to be performing acceptably if not spectacularly.

John Swanson joined Dow Corning in 1966. Ten years later, in the wake of revelations that several other companies had engaged in bribery of foreign officials to get their business, Swanson was asked to form a Business Conduct Committee that would oversee a program designed to ensure that Dow Corning did not engage in unethical activities. Swanson developed a code of ethics for the company, established the Business Conduct Committee, and set processes in place to monitor, audit, and prevent unethical behavior. A quiet, intelligent, gentle, polite, and loyal person eager to do what is right, Swanson was the perfect man for the job.

Dow Corning, along with several other companies, had begun selling small plastic bags filled with silicon gel to serve as breast implants in 1963 shortly before Swanson arrived. The silicon gel inside the bags was believed by everyone in the company to be biologically inert although only limited short-term (two year) animal studies had ever been conducted to evaluate the substance. Within a few years breast implants were the third most popular kind of cosmetic surgery. About 20 percent of implants were performed on women recovering from the trauma of a mastectomy. Although millions of women eventually used the surgically inserted implants, less than one percent of the company's revenues were derived from sales of the product.

Classified as a medical device, the implants were not regulated by the Federal Drug and Food Administration (FDA) until Congress passed the Medical Device Amendment in May 1976. The year Congress passed the Medical Device Amendment, Thomas Talcott, a Dow Corning materials engineer who helped develop the gel used in the implants, quit his job at Dow. A competitor, McGhan Medical Corporation, had developed softer, more natural feeling implants and had taken away half of Dow Corning's 70 percent share of the market. To counter the threat, Dow Corning decided to use a more liquid form of the gel and insert it into thinner bags in order to give the implants a softer feel. Talcott felt, however, that the more watery gel in the thinner bag might leak through the walls of the bag more easily and migrate through the body, possibly producing injuries. Talcott later testified that he argued with his superiors, but they insisted that even if the gel leaked, it was biologically inert. When they decided to move ahead with the new gel and bag, he quit in protest.<sup>2</sup>

As the company prepared to market its newly designed implants, it had an independent laboratory conduct quick animal tests of the new models. A seven-day test on rabbits dated February 7, 1975, reported a "mild to occasionally moderate acute inflammatory reaction," but the lab attributed this to the trauma of inserting the implants under the animals' skin.<sup>3</sup> On February 28 another report indicated that the inflammation in the animals was persisting. Tests on three monkeys described in a report dated February 14 had found some migration of the gel into the animals' bodies, but researchers felt that since the gel was biologically inert, any migration would be harmless.

In 1976 A. H. Rathjen, chairman of the group in charge of developing and launching the new implants received several complaints from doctors who had observed severe inflammatory reactions in patients after the implants had been in place for a short time, as well as indications that the silicone was migrating in patients' bodies. In a memo dated June 1976, Rathjen wrote, "I have proposed again and again that we must begin an in-depth study of our gel, envelope, and bleed phenomenon." In another memo that same year he complained that in place of scientific data on the performance of the new implant, the company still had nothing but "unqualified speculation." Expressing concerns about the potential for leakage in the new model he wrote: "Nothing to date is truly quantitative. Is there something in the implant that migrates out or off the mammary prosthesis? Yes or no! Does it continue for the life of the implant or is it limited or controlled for a period of time? What is it?"<sup>4</sup>

Studies conducted on rats during the later 1970s suggested that cancerous tumors were produced by the silicon gel in as many as 80 percent of the rats tested. These numbers were so high, however, that an FDA review panel concluded the studies were probably erroneous. Another series of studies conducted ten years later also found that silicone could induce tumors in rats, but they were also discounted by the FDA which felt that the tests did not provide good evidence that similar tumors would be produced in humans.<sup>5</sup> In January 1985, ten years after the new soft implants were put on the market, Dr. Robert R. Levier, technical director of Dow Corning's health care businesses, wrote a memo noting that the FDA, in an "ominous" shift, had begun to require lifetime tests in animals. This could cause trouble for the company since "most of our claims to date have been based on a 2-year dog study."

In 1984 Maria Stern, a woman who had a silicon implant and who subsequently suffered injuries allegedly caused by the implant, sued Dow Corning, alleging that the company had fraudulently failed to disclose to patients the risks the company knew were associated with use of the implants. A San Francisco federal court jury awarded her \$1.5 million in punitive damages against the company. Presiding Judge Marilyn Patel declared in her opinion that the animal studies conducted by the company "cast considerable doubt on the safety of the product."

After losing the case, Dow Corning decided to include with its product an insert warning doctors of the risk of damage to the immune-system as well as other medical problems if the implant should rupture. Publicly, however, the company continued to insist that the silicon gel was safe and that it was now using a more purified formulation of the gel anyway. Additional suits, however, were mounting against the company. Moreover, in 1989 someone leaked an internal company study that showed “an increased incidence of fibrosarcomas at the implant site.” At the request of the Public Citizen’s Health Research Group, a public interest group headquartered in Washington, a U.S. district court judge subsequently ordered the FDA to release all safety studies of silicon gel that Dow Corning had conducted during the past two decades on animals. Congress shortly announced it would hold hearings on implant safety.

Over the years the company had received numerous complaints about its product from doctors alleging complications such as rupture, leakage, infections, hardening, tumors, sterilization, and other illnesses. The complaints, compiled at company headquarters, eventually covered some 20 pages of computer printouts.

In 1991 the company lost an important lawsuit. Mariann Hopkins, a woman who claimed her 1976 implants had ruptured and damaged her immune system, sued Dow Corning and called Thomas Talcott, the former Dow Corning engineer, to testify as an expert witness on her behalf. Not only did Talcott agree to testify, he also provided several confidential company documents that suggested that the company had suspected for over a decade that the gel was unsafe but had failed to warn users. The documents were passed on to the FDA officials and then to Congress. Hopkins was awarded \$7.34 million by the jury. On November 14, 1991 the FDA convened an advisory panel which, after three days of hearings that including numerous anecdotes of harrowing illnesses, voted that the breast implants should be allowed to remain on the market only if there was urgent “public health need.” The advisory panel had reviewed 10,000 pages of reports on studies that the company had conducted on women when the FDA had called for such studies in 1987. The panel concluded that all the studies were inadequate because too few women were studied for too short periods of time and that, consequently, the company did not yet have enough evidence that the implants were safe.

As these events unfolded around him, John Swanson was uncertain what to do. His wife Colleen had suffered a series of debilitating illnesses since she, like millions of other women, had Dow Corning implants inserted into her breasts. In June 1991 she had her implants surgically removed and it was discovered that one had ruptured and the other had been leaking silicon into her body. That same month John read stories in the press that cited evidence that the company had known for several years of the animal studies linking the silicon gel to cancer and other sicknesses. Swanson considered quitting, but he had no clear scientific studies proving that silicon was unsafe. His wife’s medical bills were averaging over \$50,000 a year. He had only two years to go before qualifying for retirement and a pension. And he still loved the company. His wife supported him, saying that quitting “would prove nothing.”<sup>6</sup> Although he had told the company it should withdraw the implants from the market, it had refused on the grounds that doing so might be construed by courts as admission of fault. Swanson had then asked to be “recused” from having anything to do with any matter related to the implants.

On January 6, 1992, in response to the growing concern over the safety of the implants, Dr. David Kessler, head of the FDA, ordered a moratorium of 45 days on the sale and use of all silicone gel implants and ordered the industry to carry out tests “to prove that the devices are safe.” Other countries did the same. By now between one and two million women in the United States had received silicon implants. The moratorium on implants would remain in place for the next several years allowing only for their limited use in clinical studies aimed at examining the effects of the implants on human health, and only in women needing the implants for reconstructive surgery after mastectomies.<sup>7</sup>

In May 1993 the company settled its lawsuit with Colleen’s wife for an undisclosed sum. Three months later, in August 1993, on the day he became eligible for retirement, John Swanson left the company.

On May 15, 1995, Dow Corning filed for bankruptcy protection when a federal judge ruled that the \$4.23 billion it and two other major manufacturers of implants had agreed to set aside to pay the lawsuits was inadequate to pay the 410,000 lawsuits filed against the companies. By the end of 1995, Dow Corning had spent over \$1 billion defending itself. The company was forced to sue 100 insurance companies who were refusing to pay several separate insurance policies valued at more than \$2.5 billion because, they said, Corning had engaged in fraud. On September 13, 1995, a federal judge ruled that the lawsuits against Dow Corning Corporation, could proceed against the parent companies, Dow Chemical Inc., and Corning Inc., in spite of the fact that Dow Corning had filed for bankruptcy protection.

A study published in 1994 reported that only 30 percent of implants among women surveyed remained intact after 15 years; another study in 1995 reported that 71 percent of the breast implant patients surveyed in the study had experienced rupture or severe leakage.<sup>8</sup> More recent studies conducted at the Harvard Medical School and the Mayo Clinic concluded, however, that they had failed to find any link between implants and certain illnesses such as lupus and other autoimmune diseases.<sup>9</sup>

## QUESTIONS

1. Evaluate the actions of Dow Corning in terms of the three theories of the manufacturer's duties to consumers. Explain which theory is most appropriate for this context.
2. What, in your judgment, should Dow Corning have done that it did not do? Explain your answer.
3. Put yourself in the position of John Swanson. Do you think you should have and would have done anything he did not do? Explain your answer fully.

## NOTES

1. John A. Byrne, "Informed Consent," *Business Week*, 2 October 1995, pp. 104–16.
2. Tim Smart, "This Man Sounded the Silicone Alarm—in 1976," *Business Week*, 27 January 1992, p. 34.
3. Philip Hiltz, "Maker of Implants Balked at Testing, Its Records Show," *New York Times*, 13 January 1992, p. 1.
4. *Ibid.*
5. Tim Smart, "Breast Implants: What Did the Industry Know, and When?" *Business Week*, 10 June 1991, p. 94.
6. Byrne, "Informed Consent," p. 112.
7. "Silicone-gel breast implants resume with restrictions," *The Boston Globe*, 4 November 1992.
8. Jennifer Washburn, "Reality Check: Can 400,000 Women Be Wrong?" *Ms.*, March/April 1996, p. 51.
9. Byrne, "Informed Consent." p. 116.