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CASE STUDY 6

The Sulzer Hip Replacement Recall Crisis

A Patient's Perspective

Keri K. Stephens, Scott C. D'Urso, and Penny Holmes

This case discusses a product recall that resulted from a manufacturing defect and the degree to which the company distributed accurate and timely information to affected patients. More specifically, the case examines the crisis communication of Sulzer Orthopedics and its efforts to negotiate the interests of various stakeholders, while limiting liability. Written from the perspective of a patient, the case raises interesting questions regarding organizational duties related to product liability. It also provides valuable insights into how organizational communication may have both short- and long-term effects on its relationship with patients and physicians, among others.

Organizations can find themselves in ethical dilemmas when unexpected problems occur. Product recalls resulting from manufacturing defects are one of those unexpected situations because companies need to decide when to announce the recall, how to distribute information, and whether they will compensate those affected adversely. One major challenge that companies face when they need to

recall a product is how to remedy the situation without exposing themselves to extensive financial liability. If they say the wrong things, the crisis can bankrupt them.

Companies that manufacture medical products have a particularly difficult dilemma during a crisis. Typically, they have many constituent groups—*stakeholders*—that they need to simultaneously please. As they communicate to diverse groups such as patients, doctors, the public, and the Food and Drug Administration, the actual words they use can matter substantially. In the case that follows, Sulzer Orthopedics, a medical device manufacturer, is faced with the dilemma of how and when to tell their various stakeholders that one of their products, an artificial hip, was contaminated during production. This is particularly sensitive because this recalled product was surgically implanted inside of people and now requires additional surgery to remove it.

Whereas many organizational ethical issues are explored from the organization's viewpoint, this case includes the voice of Tom, a patient experiencing complications after both of his hips were replaced. Here, we provide his perspective to show the severity of the recall situation, and the ramifications of poorly executed communication decisions. In Tom's efforts to seek information about the recall, he relies heavily on the Internet because Sulzer chooses to avoid direct communication with the affected victims. By accessing the Internet, Tom realizes that Sulzer is telling different stories to its various stakeholders, likely for legal reasons. The case that follows is presented in two parts: (a) a historical description of a product recall that resulted in the initial communicative response of Sulzer Orthopedics, and (b) the continued development of the case including latter communicative responses by Sulzer Orthopedics.

❖ PART 1: WE WILL TAKE CARE OF YOU

Christmas 2000

It was not a very merry Christmas for the Taylor[1] family. Tom, a formerly physically active man in his mid-50s, was in constant pain. He was unable to ride in a car and he had to sleep upright in a lounge chair. In April of 2000, Tom had both of his hips replaced and, after rapid improvement through the first six to eight weeks of physical therapy, he hit a wall in his recovery. Despite his continual efforts to seek assistance at orthopedic and pain management centers in his city,

he was making no progress. His surgeon treated him as if his problems were all in his head and offered him and his family little support. Then, on Christmas Eve, eight months after his surgery, Tom's surgeon called him at home to notify him that his hip replacements were being recalled.

Analysis of Product Failure

In October of 1999, after a manufacturing review, Sulzer began producing a new lot of artificial hips. Almost a year later, in July of 2000, complaints began to surface from surgeons who were reporting that some of their patients were having problems during rehabilitation. After these cases mounted, Sulzer began an investigation to see if there were any abnormalities that could be associated with their product. As part of this investigation, Sulzer hired North American Science Associates (NAMSA), an outside firm specializing in nonclinical fine testing services to ensure medical device safety and compliance, to test the hips in question. In mid-November, NAMSA reported back to the company that during their tests, they had discovered an oily residue present on the surface of the hip socket portion of the device. They believed that this residue could prevent the device from properly attaching to the patient's existing bone. Approximately three weeks later, Sulzer's parent company, Sulzer AG of Europe, announced through an overseas press release that they were voluntarily recalling the affected hip product, which included some 40,000 units. Three days later, they officially notified the U.S. Food and Drug Administration of the recall. On December 7, 2000, Sulzer notified all the surgeons who had performed hip replacement surgeries using their products. This notification is what the FDA currently requires. Sulzer gave the physicians copies of a suggested letter template that they could use to contact all their patients directly.

To best understand the ramifications of this recall, it is helpful to understand the complex nature of the surgery involved. The surgery involves removing a portion of the upper leg bone that includes the ball section of the hip joint. This is replaced by one portion of the artificial hip. In addition, part of the patient's hipbone is graded away in order to implant the hip shell, or socket portion. This section has a semi-porous side that comes into contact with the bone. In normal situations, the bone will grow into these pores, forming a strong bond with the implant.

Most patients who received the hip implant, like Tom, did well at the outset of the procedure; however, within a few weeks some patients began noticing problems. Sulzer describes the problems in their recall letter to surgeons (G. Sabins et al., personal communication, December 7, 2000):

> 4–6 Weeks: Patient progressing well or reporting groin or anterior pain.
>
> Up to 6 Weeks: Observe increased groin pain
>
> Patient has significant startup pain with rising from a seated position, may have buttock pain.
>
> X-Ray evaluation may show component migration
>
> 6 Weeks to 3 Months: Significant pain with weight bearing, may require cane or crutch.
>
> Patient cannot exert resistance in leg movement tests.
>
> 3 Months +: X-rays may reveal a slight separation between the implant and the bone and may show some component movement.

In short, because of the residue found on the porous portion of the hip shell, the hipbone could not properly bond. In some cases, this led to poor attachment and, in more dramatic instances, it produced complete hip failure.

Sulzer's Position

Sulzer Orthopedics, the fourth-largest supplier of orthopedic implants in the world at the time of the recall, was often seen as the premier manufacturer in this industry. As of 2002, between 150,000 and 200,000 hip replacements were being performed each year (Hip Replacement Surgery, 2002) and Sulzer was particularly well known for their hip and knee replacement devices.

The hip replacement recall can be considered a crisis for Sulzer. Fink (1986) defines an organizational crisis as a situation that can potentially escalate in intensity, fall under close government or media scrutiny, jeopardize the current positive public image of an organization, or interfere with normal business operations, including damaging the bottom line in any way. According to Pearson and Mitroff (1993), crises are composed of five dimensions: 1) high visibility, 2) immediate

attention is required, 3) surprise is a common part of the crisis, 4) action is needed, and 5) control is not always possible. Sulzer's crisis fits all five of these dimensions.

In Sulzer's situation, they quickly found themselves needing to contain the damage being caused by the tragic product contamination. This phase, called *damage containment,* is common to nearly all crises (Pearson & Mitroff, 1993). The purpose of damage containment is to prevent the crisis from contaminating other parts of the organization or environment not immediately affected. During this crisis phase, organizations seek to protect their image by modifying public perception of responsibility for the crisis or to manage the public's impression of the organization in crisis (Coombs, 1999).

When the recall was made public, Sulzer began to contain the damage by initially issuing a statement to the press that they would cover all medical expenses and lost wages resulting from the defective implants. "It was our fault," said Sulzer's Steven Whitlock in February of 2001 (Roser & Park, 2001). In an open letter to surgeons published in several central Texas newspapers, Sulzer pledged openness and restitution for the patients who received defective implants. In the crisis communication literature, how an organization responds to a crisis is called a *message strategy* and Coombs (1999) has developed a comprehensive typology describing these strategies. In this phase of the crisis, Sulzer consistently used a message strategy known as *remediation,* since they accepted blame and offered to correct the damage their implants caused.

Tom's Second Surgery

Considering the previous lack of support from his surgeon, Tom had no desire to continue the relationship with the surgeon that had performed his first hip replacement surgery. He and his wife began searching the Internet to find surgeons that specialized in the removal and replacement of these defective parts. They found a surgeon in Houston and scheduled the first available appointment.

The specialist worked exclusively with joint replacements of this type and had had years of prior experience using Sulzer products. The specialist assured them that Sulzer was a solid company that would take care of its customers, so they rescheduled the second hip replacement surgery. Since Sulzer made the "Cadillac" of hip replacements, the specialist recommended that they replace the defective parts with new Sulzer parts. Tom agreed and wanted both hips replaced at once;

however, the specialist explained that a second hip replacement surgery was much more serious and he recommended doing two surgeries, to replace each hip separately. By May of 2001, both of the defective hips had been removed and replaced with new materials. The rehabilitation began for the second time.

The surgeons are in a unique position during a medical recall. Usually, they are responsible for making the selection of the medical device, such as the artificial hip, and the patient has no input. Essentially, the surgeon has the direct relationship with Sulzer. When we talk about direct and indirect relationships between communication parties, it is useful to look at *stakeholder theory* (Freeman, 1984). This theory defines a stakeholder as any group or public impacted by the organization's operation. Wolfe and Putler (2002) explain, "the purpose of stakeholder management is to facilitate our understanding of increasingly unpredictable external environments, thereby facilitating our ability to manage within these environments" (p. 64). But in addition to the managerial concerns of stakeholder theory, it can also be used to expand the ethical considerations of organizations to actively include the voice of their stakeholders (Deetz, 2001). As these definitions suggest, stakeholder theory provides a solid way to ground an understanding of health-related crisis communication.

The relationships with stakeholder groups are often quite dynamic, especially during a crisis. Botan and Soto (1998) explain that the relationship with the public stakeholder group can be defined by its longitudinal nature and the relationship complexity. Strategic communication campaigns "are characterized by their intended role in positioning an organization or group to negotiate relationships with relevant environmental forces" (p. 23). One way to think of stakeholder relationships is using a framework of coalitional relationships (Pfeffer & Salancik, 1978). In coalitional relationships, organizations respond to pressures from the environment, accede to the demands of some coalitional interests, avoid the demands of others, establish relationships with some coalitions, and avoid them with others. Shifting stakeholder relationships creates problems for organizations because the criteria and expectations may be incompatible or competing. Faced with conflicting demands, the organization must decide which groups to attend to and which to ignore (Pfeffer & Salancik, 1978). These difficult decisions contributed to the complexity of the ethical issues Sulzer faced.

❖ PART 2: SULZER AS A "NON-ENTITY" IN THE PATIENT'S MINDS

As of February 2, 2002, nearly 2,800 hundred Sulzer patients had undergone surgeries to replace the defective hips. In addition, a similar defect was found with Sulzer's knee replacement parts, and an additional 560 patients have had surgeries to replace defective knee implants. It was still unknown how many more surgeries needed to be performed.

April 2002–What Happened Since Part 1?

It is now several years since Tom's first hip replacement, and one year since the second surgeries. Tom is still not completely recovered. His wife, Mary, explains, "We have not been able to leave town for two years." She further explains that only recently can he travel in a car and when he goes to a movie he has to get up and walk around five times. Furthermore, he still cannot put on his shoes and socks without her help. He had to quit his job shortly after the problems began and every day he spends hours at the gym working on his rehabilitation. He is also out tens of thousands of dollars for medical expenses that have *not* been reimbursed by Sulzer. Now Tom's hip replacement surgeon has adopted a more neutral tone toward Sulzer and no longer suggests that Sulzer will take care of these patients.

Severity of Effects

While some patients who received the recalled implants have shown no signs of problems, there are a significant number who have. Some have experienced minor discomfort not requiring surgery, while others have had near catastrophic incidences with the defective parts. One patient has had to endure the situation twice. "I was told if I had this hip replacement, I'd be as good as new," said Rhonda Silva, one of 15 plaintiffs in a subsequent class action lawsuit filed in San Francisco (Bernstein, 2001). "It has ruined my entire life." Silva's first hip failed a few weeks after the surgery when the synthetic hip separated from the bone, leaving her leg unattached to the rest of her body structure. Her doctors recommended another replacement. However, this happened before the recall was announced. The second hip came from the same batch of flawed hips and the operation failed once again. She is

currently scheduled for a third surgery with a new doctor who has been instructed not to use Sulzer equipment.

Legal Battles

Almost immediately after the recall announcements, lawsuits were filed on behalf of some of the early recipients of the recalled devices, and new surgeries were scheduled to replace the defective units. The problems for Sulzer continued. In May of 2001, they announced a second recall because a similar manufacturing problem had been discovered with the company's artificial knee implant. This recall affected nearly 1,500 individuals.

Sulzer made its first offer to settle the growing number of lawsuits related to the first recall in August of 2001. They proposed a settlement of $750 million to cover all affected parties. This offer would have given each hip replacement patient who had one hip replaced approximately $51,500, while patients with two hip replacements would receive about $97,000. Most patients rejected the offer outright.

Just over two weeks after the initial proposed settlement, the first court case involving the recalled implants ended in Corpus Christi, Texas. There, a jury awarded three women over $15 million dollars, saying that Sulzer had acted with "malice" for not informing patients and doctors sooner, and for continuing to sell the product while it was under investigation. Earlier in this case we mentioned that Sulzer waited to report the recall until after they investigated the concerns. Sulzer called the decision way out of line ("Sulzer to appeal $15.1M verdict," 2001). They believed they had communicated the problem appropriately. Within days, Judge Kathleen O'Malley, U.S. district judge in Cleveland, Ohio, ordered a halt to all court trials involving the recall until the settlement offer from Sulzer was reviewed.

A few days later, Sulzer scrapped its initial settlement offer and proposed a new one. In the revised settlement offer, Sulzer agreed to pay $1 billion dollars to settle the pending lawsuits. This would give the average patient an award of approximately $200,000, which would cover medical expenses, legal fees, and other expenses. It was Sulzer's contention that the problems associated with the recalls were not as significant as portrayed in the media. "We are trying to make sure all parties are comfortable [with the settlement]," said Harlan Loeb, a Sulzer spokesman ("Sulzer Agrees to Negotiated Settlement," 2001). Judge O'Malley set a hearing for May 14, 2002, to discuss approval or rejection of the class-action settlement offer.

Sulzer defends itself in court

Despite Sulzer's initial acceptance of blame for the recall—a remediation message strategy—the company told a different story in the courts. Documents filed by Sulzer in March of 2001 indicated that the patients and unidentified third parties are at fault for the hip failures (Roser & Park, 2001). When explaining the crisis in court, they not only failed to accept blame, but they also blamed others for the product problem. Sulzer spokesperson, M. J. Nicchio, said that the arguments presented are standard in this type of case because they give the company every means of defense in a case. However, Ron Weddington, a lawyer for one of the plaintiffs, questions this legal move by saying, "It's rare that there is such a stark contrast between what they are saying in the newspaper and what they are saying in court" (Roser & Park, 2001). Not only did they change their message strategy from one of accepting blame to blaming others, but Sulzer also refused to identify the third parties mentioned in their defense. This raised concerns for many of Sulzer's stakeholders.

During damage containment and recovery, organizations experiencing a crisis must decide how to address the concerns of multiple individuals and organizations, yet maintain their own legitimacy. Suchman (1995) describes legitimacy as "a generalized perception or assumption that the actions of an entity are desirable, or appropriate within some socially constructed systems of norms, values, beliefs, and definitions" (p. 574). Pearson and Clair (1998) state that the "failure to provide consistent information" (p. 72) exacerbates and elongates crisis situations. Massey (2001) claims that consistency during a crisis response requires that the focal organization provide the same account to all stakeholders. In Sulzer's situation, they were inconsistent in many areas. Not only did they change their strategy over time, but they also used different strategies across stakeholder groups. The problem is that with the proliferation of technology, these inconsistencies can become much more transparent.

Implications for the doctors

Throughout most of this recall, the doctors have found themselves in a precarious ethical position. They are caught between the manufacturer with a defective product, and patients with problems resulting from the device. While it appears that the majority of the patients' anger and legal actions are being directed at the manufacturer, some doctors may get caught in the fray. We can see that despite their direct

stakeholder relationship with Sulzer, they also need to satisfy their patients, who barely know Sulzer.

Some surgeons now refuse to use Sulzer equipment, while others publicly blame Sulzer for the problems associated with the recall. Dr. Ira Kirschenbaum, a prominent orthopedic surgeon in New York who did not use Sulzer equipment, said that the company should have halted manufacturing and distribution immediately, "the minute somebody said we may have a problem here." Not only were the surgeons left in the dark, but Sulzer's own quality-assurance head was not informed of the problem until September of 2000 (Roser & Park, 2001).

The Affected Patients

Lawyers for the patients see problems ahead for the company. "Sulzer cost these people the first good chance," said Chad Roberts, a lawyer with the law firm of Spohrer, Wilner, Maxwell, and Matthews. "The second one's never as good. They should've done the Tylenol thing which is [say], 'Hey, we don't know why people are dropping dead after taking Tylenol, but we want you to stop buying our Tylenol'" (Park, 2001). He referred to the 1982 incident in which seven people were killed by tampered with, cyanide-laced Tylenol pills. Tylenol issued a very quick, yet financially costly recall strategy that is often considered an excellent example of how to handle a product recall crisis. This is particularly worth noting considering that Johnson & Johnson (makers of Tylenol) is one of Sulzer's competitors in the hip replacement market.

Tom's Relationship With Sulzer

Though Sulzer did begin to send out e-mail updates to hip replacement patients in early 2002, Tom and his family never received any direct, personal communication from Sulzer. These e-mails were typically a recap of what was already known about both the recall and the settlement initiative. When they learned new information, it was from the newspaper, the Internet, or their attorney. They actually know the names of the various reporters for the *Austin American-Statesman*, including Amy Schatz, who writes articles concerning the recall. The Taylors also know which Internet sites provide the most complete and credible medical information to help Tom with his recovery. Finally, despite the fact that they have never sued anyone before, the family felt compelled to hire an attorney to learn more about their options.

The Taylors expected to receive their first piece of direct communication from Sulzer on March 26, 2002, since they thought it was court mandated; but this never occurred. Mary, Tom's wife, explains that Sulzer is a "non-entity" in their minds: "They have a wonderful media blitz going, since the public thinks we are being taken care of, but that could not be further from the truth." The Taylors also explained that the settlement proposed in the federal court for the class-action lawsuit had some significant issues that were not being publicized. The $200,000 per hip settlement offer includes out-of-pocket expenses and approximately 15% covers attorney fees. Thus, there is little left to compensate for lost wages, the fact that Tom will never work again, the years of physical therapy ahead, and the pain and suffering experienced when you learn that a piece of metal in your body is making you sick. Despite the fact that he can no longer work, under the terms of the settlement, Tom does not qualify for extra compensation, provided for in extreme cases, because there is no way for him to prove that the pain he is now suffering is a direct result of the recall issue. He believes that no doctor is willing to step forward to support his claim because that risks his or her relationship with Sulzer.

On May 8, 2002, Judge O'Malley accepted the settlement offer in its final revised form. One witness testified in the final hearing that the agreement was "the best opportunity for the most people to recover the most money the soonest" (Lieff, Cabraser, Heimann, & Bernstein, 2003). The final settlement totaled $1.035 billion, which was deposited into a settlement trust on November 4, 2002. During this time, Sulzer Medica and its subsidiary, Sulzer Orthopedic, changed their corporate names to Centerpulse and Centerpulse Orthopedics, respectively. It is expected that upon verification of claims by the claims administrator of the settlement, claimants in the case will have received full compensation by the middle of 2003.

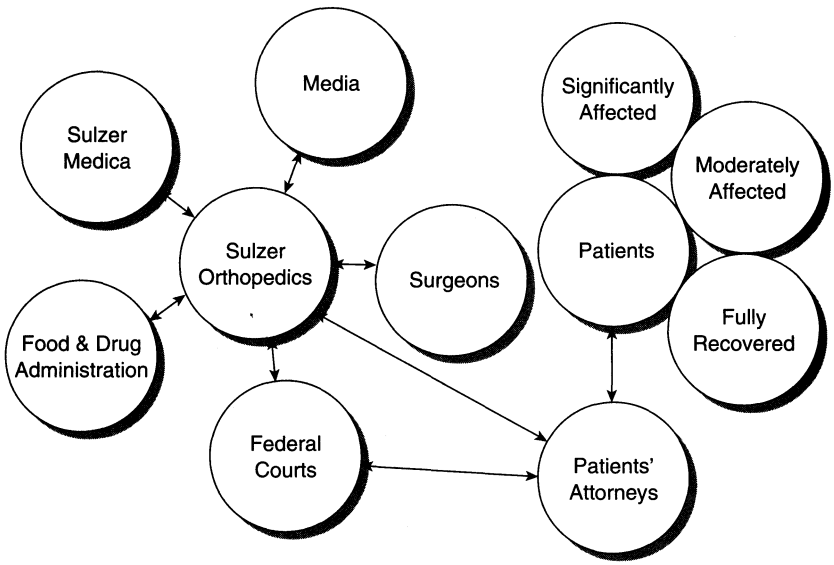
Tom and his family are unsure of what lies ahead. They were unaware that money had been placed in the trust or that they could see compensation relatively soon until the authors of this case study informed them of this in late January 2003. They feared that Sulzer would drag out the legal case as long as possible, since most of the hip replacement patients are over 65 years of age and will probably not live another 10 years. The Taylors also feared that Sulzer would simply declare bankruptcy, preventing any of the victims in this case from ever seeing compensation. They had completely lost faith in Sulzer as a company and are in a state of disbelief that they have never even

received an apology, and to date, no compensation for the second surgery has been received.

Discussion Questions

1. How could Sulzer have done a better job of balancing its liability concerns with its stakeholders' need for information?
2. Given the difficulties and constraints of this balance, did Sulzer act ethically? In what ways might it have used more ethical means of communication?
3. With the tremendous impact that the Internet has had on information retrieval, what potential effects might we expect from organizations dealing with a crisis involving multiple stakeholders? How could an organization faced with this situation avoid sending conflicting messages to the various stakeholders?
4. Using this distributed set of relationships as a guide, on which stakeholders did Sulzer choose to concentrate its crisis communication efforts? What suggestions do you have to improve this process in the future?

Figure 6.1 Sulzer Stakeholders



5. If you were a physician needing to contact your patients and tell them about the recall, how would you approach this task?

6. If you worked for Sulzer and were challenged to study this case and make suggestions for how future recalls should be handled, what would you recommend?

❖ NOTE

1. The Taylor family name, including the first names of Tom and Mary, are pseudonyms. This is at the request of the family that was interviewed.

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