FAST COMPANY

Harry Kraemer's Moment of Truth

By Keith H. Hammonds

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In an era when the business section read like the police blotter, the CEO of Baxter International faced a tough ethical dilemma. And he did something noteworthy: He actually did the right thing.

As far as anyone knows, the first few deaths occurred in Madrid starting on August 15, 2001.

The Spanish patients, two men and two women, were elderly and very ill. All four had undergone routine dialysis at the Hospital de la Princesa. Soon after, they began sweating and vomiting, some of them in excruciating pain. They died within a few hours of receiving treatment.

PHARMACEUTICALS
WHO'S FAST Harry Kraemer
AGE 47
COMPANY Baxter International Inc.
LOCATION Deerfield, Illinois

Nothing seemed exceptional about the deaths of those old, sick patients on dialysis, even though four deaths had occurred in four days at the same place. Hospital officials notified the manufacturers of the equipment involved, as dictated by protocol. But no one paid the incident much attention - until the following week, when people started dying in Valencia.

As in Madrid, the six patients who died after dialysis at the clinic Virgen del Consuelo were mostly old and sick. But they had one more thing in common. It was inconclusive evidence, but regional health officials told the media anyway: The dialysis filters used in all of the cases had come from a single lot - the same lot as the filters used in Madrid. They had been manufactured by Althin Medical AB, which had been acquired in March 2000 by the American company Baxter International Inc.

The U.S. business press didn't report much on the situation. News of the deaths was soon eclipsed, first by the profound tragedy of September 11 and then by the opening bars of Enron's opera of greed and deceit. Over the next few weeks, though, a total of 53 deaths in the United States and six other countries would be linked circumstantially to Baxter's filters. It wasn't clear until later that the filters were to blame. To this day, it isn't clear exactly what went wrong.

But what was certain was this: Baxter and its CEO, Harry M. Jansen Kraemer Jr., faced a moment of truth. How Baxter responded would leave a lasting imprint on the company's relationships with patients and doctors, with employees, and, of course, with investors. The episode would, for better or worse, open a window onto Baxter's corporate soul.

What did Harry Kraemer do? He did something that feels unusual - subversive, almost - in light of the air of mistrust and criminality that pervades big business. "When in the past nine months have you ever heard a corporate executive apologize?" marvels William W. George, the recently retired CEO of medical-instrument maker Medtronic Inc. The answer: almost never.

Baxter's response to its filter crisis wasn't perfect. But Baxter's CEO owned up to the situation. He told the truth. He took responsibility when it would have been easy not to. His company took a $189 million hit, and he recommended that the board reduce his bonus. In other words, Kraemer did the right thing.

"There Was Too Much There to Be a Coincidence"

Baxter International is a $7.7 billion company with 48,000 employees. Founded in 1931 by Dr. Don Baxter to manufacture and distribute intravenous solutions, it still sells IV bags as well as biopharmaceuticals and drug-delivery systems. Its products treat millions of patients a year who suffer from hemophilia, infectious diseases, and cancer.

The thing about selling all of those drugs, devices, and solutions is that a lot can go wrong. Nearly every product that Baxter delivers is a matter of life and death. But when the outcome is death, it can be incredibly difficult to determine a treatment's effectiveness. Was the death normal and predictable? Or did the treatment somehow fail? The answers aren't always obvious. If medical-products companies pulled their wares every time someone died, there would be no medical products.

That is the reason why, even as Baxter quickly recalled the lot of filters associated with the patient deaths in Spain, it did not at first accept responsibility. The recall was a sensible precaution, no more. And on October 9, Baxter announced the results of a set of internal analyses, plus another set commissioned of an independent consultant. There was, in fact, no evidence that the dialysis filters in Spain had malfunctioned in any way. Nor had the clinics' water supplies been contaminated. Basically, the deaths remained unexplained.

But that Saturday morning, October 13, Alan Heller checked his voice mail from his hotel in San Francisco, where he was attending a conference. Heller had joined Baxter less than a year before to serve as president of its $1.9 billion renal division. The Althin operation, acquired to complement Baxter's existing dialysis products, was part of his business.

The phone message was shocking. Newspapers and television in Croatia were reporting that 23 dialysis patients had died during the previous week at clinics across the country. The government was blaming Baxter.

The studies that were done after the deaths in Spain had exonerated the dialyzers. But now, says Heller, "I knew that there was too much there to be a coincidence." The filters in Croatia were probably manufactured around the same time as the ones in Spain. What's more, the recent deaths had occurred at six locations, and the patients weren't all elderly. The clustering in two different countries was highly unusual. Something was wrong with the filters.

Suddenly, Baxter's world exploded. The deaths were front-page news every day in the Croatian newspapers. The Croatian health ministry, like regional officials in Valencia, refused to release the used filters to Baxter for testing. The possibility of tampering was broached.

For Heller, the first decision was obvious. He ordered a global recall of all of Althin's filters and a distribution hold on the ones that had already been made. The action, Heller says, cost Baxter about $10 million. "But the cost was minimal compared to the potential cost to patients if we went ahead with the product," Heller says. Clearly, too, Baxter's legal liability would have been enormous if it had failed to act and more patients died.

Heller assigned Marla Persky to head an internal task force charged with confronting the debacle. Persky, a deputy general counsel who was responsible for the renal division's legal and government affairs, had overseen the integration of the Althin acquisition. Persky pulled in staffers worldwide from quality, manufacturing, toxicology, marketing, communications, clinical affairs, and other departments. That evening, the team of 27 gathered for their first conference call. They would talk twice a day for the next month, working to identify the gaps in their information and where they needed expertise. They hired forensic toxicologists to reexamine the returned filters. They combed through documents, hoping to find anything - a change in the manufacturing process, a new supplier, perhaps different packaging.

And they found nothing. Neither did a team of European physicians assembled by Baxter. Finally, a quality engineer in Althin's Ronneby, Sweden plant noticed something unusual about one of the recalled filters. At one end of the device, between the fibers and a potting compound, were a few bubbles. The bubbles weren't supposed to be there.

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A dialysis filter is a disposable product that costs less than $15. The technology is pretty straightforward.At Althin, each filter was tested several times before shipping. An air test determined whether there were any leaks. For the 10% of filters that did leak, workers injected a solution to locate the problem for repair. That solution was supposed to be vacuumed and evaporated from the filters. But the bubbles were evidence that trace amounts of the liquid remained. The solution, made by 3M, had been labeled as nontoxic - and chemically, it was. But when heated to body temperature in a patient's bloodstream, the toxicologists theorized, it gasified, causing a fatal pulmonary embolism.

No one at Baxter knew why the solution was removed from some filters and not others. The apparent randomness made little sense. "Why now?" Persky remembers wondering. "Why not a year earlier? Why not for other manufacturers?" Why wasn't the solution tested for reaction to temperature? Because 3M never intended it to come into contact with anyone's bloodstream. Why was it used at Ronneby? Because the contractor who designed the process there had done the same thing for another company. Why hadn't the earlier analyses identified the problem? Because when technicians opened the filters for testing, the trace liquid evaporated.

"There will always be a thousand 'why's," Persky says now. "So we had to focus on the 'what.' " And on November 2, when test results confirmed Baxter's working hypothesis, the what became unavoidable. Rabbits injected with the 3M solution had nearly died, exhibiting the same symptoms as the patients in Spain and Croatia. The following morning, a Saturday, Heller called Kraemer at home to lay out the situation. Kraemer was packing the car for a camping trip with his daughter. Heller reported on the animal tests and their implications. He explained Baxter's options. After a discussion about Baxter's likely strategy, Kraemer told Heller, "Let's make sure we do the right thing." Then he went camping.

"What Harry Says He Believes In"

What is it, exactly, that makes Kraemer so different from your typical big-company CEO? He has a rumpled, boyish look to him, resembling the actor Michael Keaton in dowdy pinstripes and a button-down shirt. He is an accountant by training, with an MBA from Northwestern's Kellogg School of Management. He is a Midwestern native and a devout Catholic. He drives a Toyota Avalon.

It's not any of that. What separates Kraemer from most CEOs you've read about is this: He is relentlessly authentic. He tells the truth, and he acts on his beliefs. "There are relatively few people in the world like Harry," says Donald P. Jacobs, dean emeritus at the Kellogg School. "Harry lives his life the way most of us would like to live our lives. What Harry says he believes in, you can put it in the bank. The way he treats his coworkers is the way he'd like people to treat him."

Kraemer has attracted attention for his vocal insistence that he remain a deeply involved dad to his five children - and for his hope that others at Baxter will get a life too. But that's just part of the deal. What he's done in a short time at Baxter is change the way an entire company thinks.

Back in 1993, Baxter International pled guilty to cooperating illegally with an Arab boycott of Israel. That same year, the U.S. Department of Veterans Affairs temporarily banned Baxter from selling to its hospitals, alleging that the company fraudulently oversold products to the government. Around that time, Baxter put forth a set of "shared values" for the company: respect, responsiveness, and results. The response would have seemed like typical corporate window dressing, a predictable, shallow response to public scrutiny, but for the guy who directed the effort: Baxter's newly appointed, 38-year-old chief financial officer, Harry Kraemer.

Respect, responsiveness, results - people at Baxter actually believe that stuff. "Do the right thing" - Kraemer repeats it ad nauseum. So does everyone else. People know what it means. And it sticks. That's why Kraemer could drive off that Saturday confident that Heller would act responsibly. "If I didn't think Al would do the right thing on this one, I had a much bigger issue," he says.

Do the right thing. "We have this situation," Kraemer continues, describing the filter crisis. "The financial people will assess the potential financial impact. The legal people will do the same. But at the end of the day, if we think it's a problem that a Baxter product was involved in the deaths of 50 people, then those other issues become pretty easy. If we don't do the right thing, then we won't be around to address those other issues.

"I'm not a very smart guy, so let's keep it simple. Think of any problem you need to deal with. There are a million pieces of information that can get involved in a decision. But let's get above the tree line and ask some simple questions. What is the issue? What are the alternatives? What are the pros and cons? What is the best solution? Life is complex, but you can boil the morass down to thinking simply."

"This Problem Will Never Happen Again"

Baxter could have ducked the blame. It could have pulled the filters ever so quietly from the market - and since the line accounted for less than $20 million in revenue, it's likely that few would have noticed. With some justification, it could have blamed Althin's former owner, since Baxter had only recently taken over the business. It could have blamed 3M, for that matter. It could have faulted the lack of cooperation from Croatian and Valencian authorities.

Too often, that is how it works in business. "You bring in lawyers and PR companies, and you find ways to say, 'This is not our fault,' " says Brad Googins, executive director of the Center for Corporate Citizenship at Boston College. Companies and their executives duck, shirk, and deny. And in doing so, they destroy trust.

On November 5, 2001, Baxter announced that it had identified the probable cause of the dialysis-patient deaths. In a press release, Kraemer made this statement: "We are greatly saddened by the patient deaths and I would like to extend my personal sympathies to family members of those patients. We have a responsibility to make public our findings immediately and take swift action, even though confirmatory studies remain under way."

Baxter could have stopped selling only the 10% of filters that needed repair. After all, those were the only ones in which the solution had been used. But the tragedy had compromised the entire Althin brand. And Baxter didn't have all of the facts; it never did see the filters from Croatia. Perhaps some patients had died from filters that hadn't been exposed to the solution. "Were we 100% confident?" Kraemer asks. "No. We didn't know."

So Baxter shut down Althin for good. It closed the factory in Ronneby and another in Florida. It took a charge to earnings of $189 million to cover the costs of the closure and its anticipated settlements with the families of patients who had died. By year's end, it would pay the Spanish families a reported $290,000 each. (The company won't confirm the amount or disclose the sums paid to families in Croatia, who also have settled.) The lone suit involving an American patient has also been resolved. The plaintiff's attorney in the case, Kenneth Moll, says that Baxter "behaved appropriately and responsibly."

The next day, Kraemer and Heller flew to Washington, DC to brief officials at the Food and Drug Administration on the company's findings and its plan of action. Baxter executives had similar conversations with regulators in Spain, Croatia, and other affected countries. Baxter had warned 3M of the problem over the weekend. It also had reported the problem with the dialysis filters to rival manufacturers it knew or suspected were using the same process.

In the months that followed, Baxter searched through records for hundreds of thousands of its products and product parts, looking for processes that might resemble the faulty one at Ronneby. It added steps to qualify any material used in manufacturing, even if that material wasn't designed to stay in the end product. "This made us second-guess systems that we'd had for 20 years and that had always worked," Persky says. Adds Jose Divino, the associate medical director who had been Baxter's point man in Spain and Croatia: "What we know for sure is, this problem will never happen again."

And there was one more thing. Kraemer recommended that the compensation committee of Baxter's board of directors reduce his performance bonus by at least 40% for 2001. (In the end, he still got paid $1.4 million.) He also suggested to the committee that his top executives take a 20% cut. Patients had died on their watch. They had been responsible.

So Baxter admitted that it was wrong. It took the hit. And guess what? The world didn't end. The company's stock dropped slightly on news of the charge to earnings but soon recovered. "Baxter didn't try to assign blame away," says David Lothson, an analyst who follows Baxter for UBS Warburg LLC. "It showed signs of dealing with it decisively rather than letting it drag on. Investors tend to react very favorably to that."

The message to CEOs: Investors like honesty, including public apologies. (Kraemer visited New York to apologize in person to the president of Croatia.) So, it turns out, do employees. Kraemer was flooded with appreciative emails and phone messages from Baxter workers. As for customers, Heller admits that his renal business has dropped off in Europe - but he hopes to win that back too. "We violated the physicians' trust," he says. "It wasn't intentional, but our product failed. We have to rebuild that trust.

"In the short run," Heller allows, "our results are probably worse for the way we handled things. But in the long run, they'll be better. Bad ethics and bad judgment ultimately come back to burn you." (Of course, good ethics don't guarantee safe passage either. At press time, the FDA announced that on September 6, 2002, Baxter notified hemodialysis centers that tubing and needles used with its dialysis machines might have been linked to five deaths in the United States in late August.)

Nearly a year after the first death in Spain, Kraemer sits in his office, pondering the aftermath. To him, there is nothing extraordinary about what Baxter has done. This is simply how organizations and their people should behave. "Simplicity," he says. "Open communication of values." Respect, responsiveness, results. "Over and over and over again." If the values are authentic, then so are the decisions and the actions.

He pauses, then finishes the thought. "Of course we'll do the right thing," he says. "As opposed to what?"

Sidebar: What's Fast

Confidence and Humility
Handcuffs have replaced cuff links as the most visible wrist wear for CEOs - which makes Baxter International CEO Harry Kraemer's philosophy of leadership all the more refreshing.

"Leadership is a delicate blend of self-confidence and humility. You have to have the self-confidence to say, 'You don't want to make that decision without my input!'

"But self-confidence without humility becomes a problem. I may be the CEO. But part of that was having a few skills, and part of it was luck. Part of it was the man upstairs. So I'm no better than anyone else. Self-confidence and humility: Blend those two together, and you have someone who has a good chance of leading effectively.

Ninety-nine percent of people want to do the right thing. I've got 48,000 employees, most of whom care about the environment, or they have parents, or they are parents. I'm representing them. I've got 48,000 people who assume that we're going to do the right thing."

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