

## A case of shattered trust

### If regulators don't enforce standards at a manufacturer of sterile health care products, is anybody really safe?

By [Raquel Rutledge](#) and [Rick Barrett](#) of the Journal Sentinel

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**Houston** - They walk together through the hospital hallway, 2-year-old Harrison Kothari smiling as he reaches up to hold his parents' hands, his blue gown nearly touching the floor.

Mom and Dad gaze down at the "little angel" they tried for two years to conceive.

"I would give anything to go back to that day," says Shanoop Kothari, the boy's father. "Anything."

Days later, Harry would be sleeping.

The hospital is quiet. Shanoop, an investment banker, sits by Harry's bed doing paperwork. His wife of 13 years, Sandy, has gone home to get some sleep. She will be coming in the morning to bring Harry home. He is well, the doctors and nurses say, recovering from a low-risk surgery.

Harry stirs. It is about 10 p.m. He becomes agitated and begins to throw up.

The nurses give him some medicine and don't seem too worried. *Probably a food bug*, Shanoop thinks.

But Harry's temperature shoots to 102. He asks for water. Lies back down. Then sits up for more water. He starts to hit his hands against his head.

About 1 a.m. Shanoop calls Sandy: "I think you need to come down."

Harry clutches his dad's shirt in desperation.

"Da, Da," he says.

Then his eyes roll back in his head and he has a seizure.

He's never had a seizure before, but he has another one. Doctors give him anti-seizure drugs.

It's just 3.2 miles from the Kotharis' house to Memorial Hermann Hospital in Houston. Sandy races through the empty streets.

It is Nov. 29, 2010.

### **A strangely urgent inspection**

That same day, some 1,200 miles away, three investigators and a consumer safety officer with the U.S. Food and Drug Administration are dispatched to a pharmaceutical company on the edge of a suburban office park in Hartland, Wis.

The Triad Group sells an array of health care products, including cough syrups, suppositories, creams and ointments. Its sister company, H&P Industries, manufactures the products.

H&P also makes alcohol and iodine wipes used to clean skin before injections and surgical incisions.

The family-owned firm, started in 1976, has grown into one of the nation's largest manufacturers of wipes and swabs, supplying hundreds of millions each year to hospitals and drugstore chains.

FDA investigators have been to the factory before, but this time is different.

They bring cameras and other equipment. They take notes continually.

"I had never seen an audit like that before," said a former employee who did not want his name published out of fear of reprisal. "Usually they would come in, point out a few things."

This time, investigators came back the next day. And the next.

They stayed for weeks.

"They weren't fooling around," the longtime employee said. "I think they knew exactly what they were looking for."

What they were looking for - and found - was a dangerous bacterium.

And they would find dozens of other serious problems: children's cold medicine being made without its active ingredient; workers packaging acne pads with their bare hands; a water supply that could contaminate products; dirty utensils and equipment.

They found workers who changed the specifications of products when the products didn't meet the proper standards and sent them out anyway.

The plant did not have a microbiologist on staff. And inspectors found that some employees could not read or write English, raising questions about whether they had followed directions in making products.

Each of the four investigators was familiar with the plant. FDA records show they found major problems there six months earlier - including workers not following proper procedures to sterilize alcohol wipes and suppositories containing metal shavings.

They also had found problems the previous year.

In fact, the FDA - the federal agency tasked with protecting public health - had known about critical issues at the company for at least a decade but failed to take any enforcement action, an investigation by the Journal Sentinel has found.

Instead, inspectors gave verbal warnings and repeatedly accepted the company's promises to correct problems.

And tainted products landed on store shelves and in hospital supply rooms.

"What's alarming . . . is the FDA had evidence that Triad was screwing up, talked to them about it, but did not force the issue," said Larry Smith, president of the Institute for Crisis Management, a Louisville, Ky., consulting firm not affiliated with Triad or the H&P manufacturing operation.

In January, five weeks after launching its probe, the FDA announced the firm's voluntary recall of Triad's alcohol wipes and swabsticks, citing concerns about potential contamination with deadly bacteria .

But the assembly lines continued to churn out other products - one of which would later be recalled as well.

The plant would not be shut down until April.

### **A seemingly routine surgery**

Harry Kothari was a healthy boy last August when he fell off a couch and conked his head on the wood floor of his home on Houston's southwest side.

He rode a tricycle, stacked blocks and said all the words a not-quite 2-year-old typically says: mama, airplane, thank you. He even spoke a little Spanish, thanks to the housekeeper.

The fall didn't change anything, but Sandy worried about the lump on Harry's head, so the family pediatrician ordered a scan to ensure he hadn't fractured his skull.

The scan showed something else. Harry had not fractured his skull, but had a cyst on the other side of his head. If left untreated, the benign cyst had the potential to cause speech and other problems.

The Kotharis consulted three surgeons. All said the cyst was treatable and the risk of surgery was very low. So the Kotharis decided to go ahead.

In September, Stephen Fletcher, head of pediatric neurosurgery at the University of Texas Medical School, removed the cyst. All appeared to go well, according to medical records, and Harry was sent home a week later.

He celebrated his second birthday on Oct. 23. A photo shows him happily perched on his mom's hip. A cake decorated with a giant airplane sits on the table in front of them. Home videos show him running around the house playing with his 7-year-old sister, Hannah.

The next week, he went trick-or-treating dressed up as a UPS driver. He walked to a few houses but soon became bored.

"I remember thinking, 'Next year will be the perfect year. He'll be 3 and he'll be all excited,' " Sandy said.

At a follow-up visit, Fletcher noticed cerebrospinal fluid - the fluid that cushions the brain and circulates into the spinal cord - leaking at the site of Harry's surgical incision on his forehead.

Medication didn't stop the leakage, so on Nov. 8, he was admitted to Memorial Hermann Hospital to have a lumbar drain inserted. The small catheter in his lower back would relieve pressure from the fluid, allowing the incision to heal.

Tests of the fluid showed no signs of infection. Doctors surmised Harry had an allergic reaction to the adhesive used during surgery to glue his skin back together.

During the next three weeks, nurses regularly drew cerebrospinal fluid from the lumbar drain to test for any infection.

Before drawing the samples - following typical protocol - they wiped the area around the drain with what they assumed were sterile alcohol wipes.

## **In Colorado, alarming infections**

In October, weeks before Harry would be readmitted to the Houston hospital, officials at the Children's Hospital in Aurora, Colo., noticed strange infections cropping up.

A child with leukemia became gravely ill after hospital workers implanted an IV port in his chest. Then, an infant with congenital heart disease developed a fever and was having trouble breathing a few days after doctors replaced an IV tube.

Blood cultures from both patients revealed something alarming: *Bacillus cereus*, a cousin to the more widely known and feared *Bacillus anthracis*, or anthrax.

*Bacillus cereus* (pronounced buh-sil-us seer-ee-uhs) is often associated with food-borne illness. While common in the soil and elsewhere in the environment, it rarely causes infections in hospitals.

"It seemed unusual," said Sue Dolan, an epidemiologist at the hospital. "The patients were pretty ill, pretty quickly."

Dolan and a team of infection prevention experts launched an investigation to pinpoint the source.

They looked at each patient, at each procedure, and sought common factors. They sorted through all the products the patients came in contact with, looking for matches.

They narrowed the possible culprit to three products, all disposable and all found in hospitals everywhere: syringes, applicators and alcohol wipes.

The syringes and applicators tested negative for any bacterial contamination.

Lab tests showed the alcohol wipes were tainted with *Bacillus cereus*.

Hospital [investigators found](#) 40 of 60 wipes from about 10 different lots were contaminated with the bacteria or related species.

According to Dolan, all the wipes came from one company: Triad Group.

"We began pulling the alcohol prep wipes immediately that day," she said. "We didn't wait for a recall."

Hospital investigators also notified the Colorado Department of Public Health and Environment.

It was Nov. 18, 11 days before Harry Kothari grew suddenly ill in Houston.

The state health department took no immediate action. Instead, it waited until the following week to alert the U.S . Centers for Disease Control and Prevention, and the FDA.

Children's Hospital "notified us they had a suspicion," said Wendy Bamberg, medical epidemiologist with the Colorado health department. "At that point the information was very preliminary.

"When we talked the following week, they had really confirmed they were getting positive results."

Yet even then, the findings didn't trigger a nationwide alert as they would have if the hospital had confirmed an outbreak of, for example, smallpox or botulism.

Six more weeks would pass before Triad and the FDA announced a [voluntary Class II recall](#) of the wipes.

Class II recalls are meant for products in which adverse health effects are considered "temporary and reversible."

## **Bacterium with deadly potential**

*Bacillus cereus* is a spore-forming bacterium undaunted by heat or high concentrations of alcohol. It lingers dormant in the soil but springs to life when it finds nourishment. If ingested, it typically causes vomiting or diarrhea before the body's natural defenses knock it out.

Most people survive the usual types of exposure to *Bacillus cereus*, microbiologists and other medical experts say.

But when *Bacillus cereus* enters the blood or cerebrospinal fluid and finds a host - such as a tube or valve - it thrives. It sets up shop feeding on simple sugars and proteins, spewing out deadly toxins. And it acts quickly.

"It's got to find a niche in the body where it can multiply," said David Warshauer, deputy director of communicable disease with the Wisconsin State Laboratory of Hygiene. "Then you're going to see some serious complications."

Antibiotics such as ciprofloxacin can - but don't always - kill it.

"These are bugs that don't cause diseases unless they get somewhere where they shouldn't be," said Alex Kallen, a medical officer with the Centers for Disease Control.

It's impossible to know the true scope of such infections and where they occur because *Bacillus cereus* is not an infection the CDC recommends that hospitals report. And states - which set their own reporting requirements - don't usually notify the CDC unless they discover an outbreak.

Furthermore, the discovery of *Bacillus cereus* outbreaks is fairly rare, and particularly challenging.

That's partly because hospitals don't typically track incidental products used in patients' care. A patient's record doesn't include the brand of gloves a nurse was wearing when blood was drawn or a shot was given.

Improved tracking, like retailers use with bar codes, would be helpful in identifying tainted products, Kallen said.

"It would require an unbelievable amount of work," he said. "But having as much information as to what every patient is exposed to is important."

## **The role of purchasing groups**

The way some disposable products wind up in hospitals depends on purchasing contracts for thousands of items.

Years ago, operating room nurses and other hospital staff were more involved in making decisions about which products and supplies they should buy. Hospitals today often use group

purchasing organizations to buy things ranging from expensive lab equipment to antiseptic wipes.

Purchasing groups represent multiple hospitals and negotiate prices.

They rely on manufacturers and the FDA to ensure product quality and safety. If something is labeled sterile, they trust it's sterile. And when there is little difference in functionality, as with an alcohol wipe, more emphasis is placed on price.

Hospitals don't visit manufacturing plants to assess quality. Purchasing organizations don't typically do that either.

"I don't really see it as our place to go into a plant," said Curtis Rooney, president of the Health Industry Group Purchasing Association, a national trade group.

Spokeswoman Elizabeth Whitehead from the Children's Hospital in Colorado said her hospital has a "Value Analysis Multidisciplinary team" that reviews products on a regular basis. Input from infection prevention staff is included, she said.

She wouldn't say what, if anything, the hospital is doing differently now to ensure it doesn't get another batch of bad products.

And Whitehead would not say what company now supplies the hospital with alcohol wipes. She would only reiterate: They are "not manufactured by the Triad Group."

### **As business grew, so did complaints**

For decades, H&P and Triad flew below the radar of consumers and even hospital staffs.

At various times H&P operated plants in Franklin, Mukwonago, Pewaukee and Hartland. It churned out all sorts of items from suppositories to cough syrup, often generically so distributors and retailers could affix their own labels.

When founder Richard Haertle died in 1988, his three adult children, Eric Haertle, David Haertle and Donna Petroff, took over as co-owners. His wife, Joanne, also helped run the business.

"Our family came together from all over and banded together to try and keep this company going," Eric Haertle, chief operating officer, said in an interview with the Journal Sentinel in April. "We worked there every summer through high school and college."

The siblings continued to expand the business in the early 1990s, but it didn't take long for trouble to surface.

At first, the problems centered on worker safety at the plant in Franklin.

In 1991, the federal Occupational Safety and Health Administration fined H&P for "willful, repeat and serious" health and safety violations. As the company grew, opening a plant in Mukwonago in 1992 and adding employees to locations in Brookfield and Pewaukee, more worker-safety issues arose.

In 1998, OSHA again found workplace health and safety violations , this time at the Mukwonago plant.

In recent Journal Sentinel interviews, former employees said the Mukwonago plant wasn't clean - especially troublesome because it made medical products.

They complained to supervisors about conditions in the bathrooms, including broken toilet seats, sewage on the floor and no hot water. They complained about alcohol-wipe machines not being properly sanitized.

"There was nothing sanitary there at all," Ed Westrick, a seven-year machine repairman, said of the Mukwonago plant.

Westrick, who left his job in 2007, said the production room was always filled with a red cloud from manufacturing iodine prep pads and swabs. The company hired people who didn't know how to run the machines, he said. Making matters worse, safety switches on the machines were often bypassed to keep lines moving, he said.

"You might come into work and find a finger that somebody lost the night before," he said.

Westrick wasn't exaggerating; he knew of at least two workers who lost fingers.

While OSHA inspects factories for worker-safety issues, it does not examine product safety. That task falls to the FDA.

Quality-control employees said they also complained to managers about sloppy manufacturing practices.

"They (the Haertles) had plenty of people telling them the right things to do, but they just didn't do them," said Frances Lee, a microbiologist who headed up Triad's quality/regulatory/product development unit for three years ending in 2002.

Lee said she left the company over disputes about the manufacturing process.

She and others said previous president and co-owner David Haertle showed little concern for keeping the plants sterile.

"I can't make the president of the company stop eating a banana and drinking coffee on the production line," Lee said.

## **Family's world turns upside down**

When Sandy Kothari arrives at Hermann Memorial Hospital, her husband, Shanoop, is slumped in the corner of Harry's room, crying. Doctors and nurses are in panic mode, crowded around Harry's bed.

Sandy can't get to him. She can't even see him. Minutes pass.

They rush Harry out and down the hall for a brain scan. Sandy grabs the bedrail and runs alongside.

Harry's body is under siege.

Nobody has any idea what is ravaging his insides, shutting down his system.

Tiny bacteria are waging a full attack on Harry's mitochondria - the power plants of his cells. As the bacteria grow and multiply, their potent poison shuts down energy production. Without power, none of Harry's organs can function.

His breathing becomes labored. Doctors insert a tube in his mouth, forcing his lungs to work. They hook him to an IV and start antibiotics. His brain swells. They give him drugs to boost his blood pressure and steroids to try to stop the swelling.

Nothing works.

His brain continues to swell.

They take blood and spinal fluid samples and send them to the lab.

Harry's 35-pound body is losing the fight.

Machines keep his heart pumping and lungs inflating.

Tests confirm he is brain-dead.

"That was it," said Sandy.

A boy who was walking around, eating, playing, happy, hours before, is gone.

Results from the lab come back that afternoon: *Bacillus cereus*.

Like the doctors, the Kotharis have no idea how it got into Harry's body.

Hannah, too, cannot understand what has happened.

Nothing makes sense. He is her baby brother. She used to run across the hall to his crib every morning. They chased around the house, took baths together. On Harry's second birthday, a month earlier, Hannah gave him a talking teddy bear and showered him with kisses.

"Why can't we just keep him on the machine?" she asks.

"Just don't take him off the machine," she pleads.

Sandy and Shanoop try to explain that Harry is broken and they can't fix him.

The next day, Hannah lays her head on Harry's chest as all life support is turned off.

"His heart stopped," she whispers.

## **Inspection reports redacted**

It's impossible for the public to know when regulators first discovered *Bacillus cereus* at H&P's plant because the FDA heavily redacted details from a decade's worth of inspection reports provided to the Journal Sentinel under the Freedom of Information Act.

Records do show inspectors [found the bacterium](#) - which was the basis for the January recall of the alcohol wipes - during their weeks-long inspection starting Nov. 29. That was revealed only after the newspaper challenged the redaction.

The newspaper's review shows H&P had serious problems including trouble with cleanliness - and that FDA inspectors knew it - as far back as 2000.

Medikmark Inc., an Illinois company that sold medical kits that included Triad products, alleges Triad was aware of sterility issues as early as 2002 and continuing until the recent product recalls.

"The products Medikmark purchased from Triad were unreasonably and inherently dangerous," according to a lawsuit Medikmark filed this year after the nationwide recall of antiseptic wipes.

Triad has strongly denied the allegations, saying its products met FDA requirements.

"We would not be manufacturing for more than 30 years if we did not take quality seriously," Eric Haertle told the Journal Sentinel in April.

From 2000 through 2003, [inspection records](#) show the FDA noted 14 violations of good manufacturing practices at H&P's plants, including not properly testing its water supply for purity and mislabeling products. The labeling is important to make sure rejected products don't get mixed with approved ones or that unsterile products aren't marked as sterile.

In a two-year period, from 2002 to '03, the company received more than 250 complaints from customers voicing concerns about product-related rashes and dry antiseptic wipes and swabs.

FDA inspectors found the company did not adequately investigate the complaints. Yet the agency took no enforcement action.

In October 2004, Triad began receiving a higher than usual number of complaints, this time about moldy cosmetic wipes. Yet it took more than two months for the company to notify the FDA and announce a recall, according to a February 2005 FDA inspection report. In addition, the company failed to recall all affected lots and didn't log all customer complaints, as required.

Inspector Jeffrey A. Bernhardt wrote: "I questioned (the vice president of quality assurance) why none of the lots with associated complaints were being recalled and why none of the recalled lots have complaints in the file. He stated that he was new in his position at the time the complaints came in and he did not handle them as formal complaints."

Bernhardt suggested the company improve its complaint tracking system and took no enforcement action.

Around that same time, in 2004 and 2005, a cluster of people in Beverly Hills sued Triad after they had liposuction procedures, alleging the company's lubrication jelly used in the process had caused infections. The 16 people settled the case out of court. Terms were not disclosed.

In 2006, customers began reporting odd colors on alcohol prep wipes. When an FDA inspector went to the plant, he wrote up the company for "failure to adequately address potential contamination in Raw Material."

Again, the violation resulted in no penalties.

## **Employees concerned**

When H&P opened the Hartland factory in 2007 - consolidating operations from Mukwonago, Brookfield and Pewaukee - Eric Haertle told Hartland officials it would be a "world class" manufacturing plant .

Yet Kathleen Smith and other former employees interviewed by the Journal Sentinel say it didn't turn out that way.

Smith, a former quality control inspector at the Hartland plant, predicted Triad's products might kill someone someday.

The company's inspectors were threatened with their jobs if they tried to stop a production line because it was not properly sanitized, or if they complained about employees having dirt under their fingernails, according to Smith and other former employees.

After working two stints at H&P covering about eight months in 2009 and 2010, Smith said she was fired for unsatisfactory work performance. She believes it was because she complained about things such as employees sneaking food and personal items into areas of the factory that made sterile products.

"Oh, God, people knew what was going on," Smith said. "We called attention to problems constantly."

When an employee cut her finger while packing alcohol wipe packets, according to Smith, the wipes were shipped with blood inside and outside the box.

Smith said she brought it to the attention of a supervisor but nothing was done.

"We were told to keep things running at all cost. But I asked, at the cost of what? People's lives? You don't care if people die?"

"I should have gone to the FDA and told them what was going on," Smith said. "But they were there and knew it. And they kept letting them run and letting them run."

In 2009, the FDA found serious problems at the Hartland plant.

The inspectors - Marie A. Fadden, Sandra A. Hughes and Joel D. Hustedt - noted 21 violations of good manufacturing practices, a set of guidelines used to assure public safety.

For example, drugs that didn't meet product specifications were tagged as being acceptable; equipment was dirty; products were left uncovered. The firm had not been reporting health-related complaints to the FDA and it was not able to produce any documentation that bottles and tubes of lubricating jelly were sterile.

Still, the FDA took no enforcement action.

"This is an area that should be covered in depth during the next inspection," inspectors wrote about proof of sterilization.

In May 2010, Hughes and Hustedt went back to the plant along with another inspector, Justin A. Boyd, and found the company still wasn't able to verify it had sterilized the lubricating jelly. This time they found evidence the sterilization process the company used was not adequate, according to documents.

After the inspection, Triad recalled hundreds of cases of suppositories with the Walgreen's label on them. The recall was initiated because of potential contamination and involved nearly 750 cases of products. The recall notice didn't specify the contaminant, but a partially [unredacted FDA document](#) shows they were tainted by aluminum and stainless steel shavings.

H&P spokeswoman Christy Maginn said that none of the suppositories in question ever reached the public and that the company has installed a metal detector.

Again, the investigators took no enforcement action and left with only promises that improvements would be made.

## **Feds finally shut plant**

Six months after that inspection, word came from the Colorado health department: A hospital had discovered Triad's alcohol wipes were contaminated with *Bacillus cereus*.

And on Nov. 29, the same four inspectors who had been at the plant in 2009 and earlier in 2010 were sent back to 700 W. North Shore Drive in Hartland. They scoured the plant for weeks and found 46 violations of good manufacturing practices.

A bucket labeled "purified water" was actually deionized water used to rinse equipment after cleaning. Water pipes leading to vats that made batches of mouth rinse and glycerin suppositories had microbial contamination.

And there, listed as ["Observation 7" on page 5](#) of the [30-page report](#) by FDA inspectors, is the one violation most devastating to the Kothari family:

"Sterile alcohol prep wipes were found to be contaminated with *Bacillus cereus* organisms and were released for shipment after confirmation of the results," the inspection report noted.

In the copy of the inspection report initially provided to the Journal Sentinel, the FDA redacted the name of the specific organisms that contaminated the wipes saying it was considered trade secret and confidential information. After the newspaper appealed, the agency on Friday provided a new version that included the *Bacillus cereus* reference.

"The name of the bacteria is obviously a public health issue" rather than a trade secret, said Sydney Wolfe, a physician and official with Public Citizen, a nonprofit consumer advocacy group. "It isn't as though the company invented this bacteria."

Maginn, the H&P spokeswoman, said Friday the wipes contained only a "trace amount" of *Bacillus cereus*. She acknowledged some of the product was shipped - inadvertently - but said it did not reach the public.

Six months earlier, the same inspectors had noted that H&P employees were not following proper procedures for sterilizing alcohol wipes. The specifics of that violation were also redacted.

On Jan. 3, Triad voluntarily recalled all lots of its alcohol wipes and swab sticks - saying it was taking the action "out of an abundance of caution" and contending that no link had been made to an illness. A [separate announcement](#) by the FDA identified the potential contaminant as *Bacillus cereus*.

H&P assembly lines kept making other products, including iodine wipes that would later be recalled after inspectors found lots at the factory contaminated with another dangerous bacterium.

No investigation was conducted to identify the source of the contamination, according to a March 28 report. The raw material and foil were identified as potential sources of contamination of the alcohol wipes, the report said.

Moreover, FDA investigators found *Bacillus cereus* in benzalkonium chloride towelettes, an antiseptic wipe.

Finally, on April 4, FDA regulators took a rare step and sought the help of U.S. marshals, who swept into the factory and seized \$6 million worth of products, effectively shutting the plant down.

"The firm was certainly aware of the (Colorado) hospital's findings and the CDC's findings," said Michael Rogers, acting director of the FDA's Office of Regional Operations. "If a firm disagrees with our belief that products should be removed from the market, then we have to take more aggressive steps."

Eric Haertle defended his company's decision to keep production going even after the discovery of contaminated alcohol wipes in Colorado, Harry's death and the FDA's findings.

The company shut its alcohol products production line one day after the FDA said there was potential contamination, Haertle said in a written statement last week in response to [questions from the newspaper](#). "The info provided (from Colorado) was all verbal without any supporting proof other than their word. We immediately opened up an investigation to assess the complaint and, without receiving any further information from the FDA, decided to be proactive and shut down our (alcohol) pad manufacturing lines," Haertle said.

He said it takes weeks to get some microbial test results.

"At no time did the company knowingly allow contaminated material to leave the factory or release products slated for hold due to various reasons," he said. "In the case of shipments mistakenly sent, product was immediately recalled."

When the marshals arrived, H&P employees were told to go to the lunchroom.

Marshals searched the building to make sure no one was still at a work station. They guarded the doors to the lunchroom.

Eric Haertle told employees the plant was being asked to close - at least temporarily. Then employees were told to go home.

"I have people who are very hurt by what has transpired," Haertle said in April. "When I had to look them in the eye and tell them that we were done for the time being, it wasn't easy."

### **FDA defends prior leniency**

Under its own rules, the FDA could have acted sooner and with more force at H&P. The agency could have issued warning letters demanding that problems with contamination and sterilization be corrected. Those letters become a public blemish on a company's record.

The FDA also could have sought a court order to shut the plant. And it has the authority to seek criminal prosecution that could result in jail time and fines.

According to an FDA manual, when inspectors find even one problem that jeopardizes the "quality, identity, strength and purity" of products, they should classify the report as "official action indicated" - the precursor to formal agency action.

Inspectors didn't do that, according to inspection reports from 2000 to 2010. Instead they classified the reports as "voluntary action indicated" or "no action indicated," even when they found the company wasn't properly testing its water and when batches of products didn't meet specifications.

In an interview in May, Rogers of the FDA defended the agency's oversight of H&P, including the lack of warning letters and other corrective measures.

He said the agency took action as soon as officials believed there was a true threat to public safety. That was four months after Harry Kothari died.

"The actions that we take have to be supported with evidence," Rogers said. "And in this case when we obtained that evidence, we immediately approached the firm about removing unsafe products from the market."

The FDA expected H&P would live up to its promises to correct problems in the plant, according to Rogers.

Eventually, he said: "We got to a point where we felt the firm was not living up to their obligations."

The FDA took weeks to gather evidence at the plant. It was a time-consuming process, according to the agency, because it involved sampling of products and an assessment of the company's practices and procedures, employee training methods, and how the company handled its manufacturing from raw materials to finished products.

Voluntary recalls of Triad products, including alcohol wipes, iodine wipes and lubrication jelly, were adequate, Rogers said.

Several weeks later, though, the FDA admitted it should have at least issued a warning letter.

The lengthy investigation leading up to a recall is understandable considering the agency's case has to hold up in court, said Ed Elder, director of the pharmaceutical experiment station at University of Wisconsin-Madison.

Elder worked for 16 years in the pharmaceutical industry, mostly in drug research.

Product recalls are not strictly a public safety issue; they include a mix of business, legal and publicity decisions, according to Elder.

"There are a lot of downsides. It costs a lot of money to recall a product; sales are going to be lost and negative publicity is going to occur," he said. "Yet if you don't make that call, and someone gets sick or dies, that's an even bigger downside."

### **Triad denies liability in death**

Triad officials deny their products had anything to do with Harry Kothari's death and have vowed to fight all allegations raised in at least six lawsuits, including one filed by the Kotharis. In its March 28 response, the business denies its wipes were contaminated with *Bacillus cereus* and contends any contamination came after the products left the company's control.

"They're disgusting," Sandy Kothari said. "I am just so angry. These people can go on and they have no idea what the loss is. They have no idea."

In addition to suing Triad and H&P, the Kotharis have named a hospital group purchasing organization, a raw material supplier and a sterilization equipment and services company in their lawsuit, which seeks up to \$40 million. They are not suing the Houston hospital.

Hospital officials declined to comment about the case, other than to say they removed Triad alcohol wipes and swabs from all their facilities.

The Kotharis also blame the FDA and say there must be greater accountability and higher standards for health care products.

"This company would have sold products forever until somebody put two and two together," Shanoop said. "I think there are some other people who have gone through some pain and haven't put two and two together. . . . They had no idea. They just walked out of the hospital and had to deal with it."

A 55-year-old Tennessee man has filed a \$30 million lawsuit against Triad, saying he is permanently disabled after he developed a *Bacillus cereus* infection from Triad's alcohol wipes and had to undergo open-heart surgery.

Triad's future is unclear. The week after the alcohol wipes recall in January, David Haertle registered for a new limited liability company called Trivaria.

A company spokeswoman wouldn't answer questions about why the new company is being created.

Meanwhile, the FDA laid out a list of strict protocols for H&P to follow to resume production.

The conditions, outlined in a June 10 consent decree, cover virtually every aspect of the company's manufacturing process and would cost the company millions of dollars. Violations could result in the company being permanently shut down by the FDA.

"This is the all-important first step in resuming our manufacturing operations," Eric Haertle said at the time. "We are fully committed to addressing FDA's concerns and rebuilding the confidence of the customers we have served for so many years."

## **Grieving mom learns of recall**

The house in Houston is empty now.

Striped shades still hang on the windows in Harry's bedroom, but the monkeys and other jungle animals that decorated the pale green walls have come down.

The carpet is worn where his crib and changing table once stood.

It's early May.

Sandy looks around the room for the last time.

She remembers Harry climbing on the rocking chair and peering out the window with his big brown eyes. She pictures his little clothes filling the armoire in the corner.

She doesn't want to leave him behind.

But she can't stay.

"We just had to get out . . . ," she says. "You could paint it a different color, you could put all different, new furniture in it, but it won't . . . "

Sometimes, she and her husband look at the photo, the one taken in the hospital, the one that marks a day they desperately long to return to, before *Bacillus cereus* and Triad.

But what they learned on a different day drives them now.

About five weeks after Harry's death, still wondering how Harry had been infected, Sandy was talking with her aunt on the telephone. The aunt, a teacher, said she had just read about an FDA recall of alcohol wipes. The reason: *Bacillus cereus*.

Sandy went straight to Harry's room where she had kept a box of alcohol wipes sent home with Harry when he was first discharged from the hospital.

She turned over the box. The label matched.

It was the first time Sandy had ever heard of the Triad Group.