Shattered Trust

By Raquel Rutledge, Rick Barrett, John Diedrich and Ben Poston
If regulators don’t enforce standards at a manufacturer of sterile health care products, is anybody really safe?

SHATTERED TRUST

By RAQUEL RUTLEDGE and RICK BARRETT • rrutledge@journalsentinel.com

Houston — In the photograph, 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

KEY FINDINGS

- Triad Group’s sister company, H&P Industries, had dozens of problems with cleanliness, quality control and processes at its plants dating to at least 2000, according to U.S. Food and Drug Administration inspection reports.
- The FDA took no enforcement action, even after identifying concerns in May 2010 about sterilization of the company’s alcohol wipes. Instead, the agency accepted promises the company would fix the problems.
- After a Colorado hospital discovered in November that Triad’s wipes were contaminated with Bacillus cereus, a dangerous bacterium, Triad and the FDA did not announce a recall for six more weeks.
- During that time, a 2-year-old Houston boy died from the same bacterium. In a lawsuit, his family blames Triad and H&P for the death.
- There is no alert system for Bacillus cereus infections. The U.S. Centers for Disease Control and Prevention doesn’t recommend that states notify the agency unless they discover an outbreak, making it impossible to know the scope of infections.

COMPANY’S RESPONSE

Triad and H&P have strongly denied their alcohol wipes are linked to any deaths or injuries. The business says it adheres to good manufacturing practices, responded quickly to FDA concerns and voluntarily recalled alcohol wipes out of “an abundance of caution” when concerns were raised about Bacillus cereus.

Shanoop Kothari stands in the Houston home he once shared with his wife and children. The couple’s son, Harry (top), contracted a bacterial infection after a low-risk medical procedure, and the Kotharis allege a contaminated alcohol wipe made by Triad Group Inc., of Hartland, was the culprit.
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

A look at Bacillus cereus

In October, patients at the Children’s Hospital in Aurora, Colo., became infected by Bacillus cereus, a common bacterium that can be deadly if it finds a host within the body. Weeks later, a 2-year-old Houston boy died after he was infected by the same bacteria while in the hospital. Here is a look at the bacterium.

A common bacterium: Bacillus cereus is a common bacterium, widespread in soils and often found on the surfaces of meats, grains and plants. Small amounts in healthy individuals generally pose no problem, though in some cases, it can be a factor in food poisoning.

It can be deadly: When the bacterium is introduced into the blood or cerebrospinal fluid, it can cause serious problems and can even be fatal.

How it happens: Bacillus cereus produces enzymes that are toxic to human cells. It interferes with the production of proteins needed for energy.

Strong defense, rapid damage: Bacillus cereus is particularly deadly because of its defense system. It produces endospores, tough, well-protected “seeds” that form inside the bacteria. The spore coat is a many-layered shell that is resistant to high heat, irradiation, acids, disinfectants and other environmental stresses. In favorable conditions its rapid reproduction and resistant structure make it hard to overcome.

Sources: Todar’s Online Textbook of Bacteriology; U.S. Food and Drug Administration; National Institutes of Health

LOU SALDIVAR/saldivar@journalsentinel.com
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 concussed 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 see-ee-uh-sehs) is often associated with foodborne 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 posi-
five 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 busi-
ness 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 redact-
ed 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 Jeffry 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 busi-
ness 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.
# A look at the Triad case

The family-owned Triad Group and its sister company, H&P Industries, are one of the nation’s largest manufacturers and suppliers of alcohol wipes and other disposable medical products. For the past decade, the U.S. Food and Drug Administration has been aware of problems at H&P’s plants but did not take enforcement action against them. After a voluntary recall in January of alcohol wipes because of concerns about contamination, the Hartford plant shut down in April. In a federal lawsuit, a Hartford jury in March awarded $2.6 million to three former workers with chemical injuries.

## Events

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>2002-2003</td>
<td>The U.S. Food and Drug Administration finds 34 violations of good manufacturing practices, which are standards that are part of a quality management system.</td>
</tr>
<tr>
<td>2005</td>
<td>Triad announces a voluntary recall of cloudy cosmetic wipes. The company has about 200 employees and announced plans to consolidate its operations into a new facility in Hartford.</td>
</tr>
<tr>
<td>2004-2005</td>
<td>More than a dozen people sue Triad, alleging the company’s antibiotic jelly caused infections during laparoscopic surgery. The matter is later settled out of court.</td>
</tr>
<tr>
<td>2006</td>
<td>FDA inspectors cite H&amp;P for “failure to adequately address potential contamination in new material.” No enforcement action is taken.</td>
</tr>
<tr>
<td>2007</td>
<td>The business moves into its new plant and has a new business in Hartford, closed the other locations. The Hartford plant unit is inspected by the FDA until July 2009; Triad has become one of the nation’s largest suppliers of alcohol wipes and other disposable medical products.</td>
</tr>
<tr>
<td>Oct. 23, 2008</td>
<td>Harry Kothan is born in Houston.</td>
</tr>
<tr>
<td>July 1, 2009</td>
<td>FDA inspectors find 21 violations of good manufacturing practices in H&amp;P, including dirty equipment and drugs that don’t meet specifications tagged as acceptable.</td>
</tr>
<tr>
<td>Jan. 10, 2010</td>
<td>Triad recalls hundreds of cases of suspensions because of contamination. FDA inspectors note 23 plant violations including not following proper procedures to store alcohol prep pads. No enforcement action is taken.</td>
</tr>
<tr>
<td>Aug. 1, 2010</td>
<td>Harry Kothan dials of a couch, biting his head. He goes for a CT scan to make sure his head isn’t fractured. Doctors find an unlocated cyst.</td>
</tr>
<tr>
<td>Sept. 20, 2010</td>
<td>Doctors remove a benign cyst from Harry’s brain. He goes home a week later.</td>
</tr>
<tr>
<td>Oct. 1, 2010</td>
<td>Nurses at the Children’s Hospital in Aurora, Colo., notice strange infections cropping up.</td>
</tr>
<tr>
<td>Nov. 6, 2010</td>
<td>Harry is admitted to Memorial Hermann Hospital in Houston.</td>
</tr>
<tr>
<td>Nov. 18, 2010</td>
<td>Workers at Children’s Hospital in Colorado suspect alcohol wipes are contaminated with Bacteroides. The police call the Colorado Department of Public Health and Environment.</td>
</tr>
<tr>
<td>Nov. 23, 2010</td>
<td>Colorado health department notifies U.S. Centers for Disease Control and Prevention.</td>
</tr>
<tr>
<td>Nov. 24, 2010</td>
<td>Colorado health department talks with the U.S. Food and Drug Administration.</td>
</tr>
<tr>
<td>Nov. 29, 2010</td>
<td>Harry plays a fewer, has a seizure and is rushed into intensive care.</td>
</tr>
<tr>
<td>Dec. 22, 2010</td>
<td>Triad issues a voluntary recall of sterile lubricating jelly due to ongoing site contamination.</td>
</tr>
<tr>
<td>Jan. 5-7, 2011</td>
<td>FDA and Triad announce a voluntary recall of alcohol pads and swabs due to potential contamination with Bacteroides. An FDA report confirms alcohol pads in plant contaminated with Bacteroides.</td>
</tr>
<tr>
<td>Feb. 13, 2011</td>
<td>The Kothans file a federal lawsuit against Triad and H&amp;P alleging tainted wipes caused Harry’s death. Other plaintiffs have also sued the company for illness and injuries they say are tied to the recalled products. Later, the Kothans amend their complaint to include a raw material supplier, a distribution equipment and services company, and a hospital in which the family was treated.</td>
</tr>
<tr>
<td>March 15, 2011</td>
<td>Triad recalls more wipes used to prep skin before surgery. Tests showed contamination with bacteria, a raw material supplier, a distribution equipment and services company, and a hospital in which the family was treated.</td>
</tr>
<tr>
<td>April 4, 2011</td>
<td>U.S. marshals seize $6 million worth of products from the H&amp;P plant in Hartford, and the company voluntarily shuts down production, saying off several hundred employees.</td>
</tr>
<tr>
<td>April 8, 2011</td>
<td>In a Journal Sentinel interview, Eric Haast, H&amp;P’s president and CEO, vows to fight all allegations against Triad and H&amp;P: He says the company intends to resume production but all options are being considered.</td>
</tr>
<tr>
<td>April-May 2011</td>
<td>Triad fires lawsuits from medical supply companies that used its products and were affected by the recalls. Medicaid data show that few new severe problems involving the industry and contaminated products as early as 2002. Triad denies the allegations.</td>
</tr>
<tr>
<td>June 9, 2011</td>
<td>FDA advises it should have taken stronger enforcement action against Triad, such as issuing a warning letter after previous inspections.</td>
</tr>
<tr>
<td>June 10, 2011</td>
<td>FDA lays out terms in a consent decree that allows Triad/H&amp;P to resume operations under strict government oversight.</td>
</tr>
<tr>
<td>June 21, 2011</td>
<td>Eric Haast, gives a written response to Journal Sentinel questions, denying the company’s alcohol pads are responsible for deaths or injuries. He also says the company never knowingly shipped contaminated products. In the case of shipments mistakenly sent, products were immediately recalled.</td>
</tr>
</tbody>
</table>
June 26, 2011

Video

http://jsonline.com/shatteredtrust

Parents blame boy’s death on Wisconsin company
Shanoo and Sandra Kolheri, discuss the death of their 2-year-old son, Harry. In a lawsuit, the Houston couple says their son’s death was the result of an infection contracted from contaminated alcohol wipes made in Wisconsin. Video by Mike De Sisti
More than six months after a worldwide recall, potentially deadly alcohol wipes remain in personal medicine cabinets and possibly on store shelves.

The U.S. Food and Drug Administration, tasked with protecting public health, says the recall was effective but refuses to release audit reports detailing findings and measures taken by the company that made and distributed the wipes: Hartland-based Triad Group and its manufacturing arm, H&P Industries.

Meanwhile, another company that hospitals and others have turned to for supplying wipes since the recall has its own history of manufacturing problems, twice in the last 18 months recalling wipes that didn't meet specifications, the Journal Sentinel has learned.

Further complicating matters is a disjointed product coding system that hampers the ability of hospitals, distributors and the public to identify and track recalled products.

“It’s alarming,” said Mary Ann Beaumont, a Milwaukee resident who had a package of recalled swabs at home and only learned of the contamination months after the recall when she read a story in the Journal Sentinel in June.

Like many other Triad wipes, Beaumont’s box did not carry the Triad or H&P label. Instead, hers was sold under the Walgreens brand.

Family-owned Triad, one of the nation’s largest distributors of alcohol wipes, sold products to a variety of private-label companies such as CVS, Walgreens, Cardinal Health and Leader.

Triad recalled all of its alcohol wipes and swabs in January after the FDA found some lots were contaminated with *Bacillus cereus*, a bacterium responsible for killing a 2-year-old Houston boy. FDA actions effectively shut down the plant in April.

The FDA’s Office of Surveillance is looking into reports of a total of eight deaths that may be connected to the company’s alcohol wipes, though only two — the Houston boy and a 66-year-old man — cited the bacterium directly, an agency document shows. Some 200-plus other reports have been received by the FDA that cite other problems, ranging from rashes to severe illnesses.

Triad and H&P have strongly denied any ties between their products and the illnesses and deaths, and are planning to restart operations under an FDA consent decree that will closely monitor manufacturing and product quality control.

Triad spokeswoman Christy Maginn said the company would not comment on the recall effort because it’s the subject of litigation.

Alcohol wipes are typically used to cleanse the skin before injections or incisions. Beaumont said she bought hers for a number of reasons, including to clean her thermometer between uses.

When she called Walgreens to inquire about the recall, the company would not tell her whether the box she had was part of the recall.

“Walgreens stonewalled me,” she said. “They said they had an agreement with the manufacturer not to release who the manufacturer is. I said, ‘That’s not acceptable.’ ”

After a second phone call, Walgreens agreed to ask the manufacturer to call her. A few hours later, she received a call from Triad telling her to throw away the swabs or return them to the store.

“I had to push to get any information,” she said. “A lot of people would have just hung up.”

Beaumont said she never saw a recall notice posted at Walgreens.

A spokesman from Walgreens said customers should return items to the store if they have any concerns.

**Effectiveness unknown**

It’s impossible to know how effective Triad’s recall has been. The FDA says releasing
its reports could disclose trade secrets and interfere with enforcement actions, according to the June 13 denial letter responding to the Journal Sentinel’s request for the recall audits.

The FDA also initially redacted the name of the bacterium found on the Triad wipes, citing trade secret and confidential information. After the newspaper appealed, the agency provided the information showing *Bacillus cereus* was found on the wipes.

Inspectors with the Government Accountability Office recently found major gaps in the FDA’s oversight of recalls of medical devices, noting that the agency didn’t complete audit checks as required or conduct post-recall inspections.

“If unaddressed by FDA, the combined effect of these gaps may increase the risk that unsafe medical devices could remain on the market,” GAO officials wrote in a June report.

Alcohol wipes fall into the medical device and drug categories within the FDA.

The Journal Sentinel bought a Leader brand first aid kit, containing alcohol wipes, from a Milwaukee-area pharmacy several months after the recall. Representatives at Cardinal Health, Leader’s distributor, and at Triad and H&P said they couldn’t tell whether the kit’s wipes were part of the recall or whether they had been replaced by a new manufacturer.

U.S. Sens. Michael Bennet (D-Colo.) and Lamar Alexander (R-Tenn.) are calling for better FDA oversight of medical product manufacturing.

“It’s a consumer safety issue,” said Adam Bozzi, a Bennet spokesman. “The things that people use to make them well, in some cases, are making them sick or worse.”

As part of the reauthorization of the FDA by Congress, Bennet plans to press for tougher enforcement of pharmaceutical industry regulations. Issues that have to be addressed include manufacturing quality and cleanliness, overseas drug suppliers and recall notifications, according to Bozzi.

“When you are worried about alcohol wipes before you get a flu shot, that’s not a partisan issue,” Bozzi said.

**Other maker has issues**

Manufacturing problems aren’t unique to Triad.

The company that now supplies Children’s Hospital of Wisconsin, Walgreens and others recently recalled at least three wipe products, for example.

In February, Professional Disposables International of Orangeburg, N.Y., recalled more than 19,000 cases of antiseptic wipes and towelettes that had an insufficient amount of the active ingredient, benzalkonium chloride, according to an FDA enforcement report.

In August, there was a recall of 30 lots of Sani-Cloth Bleach Wipes due to a quality concern. And earlier in 2010, Professional Disposables recalled 403,266 packs of Up & Up baby wipes that had an uncharacteristic “off odor,” the FDA noted.

At least two of the recalls were characterized by the agency as Class III, meaning they were for technical violations rather than health risks. The FDA labeled the Triad recall Class II, a designation typically assigned to products in which adverse health effects are considered “temporary and reversible.”

However, Triad wipes are blamed in the Dec. 1 death of the 2-year-old Houston boy, Harrison Kothari, in a lawsuit filed by his parents. Even though a Colorado hospital tied several cases of patients becoming suddenly ill from *Bacillus cereus* to Triad wipes in October, the FDA did not visit the company until Nov. 29, the day the boy became ill at a Houston hospital where he was set to be released after surgery.

In addition to the Class III recalls, Nice-Pak, affiliated with Professional Disposables, had a Class I recall of provodine wipes in 1999 due to contamination with salmonella, according to FDA documents. The FDA defines a Class I recall as one with a reasonable probability that a product could make people seriously ill or kill them.

Professional Disposables International has a manufacturing plant in Green Bay, but the recently recalled products were made in Orangeburg, N.Y. and Mooresville, Ind.

The company did not publicize the Class III
recalls or put the information on its website. That’s because the FDA did not require it, said Melanie Leibowitz, senior director of regulatory affairs for Professional Disposables International.

“The recall only had to go to the distributor level,” she said.

The antiseptic wipes recall is ongoing, and the baby wipes recall has been completed, according to the company.

Leibowitz would not disclose how effective the recalls have been.

“I am sure that some material did get into the marketplace, but it was a non-health issue,” she said, adding that with most recalls a company doesn’t get 100% of the items back.

**Suppliers are limited**

Tracy Cleveland, director of materials services for Children’s Hospital of Wisconsin, said that when its distributor, Cardinal Health, announced it would be switching to Professional Disposables after Triad’s recall, the hospital was in a bind.

“We didn’t have a lot of choice,” he said. “There just aren’t a lot of good alternatives. We struggle on a daily basis to make sure we’ve got the right product and a safe product . . . It really puts pressure on the supply chains for these commodity items.”

Cleveland said the hospital has quarterly meetings with distributors and is evaluating all the longer-term options. With Triad out of the mix, demands on other suppliers — foreign and domestic — have soared. Many of the alcohol wipes now on store shelves are made in China.

The FDA on at least one occasion has refused to allow Professional Disposables to import alcohol swabs.

In an Import Refusal Report dated June 17, the FDA cites “misbranding” of the imported products as the reason for the refusal.

**Bar code would help**

Cleveland and other logistics experts say if the industry adopted a bar code system for recall alerts, it could speed the recall process and make it clear when troublesome products remain in the marketplace.

It would take health care workers only a moment to scan something, such as a box of disposable alcohol pads, to determine whether it’s on a national recall list, according to Barbara Duck, a California-based medical bar code advocate who has written medical records software for doctors.

They could even use their smartphones for the task — but only if the recall information were readily available and bar codes were programmed to display it. Now, the technology is used more for inventory control and sales purposes than to send out recall alerts.

“I can take my smartphone to a Best Buy store, scan something like a Canon printer, and it tells me everything about it,” Duck said. “But when it comes to a product recall that might save my life, I can’t get anything.”

She believes that hospitals have missed product recalls when a simple bar code could have alerted them to the information.

“One company found that even after a medical device with a potentially dangerous flaw was pulled from the market, doctors at more than 40 hospitals implanted it in at least 50 patients,” Duck said.

Finding information on recall notices on the FDA website can be difficult.

“Users may review hundreds of serial numbers and/or lot numbers published by the FDA and companies,” Duck said. “Then they have to manually compare the information on a product label.”

In some cases, key identifying information — such as lot numbers — may be on an inside flap and not the exterior of a box at all.

Smartphones can be a tool to check the status and provide key information to consumers, said Greg Smith, chairman and CEO of Medical Tracking Solutions, a Florida firm that’s developed an iPhone app to help hospitals and clinics track medical devices.

The company has its own database of product recalls and works with manufacturers to keep the information current. Medical Tracking sends out recall alerts as it receives them.

Smith said he developed the system, launched in October, after seeing how slowly recall information was disseminated involving an implant product.

“I thought it was somewhat of a debacle,” he said.

**‘Phantom recall’**

Last summer, Congress launched an investigation into an alleged “phantom recall” by drug-maker Johnson & Johnson, in which the company hired a contractor to buy up defective painkillers instead of issuing an immediate recall.

The investigation focused on more than 88,000 Motrin packets distributed in 2008.

Congressional investigators obtained a company memo, titled “Motrin Purchase Project,” that instructed the contractor: “You should simply ‘act’ like a regular customer while making these purchases. There must be no mention of this being a recall of the product!”

Johnson & Johnson recalled the medication in July 2009, after the FDA learned about the contractor’s activities. Agency documents show the concern centered on questionable potency of the product.
But “it raises the question of whether Johnson & Johnson placed a higher priority on preserving the reputation of its Motrin brand than it did on consumer protection,” U.S. Rep. Edolphus Towns (D-N.Y.) wrote in a letter obtained by The Associated Press.

Last fall, Johnson & Johnson executives told federal lawmakers the company “made a mistake” in conducting the phantom recall.

Big recalls hard

Large-scale recalls can be challenging, especially in the case of medical products — such as individually wrapped alcohol wipes — that may be separated from their original box.

In 2006, Eastern Research Group Inc. of Lexington, Mass., provided a report to the FDA that acknowledged, among other things, the difficulties of manual searches for items in medical facilities.

“With manual searching, delays and failures to locate recalled products can occur, potentially affecting product safety,” the report said. “Electronically readable labeling that includes primary and secondary information on packaging (i.e., including lot numbers) could address this problem.”

A lack of international product identification systems complicates recall efforts for products made in countries and shipped around the world.

It can be a “very ugly situation,” said Dennis Byer, senior director of industry standards for Novation LLC, a group purchasing organization that negotiates contract prices for hospitals.

“It’s going to take cooperation with a lot of countries” to change things, Byer said.
Pads used despite bacterium

N.Y. firm recalls product months after flaw found

By JOHN DIEDEICH jdiedrich@journalsentinel.com

A potentially deadly bacterium was detected on alcohol prep pads produced by a New York medical manufacturer three months ago, but the product was not recalled until this week because federal regulators didn’t require it, the company said Wednesday.

A day after the recall was launched Tuesday, word of it was slowly dribbling out to hospitals and clinics responsible for pulling the potentially contaminated products. Children’s Hospital of Wisconsin, for instance, was not aware of it until told by a Journal Sentinel reporter.

Professional Disposables International of Orangeburg, N.Y., said it detected Bacillus cereus, a bacterium that was responsible for killing a 2-year-old Houston boy last year, on its non-sterile alcohol prep pads in June.

The same bacterium was found on wipes produced by Wisconsin-based Triad Group, leading to a nationwide recall and at least six federal lawsuits — including by the family of the Houston boy — alleging the death or product caused illness or death.

A Journal Sentinel investigation this year found that the U.S. Food and Drug Administration — the agency in charge of protecting public health — had known about critical issues at Triad for at least a decade but failed to take any enforcement action.

The FDA, as the sole source of sterile wipes, has a concern about depending on PDI and FDA agreed on the current recall earlier this month, and it was launched on Tuesday.

However, Tracy Cleveland, director of materials services at Children’s Hospital of Wisconsin and its nearly 100 facilities, said he knew nothing of the recall until contacted Wednesday by a Journal Sentinel reporter.

Cleveland immediately called PDI and was directed to a website through typical search engines and was not connected to the company’s main website. However, late Wednesday a prominent notice of the recall appeared on the company’s website.

Cleveland said Children’s Hospital did not have any of the non-sterile pads but he was reaching out to his counterparts at hospitals to make sure they knew about the recall, even though official notification was expected Thursday.

He said the bacterium could be life-saving.

“It really is important,” Cleveland said. “If there is a child already immunocompromised, you don’t want to introduce another bacterium.”

Cleveland said typically companies move much faster on recalls. He was surprised nothing had been done months after the tests confirming the 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. In the bloodstream, it can be fatal.

Professional Disposables, which picked up business and had been supplying Wisconsin hospitals after Triad was raided by U.S. marshals and closed in April, halted shipments of the contaminated pads and now is recalling products shipped earlier, Leibowitz said.

“We have taken this precaution and recalled the product,” she said. “We have been working with FDA for some time, knowing the agency has a concern about this.”

Leibowitz said PDI is investigating if the contamination was connected to one of its suppliers, Tudor Converting Products Inc. of Summerville, S.C.

MSNBC.com reported Tuesday that Triad also used Tudor as a supplier. An employee at Tudor said Wednesday a prominent notice of the recall appeared on the company’s website.

Leibowitz said PDI and FDA agreed on the current recall earlier this month.

Early Tuesday, Leibowitz said PDI and FDA agreed on the current recall earlier this month.

In February, PDI recalled more than 19,000 cases of antiseptic wipes and towelettes that had an insufficient amount of the active ingredient, benzalkonium chloride, according to the FDA enforcement report.

In August 2010, the company withdrew 30 lots of San-Cloth Bleach Wipes due to a quality concern, according to the company.

In February, PDI recalled more than 19,000 cases of antiseptic wipes and towelettes that had an insufficient amount of the active ingredient, benzalkonium chloride, according to the FDA enforcement report.

In August 2010, the company withdrew 30 lots of San-Cloth Bleach Wipes due to a quality concern, according to the company. In early 2010, Professional Disposables recalled 403,266 packs of Up & Up baby wipes that had an uncharacteristic off odor, the FDA noted.

Leibowitz said PDI and FDA agreed on the current recall earlier this month.

Over the eight inspections, regulators repeatedly found problems as the sole source of sterile wipes.

In August 2010, the company withdrew 30 lots of San-Cloth Bleach Wipes due to a quality concern, according to the company.

In February, PDI recalled more than 19,000 cases of antiseptic wipes and towelettes that had an insufficient amount of the active ingredient, benzalkonium chloride, according to the FDA enforcement report.

In August 2010, the company withdrew 30 lots of San-Cloth Bleach Wipes due to a quality concern, according to the company. In early 2010, Professional Disposables recalled 403,266 packs of Up & Up baby wipes that had an uncharacteristic off odor, the FDA noted.

Leibowitz said PDI and FDA agreed on the current recall earlier this month.

Over the eight inspections, regulators repeatedly found problems as the sole source of sterile wipes.

In August 2010, the company withdrew 30 lots of San-Cloth Bleach Wipes due to a quality concern, according to the company. In early 2010, Professional Disposables recalled 403,266 packs of Up & Up baby wipes that had an uncharacteristic off odor, the FDA noted.

Leibowitz said PDI and FDA agreed on the current recall earlier this month.

Over the eight inspections, regulators repeatedly found problems as the sole source of sterile wipes.

In August 2010, the company withdrew 30 lots of San-Cloth Bleach Wipes due to a quality concern, according to the company. In early 2010, Professional Disposables recalled 403,266 packs of Up & Up baby wipes that had an uncharacteristic off odor, the FDA noted.
FDA falling short on safety checks

Little or no enforcement action taken against makers of contaminated wipes

By JOHN DIEDRICH and RICK BARRETT
jdiedrich@journalsentinel.com

Five years ago, whistleblowers sent a letter to federal regulators warning that contaminated baby wipes were streaming out of an Arkansas factory — and the Wisconsin-based owner wasn’t telling the government or the public.

The two employees wrote to the U.S. Food and Drug Administration that Sheboygan-based Rockline Industries knew of the contamination but continued to ship potentially dangerous wipes to “the hands and bodies of thousands of Americans.”

They even warned that plant officials had a code phrase they would broadcast over the intercom — “Judy Life to the front desk” — in the event of a surprise inspection.

Two weeks later, on Nov. 7, 2006, an FDA investigator arrived unannounced and found problems including faulty product testing and poor sanitation. Company records show customers had been complaining about mold and foreign objects in the wipes, such as a dead cockroach and razor blade.

Rockline, which makes wipes for retailers under different brands, was repeatedly cited for regulatory violations.

“We are all about doing the right thing, and it’s the reason we are having success with our major customers. I am damn proud of what we do here.”

Randy Rudolph, Rockline president

“Wet wipes are not well-regulated, which has shown itself to be a problem as they are difficult to preserve as a product and difficult to manufacture in a sanitary manner.”

Scott Sutton, New York-based microbiologist and consultant to cosmetic manufacturers

Packaging operator Isidro Garcia unloads boxes at the Rockline Industries plant in Springdale, Ark., which has had problems with contaminated baby wipes.
names, announced a nationwide recall later that month of 20 brands of potentially contaminated baby wipes but said they posed little risk.

FDA test results soon came back, proving the suspect wipes were contaminated with *Burkholderia cepacia*, a bacterium that poses a health risk to anyone with a compromised immune system. The levels were thousands of times higher than FDA and industry guidelines, enough to sicken anyone, even those with healthy immune systems, experts told the Journal Sentinel.

“I wouldn’t want to use a wipe with organisms at that level, especially on a baby,” said Charles Gerba, a microbiology professor at the University of Arizona and a member of an FDA advisory board.

Industry experts contacted by the Journal Sentinel say the sky-high levels suggested poor manufacturing practices, filthy conditions or both.

The FDA took no enforcement action. Internally, Rockline worked to find and punish the person top executives referred to as “the mole,” doing handwriting analysis and considering DNA samples and fingerprints of workers, records filed in court show.

Now, the same plant is in the midst of recalling the same product, again because of contamination. The FDA has returned and found fresh problems, but once again hasn’t taken any enforcement action.

And the public knows even less about this recall.

Rockline, one of the largest makers of baby wipes and coffee filters in North...
America, is the second Wisconsin company — and the third nationwide — to launch recalls of potentially contaminated wipes this year.

The Hartland-based Triad Group was raided by federal agents in April and recalled sterile alcohol wipes used in hospitals and other products. The FDA has received reports of 11 deaths and hundreds of illnesses possibly connected to the use of Triad wipes. New York-based Professional Disposables International is in the midst of its own recall of alcohol prep wipes because of bacterial contamination. A review of case files and an analysis of the FDA’s inspection database by the Journal Sentinel shows lax manufacturing practices by the wipes manufacturers, shoddy oversight by the FDA and a failure by anyone to adequately notify the public of health risks.

While the disposable wipes industry has grown rapidly, churning out everyday products that millions use in hospitals and at home, the nation’s public health watchdog has not kept up.

The Journal Sentinel found:

■ The FDA has not inspected several thousand drug and device makers in at least five years, and hundreds of plants have not seen an inspector in a decade. Despite the whistleblower’s warning and serious problems found in the Arkansas plant, Rockline’s flagship plant in Sheboygan was last inspected in 1992. FDA records show Rockline’s plant in south China and products shipped from there have not been inspected. By law, both plants are supposed to be inspected every two years.

Recalled baby wipes
Rockline Industries recalled the following wipes on April 12, 2011. People with these product wipes purchased earlier this year should return them to the store where they were purchased. The FDA posted the recall in June:

- KozyKids Ultra Thick baby wipes; Giant Cotton tails baby wipes unscented and sensitive; Stop & Shop Cotton tails; Lulabies All Purpose Wipes; For Baby, America’s Choice baby wipes; Home 360 Baby, baby wipes, unscented; HyVee Mother’s Choice baby wipes and fresh scent and fragrance free; Comforts For Baby, scented baby wipes, and fragrance free baby wipes;
- Meijer Baby, softly scented, fragrance free, and shea butter wipes;
- Roundys Baby Wipes, Hypoallergenic, Alcohol Free; Compliments unscented baby wipes;
- Stater Bros. since 1936, Baby Wipes unscented and Baby Wipes scented; Baby Basics, fragrance free; Top Care Baby, Baby Soft Baby Wipes, fragrance free; Best Choice Baby Wipes, unscented;
- W Premium Thick Baby Wipes, Shea Butter with Aloe; Moist Wipes packaged under the brand name Equate, fragrance free and shea butter;
- Kuddles, exclusively at Winn Dixie, Baby Wipes, fresh scent and fragrance free.

Erlinda Gibbons, a packaging operator, watches the line at the Rockline Industries plant in Springdale, Ark., which makes baby wipes for retailers under different brand names.

Megan Terschner makes sure plastic canisters stay in position on the production line at Rockline Industries in Sheboygan.
FDA inspectors found problems at Rockline’s Arkansas plant in 2001, in 2006 and again in June — sometimes in the same areas — but the agency did not take enforcement action.

An FDA inspector overlooked key problems in the Arkansas plant in 2006. A bacterium that can cause toxic shock syndrome was listed in company lab results, but not noted in FDA reports. The inspector also failed to note customers had complained about foreign objects in the wipes.

No serious injuries or illness have been definitively linked to the contaminated wipes. However, the only public notice of the current recall has been an item buried deep in the FDA website. If people were sickened, they may not have known the cause.

Rockline officials said they put consumer safety first and denied they knowingly shipped contaminated products. They said as soon as they knew there was a problem they took action. If the problems were serious, they said, the FDA would have taken action.

Rockline president Randy Rudolph says the company has a strong track record for making safe products, and that the problems in Arkansas were an anomaly that led to improvements at all of its plants.

“We are all about doing the right thing, and it’s the reason we are having success with our major customers,” he said. “I am damn proud of what we do here.”

Rockline history

Rockline founder Ralph Rudolph, father of Randy, was a pilot for the German military during World War II before he immigrated to the United States after the war, by his own account. He worked as a janitor when he arrived, later rising to vice president of a Sheboygan-area factory before the plant moved and he was laid off.

Unemployed at 54, he started Rockline in 1976 with a focus on coffee filters. By the mid-1980s sales flattened, but stores soon asked the company to get into a promising new market: Disposable wipes.

In 1989, the family-run company bought a plant owned by Midwest Converting in Springdale, Ark. The plant made moist towelettes and baby wipes for private label customers. Rockline produced the products for others, including Wal-Mart and Roundy’s.

Over 15 years, the Arkansas plant expanded from a $5 million-a-year operation to one that brought in more than $150 million in revenue, according to court documents.

The company eventually expanded to six plants — four in the United States, one in China and one in England — and raced to the forefront of a billion-dollar industry. The Sheboygan plant added baby wipe production in the 1990s and now has 700 workers. It recently announced a $10 million expansion.

There have been no recalls of products made in the Sheboygan plant, according to FDA records.

The last time FDA was in the Sheboygan plant was 1992, according to agency records — and that was a mistake. An FDA inspector went to Sheboygan in response to a complaint about wipes made in Arkansas. A report said company leaders knew little about wipes, three years after acquiring the Arkansas operation.

“Randy Rudolph said neither himself or anyone else at the Sheboygan plant are familiar with the baby wipe products or formulas,” the 1992 FDA report read.

Patchwork of rules

Disposable wipes are used for everything from combating infectious diseases to cleaning up household messes. Demand for wipes, both consumer and industrial, is forecast to top $2.3 billion in 2014, up from $1.4 billion in 2004.

Problems at Arkansas plant

Rockline Industries has had at least three recalls from its Springdale, Ark., baby wipe plant because of bacterial contamination. U.S. Food and Drug Administration inspectors have found repeated problems but taken no enforcement action. Inspectors have not been to Rockline’s flagship plant in Sheboygan since 1992.

In 1989, the family-run company bought a plant owned by Midwest Converting in Springdale, Ark. The plant made moist towelettes and baby wipes for private label customers. Rockline produced the products for others, including Wal-Mart and Roundy’s.

Springdale, Ark. The plant made moist towelettes and baby wipes for private label customers. Rockline produced the products for others, including Wal-Mart and Roundy’s.

Over 15 years, the Arkansas plant expanded from a $5 million-a-year operation to one that brought in more than $150 million in revenue, according to court documents.

The company eventually expanded to six plants — four in the United States, one in China and one in England — and raced to the
But as their popularity has surged, the FDA is saddled with a patchwork of rules.

Wipes labeled as sterile are required to be free of bacteria and are classified as drugs, used to treat or prevent diseases. That’s because they can come in direct contact with wounds, bloodstreams and spinal fluid. They are tested prior to going on the market, and production plants are supposed to be inspected by the FDA every two years. Wipes also can be considered devices if they are included in an injection kit, for instance.

Non-sterile wipes are not subject to clear bacteria limits but are regulated as a drug if they are anti-bacterial. They are typically used for tasks such as wiping down countertops and cleaning hands.

Other non-sterile products, such as baby wipes, are regulated as cosmetics and are subject to less oversight. When it comes to baby wipes, Congress has left the FDA largely toothless.

Federal law says a cosmetic must not be “adulterated” — meaning made in unsanitary conditions — or have high levels of organisms on it.

The agency can take legal action against a company in such cases. But the law does not spell out what conditions or organism levels are violations, leaving each company to set its own standards, microbiologists said.

“Wet wipes are not well-regulated, which has shown itself to be a problem as they are difficult to preserve as a product and difficult to manufacture in a sanitary manner,” said Scott Sutton, a New York-based microbiologist who has worked as a consultant to cosmetic manufacturers for 25 years.

Baby wipes are made from non-woven paper material that is soaked in water, with a small amount of sanitizer and preservative. When packaged and sealed, it creates a ripe environment for bacteria growth once contaminated.

Companies are not required to report contamination but are encouraged to notify the FDA of a recall. The agency cannot order a recall of wipes — sterile or not.

Congress requires the FDA to inspect drug firms every two years, but the Journal Sentinel found that roughly 1,400 drug-making locations have not been inspected in five years or more. FDA officials, who did not dispute the findings, said they focus limited resources on plants that pose the most risk to the public.

As for cosmetic manufacturers, registration is voluntary, and the FDA has no mandate to track or inspect the plants.

FDA manuals suggest examining cosmetic firms that make “high-risk” products such as those used on infants, because they pose “the greatest potential health hazard if they become contaminated with bacteria.”

Customer complaints

In 2001, an FDA investigator visited Rockline’s Arkansas plant after learning the company was recalling baby wipes because of bacterial growth, agency records show. The company pledged to do a better job keeping the plant clean.

The FDA did not check that promise until 2006. It returned only after receiving the whistleblower letter.

The whistleblowers were ultimately fired. A subsequent lawsuit provided a rare view into the wipes maker’s operations by making public a series of internal Rockline documents.

Those documents show Rockline was receiving a stream of customer complaints about mold in 2006.

“This is a very serious situation, and we need to respond immediately to insure (sic) the manufacturing of safe product until we can isolate the exact cause of the contamination,” a company memo to the production team read.

Around that time, customers reported finding a razor blade, tape and dead bugs in the wipes. There also were reports of rashes and infections possibly due to the wipes.

Randy Rudolph, the company president, told the Journal Sentinel that mold and bacteria sometimes grow on wipes, if a worker touches the material with a bare hand, water drips from a roof leak or an insect flies through an open plant door.

“You just can’t control everything unless maybe it’s a sealed plant that is building microchips,” he said.

Report of bacterium

In September 2006, Rockline received a report from its outside lab that there was *Burkholderia cepacia* on its wipes, according to the company records.

That bacterium threatens people with compromised immune systems, is antibiotic-resistant and can live even in alcohol solutions, according to Dave Warshauer, chief bacteriologist at the Wisconsin State Laboratory of Hygiene.

Potentially contaminated wipes were making it to market because the company routinely shipped them before the results of lab testing were available, according to FDA and company documents. Experts said it is very unusual to ship a product before receiving test results.

“I can’t imagine releasing without test-
“You would lose control.”

The company received positive results of four different bacteria in September and October 2006, yet no recall was launched and no customers were notified, according to FDA reports and company documents.

Sam Wilson, the plant’s human resources director, and Teri Jacques, who worked for him, were alarmed that the company was not telling anyone about the contamination. They sent the whistleblower letter to the FDA in October 2006. They also sent it to Rockline’s wholesale customers.

A spokesman for Rockline told the Journal Sentinel the initial test results were contradictory but once the company saw there was a problem, it notified customers and the FDA.

A company official contradicted that statement, saying in sworn testimony that Rockline never notified the FDA of the 2006 recall, court records show. He noted the law did not require it.

FDA records show the agency learned of the contamination from the whistleblower letter, and the FDA didn’t know the company was doing a recall until its unannounced inspection.

FDA inspector Janice Hickok arrived at the Springdale, Ark., plant on Nov. 7, 2006 — two weeks after the whistleblower letter was sent.

She was allowed to look at complaints and lab reports but was blocked by plant officials from copying them.

Rockline spokesman Evan Zeppos said Hickok was not allowed to make copies because of a policy that only employees can use company equipment such as a copy machine.

That kind of defiance has landed other companies in trouble with the FDA, according to Marcia Crosse, head of health care for the General Accountability Office, the investigative arm of Congress.

“That is unusual and would likely be cause for heightened alarm at the agency,” Crosse said.

Yet the agency took no enforcement action.

Behind the scenes, plant manager Joel Slank tried to thwart the inspector, according to his assistant.

“I heard Joel Slank on his phone in his office ordering someone at an off-site warehouse to get rid of and destroy that contaminated product before the FDA found where it was located,” Pam Ogden said in a deposition taken for one of the whistleblower lawsuits.

Ogden, Slank’s assistant, was fired with Wilson and the other whistleblower after they were accused of violating the company’s email policy by making unprofessional comments about supervisors. Ogden would only say in a phone interview that everything in her deposition was true.

Hickok wrote in her inspection report that the firm used tap water without additional filtration or treatment. Experts said using plain tap water could contribute to contamination. But there are no rules governing baby wipes manufacturers, only suggestions.

Hickok told the company in November 2006 to cover the assembly line to avoid contamination. Managers said conveyors were not covered at other plants in the industry and refused.

Company records showed a more virulent bacterium, *Staph aureus*, was found on Rockline wipes twice in 2006. A form of *Staph aureus* was implicated in the toxic shock syndrome that sickened and killed women through contaminated tampons in the 1970s.

But FDA documents do not even mention that bacterium. It was listed in Rockline’s internal lab results — which the inspector could not copy. The company’s lab results were entered in court records through one of the whistleblower’s lawsuits.

The FDA test of Rockline wipes revealed levels of a different bacterium, *Burkholderia cepacia*, that microbiologists interviewed by the Journal Sentinel called “gross contamination.”

While federal law does not set a maximum, the FDA has said a cosmetic should not contain an excessive level of bacteria. It quotes industry guidance, which says baby products should not have more than 500 microorganisms per gram.

The Rockline baby wipe tested by FDA showed 97 million to 190 million parts per gram — thousands of times over that recommended level.

“That is profound,” Geis said. “It is about as high as you can get.”

Experts said such a high contamination level qualifies as “adulterated,” a violation of the cosmetics law. And it could sicken a healthy person, not only someone with a compromised system.

“That is filthy,” Sutton said. “It was either manufactured filthy or it is inadequately preserved and allowed low numbers of microorganisms to grow to unacceptable levels.”

Zeppos said the Arkansas facility was clean. And he said the plant’s use of tap water and its policy to ship before receiving test results were accepted industry practices, de-
spite what the experts told the Journal Sentinel.

“If we were filthy, we would be shut down,” he said.

Zeppos said the bacterium levels listed in the FDA test were artificially high because of testing techniques. Microbiologists told the Journal Sentinel that regardless of the exact level, the FDA test indicates the product was adulterated.

“Whether 97,000 or 9.7 million, it is just not relevant,” said David Steinberg, a microbiologist and industry consultant who works for Rockline. “It is contaminated. It is a cause for concern.”

Zeppos acknowledged problems in the Arkansas plant in 2006 but said the company took swift action.

“We have a strong track record at Rockline that when we make mistakes, we do our levelheaded best to solve them,” he said. “When we find them, we spend millions to fix it.”

Ron Johnson, a former FDA official hired by Rockline in the whistleblower lawsuit, told the Journal Sentinel that the company acted correctly during the 2006 recall. He said it was the first major recall in the country of baby wipes for bacteria.

“This episode was problematic. There is no doubt about that,” he said. “This occurred and the industry said, ‘We need to tighten things up.’ ”

**Hunt for whistleblowers**

As the FDA investigated Rockline’s 2006 contamination, the hunt was launched in the Arkansas plant for the whistleblowers.

Ralph Rudolph, the company’s founder, told executives to spend whatever money they had to, “as long as we find the ‘mole,’” according to an email sent to Wilson, one of the whistleblowers.

Wilson wrote back that the private investigator hired by Rockline had interviewed employees and done handwriting analysis and computer searches. Fingerprinting and DNA swabs were next.

Wilson asked if it was legal to take DNA and wondered in an email what Wal-Mart would think.

“Should we not be more focused on fixing the quality issues and the rest will take care of itself?” he wrote.

Wilson and Jacques were fired in early 2008. Both sued in federal court.

Wilson, 68, who worked at Rockline for 15 years, contended in his lawsuit that he was fired because he was a whistleblower and also because he was old. A jury found in Wilson’s favor last year, on both complaints. He received $72,000 in back pay and insurance costs. He could not sue under the federal whistleblower law because he worked for a private company. Under Arkansas law, he was not allowed to sue for punitive damages. Jacques’ case is pending.

Wilson could not be reached for comment. Randy Rudolph told the newspaper that Wilson was an unstable man who tried to hurt the company, and his letter to FDA was riddled with inaccuracies.

“Sam Wilson was a very disgruntled employee,” Rudolph said. “I would not put stock into his comments.”

**New recalls**

In 2007, Rockline issued a new recall of wipes from the Arkansas plant, FDA documents show. No FDA inspector returned to the plant.

Rockline recalled wipes from its China plant in 2010 because they did not have enough preservative and listed no expiration date. FDA has the authority to inspect overseas operations if their product comes to the U.S., but no inspection has been performed, according to agency records.

In March 2011, the company again found bacterial contamination on wipes made at the Arkansas plant.

The company notified the agency it was recalling 18 brands of wipes, including Wal-Mart’s Equate and Roundy’s Baby Wipes, because of possible contamination with *Enteroabacter gergoviae*, a bacterium experts said is associated with fecal matter.

In response to the recall, the FDA arrived at the Springdale plant last June, its first visit since 2006. The plant had added an in-house lab and treatment of its tap water.

An FDA report noted that company leaders thought sanitation problems were to blame for the current contamination. The inspector also found the plant was not investigating complaints and making basic errors in testing.

Zeppos said all the problems have been addressed.

Rockline has not alerted the public about the latest recall. Zeppos said the FDA told the company a news release was not necessary.

Kim McCarthy, a Kenosha County mother of a baby girl, unknowingly used two of the products on the current recall list. She said the recall should have been widely publicized.

“Contamination doesn’t seem like something I should have to worry about, but obviously there is cause for concern,” she said. “We give these companies our business, and we trust they are putting out a safe product.”

*Ben Poston of the Journal Sentinel staff contributed to this report.*
The U.S. Food and Drug Administration is required to inspect drug makers every two years, but the Journal Sentinel found roughly 1,400 drug firms that have not been inspected for five years or more.

Examining inspection data since 1999, the newspaper found a similar pattern with medical device makers. But Congress has set no time period on when device makers should be inspected.

FDA officials did not dispute the newspaper’s findings, but said not all drug plants deserve the same oversight.

David Elder, director of the FDA’s Office of Regional Operations, said the agency would focus on a prescription drug maker over firms that repackage drugs or those that test materials for quality.

“We cover the industry as well as we can with the available resources,” said Elder. “I don’t think there is a large gap in our areas of coverage that has a public health impact.”

Roughly one-quarter of the 7,000 U.S. drug firms were inspected last year. About 11% of the device makers were inspected.

The agency uses a risk-based approach to decide which locations to inspect. The FDA says it considers type of product, previous violations and recalls, along with the time since the last inspection in deciding which locations to inspect.

“If a company has a decent compliance history and no changes in ownership, they might not have been (inspected),” Elder said. “We have to look at the risk factors. As we look at all different firms, if we get into one of those (not inspected for years), we are not getting into another location.”

The agency’s number of inspectors has climbed to 1,800 in recent years but is still not enough to get to all plants, officials said.

Industry observers say the FDA tends to target large operations while sometimes missing smaller ones.

“Industry has proven time and time again we are no angels and there is a segment that will do whatever they can to increase profits,” said Scott Sutton, a microbiologist who runs a consulting firm and advises cosmetic and drug firms.

“There is a strong sense that many ethical companies are being held to very high standards of documentation practice, which may have minimal effect on the finished product, while other manufacturing facilities are going unchecked.”

The FDA gets to even fewer cosmetic firms. The agency inspects about 115 cosmetic firms a year, in the U.S. and overseas, the Journal Sentinel’s analysis shows. The FDA has authority over plants that produce products brought into the U.S.

The agency doesn’t know how many cosmetic firms there are because registration is voluntary. It estimates there are 1,150 domestic cosmetic firms, plus an unknown number overseas. Industry observers say there could be closer to 5,000 in the U.S. alone.

Elder said the risk is lower with cosmetics, and the law does not require specific manufacturing standards as it does with drugs, devices and food. The law also does not require cosmetic companies to tell the FDA of a serious illness or injury suspected of being caused by their product.

Along with other groups, the Personal Care Products Council, which represents the cosmetics industry, has lobbied to create tougher standards, among others. Congress did not act on a bill to do so in 2009.
RAQUEL RUTLEDGE

Raquel Rutledge is an investigative reporter for the Milwaukee Journal Sentinel, where her investigation into fraud in Wisconsin’s day care subsidy program won the 2010 Pulitzer Prize for Local Reporting. Her investigation also won the Worth Bingham Prize for Investigative Reporting, George Polk Award and Goldsmith Prize for Investigative Reporting and other national recognition.

Raquel is currently the Louis Stark Nieman Fellow at Harvard University, where she is examining federal regulation and oversight of the nation’s food supply as it relates to public health. Rutledge also won a Silver Award in the 2011 Barlett & Steele contest for a story investigating a local company responsible for tainted alcohol wipes that may have killed a 2-year-old boy.

A graduate of the University of Wisconsin-Milwaukee, Rutledge joined the Milwaukee Journal Sentinel staff in 2004 from The Gazette in Colorado Springs, where she spent nearly seven years covering education, the military and city hall.
RICK BARRETT

Rick Barrett has been a business reporter at the Milwaukee Journal Sentinel for 11 years, covering Harley-Davidson Motor Co., Oshkosh Corp. and other large manufacturers. His beat also includes agriculture and telecommunications. Barrett won a Silver Award in the 2011 Barlett & Steele contest for a story investigating a local company responsible for tainted alcohol wipes that may have killed a 2-year-old boy.

Among other issues, he has written extensively about labor disputes and the changing nature of manufacturing.

A graduate of Central Michigan University, he previously worked at the Wisconsin State Journal, as well as Gannett newspapers in Florida and Michigan, and was a news photographer in Little Rock, Ark.
JOHN DIEDRICH

John Diedrich covers the criminal justice system and federal issues for the Milwaukee Journal Sentinel. Recent works include the "Wiped Clean" investigation, which revealed how Congress created loopholes that allowed gun stores to easily thwart federal oversight. That series was honored in 2011 with a George Polk Award for criminal justice reporting.

Diedrich launched a second major investigation in 2010 that continued in 2011, "Dangerous & Free," which revealed how murder suspects and gang leaders have gone free because of communication breakdowns and miscalculations by law enforcement, leniency from prosecutors, breaks from judges and other failures in the system.

In 2009, Diedrich led a team of reporters that revealed how a suspected serial killer had escaped justice while working as an informant, and how the state failed to gather DNA for thousands of prisoners. Those reports received the Investigative Reporters and Editors award for breaking news investigations. Also in 2009, Diedrich wrote a five-part series, "The Preacher’s Mob," which documented the rise and fall of a crime boss and law enforcement’s failures to stop him.

Diedrich has placed three times in the national Al Nakkula Award for Police Reporting. In 2006, Diedrich won the Nakkula Award for exposing police beatings and the city’s failure to properly screen new officers.

He joined the newspaper in 2004. Before joining the Journal Sentinel, Diedrich covered the military and national security for The Gazette of Colorado Springs, traveling to Iraq, the Balkans and former Soviet Georgia. He was a finalist in 2000 for the Livingston Awards for Young Journalists. Diedrich, 41, graduated summa cum laude and with honors from the University of Wisconsin-Milwaukee with a degree in print journalism in 1992.
BEN POSTON

Ben Poston is the Milwaukee Journal Sentinel’s data editor. Since joining the newspaper in 2007, he has written about problems with Wisconsin’s DNA databank, the federal stimulus package, dysfunction at the U.S. Patent and Trademark Office, leniency in drunken driving sentencing and the impact of the subprime mortgage crisis. In 2010, he worked on the “Wiped Clean” investigation, which revealed how Congress created loopholes that allowed gun stores to easily thwart federal oversight. That series was honored in 2011 with a George Polk Award for criminal justice reporting.

Poston was named a 2009 Livingston Awards for Young Journalists finalist for coverage of the federal stimulus in Wisconsin. He was on a team of five reporters that won a 2009 IRE Award for breaking news investigations. His work on a two-part series about the U.S. patent system was a finalist in the Scripps Howard National Journalism Awards and the National Headliner Awards. Previously, he worked as a data analyst at the National Institute for Computer-Assisted Reporting in Columbia, Mo.

Poston holds a bachelor’s degree in international studies from Miami University (Ohio) and a master’s degree in journalism from the University of Missouri School of Journalism.