

Sanitation spotty at H&P, say ex-workers

They say medical products firm frowned on reports of flaws

By [Rick Barrett](#) of the Milwaukee-Wisconsin Journal Sentinel

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Addendum:

H&P Industries was also recently stung by a 46-count FDA Form 483 inspection report

A former quality control inspector at H&P Industries says she regrets not having told government authorities about unsanitary conditions she saw in 2010 at a Hartland factory that was [shut down last week](#) after federal regulators said the medical products made there "may pose a risk to public health."

The former inspector, Kathleen Smith, said she was fired last May 31 for unsatisfactory performance after working two stints at H&P covering about eight months in 2009 and 2010.

She believes she was actually fired because she complained to supervisors that machines weren't being cleaned properly and that some employees were doing things such as sneaking food and personal items into areas of the factory that made sterile products.

"I should have opened my mouth sooner, but I was afraid that everybody was going to look at me as just another disgruntled ex-employee," Smith said.

Smith - one of seven former H&P Industries employees interviewed for this story, including three who agreed to let their names be used - says she decided to speak up after hearing about a lawsuit filed against the company in the death of a 2-year-old Houston boy. The boy's parents, Shanoop and Sandra Kothari, say in the lawsuit that an alcohol wipe made by H&P was the likely source of bacterial meningitis that killed their son, Harry, in November.

The company strongly denies any wrongdoing and says it hopes to resume production soon.

"We would not be manufacturing for more than 30 years if we did not take quality seriously," Eric Haertle, H&P co-owner and chief operating officer, said in an interview with the Journal Sentinel.

Last week, the [U.S. Marshals Service](#), at the request of the Food and Drug Administration, seized more than \$6 million in products made by H&P in Hartland. The seized products, normally distributed by Triad Group LLC, included cough and cold medicines, nasal sprays, suppositories, medicated wipes, hemorrhoidal wipes and anti-fungal creams.

"We took this action to stop Triad from continuing to distribute products which may pose a risk to public health," Dara Corrigan, FDA associate commissioner for regulatory affairs, said in a statement.

H&P has voluntarily launched three [product recalls](#) in recent months, including all of its sterile and non-sterile alcohol wipes and swabs used in hospitals, medical clinics and households. The pads might be contaminated with *Bacillus cereus* bacteria that could lead to life-threatening infections, especially in at-risk populations, including immune-suppressed and surgical patients, according to the FDA.

[FDA inspections](#) from last Nov. 29 through March 28 of this year revealed [numerous issues](#) at the Hartland plant, including:

- Employees performing microbiological testing of finished products and water used to manufacture products and clean equipment did not have an education in microbiology.
- The plant's high-purity water system was susceptible to contamination by a storm sewer because of a flaw in the plumbing. Several leaks were found in the system, including one that dripped several drops per second.
- A bucket labeled as "purified water" was actually deionized water used to rinse equipment after cleaning.
- Sterile alcohol prep pads were found to be contaminated with bacteria, yet they were released for shipment after confirmation of the test results.

In addition, the former employees told the Journal Sentinel there was poor communication between them and Spanish-speaking employees who did various jobs in the plant and could not understand English. Smith said she was told to falsify training test results for employees who could not read English.

She and other former employees also told the Journal Sentinel that machines producing disposable medical pads were not always sanitized, and that people were threatened with being fired if they reported it.

Smith said she witnessed employees packing medical pads with their bare hands instead of using rubber gloves, and bringing food, chewing gum and personal items into areas of the plant where such items were prohibited.

In February 2010, an employee's medication was accidentally packed into a box of iodine wipes, according to Smith. The blue pills were wrapped in pieces of paper tucked in with the iodine-wipe packets, she said, and the box was returned by a retailer, unused, in May when the pills were discovered.

Employees and managers ignored sanitation rules when taking the time to properly clean a machine slowed the production lines, according to Smith.

"I told (management) that these things were going to come back to haunt them," she said.

When an employee cut her finger while packing alcohol-wipe packets last May, 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.

"Our job as quality inspectors was to watch what people were doing and report problems," she said. "But, when we said something, we were told to shut up or we would lose our jobs."

Haertle strongly disputed the allegations.

"I think there are a lot of people working at Triad who would dispute those allegations, and not just the company owners," Haertle said. "We have people in the facility with the appropriate training and experience and qualifications to manufacture and to test and release products."

An H&P employee mixed a batch of children's cold medicine without including the active ingredient, something an FDA inspector confirmed in a Jan. 7 report.

It was an innocent mistake caught by the employee and the medicine was never packaged, the company said last week.

"Our processes worked. And this guy (who mixed the batch) felt so bad that he could not sleep. That's the kind of people we have here who care about doing the right thing," Haertle said.

H&P's Hartland plant opened in the fall of 2007, consolidating some work that had been done at a now-closed plant in Mukwonago. Some former employees say there were also issues with quality at the old plant.

Laura Martin said she quit her job as a machine operator at the Mukwonago plant in 2004 after her complaints about cleanliness were ignored. She said she saw moldy products in the Mukwonago plant, and she saw packets of medical swabs knocked on the floor and then put in a bin for shipment.

"There were many times I would not put my initials on something because I knew it was wrong," Martin said. "I have been known as a perfectionist, to the point where if something was not done to my standards I would not accept it."

Frances Lee, a microbiologist who headed up the company's quality/regulatory/product development unit for three years ending in 2002, said she left the company over disputes about the manufacturing process.

"It's like an onion. You keep peeling back the layers, and it's rotten in the middle," Lee said.

The family-owned company, founded in the 1970s, stands by its track record as one of the nation's largest suppliers of medical prep pads used in hospitals, clinics and households to help prevent infections.

Privately held H&P does not reveal its sales figures. But last fall, it had about 350 employees, according to the company.

Haertle said he doesn't believe former employees' allegations that H&P had a plethora of sanitation problems, that sanitation rules were ignored, and that employees were threatened with their jobs if they reported violations.

"None of those kinds of practices would ever be condoned in a pharmaceutical manufacturing operation," he said. "If I was aware of those, they certainly would not have continued. I do not believe they occurred."

H&P has hired consultants, including former FDA regulators, to help it resolve issues and resume production. The company also is looking for a chief operating officer to fill one role currently held by Haertle.

"We are looking to get someone with more pharmaceutical experience into our operation, with an operational background that can make us better. That is the only intent for us, to improve," Haertle said.

The company has filed plans with the FDA to correct problems in the plant and address any outstanding issues.

"There are always things that we could have done differently. We learn from it and try not to make the same mistakes going forward," Haertle said.

H&P intends to resume production, but all options - including selling the company - are on the table, according to Haertle.

"If there has been any encouraging sign over the last few months, it's the way that some of our customers have hung with us," he said. "We have customers saying 'we will wait for you. We like your products, we know they are safe, and we want you to come back.' "

Smith now works in a food processing plant.

"To be honest with you," she said, "I celebrated the day after I got fired because it felt like this big weight had been lifted from my shoulders.