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Photograph by George Sakkestad

Burning Questions: Kaitlyn Langstaff of Saratoga is fighting a life threatening, blistering and burning disease that started as a rash and has been linked to some antibiotics, anti-convulsants and over-the-counter pain relievers. Her family is suing the maker of Children's Motrin.

Without Warning

A rare but debilitating and potentially deadly allergic reaction to some drugs, including Children's Motrin, may be on the rise. But you won't read about it on drug labels.

By [Loren Stein](#)

KAITLYN LANGSTAFF'S catastrophic injuries are the stuff of nightmares. In 12 months, this 9-year-old girl from Saratoga has gone from being active and healthy to wheelchair-bound, blind and unable to eat or speak. With massive scarring in her

lungs and airways, she breathes bottled oxygen through a tube inserted in her neck. She relies on a feeding tube in her stomach. She mouths words with the aid of an electronic larynx. She will need countless surgeries to reclaim what's left of her health.

Langstaff's story--her courage, the poems she's written (one of which was recorded as a rock song by the band Miggs) and her family's resilience--has made national news. So has her incredible survival, against all odds, after she was diagnosed in April 2002 with toxic epidermal necrolysis, a relatively rare and often lethal form of Stevens-Johnson syndrome, a frightening blistering and burning disease brought on by a severe, systemic allergic reaction to certain drugs.

But what many people haven't heard are claims of an alarming rise in case reports of Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN), according to some observers. Support groups for the disease's survivors have popped up. Complaints to the FDA's MedWatch database are reportedly mounting, accompanied by a surge of lawsuits filed against doctors, hospitals and drug manufacturers.

The medications that most often provoke this extreme allergic reaction are widely used by both adults and children. They include antibiotics such as penicillin and bactrim; anti-convulsants such as phenobarbital and Dilantin; and prescription pain relievers--called nonsteroidal anti-inflammatory drugs (NSAIDs)--such as Bextra and Daypro. And perhaps even more worrisome, over-the-counter NSAIDs such as ibuprofen--including Children's Motrin and Children's Advil--are also triggering the reaction.

Growing List

No accurate count exists of how many people have been stricken with TEN or SJS, or its milder version, erythema multiforme. Once a drug is approved, physicians are not legally required to report adverse reactions to the FDA. (Less than 1 percent of drug reactions are reported to the federal government.) Some estimate that there have been 200,000 SJS and TEN cases worldwide, but that's only a rough guess.

At least 50 percent of known SJS cases are drug related, experts say; other cases may have viral or bacterial origins. (TEN, however, is predominantly caused by drug reactions.) Children in particular seem to be more susceptible to SJS, and some say women are as well. SJS and TEN often cause blindness, and in 10 percent to 30 percent of cases, death. More than half of the patients who have TEN die.

While stressing that the reaction is rare, some of those who track SJS and TEN say the number of cases is climbing, although the evidence remains anecdotal. Jean McCawley of Denver, Colo., president and founder of the Stevens Johnson Syndrome Foundation, says her group now has 1,500 members. (Her daughter had SJS.) The website posts wrenching personal testimonials from people who have lived through the disease. McCawley says she has also seen a steady rise during the last two years of children getting SJS after using Children's Motrin, about one new case each month.

Paula Fillari, a veteran registered nurse with the Bothin Burn Center at St. Francis Memorial Hospital in San Francisco--which treats only the most dire cases of TEN--says the hospital now sees five patients a year, more than double the previous number of admissions. (Fillari presented a pilot study on new protocols for treatment of the disease at an international burn conference last year.)

"As more medications, antibiotics and anti-inflammatories get onto the market, there's potential for more medications causing this," Fillari says. "The list is getting longer."

But other experts caution that there is no evidence that more people are getting the allergic reaction. With no mechanism in place to monitor the incidence of the disease, it's just impossible to tell, says Dr. Bernard Cohen, director of pediatric dermatology at Johns Hopkins Children's Center in Baltimore, Md. The overall incidence is thought to be 1 to 6 per million patients, he notes.

"The bottom line is, any time you use a drug you can have an adverse reaction; you're always taking a risk," Cohen says. SJS and TEN are uncommon, he adds, "but when it happens, it can be devastating. ... With TEN, it's a disaster."

"I think it's a bigger problem than people realize," says Valerie Chereskin, a San Diego PR consultant who had SJS in 1990. "When you talk to someone, you quickly discover other people who've also had [SJS]; they just come out of the woodwork."

Both Chereskin and Cohen agree, however, that doctors are often unfamiliar with the disease, its symptoms and its debilitating effects, and can misdiagnose it. "When you get SJS, [many] doctors don't even recognize it," Chereskin says. "So they give you more of the drug that caused it--doing you more harm, which could end up killing you."

Like Swallowing Lye

This is precisely what Brad and Kerry Langstaff think happened to their daughter Kaitlyn. On April 6 of last year, while on a family trip, Kaitlyn, then 8

years old, was given Children's Motrin by her parents for fever and a sore throat. (She had no known drug allergies and was given the correct dosage.)

The next day, Kaitlyn broke out in a severe rash and high fever. She continued taking the drug every four to six hours when she was taken to Fresno's Children's Hospital, where she was diagnosed with TEN and admitted to the pediatric intensive-care unit. It wasn't until the third or fourth night in the PICU that a doctor at the hospital recommended that she stop taking the drug.

In the meantime, Kaitlyn rapidly developed blisters and lesions resembling second-degree burns throughout her body. With SJS and, especially, the more severe TEN, the immune system attacks the body inside and out--in particular, the skin and mucous membranes. Kaitlyn's skin sloughed off, and with all her nerve endings exposed, she was in excruciating pain. Blisters on the inside of her eyelids fused her eyes shut, and scarring on her corneas left her unable to see. Her tongue stuck to her palate and had to be surgically separated.

Filled with scar tissue, her lungs and airways closed down, forcing doctors to give her a permanent tracheostomy. She suffered severe kidney damage and loss of hearing. She endured multiple blood transfusions and operations to remove vast amounts of dead and damaged skin, among other treatments. She had to be heavily sedated and tied to her bed.

In all, Kaitlyn was hospitalized for 110 days at four different hospitals, and she was close to death several times. On April 15, she was airlifted to Los Angeles' Children's Hospital because it appeared she might need a heart-lung machine. On May 28 she was transferred to Lucile Salter Packard Children's Hospital at Stanford for more treatment, later to be

moved to the Santa Clara Valley Medical Center. Kaitlyn will have to wait years before surgery is attempted to open her airways or to try corneal transplants to have her vision restored.

Kaitlyn's mother, Kerry Langstaff, has said that doctors likened the condition of Kaitlyn's throat to a patient who has swallowed lye, and her lungs to someone who has cystic fibrosis. (Because they were accompanying Kaitlyn, who was receiving a medical procedure last week, Kerry and Brad Langstaff were unavailable for comment.)

Another parent describes a similar set of circumstances. Melanie Eden's 7-year-old son, Sam, also got SJS last year after taking Children's Motrin. "In my gut, I feel like it was the Children's Motrin, but no one can prove that," says Eden, who lives near Phoenix, Ariz. Five days after he was given the drug for a cold, Sam couldn't go to the bathroom or swallow, and he had bright red eyes and blisters on his tongue. The doctors at the hospital misdiagnosed his symptoms, which got worse. But doctors at another hospital quickly realized that he had SJS and put him in the ICU for 10 days, the entire time on morphine.

"I was in shock," Eden says. "I couldn't leave his side. I kept my hands on him; I felt if I could touch him, he wouldn't go away." Because of the burning and blistering, Sam now has asthma; his eyes won't tear; and his nose is painfully dry.

"It breaks my heart, but he can see; many kids come away blind," she says. "There's a reason why hospitals give children Tylenol," she adds. "It doesn't react with the body's systems the way NSAIDs do. People need to know what the risks are."

Jean McCawley's daughter, Julie, then only 11 months old, reacted violently

after she was given both phenobarbital and Children's Motrin.

"There, right in front of my eyes, I watched the blisters erupting," McCawley says. The doctors thought the infant had chickenpox; it was only later that she was correctly diagnosed with SJS. "She looked like she was deep-fried. I was terrified," McCawley recalls. Julie is now blind and has scarring in her nose, mouth, esophagus and lungs. "No amount of money will be enough to compensate for what this child has suffered," McCawley says from a hotel room in Boston, where Julie was undergoing a medical procedure to help restore her eyesight. (McCawley sued her doctor and lost.)

But it's not just children who have been diagnosed with the disease after taking medication. Valerie Chereskin was 35 when she was given Septra, a sulfa-based antibiotic, which precipitated her severe case of SJS in 1990.

"I looked like I was from another planet. ... I was in agony," she says. Her skin melted away; a minister was called in to perform last rites. She has since recovered. However, it was two years until she could go out in the sun, and now has an artificial tear duct to regulate moisture in her eyes. "People take drugs without even thinking about it, but drugs are not candy; they contain strong chemicals," she says. (She also sued her doctor, unsuccessfully.)

Marlene Kerber, a 48-year-old Los Angeles resident, contracted a severe case of TEN in 2000 after she was prescribed an anti-convulsant medication. She was in a drug-induced coma for 2 1/2 months and was burned over her entire body. "I had none of my own skin left," she says. Kerber regained her sight after numerous surgeries. "I count my blessings every day, believe me," she says. She sued her doctor for medical malpractice and won.

Rash Decisions

On March 12, 2003, Kaitlyn's parents sued the manufacturer of Children's Motrin: McNeil Consumer & Specialty Pharmaceuticals (a subsidiary of Johnson & Johnson). The suit, filed in U.S. District Court in San Jose, claims that the drug caused Kaitlyn's extreme allergic reaction. The suit alleges that the company failed to adequately test the drug for over-the-counter use with children and did not fully report its clinical trials on the drug. (Ibuprofen was approved for nonprescription use in children in 1996.)

Kaitlyn's parents also claim that the company failed to warn consumers in any of its materials or package inserts or on the drug box that the drug could cause SJS or TEN and, furthermore, what to do if a rash or mucosal lesions develop.

"We're aware of a report of a 9-year-old girl who was diagnosed with [TEN] allegedly associated with the use of Children's Motrin," says a company spokesperson. "As the manufacturer of Motrin/ibuprofen products, we're deeply concerned about all matters relating to our products and are investigating the incident."

"You have to be cautious about giving adult drugs to children," says James C. Barber, the Langstaffs' lead attorney, who is based in Dallas, Texas. "It wasn't until the last few years that drugs were even tested separately on children."

Barber adds, "The [drug's] warning says nothing about SJS and nothing about stopping and calling a doctor if a child develops a rash." (The drug's label does warn of severe allergic reactions including hives, facial swelling, asthma and shock, and advises that the drug be stopped and to consult a doctor if pain or fever gets

worse, or if an allergic reaction or any new symptoms appear, among other signs.)

Barber's firm successfully sued Pharmacia and G.D. Searle, the manufacturers of Daypro, a prescription NSAID, on behalf of an adult woman who came down with a severe case of TEN after taking the drug. (The suit settled in 2002.) Barber is about to file two new suits on behalf of two children who contracted SJS, one after taking Children's Motrin and another after taking Children's Advil. (The anti-inflammatory Bextra now includes warnings about the risk of serious skin problems, including SJS, after a recent legal settlement.)

"If suing is going to make drug manufacturers more conscientious about warnings on drug labels, then that's good," says Lisamaria Martinez, a senior at UC-Berkeley who was blinded from a childhood bout of SJS. "It's really important to know what's in these drugs."

Dr. Cohen is skeptical that warnings about SJS will make a difference. "There's no test to predict who will get [SJS or TEN]," he says. "Even if a drug has a warning, with one in a million people getting [the illness], it won't stop people from using the medication."

Meanwhile, Kaitlyn battles on. "She is a brave, courageous little girl that represents everything good about the human spirit," says Mark Mills, legal assistant for Barber's firm. "She's an impressive child, and she has an impressive family. They have been devastated by this disease."

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