

# Pediatric safety of OTC Ibuprofen challenged

Girl set to testify against painkiller, Ibuprofen. She allegedly developed Stevens-Johnson syndrome. Now her parents demand a warning notice for over-the-counter drug.

By Linda Goldston, Mercury News, 17 Feb 2005

<http://www.mercurynews.com/mld/mercurynews/living/health/10921557.htm> (  
<http://www.mercurynews.com/mld/mercurynews/living/health/10921557.htm> )

(by same author, article on related lawsuits

[http://seattletimes.nwsourc.com/html/health/2002139686\\_ibuprofen04.html](http://seattletimes.nwsourc.com/html/health/2002139686_ibuprofen04.html) (  
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When 7-year-old Sabrina Brierton Johnson is led to the microphone at a federal drug safety hearing in Maryland today, she plans to talk about an over-the-counter drug that allegedly left her blind and unable to attend school.

Sabrina will be one of the youngest people to ever testify in front of an advisory panel to the Food and Drug Administration, but committee members will not be able to see her face.

After an apparent reaction to Children's Motrin, Sabrina wears a hat over her face because her eyes are sensitive to light. And she's no longer able to attend school because her immune system became too weak after she developed Stevens Johnson Syndrome, a rare and sometimes fatal disease.

"Taking Children's Motrin is why I am blind today," the Southern California girl said in a prepared statement filed with the FDA before today's joint hearing of the agency's Arthritis Advisory Committee and the Drug Safety and Risk Management Advisory Committee.

"Now, I wear a hat that covers my entire face --- even indoors --- because the light hurts my eyes. When I go outside, I get teased because of my hat. People say mean things to me about it and that really hurts my feelings."

After months of controversy, the three-day hearing in Gaithersburg, Md., was called by the FDA to consider the safety of such prescription pain relievers as Bextra, Celebrex and Vioxx, which have been linked to sharply increased risks for heart attack and stroke.

.... Sabrina and her mother are scheduled to appear this morning on NBC's *The Today Show* and the parents of 3-year-old New Jersey girl Heather Rose Kiss --- whose family attributes her death to taking Children's Advil --- were on the show Monday. Their stories were published in the Mercury News on Jan. 1.

... parents have asked the FDA to change the labeling on the popular children's medications to include a warning about Stevens Johnson Syndrome and toxic epidermal necrolysis, which has a mortality rate of about 30 percent.

...Doug Petkus, a spokesman for Wyeth Consumer Health Care, the maker of Children's Advil, said Wednesday that the company stands by the ``safety record of Advil and Children's Advil."...  
(full article ( <http://www.mercurynews.com/mld/mercurynews/living/health/10921557.htm> ) )

