

# Judge: 'Implied malice' may nail drugmakers

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A drug manufacturer may be held liable for punitive damages on a theory of "implied malice," a federal judge has ruled, where evidence suggests the manufacturer withheld information from the U.S. Food & Drug Administration that would have led to stronger warning labels.

In his 25-page opinion in *Wolfe v. McNeil-PPC Inc.*, Senior U.S. District Judge Jan E. DuBois, of the Eastern District of Pennsylvania, said a jury must decide whether the manufacturer of Children's Motrin withheld from the FDA reports of two instances in which patients developed Stevens-Johnson Syndrome, a rare and life-threatening condition affecting the skin in which cell death causes the epidermis to separate from the dermis, causing severe rashes, blisters and skin death.

Lawyers for plaintiff Kiley Wolfe argued the evidence showed that McNeil — a pharmaceutical



Senior U.S. District Judge Jan E. DuBois

division of Johnson & Johnson — concealed from the FDA two cases of SJS found in patients during a massive study it commissioned on the safety of selling Children's Motrin over the counter.

Although McNeil acknowledged receiving reports of the two cases, the plaintiffs argued that a subsequent clinical study report issued by McNeil describing the results of the study did not mention the two reports.

Lawyers for McNeil insisted that the FDA was apprised of the

two reports.

But Judge DuBois concluded the plaintiffs' evidence was enough to raise a dispute that must go to the jury.

Although Judge DuBois said it "may be true" that the FDA was given the reports, he found that "a reasonable jury viewing the evidence in the light most favorable to plaintiff could conclude otherwise."

Judge DuBois also found that if the jury concludes that McNeil "deliberately concealed information from the FDA — both to win FDA approval of [over-the-counter Children's Motrin and to avoid the need to warn of SJS or its symptoms — the jury could well find that plaintiff demonstrated, by clear and convincing evidence, the sort of outrageous conduct that would justify the imposition of punitive damages."

According to court papers, Kiley Wolfe was 9 years old in 1996 when she developed a headache, stomach pains and a fever, and her pediatrician recommended Children's Motrin.

When her symptoms did not subside and Kiley developed a rash on her cheeks, nurses at the pediatrician's office advised her mother to continue giving the Motrin.

Several days later, when Kiley's rash worsened, she was taken to Boston Children's Hospital where doctors diagnosed her with Stevens-Johnson Syndrome.

During her hospitalization, her symptoms worsened to include an acute case of vanishing bile duct syndrome.

Because of damage to her liver, Kiley eventually required a liver transplant.

The suit alleges that McNeil was aware of the need for stronger warning labels due to the possibility of SJS in a small number of patients, but resisted changing the labels until 2006 when the FDA recommended it.

The prior label told patients to "call your doctor" if a rash occurs.

The new label tells patients to "seek medical help right away" if they see skin reddening, rashes

or blisters. Kiley's mother, Janet Leland, testified that she hadn't read the warning labels before giving her daughter the first dose, but that she had later consulted the package several times after her daughter's condition started getting worse.

The suit — filed by attorneys Thomas N. Sweeney and Joseph L. Messa of Messa & Associates in Philadelphia, along with Darryl J. Tschirn of La Jolla, Calif., and John M. Robin of Covington, La. — alleged negligence, warranty and strict liability claims, as well as failure-to-warn and consumer protection claims.

Now Judge DuBois has concluded that only the failure-to-warn claims and a claim for punitive damages may proceed.

Turning to the issue of punitive damages, Judge DuBois said he had previously ruled that Maine law applied to that claim, so that punitive damages may be awarded "only upon a showing that the defendant acted with express or implied malice."