

## Knowledge Is Power In Failure-To-Warn Claims

Law360, New York (January 06, 2012, 2:08 PM ET) -- Before Cartoon Network, Nickelodeon and the Disney Channel, cartoons were reserved for Saturday mornings. And, if you were a pre-teen boy in the mid-1980s — or are now married to someone who was — you are probably familiar with the G.I. Joe cartoon series.

If so, you also probably know that each episode ended with a public service announcement (PSA) in which Joe quipped: “Now you know, and knowing is half the battle.”

From that same generation, and still enjoyed by kids today, is Schoolhouse Rock’s “Knowledge is Power.” Or, while not cartoon-based but just to get a little more current, there is NBC’s series of PSA’s entitled “The More You Know.”

All of these are certainly true in the case of a pharmaceutical failure-to-warn claim — the prescriber’s knowledge is crucial, and if the prescriber knew about the risks, there is no failure to warn.

That’s what a California district court said in *Wendell v. Johnson & Johnson* (N.D. Cal. Dec. 15, 2011).

At issue was the treatment of inflammatory bowel disease with combination therapy of two prescription drugs — one an immunosuppressive drug and the other a TNF inhibitor (anti-tumor necrosis factor drug).

Studies had reported incidences of lymphomas in patients being treated with this type of combination therapy. *Id.* at \*2. In addition, a different TNF inhibitor carried a black-box warning regarding the development of lymphomas with concomitant use of the two classes of drugs. *Id.* at \*3.

Unfortunately, the plaintiff was diagnosed with lymphoma and passed away. *Id.* at \*5.

Putting aside the adequacy of the defendants’ warnings, the court focused on causation — did the absence of a warning cause the plaintiff’s injury? *Id.* at \*6. Here it is all about the doctor’s knowledge: (1) Where did he get his knowledge? And, (2) what did he know?

Question 1: The prescriber testified that

"[h]e received information on medications from multiple sources, including meetings, other professionals in the field, articles and occasional meetings with drug representatives." Id. at \*1.

He also testified "that it was not his regular practice to look at drug labeling." Id. He looked at labels more often for new drugs or drugs less familiar to him. Id.

It was also clear that he relied on medical literature, as he was aware of studies regarding the development of lymphomas. Id. at \*2. Since this isn't a case where the causal link was broken because the doctor never read the label or never relied on information from the manufacturer, the court moved on to question 2.

Question 2: The answer was clear — "[The prescriber] knew of the risk of malignancies associated with [combination therapy], but still prescribed the medication." Id. at \*6.

In fact, the prescriber in this case, based on his knowledge of the risks, warned his patients of a "nonzero increased risk of serious infections and malignancies related to immunosuppressives and anti-tumor necrosis factor drugs." Id. at 2.

Giving the benefit of the doubt to plaintiff and assuming that the prescriber read the labeling, the court still granted summary judgment to the defendants because "the physician knew of the risk for which the plaintiff sought a warning" and "no harm could have been caused by failure to warn of a risk already known." Id. at \*6.

Given that the doctor's own knowledge of the risk did not "persuade[ ] him to cease recommending or prescribing the drug," the court found there was insufficient evidence that any additional warning suggested by plaintiffs would have altered the physician's course of treatment. Id.

Finally, it is also worth mentioning the court's discussion of the prescribing physician's prescription habits after the incident at issue — a favorite topic of plaintiffs:

"Contrary to [plaintiff's] contention, evidence that [the prescriber] ceased prescribing TNF-blockers in combination with [the immunosuppressive] after [plaintiff] was diagnosed with hepatosplenic lymphoma does not prove that he would have changed his prescription practices based on the warning they suggest. A warning about rare occurrences of hepatosplenic lymphoma associated with therapy combining [these drugs] is bound to have less persuasive power than an instance of the disease affecting a doctor's own patient followed that therapy." Id. at \*7.

A good point to keep in mind if plaintiffs try to argue the persuasiveness of the doctor's post-incident prescribing habits.

So what did we learn from today's episode? It's what you know, not where you learned it, that counts! Don't forget to tune into our next episode where Josie and the Pussycats explain why, like Twlqbal, facts do matter.

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