Products Liability Law Daily Wrap Up, TOP STORY—WARNINGS ISSUES—9th Cir.: Summary judgment reversed in drug suit because warning might have changed treatment, (Jun. 5, 2017)

Products Liability Law Daily Wrap Up

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By Robert B. Barnett Jr., J.D.

In a suit by the parents of a deceased child against Teva Pharmaceuticals USA, Inc. for failing to warn of the dangers of the drug Purinethol®, which was used to treat their son's inflammatory bowel disease, a genuine dispute of material fact existed as to whether the treating physician's conduct would have changed had adequate warnings been provided, the U.S. Court of Appeals for the Ninth Circuit ruled, reversing a trial court's grant of summary judgment for Teva. The genuine dispute was established by evidence that the physician had changed drugs earlier in the boy's treatment because of a warning (*Wendell v. GlaxoSmithKline LLC*, June 2, 2017, Gould, R.).

The boy was diagnosed at age 12 in 1998 with ulcerative colitis, an inflammatory bowel disease. His pediatric gastroenterologist prescribed Purinethol, an immunosuppressant manufactured by GlaxoSmithKline LLC. Three years later, the boy also was prescribed Remicade®, a tumor necrosis factor alfa antagonist. His last dose of Remicade was in March 2006, at which point his inflammatory bowel disease went into remission. Two months later, the Food and Drug Administration (FDA) approved a new label containing a warning reporting cases of Hepatosplenic T-cell lymphoma (HSTCL) in treatments in which patients took Remicade in combination with drugs such as Purinethol. Remicade's manufacturer sent a letter alerting prescribers to the change. When the boy's symptoms returned, his physician switched from Remicade to Humira®, which contained no such warning. The boy continued taking Humira until June 2007. Meanwhile, the boy had continued taking Purinethol from 1999 until 2004, at which point the physician switched him to a generic version. In 2003, GlaxoSmithKline stopped marketing Purinethol and transferred ownership rights to Teva. In 2007, the boy asked to stop using any version of Purinethol after reading a magazine article about the dangers of getting HSTCL after combining Purinethol and Remicade. In July 2007, the boy was hospitalized, was diagnosed with HSTCL, and died five months later at age 21.

The boy's parents sued multiple drug companies in California state court for negligence and strict liability, alleging that the companies failed to give adequate warnings about the drugs' risks. The drug companies removed the case to federal court. As the case progressed, the only remaining defendant was Teva Pharmaceuticals USA, Inc., with the other drug companies either settling with the parents or being granted summary judgment. Subsequently, the trial court granted summary judgment to Teva on the duty to warn claim for two reasons: (1) the parents failed to establish evidence that the physician relied on Teva's warning labels; and (2) the testimony of the parents' causation experts was inadmissible as unreliable. The parents appealed the decision to the Ninth Circuit.

Reliance on label warnings. The trial court concluded that the parents failed to establish that an adequate label would have made any difference because the physician testified that he did not routinely look at drug labels. Although the treating physician testified that looking at drug labeling was not his regular practice, the Ninth Circuit said, he also testified that such warnings were part of his decision-making process. He testified that if a drug came with a "black box warning," he paid particular attention to it because a black box warning usually meant that there was a significant side effect. In fact, the manufacturer sent a black box warning about Remicade that caused the treating physician to switch the boy's drug treatment to Humira, largely because the latter contained no such warning. The physician further testified that he switched to Humira because it had a "better safety profile," which included the absence of any reports that patients using Humira developed HSTCL.

This change in practice, the court said, at least in part attributed to the lack of a warning, created a question of material fact as to whether the presence of a warning would have changed the physician's prescribing practices. Moreover, the physician's prescribing practices generally evolved as more information about the dangers of combining the two drugs was revealed. He now only used monotherapy and no longer prescribed drugs in combination for this condition, which was further evidence that a warning may have affected his prescribing practices.

Expert testimony. The Ninth Circuit also concluded that the trial court erred when it ruled that the testimony of the parents' two experts on causation failed to meet the *Daubert* reliability standards. Calling it a "close question," the appellate court concluded that the trial court erred in looking too narrowly at each individual consideration established in *Daubert* without considering the broader picture of the experts' overall methodology. For example, the lower court cited the fact that experts had never conducted any independent research on the relationship between this class of drug and HSTCL while ignoring the experts' extensive experience and their reliance on a variety of literature and studies. Because the doctors employed sound methodologies to arrive at their conclusions, their testimony should not have been excluded.

Motion to reconsider. In its order granting summary judgment for Teva, the trial court also denied the parents' motion for leave to file a motion for the court to reconsider its 2012 order granting summary judgment to GlaxoSmithKline. Because the court's denial of that request for leave was based on the court's determination that the parents could not prevail against GlaxoSmithKline for the same reasons they could not prevail against Teva, the appellate court ruled that the denial of the motion for leave also should be reversed.

As a result, the Ninth Circuit reversed and remanded both the lower court's grant of summary judgment for Teva and the denial of the parent's motion for reconsideration of the grant of summary judgment for GlaxoSmithKline.

The case is No. 14-16321.

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Companies: GlaxoSmithKline LLC; Teva Pharmaceuticals USA, Inc.

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