

GSK Trial Shows Jury's New Role In Drug Labeling Cases

By **Emily Field**

Law360, New York (April 25, 2017, 10:01 PM EDT) -- An Illinois federal jury's \$3 million verdict for the widow of a Reed Smith LLP partner who committed suicide after taking a generic version of GlaxoSmithKline's Paxil shows the increased role juries have in labeling suits, after the Supreme Court in 2009 raised the bar for companies to sidestep such claims with preemption arguments, experts say.

Wendy Dolin's suit over her husband Stewart's 2010 suicide was greenlighted for trial a little more than a year ago, when U.S. District Judge James B. Zagel rejected GSK's arguments that the dispute was preempted by federal law and refused to determine whether the Paxil label was adequate, saying it was up to a jury to decide per a recent Supreme Court ruling. Dolin had started taking the generic form of Paxil, also known as paroxetine, a few days before his death after jumping in front of a train in downtown Chicago.

Citing the Supreme Court's landmark *Wyeth v. Levine* in 2009, the judge maintained that drug manufacturers have to show "clear evidence" that the U.S. Food and Drug Administration would have rejected a higher warning sought by a plaintiff, effectively raising the bar for the proof a drugmaker must show for a preemption defense. He ruled that GSK had not met that bar, and thus a jury trial was required.

Over the course of the five-week trial, jurors heard testimony that GSK tried to update the label based on a 2006 analysis finding that some adults could experience heightened suicidal ideation while on the drug.

However, the FDA rejected the label change four times, instead adopting in 2007 uniform language across the entire class of antidepressants known as selective serotonin reuptake inhibitors, or SSRIs, that Paxil falls into, GSK argued during the trial.

For a company in GSK's position, "that's a major whip-saw, that's a major Catch-22," Joseph Price of Faegre Baker Daniels said.

"I think that's a huge appellate issue that Glaxo has in its quiver because I think that is a preemption issue," Price said. "In *Levine*, there was some language in there that gave hope to companies to the effect that it would be a different story if the company had gone to the FDA with a proposal that the FDA had specifically rejected and then suit was brought on that specific issue. I think that's what the Dolin case really revolves around."

Price noted that it was a different judge, U.S. District Judge William T. Hart, who presided over the trial and who may ultimately rule on a post-trial motion that the claims were preempted.

GSK has also stated it will appeal the verdict to the Seventh Circuit, but a recent decision from the Third Circuit — which held in March that a drugmaker must prove to a jury that the FDA blocked a proposed warning for a drug — may complicate a possible preemption argument, attorneys said.

In that ruling, the Third Circuit said there was a valid argument that the FDA would have approved the warning if Merck Sharp & Dohme Corp. had described fractures related to its osteoporosis drug Fosamax in a different way.

“It wouldn’t surprise me if they raised a preemption defense on the clear evidence test, but they are playing a little bit with fire there,” Max Kennerly of Kennerly Loutey LLC said. “The Seventh Circuit may swiftly agree with the Third Circuit.”

Merck had urged the panel to rethink its ruling, arguing a jury shouldn’t decide whether the FDA would approve warning language, but the panel shot down its request for an en banc review on April 24.

Along with the Third Circuit’s opinion, Kennerly pointed to a decision last year by the Massachusetts Supreme Court, which found that the Levine decision did not bar claims that warnings about the health risks posed by Johnson & Johnson’s fever and pain drug Children’s Motrin were allegedly inadequate.

The Supreme Court in January declined to review that decision, which upheld a \$140 million jury verdict in favor of a teenager who had developed a life-threatening skin condition.

The trend now in interpreting Levine is that unless there’s a very clear rejection by the FDA under all the evidence available to a manufacturer, that isn’t enough for a preemption defense and a jury needs to resolve the issues, Kennerly said.

“Now, you’re seeing more of a trend that preemption is a demanding defense, in the Supreme Court’s own words, and it’s an affirmative defense that the defendants have to prove,” Kennerly said.

Despite the Third Circuit’s Fosamax decision, the Seventh Circuit may yet side with GlaxoSmithKline if it raises the issue on appeal, Randall L. Christian of Bowman and Brooke LLP said, pointing to the panel’s ruling seven years ago in *Robinson v. McKeil Consumer Healthcare*.

Like the case from the Massachusetts Supreme Court, that ruling also involved allegedly inadequate warnings on Children’s Motrin, but the panel found in favor of the drug company.

“In that case, the manufacturer had not actually submitted the label change that got rejected [by the FDA], so GSK has better facts in this case,” Christian said.

Absent a clear definition from the Supreme Court of what would constitute clear evidence under Levine, jurors are put in the position of pondering different scenarios why the FDA wouldn’t allow a warning change, Christian said.

“No matter what a company submits, there’s always going to be a clever plaintiffs lawyer who would come up with slightly different language and argue that we don’t know if [the FDA] would have rejected this language,” Christian said.

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