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Phone: +1 646 783 7100 | Fax: +1 646 783 7161 | customerservice@law360.com

GSK's Paxil Loss Forces 7th Circ. Generic Liability Showdown

By **Jessica Corso**

Law360, Chicago (April 21, 2017, 8:29 PM EDT) -- Thursday's $3 million jury verdict finding GlaxoSmithKline liable for a Reed Smith LLP partner's death means that the Seventh Circuit may finally have to answer a question it avoided three years ago, one that is a hot topic among product liability lawyers: Can brand-name manufacturers be held liable for an injury caused by a generic drug?

The court of appeals was asked to review that question in 2014 after a district court ruled GSK could be held liable for Stewart Dolin's suicide, which his wife, Wendy Dolin, says was caused by a bad reaction to a generic version of GSK's Paxil.

But the Seventh Circuit said it was too early to hear the "debatable legal issue" and told the drug company to try again after a final judgment was issued.

Following Wendy Dolin's **$3 million jury victory** and GSK's promise to appeal the verdict, the appellate court will likely be dragged into that debate, which has largely gone in favor of the drug companies.

"It is incredibly hotly contested," Bill Curtis of Curtis Law Group told Law360.

"There have been several courts that have gone in the same direction: that if the brand makes a label, that brand is responsible," he said, pointing to rulings in Alabama, California and Vermont.

Still, that view is in the minority. In a filing in district court, GSK said that over 100 courts in 29 states have ruled that state product liability laws don't allow those injured by ingesting generic drugs to sue brand-name manufacturers.

Alan Klein of Duane Morris LLP said that those rulings uphold a traditional principle of tort law: that one party cannot be held liable for an injury caused by another.

"There's a long tradition in tort law that only the manufacturer of the product that harms you is the culpable party," Klein told Law360. "This militates on GSK's side."

However, as Klein acknowledged and the attorneys for Wendy Dolin argued, there is no current way to hold generic companies liable for inaccurate warning labels.

The U.S. Supreme Court shielded generic manufacturers from liability in 2011 in Pliva v. Mensing by noting that only brand-name manufacturers can independently update a drug's label to alert doctors to a newly discovered risk.

The high court **issued a similar ruling** in 2013's Mutual Pharmaceutical v. Bartlett, holding that state law design defect claims cannot apply to generic-drug manufacturers.

Plaintiffs' lawyers like Andy Vickery of Vickery & Shepherd, who helped win the very first verdict against GSK on the issue of Paxil's suicide and homicide risks in a 2001 case, said the unique power that brand manufacturers have to alter drug labels means they shouldn't be allowed to hide

behind traditional tort law as a defense.

"[GSK] well knows that the generic manufacturers cannot change their label until [GSK] changes their label, and they know that the Supreme Court has insulated generic manufacturers from liability," Vickery told Law360. "I hope the Seventh Circuit will see through that and hold them accountable."

If it does, it could become the first federal appellate court to do so.

A few months after U.S. District Judge James B. Zagel declined to grant summary judgment to GSK in Wendy Dolin's suit, the Sixth Circuit referenced the judge's ruling in a **decision over allegedly misbranded painkillers**.

"We disagree with the Dolin court's holding," that circuit court said in June 2014.

Though Zagel said it was foreseeable to GSK that any mistakes made in Paxil's label would carry over into the generic label, the Sixth Circuit said that's the fault of the federal Hatch-Waxman Act, which requires generic companies to mirror the language on brand name drug labels in order to fast-track the approval process.

"Generic consumers' injuries are not the foreseeable result of the brand manufacturers' conduct, but of the laws over which the brand manufacturers have no control," the Sixth Circuit said.

In 2013, the Eleventh Circuit **came to a similar conclusion** when it held that Teva Pharmaceuticals could not be held liable under Florida state law for a neurological disorder a woman says she suffered after taking a generic version of Teva's heartburn drug Reglan.

In coming to that decision, the appeals court acknowledged that the ruling could leave those injured by generic drugs without a remedy but said that "as federal judges, we are bound merely to interpret and apply the law as promulgated by Congress and the political divisions of government."

The U.S. Food and Drug Administration has proposed a rule that would allow generic companies to unilaterally update their warning labels, but Scott Gottlieb, who was nominated by President Donald Trump to head the agency, has **publicly derided the rule**.

"The FDA should scrap this draft rule immediately," Gottlieb wrote in a Wall Street Journal column in August.

Gottlieb hasn't yet been confirmed, and the proposed rule remains in circulation. Klein believes it's unlikely that the Supreme Court will take up the Dolin case or a similar dispute while the proposal remains in place.

"If I were on the Supreme Court or advising the Supreme Court, I think I would wait to see if the FDA takes it up," Klein said.

GSK says it stopped selling Paxil in the United States in 2014, when it "divested responsibility" for the drug to Apotex Inc. Company spokeswoman Frances DeFranco says the company still sells Paxil outside the United States.

Wendy Dolin is represented by R. Brent Wisner, Michael L. Baum, Bijan Esfandiari and Frances M. Phares of Baum Hedlund Aristei & Goldman PC and David Rapoport and Matthew Sims of Rapoport Law Offices PC.

GSK is represented by Andrew T. Bayman, Todd P. Davis, Ursula Henninger and Heather M. Howard of King & Spalding LLP and Alan S. Gilbert and Anders C. Wick of Dentons.

The case is Dolin v. SmithKline Beecham Corp. et al., case number 1:12-cv-06403, in the U.S. District Court for the Northern District of Illinois.

--Additional reporting by Juan Carlos Rodriguez, Jeff Sistrunk and Jeff Overley. Editing by Philip Shea and Brian Baresch.
