Products Liability Law Daily Wrap Up, TOP STORY—DRUGS—7th Cir.: Citing preemption, 7th Circuit tosses $3M award to suicide's widow, (Aug. 23, 2018)

Products Liability Law Daily Wrap Up

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By Georgia D. Koutouzos, J.D.

A $3-million jury award to the widow of a man who had killed himself while taking the generic version of the prescription anti-depressant Paxil® was reversed by a panel for the U.S. Court of Appeals for the Seventh Circuit, which concluded that the state-law negligence claim on which the drug developer's liability had been based was federally preempted because the U.S. Food and Drug Administration (FDA) had rejected the company's repeated attempts to add a warning regarding the risk of suicide in adults taking the drug (*Dolin v. GlaxoSmithKline LLC*, August 22, 2018, Hamilton, D.).

The widow of a 57-year-old attorney who leapt in front of a Chicago elevated train, committing suicide, while he had been taking the prescription medication paroxetine—the generic form of the anti-depressant Paxil®—sued the drug's developer-manufacturer, GlaxoSmithKline LLC (GSK), seeking damages for her husband's death. The case went to trial on the Illinois-law claim that GSK negligently failed to include a warning in the label that the medication can be a cause of adult suicide despite the drug maker having been aware of a significant risk of that potential since 2006.

GSK moved for summary judgment three times—on two of which it argued that any state-law claim was preempted because the FDA had rejected the company's efforts to place certain warnings on the label [see *Products Liability Law Daily*'s February 17, 2016 analysis]. The jury returned a $3-million award for the widow [see *Products Liability Law Daily*'s April 26, 2017 analysis], after which GSK moved for judgment as a matter of law or for a new trial.

The trial court refused to set aside the award, however, finding that there was no basis to reject the jury's finding that the decedent's death had been caused by his ingestion of a generic formulation of the drug [see *Products Liability Law Daily*'s September 15, 2017 analysis]. GSK appealed the trial court's decision, challenging the court's conclusions about liability under Illinois law and federal preemption, as well as arguing that the evidence presented at trial did not support the jury's verdict.

Specific warning. The appeals court noted that the widow's theory of liability had been based on GSK's ability to change the paroxetine label to reflect the adult-suicidality risk after the label's original approval by the FDA in 1992. In order to implement a label change, a drug manufacturer can seek FDA permission to change the label or, under certain circumstances, can make a change unilaterally under the so-called "changes being effected" (CBE) regulation—which allows manufacturers to change a label to reflect newly acquired information if the changes add or strengthen a warning for which there is evidence of a causal association.

GSK found just such a causal link between paroxetine and suicide in adults in 2006, after which the company made a unilateral change to the label using the CBE regulation and adding a warning "that the higher frequency" of suicidality "observed in the younger adult population … may extend beyond the age of 24." The drug maker submitted its data underpinning the change to the FDA, but within a year the agency completed its own analysis of the same data and ordered GSK to remove the warning.

In 2007, the FDA notified manufacturers that all selective serotonin reuptake inhibitors (paroxetine is an SSRI) needed to contain the same warning, stating that there was a risk of suicide in patients under 24 but that "studies d[o] not show an increase in the risk of suicidality … in adults beyond age 24." After the FDA effectively told GSK to remove its warning, the company followed up with four requests to reconsider that directive and to allow the

paroxetine-specific warning. The agency denied those requests, with responses clearly documented and not subject to reasonable dispute.

As for the issue of whether GSK could have added the warning between 2007 and 2010 (the year in which the decedent committed suicide), the Seventh Circuit panel found that the decedent's widow failed to offer evidence that the drug maker had acquired new information after 2007 that would have justified a second CBE-based unilateral change in the label and, thus, undermine the company's preemption defense.

Federal preemption. In sum, GSK asked the FDA for permission to modify the paroxetine label as the widow had argued was necessary. The agency repeatedly said no. Therefore, as a matter of law: (1) there was clear evidence that the FDA would have rejected the warning in 2007; and (2) GSK lacked new information after 2007 that would have allowed it to add an adult-suicidality warning under the CBE regulation. Under that scheme, no reasonable jury could find that the agency would have approved an adult-suicidality warning for Paxil under the CBE regulation between 2007 and the decedent's suicide in 2010.

Consequently, the appeals court found that federal law conflicted with and, therefore, preempted the widow's Illinois negligence-law claim that the drug manufacturer should have warned of a risk of adult suicidality on the paroxetine label in 2010. The evidence of federal preemption being decisive, the trial court's judgment was reversed with the direction that the case be dismissed.

The case is No. 17-3030.

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Companies: GlaxoSmithKline LLC f/k/a SmithKline Beecham Corp.

MainStory: TopStory PreemptionNews WarningsNews DrugsNews IllinoisNews IndianaNews WisconsinNews