Products Liability Law Daily Wrap Up, PREEMPTION—DRUGS—S.D.N.Y.: GI bleeding claims against Bristol-Myers Squibb, Pfizer dismissed, labels adequate, (Jul. 27, 2017)

Products Liability Law Daily Wrap Up

Click to open document in a browser

By Harold Berman, J.D.

A consumer's claims against Bristol-Myers Squibb and Pfizer for her gastrointestinal bleeding allegedly resulting from taking the companies' drug, Eliquis, were dismissed with prejudice because her claims were preempted and Eliquis' label was adequate as a matter of law, a federal district court in New York ruled. The court relied on two earlier decisions it had issued involving the same issues and a different consumer in the multi-district litigation to which both consumers' cases had been consolidated, finding that the various design defect and failure to warn claims were preempted under federal law, and the Eliquis label adequately warned about each risk identified in the complaint (*Fortner v. Bristol-Myers Squibb Company*, July 26, 2017, Cote, D.).

A consumer, a Tennessee resident, brought claims of negligence, strict products liability, breach of express warranty, breach of implied warranties, fraudulent misrepresentation, fraudulent concealment, negligent misrepresentation, and violation of Tennessee's consumer protection laws against Bristol-Myers Squibb and Pfizer, alleging that she suffered gastrointestinal bleeding from taking Eliquis, a drug manufactured by the two companies. Her lawsuit was transferred to the Southern District of New York as part of multi-district litigation initially involving 68 cases concerning Eliquis.

Utts opinions. The court had issued two previous opinions in another case in the consolidated litigation (Utts I and Utts II), in which the court addressed the principles of preemption that govern state law failure to warn and design defect claims against brand name drug manufacturers, and whether various complaints in the consolidated litigation satisfied the pleading requirements. The Tennessee consumer then was allowed to amend her complaint based on the principles articulated in the Utts opinions.

Preemption. Based on these principles, the court found that the Tennessee consumer's various failure to warn and design defect claims were preempted, and dismissed them with prejudice. The Utts opinions held that pre-FDA approval design defect and failure to warn claims were preempted under federal law, and post-approval design defect claims were preempted under federal law when FDA regulations prohibited a change of the type implicated by the claim. The Utts opinions also ruled that post-approval failure to warn claims were preempted unless the plaintiff could plausibly allege that there was "newly acquired information" sufficient under the Changes Being Effected (CBE) regulation for the manufacturers to have independently updated the Eliquis label to include those warnings. There was, therefore, no need to analyze state law claims because the existence of newly acquired information was not plausibly alleged.

The Tennessee consumer's complaint alleged that Eliquis was defective because it was manufactured and distributed without an effective antidote or specific test to monitor the drug's anticoagulation effect, and questioned the instructions to take Eliquis twice daily. Because these claims concerned Eliquis' design, they were preempted under the principles articulated in Utts I. The consumer also alleged that the Eliquis label did not adequately warn of irreversible bleeding, the inability to measure Eliquis drug concentration, or the lack of an antidote. These allegations also were preempted as design defect claims. However, even if considered as failure-to-warn claims, the complaint did not plausibly allege the existence of newly acquired information that would have enabled the companies to alter the Eliquis label consistent with the CBE regulation. Although the consumer urged the court to reconsider the Utts analysis of preemption of pre-FDA design claims, she did not identify any controlling authority concerning this issue that contradicted Utts.

Adequacy of the Eliquis label. The court also found a second and independent reason to dismiss the consumer's complaint because the Eliquis label was adequate as a matter of law. Utts II analyzed California law concerning adequacy of labeling, which was substantially similar to Tennessee law, both requiring a drug manufacturer to unambiguously warn of the specific risk that caused the injury, and both adopting the "learned intermediary" doctrine which provides that a drug manufacturer discharges its duty to warn by adequately warning the treating physician.

The complaint's allegations concerning inadequate warnings did not articulate any risks that were not identified and analyzed in Utts, and so, consistent with the reasons given in Utts, the court held that the Eliquis label, as a matter of law, adequately warned about each risk identified in the Tennessee consumer's complaint.

Causes of action. The court went on to clarify further the extent to which each of the complaint's specific causes of action could be resolved on grounds of preemption or labeling adequacy. The court affirmed that the consumer's negligence and strict liability claims based on design defects were preempted, and to the extent they were based on failure to warn, were dismissed with prejudice because the consumer did not plausibly allege the existence of newly acquired information, and the Eliquis label was adequate as a matter of law. The complaint, like the complaint in Utts, failed to identify specific statements upon which its warranty claims were based or how the warranties were breached, and, so, for the reasons already explained in Utts, were dismissed with prejudice.

The complaint's fraudulent concealment and negligent misrepresentation claims repeated verbatim the same claims already dismissed in Utts I. Although Utts I did not include a fraudulent misrepresentation claim, its dismissed claim of "fraud" was substantially similar to the consumer's fraudulent misrepresentation claim. The complaint's allegation of violation of the Tennessee Consumer Protection Act, for the reasons detailed in Utts II, also was preempted, and failed to meet federal pleading standards because the allegations did not specify the contents of the alleged fraudulent misrepresentations, when the misrepresentations were made, why they were misleading, or that any information existed that undermined or contradicted the information in Eliquis' labeling and advertising.

The case is No. 17cv1562 (DLC).

Attorneys: Lisa Causey-Streete (Salim-Beasley, LLC) for Sheila Fortner. Loren H. Brown (DLA Piper LLP) for Bristol-Myers Squibb Co. and Pfizer Inc.

Companies: Bristol-Myers Squibb Co.; Pfizer Inc.

Cases: CourtDecisions PreemptionNews WarningsNews DrugsNews NewYorkNews