Products Liability Law Daily Wrap Up, TOP STORY—PREEMPTION—S.D.N.Y.: Failure-to-warn claims based on adequacy of FDA-approved labeling preempted in Eliquis® case, (Dec. 27, 2016)

Products Liability Law Daily Wrap Up

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By Jeffrey H. Brochin, J.D.

California products liability claims based on two drug manufacturers' alleged failure to adequately warn of risks on Food and Drug Administration (FDA)-approved labeling were properly dismissed based on federal preemption, a federal district court in New York ruled. The patient's design defect claims were dismissed with prejudice while leave to amend was granted as to his fraud claims (*Utts v. Bristol-Myers Squibb Co.*, December 23, 2016, Cote, D.).

Background. The patient and his wife were both residents of California. He was diagnosed with atrial fibrillation sometime before July 2014 and was prescribed Eliquis®, an anticoagulant. He subsequently experienced severe internal bleeding after taking the drug, but unlike other anticoagulant medications, Eliquis did not have a known antidote or reversal agent. The FDA approved Eliquis for sale and marketing in the United States in 2012 after the manufacturers, Bristol-Myers Squibb Company and Pfizer Inc., submitted a New Drug Application (NDA) which included a description of the clinical investigations of the drug with the results of the international clinical trials known as ARISTOTLE. The patient alleged several deficiencies with the study, including that the manufacturers had used incompetent and untrustworthy sources to conduct the study. The patient further alleged that the manufacturers concealed several side effects experienced by study participants. While the NDA was pending before the FDA, an FDA employee, who was appointed to review the application, recommended that the proposed label discuss the quality control problems associated with the study. In response to concerns about the study, the manufacturers decided to submit additional data to the FDA for its consideration. At the time the patient was prescribed the drug, the label contained several warnings about the risk of internal bleeding, and it referenced the ARISTOTLE study.

Procedural background. The patient and his wife filed a 12-count complaint against the manufacturers in July 2016 that included products liability counts of design defect, manufacturing defect, and failure to warn. The manufacturers filed their motion to dismiss in October 2016, which the court largely granted, but with leave to amend most of the dismissed claims. In first disposing of the conflicts of law issue, the court ruled that for the purposes of its opinion, it assumed that the parties agreed that California law was controlling.

FDA approval process. The manufacturers asserted that several of the patient's claims were preempted by federal law due to the FDA regulatory process which governed approval of the drug. Under the provisions of the federal Food, Drug and Cosmetic Act (FDC Act), in order to market a new drug, a drug manufacturer must submit an NDA which includes full reports of investigations which have been made to show whether or not the drug is both safe and effective. They also must submit proposed labeling, and, after FDA approval, the manufacturers have an ongoing obligation to monitor a drug's risks and report adverse drug responses to the FDA. Federal law also regulates changes to drug labeling, and although generally a manufacturer only can change a drug label after the FDA approves a supplemental application, a manufacturer may make certain label changes prior to FDA approval by way of the "changes being effected" (CBE) regulation.

Requirement of newly acquired information. The CBE regulation provides that if a manufacturer is changing a label to add or strengthen a contraindication, warning, precaution, or adverse reaction for which there is sufficient evidence of a causal association, or to add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product, that manufacturer can make the labeling change upon its filing a supplemental application without waiting for FDA approval. However, such CBE changes can be

made only on the basis of "newly acquired information" which is defined as data, analyses, or other information not previously submitted to the FDA. Such information may include data derived from new clinical studies, reports of adverse events, or new analyses of previously submitted data. Information previously known to the manufacturer, but not submitted to the FDA, may constitute "newly acquired information," if the information meets the other CBE requirements.

Federal preemption. The manufacturers contended that federal law preempted many of the patient's claims including all of his products liability claims. The court noted that as concerns state law conflicting with a federal statute, conflict preemption exists if it is impossible for a private party to comply with both a state and federal law. It discussed at length recent opinions addressing conflict preemption in the context of state liability claims against drug manufacturers and found that state law failure to warn claims against generic drug manufacturers were preempted by federal law.

Preemption and brand name drugs. As concerns a failure to warn and design defect claim for a branded drug, the claim may be preempted: if a claim addresses newly acquired information and addresses a design or labeling change that a manufacturer may make unilaterally without FDA approval, then there may be no preemption of the state law claim. Conversely, a post-approval design defect claim is clearly preempted by federal law when FDA regulations prohibit a change of the type implicated by the claim.

Failure-to-warn claims preempted. The patient's complaint identified 14 different warnings that he alleged the Eliquis label failed to include. The court concluded that to the extent that the failure to warn claims were premised on the adequacy of the label as approved by the FDA when the drug was first marketed in the United States, those claims were preempted. Furthermore, because the complaint focused almost exclusively on the ARISTOTLE study, it was not premised on any information known by the manufacturers at the time of manufacture and distribution which might constitute "newly acquired information" under the CBE regulation. The court, therefore, dismissed the failure to warn claims whether under strict liability or negligence theory, but with leave to amend.

Design defect claims. The court dismissed with prejudice, the strict liability design defect claim due to its being barred by California law. As to the negligent design defect claim, the court ruled that that was preempted. It further held that this claim also failed because it was based on the argument that the manufacturers never should have sold the FDA-approved formulation of Eliquis. The Supreme Court has consistently rejected the rationale that a drug manufacturer should simply have "pulled the drug from the market" in order to comply with both state and federal law. Accordingly, the court determined that leave to amend was not appropriate for that claim.

State fraud claims. Finally, the patient alleged that the manufacturers' concealment of certain data to the FDA constituted fraud. The court disagreed, noting that it is well established that a claim premised on a drug manufacturer's failure to provide data to the FDA is preempted because such claims inevitably conflict with the FDA's responsibility to police fraud consistent with their judgment and objectives. Therefore, it is the FDA which is empowered to investigate suspected fraud and it may bring court actions to respond to such suspected fraud. Accordingly, the motion to dismiss the patient's three fraud claims was granted with leave to amend.

In sum, the design defect claims were dismissed with prejudice and the patient was granted leave to amend his remaining claims.

The case is No. 16cv5668 (DLC).

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

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