Products Liability Law Daily Wrap Up, TOP STORY—WARNINGS ISSUES—DRUGS—D. Mass.: Adequacy of physician warnings on pulmonary dangers of anti-obesity medication raised jury question, (Dec. 16, 2013)

By Pamela C. Maloney, J.D.

The learned intermediary doctrine did not, as a matter of law, apply to immune the manufacturer of a drug used to treat obesity because a patient introduced sufficient evidence to raise a question of fact as to whether adequate warnings regarding the risks of using the drug to treat obesity had been given to the patient's prescribing physician, the U.S. District Court for the District of Massachusetts held (*Tersigni v. Wyeth-Ayerst Pharmaceuticals, Inc.*, December 13, 2013, Stearns, R.).

Background. After being diagnosed with extreme obesity and other "comorbidities," including hypertension, high cholesterol, and high triglycerides, Michael Tersigni was prescribed the drug Pondimin (trade name for the drug fenfluramine), an anti-obesity medication manufactured by Wyeth-Ayerst and popularly known as "Fen-Phen." Tersigni took the drug for about six months, after which his treating physician discontinued his prescription in response to medical warnings about the side effects of fenfluramine. Fourteen years later, Tersigni was diagnosed with Primary Pulmonary Hypertension (PPH), which his treating physician attributed to the patient's ingestion of Pondimin.

Tersigni filed breach of warranty—design defect, breach of warranty—failure-to-warn, negligence or products liability, fraudulent misrepresentation, and fraudulent concealment claims against the drug manufacturer. This claim was transferred to the Multidistrict Litigation action pending in Pennsylvania, and following completion of pre-trial discovery, the case was remanded to the federal court in Massachusetts. After unsuccessful mediation between Tersigni and the manufacturer, the manufacturer moved for summary judgment on the basis of the learned intermediary doctrine, asserting that Tersigni failed to prove that different or additional warnings would have changed the outcome because the prescribing physician was aware of the association between the drug and the risk of PPH when he prescribed the medication to Tersigni.

Learned intermediary doctrine. The learned intermediary doctrine permits a drug manufacturer to discharge its duty to warn the consumer by providing appropriate warnings to the prescribing physician. The immunity is not available if the manufacturer breaches its duty to warn the doctor; in that event, the manufacturer remains directly liable to the patient. Tersigni argued that the manufacturer failed to adequately and timely warn physicians about the extent of the risk of PPH. Specifically, Tersigni stated that although the manufacturer knew of the risk of PPH as early as 1989, it did not update the product's labeling to include the mention of PPH until 1996. Tersigni further alleged that it was not until 1997 when the manufacturer added a full warning of the risks of PPH, after the drug had been withdrawn from the market at the request of the U.S. Food and Drug Administration.

Adequacy of warning. Tersigni's treating physician testified that he had no reason, based on the information he had been supplied, to believe that the drug posed a fatal risk of contracting PPH. The treating physician based his conclusion on a study performed by a noted pharmacologist who discovered Fen-Phen had been shown to be significantly more effective than dieting or exercise in treating chronic obesity. According to the physician, given the publicity surrounding the study—referred to as the Weintraub study—he was convinced that the drug, in the dosage prescribed, had no major side effects. The manufacturer countered that the physician knew of the PPH risk before prescribing the drug to Tersigni, pointing to revisions to the Physician's Desk Reference entry and changes to the drug's labeling, along with "dear doctor" letters that had been sent to him. According to the manufacturer, although the physician knew of the risk, he would have prescribed the drug because of the potential benefit of treating Tersigni's obesity.

The court determined that when the physician's somewhat ambiguous testimony was considered in light of evidence that the manufacturer had suppressed information about the number and extent of the drug's Adverse Drug Events that it had compiled, there was a triable issue of fact on Tersigni's failure-to-warn claim.

The case number is 11-10466-RGS.

Attorneys: Paula S. Bliss (Bubalo Goode Sales & Blisse PLC) for Michael J. Tersigni. Wilfred P. Coronato (Huhes Hubbard & Reed, LLP), Zachary N. Coseglia (DLA Piper US LLP) for Wyeth. James A. Frederick (Goodell, DeVries, Leech & Dann, LLP) for American Home Products, Wyeth Ayerst Laboratories, Wyeth Pharmaceuticals, Inc., Wyeth-Ayerst Pharmaceuticals, Inc., AHP Subsidiary Holding Corp., Ayerst Laboratories, Inc.

Companies: Wyeth; American Home Products; Wyeth Ayerst Laboratories; Wyeth Pharmaceuticals, Inc.; Wyeth-Ayerst Pharmaceuticals, Inc.; AHP Subsidiary Holding Corp., Ayerst Laboratories, Inc.

MainStory: TopStory WarningsNews DrugsNews MassachusettsNews