Products Liability Law Daily Wrap Up, WARNINGS ISSUES—DRUGS—M.D. Fla.: Learned intermediary doctrine only goes so far in protecting makers of arthritis treatment drug, (Sept. 28, 2015)

Products Liability Law Daily Wrap Up

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By Kayla R. Bryant, J.D.

Allegations that drug manufacturers failed to warn patients of the risk of potential injuries related to the use of a drug used to treat rheumatoid arthritis were barred by the learned intermediary doctrine, the U.S. District Court for the Middle District of Florida ruled. However, the court disagreed with the manufacturers' arguments that the learned intermediary doctrine protected them from claims based on design and manufacturing defects and breach of express warranty (*Small v. Amgen, Inc.,* September 25, 2015, Steele, J.).

Background. The patient began taking Embrel® in 2002 to treat her rheumatoid arthritis as part of a clinical study, and continued this treatment until August 29, 2008. On that date, she was admitted to the hospital and diagnosed with a perforated bowel. This was caused by a diverticulitis infection, which was allegedly traced back to the drug. She restarted treatment in 2009 after her doctor allegedly consulted with a sales representative for the drug companies and was assured that it was safe to resume taking the drug. She experienced another round of complications within about 60 days after restarting treatment and had not taken the drug since that date. The patient required several surgeries after both incidents and subsequently filed a products liability action against three drug companies, Amgen, Inc., Wyeth, Inc., and Pfizer, Inc., setting forth counts for: strict liability based on a design defect, strict liability based on a failure to warn, breach of an express warranty, negligence, and loss of consortium. The court previously had dismissed the claim for negligence to the extent that the patient asserted negligent failure to test or inspect and negligence per se (*see Products Liability Daily's* March 7, 2014 analysis).

Failure to warn. A failure to warn claim must show that a manufacturer or distributor did not adequately warn of a known or knowable risk, and that the inadequate warning was a proximate cause of the injury. Under Florida's learned intermediary doctrine, the duty to warn is directed to physicians. However, if a manufacturer does not warn the physician of the risk and the physician has independent knowledge of the risk, the manufacturer's failure to warn is not a proximate cause of the injury. The patient argued that the FDA's regulations requiring the distribution of a medication guide, or patient labeling, when it could help prevent serious adverse effects (21 C.F.R. Section 208.24) indicates a duty on the part of a manufacturer to provide safety information directly to consumers. The court found that these regulations have no impact on the application of Florida law, and pointed to the FDA's explicit statements indicating that the agency did not intend to change state tort law. The court declined to "create a special exception to the learned intermediary doctrine" and concluded that the duty to warn ran to the patient's physician. The failure to warn claim was dismissed.

Design defect claims. The complaint also alleged that the drug contained an unreasonably dangerous defect and that it was negligently manufactured. The manufacturers argued that the learned intermediary doctrine also applies to these claims, as products which are "unavoidably unsafe" are exempt from this type of liability if the benefits outweigh the risks, and if adequate warnings accompany the product. The court found that the manufacturers did not show that the product was as safe as it could have been at the time the patient was injured, and because the discovery period was still open, summary judgment was inappropriate at this point in the proceedings.

Breach of express warranty claim. In addition, the court declined to extend learned intermediary doctrine protection to the manufacturers for the breach of express warranty claim. The complaint alleged that the manufacturers expressly warranted through various documents that the drug was safe to use and not injurious to the patient's health, and that the product did not conform to the representations. The court rejected the

manufacturers' arguments that this claim was based on failure to warn of infections, as the complaint does not approach this topic. Thus, those claims were allowed to proceed.

The case is No. 2:12-cv-476-FtM-29MRM.

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Companies: Amgen, Inc.; Pfizer, Inc.; Wyeth, Inc.

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