Products Liability Law Daily Wrap Up, DESIGN AND MANUFACTURING DEFECTS—DRUGS—M.D. Fla.: Court declines to dismiss claims against rheumatoid arthritis drug manufacturers, (Mar. 7, 2014)

Products Liability Law Daily Wrap Up

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By Patricia K. Ruiz, J.D.

A request by manufacturers and marketers of the rheumatoid arthritis drug, Enbrel®, to dismiss claims by a patient and her husband alleging that the drug caused the patient's injuries was granted in part and denied in part by a federal district court in Florida. The court dismissed the patient's claims of negligent testing and negligence per se, leaving her failure-to-warn, defective design, breach of express warranty, and negligent manufacturing claims to proceed (*Small v. Amgen, Inc.*, March 6, 2014, Steele, J).

Background. Rebecca Small received subcutaneous injections of Enbrel to treat her rheumatoid arthritis. Six years into her treatment, Mrs. Small was diagnosed with a perforated bowel, caused by an asymptomatic diverticulitis infection spurred by her use of Enbrel. She underwent multiple surgeries to treat the infection. After she was released from the hospital, she continued her Enbrel treatment, at the direction of her rheumatologist, who had consulted an Enbrel sales representative to ensure that it was appropriate to do so. Mrs. Small again experienced complications from her use of Enbrel.

Mrs. Small and her husband Lawrence Small filed suit against Amgen, Inc., the original developer and marketer of the drug, as well as Wyeth, Inc., another marketer of the drug, and Pfizer, Inc., which acquired Wyeth in 2009. The suit alleged strict liability based on design defect, strict liability based on failure to warn, breach of express warranty, negligence, and loss of consortium. The corporations filed a motion to dismiss.

Defective design. In order to allege strict products liability in Florida, three allegations must be made: "(1) the manufacturer's relationship to the product in question, (2) the unreasonably dangerous condition of the product, and (3) the existence of a proximate causal connection between such condition [and] the user's injuries or damages." The corporations argued that the Smalls' defective design claim should be dismissed for failing to allege any facts in support of the allegation that the drug created an unreasonably dangerous condition. However, the court concluded that it was not necessary for the Smalls to pinpoint a specific source of the defect and that the complaint placed the corporations on notice of the type of harm allegedly caused.

Failure to warn. In determining whether a warning is adequate, the court stated that "the critical inquiry is whether it was adequate to warn the physician of the possibility that the drug may cause the injury alleged by the plaintiff." The corporations argued that the packaging insert that accompanied the drug was adequate as a matter of law, because it broadly and clearly warned Mrs. Small's physician of the infection risk. Because the warning label included warnings of specific types of infections, but not asymptomatic infections, the court determined that the adequacy of the label was a question better left to the factfinder and declined to dismiss the claim.

Breach of express warranty. The Smalls alleged that: (1) warranties existed in the package inserts, the Physician's Desk Reference, other marketing literature, and documents provided to the FDA; (2) the representations were material to Mrs. Small's decision to use Enbrel; (3) the drug did not conform to the representations; and (4) she was injured as a result of the nonconformity. Because the court found that the question of whether an express warranty existed should be determined by the jury, it determined that the Smalls allegations were sufficient to survive the motion to dismiss.

Negligence. Drawing on the allegations supporting the Smalls' design defect claim, the court declined to dismiss their negligent manufacturing claim. The court dismissed the Smalls' claim of negligent testing, reasoning that

it was subsumed in claims for defective design and failure to warn. Finally, the court dismissed the Smalls' negligence per se claim because it was based on violations of Food and Drug Administration regulations, and Florida did not recognize such causes of action.

The case number is 2:12-cv-476-FtM-29DNF.

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

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