

SUPERIOR COURT OF NEW JERSEY

CHAMBERS OF  
BRYAN D. GARRUTO  
JUDGE



MIDDLESEX COUNTY COURT HOUSE  
P.O. BOX 994  
NEW BRUNSWICK, NEW JERSEY 08903 - 0994

MEMORANDUM OF DECISION ON MOTION

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**FILED**

JUN 22 2007

BRYAN D. GARRUTO, J.S.C.

RE: *Deutsch v. Wyeth, Inc.*, HRT Mass Tort Case Code 266, MID-L-998-06 MT

**NATURE OF MOTION: Defendant Wyeth, Inc.'s Motion for Summary Judgment to Dismiss Plaintiffs' Inadequate Warning Claim as to Prempro™ on Federal Preemption Grounds**

Having carefully reviewed the moving papers and considered the oral arguments set forth on the record on Tuesday, June 12, 2007, I have made the following determination:

This matter comes before the Court on Wyeth, Inc.'s ("Wyeth") Motion for Partial Summary Judgment to Dismiss Plaintiffs Ellen and David Deutschs' Inadequate Warning Claims as to Prempro™ on Federal Preemption Grounds. Plaintiffs' claims arise out of breast cancer injuries allegedly sustained as a result of her ingestion of the FDA-approved Hormone Replacement Therapy ("HRT") drugs Premarin® and Prempro™, which are manufactured, designed, and/or distributed by defendant Wyeth. According to the facts on record, Ms. Deutsch used Premarin® from February 1995 to July 1996 and Prempro™ from August 1996 to April 2002 for menopausal symptoms such as hot flashes.

Wyeth contends that the plaintiffs' state law failure to warn claims, brought pursuant to the Products Liability Act ("PLA"), N.J.S.A. 2A:58C-1, are preempted by federal law,

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specifically the Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, because they impliedly conflict with federal labeling regulations promulgated and interpreted by the Food and Drug Administration ("FDA"). Defendants maintain that a Preamble to a Final Rule ("Final Rule") governing the "Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products", 71 *Fed. Reg.* 3922 (issued Jan. 24, 2006, effective June 30, 2006) intended to preempt state tort law claims for failure to adequately warn and that this Court should defer to such Preamble and dismiss the plaintiffs' state law-based failure to warn claims. The effect of the Final Rule was to add new labeling requirements meant to "make it easier for health care professionals to access, read, and use information in prescription drug labeling" and "enhance the safe and effective use of prescription drug products and reduce the number of adverse reactions resulting from medication errors due to misunderstood or incorrectly applied drug information." 71 *Fed. Reg.* at 3922.

Wyeth argues that because the FDA requires all drug manufacturers to determine the content on labels of pharmaceutical drug products, 21 U.S.C. § 355(d), it is within the sole purview of the FDA to determine whether their products contained adequate warnings. Wyeth contends that because it could not strengthen its warning label without prior FDA approval, if it were to do what the plaintiff alleges it should have done – specifically strengthen its label warnings about breast cancer – it risked becoming "misbranded" under federal law. 21 U.S.C. §§ 331(a), (b), & (k), 352, & 321(n). Wyeth further contends that because it provided the FDA with information about all known warnings and risks associated with HRT in its New Drug Application and because the FDA subsequently approved Prempro™ based on Wyeth's submissions, the plaintiff cannot second-guess the determinations made by a federal regulating body.

The Preamble to the Final Rule ("Preamble") expressed the FDA's concern with state law-based products liability actions against pharmaceutical drug manufacturers and how such claims impacted its own regulation of prescription drug warning labels. The Preamble stated:

State law actions ...threaten FDA's statutorily prescribed role as the expert Federal agency responsible for evaluating and regulating drugs. State actions are not characterized by centralized expert evaluation of drug regulatory issues. Instead, they encourage, and in fact require, lay judges to second-guess the assessment of benefits versus risks of a specific drug to the general public – the central role of FDA – sometimes on behalf of a single individual or group of individuals. That individualized reevaluation of the benefits and risks of a product can result in relief – including the threat of significant damage awards or penalties – that creates pressure on manufacturers to attempt to add warnings that FDA has neither approved nor found to be scientifically required. This could encourage manufacturers to propose "defensive labeling" to avoid State liability, which, if implemented, could result in scientifically unsubstantiated warnings and underutilization of beneficial treatments.

*Id.* at 3935. Indeed, Wyeth contends, this Preamble demonstrates the FDA's intent to preserve its Congressionally-delegated authority to implement the provisions of the FDCA, namely the ability to approve all labeling for pharmaceutical prescription drugs. It is Wyeth's view that this Court and a state jury – or any state court and jury for that matter – should not substitute its own interpretations of FDA-approved pharmaceutical drug label warnings for the learned judgments of the FDA's expert scientists and skilled medical professionals. To do so, according to Wyeth, would conflict with the implied intent of the FDA and would offset the "somewhat delicate balance" between communicating relevant risk information to prospective pharmaceutical product consumers and promoting the health benefits of using such treatments.

Wyeth further contends that it is possible that implied conflict preemption could exist because the U.S. Supreme Court recently held in *Buckman Co. v. Pls.' Legal Comm.*, 531 U.S. 341, 348 (2001) that state law "fraud on the FDA" claims conflict with the FDCA and are impliedly preempted by federal law. If a state law claim could only be preempted by explicit

Congressional intent, then the Supreme Court wrongly decided the doctrine of implied conflict in *Buckman*.

The plaintiffs object to Wyeth's attempts to preempt an entire class of claims based on language in a Preamble that was not subject to any debate or comment by either the public, private citizens groups, Congress, or any state governing bodies, but was instead written as a comment to an FDA regulation that specifically did not contain any language indicating it was intended to preempt state law claims. Plaintiffs maintain that because FDA regulations explicitly permit drug companies to strengthen their warning labels without FDA approval, there is no implied conflict between federal and state law that would impede the FDA's ability to enforce its drug labeling regulations. Moreover, numerous decisions in both state and federal law cases hold that FDA approval of a drug's warning label alone is insufficient to preempt a state's authority to provide laws that protect the health, safety, and welfare of its citizens and to deprive litigants injured by a product's inadequate warning from a remedy at law.

This Court adopts U.S. District Judge Jack. B. Weinstein's reasoning and findings in *In re: Zyprexa Products Liability Litigation*, No. 04-MD-1596, 06-CV-1729 (E.D.N.Y. June 11, 2007), and Superior Court Judge Carol E. Higbee's reasoning findings in *Cona/McDarby v. Merck*, Nos. ATL-L-3553-05 MT, ATL-L-1296-05 MT (N.J. Super. Law. Div., June 8, 2007), which both hold that the FDCA does not preempt state law tort claims based on a pharmaceutical company's inadequate warnings of the risks involved in ingesting its FDA-approved product.

**DATE OF DECISION: June 22, 2007**

  
HON. BRYAN D. GARRUTO, J.S.C.

**ORDER ATTACHED:** 1