IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

RENEE NOLL BAUMGARDNER, et al.	:	CIVIL ACTION
	:	
v.	:	
	:	
WYETH PHARMACEUTICALS	:	NO. 05-5720

RENEE NOLL BAUMGARDNER,	:	CIVIL ACTION
COREY FOSTER BAADSGAARD,	:	
MELODY BROWN,	:	NOS. 06-2518
LEAH CRAIG CHUMBLEY,	:	06-2519
PAULETTE FORD, JOAN HENNING,	:	06-2520
JAMES W. HILL, SHARON RODGERS,	:	06-2521
LORRAINE AND ROBERT SLATER,	:	06-2522
JAME CHARLEA TIERNEY	:	06-2523
	:	06-2524
v.	:	06-2525
	:	06-2526
WYETH PHARMACEUTICALS	:	06-2527

MEMORANDUM

Fullam, Sr. J. August 31, 2010

The ten sets of plaintiffs in this series of related cases are persons or surviving family members of persons who took the antidepressant Effexor (the regular or the extended release version) between August 8, 2000 and August 4, 2003. They have filed a products liability suit against the manufacturer of Effexor, Wyeth Pharmaceuticals, asserting that Wyeth failed to provide adequate warnings of Effexor's risks, particularly the danger that those taking the drug might try to harm themselves or

others. The plaintiffs' claims have been consolidated for pretrial discovery.

Wyeth has filed a motion for summary judgment arguing that the plaintiffs' state-law tort claims must be dismissed as preempted by federal law; specifically because the plaintiffs' claims under state law would require the defendant to provide different or additional suicide-related warnings for Effexor, while federal law, during the time periods relevant here, provided that the then-existing suicide-related warnings were appropriate.

The parties agree that in light of the United States Supreme Court's decision in Wyeth v. Levine, 129 S. Ct. 1187 (2009), the narrow issue for the Court is whether the defendant has presented "clear evidence that the FDA would not have approved a change to [the drug's] label." Levine, 129 S. Ct. at 1198. Only if a defendant makes that showing will the plaintiffs' state-law tort claims be preempted; Wyeth has not done so.

Wyeth argues that the FDA would have rejected any additional suicide-related warnings that it provided because, at all times before 2003, it was the FDA's scientific judgment that there was no association between suicide and antidepressants. As evidence, Wyeth points to the FDA's rejection of three citizen petitions, which sought the removal of antidepressants from the

market or the strengthening of their suicide-related warnings, as well as various statements and reports made by the Psychopharmacological Drugs Advisory Committee, a group commissioned by the FDA, which concluded that the connection between antidepressants and suicide was not scientifically supportable. None of this evidence proves that the FDA would have rejected relevant warnings had Wyeth, the manufacturer, proposed them. In attempting to, in effect, shift the responsibility for its labeling decisions onto the FDA, Wyeth has lost sight of the Supreme Court's statement that "the manufacturer bears responsibility for the content of its label at all times." Levine, 129 S. Ct. at 1197-98.

According to Wyeth, there is "clear evidence" that the that the FDA would have rejected a new warning. Wyeth did propose a change to Effexor's label in 2003, adding a pediatric precaution to Effexor's package insert to state in part "[i]n pediatric clinical trials, there were increased reports of hostility and, especially in Major Depressive Disorder [patients], suicide-related adverse events such as suicidal ideation and self-harm." Wyeth asserts that in March 2004, the FDA directed it not to use the proposed labeling, however, after closely examining the record, it seems to me that the FDA did not reject the defendant's proposed labeling change, but let the defendant's then-existing label stand until early 2004 when the

FDA decided to issue a different, and arguably more comprehensive warning to Effexor users and their families and prescribers of the drug. The plaintiff has pointed to the Congressional testimony of the FDA's Director of the Office of Drug Evaluation, given in 2004, which asserts that Wyeth was permitted to unilaterally strengthen Effexor's warnings until a different warning was imposed on antidepressant manufacturers by the FDA. Other cases examining the warning labels on antidepressants have reached the same conclusion. See Mason v. SmithKline Beecham Corp., 596 F.3d 387 (7th Cir. 2010); Forst v. SmithKline Beecham Corp., 639 F. Supp. 2d 948 (E.D. Wis. 2009); Aaron v. Wyeth, No. 07-927, 2010 WL 653984 (W.D. Pa. Feb. 19, 2010). The reasoning in those cases is persuasive.

In sum, the defendant has not shown that the FDA would not have approved a change to Effexor's label. The defendant's motion for summary judgment is denied.

An order will be entered.

BY THE COURT:

/s/ John P. Fullam
John P. Fullam, Sr. J.