IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF KANSAS

DEBRA VANDERWERF, Individually and as Next Friend for Riley and Tanner Vanderwerf, Minors, and ESTATE OF WILLIAM K. VANDERWERF,	)	
Plaintiffs,	)	
v.	)	**CIVIL ACTION**
SMITHKLINEBEECHAM CORPORATION d/b/a GLAXOSMITHKLINE and ELI LILLY AND COMPANY,	)	**No. 05-2271-KHV**
Defendants.	)	

MEMORANDUM AND ORDER

Debra, Riley and Tanner Vandwerf, and the Estate of William K. Vanderwerf, filed this products liability suit against Eli Lilly and Company ("Lilly") and SmithKlineBeecham Corporation d/b/a GlaxoSmithKline ("GSK"). Plaintiffs allege that William Vederwerf committed suicide after taking the prescription drug Zyprexa, which Lilly manufactured, in conjunction with the prescription drug Paxil, which GSK manufactured. This matter is before the Court on Defendant Eli Lilly And Company's Motion To Dismiss Pursuant To Rule 12(b)(6) (Doc. #2) filed June 28, 2005 and Defendant SmithKline Beecham Corporation d/b/a GlaxoSmithKline's Motion To Dismiss Counts I, III and IV Of Plaintiffs' Complaint For Failure To State Claims Upon Which Relief Can Be Granted And Memorandum Of Law In Support (Doc. #41) filed November 14, 2005. For reasons stated below, the Court sustains defendants' motions in part.

Factual Background

Plaintiffs' complaint alleges the following facts:

William and Debra Vanderwerf were married from May 8, 1993 until William's death on February 21, 2003. They had two children – Riley and Tanner Vanderwerf.

GSK manufactures, designs, tests, markets, warns and advertises Paxil, an antidepressant medication. Lilly manufactures, designs, tests, markets, warns and advertises Zyprexa, an antipsychotic medication.

William received medical treatment for depression from his primary care physician, Dr. John Crane. On March 1, 2002, Dr. Crane increased William's dosage of Paxil to 40 milligrams per day. On February 7, 2003, William reported problems sleeping and a decrease in interest in normal activities, but he was not suicidal. Dr. Crane instructed William to continue taking 40 milligrams per day of Paxil but to also take Zyprexa and see a psychologist. William began taking Zyprexa in conjunction with Paxil. Shortly thereafter, he began experiencing paranoia, delusions and hysteria. On February 21, 2003, William shot himself in the head.

The family and Estate of William Vanderwerf filed this products liability suit against Lilly and GSK. Plaintiffs allege that defendants' products were defective in design and manufacture and in instructions to doctors and the consuming public. Plaintiffs assert claims for strict liability, negligence, negligence per se and breach of the implied warranty of merchantability. Defendants seek to dismiss three of plaintiffs' claims under Rule 12(b)(6), Fed. R. Civ. P. Defendants argue that (1) plaintiffs have not stated claims for strict liability (Count I) or breach of the implied warranty of merchantability (Count IV) because they have not alleged a specific defect in defendants' products; and (2) plaintiffs have not stated a claim for negligence per se (Count III) because the Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, does not provide a private right of action.

Standards For Motions To Dismiss Under Rule 12(b)(6)

A Rule 12(b)(6) motion should not be granted unless it appears beyond doubt that plaintiffs can prove no set of facts in support of their claim which would entitle them to relief. Conley v. Gibson, 355 U.S. 41, 45-46 (1957); GFF Corp. v. Associated Wholesale Grocers, Inc., 130 F.3d 1381, 1384 (10th Cir. 1997). The Court accepts all well-pleaded factual allegations in the complaint as true and draws all reasonable inferences from those facts in favor of plaintiffs. See Shaw v. Valdez, 819 F.2d 965, 968 (10th Cir. 1987). In reviewing the sufficiency of plaintiffs' complaint, the issue is not whether plaintiffs will prevail, but whether plaintiffs are entitled to offer evidence to support their claims. See Scheuer v. Rhodes, 416 U.S. 232, 236 (1974). Although plaintiffs need not precisely state each element of their claims, they must plead minimal factual allegations on those material elements that must be proved. See Hall v. Bellmon, 935 F.2d 1106, 1110 (10th Cir. 1991).

Analysis

I. Strict Liability (Count I)

Plaintiffs' strict liability claim is governed by the Kansas Product Liability Act ("KPLA"), K.S.A. §§ 60-3301 to 60-3307, which applies to all product liability claims regardless of the substantive theory of recovery. See Savina v. Sterling Drug, Inc., 247 Kan. 105, 126, 795 P.2d 915, 931 (1990). Kansas law recognizes three ways in which a product may be defective: (1) a manufacturing defect, (2) a warning defect or (3) a design defect. See Delaney v. Deere & Co., 268 Kan. 769, 774, 999 P.2d 930, 936 (2000). Plaintiffs assert that defendants are liable under all three theories. Defendants argue that plaintiffs have failed to state a claim for strict liability because they have not alleged a *specific* defect in their products.

The Kansas Supreme Court noted that "some specific defect must be established to prove a strict liability claim." Jenkins v. Amchem Prods., Inc., 256 Kan. 602, 635, 886 P.2d 869, 889 (1994), cert. denied, 516 U.S. 820 (1995). Jenkins, however, addressed the standard of proof at trial and on a motion for summary judgment, not the standard for pleading a strict liability claim. See id. (noting definition of defect under pattern jury instructions). Defendants cite Burton v. R.J. Reynolds Tobacco Co., 181 F. Supp.2d 1256, 1261 (D. Kan. 2002), for the proposition that plaintiffs must allege a specific defect. In ruling on a motion for summary judgment, Burton held that plaintiff may not simply rest upon his pleadings but must set forth specific facts that would be admissible in evidence in the event of trial. Id. at 1260 (citation omitted). In an earlier opinion in Burton, the Honorable John W. Lungstrum held that to survive a motion to dismiss on a strict liability claim, plaintiff need not allege a specific defect in defendant's product. See Burton v. R.J. Reynolds Tobacco Co., 884 F. Supp. 1515, 1522 (D. Kan. 1995) (plaintiff *ultimately* must specifically identify what aspect of product was defective) (citing Jenkins). Here, defendants challenge the sufficiency of plaintiffs' complaint on a motion to dismiss. At this stage, plaintiffs need not specifically allege how defendants' products were defective. Accordingly, the Court overrules defendants' motions to dismiss plaintiffs' strict liability claim (Count I).

II. Implied Warranty of Merchantability (Count IV)

Defendants also argue that plaintiffs' claim for breach of the implied warranty of merchantability is defective because they have not alleged a specific defect. "To demonstrate a breach of the implied warranty of merchantability, plaintiff must show that the goods were defective, that the defect was present when the goods left the manufacturer's control, and that the defect caused the injury sustained by plaintiff." Dieker v. Case Corp., 276 Kan. 141, 162, 73 P.3d 133, 146-47 (2003); see K.S.A. § 84-2-314. A

pleading that is adequate for a strict liability claim will suffice for an implied warranty of merchantability claim. Lane v. Redman Mobile Homes, Inc., 5 Kan. App.2d 729, 733-34, 624 P.2d 984, 988 (1981) (same requirements to prove negligence, breach of implied warranty or strict liability). For reasons stated above, plaintiffs' complaint is not required to precisely allege how defendants' products were defective. The Court therefore overrules defendants' motions to dismiss plaintiffs' claim for breach of the implied warranty of merchantability.

III. Negligence Per Se (Count III)

Plaintiffs assert a state law claim of negligence per se based on defendants' violation of the Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*[1] Defendants argue that plaintiffs have not stated an actionable claim under Kansas law because the FDCA does not provide a private right of action.

Plaintiffs maintain that under Kansas law, violations of federal statutes are relevant and are sufficient to sustain a claim of negligence per se. The elements of negligence per se are (1) a violation of a statute, ordinance or regulation, and (2) damages which result from the violation. OMI Holdings, Inc., v. Howell, 260 Kan. 305, 339, 918 P.2d 1274, 1296 (1996). In addition, plaintiffs must establish that the legislature intended an individual right of action for injury arising out of the violation. Cullip v. Domann, 266 Kan. 550, 555, 972 P.2d 776, 782 (1999). A violation of a statute that neither establishes nor intends a private right of action cannot give rise to a negligence per se claim. See id.; OMI, 260 Kan. at 341, 918 P.2d at 1297; Ks. State Bank & Trust Co. v. Specialized Transp. Servs. Inc., 249 Kan. 348, 370-71, 819 P.2d 587,

[1] Plaintiffs' complaint also refers to a violation of the "Sherman Food, Drug, and Cosmetic Law," a California law. Complaint ¶ 36, attached to Notice Of Removal (Doc. #1). Plaintiffs do not dispute defendants' contention that California law does not apply in this case.

603 (1991).

The parties agree that the FDCA does not expressly provide a private right of action. The critical question is therefore whether, in passing the FDCA, Congress nonetheless intended to allow civil liability based on a violation of the statute. If so, plaintiffs may assert a negligence per se claim under Kansas law based on a violation of the FDCA.

To show that a statutory violation can give rise to a private right of action, plaintiffs must establish that (1) the statute was designed to protect a specific group of people rather than the general public and (2) the legislature intended a private right of action. See Nichols v. Ks. Political Action Comm., 270 Kan. 37, 48, 11 P.3d 1134, 1143 (2000) (quoting Nora H. Ringler Revocable Family Trust v. Meyer Land & Cattle Co., 25 Kan. App. 2d 122, 126, 958 P.2d 1162 (1998)). For purposes of defendants' motion, the Court assumes that plaintiffs can show that the FDCA was designed to protect a specific group of people. Even so, plaintiffs have not shown that Congress intended to let them bring a private right of action based on a violation of the FDCA.

In determining whether the legislature intended to permit a private right of action, the Kansas Supreme Court has set forth the following principles:

> Generally, the test of whether one injured by the violation of a statute may recover damages from the wrongdoer is whether the legislature intended to give such a right. While, in some cases, statutes expressly impose personal liability on persons or entities for violation of the provisions thereof, or for failure to perform specified duties, the absence of such express provisions does not necessarily negate a legislative intent that the statute shall affect private rights. The legislative intent to grant or withhold a private cause of action for a violation of a statute, or the failure to perform a statutory duty, is determined primarily from the form or language of the statute. The nature of the evil sought to be remedied and the purpose the statute was intended to accomplish may also be taken into consideration. The generally recognized rule is that a statute which does not purport to establish a civil liability but merely makes provision to secure the safety or welfare of the

public as an entity is not subject to construction establishing a civil liability.

Greenlee v. Bd. of Clay County Comm'rs, 241 Kan. 802, 804, 740 P.2d 606, 608 (1987); see Pullen v. West, 278 Kan. 183, 194, 92 P.3d 584, 593-94 (2004).

The Kansas Supreme Court has noted that it generally will not infer a private cause of action where a statute provides criminal penalties but does not mention civil liability. See id. at 199, 92 P.3d at 597. The FDCA creates criminal and administrative penalties for statutory violations without expressly providing private remedies. See 21 U.S.C. §§ 332-37. The absence of private remedies in the FDCA strongly suggests that Congress did not intend to allow a private cause of action for violation of the statute. See Pullen, 278 Kan. at 200-01, 92 P.3d at 597; Ks. State Bank, 249 Kan. at 373, 819 P.2d at 604; Greenlee, 241 Kan. at 808, 740 P.2d at 610. Indeed, the United States Supreme Court has held that Congress did not intend a private federal remedy for violations of the FDCA. See Merrell Dow Pharms. Inc. v. Thompson, 478 U.S. 804, 811 (1986). Plaintiffs argue that Congress nevertheless did intend to allow *state* common law claims for violations of the FDCA. See Plaintiffs' Memorandum In Opposition To Eli Lilly's Motion To Dismiss Counts I, III, And IV (Doc. #9) filed June 28, 2005 at 4 (citing Valente v. Sofamour, S.N.C., 48 F. Supp.2d 862, 875-76 (E.D. Wis. 1999)).[2] Although a state by legislation or

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[2] Valente held that although the FDCA did not provide an express statement regarding liability, Congress' clear expression that the Medical Device Amendments ("MDA") were enacted to protect users of medical devices was sufficient under Wisconsin law to show that Congress intended to allow the MDA as a basis for a negligence per se claim under state common law. See id. at 876. Valente emphasized that its holding was limited to the specific FDCA violation related to pre-market approval of a system for inserting screws into individual's spine. See id. The Court declines to follow Valente, which was decided under Wisconsin law. See Alexander v. Smith & Nephew, P.L.C., 98 F. Supp.2d 1310, 1321 (N.D. Okla. 2000) (violations of FDA regulations do not give rise to cause of action for negligence per se in Oklahoma); Bish v. Smith & Nephew Richards, Inc., 2000 WL 1294324, at *3 (Tenn. Ct. App. (continued...)

through common law can create a private state remedy for violations of the FDCA, Kansas has not done so. As explained above, the tort of negligence per se in Kansas is limited to violations of a statute where the legislature intended to create an individual right of action for injury arising out of a statutory violation. See Cullip, 266 Kan. at 555, 972 P.2d at 782. Accordingly, a violation of the FDCA cannot give rise to a negligence per se claim. The Court therefore sustains defendants' motions to dismiss Count III of plaintiffs' complaint.[3]

IT IS THEREFORE ORDERED that Defendant Eli Lilly And Company's Motion To Dismiss Pursuant To Rule 12(b)(6) (Doc. #2) filed April 11, 2005 be and hereby is **SUSTAINED in part**. The

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[2](...continued)
Aug. 23, 2000) (no negligence per se claim under Tennessee law based on FDCA violations); Talley v. Danek Med., Inc., 179 F.3d 154, 161 (4th Cir. 1999) (no negligence per se claim under Virginia law because FDA regulations lacked substantive content); Blinn v. Smith & Nephew Richards, Inc., 55 F. Supp.2d 1353, 1361 (M.D. Fla. 1999) (no negligence per se claim under Florida law for violation of FDCA); Uribe v. Sofamor, S.N.C., 1999 WL 1129703, at *16 (D. Neb. Aug. 16, 1999) (violation of FDCA requirement does not support claim of negligence per se); Rogozinsky v. Danek Med., Inc., 1999 WL 33537323, at *2 (N.D. Ohio July 8, 1999) (no negligence per se claim under Ohio law because FDCA does not allow private right of action); Baker v. Danek Med., 35 F. Supp.2d 875, 878 (N.D. Fla. 1998) (no negligence per se claim under Florida law because FDCA does not provide private right of action); Cali v. Danek Med., Inc., 24 F. Supp.2d 941, 954 (W.D. Wis. 1998); Miller v. Connaught Labs., Inc., 1995 WL 579969, at *9 (D. Kan. Sept. 13, 1995) (no negligence per se claim under Wisconsin law because Congress did not intend to create private right of action under FDCA for claims of misbranding or mislabeling). But see Ezagui v. Dow Chem. Corp., 598 F.2d 727, 733 (2d Cir. 1979) (violations of FDCA labeling requirement can be negligence per se under New York law); Fagan v. AmerisourceBergen Corp., 356 F. Supp.2d 198, 214 (E.D.N.Y. 2004) (same); Prohaska v. Sofamor, S.N.C., 138 F. Supp.2d 422, 448 (W.D.N.Y. 2001) (same); Menges v. Depuy Motech, Inc., 61 F. Supp.2d 817, 829 (N.D. Ind. 1999) (following Valente); Sita v. Danek Med., Inc., 43 F. Supp.2d 245, 262 (E.D.N.Y. 1999) (recognizing private cause of action for negligence per se upon violation of FDCA).

[3] Plaintiffs assert that defendants' compliance with the FDCA is relevant to other claims. Defendant does not dispute this argument. Accordingly, although the Court dismisses Count III of plaintiffs' complaint as a separate claim, plaintiffs may rely on the allegations in that count as support for their other claims.

Court dismisses Count III of plaintiffs' Complaint for failure to state a claim on which relief can be granted. Defendant's motion is otherwise overruled.

IT IS FURTHER ORDERED that Defendant SmithKline Beecham Corporation d/b/a GlaxoSmithKline's Motion To Dismiss Counts I, III And IV Of Plaintiffs' Complaint For Failure To State Claims Upon Which Relief Can Be Granted And Memorandum Of Law In Support (Doc. #41) filed November 14, 2005 be and hereby is **SUSTAINED in part**. The Court dismisses Count III of plaintiffs' Complaint for failure to state a claim on which relief can be granted. Defendant's motion is otherwise overruled.

Dated this 5th day of January, 2006 at Kansas City, Kansas.

s/ Kathryn H. Vratil
KATHRYN H. VRATIL
United States District Court