THE FIRST JUDICIAL DISTRICT OF PENNSYLVANIA, PHILADELPHIA COUNTY
IN THE COURT OF COMMON PLEAS

MARY COLLINS, et al	**: TRIAL DIVISION-CIVIL**
	:
VS.	**: FEBRUARY TERM, 2007**
	: No. 0762
	:
SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE	**: Control # 094007**
	:

F I N D I N G S and O R D E R

This matter comes before the Court on Defendant's Motion for Summary Judgment based upon principles of Federal Preemption.[1] These Findings are limited to the Federal Preemption issue and the subsidiary issues raised in Plaintiffs' Motion to Strike Evidence which is decided herein.

The Motion to Strike Evidence by Plaintiffs asks this Court to decide what may be properly considered by this Court as evidence offered by the Defendant as part of its Motion for Summary Judgment on the issue of preemption.

Before addressing this issue directly, some brief background of this litigation will put the instant issues in context.

Plaintiffs bring this action against the pharmaceutical company, Smith Kline Beecham Corporation, d/b/a GlaxoSmithKline (GSK), under a Product Liability claim for inadequate labeling of its product. Defendant claims that this State tort claim is barred under the doctrine of Federal preemption.

This Court treads deep footsteps when it states that State laws are invalidated when they interfere with or contradict with Federal law. *See Gibbons v. Ogden*, 9 Wheat 1, (1824). This principle emanates from the text of Article VI, cl. 2 of the U.S. Constitution:

> This Constitution, and the laws of the United States which shall be made in pursuance thereof; **. . .** shall be the supreme law of the land; and the judges in every State shall be bound thereby**. . . .** Id.

1 The Court notes that there are other dispositive motions outstanding which will be decided in due course.

Federal preemption can occur where Congress explicitly pre-empts State law or where there is an implied preemption; this implied preemption can be found where Congressional legislation occupies the entire field to the exclusion of State law or there is an actual conflict between Federal and State law. *See Pokorny v. Ford Motor Co.*, 902 F.2d, 1116. (1990).

Defendant claims that the preemption involved here arises because State tort law labeling requirements frustrate the requirements of the FDCA (Federal, Food, Drug and Cosmetic Act, 21 U.S.C. § 301) and thus Defendant cannot possibly comply with both State and Federal law. *See* Defendant's Motion for Summary Judgment on Preemption Grounds, Control #094007 at pp. 26-29, hereinafter "Preemption Motion." This concept is generally known as implied conflict preemption. *See Pokorny, supra*.

The specific conflict centers on Defendant's claim that any State tort claim based upon the product label failing to include specific warnings must necessarily be preempted because the content of any label is exclusively controlled by the FDCA and the FDA actions in support of same. *See* Defendant's Preemption Motion, *supra.* Defendant has offered a variety of sources represented to be statements of the FDA which establish as a matter of law, that the FDA has exclusive control over the content of the product labels and that any State claim which is based upon a different labeling requirement is precluded under Federal preemption principles.

The discussion on whether such statements may be considered under State law now follows.

When ruling on a motion for summary judgment, this Court must consider all facts in the light most favorable to the non-moving party. *See Haney v. Pagnanelli*, 830 A.2d 978, 980 (Pa.Super. 2003). Also, this Court may only consider evidence which would be admissible at trial. *See Curran v. Children's Service Center, Inc.*, 578 A.2d 8, 9 (Pa.Super. 1990).

Movant GSK asks this Court to consider the Amicus Briefs filed in similar litigation in numerous Federal Courts. These Briefs can be found at Exhibits B-E to Defendant's Preemption Motion. GSK relies upon these Briefs as evidence of the FDA's position that State tort law claims based upon labeling requirements are preempted by the FDA regulations. The following paragraphs are a representative example of the contentions found within the Amicus Briefs:

> The Plaintiff in this litigation seeks to impose tort liability on drug manufacturers for failure to warn of an alleged

danger, notwithstanding the Food and Drug Administration's (FDA's) repeated determination during the relevant period that there was not an adequate scientific basis for such a warning. The Court has requested FDA's views on preemption, including specifically the extent to which a court may consider agency views on preemption articulated in the course of a rule-making that post-dates the conduct giving rise to this litigation. The Court has also inquired about the administrative law requirements, if any, applicable to agency views articulated in a preamble to a final rule.

Although FDA has the deepest sympathy for the Plaintiff because of the loss of his wife, it is vital to ensure that State tort law does not undermine FDA's authority to protect the public health through enforcement of the prohibition against false or misleading labeling of drug products in the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §301 et seq. (FDCA). To base a tort judgment on drug manufacturer's failure to warn in October 2003 of an association between adult use of paroxetine hydrochloride and suicide or suicidality, despite FDA's judgment at that time that there was not reasonable evidence of such an association, would be to demand a warning statement that would have been false or misleading, and thus contrary to federal law. In such a case, federal law must prevail.

The preemption principles that require dismissal of the Plaintiff's failure-to-warn claims are well-established, and have been recognized by FDA both in rule-making and in other contexts, dating back long before the events giving rise to this litigation. As the Supreme Court has recognized, it is entirely appropriate for a court applying principles of federal preemption to consider an agency's assessment of its regulatory interests and the extent to which State tort liability would conflict with those interests, even if - which is not the case here - the agency's views are set out after the operative events in question, mark a change in agency position, and are expressed in an amicus brief or other public statement that is not the product of notice-and-comment rulemaking. To the extent that the preamble to the final labeling rule promulgated in 2006 bears on this case, it is appropriately considered by the Court.

Nevertheless, in responding to this Court's inquiries regarding the operative effect of the preamble to the 2006 rule, FDA believes it important to emphasize that the basis for federal preemption in this litigation is not the preamble itself. The agency actions that are the basis for federal preemption in this litigation are FDA's repeated

> determinations between 1991 and 2003 that reasonable evidence did not support a warning on the label for paroxetine hyrocholoride of an association between adult use of the drug and suicide or suidicidality. As we next explain in greater detail, those labeling decisions should be given full force and effect under the Supremacy Clause.

See Defendant's Preemption Motion, Exhibit B, Preemption Brief for Amicus Curiae, The United States of America.

The Brief was authored by various counsel for the FDA, U.S. Dept of Health and Human Services and the Office of the U.S. Attorney General. It is their collective opinion that the various acts and statements of the FDA support the legal conclusion that State tort law in this area would conflict with Federal law.

GSK has identified these documents as Public Records, pursuant to 42 Pa. § 6104, and that as such they are an exception to the Hearsay Rule. *See* Defendant GSK's Opposition to Plaintiffs' Motion to Strike Evidence. Assuming that the documents qualify as Public Records and ostensibly fall under an exception to the Hearsay Rule, they still fail to satisfy the requirements for admission as evidence for purposes of this Summary Judgment Motion.

Pa. R.E. 803(8) governs the admissibility of Public records and reports and states clearly that Pennsylvania has not adopted F.R.E. 803(8):

803(8) Public records and reports [not adopted].

> Comment of the Committee on Rules of Evidence:
> Pennsylvania has not adopted F.R.E. 803(8). An exception to the hearsay rule for public records is provided by 42 Pa. C.S. §6104:
> (a) General rule. -- A copy of a record of governmental action or inaction authenticated as provided in section 6103 (relating to proof of official records) shall be admissible as evidence that the governmental action or inaction disclosed therein was in fact taken or omitted.
> (b) Existence of facts. -- A copy of a record authenticated as provided in section 6103 disclosing the existence or nonexistence of facts which have been recorded pursuant to official duty or would have been so recorded had the facts existed shall be admissible as evidence of the existence or nonexistence of such facts, unless the sources of information or other circumstances indicate lack of trustworthiness.
>
> Subsection (b) of the statute is limited to "facts." It does not include <u>opinions</u> or diagnoses. This is consistent with Pa.R.E. 803(6), as well as Pennsylvania decisional law interpreting 42 Pa. C.S.A. §6108 (Uniform Business Records

As Evidence Act). See Comment to Pa.R.E. 803(6).

As demonstrated above, Subsection (b) of § 6104, limits the admissibility of official records to facts only and refers to Pa.R.E. 803(6), whose comment further explains why both the statutory provision, 42 Pa.C.S.A §6104, and the Civil Rule do not allow for the admission of opinion in a hearsay document:

> Pa. R.E. 803(6) is similar to F.R.E. 803(6) but with two (2) differences. One difference is that Pa. R.E. 803(6) does not include opinion and diagnoses. *See Williams v. McClain*, 513 Pa. 300; 520 A.2d 1374 (1987).

See Comment to Pa.R.E. 803(6).

In *Williams v. McClain, supra*, our Supreme Court affirmed the principle that hearsay opinion evidence is inadmissible.[2]

Because these Amicus Briefs, under Pennsylvania law, are considered hearsay documents containing inadmissible opinion evidence, they will not be considered by this Court for the purpose of this Preemption Motion.[3]

The predicate facts are that the instant action is brought by Mary A. Collins, individually and as Personal Representative of the Estate of Bobby R. Collins ("Decedent"), and by Dwayne R. Collins and Kristin Collins, Individually. Plaintiffs are the wife and adult children of the deceased. *See* Short-Form Complaint, ¶ 1. Decedent was initially seen by a gastroenterologist on January 16, 2002, for symptoms of colitis. The doctor diagnosed Decedent with stress related depression which was exacerbating his colitis. He was prescribed Paxil, 20mg, by the gastroenterologist and then referred to a psychiatrist. *See* Short-Form Complaint, ¶ 2. On or about January 16, 2002, Decedent began taking his recommended dosage. His daily dosage was increased to 30mg on January 30, 2002, which he took until February 14, 2002, the day he committed suicide. *See* Short-Form Complaint, ¶ 3.

The gravamen of Plaintiffs' action here is that Defendant GSK failed to adequately warn decedent of the association between the ingestion of Paxil and suicide or suicidality.

GSK answers in part that the issue of the adequacy of the content of the Paxil label at the time of Decedent's use and subsequent suicide cannot be the subject of a

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2. See generally, Bernstein, 2008 Pa. Rules of Evidence, Comment 7 to Pa.R.E. 803(6), Gann.
3. As will be discussed below, even if these Amicus Briefs were considered admissible evidence regarding the FDA's opinion on the issue of Federal Preemption, such is accorded no weight in this Court's decision on Federal Preemption.

State tort claim because Federal law has preempted any such review. There is no question that if there is conflicting Federal law on this issue, the Supremacy Clause of the U.S. Constitution mandates such an outcome. *See Pokorny, supra*.

There is also no question that any such analysis of preemption must be viewed through the prism of Federalism which recognizes that the States are independent sovereigns in our Federal system and that Congress does not cavalierly preempt State causes of action. *See Rice v. Santa Fe Elevator Corp*.331 U.S. 218, 230, 91 L.Ed.1447.

In *Retail Clerks v. Schemerhorn,* 375 U.S. 96, 11 L.Ed. 2d 179, 84 S.Ct. 219 (1963), the Court began its analysis of the preemption issue by first focusing on "[t]he purpose of Congress [as] the ultimate touchstone." *Id*. at 103 (emphasis supplied). Where Congress has legislated in a field which the States have traditionally occupied, we must begin with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress. *See Rice, supra*.

Historically, the several States have possessed broad powers to protect the "lives, limbs, health, comfort and quiet of all persons" within the State. *Slaughter House Cases,* 16 Wall 36, 62 (1873) (quoting, *Thorpe v. Rutland & Burlington R. Co*., 27 Vt. 140, 149 (1855)).

In *Metropolitan Life Insurance Co. v. Massachusetts*, 471 U.S. 724, 105 S.Ct. 2380, 85 L.Ed. 2d 728 (1985), the Court had before it a case wherein it was required to interpret two competing statutory provisions of the Federal Employee Retirement Security Act (ERISA) which appeared to give back to the States what it had previously taken away in the same Act (referring to a general preemption clause which was qualified by a savings clause). The Court said:

> [Although] [f]ully aware of this statutory complexity, we still have no choice but to 'begin with the language employed by Congress and the assumption that the ordinary meaning of that language accurately expresses the legislative purpose.' We also must presume that Congress did not intend to pre-empt areas of traditional State regulation.

Id. at 740 (internal citations omitted).

As an additional component to this analysis, we view this from the understanding that where preemption is at issue under the Supremacy Clause, the burden falls upon the party promoting preemption because there is a presumption against preemption in our

system of co-equal sovereigns. *See Rice, supra*.

Therefore, this Court proceeds guided by these "bedrock" principles of Federal Preemption analysis:

1. If the police powers of the State are to be superseded it must be the clear and manifest purpose of Congress; and

2. There is a presumption against preemption which must be rebutted by the entity claiming such.

This issue comes to this Court in the form of the action filed by Plaintiffs which centers on the content of the label accompanying the Paxil product at the time it was prescribed for and ingested by the Decedent. Plaintiffs claim that the label inadequately expressed the relationship between ingestion of the drug and suicide or suicidality.

Plaintiffs further claims that she has a right to test this issue in State Court under the State's common-law tort law to determine whether Defendant GSK fulfilled its duty to warn. Thus, the question before this Court is whether Congress has precluded Plaintiffs from bringing this action.

It is uncontested that Defendant claims preemption not through express preemption as a result of any specific Congressional enactment or through field preemption as a result of Congress' intent to occupy the area under scrutiny as a whole. What Defendant claims is that there is conflict preemption, because allowing Plaintiffs' action to proceed under State law to determine the adequacy of Defendant's label would conflict with the FDA's exclusive authority to determine the content of the label.

A review of this legislation and accompanying regulation supports the opposite view.

The first expression of Congress' intent not to preempt this State cause of action is found in the Congressional Hearings leading up to the passage and implementation of the original version of the FDCA. The draft version of the Act included a provision for creating a Federal cause of action. This provision was rejected because, "a common law right of action exists." *See* Adler v. Mann, Preemption and Medical Devices: The Courts Run Amok, 59 Mo. L. Rev. 895, 924 and supporting cite at N. 130.[4]

The next expression of Congress, or in our case lack thereof, regarding preemption, may be found in the text of the statute under consideration.

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4. H.R.6110, 73d Cong., 1st Sess.Section 25 (1933); S. 1944, 73d Cong., 2d Sess. Section 24 (1933). See Hearings Before a Subcommittee of the Committee on Commerce of the United States Senate on S. 1944, 73d Cong., 2d Sess. 400, 403 (1933).

The process for approval of any new drug in the Unites States begins with an application for approval, pursuant to Section 505(b) of the Federal Food, Drug and Cosmetic Act, (FDCA), 21 U.S.C. § 355b. On November 20, 1989, Defendant, (then known as Smith Kline Beecham Pharmaceuticals) filed a New Drug Application (NDA) for Paxil (paroxitine) for the treatment of depression in adults. *See* Defendant's Preemption Motion, Exhibit A, Arning Decl. ¶ 19. It is undisputed that the drug was approved and was then marketed and sold.

The over-arching section of the FDCA which controls the labeling of Paxil is 21 U.S.C. § 355d, which prohibits false and misleading statements in product labeling as part of the requirements for approval of a NDA. A review of 21 U.S.C. § 355d shows that the burden on an applicant at all stages of the NDA is to support its claims with, "investigation," "adequate testing," and "substantial evidence" that the drug will do what it claims in the proposed labeling thereof.[5] With respect to the labeling requirement, Subsection (7) provides that the NDA may be refused if the labeling is false or misleading in any particulars. Of note is the definition of the term "substantial evidence" which means "evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof." *See* 21 U.S.C. § 355d.

Subordinate regulations which govern this area are 21 C.F.R. § 201.80(e). 21 C.F.R.201.80 generally controls the "specific requirement on content and format of labeling for human prescription drugs . . ." Subsection (e) further requires that "[t]he labeling shall be revised as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved." *Id.* (emphasis supplied).

Further and critical to our analysis here is C.F.R § 314.70(c) (6) (iii). Section 314.70 is titled "Supplements and Other Changes to an Approved Application" and subsection (a) thereunder requires that "an applicant must notify the FDA about each change in each condition established in an approved application." Under Subsection (c)

5.This again demonstrates the level of burden upon the applicant to supply the "evidence" necessary for application approval.

(6), "the holder of an approved application may commence distribution of the drug product involved upon receipt by the agency of a supplement for change."

> These changes include but are not limited to . . .
> Changes in the labeling … to accomplish any of the following:
> (A) To add or strengthen a contraindication warning, precaution or adverse reaction;
> (B) To add or strengthen a statement about drug abuse, dependence, psychological effect or overdosage.

See C.F.R § 314.70(c) (6).

Therefore, under a plain reading of these Statutes and Regulations, a possessor of an existing NDA shall supplement the label on its product when it has reasonable evidence of a hazard, "a causal relationship need not have been proved." *See* C.F.R § 314.70(c) (6); 21 C.F.R. § 201.80(e).

Plaintiffs are litigants in this Court's Mass Tort Paxil Program and have alleged (along with all members in the Mass Tort Paxil Program) that:

> GSK breached said duty by failing to comply with federal regulations concerning the study, testing, design, development, manufacture, mixing, inspection, productions, labeling, advertisement, marketing, promotion, distribution, and/or sale of prescription drugs ,including but not limited to, 21 CFR §§ 201.57 (now 201.80(e)) and 314.70.

See Paxil Long-Form Complaint, ¶ 105. The question that Plaintiffs pose in their State tort claim is whether the manufacturer had information at the time of the Decedent's suicide that would have required it to supplement the label on its product to include information about the relationship between the use of its drug and subsequent suicidal behavior.

Defendant asserts that such inquiry is precluded by Federal law since the content of the drug's label is governed by Federal law and the duty to supplement the label is somehow subsumed into the FDA regulatory scheme. Defendant's position is clearly not sustainable. Federal law in question unquestionably places the duty upon the manufacturer and does not preempt a State's ability to allow one of its citizens to inquire into whether the manufacturer breached that duty.

Defendant fails to point to any specific statutory provision to support its position but relies instead upon Amicus Briefs submitted on behalf of the FDA:

> [I]t is critical to understand that, where warnings are concerned, more is not always better. FDA seeks to

> encourage the optimal level of use in light of reasonable safety concerns, by requiring scientific evidence that establishes an association between a drug and a particular hazard before warning of that association on a drug's labeling. *See* 21 C.F.R. § 201.80(e). Under-use of a drug based on dissemination of unsubstantiated warnings would deprive patients of efficacious and possibly lifesaving treatment . . . The plaintiff challenges the district court's reliance on public document warnings would likely reduce the impact of valid warnings by creating an unnecessary distraction and making even valid warnings less credible. In order to make appropriate judgments about drug use, prescribers need a "careful and truthful representation of benefits and risks," which does not "discourage appropriate use of a beneficial" through the inclusion of unsubstantiated risks.

See Colacicco, 3d Cir. *Amicus* Br. at 16-17, Defendant's Preemption Motion, Exhibit C.

Defendant further claims that the FDA's preamble to its January 2006 labeling rule interprets the FDCA and its accompanying regulations as preempting State law failure to warn claims:

> In the preamble to its January 2006 labeling rule, FDA explains its approach to the disclosure of additional risk information (including warnings) as follows: 'Given the comprehensiveness of FDA regulation of drug safety, effectiveness, and labeling under the act, additional requirements for the disclosure of risk information are not necessarily more protective of patients. Instead, they can erode and disrupt the careful and truthful representation of benefits and risks that prescribers need to make appropriate judgments about drug use. Exaggeration of risk could discourage appropriate use of a beneficial drug.' 71 *Fed. Reg.*at 3935 (2006); *see also* FDA *Amicus* Letter Brief, dated September 21, 2006, 2006 U.S. Dist.LEXIS 75319, at 2-4, filed in *Perry v. Novartis Pharm.,Inc., et al.,* 456 F. Supp. 2d 678 (E.D. Pa.2006) ("*Perry Amicus* Letter") (Attached as Exhibit "F").

Defendant's Preemption Motion, pp 7-8, FN. 6.

This Court rejects Defendant's theory of preemption for a number of reasons.

Initially, there is no need to resort to interpretation of either the FDCA or the supporting regulations because there is no ambiguity in either. *See Chevron, U.S.A., Inc. v. NRDC, Inc*., 467 U.S. 837, 844. As a predicate issue to interpreting a statute, the Court first looks to see, "if the statute is silent or ambiguous with respect to the specific

issue" and if so, determines whether the agency's "answer is based on a permissible construction of the statute." *See Chevron* 467, U.S. at 843-844. When a party claims that Federal law is displacing State law, it must first be established that Congress intended such displacement and the first analysis that must be conducted is to look at what Congress actually said in this regard. *See Sprietsma v. Mercury Marine*, 537 U.S. 51, 62-63 (U.S. 2002) ("[O]ur 'task of statutory construction must in the first instance focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent'"). Here, the FDCA is silent on this issue.

Second, Defendant suggests that the need to change the labeling of its product is discretionary with the manufacturer and therefore, implies that no duty is involved:

> Among others, changes to add or strengthen a contraindication, warning, precaution, or adverse reaction may be the subject of a CBE ("Change Being Effected") supplement. §314.70(c)(6)(iii)(A). The CBE regulation does not however, exist in a vacuum. Warnings added through a CBE -- like all warnings--remain subject to § 201.57(e) and may only be added when there is "reasonable evidence of an association of a serious hazard with a drug . . . ." Thus, if there is no scientific support for a warning, the CBE regulation effectively becomes unavailable.

See Defendant's Preemption Motion, p. 10 (emphasis supplied).

Defendant's interpretation is not an accurate reading of the regulation concerned. 21 CFR 201.57(e) does not currently exist as it has been re-codified. *See* 71 F.R. 3988, 1-24-06. It is currently embodied in 21 CFR 201.80(e), which, as previously discussed, provides that the manufacturer "shall" revise the label, "as soon as there is reasonable evidence of an association of a serious hazard with a drug." *Id.* The use of the word "shall" means that an act becomes mandatory and by its very nature creates a duty to act. A necessary element to maintain an action in negligence is a duty or obligation recognized by the law, requiring the actor to conform to a certain standard of conduct. *See* Prosser Law of Torts, § 30 (4th Ed., 1971).

Defendant also claims that a prescription drug could be misbranded if it "included warning information not based on reliable scientific evidence of known risks." *See* Preemption Motion, pp. 7-6, FN. 6. This is the "exaggeration of risk" argument that Defendant claims could discourage use of a beneficial drug. *See id.*

Defendant then cites 21 U.S.C. 352(a) and 352(f)(1), as containing this requirement. *See* Defendant's Preemption Motion, p. 8. A close reading of these

sections, however, reveals that neither the specific language used by Defendant or any other language contained therein support its claim. This Court will not read into these sections language Congress did not put there or was not implemented through regulations by the agency under authority granted by Congress. *See Chevron*, 467 U.S. at 843-844 ("If Congress has explicitly left a gap for the agency to fill, there is an express delegation of authority to the agency to elucidate a specific provision of the statute by regulation.").

Defendant maintains that State law should be preempted and as a result thereof Plaintiffs' State tort claim based upon Defendant's failure to warn must necessarily be dismissed. The parties do not contest that Plaintiffs would have no Federal forum to litigate their claim or any other remedy to compensate them for any damages they may suffer. This is because no Federal Statute or Regulation exists which allows recovery for such claims.

In *Merrell Dow Pharmaceuticals, Inc. v. Thompson, et al*., 478 U.S. 804, 106 S. Ct. 3229, 92 L.Ed, 2nd 650 (1986), the Supreme Court had before it a case substantially similar to the instant matter:

> The Thompson respondents are residents of Canada and the MacTavishes reside in Scotland. They filed virtually identical complaints against petitioner, a corporation, which manufactures and distributes the drug Bendectin. The complaints were filed in the Court of Common Pleas in Hamilton County, Ohio. Each Complaint alleged that a child was born with multiple deformities as a result of the mother's ingestion of Bendectin during pregnancy. In five of the six counts, the recovery of substantial damages was requested on common-law theories of negligence, breach of warranty, strict liability, fraud, and gross negligence. In Count IV, respondents alleged that the drug Bendectin was "misbranded" in violation of the Federal Food, Drug, and Cosmetic Act (FDCA), 52 Stat. 1040, as amended, 21 U.S.C. § 301 et seq.(1982 ed. and Suppl III), because its labeling did not provide adequate warning that its use was potentially dangerous. Paragraph 26 alleged that the violation of the FDCA "in the promotion" of Bendectin "constitutes a rebuttable presumption of negligence." Paragraph 27 alleged that the "violation of said federal statutes directly and proximately caused the injuries suffered" by the two infants.

Merrell Dow, 478 U.S. at 805.

The issue before the *Merrell Dow* Court was whether the Plaintiffs' allegation

regarding a violation of federal law was sufficient to trigger exclusive federal jurisdiction. The Court held that such issue raised in a State tort claim along with other tort claims was an appropriate matter to be tried in State Court. In arriving at this conclusion, the Court placed significant reliance upon the fact that the FDCA did not provide a Federal cause of action.

It is also noted that at the time of its analysis of the "federal question" issue in *Merrell Dow, supra*, the Court had before it substantially the same FDCA that is at issue before this Court. By virtue of its holding that the tort claim was an appropriate matter to be tried in State court, the Court implicitly found that preemption did not exist as an impediment to a State court action for a "misbranded label".

In *Silkwood v. Kerr-McGee*, 464 U.S. 238, 104 S.Ct. 615, 78 L.Ed. 2nd 443 (1984) the Supreme Court had before it a case where a plutonium leak was found to have injured plaintiff, an employee of defendant.

In discussing the reach of Congress' regulatory enactments, the Court said:

> Congress' decision to prohibit the State from regulating the safety aspects of nuclear development was premised on its belief that the Commission was more qualified to determine what type of safety standards should be enacted in this complex area. As Congress was informed by the AEC, the 1959 legislation provided for continued federal control over the more hazardous materials because "the technical safety considerations are of such complexity that it is not likely that any State would be prepared to deal with them during the foreseeable future." H.R. Rep. No. 1125, 86 Cong., 1st Sess., 3 (1959). If there were nothing more, this concern over the States' inability to formulate effective standards and the foreclosure of the States from conditioning the operation of nuclear plants on compliance with state-imposed safety standards arguably would disallow resort to state-law remedies by those suffering injuries from radiation in nuclear plant. There is, however, ample evidence that Congress had no intention of forbidding the States to provide such remedies.
>
> Indeed, there is no indication that Congress even seriously considered precluding the use of such remedies either when it enacted the Atomic Energy Act in 1954 or when it amended it in 1959. This silence takes on added significance in light of Congress' failure to provide any federal remedy for persons injured by such conduct. It is difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct. See, *Construction Workers v. Laburnum Corp.*, 347 U.S. 656, 663-

664 (1954).

Silkwood, 464 U.S. at 250-51.

We have here a situation while similar to that in *Silkwood,* lends even more support to Plaintiffs' position that their claim is not preempted. To wit—Congress in its enactment of the FDCA specifically chose not to provide a federal remedy under the Act in the face of the availability of a State common law right of action. *See* H.R.6110, 73d Cong., 1st Sess.Section 25 (1933), *supra; Merrell Dow, supra*. In the instant matter "Congress has neither provided nor suggested any substitute for the traditional state court procedure for collecting damages for injuries caused by tortious conduct. For us to cut off the injured [Plaintiffs] from this right of recovery. . . . will, in effect, grant Defendant immunity from liability for its tortious conduct." *United Constr. Workers v. Laburnum Constr. Corp*., 347 U.S. 656, 663-664 (U.S. 1954). Thus, in light of the foregoing and Congress' silence on this issue, Plaintiffs' damages claim is not preempted.

Therefore, considering the above and the record as a whole, Defendant's Motion for Summary Judgment based upon Federal Preemption is DENIED.

BY THE COURT:

3-11-2008
_____
DATE

_____
ALLAN L. TERESHKO, J.
COORDINATING JUDGE,
COMPLEX LITIGATION PROGRAM

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