UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

ANDREA FRISCHHERTZ, wife of/and BRAD FRISCHHERTZ, individually and on behalf of the minor child, E.F.	**CIVIL ACTION**
VERSUS	**NO. 10-2125**
SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE	**SECTION "C"(4)**

ORDER & REASONS

Before the Court are six motions: (1) Defendant GlaxoSmithkline LLC's Motion to Exclude the Testimony of Susan R. Andrews, Ph.D. Rec. Doc. 185; (2) Defendant GlaxoSmithKline LLC's Motion to Exclude the Testimony of Joseph A. Hirsch, Ph.D. Rec. Doc. 186; (3) Defendant GlaxoSmithKline LLC's Motion to Exclude the Testimony of Paul Goldstein, Ph.D. Rec. Doc. 187; (4) Defendant GlaxoSmithKline LLC's Motion to Exclude the Testimony of Shira Kramer. Rec. Doc. 188; (5) Defendant GlaxoSmithKline LLC's Motion to Strike the Testimony of Edward J. Trapido, Sc.D. Rec. Doc. 190; and (5) Defendant GlaxoSmithKline LLC's Renewed Motion for Summary Judgment. Rec. Doc. 233. On October 3, 2012, the Court held a *Daubert* hearing where oral argument was heard on motions (3) through (5). Rec. Doc. 229. The plaintiffs and defendant also filed post-hearing briefs. Rec. Docs. 245, 246. The most significant motions in terms of impact upon the case are Rec. Doc. 187 and Rec. Doc. 188 concerning the testimony of Paul Goldstein, Ph.D. and Shira Kramer, Ph.D. and Rec. Doc. 233, the defendant's renewed motion for summary

judgment. For that reason the Court will address these only.

1. Defendant GlaxoSmithKline LLC's Motion to Exclude the Testimony of Paul Goldstein, Ph.D. is GRANTED. Rec. Doc. 187

2. Defendant GlaxoSmithKline LLC's Motion to Exclude the Testimony of Shira Kramer is GRANTED. Rec. Doc. 188.

3. Defendant GlaxoSmithKline LLC's Renewed Motion for Summary Judgment is GRANTED. Rec. Doc. 233.

Plaintiffs Andrea Frischhertz and her husband Brad Frischhertz bring this claim on behalf of their son, E.F., a minor (hereinafter collectively "plaintiffs") against GlaxoSmithKline ("GSK"), the manufacturer of Paxil. Plaintiffs concede that their only claim remaining is for inadequate warning under the Louisiana Products Liability Act ("LPLA"). Rec. Doc. 139, p.1., n.1.

I. BACKGROUND

The petition for damages alleges that plaintiff, Andrea Frischhertz, took Paxil as prescribed by her doctor while she was pregnant with E.F. Rec. Doc.1. Paxil is a Selective Serotonin Reuptake Inhibitor (SSRI) commonly prescribed to treat depression. As a result of the medication, the petition for damages and the first amended and supplemental complaint allege that E.F. was born with "incomplete development of the cardiac septum, and irreversible birth defects" including cardiac deformities and Holt-Oram Syndrome. (Rec. Doc. 64). Holt-Oram Syndrome is a heart-hand syndrome that is characterized by hand abnormalities and an atrial septal defect. The defendant contests whether E.F. has this syndrome. The parties agree that E.F. has a limb abnormality that

makes his fingers on his right hand smaller than his left. E.F. was born March 30, 2005. Plaintiffs allege that GSK had knowledge that Paxil caused birth defects while taken during pregnancy before Mrs. Frischhertz took the medication during her pregnancy with E.F. but did not release this information until September 2005.

II. LEGAL STANDARDS FOR ADMISSIBILITY–*DAUBERT*

The United States Supreme Court revised the standards for admitting scientific evidence under the Federal Rules of Evidence in *Daubert v. Merrell Dow Pharmaceuticals Inc.*, 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993). The Court began with the "baseline" principle that "all relevant evidence is admissible" unless excepted by the Constitution, a statute or rule and that the standard of relevance "is a liberal one." FED.R.EVID. 402; *Daubert*, 509 U.S. at 585-589, 113 S.Ct. at 2793-94. The Court found that Rule 702[1] obliges the trial judge to act as a "gatekeeper" and screen scientific evidence for reliability and relevance. FED.R.EVID. 702; *Daubert*, 509 U.S. at 595, 113 S.Ct. at 2798. Regarding reliability, the Court said: "the subject of an expert's testimony must be 'scientific . . . knowledge.' The adjective 'scientific' implies a grounding in the methods and procedures of science. Similarly, the word 'knowledge' connotes more than subjective belief or unsupported speculation." *Daubert*, 509 U.S. at 589-590, 113 S.Ct. at 2795.

[1]A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.

The Court suggested several factors in determining reliability. Of particular importance is whether "the theory or technique . . . can be (and has been) tested." *Daubert*, 509 U.S. at 593, 113 S.Ct. at 2796. Another factor is whether the theory or technique has been subjected to evaluation by peer review and publication. A third factor is the known or potential rate of error in the technique and the existence and maintenance of standards governing its operation. A final consideration is whether the theory or technique has been generally accepted in the scientific community.

The Court stressed that the standard under Rule 702 is a "flexible one." The Court emphasized also that the focus of the inquiry is "solely on principles and methodology, not on the conclusions that they generate." *Daubert*, 509 U.S. at 595, 113 S.Ct. at 2797.

The Court favored admission of evidence on the borderline. "Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional, and appropriate means of attacking shaky but admissible evidence." *Daubert*, 509 U.S. at 596, 113 S.Ct. at 2798. At the same time, the Court recognized the significant difference between the "quest for truth in the courtroom and the quest for truth in the laboratory." *Daubert*, 509 U.S. at 596-97, 113 S.Ct. at 2798. Scientific inquiry must necessarily be broad and far-reaching, with the reliability of theories under continuous study and revision. Resolution of a legal dispute, on the other hand, involves binding, final judgments that cannot be based on conjecture. Consequently, there may well be "authentic insights and innovations" of science that are nonetheless inadmissible in a court of law. *Daubert*, 509 U.S. at 595-99, 113 S.Ct. at 2798-2799.

III. ADMISSIBILITY OF EXPERTS

A. Testimony of Paul Goldstein, Ph.D.

Dr. Goldstein is a toxicology and genetics expert. He has a Ph.D. in genetics from York University in Toronto. Rec. Doc. 211, Exh. A. At the time Dr. Goldstein received his Ph.D., there was no formal toxicology degree available. Rec. Doc. 211. Despite that, his research and teachings demonstrate his qualifications in toxicology. Defendant wishes to exclude him based on his lack of training in epidemiology, pharmacology and teratology and the fact that he does not have a formal degree in toxicology. Rec. Doc. 187. Dr. Goldstein, a toxicologist, has the relative expertise to opine on the toxicological effects of Paxil. He is not disqualified from rendering a causation opinion because he does not have a medical degree. *In re Fema Trailer Formaldehyde products Liability Litigation*, No. 07-1873, 2009 WL 4508546 (E.D. La. Nov. 24, 2009).

However, Dr. Goldstein's methodology does not meet the requirement for scientific knowledge under *Daubert.* 509 U.S. at 589-590, 113 S.Ct. at 2795. Dr. Goldstein bases his general causation opinion on the "Sloot Paper." Dr. Anthony Scialli testified at the *Daubert* hearing. He is a physician and board certified in OB-GYN and is the director of the Reproductive Toxicology Center, which provides information to physicians and others on the effects of chemicals on reproduction. Rec. Doc. 239, pp.56-60. At the *Daubert* hearing, Dr. Scialli testified in detail regarding the Sloot Paper. He opined that Whole Embryo Cultures as described in the article are inappropriate for assessing what is a teratogen in human risk assessment. He in fact wrote a letter to the journal criticizing the article which was subsequently published as well. As a result of the article, the authors clarified that Whole Embryo Culture tests are not intended to identify teratogens. Rec. Doc. 239, pp. 77-81. Dr. Goldstein agreed that Whole Embryo Cultures are not a basis for

predicting human risk. He stated that such studies are of value in generating a *hypothesis*, which he agreed was just the "first step in that process." Rec. Doc. 187, Exh. 2, depo. Goldstein, pp. 138-139.

Dr. Goldstein's causation analysis also did not meet the required level for peer review or the standard that is accepted in his professional community, and he appears to have inappropriately applied the Bradford-Hill criteria for both general and specific causation. The Bradford-Hill criteria can only be applied after a statistically significant association has been identified. Federal Judicial Center, Reference Manual on Scientific Evidence, 599, n.141 (3d. ed. 2011) ("In a number of cases, experts attempted to use these guidelines to support the existence of causation in the absence of any epidemiologic studies finding an association . . . . There may be some logic to that effort, but it does not reflect accepted epidemiologic methodology."). *See, e.g., Dunn v. Sandoz Pharms.*, 275 F. Supp. 2d 672, 678 (M.D.N.C. 2003). Here, Dr. Goldstein attempted to use the Bradford-Hill criteria to prove causation without first identifying a valid statistically significant association. He first developed a hypothesis and then attempted to use the Bradford-Hill criteria to prove it. Rec. Doc. 187, Exh. 2, depo. Goldstein, p. 103. Because there is no data showing an association between Paxil and limb defects, no association existed for Dr. Goldstein to apply the Bradford-Hill criteria. Hence, Dr. Goldstein's general causation opinion is not reliable.

The defendants offered Dr. Goldstein as an expert on general and specific causation, meaning that the plaintiffs allege Dr. Goldstein is an expert who can opine on (1) whether Paxil can cause birth defects at all and (2) whether Paxil caused the birth defects in this instance. Dr. Goldstein stated at his deposition that he no longer held the view that E.F. had a heart defect. Rec. Doc. 233,

Exh. S, depo. Goldstein, pp. 131-32. Dr. Goldstein's specific causation opinion as to limb defects must be excluded because it is not based on reliable scientific analysis or evidence. Dr. Goldstein testified to specific causation based on the fact that he believes Paxil is a teratogen and he believes that if a teratogen is present "it could possibly affect the developing cells in the–either the hand limb–or hand bud . . . ." *Id.*, p. 104. However, Dr. Goldstein also conceded that he knew of no evidence in humans or animals that demonstrates that Paxil is a limb teratogen, and he does not know if it is. *Id.*, p. 114. Hence, his hypothesis is pure speculation.

The Supreme Court requires that "an expert . . . employ[] in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *In re Silica Prods. Lab. Lithog.*, 398 F. Supp. 2d 563, 639 (S.D. Tex. 2005) (*quoting Kuhmo Tire Co., Ltd. V. Carmichael*, 526 U.S. 137, 152 (1999)). Dr. Goldstein has demonstrated that his causation analysis did not meet the required level for peer review or the standard that is accepted in his professional community.

B. Testimony of Shira Kramer, Ph.D.

Dr. Shira Kramer offers testimony on general causation such as whether a pregnant woman's ingestion of Paxil during the first trimester of pregnancy can cause limb or heart defects. Dr. Kramer's report did not offer an opinion as to specific causation. Rec. Doc. 233, Exh. U, depo. Kramer, pp. 44-45. Dr. Kramer's general causation opinion is that (1) Paxil affects levels of serotonin in the developing embryo, and (2) this effect can cause limb defects. Rec. Doc. 233, Exh. U, depo. Kramer, pp. 74-77.

Dr. Kramer is not qualified to offer an opinion based on serotonin's impact on limb defects.

While she theorizes about "perturbation of serotonin levels," *Id.*, pp. 81-86, 92-93, Dr. Kramer is an epidemiologist and is not qualified to make the reaching arguments she makes about serotonin levels during pregnancy. Indeed, she has in other litigation conceded she is not an expert in serotonin. Rec. Doc. 188, Exh. 19, p. 81. Dr. Kramer cites to numerous epidemiological studies in her report, Rec. Doc. 188, Exh. 3, p. 31-55, but admits that this literature is "more or less noncontributory" to the correlation between Paxil exposure and limb defects. Rec. Doc. 233, Exh. U, depo. Kramer, p. 117. Dr. Kramer relies on "biological plausibility and temporality" to support her hypothesis that Paxil can cause limb defects. *Id.*, p. 119. However, beyond this assertion, Dr. Kramer does not offer any articles supporting her serotonin theory. Indeed, plaintiffs' own expert pharmacologist, Dr. Joseph Hirsch, acknowledged that nothing in his review of the scientific literature indicated that Paxil administered to pregnant animals disrupts embryonic serotonin. Rec. Doc. 188, Exh. 25, p. 60.

Furthermore, Dr. Kramer's methodology does not meet the required standard. Dr. Kramer "lumps" all congenital malformations together to make her analysis. Rec. Doc. 188, Exh. 3, p. 30. This technique is not generally accepted by the scientific community and is unreliable. *Chambers v. Exxon Corp.*, 81 F. Supp. 2d 661 (M.D. La. 2000), *aff'd*, 247 F.3d 240 (5th Cir. 2001) (unpublished). Dr. Kramer has not demonstrated by a statistically significant measure that Paxil could be a general cause of limb or heart defects if ingested during the first trimester of pregnancy. While plaintiffs contend the fact that no epidemiology exists that provides a statistically significant association between Paxil and E.F's hand malformation is excused by the "rarity of E.F.'s malformation," the law cannot leap ahead of the science. Rec. Doc. 246, p. 4. *Wells v. SmithKline*

Beecham Corp., 601 F.3d 375, 381 (5th Cir. 2010).

IV. SUMMARY JUDGMENT

A. Plaintiffs' claims under the Louisiana Products Liability Act

Under the LPLA, there is a two-pronged test for inadequate-warning claims when the learned intermediary doctrine is applicable. The plaintiff must show (1) that the defendant failed to adequately warn the physician of a risk associated with the product that was not otherwise known to the physician; and (2) that this failure to warn the physician was both a cause in fact and the proximate cause of the plaintiff's injury." *Stahl v. Novartis Pharmaceuticals Corp.*, 283 F.3d 254, 265-266 (5th Cir. 2002) (*citing Willett v. Baxter Int'l Inc.*, 929 F.2d 1094, 1098 (5th Cir. 1991)).

B. Standard of Review

Rule 56 of the Federal Rules of Civil Procedure states: "The Court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." FED.R.CIV.P. 56. When considering whether any genuine issues of material fact exists, courts view the evidence and inferences drawn from that evidence in the light most favorable to the non-moving party. *United States ex re. Reagan v. East Texas Medical Center Regional Healthcare System*, 384 F.3d 168, 173 (5th Cir. 2004) (*citing Daniels v. City of Arlington, Texas*, 246 F.3d 500, 502 (5th Cir. 2001)).

An issue is material if its resolution could affect the outcome of the action. *Wyatt v. Hunt Plywood Co., Inc.*, 297 F.3d 405, 409 (5th Cir. 2002) (*citing Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248, 106 S.Ct. 2502, 91 L.Ed.2d 202 (1986)). A factual dispute precludes summary judgment if the evidence would permit a reasonable jury to return a verdict for the nonmoving party.

Hunt v. Rapides Healthcare Sys. LLC, 277 F.3d 757, 762 (5th Cir. 2001).

The party moving for summary judgment bears the initial burden of "informing the district court of the basis for its motion, and identifying those portions of [the record] which it believes demonstrate the absence of a genuine issue of material fact." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). "If the moving party meets the initial burden of showing that there is no genuine issue of material fact, the burden shifts to the non-moving party to produce evidence or designate specific facts showing the existence of a genuine issue for trial." *Engstrom v. First Nat'l Bank of Eagle Lake*, 47 F.3d 1459, 1462 (5th Cir. 1995) (*citing Celotex*, 477 U.S. at 322-24). In order to satisfy its burden, the nonmoving party must put forth competent evidence and cannot rely on "unsubstantiated assertions" and "conclusory allegations." *See e.g., Hopper v. Frank*, 16 F.3d 92 (5th Cir. 1994); *Lujan v. Nat'l Wildlife Federation*, 497 U.S. 871, 871-73 (1990). The mere argued existence of a factual dispute will not defeat an otherwise properly supported motion. *See Anderson v. Liberty Lobby Inc.*, 477 U.S. 242, 247-48 (1996). "If the evidence is merely colorable, or is not significantly probative," summary judgment is appropriate. *Id.* at 249-50.

C. Law and Analysis

Defendants move for summary judgment on plaintiffs claim under the LPLA on the basis that neither of Drs. Paul Goldstein nor Shira Kramer provide admissible expert testimony on general or specific causation. Rec. Doc. 233, p. 2. Therefore, defendants argue that plaintiffs have failed to establish the effect of Paxil on E.F. during Mrs. Frischhertz' pregnancy. *Id.*

Under Louisiana jurisprudence, the plaintiff in a personal injury suit, including suits under the LPLA, bears the burden of proving by a preponderance of the evidence that there was a causal

relationship between his or her injury and the accident or use of the product. *Maranto v. Goodyear Tire & Rubber Co.*, 650 So.2d 757, 759 (La.2/20/95). The test for determining the causal relationship between the accident and subsequent injury is whether the plaintiff proved through medical testimony that it is more probable than not that the subsequent injuries were caused by the accident. *Id.*

Proof of causation has two components, general and specific. *See Pick v. American Medical Systems, Inc.*, 958 F. Supp. 1151, 1164 (E.D. La. 1997); *Kemp v. Metabolife International, Inc.*, No. 00-3513, 2004 WL 2095618 (E.D. La. Sept. 13, 2004). General causation deals with whether the substance at issue can cause diseases or disorders in people in general. *Pick*, 958 F. Supp. at 1164. Specific causation focuses upon whether the substance was in fact the cause of the ailments or symptoms in the particular patient. *Id.* An inability to establish specific causation is fatal to plaintiffs' claim. *Id.* at 1163.

Plaintiffs respond to defendant's argument that summary judgment should be granted in favor of defendants based on plaintiffs' inability to establish specific causation in one paragraph. Rec. Doc. 244, p. 20. Plaintiffs submit that their experts should be permitted to testify as explained in their opposition to the four motions to exclude testimony, but plaintiffs do not address the merits of the argument. *Id.*

Plaintiffs needed both specific and general causation testimony to meet their burden of proof. Dr. Kramer offered testimony on general causation. Rec. Doc. 233, Exh. U, depo. Kramer, pp. 44-45. Her opinion did not pass the *Daubert* test and must be excluded. Dr. Goldstein also offered testimony on general causation. Rec. Doc. 233, Exh. S, depo Goldstein. Of plaintiffs' experts, only

Dr. Goldstein's testimony provided an opinion on specific causation.[2] *Id.* In particular, he needed to offer an opinion on whether Mrs. Frischhertz' alleged ingestion of Paxil while pregnant caused E.F.'s limb and alleged heart deformities. Dr. Goldstein's testimony has been excluded. Because the Court has excluded the testimony of Drs. Paul Goldstein and Shira Kramer, the plaintiffs have no expert testimony establishing general or specific causation and cannot meet their burden of establishing either general or specific causation from the ingestion of Paxil for the alleged birth defects under the LPLA.

The Court refrains from re-addressing Mrs. Frischhertz' prescribing physician, Dr. Kongara's testimony and its significance under the learned intermediary doctrine because it finds that the plaintiffs cannot establish specific or general causation. Rec. Doc. 233.

Accordingly,

IT IS ORDERED that defendant GlaxoSmithKline LLC's Motion to Exclude the Testimony of Paul Goldstein, Ph.D. is GRANTED. Rec. Doc. 187

IT IS FURTHER ORDERED that defendant GlaxoSmithKline LLC's Motion to Exclude the Testimony of Shira Kramer is GRANTED. Rec. Doc. 188.

IT IS FURTHER ORDERED that summary judgment on Louisiana Products Liability Act claim is GRANTED in favor of the defendant and against the plaintiffs. Rec. Doc. 233.

IT IS FURTHER ORDERED, considering that plaintiffs have conceded that all other claims are dismissed and the Court having granted this motion for summary judgment, that judgment be

[2]Additionally, Dr. Goldstein's testimony was only related to specific causation on E.F.'s limb defect and not on his alleged congenital heart defect. Dr. Goldstein testified that E.F. did not have a congenital heart defect.

ENTERED in this matter dismissing all of plaintiffs' claims with prejudice. Rec. Doc. 159.

New Orleans, Louisiana, this 21st Day of December, 2012.

HELEN G. BERRIGAN
UNITED STATES DISTRICT JUDGE