UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

K.E., a Minor by his Parent and Natural Guardian NICHOLE EL-MASSRI and NICHOLE EL-MASSRI, Individually,	:	
Plaintiffs,	:	
v.	:	Case No. 3:14-cv-1294(VAB)
GLAXOSMITHKLINE LLC, formerly SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE,	:	
Defendant.	:	

RULING ON DEFENDANT'S MOTIONS TO EXCLUDE EXPERT TESTIMONY AND FOR SUMMARY JUDGMENT

K.E., a minor, has a heart defect, more specifically, a bicuspid aortic valve with aortic valve insufficiency ("BAV"). K.E., along with his parent and natural guardian Nichole El-Massri ("Plaintiffs"), have sued SmithKline Beecham Corporation d/b/a GlaxoSmithKline and GlaxoSmithKline LLC ("GSK" or "Defendant"), the manufacturer of Paxil, an anti-depressant that Ms. El-Massri allegedly ingested while pregnant and which Plaintiffs claim caused K.E.'s birth defect.

In support of their claim, Plaintiffs rely on the proffered expert testimony of Dr. William Ravekes, who opines that Paxil causes BAVs generally and caused K.E.'s BAV specifically. GSK has moved to exclude Dr. Ravekes's testimony [ECF No. 89] and, for this reason and others, has also moved for summary judgment [ECF No. 88].

For the reasons that follow, both motions are GRANTED.

I. Relevant Factual Background[1]

In 2001, during the early weeks of Ms. El-Massri's pregnancy, K.E.'s heart began to grow. As K.E.'s developing heart separated into four chambers, the truncus arteriosus, which would eventually become K.E.'s pulmonary artery and aorta, began to emerge from the right ventricle. Ravekes Report, Def.'s Mot. to Preclude, Ex. 28, ECF No. 90-16, 3 ("Ravekes Report"). Around the eighth week of K.E.'s development, valves developed within his maturing arteries, regulated in part by neural crest cells. *Id.* K.E.'s aortic valve, which connects his left ventricle with his aorta, developed abnormally, growing only two cusps, or leaflets, rather than the three that most aortic valves contain. *Id.*

On January 19, 2002, Ms. El-Massri gave birth to K.E. by Cesarean section. Def.'s L. R. 56 Stmt., ¶ 49; Scialli Report, Def.'s Mot. to Preclude, Ex. 7, ECF No. 90-4, 9. While K.E. initially seemed healthy, his family later learned about his defective aortic valve. In 2009, a doctor diagnosed Ms. El-Massri's husband, Ameen El-Massri, with idiopathic hypertrophic subaortic stenosis ("IHSS"), a heart disease characterized by abnormalities to the left ventricle. Def.'s L. R. 56 Stmt., ¶ 51. The doctor also referred K.E. to a cardiologist to determine whether he risked developing the disease, which is a genetic condition. *Id.* at ¶ 52 (citing Ravekes Report, 7).

Dr. Richard Berning evaluated K.E. and discovered that K.E. suffered from mild aortic valve insufficiency. *Id.* at ¶53; Letter from Dr. Berning, Def.'s L.R. 56 Stmt., Ex. 17, ECF No. 93-18, 6. At a subsequent evaluation in September 2010, Dr. Alicia Wang observed that K.E. had a BAV due to fusion between his right and left coronary artery cusps. *Id.* at ¶ 54; Letter from Dr. Wang, Def.'s L.R. 56 Stmt., Ex. 17, 2-3. Since then, K.E.'s echocardiograms have confirmed that he has a BAV, but that he does not yet require surgery or another medical intervention. Ravekes Report, 6.

[1] The relevant facts are taken from the Defendant's Local Rule 56(a)1 Statement and Exhibits attached to the Local Rule 56(a)1 Statement (ECF No. 88-14, and Nos. 88-15 – 88-47) and Plaintiffs' Local Rule 56(a)2 Statement, ECF No. 106-5, and Affidavit and attached Exhibits (ECF Nos. 106-6 - 106-14). *See* D. Conn. L. Civ. R. 56(a).

In addition to the costs of regularly monitoring K.E.'s heart, the BAV could cause greater harm as he grows. Currently, K.E.'s defective valve causes some "leakage"—or "backflow" of blood to his heart—which indicates that he may require further treatment or surgery at some point. Dr. Wang also noted that the BAV could put K.E.'s health at risk if he continued playing competitive sports as he got older. Letter from Dr. Wang, 3. K.E.'s BAV also takes an emotional toll on him and his family, all of whom must accept the possibility of further harm and the uncertainty of his prognosis.

Between one and two percent of the American population—and a greater proportion of American males—has a BAV. Ravekes Report, 8; Scialli Report, 10. Like many birth defects, the exact cause of the BAVs in these patients is unknown. Some researchers suggest that the defect has a genetic cause, while others point to environmental agents that cause birth defects. These agents, also called "teratogens," include chemicals or hormones that may cause birth defects after a certain amount of exposure. The cause of birth defects also could be multi-factored, with some individuals having a genetic susceptibility to teratogens which would cause them to develop a BAV in situations when others would not. *Id.*

Paroxetine hydrochloride, commonly known as Paxil, is a prescription medication designed primarily to treat depression. Def.'s L.R. 56 Stmt., ¶¶ 59-60. Paxil, along with other antidepressants such as Zoloft and Celexa, belongs to a class of drugs called selective serotonin reuptake inhibitors ("SSRIs"), which alter the body's sensitivity to the neurotransmitter serotonin. *Id.* Since 1992, the FDA has approved of the use of Paxil to treat adult depression as well as other conditions. *Id.* By 2001, the FDA had approved of the use of the drug for obsessive compulsive disorder, panic disorder, social anxiety disorder, and generalized anxiety disorder. *Id.* at ¶ 70. Some researchers have suggested that paroxetine, the chemical present in Paxil, might be a teratogen that causes birth defects in the developing fetuses of women who take the drug while pregnant. *See, e.g.* Ravekes Report, 4. These researchers rely on epidemiological data that suggests that the incidence of certain

birth defects is higher among women who took Paxil when pregnant, as well as animal studies in which chemical changes in the amount of serotonin in the prenatal environment have caused similar defects in developing embryos. Plaintiffs cite this research and allege that Defendant caused K.E.'s birth defect because it manufactured Paxil, which Ms. El-Massri allegedly consumed while she was pregnant. Def.'s L.R. 56 Stmt., ¶ 6, ¶ 59.

As Plaintiffs acknowledge, in order for Paxil to have caused K.E.'s birth defect, the BAV, Ms. El-Massri would have to have consumed it during the first trimester of her pregnancy, when K.E.'s heart was developing. *See* Pl.'s Opp. To Mot. to Preclude, ECF No. 105, 1 ("Dr. William Ravekes, a well-respected physician … used a differential diagnosis to determine that the first-trimester exposure of K.E. to Paxil, to a reasonable degree of scientific and medical certainty, is a cause of his … congenital heart defect."); Ravekes Report, 1 ("The purpose of this review is to provide my opinion regarding the role of Paxil (paroxetine), a SSRI taken by [Ms. El-Massri] during the first trimester of his gestation and its potential teratogenic effect on the development of Khalid's heart."); Ravekes Dep., Pl.'s Opp. To Mot. to Preclude, Ex. C, ECF No. 105-3, 361: 18-22 ("Q: After you ruled out all those factors, what was the one cause you were able to come up with? A: [The] Paxil exposure during the first trimester").

1. Ms. El-Massri's Alleged Consumption of Paxil

Ms. El-Massri saw two doctors while she was pregnant: Dr. David DeLucia, who first treated Ms. El-Massri on November 3, 2000, and Dr. Eleanor Berry, an obstetrician, who first treated Ms. El-Massri on May 30, 2001. *Id.* at ¶ 7, ¶ 38. Ms. El-Massri likely conceived K.E. between April 25, 2001 and May 6, 2001, and gave birth to him on January 19, 2002. Def.'s L. R. 56 Stmt., ¶ 6. During her pregnancy, Ms. El-Massri saw Dr. DeLucia only twice, on April 24 and April 30, 2001. *Id*. at ¶ 8. After that, she did not see him again until 2003. *Id.*

Ms. El-Massri claims that Dr. DeLucia prescribed Paxil to her from the year 2000 until the year 2002 and also gave her samples of the drug during that time. Def.'s L.R. 56 Stmt., ¶ 9, *see also*

N. El-Massri Dep., Def.'s L.R. 56 Stmt., Ex. 5, ECF No. 93-6, 152: 2-5; 169-70: 22-1. She does not claim to have received Paxil from any other source while she was pregnant. *Id.* at 189: 11-20. She alleges that a different physician, Dr. Landry, prescribed the drug to her when she was discharged from the hospital after giving birth to K.E. *Id.* at 189: 21-25.

Ms. El-Massri testified that she does not remember how much Paxil that she took during her pregnancy or how often she took it. N. El-Massri Dep., Def.'s L.R. 56 Stmt., Ex. 5, 169: 16-21. She also does not recall how many prescriptions Dr. DeLucia allegedly wrote for her or how many samples he allegedly gave her. *Id.* at 182-83: 19-18; 169: 22 - 170: 5 (Q: "How many [samples were you given by Dr. DeLucia]? A: "I don't remember the exact number." Q: "Can you ballpark it?" A: "No.").

2. Doctors' Testimony and Medical Records of Alleged Paxil Consumption

There are no contemporaneous medical records indicating that Ms. El-Massri took Paxil while pregnant and, if she did, how much she consumed. Pharmacy records are similarly sparse. Ms. El-Massri's then-boyfriend and now husband, Ameen El-Massri, testified that, during her pregnancy, he filled two to three prescriptions for Paxil at the local CVS and Walgreen's pharmacies where she regularly filled prescriptions. Def.'s L.R. 56 Stmt., ¶ 10; A. El-Massri Dep., Def.'s L.R. 56 Stmt., Ex. 15, ECF No. 93-16, at 315:18-318:8 (agreeing that he filled a Paxil prescription "maybe two times at Walgreens, one time at CVS … I can't remember the exact times."). Both pharmacies kept records for Ms. El-Massri dating back to 2000. *Id.* at 11-15. The only Paxil prescription in CVS's records for Ms. El-Massri is from 2002, after K.E. was born. Def.'s L. R. 56 Stmt. ¶ 14. Walgreen's records contain no reference to a Paxil prescription in Ms. El-Massri's name. *Id.* at ¶ 15. Mr. El-Massri also suggested that he may have filled a prescription at Arrow pharmacy, but neither party provided records from that pharmacy. A. El-Massri Dep., Def.'s L.R. 56 Stmt., Ex. 15, 316:9.

In medical records from 2001 and early 2002, Ms. El-Massri represented that she took some medications, but not that she took Paxil. In a Patient Questionnaire from Dr. Berry's practice dated January 30, 2001, Ms. El-Massri wrote "Keflex" in response to a question asking her to list prescription medications she took. Women's Healthcare Records, Def.'s L.R. 56 Stmt., Ex. 12, January 30, 2001 Note at 564265.014.MED00053. Similarly, a July 27, 2001 record from Waterbury Hospital noted only "macrodantin and prenatal vit[amin]s" as Ms. El-Massri's current medications. *See* Medical Records, Def.'s L.R. 56 Stmt., Ex. 8, at 564265.034.DIS00374-77. A form completed on January 19, 2002, when Ms. El-Massri was admitted for delivery of K.E, listed her current medications as "Zithromax and PNV (prenatal vitamins)." *See id*, at 564265.034.DIS00160.

Ms. El-Massri's doctors also fail to provide much evidence regarding her alleged consumption of Paxil.

a. Dr. DeLucia

Dr. DeLucia testified that he did not prescribe Paxil or provide samples to Ms. El-Massri. Def.'s L. R. 56 Stmt., ¶¶ 27-28. Dr. DeLucia also testified that he did not treat or diagnose Ms. El-Massri for depression and that, if he prescribed Paxil to Ms. El-Masri, he would have noted it in his records. *Id*. at ¶¶ 20-25. Dr. DeLucia's records note that Ms. El-Massri reported taking several medications, but not Paxil, at a November 3, 2000 visit. *Id.* at ¶ 17. On April 24, 2001, Ms. El-Massri visited Dr. DeLucia and reported that she thought she was pregnant, which he also noted in his records. *Id.* at ¶31, *see also* De Lucia Records, Def.'s L.R. 56 Stmt., Ex. 2, ECF No. 93-3, MED00055 ("DeLucia Records"). These records also contain a note that says "no meds for now. (at all)." Def.'s L.R. 56 Stmt., ¶ 32, *see also* De Lucia Records, MED00055 (emphasis in original). Dr. DeLucia saw Ms. El-Massri again on April 30, 2001 and after that visit did not treat her again until 2003. *Id.* at ¶ 8. Plaintiffs admit that DeLucia does not recall prescribing Paxil to Ms. El-Massri and agree that his notes do not suggest that he did. Pl.'s Stmt. of Disputed Facts, ECF No. 106-6, at ¶¶ 27-28.

b. Dr. Berry

Dr. Eleanor Berry, an obstetrician, treated Ms. El-Massri during her pregnancy. Def.'s L. R. 56 Stmt., ¶ 38. Ms. El-Massri's first prenatal visit with Dr. Berry was on May 30, 2001. *Id.* Dr. Berry testified that she did not recall prescribing Paxil to Ms. El-Massri before or during Ms. El-Massri's pregnancy with K.E. *Id.* at ¶ 39, *see also* Berry Dep., Def.'s L. R. 56 Stmt., Ex. 10, ECF No. 93-11, 194: 21-23 ("Def.'s Berry Dep."). None of Dr. Berry's prenatal records regarding Ms. El-Massri contain any reference to Paxil. *Id.* at ¶ 41, *see also* Def.'s Berry Dep., 190: 17-21 (agreeing to the statement "you don't have any records from during the pregnancy indicating Paxil as a current medication, correct?"). Dr. Berry does not remember personally giving Ms. El-Massri any samples of Paxil, but testified that she "[did not] remember all the samples that came through [her] office" and that "it could be a possibility" that Ms. El-Massri obtained samples from Dr. Berry's office during her pregnancy. Pl.'s Stmt. Disp. Facts, ¶ 2; *see also id.* at Ex. A, ECF No. 106-1, Berry Dep., 251:7-12.

Dr. Berry stated that Ms. El-Massri reported that she was taking Paxil to Dr. Berry at an appointment while she was pregnant. Specifically, she attested:

> It is my understanding that [Ms. El-Massri] was taking Paxil when she became pregnant and continued to take Paxil throughout her first trimester and throughout the remainder of her pregnancy. …Based upon my recollection and review of medical notes, Nichole was taking Paxil pursuant to a prescription written by her primary care physician, Dr. David Delucia.

Berry Aff., Def.'s L.R. 56 Stmt., Ex. 10, ECF No. 93-12, ¶¶ 4-5. Dr. Berry said that this statement was based on her "recollection that [Ms. El-Massri] took Paxil throughout the pregnancy" and on "conversations" that she remembered. Def.'s Berry Dep., 248: 18-21. Dr. Berry admitted having no direct knowledge that Ms. El-Massri received any samples of Paxil from Dr. Berry's office or from any other source. *See* Def.'s L.R. 56 Stmt., ¶ 40; Def's Berry Dep. 251: 3-6 (agreeing to the statement "you don't have any personal knowledge about Ms. El-Massri getting samples, correct?").

c. Other Records

The record contains evidence suggesting that Ms. El Massri took Paxil just after K.E.'s birth. Records from the Waterbury Hospital Health Center dated January 22, 2002 indicate that a healthcare provider initially recommended that Ms. El-Massri take Celexa on January 21, and then switched his or her recommendation to Paxil the next day. Women's Healthcare Records, Def.'s L. R. 56 Stmt., Ex. 12, 564265.034.DIS00182-83; *id*. at 564265.034.DIS00159. The records also indicate that Ms. El-Massri "seemed to feel comfortable with the switch." *Id.* One of these records, made after K.E.'s birth, suggests that Ms. El-Massri may have taken Paxil before giving birth. At a consultation on January 23, 2002, just after K.E. was born, Nurse Laurie Duncan reported that Ms. El Massri had "been trialed on medications Zoloft and Paxil in the past by her primary care physician Dr. DeLucia." Medical Records, Def.'s L.R. 56 Stmt., Ex. 2, ECF No. 93-3, 564265.034.DIS00186.

Whenever she started, Ms. El-Massri stopped using Paxil shortly after giving birth. *See* Women's Healthcare Records, 64265.014.MED00050. At a consultation on January 3, 2003, Dr. Reinhardt noted that "Dr. Berry had placed [Ms. El-Massri] on Paxil for two weeks which the patient stopped due to side effects." *Id.* at Ex. 8, ECF No. 93-9, Prenatal Flow Record at 64265.014.MED000256. A 2002 medical form indicates that Ms. El-Massri stated to a medical professional that "her combination of meds made her spacey," presumably prompting her to discontinue the use of Paxil. *Id.* The only record of a Paxil prescription at Ms. El-Massri's local CVS was from January 23, 2002, after K.E.'s birth. *Id.* at ¶ 14.

3. Paxil's Label

In May 1996, after prompting by the FDA, GSK changed the label on Paxil to include the following passage:

> There are no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Def.'s L. R. 56 Stmt., ¶ 68 (citing May 1996 Paxil Prescribing Information, Ex. 26, ECF No. 88-40). At that time, the company also changed the label to state that "[p]atients should be advised to notify their physician if they become pregnant or intend to become pregnant." *Id.* at ¶ 69. The label also indicated that Paxil was a Category C drug, referencing an FDA designation that meant that:

> (1) animal reproduction studies have shown an adverse effect on the fetus, there are no adequate and well-controlled studies in humans, and the benefits from the use of the drug by pregnant women may be acceptable despite its potential risks, or (2) there are no animal reproduction studies and no adequate and well-controlled studies in humans.

Id. at ¶ 61. In addition to "Category C," the FDA used two other categories to indicate to healthcare professionals that a drug was not advisable for pregnant women, "Category D" and "Category X." *Id.* The FDA used Category D to indicate there was "adverse reaction data from investigational or marketing experience or studies [of the drug] in humans," and Category X to indicate "studies [of the drug] in animals or humans have demonstrated fetal abnormalities or there is positive evidence of fetal risk." *Id.* In 2005, GSK announced that it would revise its label to make Paxil a Category D drug. Provider Letter, Pl.'s Stmt. Disp. Facts, Ex. 6, ECF No. 107-2, 1.

Dr. DeLucia testified that he would not have prescribed an SSRI, including Paxil, to a patient he suspected to be pregnant. Def.'s L. R. 56 Stmt. ¶ 30 (quoting DeLucia Dep. Def.'s L. R. 56 Stmt. Ex. 7, ECF No. 93-8, 203: 3-6) ("I believe Paxil was a Category C drug [in 2001], but I would not have deemed it safe for use by women who were pregnant.") Dr. Berry stated at deposition that "in light of the new information [concerning Paxil] and the different pregnancy category rating," she would have "talked to [Ms. El-Massri] about switching to a different drug, a "Category B or Category C rather than Category D drug." *Id.* at Def.'s Berry Dep. at 220:8-16. Dr. Berry further stated that she "usually" would tell a patient being prescribed a Category D drug that "you should talk to your doctor and see if they can give you something different." *Id.* at 221: 1-12.

In 2005, GSK circulated a letter to healthcare professionals suggesting that studies had reported "positive evidence of human fetal risk" and that Paxil can "cause" fetal harm. Pl.'s Stmt.

Disp. Facts, 5; *see also* Provider Letter, Pl.'s Stmt. of Disp. Facts, Ex. 6, ECF No. 107-2. The letter stated that "updated analyses" from an epidemiological study and "new data from another study utilizing a large medical birth registry" had "now become available." *Id*. The letter referred to "recent findings" and a "new study," as well as two abstracts presented at 2005 conferences. *Id*. at 2, 7. The letter stated that GSK "considered [it] appropriate at the current time to revise the pregnancy precaution [of Paxil] to Pregnancy Category D." *Id*. at 2.

4. Procedural History

Ms. El-Massri learned that K.E. had a BAV during a visit to the cardiologist in September 2010. Letter from Dr. Berning, Def.'s L.R. Stmt, Ex. 17. On June 28, 2011, she visited K.E.'s pediatrician, who noted in her records that Ms. El-Massri "took Paxil during pregnancy." Bristol Pediatric Center Records, Def.'s L.R. 56 Stmt., Ex. 13, ECF No. 93-14, 1. Ms. El-Massri testified that, at this point, she was "having concerns" about whether or not Paxil had caused her son's health issues. N. El. Massri, Dep., 325: 9-13.

> Q: Well, by this point in time, were you considering filing a lawsuit and thinking about the issue of whether or not Paxil caused your son's heart issues?
> A: Yes. I have concern over it.
> Q: And by this point in time, those thoughts had already started to formulate, right?
> A: Yes.

Id. at 325: 9-16. Ms. El-Massri suggested at deposition that the basis for her belief that her use of Paxil caused K.E.'s birth defect was a television commercial. *Id.* at 330: 18-25 ("Q: What's the basis for that belief [that Paxil use during pregnancy caused K.E. to have a heart defect]? A: His symptoms are similar to what I have seen on the commercial. The exact same diagnosis."). The record does not establish when in 2011 she viewed these advertisements. Def's L. R. 56 Stmt., ¶¶ 46-48. However, it is clear that Ms. El-Massri and her husband had seen the advertisement at least once before calling a law firm. *Id.* at ¶ 48; A. El-Massri Dep., 408: 2-7 (Q: "Well, did you see the commercial on more than one occasion? A: Yes. Q: Had she seen the commercial previously? A: Yes. Q: And what -- had

she already called when you saw the commercial? A. No."). Ms. El-Massri called a law firm about this dispute on July 27, 2011. Def.'s L.R. 56 Stmt., ¶ 46; Pl.'s Opp. Mem., 5-6.

Ms. El-Massri signed a contract with the law firm on Sept. 30, 2011, after submitting "paperwork" by mail. *See* Paxil Birth Defects Claims – Contract of Employment, Pl.'s L.R. 56 Stmt., Ex. 5, ECF No. 106-10, 1. The contract confirms that the firm opened a file for Ms. El Massri on July 27, 2011. *Id.* Ms. El-Massri testified that she did not hear from the law firm for several years after signing the contract. N. El. Massri, Dep., 348: 14-23.

Ms. El-Massri filed her original complaint on July 25, 2014 in the Court of Common Pleas of Philadelphia County. *See* Compl., ECF No. 1; Pls.'s Opp. Mem. 6. Plaintiffs' cause of action was then removed to federal court in the Eastern District of Pennsylvania on August 19, 2014. *Id.* Plaintiffs and GSK subsequently filed a Joint Motion to Transfer Venue to this Court on September 4, 2014. *See* Joint Motion to Transfer, ECF No. 6. The action was transferred to this Court for further proceedings on September 8, 2014. *See* Notice of Transfer, ECF No. 10.

In their short form complaint, which GSK references in its motion for summary judgment, Plaintiffs bring sixteen claims. Short Form Complaint/Notice to Defend, Ex. B, ECF No. 1-3. These claims are: (1) breach of express warranty (Count I); (2) breach of implied warranty (Count II); (3) fraud (Count III); (4) intentional infliction of emotional distress (Count IV); (5) loss of consortium (Count V); (6) negligence (Count VI); (7) negligence per se (Count VII); (8) negligent pharmacovigilance (Count VIII); (9) failure to warn (Count IX); (10) negligent misrepresentation (Count X); (11) strict products liability (Count XII); (12) loss of income (Count XVI); (13) violation of Connecticut's consumer act (Count XIV); (14) medical expenses (Count XVII); (15) design defect (Count XVIII), and (16) punitive damages (Count XI). Plaintiffs' long form complaint references many of the same claims, but uses different numbers. *See* Case Management Track Form, ECF No. 1-4.

5. The Present Motions

In support of their claims, Plaintiffs intend to call Dr. William Ravekes, a medical doctor and an expert in pediatric cardiology. Dr. Ravekes seeks to testify that Ms. El-Massri's consumption of Paxil caused K.E.'s BAV.

On June 16, 2015, GSK moved to exclude Dr. Ravekes' opinion testimony. On the same date, GSK moved for summary judgment. GSK argues that it is entitled to summary judgment because (1) all claims are time-barred and (2) even if not time-barred, all claims fail because Plaintiffs cannot establish that Ms. El-Massri's alleged use of Paxil was the proximate cause of K.E.'s BAV. GSK also makes specific arguments about the insufficiency of Plaintiffs' claims for breach of express and implied warranty, fraud and negligent misrepresentation, intentional infliction of emotional distress, loss of consortium, negligence per se, negligent pharmacovigilance, strict liability and design defect, violation of the Connecticut Unfair Trade Practices Act, and punitive damages. Because Dr. Ravekes' testimony is crucial to Plaintiffs' case, the Court addresses the motion to exclude his testimony first and then will address the motion for summary judgment on these and any other grounds.

II. GSK's Motion to Exclude the Testimony of Dr. Ravekes

Dr. William Ravekes, a medical doctor licensed in the State of Maryland, is an Assistant Professor of Pediatric Cardiology at Johns Hopkins University School of Medicine. *See* Ravekes CV, Pl.'s Mem. in Opp., Ex. A, ECF No. 105-1 ("Ravekes CV"). He is also an attending physician of Pediatric Cardiology at Johns Hopkins Hospital and sees patients in several other hospitals in the Baltimore area. Ravekes Report, 1. He has practiced medicine for sixteen years and also participates in research, academic leadership, and the education of future pediatric cardiologists. *Id.* at 2. In his report, he reviewed various publications on the causes of and risk factors for congenital heart disease, opines on the biological effects of serotonin on fetal development and reviews Ms. El-Massri's

medical history. *Id.* He concluded that Paxil was a "significant contributing factor" to K.E.'s heart defect. *Id.* at 12.

Defendants move to exclude his testimony generally, because he is unqualified, and also move to exclude his testimony on general and specific causation. Def.'s Mot. to Preclude, ECF 89-1. While the Court finds that Dr. Ravekes is qualified to offer opinions in this case, it concludes that his opinions on the issue of general causation are, in part, inadmissible and that his opinions on the issue of specific causation are wholly inadmissible. As a result, Defendant's motion to exclude Dr. Ravekes' expert testimony is granted.

A. Standard of Review

Expert opinions must be both reliable and relevant to the issues in a given case before they can be presented to the trier of fact. *See Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993) ("under the Rules the trial judge must ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable"); Fed. R. Evid. 702, Advisory Committee Notes, 2000 Amendments (noting that trial judges have "the responsibility of acting as gatekeepers to exclude unreliable expert testimony"). Evidence is relevant if the testimony "has any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." *Amorgianos v. Amtrak*, 303 F.3d 256, 264 (2d Cir. 2002).

If expert testimony is relevant, the trial court must then determine "whether the proffered testimony has a sufficiently 'reliable foundation' to permit it to be considered" by the trier of fact. *Amorgianos*, 303 F.3d at 265 (quoting *Daubert*, 509 U.S. at 597). An expert's testimony is reliable if (1) it is based upon sufficient facts or data, (2) it is the product of reliable principles and methods, and (3) if the witness has applied the principles and methods reliably to the facts of the case. Fed. R. Evid. 702.

Generally, when an expert reliably utilizes scientific methods to reach a conclusion, any asserted lack of textual support for these methods goes "to the weight, not the admissibility" of his or her testimony. *Amorgianos*, 303 F.3d at 267. A "contrary requirement," the Second Circuit has noted, would "be at odds with the liberal admissibility standards of the federal rules and the express teachings of *Daubert*." *Id.* At the same time, "nothing in *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert." *Id.* (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)). A district court's assessment of expert testimony thus requires a case-specific and "rigorous" consideration of the "facts on which the expert relies," the expert's "method," and how he or she "applies the facts and methods to the case at hand." *Id.* at 267.

B. Discussion

1. Qualifications of Dr. Ravekes

GSK argues that Dr. Ravekes is not qualified to testify to the relationship between birth defects and exposure to the chemicals in Paxil because he draws on literature from the fields of teratology and epidemiology, which are far from his clinical expertise. Def.'s Mot. to Preclude, 12-15. The Court disagrees.

Expert opinion testimony is permitted only if the witness "is qualified as an expert by knowledge, skill, experience, training, or education," and the expert's "scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine the fact in issue." Fed. R. Evid. 702. District courts have broad discretion to determine whether an expert is qualified and may determine that an expert is qualified to testify outside of his or her formal training or specialty. *See McCullock v. H.B. Fuller Co.*, 61 F.3d 1038, 1042-43 (2d Cir. 1995) (rejecting argument that because the causation expert, a medical doctor, had "no experience performing or interpreting air quality studies" he was not qualified to testify).

There is no bright-line rule about whether experts in clinical medicine can also assist the jury in determining general causation. Courts have allowed medical doctors to testify about epidemiological studies. *See, e.g.*, *United States v. Thorn*, 317 F.3d 107, 114-15 (2d Cir. 2003) (approving of district court's decision to allow medical doctor specializing in asbestos-related disease to testify about various epidemiological studies of asbestos exposure); *Danley v. Bayer (In re Mirena IUD Prods. Liab. Litig.)*, 169 F. Supp. 3d 396 (S.D.N.Y. 2016) (admitting medical doctor's testimony concerning epidemiological studies); *Lyman v. Pfizer, Inc*., No. 2:09-cv-262, 2012 U.S. Dist. LEXIS 101150, at *11 (D. Vt. July 20, 2012) (allowing medical doctor's testimony that "metoclopramide use produces tardive dyskinesia at a higher rate than that of certain other drugs, and an explanation of why that may be so," because the expert had "explained his methodology, and his methods and opinions have been published in peer-reviewed journals"). In *Danley*, for example, the court denied the plaintiff's motion to exclude expert opinions regarding epidemiological studies because the experts were clinicians, familiar with the allegedly tortious product, and had "experience evaluating (and in some cases conducting) epidemiological studies as part of their clinical work." *Danley*, 169 F. Supp. 3d at 426.

Courts have excluded the testimony of clinicians about general causation, but only when the clinicians had either negligible experience with pharmacology or little familiarity with observational studies in general. In *Smith v. Pfizer, Inc.*, which GSK cites, the court decided that the plaintiff's expert, a psychiatrist, was not qualified to opine about general causation. *Smith*, No. 98-4156-CM, 2001 U.S. Dist. LEXIS 12983, at *24 (D. Kan. Aug. 14, 2001). The psychiatrist, an expert in suicidiality, did not have expertise in either epidemiology or pharmacology, which, the court reasoned, would be necessary to show general causation. *Id.* In *Bextra*, which defendant also cites, the court excluded general causation testimony from a medical doctor who had "never participated in an observational study of any kind," and thus was unqualified "to opine that one or two observational studies are correct while all the other studies … are wrong." *In re Bextra & Celebrex Mktg. Sales*

Practices & Prod. Liab. Litig., 524 F. Supp. 2d 1166, 1176 (N.D. Cal. 2007). The fact that the expert in question had only reviewed the relevant data for the purposes of litigation also weighed in the *Bextra* court's decision to exclude his testimony. *Id.*

Dr. Ravekes, however, has extensive experience and understanding of the biological mechanisms by which chemicals might affect neonatal development. He also has experience designing observational studies due to his work with the National Registry of Genetically Triggered Thoracic Aortic Aneurysms and Cardiovascular Conditions (GenTAC). *See* Ravekes Rept., 3. As co-primary investigator and steering committee member of GenTAC, Dr. Ravekes analyzed relevant data and summarized the results of GenTAC's studies. Ravekes CV, 3-4. Additionally, he has published observational studies in many journals. *See id.* (listing articles under "peer-reviewed original science research," including No. 28 "Longitudinal systolic ventricular interaction in pediatric and young adult patients with TOF: a cardiac magnetic resonance and M-mode echocardiographic study," No. 48 "Echocardiographic Reference Values for Right Atrial Size in Children with and without Atrial Septal Defects or Pulmonary Hypertension," and No. 5 "Magnetic resonance imaging of a distorted left subclavian artery course: an important clue to an unusual type of double aortic arch"). Moreover, Dr. Ravekes has examined defective aortic valves in numerous patients, accumulating knowledge that would help him understand the relevant epidemiological literature. The relationship between Dr. Ravekes' clinical expertise and the epidemiology in question makes him sufficiently qualified to testify about epidemiological studies under *Daubert*.

Similarly, Dr. Ravekes is qualified to testify about hypothetical ways that Paxil might affect embryonic serotonin levels and cause heart defects. He has conducted "clinical research in the area of pediatric cardiology" and has "published over 70 articles, editorials, annotations and book chapters" in peer-reviewed journals including *Pediatric Cardiology*, the *American Heart Journal*, the *International Journal of Cardiology*, and the *Journal of the American Society of Echocardiography*. Ravekes Rept., 1-2; Ravekes CV, 2-5. He is accustomed to reading and reviewing scientific studies

and evaluating arguments about the heart's biological functions. GSK argues that Ravekes "has never conducted original research or published an article on Paxil, SSRIs, serotonin, or serotonin's role in heart development," Def.'s Mot. to Preclude, ECF 89-1, 14, but an expert need not testify on his original research, provided that he or she has expertise in the research topic more generally. *Gussack Realty Co. v. Xerox Corp*., 224 F.3d 85, 94 (2d Cir. 2000) ("[A]n expert may rely on data that she did not personally collect.").

As a result, the Court finds that Dr. Ravekes has the expertise necessary to testify about the relationship between birth defects and Paxil.

2. Dr. Ravekes' Opinions on General Causation

Of course, the fact that Dr. Ravekes is qualified to offer opinions does not mean that the opinions he offers are admissible. Fed. R. Evid. 702 ("[A] witness qualified as an expert … may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.") GSK also moves to exclude Dr. Ravekes' opinions on general causation because his report ignores recent analyses of the relationship between Paxil and birth defects, does not eliminate other causes—including chance, bias and confounding—in assessing the association and does not follow a "set, written-down methodology" to establish general causation. Def.'s Mot to Preclude, 15. The Court agrees with respect to Dr. Ravekes' review of epidemiological evidence, but disagrees with respect to his opinion on biological plausibility.

a. Dr. Ravekes' Review of the Epidemiological Evidence

GSK argues that Dr. Ravekes' report is unreliable because it does not account for seven meta-analyses on the relationship between Paxil and birth defects, which are provided by Defendants as exhibits 31-37. Def.'s Mot. to Preclude, 18-24; *id.* at 20, n. 128. The Court agrees. Even if this

omission was not ill-intentioned, it renders Dr. Ravekes' review of the evidence incomplete. This portion of Dr. Ravekes' general causation opinion is therefore unreliable.

When experts rely on epidemiological evidence to support causation, they must provide the jury with a full picture of the state of the field. *Guardians Asso. of N.Y.C. Police Dept., Inc. v. Civil Serv. Com.*, 633 F.2d 232, 240 (2d Cir. 1980) ("If the sample is adequate, the data gathering techniques reliable, and the conclusions drawn demonstrated to be statistically significant, such estimates and projections may properly be admitted into evidence."); *see also Norris v. Baxter Healthcare Corp.*, 397 F.3d 878 (10th Cir. 2005). In *Norris*, the Tenth Circuit approved of the exclusion of expert testimony that "completely ignored the many epidemiological studies that do not find a link between silicone gel breast implants and any systemic disease" and rather "stated that epidemiological studies relied on by the industry 'are not definitive.'" *Id.* at 885. In *In re Zoloft*, the court excluded the testimony of two experts on causation who had "given scant attention to the epidemiology research in their reports [and] failed to reconcile inconsistent epidemiological evidence with their opinions on human causation." *In re Zoloft (Sertraline Hydrocloride) Prods. Liab. Litig.* 26 F. Supp. 3d 466 (E.D. Pa. 2014); *see also In re Rezulin Prod. Liab. Litig.*, 369 F. Supp. 2d 398, 425 (S.D.N.Y. 2005) ("[I]f the relevant scientific literature contains evidence tending to refute the expert's theory and the expert does not acknowledge or account for that evidence, the expert's opinion is unreliable").

In these cases, the experts had ignored epidemiological research that was contrary to their eventual conclusion, "cherry-picking" among studies to give the illusion of clarity in favor of their position. *See, e.g. In Re Rezulin*, 369 F. Supp. 2d at 425 ("Courts have excluded expert testimony where the expert selectively chose his support from the scientific landscape") (internal citations omitted). In this case, Dr. Ravekes' error may be more benign. Some of the research he excluded from his report actually supports his position. The recently published meta-analysis by Anick Bérard, et. al., for example, actually observes a "trend towards increased risk" of heart defects after

exposure to Paxil's component chemicals. Abstract, Bérard et. al, (2015), Def.'s Mot. to Preclude, Ex. 32. Myles, et. al. also report that Paroxetine "was associated with increased risk of cardiac malformations." Abstract, Myles, et. al. (2013), Def.'s Mot. to Preclude, Ex. 33. Nevertheless, while Dr. Ravekes' report does not "selectively" cite supporting science, it does present an incomplete and therefore unreliable view of the secondary literature.

For this reason, the portion of Dr. Ravekes' expert testimony that summarizes the epidemiological data about general causation is excluded.

b. Dr. Ravekes' Opinion on Biological Plausibility

GSK further argues that the second half of Dr. Ravekes' report, which relies on "biological plausibility," is unreliable and inadmissible because it makes conclusions about Paxil's effect on humans from data concerning animals or isolated tissues. Def.'s Mot. to Preclude, 31. The Court disagrees.

Dr. Ravekes refers to "numerous animal studies" to show that changes to a mother's serotonin level can "interfere with neural crest cells" in her developing fetus. Ravekes Report, 4. GSK contends that Dr. Ravekes does not explain whether Paxil alters serotonin levels in utero and "cites no data" to support this conclusion. Def.'s Mot. to Preclude, 32. Furthermore, GSK argues that Dr. Ravekes improperly draws conclusions from a controversial study by Sloot, et. al., which used Whole Embryo Cultures ("WECs") from rats to predict the teratogenic effect of SSRIs on humans (the "Sloot Paper"). *Id.* at 33.

GSK also points to a general flaw in the literature on toxic chemicals, in which scholars often draw conclusions about the human experience from *in vitro* research—research "concerning the effects of a chemical on human or animal cells, bacteria, yeast, isolated tissues, or embryos"—because it would be unethical to test the chemical on humans extensively. *See* Bernard D. Goldstein & Mary Sue Henifin, *Reference Guide on Toxicology, in* FED. JUD. CTR., REFERENCE MANUAL ON

SCIENTIFIC EVIDENCE, 663 (3rd Ed. 2011) (hereinafter "Reference Manual"). Toxicology studies that use live animals are often similarly implicated.

While animal studies are necessarily inconclusive as evidence of causation in humans, they may be admissible when the "gap between what these sources reasonably imply and more definitive scientific proof of causality is not too great," and when "the inferences are of a kind that physicians and scientists reasonably make from good but inconclusive science." *In re Ephedra Prods. Liab. Litig.*, 393 F. Supp. 2d 181, 197 (S.D.N.Y. 2005); *see generally In re "Agent Orange" Prod. Liab. Litig.*, 611 F. Supp. 1223, 1241 (E.D.N.Y. 1985) ("[L]aboratory animal studies are generally viewed with more suspicion than epidemiological studies, because they require making the assumption that chemicals behave similarly in different species"). When animal studies are admissible, the expert's "extrapolation from studies to support [his or her] conclusions, as well as [his or her] use of *in vitro* versus *in vivo* studies [goes] to the weight and not the admissibility of expert testimony." *Danley*, 169 F. Supp. 3d at 432 n.23 (S.D.N.Y. 2016) (citing *In re Ephedra*, 393 F. Supp. 2d at 189).

GSK cites to several cases where courts excluded expert testimony that inferred from animal and in vitro studies a corresponding effect of SSRIs on developing embryos. For example, a court in a similar case found that plaintiff's causation expert failed to consider the "dose response relationship" and relied instead on studies in which animals were exposed to concentrations of Zoloft that were "well above the maximum recommended human dose." *In re Zoloft*, 26 F. Supp. 3d at 478. That court also found that the expert's report was unreliable because it did not consider studies of Zoloft in living mammals, or otherwise considered studies that did not provide evidence that serotonin pathways were similar across species. *Id.* at 480. This was especially troubling, the court reasoned, because the "optimal range of serotonin in pregnant women" was unknown. *Id.*

In another case, the court excluded expert testimony on "alteration of serotonin signaling [that] can impact embryonic development resulting in ... congenital malformations," stating that these decisions were "nothing but speculation without support since [the expert had] no information as to

the baseline level of serotonin causing signaling" or how SSRIs changed serotonin levels. *Porter v. SmithKline Beecham Corp., et al.*, No. 03275, 2015 WL 5970639 at *6 (Pa. Com. Pl. Oct. 5, 2015). The expert in question also had not reviewed animal studies from after 1998 and had not "acknowledged … a significant body of human exposure studies." *Id.* at *4.

Dr. Ravekes, like the experts in the Zoloft cases defendant cites, does not specify exactly how Paxil or another SSRI would impact the prenatal environment in a human. He also does not attest to the optimal range of serotonin in pregnant women, so his assessment of the effect of changing serotonin levels on the prenatal environment, which is based partially on animal studies, suffer from that drawback. Potential plaintiffs, however, would be overly burdened by a standard that would disallow any expert testimony on serotonin's effect on animals because the optimal range of serotonin in pregnant women is unknown. *See Heller v. Shaw Indus., Inc.*, 167 F.3d 146, 155 (3d Cir. 1999) ("Given the liberal thrust of the Federal Rules of Evidence, the flexible nature of the *Daubert* inquiry, and the proper roles of the judge and the jury in evaluating the ultimate credibility of an expert's opinion, we do not believe that a medical expert must always cite published studies on general causation in order to reliably conclude that a particular object caused a particular illness. … To so hold would doom from the outset all cases in which the state of research on the specific ailment or on the alleged causal agent was in its early stages.").

In this case, the Court recognizes the significant limitations of the studies on which Dr. Ravekes relies, but believes these would be best addressed with precautionary instructions to the jury and rigorous cross examination. *See* 1-4 Drug Product Liability § 4.04; *see also Daubert*, 509 U.S. at 596 ("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."); *McCullock*, 61 F.3d at 1044 (disputes about an expert's use of differential diagnosis "go to the weight, not the admissibility, of [the expert's] testimony").

In any event, GSK's own proposed expert, Dr. Anthony Scialli, plans to testify in detail about the Sloot Paper. Dr. Scialli opines that studies involving WECs, like Sloot's, are inappropriate for assessing what is a teratogen in human risk assessment. *See* Scialli Report, 16-17. He addressed the errors in the Sloot Paper in a subsequent publication as well as in his report. *Id*. As a result of the article, the authors of the Sloot Paper clarified that their definition of teratogenicity was "made for the purposes of Whole Embryo Culture tests" and might not speak to the effect of paroxetine on human embryos. *Id.; see also Frischhertz v. SmithKline Beecham Corp.*, No. 10-2125, 2012 U.S. Dist. LEXIS 181507, at *8 (E.D. La. Dec. 21, 2012) (commenting on Dr. Scialli's testimony as to the Sloot study in that case). If the jury heard Dr. Ravekes' testimony, it would be able to draw on Dr. Scialli's opinions to form its own assessment of Dr. Ravekes' reliability, to the extent that his testimony is admissible and necessary.[2]

As a result, Dr. Ravekes' testimony on the biological plausibility of Paxil's causation of BAVs generally is admissible, even though it relies on animal studies.

3. Dr. Ravekes' Opinion about Specific Causation

Dr. Ravkes' testimony that Paxil can cause BAV generally is of no value if he cannot also testify that Paxil caused K.E.'s BAV. *Amorgianos*, 303 F.3d at 268 ("[T]o establish causation, [the plaintiff] must offer admissible expert testimony regarding both general causation, i.e., that xylene exposure can cause the type of ailments from which Amorgianos claims to suffer; and specific causation, i.e., that xylene exposure actually caused his alleged neurological problems."); *Blanchard v. Eli Lilly & Co.*, 207 F. Supp. 2d 308, 314 (D. Vt. 2002) ("Plaintiffs … must prove both general and specific causation in order to prevail on their claim.") (citations omitted).

[2] Pending before the Court is a separate motion regarding the admissibility of Dr. Scialli's expert testimony. Pl.'s Mot. to Exclude Testimony of Anthony Scialli, ECF No. 92. Because this Court ultimately determines that Dr. Ravekes' expert testimony is inadmissible and therefore, excludes it and grants summary judgment for GSK, the Court does not reach the question of whether Dr. Scialli's expert testimony is admissible. In a subsequent ruling, the Court will declare Plaintiffs' motion to be moot.

GSK argues that Dr. Ravekes' testimony regarding specific causation is inadmissible because Dr. Ravekes improperly assumed that Ms. El-Massri took Paxil during her first trimester. Def.'s Mot. to Preclude, 31, 36 (Dr. Ravekes "simply assumed, at counsel's direction, that Ms. El-Massri took Paxil" during this time). The Court agrees that Dr. Ravekes' specific causation testimony is inadmissible.

A causation expert must rely on some evidence that the patient was exposed to the substance in question. "Although exact data on exposure need not be required, an expert should … be able to provide reasonable explanations for his or her conclusions about the amount of exposure that sufficed to cause plaintiffs' injuries." Reference Manual, 25. In most prescription drug cases, this is not a problem, because prescriptions or medical records can be used to surmise the exact amount of the allegedly toxic substance that the plaintiff consumed. *Id.* In this case, though, the record contains very little evidence that Ms. El-Massri consumed Paxil while she was pregnant and no evidence from which Dr. Ravekes can reasonably infer how much Paxil Ms. El-Massri possibly could have consumed. Since expert opinion testimony must be based "upon sufficient facts or data," Fed. R. Evid. 702, the lack of evidence of Ms. El-Massri's Paxil consumption renders Dr. Ravekes' expert testimony on specific causation inadmissible.

a. Dr. Ravekes' Research and Method

Generally, when the "reliability of certain facts accepted by an expert is questionable," the Court can rely on "the exercise and process of cross-examination to allow a [party] to bring any such factual disputes to the attention of the jury." *Howard v. Walker*, 406 F.3d 114, 127-28 (2d Cir. 2005). In some cases, courts have allowed experts to testify that a toxic substance caused a plaintiff's injury without concrete knowledge of whether the plaintiff was exposed to the substance, reasoning that the issue of exposure is best left for the jury to determine. *See, e.g. Green v. McAllister Bros.*, No. 02 Civ. 7588 (FM), 2005 U.S. Dist. LEXIS 19789 (S.D.N.Y. Sep. 6, 2005), *3-4. In *Green*, the court admitted the testimony of a plaintiff's expert even after the expert conceded

that his opinion that the plaintiff's injury was caused by exposure to WTC dust while working on the defendant's boat was "based on the assumption that Green had not previously been exposed to WTC Dust at [another point]," because "if a jury accept[ed] Green's testimony that he had no prior exposure to WTC Dust, [the] expert opinion would permit the jury to find that Green's asthma was caused by his work for McAllister." *Id.*

In some cases, though, the duration and amount of exposure is so crucial to an expert's causal argument that the expert must rely on at least circumstantial evidence of exposure. This is especially true where, as here, a substance is allegedly toxic or teratogenic only at certain levels, but can be consumed safely at others. In *Wills*, the court evaluated the report of an expert doctor whose causation testimony was based on the theory that even a small amount of exposure to benzene, the toxic substance that was allegedly present on defendant's ship, would cause cancer. *Wills v. Amerada Hess Corp*., No. 98 -7126, 2002 U.S. Dist. LEXIS 1546, at *29-52 (S.D.N.Y. Jan. 31, 2002). The expert doctor's animal studies suggested that benzene was carcinogenic at certain doses, which rendered his specific causation opinion unreliable unless it was based on non-conclusory allegations about the amount of benzene to which plaintiff was exposed. *Id.* at *36. "Theoretically," the court noted, "any exposure at all to mutagens may increase the risk of cancer, although the risk may be very slight and not achieve medical probability." *Id.* at *44-45 (citing Bernard D. Goldstein & Mary Sue Henifin, *Reference Guide on Toxicology, in* FED. JUD. CTR., REFERENCE MANUAL ON SCIENTIFIC EVIDENCE, 426 (2d ed. 2000)).

In *Amorgianos*, the Second Circuit affirmed the district court's exclusion of the testimony of plaintiff Amorgianos' treating physician, Dr. Moline. *Amorgianos*, 303 F.3d at 270. Dr. Moline relied on a number of published articles to conclude that exposure to xylene at defendant's workplace caused Amorgianos' injury. The court concluded that the studies on which Dr. Moline relied did not speak to specific causation because they differed from Mr. Amorgianos' situation in key areas, including exposure. None of the studies provided "evidence of the neurological effects of short-term

xylene exposure," which would be key to establishing causation in Amorgianos' case. As a result, the district court concluded that there was "too great an analytical gap between the conclusions reached by the authors of Dr. Moline's cited articles and the conclusions that she draws from their work." *Id.* (citing *Amorgianos v. Amtrak*, 137 F. Supp. 2d 147, 185 (E.D.N.Y. 2001)); *see also* Reference Manual, 613, n. 196 ("a risk estimate from a study that involved a greater exposure is not applicable to an individual exposed to a lower dose") (citing *In re Bextra*, 524 F. Supp. 2d at 1175-76 (relative risk found in studies of those who took twice the dose of others could not support expert's opinion about causation for latter group); *Wright v. Willamette Indus.*, 91 F.3d 1105, 1106 (8th Cir. 1996) ("[A] plaintiff in a toxic tort case must prove the levels of exposure that are hazardous to human beings generally as well as the plaintiff's actual level of exposure to the defendant's toxic substance before he or she may recover.")).

The epidemiological studies on which Dr. Ravekes relies base their conclusions on some proof of exposure. As a result, there is an "analytical gap" between these studies and his conclusions about specific causation. Many of the researchers Dr. Ravekes cited were unable to identify the exact dose or duration of Paxil exposure in the women they studied. *See* Kallen (2007), Def.'s Mot. to Preclude, Ex. 11, ECF No. 89-12, 306 ("The … problem is that little is known about actual dosage and timing of drug use" among the subjects studied). Generally, though, these studies draw conclusions from women who reported regular use of Paxil for at least the first trimester of their pregnancy. Furthermore, while many of the cited scientists determined exposure using self-reports, most of these reports were obtained at interviews taken during or immediately after pregnancy, making them more reliable gauges of actual exposure.[3]

A report by Alwan (2007), for example, limited its conclusions to mothers who had taken the drug during the period lasting from one month before pregnancy until three months after conception.

[3] Louick (2007) used self-reports given within six months of delivery. *See* Louick (2007), Def.'s Mot. to Preclude, Ex. 6, 2676. Kallen (2007) used data from routine midwife interviews at the first antenatal care center visit. *See* Kallen (2007), Def.'s Mot. to Preclude, Ex. 11, ECF No. 89-12, 302.

See McDonagh, et. al. (2014),[4] Def.'s Mot. to Preclude, Ex. 36, ECF No. 89-37, E-32; *see also* Louick (2007), Def.'s Mot. to Preclude, Ex. 6, ECF No. 89-7, 2681 (presuming that the drugs studied were "used on a regular basis for nontrivial indications"). In Bérard (2007), one of the few studies in which exposure was measured precisely, the average dose among the 542 subjects who had taken Paxil was 22.4 m.g. for an average duration of 64 days. McDonagh, et. al. (2014), E-33. For Dr. Ravekes to draw parallels between these epidemiological studies and this case, he would need to rely on some evidence that Ms. El-Massri took a "non-trivial" amount of Paxil during most or all of the first trimester of her pregnancy.[5]

This evidence, however, is lacking in the record. Dr. Ravekes admitted that his opinion on causation was "based on the assumption that [Ms. El-Massri] took" Paxil during the critical period of fetal heart development. Ravekes Dep., Def.'s Mot. to Preclude, Ex. 8, ECF No. 90-5, 282: 10-25. He also acknowledges that dosage and duration of exposure are important components of his method of analyzing causation. "In forming my opinions," Ravekes explains, "I engaged in an appropriate causation assessment, considering many factors, including temporal relationships, dose, duration of exposure, biological plausibility/mechanism [and] the medical records of both [Plaintiffs]." Ravekes Rept., 3. Thus, in Ravekes' opinion, the consideration of exposure to a teratogen is an important factor when assessing whether the teratogen caused a particular birth defect.

This Court must consider "the indicia of reliability identified in Rule 702" and assess whether Dr. Ravekes drew on "sufficient facts or data" in making his testimony, used "reliable principles and methods" in his conclusions and "applied the principles and methods reliably to the facts of the

[4] The Court relies on McDonagh, et. al., Def.'s Mot. to Preclude, Ex. 36, for its overview of many of the studies the parties reference, both because the review provides a helpful assessment of the studies and because the record does not contain all of the scientific articles that Dr. Ravekes cited.

[5] While some epidemiologists draw conclusions about causation without precise data on dose or duration of exposure in populations studied, most acknowledge the importance of this problem and try to correct it. *See* Louick (2007), 2681 (acknowledging difficulty of "recall bias" in study that relied on maternal self-reports of drug exposure, but considering such bias unlikely because anti-depressants are generally taken for long periods). Other studies use prescription data to speak more precisely to the importance of extent and duration of exposure in the relationship between Paxil and birth defects.

case." Fed. R. Evid. 702; *see also Amorgianos*, 303 F.3d at 267 (requiring a "rigorous examination" of these factors). In *Amorgianos*, the Second Circut upheld a lower court's determination that an expert was unreliable because he "failed to apply his own methodology reliably." *Id.* Here, Dr. Ravekes did not "apply his own methodology reliably," because there is nothing in the record from which he could consider thoroughly, much less reasonably, the dose of Paxil Ms. El-Massri consumed during her pregnancy and the duration of her exposure to the drug. These fundamental flaws in his expert testimony render any opinion he may wish to provide on specific causation inadmissible.

b. Dr. Ravekes' Use of Differential Diagnosis

Plaintiffs suggest that the fundamental flaws identified in Dr. Ravekes' expert testimony—the lack of evidence of the dosage and duration of Ms. El-Massri's Paxil use—are overcome by his reliance on differential diagnosis to show causation in the absence of such evidence. The Court disagrees.

Differential diagnosis is a "patient-specific process of elimination that medical practitioners use to identify the most likely cause of a set of signs and symptoms from a list of possible causes." *Ruggiero v. Warner-Lambert Co.*, 424 F.3d 249, 254 (2d Cir. 2005) (internal quotation marks and citations omitted). As the Second Circuit recognized in *Ruggiero*, "[t]here may be instances where, because of the rigor of differential diagnosis preformed, the expert's training and experience, the type of illness or injury at issue, or some other case-specific circumstance, a differential diagnosis is sufficient to support an expert's opinion in support of both general and specific causation." *Ruggiero*, 424 F.3d at 254; *Plourde v. Gladstone*, 190 F. Supp. 2d 708, 722 n.7 (D. Vt. 2002) ("courts have looked favorably on causation testimony that is primarily based on differential diagnosis"); *see also Perkins*, 299 F. Supp. 2d at 57 ("Differential diagnosis is a reliable basis to prove general causation in this circuit"). Dr. Ravekes' differential diagnosis here, however, is not one of those instances.

An expert's use of differential diagnosis to determine specific causation does not absolve the expert of having to satisfy Rule 702 of the Federal Rules of Evidence. Indeed, the Second Circuit's decision in *Ruggiero* expressly relies on its previous decision in *Amorgianos*, citing this earlier decision to support the proposition that: "When an expert opinion is based on data, a methodology or studies that are simply inadequate to support the conclusion reached, *Daubert* and Rule 702 mandate the exclusion of that unreliable opinion testimony." *Ruggiero*, 424 F.3d at 253 (quoting *Amorgianos*, 303 F.3d at 266). In other words, Dr. Ravekes' testimony on specific causation cannot be admitted if there is insufficient evidence in the record for Dr. Ravekes to conclude that Ms. El-Massri took Paxil and, if so, how much and for how long, or, to put it in Rule 702's terms, inadequate data "to support the conclusion" that Paxil caused K.E.'s BAV. That certainly is the case here.

Dr. Ravekes employed differential diagnosis to rule in all potential causes of K.E.'s BAV and then "rule[] out all other potential causes" besides Paxil. Ravekes Dep., Def.'s Mot. to Preclude, Ex. 8, ECF No. 90-5, 361:23-25 ("Q: After ruling out everything else, is it fair to say the only thing you were left with was the Paxil usage? A: Correct."). He acknowledges, however, that he "cannot rule out a genetic/familial risk factor or predisposition to congenital heart disease." Ravekes Rept., 12. This concession alone undermines the notion that Dr. Ravekes was able to rule out every potential cause but Paxil and exposes the inadequacy of this methodology in this case.

Dr. Ravekes' analysis also failed to "rule out" factors including Ms. El-Massri's experience of several infections while pregnant. Def.'s Mot. to Preclude, 11, 39. Since both parties agree that birth defects can be caused by a variety of factors and that the majority of defects have an unknown cause, *see* Ravekes Report, 8 ("[a]pproximately 40% of birth defects have a known cause"), these omissions further reveal the inadequacy of the differential diagnosis performed here

Just as importantly, Dr. Ravekes' differential diagnosis fails to overcome the lack of evidence of exposure to Paxil. Sufficient proof of exposure can be and, in this particular case, is critical to a differential diagnosis. In *Mancuso*, the court reviewed the "generally accepted methodology for

determining whether a person's illness was caused by a specific toxin." *Mancuso v. Consol. Edison Co.*, 967 F. Supp. 1437, 1445-46 (S.D.N.Y. 1997); accord *Mancuso v. Consol. Edison Co.*, 56 F. Supp. 2d 391, 399 (S.D.N.Y. 1999), *aff'd in relevant part* 216 F.3d 1072 (2d Cir. 2000). According to *Mancuso*, the proper methodology in such situations is:

> First, the level of exposure of plaintiff to the toxin in question must be determined; second, from a review of the scientific literature, it must be established that the toxin is capable of producing plaintiff's illness—called 'general causation'—and the dose/response relationship between the toxin and the illness—that is, the level of exposure which will produce such an illness—must be ascertained; and third, 'specific causation' must be established by demonstrating the probability that the toxin caused this particular plaintiff's illness, which involves weighing the possibility of other causes of the illness—a so-called 'differential diagnosis.'

Id. (citing Bernard D. Goldstein & Mary Sue Henifin, *Reference Guide on Toxicology*, *in* FED. JUD. CTR., REFERENCE MANUAL ON SCIENTIFIC EVIDENCE, 663 (1st Ed. 1994)). The court in *Mancuso* excluded the testimony of the plaintiff's expert because he made "no serious effort to perform the first step of the methodology by evaluating the dosage of the toxin plaintiffs have received." *Id.* at 1499. Without establishing exposure, the court held, the expert's differential diagnosis was merely "circular reasoning." *Id.* at 1450. As a result, it was "improper for an expert to presume that the plaintiff 'must have somehow been exposed to a high enough dose to exceed the threshold [necessary to cause the illness], thereby justifying his initial diagnosis.'" *Id.* (citing *O'Conner v. Commonwealth Edison Co.*, 807 F. Supp. 1376, 1396 (C.D. Ill. 1992)); *see also Zwillinger v. Garfield Slope Hous. Corp.*, No. 94-4009, 1998 U.S. Dist. LEXIS 21107, at *59 (E.D.N.Y. Aug. 17, 1998) (excluding testimony of a doctor who had "no information about plaintiff's level of exposure" to the allegedly tortious product and had not reviewed plaintiff's complete medical records, which included evidence that she complained of similar injuries before being exposed to the product).

Without sufficient evidence of Ms. El-Massri's exposure to paroxetine during the crucial first trimester of pregnancy, Dr. Ravekes' differential diagnosis is unreliable. "Courts are reluctant to admit causation testimony based on a differential diagnosis where the proffered expert possesses only

weak circumstantial evidence that some exposure occurred and makes no effort to scientifically evaluate or roughly estimate the degree of exposure or dosage." *Plourde*, 190 F. Supp. 2d at 722. A differential diagnosis therefore must offer a "reliable basis" for concluding that the allegedly tortious product is "capable of causing" the injury in question, or—in other words—a "reliable ground upon which [the product] may be 'ruled in'" as a plausible cause. *Ruggiero*, 424 F.3d at n.5. In this case, for Dr. Ravekes' differential diagnosis to be relevant and reliable, it must be grounded in sufficient evidence of K.E.'s prenatal exposure to Paxil. That evidence is absent from this record.

Of course, courts should be flexible about the type of evidence on which experts rely to establish exposure or dosage levels, especially given the "liberal thrust" of the Federal Rules. *McCullock*, 61 F.3d at 1042. In *McCullock*, the Court allowed an expert's causation testimony that relied on evidence that plaintiff was "in the breathing zone of the hot-melt glue fumes" during plaintiff's four years of employment and "that she and other employees could smell the unventilated glue fumes, especially when the pot overheated." *Id.* at 1045. Thus, expert testimony on toxic injuries may be admissible where dosage or exposure levels have been roughly established through reliable circumstantial evidence. *See also Plourde*, 190 F. Supp. 2d at 723 (excluding expert testimony on causation because "in contrast to the medical doctor in *McCullock*, there is no evidence [that expert doctor] based his opinion on an objective showing that Mr. Plourde was in an "exposure zone" for any period of time"). In the Second Circuit, a district court "has broad discretion in determining whether in a given case a differential diagnosis is enough by itself to prove causation." *Ruggiero v. Warner-Lambert Co.*, 424 F.3d 249, 254 (2d Cir. 2005). In this case, however, Dr. Ravekes' differential diagnosis does not reliably assist with determining specific causation.

Birth defects such as BAVs are caused by a wide variety of factors, many of which are unknown. Because only forty percent of birth defects have known causes, it would be hard for Dr. Ravekes to "rule out" every potential alternative cause of K.E.'s BAV, even with a well-constructed differential diagnosis. *See* Reference Manual, 618 ("for diseases for which the causes are largely

unknown, such as most birth defects, a differential etiology is of little benefit"). Given this difficulty, Dr. Ravekes' differential diagnosis is unreliable. Sufficient evidence of Ms. El-Massri's exposure to Paroxetine is essential, particularly when Dr. Ravekes failed to assess several factors, such as K.E.'s genetic history, that could have caused his BAV.

C. Conclusion

Without sufficient and reliable evidence that Ms. El-Massri took Paxil during her first trimester, or, if she did, how much she took, Dr. Ravekes cannot offer reliable specific causation testimony. There is simply "too great an analytical gap" between the studies Dr. Ravekes himself relied on and Dr. Ravekes' own conclusions. *Amorgianos*, 303 F.3d at 270. For the same reason—because there was insufficient evidence of Ms. El-Massri's exposure to Paxil, in terms of dosage and duration—Dr. Ravekes does not follow an accepted methodology for assessing specific causation. While differential diagnosis may be an acceptable methodology for specific causation in some cases, it is unreliable in this one.

GSK's motion to exclude the expert testimony of Dr. Ravekes [ECF No. 89] therefore is GRANTED because of the inadmissibility of Dr. Ravekes' testimony on specific causation. Dr. Ravekes' testimony concerning general causation would be admissible to the extent that he describes the biological mechanisms by which Paxil could have caused K.E.'s heart defect. However, because of the critical role that dosage and exposure play in determining causation, Dr. Ravekes' opinion on specific causation is inadmissible. As a result, his expert testimony must be excluded in its entirety.

III. GSK's Motion for Summary Judgment

GSK also moves for summary judgment. GSK first argues that without admissible expert testimony about causation, Plaintiffs cannot create a genuine issue of material fact that would sustain any of their claims. In the alternative, it argues that summary judgment is appropriate because Plaintiffs filed this lawsuit after the expiration of the applicable statute of limitations. The Court agrees that summary judgment is warranted for both reasons. Finally, the Court notes the absence of a genuine issue of material fact regarding Count I, Count II, Count III, Count IV, Count V, Count VII, Count VIII, and Count XIV of the short-form complaint. Accordingly, GSK's motion is GRANTED.

A. Standard of Review

In a motion for summary judgment, the burden is on the moving party to establish that no genuine issues of material fact remain in dispute and that it is entitled to judgment as a matter of law. Rule 56(a), Fed. R. Civ. P. A fact is "material" if it "might affect the outcome of the suit under the governing law" and is "genuine" if "a reasonable jury could return a verdict for the nonmoving party" based on it. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986).

When a motion for summary judgment is supported by documentary evidence and sworn affidavits and demonstrates "the absence of a genuine issue of material fact," the party opposing the motion "must come forward with specific evidence demonstrating the existence of a genuine dispute of material fact." *Robinson v. Concentra Health Servs., Inc.*, 781 F.3d 42, 44 (2d Cir. 2015) (citations omitted). In doing so, the non-moving party may not merely rely on "conclusory allegations or unsubstantiated speculation." *Id.*

In reviewing the record, the court must "construe the evidence in the light most favorable to the non-moving party and to draw all reasonable inferences in its favor." *Gary Friedrich Enters., L.L.C. v. Marvel Characters, Inc.*, 716 F.3d 302, 312 (2d Cir. 2013) (citations omitted). If there is

any evidence in the record from which a reasonable factual inference could be drawn in favor of the opposing party on the issue on which summary judgment is sought, summary judgment is inappropriate. *See Sec. Ins. Co. of Hartford v. Old Dominion Freight Line Inc.*, 391 F.3d 77, 83 (2d Cir. 2004); *Anderson*, 477 U.S. at 250 (summary judgment is proper only when "there can be but one reasonable conclusion as to the verdict").

B. Discussion

1. Causation

Defendant argues that the absence of viable expert testimony on the issue of causation is fatal to Plaintiffs' claims, because Plaintiffs must establish that Ms. El-Massri's use of Paxil was the proximate cause of K.E.'s BAV. The Court agrees.

Courts in Connecticut have recognized that "expert [causation] testimony is unnecessary in cases where jurors are as capable of comprehending the primary facts and of drawing correct conclusions from them as are witnesses possessed of special or peculiar training." *Wills*, 379 F.3d at 46 (internal quotation marks omitted). But when a plaintiff's theory of causation "would not be obvious to the lay juror, expert evidence is often required to establish the causal connection between the accident and some item of physical or mental injury." *Id.* (internal citations omitted). *Compare DeBartolo v. Daimler Chrysler Corp.*, No. 10-030482725S, 2005 Conn. Super. LEXIS 3579, at *12 (Super. Ct. Dec. 22, 2005) ("[C]ourts have permitted product defects involving automobiles to be presented to a jury in the absence of expert testimony where the fact of a defect is within the common knowledge of ordinary consumers.") *with Zelle v. Bayer Healthcare, LLC*, No. 08-094019435, 2012 Conn. Super. LEXIS 481, at *23 (Super. Ct. Feb. 16, 2012) ("A finding of a defect in the drug is not within the common knowledge of an ordinary person."); *see also Wills v. Amerada Hess Corp.*, 379 F.3d 32, 46 (2d Cir. 2004) ("In a case such as this, where an injury has multiple potential etiologies, expert testimony is necessary to establish causation.").

In this case, admissible expert testimony on specific causation is necessary for all of Plaintiffs' claims to survive summary judgment. A reasonable jury would otherwise have no way to conclude that Defendant's drug—rather than K.E.'s genetic susceptibility to the disease, Ms. El-Massri's medical history, or any other factor—caused K.E.'s birth defect. *See Sanders v. Fireline, Inc*., 295 F. App'x 373, 374 (2d Cir. 2008) ("Given that Sanders' personal injury claim turned on the precise physical conditions in which ceramic cups fracture, the jury was not 'as capable [as an expert witness] of comprehending the primary facts and of drawing correct conclusions from them.'") (citing *Salem v. United States Lines Co.*, 370 U.S. 31, 35 (1962)); *see also DeVito v. Smithkline Beecham Corp.*, No. 02-CV-0745 (NPM/DRH), 2004 U.S. Dist. LEXIS 27374, at *38 (N.D.N.Y. Nov. 29, 2004) ("Because plaintiff's only causation evidence has been excluded, it necessarily follows that [the defendant] is entitled to summary judgment in its favor."); *Zwillinger*, 1998 U.S. Dist. LEXIS 21107 (granting summary judgment in defendants' favor after excluding doctor's testimony, which was plaintiffs only causation evidence).

While Plaintiffs are correct that tort law does not demand the unyielding certainty of scientific research, proof as to cause is clearly required. In the absence of expert opinion on specific causation, no reasonable fact finder could come to the conclusion that Paxil caused K.E.'s injury. Summary judgment is appropriate on all of Plaintiffs' claims.

2. Statute of Limitations

Even if the Court admitted Plaintiffs' expert testimony, summary judgment would still be proper because plaintiffs' claims are time-barred. Defendant argues that Plaintiff's cause of action accrued when Ms. El-Massri learned of K.E.'s diagnosis, or at the very least, when she told the pediatrician that she had taken Paxil while pregnant and testified that her "concerns" about Paxil had started to formulate. Def.'s Mem. for Summ. J., ECF No. 88-1, 23. Plaintiffs respond that Ms. El-Massri did not have "constructive knowledge" of the link between Defendant and her son's birth

defects until she contacted a law firm on July 27, 2011. Pl.'s Opp. Mem., 5. The Court agrees with the Defendant.

Under Connecticut law, a product liability claim must be brought within "three years from the date when the injury ... is first sustained or discovered or in the exercise of reasonable care should have been discovered." Conn. Gen. Stat. § 52-577a. The cause of action accrues "when a plaintiff suffers actionable harm" or when the plaintiff "discovers or should discover, through the exercise of reasonable care, that he or she has been injured and that the defendant's conduct caused such injury." *Gnazzo v. G.D. Searle & Co.*, 973 F.2d 136, 138-39 (2d Cir. 1992). In other words, the limitation period accrues when "a plaintiff has knowledge of the essential elements of a cause of action," including the duty she was owed, the breach of that duty, and "a causal connection between that breach and the resulting harm to the plaintiff." *Lagassey v. State*, 268 Conn. 723, 748 (2004).

While the question of when a plaintiff discovered or should have discovered the actual harm is normally reserved for the jury, the issue can be resolved as a matter of law when there is evidence of a plaintiff's concrete awareness of a causal connection between the defendant and the injury suffered. *Lagassey*, 268 Conn. 723 at 739 ("[A]lthough our cases make clear that the point at which a plaintiff discovered or in the exercise of reasonable care should have discovered an injury is generally a question of fact, that issue has been resolved as a matter of law on some occasions.").

The Connecticut Products Liability Act's ("CPLA") statute of limitations does not impose a "duty to investigate" on potential plaintiffs, and the court should limit its inquiry to the "facts known to the plaintiff at that time." *Taylor v. Winsted Mem'l Hosp.*, 262 Conn. 797, 809 (2003). In some cases, expert advice from doctors, lawyers, or reporters will be necessary for a reasonable plaintiff to be aware of her legal injury. In *Lagassey*, the Connecticut Supreme Court agreed that plaintiffs' cause of action accrued only when she received an expert's opinion explaining that the defendant physician "may have been negligent." *Lagassey*, 268 Conn. 723 at 751 (holding in the context of a motion to dismiss that "we cannot conclude, as a matter of law, that the plaintiff in the exercise of

reasonable care should have discovered actionable harm sometime prior to obtaining [the expert's] opinion"); *see also Taylor*, 262 Conn. at 810 (denying summary judgment when "the plaintiff testified, and the jury reasonably could have believed, that he was not aware of any causal connection between the medical treatment he received by the hospital on March 10, 1993, and the injuries he suffered from his subsequent stroke, until he read articles about the treatment of strokes in a magazine.").

However, when the record indicates that a plaintiff was aware of links between the defendant and the injury she suffered, her cause of action has certainly accrued. *Gnazzo*, 973 F.2d at 138-39. In *Gnazzo*, the Second Circuit approved of the district court's conclusion that plaintiff should have known of her cause of action when she learned that an IUD manufactured by the defendant had caused her sterility-related injury. At that point, she had been having trouble becoming pregnant and had testified that she "started hearing [and] reading about how damaging IUDs could be [and had] figured that was [the] problem." *Id*. Because of this testimony, the Court ruled that no genuine issue of material fact existed regarding whether or not Gnazzo knew or should have known about the cause of her injury at that point. *Id*.; *see Barnes v. Schlein*, 192 Conn. 732, 736-37 (1984) (plaintiff's cause of action accrued at the point when, according to her deposition, she "knew that something was wrong with her leg" after a second medical consultation and also had "discuss[ed her legal injury] to the point where it could be a suit"); *see also Lagassey*, 268 Conn. at n.14 (confirming that the trial court in *Barnes* was correct in concluding that the case was time-barred because "the plaintiff indicated in her deposition that she knew something was wrong with her leg in April, 1973, and had decided to bring an action against her physician at that time.").

The record here establishes that Ms. El-Massri was aware of her legal injury by the end of June 2011. The record indicates that she was "having concerns" about whether Paxil had caused her son's birth defect as early as June 28, 2011, when she visited K.E.'s pediatrician, and was "considering filing a lawsuit" at that time. N. El. Massri, Dep., 325: 9-13. Like the plaintiff in

Gnazzo, who had "figured that [the defendant's product] was the problem," *Gnazzo*, 973 F.2d at 138-39, or the plaintiff in *Barnes*, who knew that "there could be a suit," *Barnes*, 192 Conn. at 736-37, Ms. El-Massri thought K.E.'s injury was related to her use of Paxil.

Furthermore, the record indicates that before she contacted a law firm on July 27, 2011, Ms. El-Massri saw at least one advertisement connecting BAV to Paxil. Like the newspaper articles in *Taylor* or the expert consultant in *Lagassey*, the advertisement represents an outside assessment of Plaintiffs' legal injury. Ms. El-Massri's testimony about seeing the advertisement indicates that she knew or should have known of her cause of action before July 27, 2011. Plaintiffs filed their lawsuit on July 25, 2014, so this suit would be timely if their cause of action accrued any time after July 25, 2011. The exact date on which Ms. El-Massri first viewed the commercials is unclear. However, even if Ms. El-Massri viewed the commercials only between July 25 and July 27, 2011, her claim would still be time-barred. As discussed above, she was "having concerns" about Paxil as early as June 28, 2011.

While there were many possible conclusions that a layperson could come to in Ms. El-Massri's position, Ms. El-Massri's own testimony indicates that she had started to conclude that Paxil had caused her son's birth defect before July 25, 2011. Indeed, she stated that she had concerns about the effect of the drug in June of that year. Thus, we can say that Ms. El-Massri "knew or should have known" of her claims before July 25, 2011. *Gnazzo*, 973 F.2d at138-39. The Court already has determined that summary judgment is appropriate on Plaintiffs' claims because she lacks admissible evidence of causation, as discussed above. The Court notes that their claims are also time-barred.

3. Other Claims

Even if Plaintiffs had admissible expert testimony for causation purposes, and even if their claims were not otherwise time-barred, summary judgment nevertheless is warranted on Plaintiffs'

claims for breach of express warranty, breach of implied warranty, intentional infliction of emotional distress, loss of consortium, CUTPA, and punitive damages.

a. Breach of Express Warranty Claim

Defendant argues that Plaintiffs' breach of express warranty claim fails because GSK did not make any express warranties regarding the safety of Paxil use during pregnancy. The Court agrees.

Under Connecticut law, "any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise." Conn. Gen. Stat. § 42a-2-313. Generally, the fact-finder determines whether a particular statement from a manufacturer as an "affirmation or promise" on which a breach of warranty claim can be based. *See Vezina v. Nautilus Pools, Inc*., 27 Conn. App. 810, 816 (Conn. App. Ct. 1992) ("[T]he question of whether an express warranty exists is one of fact.").

In product liability cases concerning drugs, however, "a drug manufacturer's representation in advertising or a warning label that a product is safe or effective, or an advertisement or warning label that does not adequately highlight a particular known or knowable risk does not create an express warranty in the absence of a guarantee that the particular product is free from all harmful side effects." *Fraser*, 857 F. Supp. 2d at 257-58 (citing *Basko v. Sterling Drug, Inc*., 416 F.2d 417, 428 (2d Cir. 1969)) (although the issue of strict liability for defendant's failure to warn plaintiff of the risk of a drug was a jury question, plaintiff was not entitled to a jury instruction on express warranty because defendant "did not represent either (1) that its drugs were free from all harmful side effects or (2) that its drugs were absolutely harmless") (applying Connecticut law).

In *Fraser*, this Court (Arterton, J.) granted summary judgment on plaintiff's breach of express warranty claim against defendant drug company Wyeth. Plaintiff claimed that the label for Prempro stated that "most scientific studies showed [that Prempro produced] no increased risk of breast cancer." *Id.* at 257. Specifically, however, the label said that: "The effect of [the drug] on the

risk of breast cancer is unknown, although a moderately increased risk in those taking [the drug] has been reported. Other studies have not shown this relationship." *Id.* at 254 (quoting Prempro's FDA-Approved Label). Given this language, there was no basis for an express warranty because the company had not promised no risk of breast cancer from taking the drug. *Id.* at 257-58. To the contrary, Wyeth had disclosed some of the attendant risks of its consumption. *Id.*

In 2001, when Ms. El-Massri allegedly took Paxil, the product included a label stating that "[p]atients should be advised to notify their physician if they become pregnant or intend to become pregnant," Def.'s L. R. 56 Stmt. ¶ 67 (citing May 1996 Paxil Prescribing Information, Ex. 26). It further noted that Paxil was a "Category C" drug because "there are no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus." *Id.* at ¶ 69 (citing May 1996 Paxil Prescribing Information, Ex. 26). In other words, rather than promise that the consumption of Paxil posed no risk to pregnant women, GSK instead expressly stated that no such promise could be made.

Given this language, no reasonable jury could conclude that this statement was a "guarantee that the particular product is free from all harmful side effects" or constituted an express warranty. *Fraser*, 857 F. Supp. 2d at 257-58. Summary judgment therefore is appropriate on Plaintiffs' express warranty claim.

b. Breach of Implied Warranty Claim

GSK argues that summary judgment should be granted on Plaintiffs' implied warranty of merchantability claim because GSK did not imply that Paxil was fit for use by pregnant women. The Court agrees.

Under Connecticut law, a product must be "fit for the ordinary purposes for which such goods are used." Conn. Gen. State. § 42a-2-314. *See also Standard Structural Steel v. Bethlehem Steel Corp.*, 597 F. Supp. 164, 187 (D. Conn. 1984). When determining the ordinary purpose of a

product, the Court's inquiry focuses on the consumer's expectations of the product when used in the customary, usual and reasonably foreseeable manner. *See Rosenthal v. Ford Motor Co.*, 462 F. Supp. 2d 296, 310 (D. Conn. 2006).

GSK argues that the "ordinary purpose" of Paxil was to treat depression and anxiety and that it effectively served that purpose in Ms. El-Massri's case. Def's Mem., 26. While the Court does not hold that an anti-depressant or other drug's ordinary purpose is limited to its stated and FDA-approved use, here, GSK, through its labelling, expressly stated that Paxil's ordinary purpose did not include treating pregnant women. Because the drug's label stated that "[p]atients should be advised to notify their physician if they become pregnant or intend to become pregnant," the ordinary purpose of the drug would not include use by women during a pregnancy, as defined by a reasonable consumer's expectation.

Indeed, in similar cases, courts have understood the "ordinary purpose" of Paxil-like drugs to be the treatment of depression and anxiety disorders. *See, e.g. Ackermann v. Wyeth Pharms.*, 471 F. Supp. 2d 739, 745 (E.D. Tex. 2006) ("There is no evidence that Effexor is not fit for the ordinary purpose for which it is used, treating depression and general anxiety order. The gravamen of Plaintiff's complaint is that a drug which is normally fit for most patients reacts in a certain way with a small group of patients. … The fact that drugs such as Effexor may cause different reactions in a small group of patients is not tantamount to a holding that the drug is somehow inadequate.")

Summary judgment therefore is appropriate on Plaintiffs' breach of implied warranty claim.

c. Intentional Infliction of Emotional Distress Claim

Plaintiffs argue that GSK is liable for the emotional distress it caused to K.E. and his mother by manufacturing and marketing Paxil, since it knew or should have known that this would cause distress. GSK argues that Plaintiffs cannot satisfy the "very high threshold to establish their claim of intentional infliction of emotional distress." Def.'s Mem., 29. The Court agrees.

To sustain a claim for intentional infliction of emotional distress, a plaintiff must show "(1) that defendant intended to inflict emotional distress or that defendant knew or should have known that emotional distress was the likely result of its conduct; (2) that the conduct was extreme and outrageous; (3) that the conduct was the cause of the plaintiff's distress, and (4) that the emotional distress sustained by the plaintiff was severe." *Stancuna v. Schaffer*, 998 A.2d 1221, 1227 (Conn. 2010). "In assessing a claim for intentional infliction of emotional distress, the court performs a gatekeeping function. In this capacity, the role of the court is to determine whether the allegations of a complaint … set forth behaviors that a reasonable fact finder could find to be extreme or outrageous." *Id.* (internal quotation marks omitted).

In support of its motion for summary judgment on this claim, GSK argues that it "acted diligently in reviewing adverse event reports, monitoring spontaneous data, evaluating the relevant medical literature for Paxil and other SSRIs, and conducting reviews and assessments of adverse event reports." Def.'s Mem., 29. GSK also "conducted safety reviews for Paxil and submitted all required information to FDA in regulatory submissions." *Id.* Plaintiffs do not respond to GSK's motion for summary judgment on this claim. However, they generally assert that GSK "failed to adequately disclose the risk of congenital heart defects associated with Paxil use to the medical community," which resulted in "willful, wanton and outrageous" behavior. Pl.'s Opp. Mem., 19-20 (citing Pl.'s Stmt. Of Disp. Facts, ¶¶ 5-8).

The disputed facts that Plaintiffs cite for this proposition—"Dear Healthcare Provider" letters from 2005 and testimony from Mr. Stephen Hobbiger, GSK's Global Labeling Committee Chairman, regarding GSK's position on Paxil in 1996—do not support this proposition. Pl.'s Stmt. Of Disp. Facts at ¶ 7. Mr. Hobbiger's testimony only represents that GSK's position in 1996 was that Paxil "should not be used during pregnancy … unless the potential benefit outweighs the possible risk." Pl.'s Stmt. of Disp. Facts, Hobbiger Dep., Ex. 8. The provider letters refer to "new studies" and cite studies published in 2005, after K.E. was born. *See* Provider Letters, Pl.'s Stmt. of Disp. Facts, Ex.

6-7, ECF Nos. 107-2, 107-3. The letters thus do not support the notion that GSK was aware of Paxil's alleged danger when Ms. El-Massri took the drug. As a result, Plaintiffs have not put forward evidence that GSK withheld information about Paxil from the medical community or recklessly avoided studying Paxil's impact. Based on the evidence in this record, no jury could find that GSK was "extreme" or "outrageous."

Summary judgment therefore is appropriate on Plaintiffs' intentional infliction of emotional distress claim.

d. Loss of Consortium Claim

GSK argues that it is entitled to summary judgment on Plaintiffs' claim for loss of consortium of a child because Connecticut law does not recognize the claim. The Court agrees.

The majority of jurisdictions, including Connecticut, have held that "a parent may not recover from a third-party tortfeasor, as an element of damages for injury to his child, for loss of the child's society and companionship attributable to the injury." *Cimino v. Yale Univ*., 638 F. Supp. 952, 956 (D. Conn. 1986); *see also Hyun v. S. Kent Sch*., 166 F.R.D. 272, 275 (D. Conn. 1996) ("The courts of this district have repeatedly stated that there is no right to relief for loss of filial or parental consortium."). Since Connecticut law does not recognize Plaintiffs' loss of consortium claim, summary judgment is appropriate on this claim.

e. Negligence *per se* & Negligent Pharmacovigilance

GSK moves for summary judgment on Plaintiffs claim of negligence *per se*, based on GSK's violation of a "statutory duty established by federal regulations," and negligent pharmacovigilance. Def.'s Mem., 30-31. It argues that Plaintiffs have not specifically identified a statute on which to base their negligence *per se* claim and have not identified Connecticut precedent to substantiate their claim of negligent pharmacovigilance. *Id.* The Court disagrees.

In Connecticut, a requirement imposed by statute may establish a duty of care that could provide the underpinning for a tort claim. *See Commercial Union Ins. V. Frank Perrotti & Sons,*

Inc., 20 Conn. App. 253, 260 (1989) (a municipal ordinance requiring separation of combustible materials from other trash could supply the standard of care in negligent disposal of flammable fuel claim). Violations of statutory standards may form the basis of a claim of negligence per se if the plaintiff is within the class of persons whom the statute was intended to protect and if the harm was of the type the enactment was intended to prevent. *Gore v. People's Savings Bank*, 235 Conn. 360, 375-76 (1995). Contrary to Defendant's contention, the statutory basis for a negligence *per se* claim need not provide for a private right of action. *See Walker v. Barrett*, 1999 Conn. Super. LEXIS 3030, 1999 WL 1063189 (Conn. Super. 1999).

The Court recognizes that federal statutes and regulations have imposed certain duties on drug manufacturers. These statutes suggest or require companies to engage in "pharmacovigilance" by monitoring consumers' side effects and adverse reactions to a drug. The Court construes Plaintiffs' claims of negligence *per se* and negligent pharmacovigilance as components of their claim that GSK was negligent in manufacturing and marketing Paxil (Count VII). Summary judgment would thus be inappropriate on these claims, if Plaintiffs' expert testimony were admissible and their claims were not time-barred.

f. Claims under CUTPA

GSK argues that summary judgment is appropriate on Plaintiffs' CUTPA claims because of the CPLA provides the exclusive remedy for Plaintiffs' claims. The Court agrees.

Connecticut law does not allow a plaintiff to pursue damages pursuant to the Connecticut Unfair Trade and Practices Act ("CUTPA") for a claim governed by the CPLA. This is correct given the CPLA's exclusivity provision. *See* Conn. Gen. Stat. § 52-572n (a) ("[a] product liability claim as provided in sections 52-240a, 52-240b, 52-572m to 52-572q, inclusive, and 52-577a may be asserted and shall be in lieu of all other claims against product sellers, including actions of negligence, strict liability and warranty, for harm caused by a product"); *see also Hurley v. Heart Physicians, P.C.*, 278 Conn. 305, 324-25 (2006) (dismissing a plaintiff's CUTPA count in because trial court

determined that the plaintiff was "pursuing a claim for personal injuries … caused by the defendant's pacemaker" and holding that generally – "a product liability claim under the [liability] act is one that seeks to recover damages for personal injuries … caused by the defective product."); *Gerrity v. R.J. Reynolds Tobacco Co.*, 263 Conn. 120, 128 (2003) ("the language of the exclusivity provision makes clear that the product liability act was intended to serve as the exclusive remedy for a party who seeks recompense for those injuries caused by a product defect"). GSK therefore is entitled to summary judgment on Plaintiffs' CUTPA claim.

g. Punitive Damages

GSK argues that it is entitled to summary judgment on plaintiffs' request for punitive damages because it did not act with an "evil motive" or with "reckless indifference to the interests of others." Def.'s Mem., 35-36. Citing Due Process Clause jurisprudence, it further asserts that plaintiffs cannot use punitive damage awards to punish conduct directed at non-parties or conduct that post-dated the alleged injury. Def.'s Resp. Mot, ECF No. 113 (citing *Phillip Morris USA v. William*s, 549 U.S. 346,353-55 (2007)). The Court agrees that no reasonable jury would find punitive damages to be appropriate in this case.

Connecticut statutes provide for punitive damages in product liability actions when the "harm suffered was the result of the product seller's reckless disregard for the safety of product users, consumers or others who were injured by the product." Conn. Gen. Stat. § 52-240b (2016). To show the "recklessness" required for punitive damages, a plaintiff must point to defendant's "highly unreasonable conduct," or an "extreme departure from ordinary case … more than thoughtlessness, or inadvertence, or simply inattention." *Dubay v. Irish*, 207 Conn. 518, 533 (1988). Courts have granted summary judgment on claims for punitive damages when plaintiffs presented no evidence that a defendant manufacturer "ceased to be concerned for the safety and health of [consumers]." *Dunn v. Zimmer, Inc.*, No. 3:00CV1306 (DJS), 2005 U.S. Dist. LEXIS 5345, at *32-33 (D. Conn. Mar. 31, 2005). Similarly, courts have dismissed claims for punitive damages when plaintiff

"fail[ed] to state in [their] allegations that the defendants were aware of the alleged defects and continued to manufacture, sell and distribute the item despite such knowledge." *Andrews v. H.J. Heinz Co.*, D.N. CV960153316S, 1997 Conn. Super. LEXIS 461, at *4 (Super. Ct. Feb. 25, 1997).

In several cases, courts have allowed punitive damages claims regarding GSK's production of Paxil to survive summary judgment. In these cases, though, the plaintiffs had produced evidence that GSK had deliberately avoided studying the impact of Paxil on patients or disregarded studies of Paxil's risk. *See Hayes v. SmithKline Beecham Corp.*, No. 07-CV-0682-CVE-TLW, 2009 U.S. Dist. LEXIS 116081, at *19 (N.D. Okla. Dec. 14, 2009) (denying summary judgment on the plaintiffs' punitive damages claims because the plaintiffs had "provided evidence from which a jury could find that in 1993 and 1994, GSK deliberately avoided doing reproductive toxicology studies for Japanese regulators because the studies could provide potentially damaging results for labeling in the United States [and] that GSK wanted to make sure that [a particular] study would not look specifically at Paxil"); *Knipe v. Smithkline Beecham*, 583 F. Supp. 2d 602, 640-41 (E.D. Pa. 2008) (denying summary judgment on the punitive damages claim because the plaintiff had presented evidence, including internal GSK documents, "showing that GSK knew of the risk of pediatric suicidality as of 1998" but had not changed its label or warned doctors of the risk). Unlike the plaintiffs in these cases, Plaintiffs provide no evidence that GSK knew of the risks associated with Paxil, withheld information about the risks associated with Paxil consumption, or had tried to prevent future Paxil research at the time Ms. El-Massri allegedly consumed the drug. On the record before the Court, no reasonable jury could conclude that GSK willfully disregarded Ms. El-Massri's safety when promoting and manufacturing Paxil.

Plaintiffs claim that GSK "was or should have been in possession of evidence demonstrating that Paxil caused congenital birth defects … and continued to market the products by providing false and misleading information with regard to safety," and that it did so "willfully, intentionally and with reckless disregard for the rights of plaintiffs and the public." Long Form Compl., ¶¶ 112-114. In

their response to GSK's motion for summary judgment, Plaintiffs cite disputed facts to assert that GSK "failed to adequately disclose the risk of congenital heart defects associated with Paxil use to the medical community," resulting in serious injury to women taking Paxil during pregnancy. Opp. Mem., 19 (citing Pl.'s Stmt. of Disputed Facts, ¶¶ 5-8). GSK argues that it did not know about the "potential association between Paxil and birth defects" prior to 2005. Further, GSK argues that it accurately reflected what it did know—that there was inconclusive evidence that Paxil consumption caused "pup death" in animal studies—in the drug's FDA Prescribing Information sheet. Def.'s Mot. Summ. J., 45.

Even when responding to GSK's motion for summary judgment, Plaintiffs offer no evidence to suggest that GSK was aware of the alleged deficiencies in their product at the time period in which it allegedly sold the product to Ms. El-Massri. While Plaintiffs contend that GSK "knew of the heightened risks of birth defects associated with Paxil use during pregnancy as far back as 1996," they present no non-conclusory evidence to support this conclusion. Pl.'s Opp. Mem., 17 (citing Pl.'s Stmt. Of Disp. Facts, ¶¶ 5-8). While K.E. was born in 2001, the "Dear Healthcare Provider" letter and e-mail that Plaintiffs cite for this proposition are all dated 2005 and refer to "new studies" or studies published in 2005. Provider Letters, Pl.'s Stmt. of Disp. Facts, Ex. 6-7, ECF Nos. 107-2, 107-3. Plaintiffs also cite testimony from Mr. Stephen Hobbiger, GSK's Global Labeling Committee Chairman. *Id.* at ¶ 7. This testimony only represents that GSK's position in 1996 was that Paxil "should not be used during pregnancy … unless the potential benefit outweighs the possible risk." Pl.'s Stmt. Of Disp. Facts, Hobbiger Dep., Ex. 8. Plaintiffs provide no other evidence to support their claims for punitive damages.

Plaintiffs thus do not offer any evidence that GSK disregarded or misled the public as to the risk that Paxil was unsafe for pregnant women, or that it even knew of the risk that Paxil caused birth defects at the time Ms. El-Massri was pregnant. Ordinarily, the finder of fact should determine whether a defendant was reckless, but in this case there is no evidence supporting Plaintiffs' claim

for punitive damages. *See Walters v. Howmedica Osteonics Corp.*, 676 F. Supp. 2d 44, 56 (D. Conn. 2009) (granting summary judgment when there was "no indication in the record whatsoever that [the defendant] acted with reckless disregard [and the defendant had] developed trays that complied with regulatory and customer requirements"); *see also Gottlieb v. Cty. of Orange*, 84 F.3d 511, 518 (2d Cir. 1996) (in motion for summary judgment, "the opposing party is required to come forward with materials envisioned by the Rule, setting forth specific facts showing that there is a genuine issue of material fact to be tried. … The motion will not be defeated merely on the basis of conjecture or surmise").

For this reason, summary judgment is appropriate on Plaintiffs' claim for punitive damages.

IV. Conclusion

In summary, GSK's Motion to exclude the expert testimony of Dr. Ravekes [ECF No. 89] is GRANTED. Given the absence of admissible expert testimony, summary judgment is appropriate on all of Plaintiffs' claims. Furthermore, all of Plaintiffs' claims are time-barred. Finally, summary judgment would be appropriate on several of Plaintiffs' claims even if Plaintiffs could offer admissible causation testimony and had brought their case within the applicable statute of limitations. For these reasons, GSK's Motion for Summary Judgment [ECF No. 88] is granted.

SO ORDERED at Bridgeport, Connecticut this 1st day of February, 2017.

/s/ Victor Bolden
VICTOR A. BOLDEN
UNITED STATES DISTRICT JUDGE