IN THE UNITED STATES COURT FOR THE DISTRICT OF UTAH
CENTRAL DIVISION

VICTORIA CERVENY, CHARLES CERVENY, and ALEXANDER CERVENY, Plaintiffs, v. AVENTIS, INC., Defendant.	**MEMORANDUM DECISION AND ORDER** Case No. 2:14-cv-545-DB Judge Dee Benson

Before the Court is Defendant's Renewed Motion for Summary Judgment. [Dkt. 62]. The motion has been fully briefed and oral argument was held before the Court on November 14, 2017. Plaintiffs were represented at the hearing by Eric Barton and Defendant was represented by Eric Swan and Gary Wight. Having considered the written and oral arguments of the parties, and the relevant facts and the law, the Court enters the following Memorandum Decision and Order.

BACKGROUND

Clomid is a prescription fertility drug that is manufactured by Defendant. Its chemical name is clomiphene citrate and it was approved by the FDA on February 1, 1967. In September,

1992, Plaintiff, Victoria Cervey's treating physician prescribed Clomid to aid her in becoming pregnant. She took her first round of the medication in September and her second round the next month, in October, 1992. She thereafter became pregnant and her son, Alexander, was born on July 27, 1993. He was born without a thumb and a pinky finger on his left hand and a congenital dislocation of his left elbow.

Exactly twenty-one years later, on July 28, 2014, Plaintiffs filed this lawsuit against Defendant alleging several causes of action and seeking compensatory, punitive and statutory damages plus interest and attorneys' fees. The Court dismissed Plaintiffs' design defect, manufacturing defect, strict liability failure to warn, negligent failure to warn, punitive damages, breach of express warranty, negligent design, negligence per se and unjust enrichment causes of action based on Defendant's motion to dismiss for failure to state a claim pursuant to Federal Rule of Civil Procedure 12(b)(6). Dkt. 28. Defendant moved for summary judgment on the remaining claims arguing they were federally preempted. Dkt. 38. Following briefing and oral argument, the Court granted Defendant's motion. Dkt. 47.

The Tenth Circuit Court of Appeals affirmed the Court's ruling granting summary judgment for Defendant on Plaintiffs' failure to warn claim that was based on the content of its warning regarding taking Clomid *before* becoming pregnant. It is undisputed that Victoria Cerveny took Clomid as prescribed, *before* she became pregnant, and not *after*.

The appeals court remanded Plaintiff's failure to warn claim that is based on the theory that Defendant should have included a 1987 FDA-approved warning that harm to the fetus could occur if Clomid is taken *during* pregnancy. Because the FDA had approved this warning but

Defendant had not used it, the appeals court questioned whether this claim could be dismissed based on preemption grounds. The appeals court also remanded Plaintiffs' negligent misrepresentation, fraud and breach of implied warranty[1] causes of action and questioned whether the remanded claims are subject to dismissal based on federal preemption or rather, based on state law. Defendant filed this renewed motion for summary judgment.

DISCUSSION

When Victoria Cerveny took Clomid, the label did not directly state it could harm a human fetus if taken *during* pregnancy. It did, however, contain the following contraindication against use *during* pregnancy:

> Although no causative evidence of a deleterious effect of Clomid therapy on the human fetus has been seen, such evidence in regard to the rat and the rabbit has been presented (see Animal Pharmacology and Toxicology). Therefore, Clomid should not be administered during pregnancy. To avoid inadvertent Clomid administration during early pregnancy, the basal body temperature should be recorded throughout all treatment cycles, and the patient should be carefully observed to determine whether ovulation occurs. . . .

In 1987, the FDA proposed a warning directly about potential harm to the fetus when Clomid is taken during pregnancy: "Clomid may cause fetal harm when administered to pregnant women." That wording was not used by Defendant at that time. Victoria Cerveny argues that if she had known that birth defects could result from taking Clomid *during* pregnancy, she would not have taken it as she did, *before* pregnancy.

The issue presented by this motion is whether the undisputed facts in the record give rise to a cause of action for failure to warn against taking the drug *while* pregnant, fraud, or negligent

[1]Plaintiffs concede their breach of implied warranty claim. *See* Dkt. 63 at p. viii.

misrepresentation. Defendant argues they do not because Victoria Cerveny did not take Clomid while she was pregnant. Therefore, such a warning would not have applied to her and Alexander was never exposed to that risk.

A. Failure to Warn Claim - *While Pregnant*[2]

"[U]nder Utah law, a manufacturer may be held strictly liable for any physical harm caused by its failure to provide adequate warnings regarding the use of its product." *House v. Armour of America, Inc*., 929 P.2d 340, 343 (Utah 1996)(*quoting House v. Armour of American, Inc*., 886 P.2d 542, 547 (Utah Ct. App. 1994)(*citing Grundberg v. Uphohn Co.*, 813 P.2d 89, 97 (Utah 1991)). An adequate warning is one that "disclose[s] all the risks involved, as well as the extent of those risks." *House*, 886 P.2d at 551.

1. Applicability of the Proposed Warning

While Plaintiffs assert that Victoria Cerveny would not have taken Clomid *before* she was pregnant if she had known that taking it *after* she was pregnant could cause birth defects, Defendant argues this is immaterial because one may not assert a failure to warn cause of action based upon a claimed inadequacy in a warning that does not apply to her. *See Harris v. Eli Lilly & Co.*, 2012 WL 6732725 at *3 (N.D. Ohio 2012)(unpublished)("for a plaintiff to succeed on an inadequate warning claim, the risk about which the manufacturer allegedly failed to warn must be the same risk which harmed the plaintiff."). When a proposed warning does not apply to the plaintiff, she cannot prove defect or inadequacy. *See, e.g., Mills v. United States*, 764 F.2d 373,

[2]As discussed in the Court's Order on Defendant's 12(b)(6) Motion, under the Learned Intermediary Doctrine, Defendant had no duty to warn Victoria Cerveny directly, as a matter of law. Rather, its duty was only to warn the physician. *Schaerrer v. Stewart's Plaza Pharm., Inc*., 79 P.3d 922, 928 (Utah 2003).

397 (5th Cir. 1985); *Mason v. Smithkline Beecham Corp*., 2010 WL 2697173 at *5 n.3 (C.D. Ill. 2010)(unpublished). Failure-to-warn claims based on warnings that do not apply to the plaintiff fail because they are too speculative to provide standing. *See, Rivera v. Wyeth-Ayerst Labs*, 283 F.3d 315, 321 (5th Cir. 2002) (rejecting as "absurd" and "too speculative to establish Article III standing" a claim based on the allegation that "an extra warning, though inapplicable to [the plaintiff], might have scared her and her doctor from Duract").

Alexander Cerveny was not harmed by Victoria Cerveny ingesting Clomid *while* she was pregnant with him because she did not ingest Clomid *while* she was pregnant. Accordingly, the Court finds that Plaintiffs cannot prevail on their failure to warn cause of action based on Defendant's alleged failure to warn about the risk of taking Clomid *during* pregnancy.

2. Contraindication

Additionally, Defendant argues that the cause of action fails because when Victoria Cerveny took Clomid, the label contained the contraindication against use *during* pregnancy. The contraindication specifically discussed the potential for fetal harm. The Court finds that the pregnancy contraindication Defendant used in 1991 when Victoria Cerveny took the medication was an adequate warning as a matter of Utah law. *See House v. Armour of America, Inc.*, 929 P.2d 340, 343 (Utah 1996); *House v. Armour of America, Inc.*, 886 P.2d 542, 547 (Utah Ct. App. 1994)(*citing Grundberg v. Upjohn Co.*, 813 P.2d 89, 97 (Utah 1991)).

B. Fraud and Negligent Misrepresentation Claims

Plaintiffs allege causes of action for fraud and negligent misrepresentation based on the statement in the pregnancy contraindication that "no causative evidence of a deleterious effect of

Clomid therapy on the human fetus has been seen."

Under Utah law, a claim for fraud exists where a false statement is directed toward the plaintiff and is intended to induce the plaintiff to act. *Armed Forces Inc., Ex. v. Harrison*, 70 P.3d 35, 40 (Utah 2003). Similarly a negligent misrepresentation claim requires proof that "the plaintiff reasonably relied on the defendant's representation" and that the defendant 'should have reasonably foreseen that the injured party was likely to rely upon the misrepresentation.'" *Mitchell v. Smith*, 2010 WL 5172906 at *8.

Defendants argue they are entitled to summary judgment on these claims because the statement: (1) was not directed toward Plaintiff; and (2) is not an inducement. As discussed above, the pregnancy contraindication was not directed to women like Victoria Cerveny who were prescribed the medication specifically for use *before* becoming pregnant. Plaintiffs cannot sustain a fraud or negligent misrepresentation claim that was not directed toward them and those causes of action therefore fail as a matter of law.

Secondly, Clomid's warning label, including its pregnancy contraindication, were not intended to induce women to take the drug. The inducement element of a fraud claim requires Plaintiffs to prove not only that Victoria Cerveny was induced, but also that the contraindication was made for the purpose of inducing her to take the medication.

Rather than being a statement intended to induce women who are seeking to conceive, the pregnancy contraindication is intended to inform through their physicians a different class of women, those who are already pregnant, that they must not take Clomid. FDA regulations specifically define the scope and purpose of the contraindication section of prescription drug

labeling. The regulations explain that the contraindication section "must describe any situations in which the drug should not be used because the risk of use (e.g., certain potentially fatal adverse reactions) clearly outweighs any possible therapeutic benefit." 21 CFR 201.67(c)(5). If there are no such situations, then the contraindication section must contain the statement "none." *Id*. Accordingly, the fraud claim fails for lack of inducement.

Similarly, given the purpose of the contraindication, there is no evidence that Defendant foresaw that women, like Victoria Cerveny, to whom the contraindication did not apply, would rely on statements contained within the contraindication when deciding whether to take Clomid *before* pregnancy, as required for a negligent misrepresentation claim. The Court finds that because the pregnancy contraindication was not addressed to and did not apply to Victoria Cerveny, the pregnancy contraindication cannot support the Plaintiffs' fraud and negligent misrepresentation claims.

CONCLUSION

Defendant's Renewed Motion for Summary Judgment is hereby GRANTED.

IT IS SO ORDERED.

DATED this 29th day of November, 2017.

Dee Benson
United States District Judge